Clinical Practice Guidelines

for Surveillance Colonoscopy – in adenoma follow-up; following curative resection of colorectal cancer; and for cancer surveillance in inflammatory bowel disease

December 2011

PLEASE NOTE:
This resource was developed, reviewed or revised more than five years ago. It no longer represents the National Health and Medical Research Council's position on the matters contained therein. An updated version of this guideline is in progress. This version has been available for reference purposes only until the revised guidelines are available.

This project was partially funded by the Australian Government Department of Health and Ageing under the National Bowel Cancer Screening Program.
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Clinical Practice Guidelines for Surveillance Colonoscopy - in adenoma follow-up, following curative resection of colorectal cancer, and for cancer surveillance in inflammatory bowel disease
FOREWORD

Bowel cancer is common and frequently lethal. In 2007, more than 14,200 Australians were diagnosed with colorectal cancer (CRC) and more than 4,000 died from it, making it the nation’s second leading cancer killer. Lifetime risk of CRC (by age 85) was 1 in 12. Despite these sobering statistics, there is a potential window of opportunity afforded by the polyp-cancer sequence of CRC, during which colonoscopy can remove polyps or detect cancer while it is still curable.

These Guidelines are an update (and a substantial expansion) of several small sections of the 2005 Clinical Practice Guidelines for the Prevention, Early Detection and Management of Colorectal Cancer. They focus on the appropriate use of colonoscopy in CRC prevention and address three simple questions: (i) when to repeat colonoscopy after adenomatous polypectomy, (ii) when to repeat colonoscopy after curative resection for colorectal cancer, and (iii) when to perform colonoscopy in those patients with inflammatory bowel disease, who have an increased risk of developing CRC? Thus, they address the issue of appropriate scheduling of future colonoscopy in patients known to be at above-average risk for CRC development (i.e. patients who have already had adenomatous polyps removed or surgery for CRC, and patients with inflammatory bowel disease). The purpose of these Guidelines is to assist those involved in the Australian healthcare system in making decisions about the timing of surveillance colonoscopy, namely referring general practitioners and colonoscopists, with the intention of reducing the incidence of and mortality from CRC.

In the last 10-15 years, there have been major changes in thinking about colonoscopy and its effectiveness in reducing deaths from CRC. It is apparent that colonoscopy has its limitations; awareness has grown about the issue of missed lesions and it seems that colonoscopy may not be as protective against the development of CRC in the proximal colon as it is more distally. It has also become clear that the efficacy of colonoscopy in reducing the risk of CRC is crucially dependent on careful inspection; withdrawal time has emerged as an important but crude surrogate marker of procedural quality.

In assessing the literature to develop these Guidelines, it has frequently been necessary to extrapolate from published evidence. It is also challenging to interpret data from studies 10 or 20 years old, given technical improvements in colonoscopy in the meantime and growing awareness about how carefully the procedure needs to be performed to maximise its effectiveness. It remains to be seen whether the anticipated more complete clearance of colonic neoplasia by “modern” colonoscopy will translate into recommendations for longer surveillance intervals in future guidelines.

In Australia, colonoscopy has also become a public health issue since the advent of the National Bowel Cancer Screening Program. An offshoot of the NBCSP, the Quality Working Group, addressed a broad range of elements of quality in the delivery of colonoscopy, one of which is the scheduling of future colonoscopies in patients at above-average risk of developing CRC.

As guidelines, the recommendations which follow cannot be applied rigidly to each and every patient. Nevertheless, this up-to-date, evidence-based literature review may help colonoscopists to better manage not only their patients, but also their colonoscopy waiting lists and balance the demands of groups of patients with different procedural indications. Frequent surveillance colonoscopy, repeated earlier than recommended by guidelines, should not be seen as an acceptable substitute for high-quality colonoscopy. It should also be remembered, as evidenced by the Quality Working Group’s comprehensive report, that appropriately timed surveillance colonoscopy represents only one step in the overall pathway of quality colonoscopy delivery.

Dr Cameron Bell
Chair, Surveillance Colonoscopy Guidelines Working Party
SUMMARY OF CLINICAL PRACTICE RECOMMENDATIONS

These guidelines are intended for use by all practitioners and health workers who require information about surveillance colonoscopy - in adenoma follow-up, following curative resection of colorectal cancer, and for cancer surveillance in inflammatory bowel disease. They are specifically revising the colonoscopic surveillance sections of the Clinical Practice Guidelines for the prevention, early detection and management of colorectal cancer 2005 chapters 8, 9, 17, and introduce a new chapter on cancer surveillance in inflammatory bowel disease. They also cover psychosocial care (chapter 18 in the 2005 Guidelines), socio economic factors and cost effectiveness (chapters 23 and 22 in the 2005 Guidelines).

The guidelines have been produced by a process of systematic literature review; critical appraisal and consultation encompassing all interested parties in Australia (see Appendix I).

The following table provides a list of the evidence-based recommendations detailed in the text of each chapter. The table below provides details on the highest level of evidence identified to support each recommendation (I-IV). The Summary of Recommendations table includes the grade for each recommendation (A-D). The key references that underpin the recommendation are provided in the last column. Individual levels of evidence can be found in the Evidence Summaries for each recommendation in each chapter.

Each recommendation was assigned a grade by the expert working group taking into account the volume, consistency, generalisability, applicability and clinical impact of the body of evidence supporting each recommendation.

When no Level I or II evidence was available and in some areas, in particular where there was insufficient evidence in the literature to make a specific evidence-based recommendation, but also strong and unanimous expert opinion amongst the working group members about both the advisability of making a clinically relevant statement and its content, recommended best practice points were generated. Thus, the practice points relate to the evidence in each chapter, but are more expert opinion-based than evidence-based. These can be identified throughout the guidelines with the following: Practice point (PP).

<table>
<thead>
<tr>
<th>Grade of recommendation</th>
<th>Description</th>
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<tbody>
<tr>
<td><strong>A</strong></td>
<td>Body of evidence can be trusted to guide practice</td>
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<tr>
<td><strong>B</strong></td>
<td>Body of evidence can be trusted to guide practice in most situations</td>
</tr>
<tr>
<td><strong>C</strong></td>
<td>Body of evidence provides some support for recommendation(s) but care should be taken in its application</td>
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<tr>
<td><strong>D</strong></td>
<td>Body of evidence is weak and recommendation must be applied with caution</td>
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LEVELS OF EVIDENCE

Table 1. Designations of levels of evidence for intervention research questions (NHMRC, 2009)

<table>
<thead>
<tr>
<th>Level</th>
<th>Intervention</th>
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<tbody>
<tr>
<td>I</td>
<td>A systematic review of level II studies</td>
</tr>
<tr>
<td>II</td>
<td>A randomised controlled trial</td>
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<tr>
<td>III-1</td>
<td>A pseudo-randomised controlled trial (i.e. alternate allocation or some other method)</td>
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<tr>
<td>III-2</td>
<td>A comparative study with concurrent controls:</td>
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<tr>
<td></td>
<td>• Non-randomised, experimental trial</td>
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<td></td>
<td>• Cohort study</td>
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<td></td>
<td>• Case-control study</td>
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<td>• Interrupted time series with a control group</td>
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<tr>
<td>III-3</td>
<td>A comparative study without concurrent controls:</td>
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<td></td>
<td>• Historical control study</td>
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<td></td>
<td>• Two or more single arm study</td>
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<td></td>
<td>• Interrupted time series without a parallel control group</td>
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<tr>
<td>IV</td>
<td>Case series with either post-test or pre-test/post-test outcomes</td>
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Reference

1. NHMRC Levels of evidence and grades for recommendations for developers of guidelines (2009).
### SUMMARY OF RECOMMENDATIONS

<table>
<thead>
<tr>
<th>Chapter</th>
<th>Recommendations</th>
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<tbody>
<tr>
<td>2. MANAGEMENT OF EPITHELIAL POLYPS: COLONOSCOPIC SURVEILLANCE AFTER POLYPECTOMY</td>
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<tr>
<td>2.1 Adenomas and risk of developing colorectal cancer</td>
<td>Determination of risks for patients with adenomas must clearly distinguish between (1) variables that relate to the likelihood of any particular adenoma having a malignant focus and (2) variables that relate to patient, pathological and epidemiological characteristics which predict a risk of future (metachronous) adenomas and cancers.</td>
<td>PP</td>
<td>20</td>
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<td></td>
<td>Patients whose only polyps are small, pale, distal, hyperplastic polyps require no colonoscopic follow-up.</td>
<td>PP</td>
<td>20</td>
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<tr>
<td>2.1.1.6 Location of adenomas and cancer: protection against right sided cancer in adenoma follow up</td>
<td>Proximal location of adenomas may be a risk factor for metachronous neoplasia. The extent to which this is driven by the difficulty of detecting proximal polyps, because of their flat and unobtrusive nature (i.e. sessile serrated polyps), poor bowel preparation and anatomical blind spots in the right colon, is unclear. For these reasons the right colon deserves particularly careful scrutiny at colonoscopy.</td>
<td>PP</td>
<td>22</td>
<td></td>
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<tr>
<td>2.1.7 Models for risk index</td>
<td>Because of the complexity of multivariate analyses equations to predict individual patient risk of metachronous polyps, their use currently is difficult to apply to day to day practice.</td>
<td>PP</td>
<td>22</td>
<td></td>
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<tr>
<td>2.2.1 General considerations relating to polypectomy</td>
<td>All polyps should be considered for removal. Diminutive polyps may be too numerous to be cleared completely. In patients with multiple small polyps, a sample of at least three should be taken for histological study. However, if a syndromic diagnosis is under consideration, then sampling of many more polyps is important, to guide decisions on which gene should be subjected to mutational analysis.</td>
<td>PP</td>
<td>23</td>
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### 2.2.3 Tattooing polypectomy sites

Tattooing any polyp site where there is a possibility that surgical resection will be needed is important at the primary colonoscopy if at all possible, or very soon after with a second procedure. This is necessary even for conventional surgery, as the site of polypectomy may well be impalpable, but particularly important where follow-up treatment may be laparoscopic, as the surgeon has no capacity to palpate the area.

### 2.3 Malignant polyps

In general, malignant polyps which have,
1. a clear margin of excision,
2. are well or moderately differentiated,
3. lack lymphatic or venous invasion and
4. are endoscopically assessed as totally removed can be managed without subsequent surgical resection. However, the decision needs to be individualised with respect to the particular histological and endoscopic features and the patient’s age and co-morbidities.

### 2.4.2 Quality of colonoscopy

High quality colonoscopy is critically important for good practice and patient safety. Adenoma detection rates (ADRs) should be monitored, though they will be influenced by patient mix (eg. age profile, indications). ADRs within the National Bowel Cancer Screening Program provide a sound basis for benchmarking.

### 2.4.3 Approach to adenoma follow up in surveillance

Colonoscopy surveillance intervals should be planned when the colonoscopist is satisfied that the colon has been completely cleared of polyps and the polyp histology is known.

### 2.4.4 Follow-up for patients with low risk adenomas

In follow-up of patients with one or two small (<10 mm) tubular adenomas, the first surveillance colonoscopy should be performed at five years.

If that colonoscopy is normal, the individual is considered to be at average risk for metachronous disease. Options for subsequent surveillance are ten-yearly colonoscopy, or FOBT at least every two years.

Low risk adenomas are those which lack advanced features, namely three or more adenomas at one colonoscopy, adenomas 10 mm or more in size, tubulovillous or villous histology or high grade dysplasia/cancer.

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<tr>
<td>2.2.3</td>
<td>Tattooing polypectomy sites</td>
<td>PP</td>
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<td>23</td>
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<tr>
<td>2.3</td>
<td>Malignant polyps</td>
<td>PP</td>
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<td>24</td>
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<tr>
<td>2.4.2</td>
<td>Quality of colonoscopy</td>
<td>PP</td>
<td></td>
<td>24</td>
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<tr>
<td>2.4.3</td>
<td>Approach to adenoma follow up in surveillance</td>
<td>PP</td>
<td></td>
<td>25</td>
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<tr>
<td>2.4.4</td>
<td>Follow-up for patients with low risk adenomas</td>
<td>B</td>
<td>33, 64-67</td>
<td>25</td>
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<td></td>
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<td>PP</td>
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There is no conclusive evidence that one or two small tubular adenomas constitute more than average risk for metachronous advanced adenomas or cancer.

### 2.4.5 Follow-up for patients with high risk adenomas

Surveillance colonoscopy should take place at a three yearly intervals for patients with high risk adenomas (three or more adenomas, ≥10mm, or with tubulovillous, or villous histology, or high grade dysplasia).

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<tr>
<td>A</td>
<td>7, 13-15, 33, 64, 66, 69, 70</td>
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### 2.4.6 Follow up of patients with sessile adenomas and laterally spreading adenomas

If large and sessile adenomas are removed piecemeal, follow-up colonoscopy should be at three to six months to ensure complete removal. If removal is complete, subsequent surveillance should then be based on histological findings, size and number of other adenomas (as set out in 2.4.4 and 2.4.5).

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<td>B</td>
<td>21, 71, 72</td>
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### 2.4.7 Follow up following resection of serrated adenomas (SA) and sessile serrated adenomas (SSA)

At present there is not enough evidence to differentiate follow-up protocols for sessile serrated adenomas from standard adenoma follow up guidelines. Follow-up should be determined as for adenomatous polyps, taking into account parameters such as, polyp size, number and presence of high grade dysplasia.

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<td>PP</td>
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### 2.4.8 Follow up for patients with multiple numbers of adenomas

As multiplicity of adenomas is a strong determinant of risk of metachronous advanced and non advanced neoplasia, follow up should be at twelve months for those with five or more adenomas and, because the likelihood of missed synchronous polyps being present, sooner in those with ten or more adenomas.

If a polyposis syndrome accounts for the findings, follow-up colonoscopy should be within one year for patients with five or more adenomas at one examination.

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<td>B</td>
<td>13, 38, 70, 75</td>
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FAP or MYH associated polyposis should be considered with as few as ten adenomas; referral to a familial cancer clinic is advisable. Practicality dictates that these counts apply to the most recent colonoscopy, though logic may suggest it should be cumulative. Data is scarce on this point.
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<tr>
<td>2.4.9</td>
<td>Interaction of Age and Family History of Colorectal Neoplasia</td>
<td>B</td>
<td>13, 77</td>
<td>29</td>
</tr>
<tr>
<td></td>
<td>Family history should be considered separately when planning colonoscopy surveillance. Intervals should be predominantly determined by the adenoma characteristics, unless a syndromic risk mandates more frequent surveillance.</td>
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<tr>
<td>2.4.10</td>
<td>Follow up based on two or more examinations</td>
<td>B</td>
<td>33, 67</td>
<td>30</td>
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<tr>
<td></td>
<td>If advanced adenomas are found during subsequent surveillance, maintaining a three yearly schedule is prudent but the choice should be individualised. The interval can be lengthened if advanced adenomas are not found.</td>
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<td>Endoscopists, therefore, should be encouraged to assess not only the current colonoscopy findings, but those of any previous colonoscopies.</td>
<td>PP</td>
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<td>30</td>
</tr>
<tr>
<td>2.5</td>
<td>Hyperplastic polyposis</td>
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<td></td>
<td>Risk of cancer in hyperplastic polyposis is still being defined; however, there is sufficient evidence to identify these patients as being at high risk. Colonoscopy, with the aim of complete polyp removal, including the right sided sessile serrated polyps, should be the aim. Risks of polypectomy, notable because of the number and sessile nature of these polyps, should be explained.</td>
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<td></td>
<td>Surgery is an acceptable alternative in patients with well defined hyperplastic polyposis.</td>
<td>PP</td>
<td></td>
<td>31</td>
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<tr>
<td>3.</td>
<td>THE ROLE OF SURVEILLANCE COLONOSCOPY AFTER CURATIVE RESECTION FOR COLORECTAL CANCER</td>
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<tr>
<td>3.1</td>
<td>Role of pre- or peri-operative colonoscopy in CRC patients</td>
<td>B</td>
<td>7-10</td>
<td>38</td>
</tr>
<tr>
<td></td>
<td>A perioperative colonoscopy should be attempted in all patients with a newly diagnosed colorectal cancer (CRC).</td>
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<td></td>
<td>Colonoscopy should be performed three to six months after resection for patients with obstructive CRC in whom a complete perioperative colonoscopy was not performed and in whom there is residual colon proximal to the obstructing cancer.</td>
<td>B</td>
<td>7-10</td>
<td>39</td>
</tr>
<tr>
<td>3.2.2.1</td>
<td>Risk factors for metachronous neoplasia following resection for colorectal cancer</td>
<td>PP</td>
<td></td>
<td>40</td>
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<td>Patients with proved Lynch syndrome (HNPCC or hereditary non-polyposis colorectal cancer), should continue to have annual surveillance colonoscopy performed post-operatively because of the apparent rapid progression of neoplasia from adenoma to carcinoma.</td>
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<td>Chapter</td>
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|         | Patients including those  
(i) whose initial diagnosis was made younger than 40 years of age,  
(ii) with probable or possible HNPCC (i.e. patients whose tumours are MSI-high and less than 50 years old at time of initial cancer diagnosis but not proved by genetic testing to have HNPCC),  
(iii) with hyperplastic polyposis and BRAF mutation and  
(iv) with multiple synchronous cancers or advanced adenomas at initial diagnosis should be considered following surgery to continuing with more frequent surveillance than would otherwise be recommended (e.g. initial post-operative colonoscopy at one year and then annually, second-yearly or third-yearly. | PP    |      | 40   |
| 3.4     | **Intervals for surveillance colonoscopy following resection for colorectal cancer**  
Colonoscopy should be performed one year after the resection of a sporadic cancer, unless a complete post-operative colonoscopy has been performed sooner.                                                                 | B     | 8-10, 15, 21, 29, 31, 36-39, 44, 49, 51, 52 | 43   |
|         | If the peri-operative colonoscopy or the colonoscopy performed at one year reveals advanced adenoma, then the interval before the next colonoscopy should be three years.                                               | C     | 8-10, 15, 21, 29, 31, 36-39, 44, 49, 51, 52 | 43   |
|         | If the colonoscopy performed at one year is normal or identifies only one or two non-advanced adenomas, then the interval before the next subsequent colonoscopy should be five years.                                             | C     | 26   | 43   |
Patients undergoing either local excision (including transanal endoscopic microsurgery) of rectal cancer or advanced adenomas or ultra-low anterior resection for rectal cancer should be considered for periodic examination of the rectum at six monthly intervals for two or three years using either digital rectal examination, rigid proctoscopy, flexible proctoscopy, and/or rectal endoscopic ultrasound. These examinations are considered to be independent of the colonoscopic examination schedule described above.

### 4. COLONOSCOPIC SURVEILLANCE AND MANAGEMENT OF DYSPLASIA IN INFLAMMATORY BOWEL DISEASE

#### 4.2 Efficacy of colonoscopic surveillance in IBD

Colonoscopic surveillance is recommended in high risk patients with ulcerative colitis (UC) to reduce cancer-related mortality.

<table>
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<th>Grade</th>
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<tbody>
<tr>
<td>C</td>
<td>1, 6, 8-10</td>
<td>49</td>
</tr>
</tbody>
</table>

Although evidence for colonoscopic surveillance in Crohn’s disease is limited, experts recommend it be considered in at risk patients.

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<th>Grade</th>
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<tbody>
<tr>
<td>PP</td>
<td></td>
<td>49</td>
</tr>
</tbody>
</table>

#### 4.4.1 Starting time for surveillance

Patients with ulcerative colitis extending beyond the sigmoid colon and individuals with Crohn’s colitis that involves more than one-third of colon should commence surveillance no later than eight years after onset of symptoms.

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<th>Grade</th>
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<tbody>
<tr>
<td>C</td>
<td>14, 22, 24, 32, 34</td>
<td>51</td>
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</table>

If Primary Sclerosing Cholangitis (PSC) is detected before this time, surveillance should commence at the time of its diagnosis.

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<tr>
<td>C</td>
<td>14, 22, 24, 32, 34</td>
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Patients with a strong personal family history of colorectal cancer (CRC) should start surveillance earlier.

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</thead>
<tbody>
<tr>
<td>C</td>
<td>14, 22, 24, 32, 34</td>
<td>51</td>
</tr>
</tbody>
</table>
### 4.5 Optimal surveillance intervals

A. Annual colonoscopic surveillance is recommended for patients with ulcerative colitis extending proximal to the sigmoid colon or patients with Crohn’s colitis affecting more than one third of the colon and with one or more of the following risk factors:

- active disease
- Primary sclerosing cholangiitis
- Family history of colorectal cancer in first degree relative < 50 years old
- colonic stricture, patients with multiple inflammatory polyps or shortened colon
- previous dysplasia

B. Three yearly colonoscopy is recommended for patients with:

- inactive ulcerative colitis extending proximal to the sigmoid colon without any of the above risk factors
- patients with Crohn’s colitis affecting more than one third of the colon without any of the above risk factors
- IBD patients with a family history of colorectal cancer in a first degree relative > 50 years old

C. Five yearly colonoscopy recommended for patients in whom two previous colonoscopies that were macroscopically and histologically normal.

### 4.6 Optimal colonoscopic protocol

If available, the use of chromoendoscopy/dye spraying where targeted biopsies are obtained from visibly abnormal lesions or strictures is the preferred means to conduct colonoscopic surveillance in IBD. This is especially true for patients at high risk of colorectal cancer.

If chromoendoscopy is unavailable, or if an endoscopist lacks sufficient expertise with this technique, or if the presence of inflammation interferes with the interpretation of chromoendoscopy, an acceptable alternative practice is using standard white light endoscopy with random non-targeted biopsies from each colonic segment and from raised lesions.

When chromoendoscopy is used, random biopsies are required from each colonic segment to establish histological extent and severity of disease. More intensive mucosal sampling from each colonic segment is indicated in patients with a suspicious visible lesion or in situations where chromoendoscopic interpretation is compromised by factors such as active inflammation, inflammatory polyps or poor bowel preparation.
<table>
<thead>
<tr>
<th>Chapter</th>
<th>Recommendations</th>
<th>Grade</th>
<th>Refs</th>
<th>Page</th>
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</thead>
<tbody>
<tr>
<td>4.7</td>
<td><strong>Surveillance protocol practised in Crohn’s disease, indeterminate colitis and patients with ileo-anal pouches</strong>&lt;br&gt;Based on cancer risk, it is recommended that similar colonoscopic surveillance be undertaken for Crohn’s colitis as in ulcerative colitis of equivalent extent, even though supporting evidence is sparse.</td>
<td>D</td>
<td>31,46</td>
<td>55</td>
</tr>
<tr>
<td></td>
<td>Specific areas where surveillance is required in Crohn’s disease are patients with colonic strictures or complicated anorectal disease.</td>
<td>D</td>
<td>31,46</td>
<td>55</td>
</tr>
<tr>
<td>4.8.1</td>
<td><strong>Elevated dysplastic lesions</strong>&lt;br&gt;Raised lesions containing dysplasia may be treated endoscopically provided the entire lesion is removed and there is no dysplasia in flat mucosa elsewhere in the colon.</td>
<td>D</td>
<td>49, 52</td>
<td>56</td>
</tr>
<tr>
<td></td>
<td>If a raised dysplastic lesion cannot be completely removed, or if there is dysplasia elsewhere in the colon, surgical intervention is strongly recommended.</td>
<td>D</td>
<td>49, 52</td>
<td>56</td>
</tr>
<tr>
<td>4.8.2</td>
<td><strong>High grade dysplasia in flat mucosa</strong>&lt;br&gt;High grade dysplasia in flat mucosa is a strong risk factor for established or imminent carcinoma, and colectomy is usually recommended.</td>
<td>B</td>
<td>35, 53</td>
<td>56</td>
</tr>
<tr>
<td>4.8.3</td>
<td><strong>Low grade dysplasia in flat mucosa</strong>&lt;br&gt;Multifocal low grade dysplasia is associated with a sufficiently high risk of future cancer that colectomy is usually recommended. Patients who elect to avoid surgery require follow up surveillance at three months, preferably with chromoendoscopy, and if this examination is normal, annually.</td>
<td>C</td>
<td>35, 54-58</td>
<td>57</td>
</tr>
<tr>
<td></td>
<td>Unifocal low grade dysplasia may be followed by ongoing surveillance at six months, and if this examination is normal, annually.</td>
<td>C</td>
<td>35, 54-58</td>
<td>57</td>
</tr>
<tr>
<td>4.8.4</td>
<td><strong>Indefinite dysplasia in flat mucosa</strong>&lt;br&gt;Indefinite dysplasia in flat mucosa does not require surgery, but follow-up colonoscopic surveillance is justified, preferably with chromoendoscopy, at more frequent intervals.</td>
<td>B</td>
<td>35, 59</td>
<td>58</td>
</tr>
<tr>
<td>Chapter</td>
<td>Recommendations</td>
<td>Grade</td>
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<tr>
<td>5.</td>
<td><strong>PSYCHOSOCIAL ASPECTS OF SURVEILLANCE COLONOSCOPY, AFTER COLORECTAL CANCER RESECTION, POLYPS AND IN INFLAMMATORY BOWEL DISEASE</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5.6</td>
<td><strong>Amelioration of anxiety in relation to colonoscopy</strong></td>
<td>C</td>
<td>7, 12, 15, 16, 18, 19, 20, 21</td>
<td>67</td>
</tr>
<tr>
<td></td>
<td>Pre-colonoscopic advice to patients by means of educational material, video and clinical explanation can assist in improving patient experience with the procedure and in reducing anxiety.</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>5.7</td>
<td><strong>Music as an aid to improving comfort of colonoscopy</strong></td>
<td>C</td>
<td>22-24</td>
<td>68</td>
</tr>
<tr>
<td></td>
<td>Music provided to patients during colonoscopy may reduce their discomfort.</td>
<td></td>
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</tr>
<tr>
<td>5.9</td>
<td><strong>Elements of clinical care available for patients undergoing colonoscopy</strong></td>
<td>PP</td>
<td></td>
<td>69</td>
</tr>
<tr>
<td></td>
<td>Controversy continues with regard to choice of drugs for sedation and monitoring patients during colonoscopy.</td>
<td></td>
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<tr>
<td>6.</td>
<td><strong>SOCIO-ECONOMIC FACTORS</strong></td>
<td>B</td>
<td>19, 20, 21, 22</td>
<td>73</td>
</tr>
<tr>
<td></td>
<td>Clinicians may assist in improving survival outcomes in curative resection for colorectal cancer patients who are socioeconomically or otherwise disadvantaged by expediting their access to optimal clinical care.</td>
<td></td>
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</tbody>
</table>
1 ADVANCES IN COLONOSCOPY, CT COLONOGRAPHY AND OTHER METHODS OF INVESTIGATION

1.1 COLONOSCOPY

As described in Chapter 8 of the Second Edition of the Clinical Practice Guidelines for the Prevention, Early Detection and Management of Colorectal Cancer (2005), colonoscopy is the first-line investigation for assessing the colon and rectum, having a sensitivity of 95% for detection of colorectal (bowel) cancer. Colonoscopy allows biopsy and histologic confirmation of the diagnosis of cancer as well as identification and immediate removal of synchronous polyps.

The purpose of this chapter is to detail technical advances and improvements in colonoscopy relevant to surveillance. It also addresses the issue (and importance) of high-quality colonoscopy (every aspect of which relates to surveillance colonoscopy, given that the main thrust of all of the burgeoning literature about colonoscopy quality relates to polyp detection and minimisation of polyp miss rates) and mentions potential alternative colon imaging technologies, both established and emerging, since colonoscopy is not the sole modality for colonic investigation.

1.1.1 Accuracy of colonoscopy

Like most other diagnostic tests, colonoscopy has a false negative rate for detection of colorectal cancer and adenomas. This needs to be taken into consideration when decisions are made about the choice and timing of surveillance procedures. While the overall sensitivity for colorectal cancer is 95%, the available literature suggests that cancer miss rates are higher in the proximal colon than elsewhere in the large bowel. In a systematic review of polyp miss rates as determined by tandem colonoscopy, Van Rijn et al (2006) identified studies in which patients had undergone two same-day colonoscopies with polypectomy. The research yielded six studies, involving a total of 465 patients. The pooled miss rate for polyps of any size was 22%. Adenoma miss rate by size was 2.1% for adenomas ≥10 mm, 13% for adenomas 5–10 mm, and 26% for adenomas 1–5 mm, respectively. Analysis of the data suggests that, in expert hands, colonoscopy rarely misses polyps ≥10 mm, but the miss rate increases significantly with smaller sized polyps.

In a more recent study, Heresbach et al 2008 examined adenoma miss rate by performing a large multicentre study, with same-day back-to-back video colonoscopy performed by two different colonoscopists in randomised order and blinded to results of the other examination. The miss rates for all polyps, all adenomas, polyps ≥ 5 mm, adenomas ≥5 mm, and advanced adenomas were, respectively, 28%, 20%, 12%, 9% and 11%. Greater diameter (1-mm increments) and number of polyps (≥3) were independently associated with a lower polyp miss rate, whereas sessile or flat shape was significantly associated with a higher miss rate.

1.1.2 Technological developments

In recent years there has been rapid progress in instrument design to enhance colonoscopic identification of lesions, reduce miss rates and reduce complications. The new features include high definition colonoscopy, wide angle colonoscopy, narrow band imaging (NBI), hood-assisted colonoscopy and chromoendoscopy. High definition, wide angle and narrow band imaging technologies have been incorporated into most of the latest generation of colonoscopes. However, more studies are needed to assess the place of these various modifications, especially chromoendoscopy, in colonoscopic surveillance.
1.1.2.1 High definition colonoscopy

As the name suggests, high definition (HD) colonoscopy system uses a high-definition 1080-line television and a high resolution charge-coupled device (CCD) with up to 1 million pixels, which provides images double the quality of normal television. While Pellise et al did not find any improvement over standard colonoscopy, Buchner et al indicated that adenoma detection rates are improved through use of high-definition colonoscopy, which can detect subtle mucosal changes. In their retrospective study, the adenoma detection rate was higher among patients who underwent high definition white light compared with standard definition white light colonoscopy (28.8% versus 24.3%; P = .012). These findings remained after adjusting for potentially confounding variables.

1.1.2.2 Wide angle colonoscopy

With this method, the instrument has a field of vision of 170°, which is 30% more than the conventional model. The aim is to improve the detection of lesions hidden behind colonic folds. With one exception, all studies reported in the available literature from 2003 to 2010 suggest that prototype wide angle colonoscopes do not eliminate polyp miss rates, but have the potential to reduce examination time and improve visualisation in the periphery of the endoscopic field of view.

1.1.2.3 Narrow Band Imaging (NBI)

The NBI technology uses a band-restricted light source centred at 415 nm (blue) and 540 nm (green). The narrowed light penetrates the mucosa and submucosa and is absorbed primarily by haemoglobin. Thus, surface micro-vessels are visible as dark structures. Because the density and shape of micro-vessels change in neoplasia, NBI and equivalent technologies have the potential to aid in the diagnosis of neoplastic lesions. In addition, NBI helps distinguish between different histologic groups and assess depth of invasion.

In a randomised controlled trial, 401 patients were assigned to undergo wide angle colonoscopy using either conventional high-resolution imaging or NBI during instrument withdrawal. When the two techniques were compared in consecutive subgroups of 100 patients, adenoma detection rates in the NBI group remained stable (approximately 25%) whereas these rates steadily increased in the control group (8%, 15%, 17%, and 26.5%, respectively). Significant differences in the first 100 cases (26.5% versus 8%; p=0.02) could not be maintained in the last 100 cases (25.5% versus 26.5%, p=0.91). The increased adenoma detection rates with NBI colonoscopy were statistically not significant. Similar results were reported by Rex and Helbig and Kaltenbach et al.

Significant differences were, however, identified when NBI was used to detect additional polyps in members of Lynch syndrome (HNPCC) families.

Although less well-studied with regard to their potential additive benefit in polyp detection, other commercial image modification/enhancement technologies, I-Scan (Pentax instruments) and FICE (Fujinon), are available and are similarly conveniently accessible on the respective instruments.

1.1.2.4 Chromoendoscopy

Chromoendoscopy (or dye spray) has been introduced to enhance the detection of polyps particularly diminutive flat lesions that may be otherwise difficult to detect.
When combined with high magnification, chromoendoscopy was found to be highly efficient for separating adenomatous from non-adenomatous polyps and for detecting changes in patients with inflammatory bowel disease. As discussed in Chapter 4, chromoendoscopy is becoming the standard method for detection of dysplasia in inflammatory bowel disease.

However, based on results from their studies, Lapalus et al and Le Rhun could not recommend the systematic use of chromoendoscopy and structure enhancement, although the detection of small adenomas in the proximal colon was improved. In the randomised prospective study by Lapalus et al, a combination of chromoendoscopy and structure enhancement was used to increase the adenoma detection rate in high-risk patients with a personal history of colorectal adenomas and/or a family history of colorectal cancer.

Separate randomised controlled trials published within the same year also suggest that chromoendoscopy detects more polyps missed by standard colonoscopy than intensive inspection, particularly in patients with Lynch syndrome. Although very promising, its use has not yet become widespread.

More recently, Sanduleanu et al combined chromoendoscopy (C) with confocal laser endomicroscopy (CLE) that allows real-time in vivo microscopy of the mucosa and provides accurate histopathology. The study concluded that C-CLE accurately discriminates adenomatous from nonadenomatous colorectal polyps and enables evaluation of the degree of dysplasia during ongoing endoscopy.

1.1.2.5 Hood-assisted colonoscopy

Hood assisted colonoscopy is colonoscopy with a transparent retractable extension. A transparent “hood” (or “cap”) is a simple device that can be attached to the tip of a colonoscope before performing the examination. Although adding to the cost of colonoscopy, it has been proposed as a method for shortening withdrawal time in addition to improving adenoma detection rates.

Some consider that use of the hood mainly helps less experienced colonoscopists. With more experienced colonoscopists, the hood does not improve either the caecal intubation rate or the adenoma detection rate, but does shorten the caecal intubation time. It therefore should be reserved for selected cases, especially when initial caecal intubation fails.

1.1.3 Quality of colonoscopy

Many factors affect the quality of colonoscopy, including the provision and proper maintenance of appropriate equipment, adherence to up-to-date protocols for all phases of the procedure, and having processes in place for regular auditing of outcomes and on-going quality improvement.

All such factors are directly relevant to surveillance colonoscopy in the three settings covered by these guidelines, in which detection of metachronous polyps (for patients with prior adenomatous polypectomy or colorectal cancer resection) and visible dysplasia (for patients with inflammatory bowel disease) is pivotal to surveillance purposes.

Above all, the colonoscopist must have the necessary technical skills and understanding to perform colonoscopy effectively and with safety. Colonoscopy is highly operator-dependent. The colonoscopist therefore should have undergone supervised training that meets the requirements of appropriate professional bodies as well as meeting agreed standards for ongoing competence. Basic skills include torque steering, loop recognition and reduction, recognition of landmarks to confirm complete examination, and the ability to carefully withdraw the colonoscope to maximize lesion detection and to perform polypectomy.
Higher lesion detection rates are associated with adequate distension, suction and cleaning, position change, and slow and meticulous examination of the colonic mucosa, including areas behind folds. Measurement and recording of colonoscope withdrawal time (the time taken between caecal intubation and colonoscope withdrawal from the anus, excluding the time taken for biopsy and polypectomy) is a key indicator of adequacy of the examination.

Advances continue to be made in colonoscopic techniques (e.g. the use of carbon dioxide rather than air for insufflation, availability of foot pedal-operated water jets to clear faecal matter and through-channel narrow endoscopes for retroflexion in the caecum and rectum) that may allow easier examination and greater patient comfort and safety.

Colonoscopy is considered to be a relatively safe procedure for the diagnosis of colorectal disease. However, as with any invasive procedure, there is a risk of adverse events occurring either directly or indirectly as a result of the procedure.

The National Bowel Cancer Screening Program (NBCSP) Quality Working Group report recommends standards, objectives and performance indicators for use in Australia, as set out below. They are grouped together for three phases – before, during and after the procedure – as high quality colonoscopy depends on decisions and actions taken during each phase.

### 1.1.3.1 Indicators of quality for the pre-procedure phase

Indications for colonoscopy should comply with national guidelines and risk factors should be assessed, with recording of actions taken to address specific risks (Table 1.1).

#### What will your patients expect?
- That there is a valid indication for the procedure
- That risk factors (e.g. anticoagulant therapy, presence of severe co-morbidities) will be identified well before colonoscopy and action taken to minimise risk

### Table 1.1: Clinical standards, objectives and indicators for the pre-procedure phase - indications and assessment of risk

<table>
<thead>
<tr>
<th>Standard</th>
<th>Objective</th>
<th>Performance indicators</th>
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</thead>
<tbody>
<tr>
<td>Standard 1: Patient indications and risks</td>
<td>Objective 1.1: Assessment of patient indications</td>
<td>A 100 per cent documentation and reporting of the following indications for colonoscopy for:</td>
</tr>
<tr>
<td>A comprehensive assessment of indications for the procedure and risks and co-morbidities is undertaken for each patient prior to the performance of the procedure.</td>
<td>The colonoscopist ensures that there is full documentation and reporting of the indications for colonoscopy as listed for each patient category</td>
<td>○ Asymptomatic patients:</td>
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<td>– family history (as per CRC Guidelines 2005)1;</td>
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<td></td>
<td></td>
<td>– previous colorectal cancer or adenomatous polyps (as per CRC Guidelines 2005)1;</td>
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<tr>
<td></td>
<td></td>
<td>– colitis surveillance for patients with increased cancer risk; and</td>
</tr>
<tr>
<td>Standard</td>
<td>Objective</td>
<td>Performance indicators</td>
</tr>
<tr>
<td>---------------</td>
<td>---------------------------------------------------------------------------</td>
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</tr>
<tr>
<td></td>
<td>Objective 1.2: Assessment of patient risk and co-morbidity</td>
<td>A 100 per cent documentation and reporting of the assessments for:</td>
</tr>
<tr>
<td></td>
<td>The colonoscopist ensures that there is full documentation and reporting of information about patient risk and co-morbidity.</td>
<td>○ Sedation risks with reference to the American Society of Anesthesiologists (ASA) classifications.</td>
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<tr>
<td></td>
<td></td>
<td>○ Action related to specific risks including:</td>
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<td></td>
<td>– the need to cease aspirin or other antiplatelet drugs or anti-coagulants;</td>
</tr>
<tr>
<td></td>
<td></td>
<td>– the need for antibiotic prophylaxis; and</td>
</tr>
<tr>
<td></td>
<td></td>
<td>– diabetes mellitus.</td>
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<tr>
<td></td>
<td></td>
<td>○ Patients cancelled on the day due to unforeseen co-morbidities.</td>
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</table>

Informed consent should be obtained from all patients or their parent/legal guardian, using a structured approach. Preferably, it should be obtained before the period of bowel preparation. The patient needs to understand what is involved in the procedure and the possible risks, both in general and in the patient’s specific case (Table 1.2).

**What will your patients expect?**

- To be given a clear explanation of what is involved in the procedure and to have an opportunity to ask for more information
- That this information will be provided before embarking on bowel preparation
Table 1.2: Clinical standards, objectives and indicators for the pre-procedure phase - patient consent

<table>
<thead>
<tr>
<th>Standard</th>
<th>Objective</th>
<th>Performance indicators</th>
</tr>
</thead>
</table>
| Standard 2: Patient consent | Objective 2.1: Patient information, education and consent | A Every patient (or parent/legal guardian where applicable) is provided with:  
   - A full explanation about the requirements for adequate bowel preparation.  
   - A full explanation of the procedure.  
   - A full explanation of the risks and complications involved including co-morbidity and sedation risks, and also the risks associated with not having the procedure.  
   - Opportunities to ask questions and receive advice on options. |

Informed consent using a structured approach is obtained from all patients (or parent/legal guardian where applicable) for all procedures prior to the procedure(s) being undertaken.

The colonoscopist ensures that the patient (or parent/legal guardian where applicable) provides his/her informed consent to all aspects of the procedure(s) to be undertaken by confirming that the information detailed in the performance indicators is provided at all times.

Every patient (or parent/legal guardian where applicable) is provided with:

- A full explanation about the requirements for adequate bowel preparation.
- A full explanation of the procedure.
- A full explanation of the risks and complications involved including co-morbidity and sedation risks, and also the risks associated with not having the procedure.
- Opportunities to ask questions and receive advice on options.

Proper bowel preparation is required to allow full examination of the large bowel, to improve the outcome and to avoid the need for a repeat procedure (Table 1.3). The timing of bowel preparation also influences the quality of cleansing of the bowel.  

Table 1.3: Clinical standards, objectives and indicators for the pre-procedure phase - bowel preparation

<table>
<thead>
<tr>
<th>Standard</th>
<th>Objective</th>
<th>Performance indicators</th>
</tr>
</thead>
</table>
| Standard 3: Bowel preparation | Objective 3.1: Bowel preparation | A 100 per cent of patients receive bowel preparation education.  
   - There is 100 per cent documentation of the type and quality of bowel preparation.  
   - Less than 10 percent of patients require a repeat colonoscopy examination due to poor bowel preparation. |

Bowel preparation is undertaken to a high standard.

The colonoscopist ensures that high quality bowel preparation is performed that is appropriate for individual patient risk factors and preferences.
1.1.3.2 Indicators of quality for the procedure phase

Key indicators for competence include volume, i.e. the number of procedures performed annually\textsuperscript{39, 40}, caecal intubation rate\textsuperscript{41, 42}, instrument withdrawal time\textsuperscript{43, 44}, adenoma detection rate\textsuperscript{45, 46} and complication rates\textsuperscript{40, 47}.

The European Panel on the Appropriateness of Gastrointestinal Endoscopy (EPAGE) multicentre study provided a unique opportunity to examine the quality and technical performance of a large number of colonoscopies performed at multiple centres in different countries in Europe. Consecutive patients were referred for colonoscopy from 21 centres in 11 countries and 6,004 patients were included. The study found that variations in colonoscopy practice exist. Patients from centres where over 50% of the endoscopists were of senior rank were roughly twice as likely to have an adenoma diagnosed. Longer average withdrawal duration was associated with more frequent detection of adenomas\textsuperscript{48}.

The NBCSP Quality Working Group’s recommended standards, objectives and performance indicators relating to proficiency of the proceduralist are set out in Table 2.1.

<table>
<thead>
<tr>
<th>What will your patients expect?</th>
</tr>
</thead>
<tbody>
<tr>
<td>• That the colonoscopist is well trained in the procedure and meets agreed standards for competence</td>
</tr>
<tr>
<td>• That there will be skilful and thorough examination of all parts of the large bowel.</td>
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</table>

<table>
<thead>
<tr>
<th>What will histopathologists expect?</th>
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<tbody>
<tr>
<td>• That polyps sent for examination will be identified by site within the large bowel</td>
</tr>
<tr>
<td>• That colonoscopists will carefully measure and record the size of these polyps, either in situ or after retrieval, to enable adenomas to be classified as advanced (≥10 mm in diameter) or non-advanced (&lt;10 mm in diameter) on the basis of their size</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>What will quality reviewers expect?</th>
</tr>
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<tbody>
<tr>
<td>• That colonoscopists will document the extent of the examination to be able to accurately calculate their ileo-caecal intubation rate</td>
</tr>
<tr>
<td>• That colonoscopists record instrument withdrawal times, a surrogate marker of careful examination behind folds</td>
</tr>
<tr>
<td>• That colonoscopists periodically calculate their adenoma detection rate</td>
</tr>
</tbody>
</table>
Table 2.1: Clinical standards, objectives and indicators for the procedure phase - proficiency of proceduralist

<table>
<thead>
<tr>
<th>Standard</th>
<th>Objective</th>
<th>Performance indicators</th>
</tr>
</thead>
<tbody>
<tr>
<td>Standard 4: Proficiency of proceduralist</td>
<td>Objective 4.1: Measures of the proficiency of the proceduralist</td>
<td>A Each proceduralist performs more than 250 procedures per five years.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>B The caecal intubation rate for each proceduralist is 90 per cent or greater for general patients and 95 per cent or greater for screening patients.</td>
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<tr>
<td></td>
<td></td>
<td>C The mean colonoscope withdrawal time from the caecum for each proceduralist is 6 minutes or greater for procedures where there is no polypectomy performed.</td>
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<td></td>
<td></td>
<td>D The adenoma detection rate for each proceduralist is more than 20 per cent in patients over 50 years of age undertaking an initial colonoscopy.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>E The rate of polyp recovery for pathological examination for each proceduralist is more than 90 per cent.</td>
</tr>
</tbody>
</table>

Proceduralists are proficient in providing high quality colonoscopies.

The proceduralist ensures that the following data is captured and recorded:

- Number of colonoscopies he/she performs per annum.
- Caecal intubation rate determined by photodocumentation of caecal landmarks. (Definition of caecal intubation: passage of the instrument tip proximal to the ileo-caecal valve so that the entire caecal caput is visible.)
- Mean colonoscope withdrawal time from the caecum.
- Adenoma detection rate.
- Rate of polyp recovery for pathological examination.

The literature identifies a range of complications and adverse events associated with colonoscopy. One Australian study investigated the rates of these complications. The authors conducted an audit in three teaching hospitals in Western Australia from September 1989 to December 1999. The main complications identified were post-colonoscopy bleeding and post-colonoscopy perforation of the bowel. The rates of bleeding and perforation were found to be 0.21% and 0.1% respectively. Other complications included abdominal pain, nausea/vomiting, excess sedation, cardiovascular complications, cerebrovascular complications and pulmonary aspiration. The death rate associated with colonoscopy was 0.01%.

Following an extensive Medline database search (published from 2000 onwards), Panteris et al found that the frequency of perforation is 1 in 1400 for all colonoscopies and 1 in 1000 for therapeutic colonoscopies. Advanced age, female sex, the presence of multiple co-morbidities, diverticular disease, and bowel obstruction have been shown to increase the risk of perforation.

Rare complications include rupture of the spleen and acute appendicitis. These uncommon or rare procedural complications need to be balanced against the risks of not performing colonoscopy in each of the three clinical situations addressed by these guidelines (namely post-cancer resection, post-adenoma removal and in chronic inflammatory bowel disease). In each of these clinical scenarios, the patient is at above-average risk in their lifetime of developing CRC if surveillance colonoscopy is not repeated. While this risk (of developing CRC) differs amongst patients in each of the three different clinical situations (and even between patients with differing prior adenoma findings, e.g. one or two small adenomas versus multiple villous adenomas more than 1 cm in size) and may be difficult to accurately quantify for a given individual, it is in each scenario more than 1 in 17 by age 75 for males and more than 1 in 27 by age 75 for females.
Complications arising during a procedure should be well documented and reported as proposed by the NBCSP Quality Working Group (Table 2.2)

<table>
<thead>
<tr>
<th>Standard</th>
<th>Objective</th>
<th>Performance indicators</th>
</tr>
</thead>
<tbody>
<tr>
<td>Standard 5: Minimisation of patient complications</td>
<td>Objective 5.1: Measures of patient complications</td>
<td>A Colonic perforations caused by colonoscopy in less than 1 in 1,000 colonoscopy procedures.</td>
</tr>
<tr>
<td>Patient complications associated with colonoscopy are minimised.</td>
<td>The proceduralist ensures that the following data are captured and recorded:</td>
<td>B Post-polypectomy bleeding in less than 1 in 100 patients who have had a polypectomy.</td>
</tr>
<tr>
<td></td>
<td>o Colonic perforations caused by colonoscopy.</td>
<td>C Sedation complications:</td>
</tr>
<tr>
<td></td>
<td>o Post-polypectomy bleeding.</td>
<td>o Respiratory depression or airway obstruction requiring unplanned intervention in less than 1 in 100 patients.</td>
</tr>
<tr>
<td></td>
<td>o Sedation complications:</td>
<td>o Hypoxia defined as pulse oximetry greater than 10 percentage points lower than awake pre-procedural baseline for greater than 60 seconds consecutively during or after the procedure in less than 1 in 100 patients.</td>
</tr>
<tr>
<td></td>
<td>– respiratory depression or airway obstruction requiring unplanned intervention;</td>
<td>o Hypotension requiring drug or fluid therapy in less than 1 in 100 patients.</td>
</tr>
<tr>
<td></td>
<td>– hypoxia defined as pulse oximetry greater than 10 percentage points lower than awake pre-procedural baseline for greater than 60 seconds consecutively during or after the procedure;</td>
<td>o Cardiac arrhythmia requiring intervention in less than 1 in 1,000 patients.</td>
</tr>
<tr>
<td></td>
<td>– hypotension requiring drug or fluid therapy;</td>
<td>o Pulmonary aspiration of gastric contents in less than 1 in 1,000 patients.</td>
</tr>
<tr>
<td></td>
<td>– cardiac arrhythmia requiring intervention;</td>
<td>o The use of reversal agents in less than 1 in 10 patients.</td>
</tr>
<tr>
<td></td>
<td>– pulmonary aspiration of gastric contents;</td>
<td>o Patient complaint about sedation in less than 1 in 100 patients.</td>
</tr>
<tr>
<td></td>
<td>– the use of reversal agents; and</td>
<td>D Abnormal discomfort or pain in less than 1 in 100 patients.</td>
</tr>
<tr>
<td></td>
<td>– patient complaint about sedation.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o Abnormal discomfort or pain: warranting hospital admission;</td>
<td></td>
</tr>
</tbody>
</table>

What will your patients expect?

- That the procedure will be performed safely and with minimal discomfort
1.1.3.3 Indicators of quality for the post-procedure phase

Several studies have found marked variation in the quality of reports describing findings at colonoscopy. The NBCSP Quality Working Group recommendations for comprehensive reporting and management in the post-procedure phase are set out in Table 3.

<table>
<thead>
<tr>
<th>Standard</th>
<th>Objective</th>
<th>Performance indicators</th>
</tr>
</thead>
<tbody>
<tr>
<td>Standard 6: Provision of detailed performance information</td>
<td>Objective 6.1: Documenting and reporting of relevant performance information</td>
<td>A Detailed quality and performance information in relation to the Objective is</td>
</tr>
</tbody>
</table>

Table 3: Clinical standards, objectives and indicators for the post-procedure phase – documentation and reporting of performance information

What will your patients expect?
- Verbal and written information about the results of the procedure
- Verbal and written instructions about action to take if problems occur after discharge
- Information about follow-up review

What will referring doctors expect?
- Prompt receipt of a detailed report on the procedure
- A copy of any histopathology report
- Recommendations for further action

What will quality reviewers expect?
- That colonoscopists will conduct periodic audits of performance indicators
- That colonoscopists will welcome the opportunity to participate in quality improvement activities

Standard Objective Performance indicators

- delaying discharge; or patient complaint of inadequate pain relief during procedure.
- Procedure related death within 30 days.
- Procedure related death within 30 days in less than 1 in 10,000 patients.
<table>
<thead>
<tr>
<th>Standard</th>
<th>Objective</th>
<th>Performance indicators</th>
</tr>
</thead>
<tbody>
<tr>
<td>Detailed information about the quality of the procedure and the colonoscopist’s performance is provided to relevant stakeholders.</td>
<td>The colonoscopist ensures that he/she:</td>
<td>documented and provided for all patients at all times.</td>
</tr>
<tr>
<td></td>
<td>o Completes a standard structured report on the procedure, with a copy or letter provided to the referring general practitioner (and/or NBCSP) that includes information on:</td>
<td>B Self-audit and analysis of proceduralist performance on a half-yearly basis.</td>
</tr>
<tr>
<td></td>
<td>– the standard of bowel preparation;</td>
<td></td>
</tr>
<tr>
<td></td>
<td>– depth of insertion of colonoscope;</td>
<td></td>
</tr>
<tr>
<td></td>
<td>– presence of pathology;</td>
<td></td>
</tr>
<tr>
<td></td>
<td>– any intervention performed; and</td>
<td></td>
</tr>
<tr>
<td></td>
<td>– any unexpected outcomes.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o Provides a written report on colonoscopy findings for patients and ensures that patients are given contact details in case of an emergency.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o Completes and forwards a pathology request form to the pathologist, where applicable, with identification of the referring general practitioner and status as an NBCSP participant where applicable so that the information can be added to the National Register.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o Completes the required NBCSP reports where applicable.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o After a complete colonoscopy, documents a follow-up appointment with the referring general practitioner, specialist or colonoscopist and, where appropriate, provides information on the recommended time for the patient to undergo the next colonoscopy.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o After an incomplete colonoscopy, documents a plan for repeat colonoscopy, barium</td>
<td></td>
</tr>
</tbody>
</table>
1.2 BARIUM ENEMA

In the past, double contrast barium enema (DCBE) was indicated if there were difficulties with access to colonoscopy or when colonoscopy was incomplete. Despite the American College of Radiology drawing attention to quality issues associated with its performance, the rectum and rectosigmoid region are not well visualised on DCBE and lesions are commonly missed in the sigmoid colon, because of underlying diverticular disease, and on the right side of the colon.

In recent years, DCBE has been increasingly superseded by CT colonography as the preferred radiological method for imaging the large bowel.

1.3 CT COLONOGRAPHY

Computerised tomographic colonography (CTC) utilises advanced imaging that permits minimally invasive evaluation of the colon and rectum without the need for sedation. It has an established place in investigation of symptomatic patients and following incomplete colonoscopy. The risk for procedure-related complications is low, suggesting that it may be useful as a screening tool for asymptomatic people at risk for colorectal neoplasia.

CTC has been recommended for the use in surveillance following adenoma resection and for the follow-up of patients after resection of colorectal cancer. Its performance characteristics for detecting symptomatic lesions may be satisfactory, but its place in the detection of asymptomatic colorectal lesions remains controversial. Some studies reported high sensitivities, but the results of the studies are heterogeneous.

In a meta-analysis of the diagnostic accuracy of CTC for the detection of polyps and colorectal cancer, based on 47 studies that contain data of 10,546 patients, overall per-polyp sensitivity of CTC was 66% (CI 64–68%). For polyps 6–9 mm in size, per-polyp sensitivity was 59% (56–61%), and for polyps larger than 9 mm it was 76% (73–79%). For polyps 6–9 mm and for lesions larger than 9 mm, per-patient sensitivity was 69% (66–72%), 60% (56–65%) and 83% (70–85%), respectively.

Data from The National CT Colonography Trial, which included 2600 asymptomatic participants aged ≥50 years, at 15 study centres, found that that CTC failed to detect lesions ≥10mm in 10% of people.
In a recent report on a non-randomised multicentre study involving 615 participants aged 50 years or older, Cotton et al. considered that CTC is not yet ready for widespread application in surveillance and that techniques and training need to be improved. In addition, the accuracy of CTC varied considerably between centres and did not improve as the study progressed.

It should be noted that CT involves larger radiation doses than the more common, conventional x-ray imaging procedures. This raises the question of whether the benefits outweigh the risk associated with using CT in conjunction with colonography, especially in the setting of repeated surveillance examinations. For analyses of the colon the average organ dose is 15mGy which is relatively one of the higher doses used in comparison to other organs. It is well documented that there is a significant association between radiation dose and cancer. Nonetheless radiation doses from commonly performed diagnostic CT examinations are variable, highlighting the need for greater standardisation across institutions.

### 1.4 EMERGING TECHNOLOGIES

#### 1.4.1 Magnetic resonance colonography

Several studies indicate that magnetic resonance colonography (MRC) could become an alternative to CTC for imaging the large bowel, not having the disadvantage of radiation exposure. At present, access to this investigation is limited by the high cost of MR equipment and competition with other MR-based investigations.

#### 1.4.2 Video-capsule colonoscopy

Video-capsule endoscopy has become an important tool for investigation of disorders of the small bowel. While there is interest in its potential for imaging the large bowel, the place for video-capsule colonoscopy is still uncertain.

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13 Clinical Practice Guidelines for Surveillance Colonoscopy - in adenoma follow-up, following curative resection of colorectal cancer, and for cancer surveillance in inflammatory bowel disease
References


75. Redberg RF. Cancer risks and radiation exposure from computed tomographic scans: how can we be sure that the benefits outweigh the risks? Arch Intern Med 2009;169(22):2049-2050.


2 MANAGEMENT OF EPITHELIAL POLYPS: COLONOSCOPIC SURVEILLANCE AFTER POLYPECTOMY

Patients who have adenomatous polyps removed at colonoscopy are then at above-average risk for the development of metachronous adenomatous polyps and colorectal cancer. This chapter aims to review the available evidence so that such patients can be advised about an appropriate interval for subsequent surveillance colonoscopy.

2.1 Adenomas and risk of developing colorectal cancer

Adenomas are classified as tubular, tubulovillous and villous adenomas and serrated adenomas. Adenomas with a villous component have more malignant potential and are usually larger than the more common type, tubular adenomas. In 2000, the World Health Organization (WHO) define tubular adenomas as having <20% villous component, tubulovillous as 20-80% and villous as >80% villous component.1 A recent WHO update made a minor adjustment to these percentages (<25%, 25-75%, >75%).2

The concept of the risk of malignancy in any particular adenoma, and its relationship to size, villosity and dysplasia, and even focal malignancy, is well established. The larger the adenoma, the greater the chance of high levels of villosity, high grade dysplasia and malignancy and the higher the chance of multiple adenomas.3 This concept should be clearly distinguished from the predictive capacity of all these adenoma characteristics for the development of metachronous neoplasm, including cancer, in the future.3-8 Strong circumstantial evidence indicates that removal of adenomas and subsequent surveillance by colonoscopy with removal of metachronous adenomas reduce the incidence of colorectal cancer.9-12

Patients with small pale distal hyperplastic polyps only, should be distinguished from patients with adenomas. These patients require no follow-up as there is no increased risk of metachronous colorectal neoplasia.

Practice point:

• Determination of risks for patients with adenomas must clearly distinguish between
  (1) variables that relate to the likelihood of any particular adenoma having a malignant focus and
  (2) variables that relate to patient, pathological and epidemiological characteristics which predict a risk of future (metachronous) adenomas and cancers.
• Patients whose only polyps are small, pale, distal, hyperplastic polyps require no colonoscopic follow-up..

2.1.1 Identifying the risk of metachronous neoplasia after removal of adenomas

Patients with one or two adenomas <10mm in size identified at baseline, where all the adenomas are removed completely and where there are no adenomas with villous features or high grade dysplasia, are considered lower risk than patients with three or more adenomas or with adenomas of ≥ 10mm or adenomas with villous features or high grade dysplasia.

Management of Epithelial polyps: colonoscopic surveillance after polypectomy 20
2.1.1.1 **Adenoma size as a risk factor for future advanced adenoma and CRC**

The probability of developing future advanced adenomas or cancers increases with the size of adenoma found at index examination, and ranges, depending on the study, from 1.5-7.7% for adenomas less than 5mm, 3-15.9% for adenomas of 5-20mm and 7-19.3% for adenomas >20mm.\(^{4,7,13-15}\) Size is usually considered a more robust marker of risk than more advanced histological characteristics (higher grades of villosity and dysplasia) with which it is closely associated.\(^{4,13,14}\)

2.1.1.2 **Villous features and dysplasia grading as a risk factor for future advanced adenoma and CRC**

Villosity grading of patients within the high risk group is based on the accuracy of the morphopathological assessments. Most studies identify villosity as a risk factor, with some indicating it is an independent risk factor even ahead of size, dysplasia and multiplicity. Villosity does, however, closely relate to size which is generally considered easier to measure, and less prone to inter-observer variation amongst pathologists.\(^{4-21}\)

High grade dysplasia (HGD) in the index examination may independently add to the risk of advanced metachronous adenomas, though in some studies this does not achieve significance in multi-variate analysis. Information on adenomas under 1 cm with and without HGD with respect to metachronous risk is lacking.\(^{13}\)

2.1.1.3 **Serrated adenomas as a risk factor for future advanced adenoma and CRC**

Serrated polyps\(^{16,22,23}\) are categorised as hyperplastic polyps, traditional serrated adenomas (TSAs) and sessile serrated adenomas (SSAs), the latter two encompassed by the term serrated adenomas. SSAs are more prevalent in the proximal colon and lack classic dysplasia but may have mild cytologic atypia, whereas TSAs are more prevalent in the rectosigmoid and have cytologic dysplasia. Classification systems for these polyps are still evolving. Histological interpretation of these serrated polyp types differs between pathologists.\(^{17,24,25}\) The majority of studies suggest that TSA and SSA have significant malignant potential and are associated with subsequent development of metachronous neoplasia.\(^{18,21,24,26}\) Some studies suggest that SSAs have a higher potential to develop CRC,\(^{27}\) but others have indicated a similar or lower potential.\(^{28,30}\) This remains controversial and there is not yet sufficient evidence to warrant differentiated management pathways.

2.1.1.4 **Number of adenomas as a risk factor for future advanced adenoma and CRC**

The number and location of individual adenomas found at baseline colonoscopy is associated with advanced adenomas and also with the development of metachronous advanced adenomas.\(^{3,13,31,32}\) A recent analysis of pooled data from eight prospective studies proposed that absolute risks of metachronous advanced adenoma, colorectal cancer, and their combination (advanced colorectal neoplasia) within three to five years is higher in patients with greater than four adenomas at baseline than with <4 adenomas. The risk for metachronous advanced adenomas increased with the number of adenomas at base line and was 8.6%, 12.7%, 15.2%, 19.6% and 24.1% for one, two, three, four, and for five or more adenomas at baseline.\(^{13}\) Risk of a metachronous advanced adenoma approached 20% in patients who had four or more baseline adenomas, or whose largest baseline adenoma was 20 mm in size or greater. In another study the risk of developing colorectal cancer/advanced adenoma was increased in patients with three or more adenomas (0.8-1.1%) compared with less than three adenomas (0.5%) at baseline colonoscopy.\(^{33,33}\)

When the number of polyps found at baseline colonoscopy exceeds ten, familial adenomatous polyposis (FAP) or MUTYH associated polyposis may be the cause.\(^{34,37}\) Individually, these polyps are no more likely to develop cancer than other adenomas; the risk is high because of the number. These conditions
are discussed in detail in Chapter 7 of the Clinical Practice Guidelines for the prevention, early detection and management of colorectal cancer (2005).

Whether the important parameter of number of adenomas should be calculated as cumulative lifetime adenomas, or adenomas at the current colonoscopy, for the purposes of follow-up recommendations, is not clear. Pragmatically, the number at the current colonoscopy is usually assimilated into the risk assessment as the cumulative number is often difficult to ascertain in clinical practice.

### 2.1.1.5 Location of adenomas as a risk factor for future advanced adenoma and CRC

Location of baseline adenomas with respect to *metachronous* risk has been only a more recent focus of attention. Multiple adenomas located in the right colon at baseline colonoscopy are suggested to be a higher risk factor for metachronous adenomas with high grade dysplasia and colorectal cancer.\(^\text{6, 13, 31, 38}\) Ageing tends to increase the number of adenomas in the right colon, while only modestly affecting those in the left colon.\(^\text{39}\)

### 2.1.1.6 Location of adenomas and cancer: protection against right sided cancer in adenoma follow-up

Recent evidence suggests that protection afforded by colonoscopy for right sided cancer development is significantly less than left sided cancer in a range of settings, raising questions of quality in colonoscopy as it relates particularly to the right colon (poor right sided bowel preparation, incomplete colonoscopy, anatomical configurations compromising visibility, or differential biology for right sided lesions).\(^\text{10, 40}\) Thus, endoscopists should pay particular attention to the right colon in their practices – at initial and follow-up examinations. However, there is insufficient evidence to determine differential follow-up intervals for right- compared to left-sided adenoma location at index colonoscopy.

**Practice point:**

- Proximal location of adenomas may be a risk factor for metachronous neoplasia. The extent to which this is driven by the difficulty of detecting proximal polyps, because of their flat and unobtrusive nature (ie. sessile serrated polyps), poor bowel preparation and anatomical blind spots in the right colon, is unclear. For these reasons the right colon deserves particularly careful scrutiny at colonoscopy.

### 2.1.1.7 Models for risk index

A combined index based on odds ratio using regression techniques for number, size, dysplasia and grade of adenomas as well as age, gender, BMI, smoking history and family history may be used in order to quantify risk of metachronous adenomas and mortality from colorectal cancer.\(^\text{13, 41-43}\) These multivariate equations predicting risk carry a degree of complexity which is difficult to introduce into common practice but might nevertheless in the future usefully inform decision making and guidelines. The studies quoted draw attention to the importance of age and number of prior adenomas in risk assessment.\(^\text{13, 41-43}\)
Practice point:
- Because of the complexity of multivariate analyses equations to predict individual patient risk of metachronous polyps, their use currently is difficult to apply to day to day practice.

2.2 Polypectomy

2.2.1 General considerations relating to polypectomy

In the absence of magnifying endoscopy combined with dye spraying, or in some studies, Narrow Band Imaging, it is often not possible to determine the histological type of a polyp by endoscopic inspection. Diminutive hyperplastic polyps and adenomas (5 mm or less) may be indistinguishable. The unusual large hyperplastic polyp may mimic an adenoma.

Practice point:
- All polyps should be considered for removal. Diminutive polyps (5mm or less) may be too numerous to be cleared completely. In patients with multiple small polyps, a sample of at least three should be taken for histological study. However, if a syndromic diagnosis is under consideration, then sampling of many more polyps is important, to guide decisions on which gene should be subjected to mutational analysis.

2.2.2 Large sessile adenomas

In most centres, large sessile polyps are removed by piecemeal endoscopic mucosal resection (EMR) although this can make histological evaluation of completion of polypectomy difficult or impossible. EMR or Endoscopic Submucosal Dissection (ESD) (which secures the specimen in one piece) can be successfully (95%) achieved when done by well trained specialists in specialised centres with the appropriate equipment.

2.2.3 Tattooing polypectomy sites

With any lesion identified at colonoscopy, the colonoscopist should assess whether the lesion can be safely removed endoscopically. For larger polyps or those with features suspicious of malignancy such as an irregular or ulcerated surface, tattooing of the site should be systematically considered. If there is any possibility of a need for later surgical resection of the site, the area should be tattooed, as this aids the surgeon, the pathologist’s examination of the resected specimen and the accuracy of the histopathology report. The tattoo should be placed 2-3cm distal to the lesion (to avoid submucosal fibrosis which makes any further attempt at endoscopic polypectomy more difficult, dangerous and unlikely to be complete) rather than ‘at’ or under the polyp.

This is particularly important in centres where laparoscopic resections are done, as the surgeon has no capacity to feel the polyp or polypectomy site at laparoscopy.

In the event that malignancy is identified unexpectedly in a polyp which has not been tattooed and surgery is the preferred further management strategy, early re-endoscopy is needed to tattoo the site, preferably within a week.

Practice point:
- Tattooing any polyp site where there is a possibility that surgical resection will be needed is important at the primary colonoscopy if at all possible, or very soon after with a second procedure. This is necessary even for conventional surgery, as the site of polypectomy.
may well be impalpable, but particularly important where follow-up treatment may be laparoscopic, as the surgeon has no capacity to palpate the area.

2.3 **Malignant polyps**

Management of malignant polyps by polypectomy alone is now standard practice and is generally acknowledged to be safe, providing that there is adherence to a strict policy of case selection and histopathological assessment recognising four key features that together identify a very low risk of lymph node metastasis: 18-20, 46-49

- a clear margin of excision (1 to 2mm)
- cancer which is well- or moderately-differentiated
- absence of lymphatic or venous invasion
- complete removal as assessed endoscopically

Malignant polyps with unfavourable features may require further treatment, but this decision should be made on the basis of the age, health and wishes of the patient. Treatment decisions will also be influenced by site, particularly in the case of low rectal lesions for which radical surgery would involve abdominoperineal excision and colostomy. For colonic polyps, excision can be achieved successfully by laparotomy with colonic resection or laparoscopically assisted colectomy. 50-53

This section should be read in conjunction with Chapter 3 - Follow-up after curative resection for colorectal cancer.

**Practice point:**
- In general, malignant polyps which,
  1. have a clear margin of excision,
  2. are well or moderately differentiated,
  3. lack lymphatic or venous invasion and
  4. are endoscopically assessed as totally removed can be managed without subsequent surgical resection. However, the decision needs to be individualized with respect to the particular histological and endoscopic features and the patient’s age and co-morbidities.

2.4 **Follow-up surveillance for adenomas**

2.4.1 **Balance of risks and benefits**

Colonoscopy, with or without polypectomy, is an invasive procedure with a small but not insignificant risk of major complications, either from perforation (with polypectomy: 2%; without polypectomy: 0.06%), or major haemorrhage post-polypectomy (0.2-10%), depending on size of lesion. 44, 54-57

Surveillance colonoscopies also place an important burden on endoscopy services. In the US, 22% of all colonoscopies in patients over 55 years are performed for surveillance purposes. 58 For these reasons, surveillance colonoscopy should be targeted at those who are most likely to benefit and at the minimum frequency required to provide adequate protection against the development of cancer.

2.4.2 **Quality of colonoscopy**

Colonoscopy is highly operator-dependent and several aspects of the procedure (e.g. poor bowel preparation, areas hidden from view using current instruments, suboptimal technique, and ineffective
polypectomy) can lead to failure to clear the colon of neoplasia. Increasing evidence suggests that adenoma detection rates differ between colonoscopists; they are related to the time taken to withdraw the colonoscope and the risk of development of subsequent cancers. Attention to quality of colonoscopy is therefore of paramount concern. Further information on quality relating to colonoscopy is covered in Chapter 1.

**Practice point:**
- High quality colonoscopy is critically important for good practice and patient safety. Adenoma detection rates (ADRs) should be monitored, though they will be influenced by patient mix (e.g., age profile, indications). ADRs within the National Bowel Cancer Screening Program provide a sound basis for benchmarking.

### 2.4.3 Approach to adenoma follow-up in surveillance

Surveillance by colonoscopy is the preferred method for patients diagnosed with colorectal adenomas, as the chance of finding metachronous adenomas requiring removal is high. However, there are no randomised controlled trials of adenoma follow-up which include a control arm which does not have colonoscopy. Nevertheless, in some long term studies of colonoscopic surveillance of patients with all types of adenomas subjected to removal, a significant reduction in risk of developing colorectal cancer has been documented when compared with various comparative cohorts such as age- and sex-matched incidences of colorectal cancer in the same communities. In many studies, this risk of developing CRC does not fall below the average risk in the community.

**Practice point:**
- Colonoscopy surveillance intervals should be planned when the colonoscopist is satisfied that the colon has been completely cleared of polyps and the polyp histology is known.

### 2.4.4 Follow-up for patients with low risk adenomas

**Q:** What should be the surveillance colonoscopy for patients at low risk (1-2 small tubular <10mm adenomas)?

As indicated previously, patients with one or two tubular adenomas less than 10 mm in size represent a low-risk group compared with other patients with colorectal neoplasia. For these patients, a follow-up interval of five to ten years is proposed. Among patients who had only one or two small tubular adenomas at a baseline examination and then no adenomas on their first surveillance colonoscopy, the probability of high-risk findings on the next surveillance examination is similar to that for patients with a negative screening examination; thus, a ten-year follow-up colonoscopy schedule may be appropriate. Atkin’s data confirm the low risk of subsequent cancer in patients with one or two small adenomas, supporting follow-up of these patients similar to average-risk patient strategies – which includes colonoscopy in US guidelines, but only at ten yearly intervals. In Australia, recommendations for average risk patients are to undergo immunochemical faecal occult blood test (FOBT) every one to two years from age 50 years.
### Evidence summary:

<table>
<thead>
<tr>
<th>Level of evidence</th>
<th>References</th>
</tr>
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<tbody>
<tr>
<td>II</td>
<td>33, 64-67</td>
</tr>
</tbody>
</table>

Patients with one or two small tubular (<10mm) adenomas are at minimal risk for metachronous advanced neoplasia, ie. similar to (or slightly above) average risk individuals.

### Recommendations

In follow-up of patients with one or two small (<10 mm) tubular adenomas, the first surveillance colonoscopy should be performed at five years.

Grade B

If that colonoscopy is normal, the individual is considered to be at average risk for metachronous disease. Options for subsequent surveillance are ten-yearly colonoscopy, or FOBT at least every two years.

Grade B

### Practice points:

- Low risk adenomas are those which lack advanced features, namely three or more adenomas at one colonoscopy, adenomas 10 mm or more in size, tubulovillous or villous histology or high grade dysplasia/cancer.
- There is no conclusive evidence that one or two small tubular adenomas constitute more than average risk for metachronous advanced adenomas or cancer.

### 2.4.5 Follow-up for patients with high risk adenomas

Q: What should be the surveillance colonoscopy for patients at high risk (>2 and ≥10mm adenomas or with HGD)?

Patients with high risk adenomas (also sometimes referred to as “advanced adenomas”) are those in whom either (i) three or more adenomatous polyps have been removed, (ii) at least one adenoma is > 10 mm in size, or (iii) the adenomas exhibit villous or tubulovillous histology or high-grade dysplasia. Multiple studies have indicated that such high risk adenomas indicate a risk for metachronous advanced adenomas and cancers.

These studies justify surveillance stratification based on index adenoma characteristics.

The definitive study on frequency of colonoscopy in high risk adenoma patients is provided by the US National Polyp Study. In a randomised controlled trial of surveillance intervals amongst 1418 adenoma patients, this study showed no difference in detection rates of advanced or any adenoma rates in follow-up colonoscopies randomised to one or three years.

High risk adenomas may have a different risk of metachronous advanced neoplasia than resected cancers.
Evidence summary:

<table>
<thead>
<tr>
<th>Condition</th>
<th>Level of evidence</th>
<th>References</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adenomas ≥10mm predict metachronous advanced neoplasia. Size is best measured by the colonoscopist with the polyp in situ. Villosity and high grade dysplasia are risk markers for metachronous advanced neoplasia; however, there is a close relationship between size, villosity and dysplasia, making the independent contribution of villosity and dysplasia not uniformly identified in adenoma follow-up studies. High grade dysplasia, by definition is still confined to the epithelium and is not associated with any risk of invasion or extracolonic spread.</td>
<td>II</td>
<td>13, 14, 69</td>
</tr>
<tr>
<td>High rates of residual adenoma are identified following a piecemeal resection of large and sessile adenomas, generally regarded as &gt;2cm in size and sessile adenomas. If there is doubt about whether the index lesion has been totally removed, the next colonoscopy should be done within three to six months.</td>
<td>III</td>
<td>21, 71, 72</td>
</tr>
</tbody>
</table>

Recommendation

Surveillance colonoscopy should take place at three yearly intervals for patients with high risk adenomas (three or more adenomas, ≥10mm, or with tubulovillous, or villous histology, or high grade dysplasia).

Grade A

2.4.6 Follow-up of patients with sessile adenomas and laterally spreading adenomas

Q: What should be the surveillance colonoscopy following sessile and laterally spreading adenomas?

High rates of residual adenoma are identified following a piecemeal resection of large (generally regarded as >2cm in size) and sessile adenomas. If there is doubt about whether the index lesion has been totally removed, the next colonoscopy should be done within three to six months.

Recommendation

If large and sessile adenomas are removed piecemeal, follow-up colonoscopy should be at three to six months and again at twelve months to ensure complete removal. If removal is complete, subsequent surveillance should then be based on histological findings, size and number of other adenomas (as set out in 2.4.4 and 2.4.5).

Grade B
2.4.7 Follow-up following resection of serrated adenomas (SA) and sessile serrated adenomas (SSA)

In one study, when a follow-up examination was performed at a mean of 29 months after initial examination in patients diagnosed with serrated adenomas at the time who underwent complete colonoscopy with good preparation, 24% were diagnosed with adenomatous polyps. A control group without serrated adenomas at initial examination had no adenomas at a follow-up examination at average time of 31 months.74

There are suggestions that surveillance following complete removal of small SSA without dysplasia should take place at five to ten years as for small tubular adenomas.29 The same authors suggest that three years surveillance is appropriate for TSAs of any size or number. Patients with large sessile serrated adenomas with high grade dysplasia need intense follow-up between three to six months, though this depends more on the sessile nature of the polyp rather than its serrated pathology. In summary, at present there is not enough evidence to differentiate adenoma follow-up protocols for sessile serrated adenomas based on their serration alone.

Practice point:

- At present there is not enough evidence to differentiate follow-up protocols for sessile serrated adenomas from standard adenoma follow-up guidelines. Follow-up should be determined as for adenomatous polyps, taking into account parameters such as, polyp size, number and presence of high grade dysplasia.

2.4.8 Follow-up for patients with multiple adenomas

Q: What should be the surveillance colonoscopy for patients with adenoma multiplicity with or without polyposis syndrome?

Most published guidelines suggest that three or more synchronous (adenomas at baseline colonoscopy) require surveillance at three years and three to five years thereafter.13, 31, 38 As mentioned above, the percentages of patients identified with new high grade adenomas at follow-up within three to five years increases with multiplicity of adenomas at baseline with 8.6%, 12.7%, 15.2%, 19.6% and 24.1% if one, two, three, four, and five or more adenomas were found at baseline colonoscopy.13 An analysis of 697 patients in the Cleveland Clinic Foundation Adenoma Registry69 showed that, compared with one or two small adenomas, the risk of metachronous adenomas is increased five-fold following removal of multiple (four or more) small adenomas and ten-fold following removal of multiple adenomas at least one of which is larger than 10 mm. In a meta-analysis of several colonoscopic surveillance studies,75 patients with three or more adenomas at baseline were at an approximately two-fold increased risk of advanced neoplasia during surveillance compared with those with only one to two adenomas. In a more recent US pooled analysis13 which included eight studies with a combined population of 9167 men and women with previously removed colorectal adenomas, advanced adenomas were detected at follow-up within five years in 12% (n = 1082) and cancer in 0.6% (n = 58). There was a highly significant linear trend of increasing frequency of advanced neoplasia (advanced adenomas and cancers) with increasing number of baseline adenomas detected. Compared with having a single baseline adenoma, risk was increased two-fold in those with three to four adenomas and was increased four-fold in those with five or more adenomas.
The high detection rate of advanced neoplasia at follow-up after removal of multiple adenomas might result from a higher miss rate combined with a potential for such adenomas to be more advanced.

Multiplicity of ten or more adenomas could indicate the need for a further colonoscopy at three to twelve months to secure a clean colon before surveillance colonoscopy commences. As familial adenomatous polyposis (FAP) or MUTYH associated polyposis may be the cause, referral to a familial cancer clinic for mutational analysis of the APC and MYH genes should be considered. If FAP has been confirmed, lifelong follow-up after surgery, possibly including chemoprevention, needs to be tailored to patients in relation to age, retention of the rectum and its attendant risk.

### Evidence summary:

<table>
<thead>
<tr>
<th>Evidence summary:</th>
<th>Level of evidence</th>
<th>References</th>
</tr>
</thead>
<tbody>
<tr>
<td>The number of adenomas present at colonoscopy is one of the most important predictors of metachronous risk of advanced and non-advanced neoplasia. In some studies it can be identified independently of other risk factors.</td>
<td>II</td>
<td>13, 38, 70, 75</td>
</tr>
</tbody>
</table>

### Recommendation

As multiplicity of adenomas is a strong determinant of risk of metachronous advanced and non-advanced neoplasia, follow-up should be at twelve months for those with five or more adenomas and, because the likelihood of missed synchronous polyps being present, sooner in those with ten or more adenomas.

If a polyposis syndrome accounts for the findings, follow-up colonoscopy should be within one year for patients with five or more adenomas at one examination.

Grade B

### Practice point:

- FAP or MYH associated polyposis should be considered with as few as ten adenomas; referral to a familial cancer clinic is advisable.

### 2.4.9 Interaction of Age and Family History of Colorectal Neoplasia

**Q: What should be the surveillance colonoscopy for patients with family history?**

The US National Polyp Study found that the subsequent risk of developing advanced adenomas in people undergoing surveillance was increased in people aged ≥ 60 years who had a parent affected by colorectal cancer. One other study found that having a parent with a history of colorectal cancer was associated with an increased risk but other studies have not confirmed this finding. Detection rates of advanced adenomas among 1287 participants in a trial of wheat bran fibre were unaffected by inclusion of family history in a multivariate model after adjustment for adenoma characteristics at baseline. Similarly, in the recent US pooled analysis, the risk of developing advanced neoplasia during surveillance was not influenced by family history.
Thus there is no consistent evidence to suggest that recommendations on adenoma surveillance should differ for patients with a family history unless it is suspected that they have one of the inherited conditions.

<table>
<thead>
<tr>
<th>Evidence summary</th>
<th>Level of evidence</th>
<th>References</th>
</tr>
</thead>
<tbody>
<tr>
<td>There is insufficient evidence to suggest that, outside genetic syndromes, family history contributes significantly to risk. Therefore, a positive family history should not influence surveillance scheduling based on patient factors and adenoma history.</td>
<td>II</td>
<td>13, 77</td>
</tr>
</tbody>
</table>

**Recommendation**

Family history should be considered separately when planning colonoscopy surveillance. Intervals should be predominantly determined by the adenoma characteristics, unless a syndromic risk mandates more frequent surveillance.

Grade B

### 2.4.10 Follow-up based on two or more examinations

**Q: What should be the surveillance colonoscopy for patients with previous neoplasia history?**

Surveillance colonoscopy findings in conjunction with the baseline lifestyle and demographic risk factors should dictate the risk characteristics of patients, and suggest that patients with adenomas found at more than one screening/surveillance colonoscopy may be at higher risk than patients with adenomas on one examination but not on the next.\(^{33, 67}\) When the second examination shows no adenomas, the prevalence of high risk adenoma (one advanced adenoma or cancer or multiple (≥ 3) of any size) at the third examination was found to be only 4.9% if the adenoma was low risk (one or two adenomas <1 cm) at baseline, and 12.3% if the adenoma was high risk at baseline.\(^{67}\) Combined risk identification of adenomas removed at baseline and at a follow-up colonoscopy can be used as predictors for recurrence up to four years from baseline examination when risk level of adenomas are stratified by size, number and pathological examination. The presence of high grade adenomas identified at baseline colonoscopy increases the probability of metachronous adenomas at a surveillance procedure\(^{6,33, 67}\) within one to five years from baseline investigation.\(^{6}\) Hence, a combined risk after baseline and at least one surveillance examination may be a better tool for prediction of outcome.\(^{50, 51, 67}\)

<table>
<thead>
<tr>
<th>Evidence summary</th>
<th>Level of evidence</th>
<th>References</th>
</tr>
</thead>
<tbody>
<tr>
<td>There is conflicting evidence about whether screening intervals should be lengthened for patients with a history of advanced neoplasia in the colon, even with a series of normal colonoscopies.</td>
<td>II</td>
<td>33, 67</td>
</tr>
</tbody>
</table>
Recommendation

If advanced adenomas are found during subsequent surveillance, maintaining a three yearly schedule is prudent, but the choice should be individualised. The interval can be lengthened if advanced adenomas are not found.

Grade B

Practice point:

- Endoscopists, therefore, should be encouraged to assess not only the current colonoscopy findings, but those of any previous colonoscopies.

2.4.11 Stopping rules

The lead time for progression of an adenoma to cancer is around 10 to 20 years which is of the same order as the average life-expectancy of an individual aged 75 years or older, suggesting that most people over 75 years of age will not benefit from surveillance.

2.5 Hyperplastic polyposis

Many of the polyps in hyperplastic polyposis are sessile serrated adenomas (see sections 2.1.1.3 and 2.4.7). The risk of cancer may be increased if there are co-existing adenomatous lesions that may be conventional adenomas, admixed polyps or traditional serrated adenomas, or if there is a family history of colorectal cancer. 27, 78 A particular association has been demonstrated between hyperplastic polyps and cancers with microsatellite instability. 73, 79-82

It is recommended that patients with hyperplastic polyposis be offered biennial (two yearly) colonoscopy. This should also be considered for patients in whom neither of the strict definitions for the diagnosis of hyperplastic polyposis is met in full, but other risk features are present (one coexisting adenomatous lesion or a first-degree relative with hyperplastic polyposis or colorectal cancer). Colectomy should be considered when it is not possible to achieve control of polyps endoscopically.

Practice points:

- Risk of cancer in hyperplastic polyposis is still being defined; however, there is sufficient evidence to identify these patients as being at high risk. Colonoscopy, with the aim of complete polyp removal, including the right sided sessile serrated polyps, should be the aim. Risks of polypectomy, notable because of the number and sessile nature of these polyps, should be explained.
- Surgery is an acceptable alternative in patients with well defined hyperplastic polyposis.

2.6 Issues requiring more clinical research study:

- What is the optimal surveillance strategy after the removal of low risk adenomas?
What is the risk of metachronous neoplasia after a series of normal surveillance investigations, stratified by risk parameters of the index adenoma(s)?

Are sessile serrated adenomas per se indicators of excessive colon cancer risk?

What are the characteristics of colonoscopies that precede interval cancers?

Is the risk of early advanced adenomas related to quality of colonoscopy or biology and patient characteristics?

Is high grade dysplasia a risk factor independent of size and other adenoma characteristics?

Is multiplicity, independent of size, a risk factor for metachronous adenomas?

References


Management of Epithelial polyps: colonoscopic surveillance after polypectomy


Clinical Practice Guidelines for Surveillance Colonoscopy - in adenoma follow-up, following curative resection of colorectal cancer, and for cancer surveillance in inflammatory bowel disease


Management of Epithelial polyps: colonoscopic surveillance after polypectomy


35 Clinical Practice Guidelines for Surveillance Colonoscopy - in adenoma follow-up, following curative resection of colorectal cancer, and for cancer surveillance in inflammatory bowel disease


3 THE ROLE OF SURVEILLANCE COLONOSCOPY AFTER CURATIVE RESECTION FOR COLORECTAL CANCER

Patients who have surgery for colorectal cancer are at above-average risk for the development of a second, metachronous colorectal cancer (and adenomatous polyps). This chapter aims to review the available evidence so that such patients can be advised about an appropriate interval for post-operative and subsequent surveillance colonoscopies.

Preamble

After surgery for colorectal cancer (CRC), the aim of patient follow-up is to improve survival by the early detection and treatment of recurrent or metachronous neoplasia. To increase the chance of early recognition of such disease, intensive post-operative follow-up is recommended. This involves a combination of clinical review, blood tests for tumour markers, i.e. carcinoembryonic antigen (CEA), colonoscopy, radiological imaging and/or abdominal ultrasound at regular intervals after resection (the timing of which may vary according to the procedure performed and whether the cancer removed was rectal or colonic).1-4

This chapter focuses specifically on the use of colonoscopy in surveillance following curative resection of colorectal cancer. Complete, high-quality colonoscopy should be performed at the time of diagnosis of a CRC, to check for synchronous cancer and to clear the colon of synchronous adenomatous polyps. Surveillance colonoscopy following resection of CRC aims to improve patient outcome by finding metachronous cancers at an early stage, detecting anastomotic or intraluminal recurrences and removing metachronous adenomas. Hence, understanding the rate of development of and risk factors associated with either metachronous neoplasia or locally recurrent cancer may be important for reducing mortality from CRC.

The current chapter addresses the question of when post-operative colonoscopy should be performed following curative resection surgery.

3.1 Role of pre- or peri-operative colonoscopy in CRC patients

Q: What is the role of pre- or peri-operative colonoscopy in CRC patients?

A complete examination of the large bowel, preferably by colonoscopy, should be performed at the time of cancer diagnosis to check for synchronous cancers and clear all synchronous polyps. A synchronous cancer is found in up to 5% of patients and synchronous adenomatous polyps in 20-40% of patients.5-7 Clearance of synchronous lesions at perioperative colonoscopy reduces the rate of metachronous CRC.8,9 If the index cancer obstructs the lumen and prevents a clearing pre-operative colonoscopy, consideration should be given to pre-operative assessment of the proximal colon by alternative means, e.g. CT colonography or air contrast barium enema. This, however, is unnecessary if the colon proximal to the cancer is to be included in the resection specimen. Failing this, colonoscopy should be performed three to six months after surgery, providing no distant metastases are found.6
**Evidence summary**

| Evidence shows that perioperative colonoscopy (whether performed preoperatively, intraoperatively or postoperatively) reduces cancer-related mortality in patients diagnosed with CRC. | II | 7-10 |

**Recommendations**

A perioperative colonoscopy should be attempted in all patients with a newly diagnosed colorectal cancer (CRC).

Grade B

Colonoscopy should be performed three to six months after resection for patients with obstructive colorectal cancer in whom a complete perioperative colonoscopy was not performed and in whom there is residual colon proximal to the obstructing cancer.

Grade B

### 3.2 Which patients should be followed up with surveillance colonoscopy?

The Australian *Clinical Practice Guidelines for the prevention, early detection and management of CRC, 2nd edition, 2005* proposed that follow-up should be offered to all patients who have undergone curative surgery and are fit for further intervention if disease is detected. This includes patients who have had malignant polypectomy or curative endoscopic resection of Stage I CRC but excludes patients with Stage IV CRC if their treatment does not offer the possibility of cure.

#### 3.2.1 Risk Factors for local recurrence following resection for colorectal cancer

Recent studies suggest that follow-up after CRC resection could perhaps be customised according to a patient’s individual risk. For example, a number of studies have determined features of a primary CRC which increase the risk of local recurrence at the surgical anastomosis. Most importantly though, anastomotic recurrence occurs far more often in rectal cancer patients than in colon cancer patients. Local recurrence is also more likely to occur in patients undergoing local excision (including transanal endoscopic microsurgery) of their rectal primary cancers and unfortunately, many of these recurrences are associated with extra-colonic disease or local spread and are not curable. With respect to this review, the vast majority of these rectal anastomotic recurrences are within reach of digital rectal examination or sigmoidoscopy and their detection does not require full colonoscopy.

The optimal combination and frequency of investigations in follow-up of patients after CRC resection has not been determined. Importantly, the performance of annual colonoscopy has not been shown to improve five-year survival. A meta-analysis by Tjandra et al concluded that intensive follow-up increased the re-resection rate for recurrent disease and improved overall survival but the survival advantage was not due to earlier detection of recurrence and cancer-related mortality was no better.

The focus of the current chapter is on the use of surveillance colonoscopy. Although colonoscopy allows inspection of the anastomosis in passing, the principal purpose of surveillance colonoscopy after CRC resection is the detection of metachronous neoplasia. Thus, the above-mentioned risk factors for luminal/anastomotic recurrence are of limited relevance to the question of when surveillance colonoscopy should be performed following CRC surgery.
Having developed one CRC, patients are at risk for the development of metachronous polyps and their progression to metachronous cancers; Bouvier et al\textsuperscript{26} reported the incidence of metachronous cancer as being 1.8\% at five years, 3.4\% at 10 years, and 7.2\% at 20 years\textsuperscript{26} with the greatest excess risk between one and five years post-surgery.

Preoperative colonoscopy is important to detect and treat synchronous polyps and cancers but may also assist in predicting which patients are more likely to develop future adenomas and cancers during follow-up. Some authors of both original studies and literature reviews have reported that the presence of synchronous polyps or cancers is a risk factor for metachronous CRC\textsuperscript{7, 27-30} and for metachronous adenomatous polyps.\textsuperscript{30, 31} However, in a recent population-based study by Bouvier et al,\textsuperscript{26} using a cancer registry as the source of information, no patient or tumour characteristics could be identified to predict which CRC patients would develop a metachronous cancer. Other authors have likewise failed to identify any link between synchronous adenomas and the development of subsequent metachronous CRC.\textsuperscript{8, 32}

Primary tumour location is also a risk factor for the development of metachronous cancer. In a study of more than 500 CRC patients from a cancer registry database, patients whose first cancer was located proximal to splenic flexure were found to be at twice the risk for developing a metachronous cancer compared to those with a first cancer in the distal colon.\textsuperscript{17}

Metachronous and synchronous tumours are features of Lynch syndrome (also known as hereditary non-polyposis colorectal cancer or HNPCC).\textsuperscript{33, 34} A propensity for metachronous and synchronous colorectal cancers with a predilection for the proximal colon and development of cancer at an early age are well recognised characteristics of Lynch syndrome.\textsuperscript{35}

Thus, reported studies have disagreed about whether patients who have undergone CRC resection can be stratified with regard to their risk of future development of metachronous polyps and cancers. Even in those studies where a positive predictive factor was identified, the strength of the association with the development of future colonic neoplasia was insufficiently strong to exclude patients without the factor from colonoscopic surveillance.

### 3.2.2.1 Patient groups at very high risk for metachronous neoplasia following resection for colorectal cancer

In certain patients who have undergone curative resection for CRC, clinical features, family history and the findings at the pre-operative colonoscopy may dictate the need for particularly intense post-operative surveillance colonoscopy (see Chapter 7 of the Clinical Practice Guidelines for the Prevention, Early Detection and Management of Colorectal Cancer, 2\textsuperscript{nd} edition, 2005).

In other groups of patients considered to be at increased risk of metachronous disease, consideration may be given following surgery to continuing with more frequent surveillance than would otherwise be recommended (e.g. initial post-operative colonoscopy at one year and then annually, second-yearly or third-yearly. These patients include those (i) whose initial diagnosis was made younger than 40 years of age, (ii) with probable or possible HNPCC (i.e. patients whose tumours are MSI-high and less than 50 years old at time of initial cancer diagnosis but not proved by genetic testing to have HNPCC), (iii) with hyperplastic polyposis and BRAF mutation and (iv) with multiple synchronous cancers or advanced adenomas at initial diagnosis.

**Practice points:**

- Patients with proved Lynch syndrome (HNPCC or hereditary non-polyposis colorectal cancer), should continue to have annual surveillance colonoscopy performed post-
operatively because of the apparent rapid progression of neoplasia from adenoma to carcinoma.

- Surveillance of the residual colonic mucosa in patients with cancer in FAP should follow recommendations in Chapter 7 of the Clinical Practice Guidelines for the Prevention, Early Detection and Management of Colorectal Cancer, 2nd edition, 2005

- Patients including those
  (i) whose initial diagnosis was made younger than 40 years of age,
  (ii) with probable or possible HNPCC (i.e. patients whose tumours are MSI-high and less than 50 years old at time of initial cancer diagnosis but not proved by genetic testing to have HNPCC),
  (iii) with hyperplastic polyposis and BRAF mutation and
  (iv) with multiple synchronous cancers or advanced adenomas at initial diagnosis should be considered following surgery to continuing with more frequent surveillance than would otherwise be recommended (e.g. initial post-operative colonoscopy at one year and then annually, second-yearly or third-yearly.

3.3 Effectiveness of surveillance colonoscopy following resection for colorectal cancer

Surveillance colonoscopy after CRC resection has the theoretical potential to improve patient outcome by finding metachronous cancers at an early stage, detecting luminal/anastomotic cancer recurrences and removing metachronous adenomas. Nevertheless, studies have differed in their conclusions about the overall effectiveness of colonoscopic surveillance.

Several studies have demonstrated that compliance with a post-operative colonoscopy surveillance programme reduces the mortality rate of patients after CRC resection. Early detection of metachronous cancer, particularly when still asymptomatic, increases the chance that re-operation will be curative. The effectiveness of colonoscopy in detecting tumour recurrence after CRC resection has been more controversial.

Thus, while most studies show that surveillance colonoscopy improves survival, its usefulness in detecting recurrent CRC has been questioned and its benefits probably derive from detection of metachronous colorectal neoplasia.

3.4 Intervals for surveillance colonoscopy following resection for CRC

Q: What should be the follow-up colonoscopy for patients after CRC resection?

Recommendations about the timing of colonoscopy after CRC resection should be based upon the “natural history” of metachronous colonic neoplasia, in order to meet the objectives of surveillance, namely early detection of metachronous cancer and timely polypectomy for metachronous adenomas.

The natural history of metachronous cancer and polyps is best estimated by studies of the yields of colonoscopy at various time points after surgery, when pre- or peri-operative colonoscopy has excluded synchronous cancer and cleared synchronous polyps.

In the US Guidelines for Colonoscopy Surveillance after Cancer Resection, the literature to 2005 was summarised with regard to metachronous cancer development. In studies incorporating more than 9000 patients, 137 metachronous cancers were detected, 57 of which were found within 24 months of surgery. It could be argued that second cancers found so soon after surgery were in many instances...
missed synchronous (rather than metachronous) lesions but the importance of detecting them remains undiminished. The authors argued that such a rate of cancer detection (157 colonoscopies per metachronous cancer found) was comparable to the rate of prevalent cancer detection in the setting of screening colonoscopy (as practised in the US). It was this relatively high incidence of metachronous cancers within two years of surgery that led to the Guidelines’ recommendation to perform post-operative colonoscopy at an interval of one year (with subsequent colonoscopies after an interval of three years and then five years, if all surveillance examinations were normal).

In the literature prior to 2005, Barillari and Neugut found that more than one-half of metachronous adenomas and cancers arose within the first twenty four months after surgery. In a 2000 study, Togashi et al detected twenty-two metachronous colorectal cancers in 19 out of 341 patients after CRC surgery, 14 (64 %) of them within five years of surgery. Most were small, 10 mm or less in size, and many had a flat endoscopic appearance. In a study of 174 patients reported by Juhl et al in 1990, three-quarters of the colonoscopically detected neoplasms (adenomatous polyps and cancers) occurred within the first 24 months. In the period 12-30 months after surgery, four metachronous cancers and 37 advanced adenomas were detected. A retrospective review by Khouy et al concluded that annual follow-up colonoscopy for two years after CRC surgery was beneficial and that the interval between subsequent examinations be increased depending on the result of the most recent examination.

However, not all of these earlier studies advocated colonoscopy within one to two years of surgery. Among 175 patients who underwent a curative resection for CRC between 1986 and 1992, colonoscopies performed one year after surgery and then at two-year intervals revealed no metachronous cancers or advanced adenomas. The authors suggested that only patients who had had synchronous adenomas at pre-operative colonoscopy should undergo follow-up colonoscopy at three years. Similarly, Stigliano et al conducted a retrospective study of 322 patients and found no metachronous cancers within the first two years after surgery. In their 2002 review, Berman et al suggested that there were insufficient data to support the routine use of annual or more frequent colonoscopy to identify metachronous or recurrent CRC and they suggested post-operative colonoscopy be limited to every three to five years. The value of a large retrospective audit of patients after CRC resection by McFall et al, which concluded that most patients are at very low risk of developing significant colonic pathology in the five years after resection, was limited by the fact that less than one-third of the patients underwent post-operative colonoscopy and the mean interval between surgery and colonoscopy was more than four years. Similar reservations about the need for follow-up colonoscopy earlier than two to three years were expressed by Mathew et al, even though 10 out of 14 patients with neoplastic findings at surveillance colonoscopy were detected two years post-operatively.

A Western Australian study by Yusoff et al audited all patients who underwent surgical resection of CRC from 1989 to 2001 and found that no metachronous cancers (and only 1 of 11 recurrent anastomotic cancers) were found by surveillance of asymptomatic patients. The three metachronous cancers were all detected in symptomatic patients, at four, eight and nine years after surgery. In a subset of their patients, the yields for adenoma were 10 % at one year post-operatively, 28 % at two years and none at three years.

Another Australian study published in 2005 by Platell et al specifically evaluated the clinical utility of performing a colonoscopy 12 months after curative resection for CRC. In 253 patients who had undergone complete colonoscopy prior to resection, 90 % received their first post-operative colonoscopy at a mean of 1.1 years. Although no recurrent or metachronous cancers were found, 149 polyps were detected in 30 % of patients, 42 % of which were adenomas and 13 % of which were villous or tubulovillous adenomas. Having observed such a high prevalence of advanced adenomas at 12 months (7.9 % of patients), the authors raised the possibility that, in contrast to recommendations in the Clinical Practice Guidelines for the Prevention, Early Detection and Management of Colorectal Cancer 2005 (that post-operative colonoscopy be performed at three to five years), a variably intense colonoscopy surveillance schedule might be justifiable. Similarly, the large study from Taipei

The role of surveillance colonoscopy after curative resection for colorectal cancer 42
mentioned earlier concluded that a lifelong schedule of post-operative colonoscopic surveillance was necessary.

According to Hassan et al, who used a decision analysis model, early surveillance colonoscopy performed one year following CRC resection was clinically efficient and cost-effective in terms of cancer detection and prevention of cancer-specific death. Compared to "no early colonoscopy" following surgery, the number of one-year colonoscopies required to find one CRC was 143 and the number needed to prevent one CRC-related death was 926. In a 2007 analysis of 1002 operated CRC patients, Rulyak et al concluded that surveillance colonoscopy within one year of surgery was warranted because (i) 9 of the 20 metachronous cancers detected during the study period were found within 18 months of surgery and (ii) the rate of metachronous advanced neoplasia was significantly lower if colonoscopy was performed within 18 months of surgery (6.9 %) than if colonoscopy was delayed for three years or more (15.5 %).

In a 2009 study from China, Wang et al compared "intensive colonoscopic surveillance" (three monthly colonoscopy for the first year after surgery, then six monthly for the following two years and annually thereafter) with "routine colonoscopic surveillance" (at six, thirty and sixty months after surgery). In the intensive surveillance group, one metachronous cancer was detected in the second year of surveillance, one in the fourth year and the third more than five years after initial surgery. In the routine surveillance group, no metachronous cancers were found at six months, four were found at 30 months, one was found at five years and one was found thereafter. The authors concluded that the routine schedule of surveillance was acceptable, with follow-up colonoscopy at one and two years after surgery and then three to five years thereafter.

Thus, while not all of the published evidence is in agreement, most studies demonstrate a significant incidence of metachronous cancers, advanced adenomas and other types of polyps after curative resection for CRC. In many studies, a high proportion of the metachronous neoplasia was detected within the first two years after surgery. Careful, high-quality colonoscopy at 12 months after surgery would be expected to detect the vast majority of this metachronous neoplasia. In turn, this should improve survival in patients operated on for CRC, by finding second cancers at a stage early enough to be cured by re-operation, and by removing metachronous adenomas while still benign. As a result, the weight of evidence from the literature would seem to support performing the initial post-operative surveillance colonoscopy at an interval of one year. If this examination does not reveal a metachronous cancer, the intervals between subsequent colonoscopies should probably be three and five years, depending on the number, size and histologic type of polyps (if any) removed.

<table>
<thead>
<tr>
<th>Evidence summary</th>
<th>Level of evidence</th>
<th>References</th>
</tr>
</thead>
<tbody>
<tr>
<td>Follow-up colonoscopy reduces the mortality rate of patients after CRC resection. Most studies demonstrate a significant incidence of metachronous cancers, advanced adenomas and other types of polyps after curative resection for CRC. In many studies, a high proportion of the metachronous neoplasia occurred within the first two years after surgery.</td>
<td>II</td>
<td>8-10, 15, 21, 29, 31, 36-39, 44, 49, 51, 52</td>
</tr>
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<td></td>
<td>IV</td>
<td>26</td>
</tr>
</tbody>
</table>

**Recommendations**

Colonoscopy should be performed one year after the resection of a sporadic cancer, unless a complete post-operative colonoscopy has been performed sooner.

Grade B
If the peri-operative colonoscopy or the colonoscopy performed at one year reveals advanced adenoma, then the interval before the next colonoscopy should be three years.

Grade C

If the colonoscopy performed at one year is normal or identifies no advanced adenomas, then the interval before the next colonoscopy should be five years.

Grade C

**Practice point:**

- Patients undergoing either local excision (including transanal endoscopic microsurgery) of rectal cancer or advanced adenomas or ultra-low anterior resection for rectal cancer should be considered for periodic examination of the rectum at six monthly intervals for two or three years using either digital rectal examination, rigid proctoscopy, flexible proctoscopy, and/or rectal endoscopic ultrasound. These examinations are considered to be independent of the colonoscopic examination schedule described above.

### 3.5 Issues requiring more clinical research study:

- What is the optimal schedule for performing surveillance colonoscopies after surgery for colorectal cancer?

- What molecular markers in the primary colorectal cancer are predictive for patients at high risk for metachronous disease?

### References


Some patients with chronic inflammatory bowel disease are at above-average risk for the development of colorectal cancer. This chapter aims to review the available evidence so that such patients can be identified and advised about appropriate intervals for surveillance colonoscopy.

4.1 Introduction

An increased risk of colorectal cancer (CRC) in inflammatory bowel disease (IBD) has been recognised for many years, though the best way to manage this problem depends on a number of individual co-factors. Once IBD-associated CRC becomes symptomatic, the malignancy is usually advanced, and prognosis correspondingly poor. Prophylactic proctocolectomy avoids CRC, but is not justified in patients whose health is otherwise good due to significant post operative morbidity. Colonoscopic surveillance has been advocated as an alternative means to reduce cancer-related mortality among individuals who wish to retain their colon. For the first time, these Guidelines have included specific recommendations regarding colonoscopic surveillance in IBD. Many of the conclusions are similar to those contained in recent updates on this subject issued by the American Gastroenterological Association and the British Society of Gastroenterology and Association of Coloproctology for Great Britain and Ireland.

4.2 Efficacy of colonoscopic surveillance in IBD

Q: Should patients with UC undergo surveillance colonoscopy?

Over the past three decades, the results of various colonoscopic surveillance programmes in ulcerative colitis (UC) have been reported. Although the details of these programmes have differed according to patient selection, endoscopic protocol and management strategies, the experience has generally been supportive. It has shown that CRC was averted or diagnosed at an early stage with improved prognosis in some patients, and that a majority were able to safely retain their colons. On the other hand, the development of advanced carcinoma was not always prevented, and in some series, the yield of neoplasia was so low that the value of the exercise was questioned.

No randomised study has ever been conducted to substantiate the efficacy or cost effectiveness of colonoscopic surveillance in patients with UC or Crohn’s disease (CD). However, various case-control studies provide indirect evidence supporting its efficacy in UC on the basis of improved cancer-related outcome. Specifically, these studies have shown surveillance in UC is associated with reduced overall death rates, improved cancer-related survival, and an earlier stage of cancer diagnosis. In addition, theoretical modeling analysis using a computer cohort simulation evaluating 17 different surveillance strategies predicted an improved life expectancy in patients undergoing surveillance. These combined data have resulted in qualified support for surveillance in UC by a Cochrane analysis.

Data concerning the value of colonoscopic surveillance in CD are extremely limited. One series from a private practice in New York studied patients with extensive Crohns’ colitis (affecting more than 30% of the large bowel) for more than eight years duration. Sixteen percent were diagnosed with neoplasia, half of which were detected at the time of initial screening investigation. A small case control study found a protective effect on CRC risk if a colonoscopic examination was conducted for cancer screening or surveillance purposes in Crohn’s colitis (odds ratio of 0.21, 95% C.I. 0.04-0.77; p=0.02).
## Evidence summary

<table>
<thead>
<tr>
<th>Evidence summary</th>
<th>Level of evidence</th>
<th>References</th>
</tr>
</thead>
<tbody>
<tr>
<td>Indirect evidence supports colonoscopic surveillance in UC as a means to reduce cancer-related mortality in high risk patients.</td>
<td>III-2</td>
<td>1, 6, 8-10</td>
</tr>
</tbody>
</table>

## Recommendation

Colonoscopic surveillance is recommended in high risk patients with ulcerative colitis (UC) to reduce cancer-related mortality.

Grade C

### Practice point:
- Although evidence for colonoscopic surveillance in Crohn’s disease is limited, experts recommend it be considered in at risk patients.

### 4.3 Clinical and endoscopic predictors of CRC in IBD

Reported estimates of overall CRC risk in UC vary substantially, with studies from tertiary referral centres generally reporting higher rates than population-based surveys. A meta-analysis of 116 international studies found an overall prevalence of CRC to be 3.7% in any patient with UC, increasing to 5.4% for those with pancolitis. The risk of CRC in CD has been less well studied, but overall seems similar to that in UC. Emerging evidence indicates that various disease-related factors significantly influence an individual’s risk for CRC in IBD.

#### 4.3.1 Disease duration

Disease duration is recognised to be a risk factor for CRC in IBD. The development of cancer within 8-10 years of disease onset is unusual. A meta-analysis of 116 studies concluded that the risk of CRC in UC was 2% after 10 years, 8% after 20 years, and 18% after 30 years. An association between disease duration and CRC risk in CD is less clear. The development of CRC within eight years has been reported in up to 40% of some pathology series, though epidemiological studies have generally shown CD related CRC to be more common in patients with long disease duration.

#### 4.3.2 Disease Extent

In both ulcerative colitis and Crohn’s disease, patients with more extensive disease are at increased risk of CRC. Disease extent is defined on the basis of macroscopic and histological changes at any time during a patient’s illness. In a combined British and Swedish study the relative risk for patients with total ulcerative colitis was 19.2, and for those with left-sided disease, a relative risk of 2.8 was reported. In a separate Swedish cohort study, the relative risk for patients with pancolitis, left-sided colitis, and proctitis was 14.8 (95% CI, 11.4-18.9), 2.8 (95% CI, 1.6-4.4) and 1.7 (95% CI, 0.8-3.2), respectively. In contrast, the CRC risk is not increased in UC patients with proctitis or procto-sigmoiditis or individuals with ileal or ileocaecal CD.

#### 4.3.3 Primary Sclerosing Cholangitis (PSC)

UC patients with co-existing PSC are especially at risk of developing colonic neoplasia. Dysplasia occurred in 45% of patients with both PSC and UC compared with 16% with UC only (p<0.002).
absolute cumulative risk of developing CRC with UC and PSC was 9%, 31% and 50% at 10 years, 20 years, and 25 years respectively. The comparative rates for CRC in patients with UC only were 2%, 5% and 10% (p<0.001). Data concerning CRC incidence in patients with CD and PSC are unknown.

4.3.4 Family History of Sporadic CRC

According to a registry-based follow-up series, a personal family history of CRC was associated with a 2.5-fold increased risk of CRC in patients with IBD (RR 2.5; 95% C.I. 1.4-4.4). Moreover, patients with IBD who had a first-degree relative diagnosed with CRC before the age of 50 years had an even higher risk of developing CRC themselves (RR 9.2;95% CI, 3.7-23).

4.3.5 Dysplasia

The most important predictive factor for the development of CRC in IBD is the presence of mucosal dysplasia. Dysplasia is classified on the basis of its severity, and a progression from low grade to high grade has been demonstrated in some (but not all cases) before malignancy ensues. The diagnosis and classification of dysplasia is qualitative and subject to inter-observer variability. Preferably, its diagnosis and grading should be confirmed by a second independent experienced gastrointestinal pathologist. The Vienna classification is an internationally agreed standard which grades dysplasia in IBD based on the severity of histological changes. Depending on its severity and gross appearance, dysplasia is associated with a high risk of imminent or established colorectal cancer.

4.3.6 Severity of Endoscopic and Histologic Inflammation

Recent studies indicate that neoplastic transformation in IBD is related to the degree of mucosal inflammation. A case-control study of 68 patients with UC showed that the degree of colonoscopic (OR 2.5; p<0.001) or histologic (OR 5.1; p<0.001) inflammation was associated with the development of CRC. Importantly, this study also showed that colitic patients without evidence of inflammation did not have an increased risk of developing CRC (OR 0.28; 95% C.I. 0.19-73). Gupta reported that overall inflammation score was positively associated with the development of high grade dysplasia and CRC but not with low grade dysplasia. Other endoscopic indicators of past inflammation have been shown to be associated with an increased CRC risk in UC, including colonic strictures, a shortened tubular colon and the presence of post-inflammatory polyps.

In CD, clinical studies have consistently shown that CRC may develop in intestinal segments that have been bypassed or complicated by strictures or fistulae. Patients with complicated anorectal disease are particularly at risk of anorectal malignancy.

4.4 How is surveillance practised, and can it be improved?

In the past decade, two important developments have been applied to colonoscopic surveillance in IBD to improve outcome. First, contemporary guidelines have incorporated clinical and endoscopic risk factors to stratify the intensity of surveillance. Secondly, the use of improved endoscopic technology is increasingly encouraged to improve the diagnostic efficacy of colonoscopy.

Published guidelines concerning UC surveillance are generally reserved for patients with left sided or extensive disease. Patients with inflammation confined to the rectum and/or sigmoid colon do not require specific surveillance unless other risk factors for CRC co-exist. However, a proportion of patients initially diagnosed with proctitis or distal colitis may develop more extensive disease over time, and endoscopic re-assessment of disease extent is indicated in all patients with previously diagnosed
proctitis or proctosigmoiditis. If there is macroscopic or histological evidence of inflammation beyond the sigmoid colon, colonoscopic surveillance is usually recommended.

### 4.4.1 Starting time for surveillance

**Q:** When should surveillance colonoscopy be initiated for UC and Crohn’s patients, for UC and Crohn’s patients who have PSC detection, for UC and Crohn’s patients with a strong family history?

Clinical experience, supported by various studies, shows that the development of CRC in IBD before ten years of disease duration is uncommon, except in individuals with PSC where malignant transformation of the colon may occur at an earlier stage. Most expert opinion and published guidelines have recommended that surveillance should commence 8-10 years after disease onset in patients with extensive UC or Crohn’s colitis, or at the time of diagnosis of PSC if it co-exists. For patients with left sided disease in whom the risk of cancer may be delayed, the recommended starting time for surveillance varies between 8-15 years after disease onset.

Until recently, these propositions had not been tested. A recent study from The Netherlands found that nearly one in five patients developed CRC in IBD earlier than recommended initiation of surveillance. Some of these patients were not known to have IBD at the time of cancer detection, some had left sided-colitis, others had PSC and a proportion had Crohn’s colitis. As a result, experts now advise that in patients with either PSC or a family history of CRC, surveillance be initiated as soon these historical co-factors are recognised, and in others, surveillance should be initiated eight years after the onset of symptoms.

<table>
<thead>
<tr>
<th>Evidence summary</th>
<th>Level of evidence</th>
<th>References</th>
</tr>
</thead>
<tbody>
<tr>
<td>The risk of CRC in IBD is uncommon within eight years of disease onset except in those with co-existing PSC or a personal family history of CRC.</td>
<td>III-1</td>
<td>14, 22, 24, 32, 34</td>
</tr>
</tbody>
</table>

### Recommendations

Patients with ulcerative colitis extending beyond the sigmoid colon and individuals with Crohn’s colitis that involves more than one-third of colon should commence surveillance no later than eight years after onset of symptoms.

**Grade C**

If Primary Sclerosing Cholangitis (PSC) is detected before this time, surveillance should commence at the time of its diagnosis.

**Grade C**

Patients with a strong personal family history of colorectal cancer (CRC) should start surveillance earlier.

**Grade C**

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4.5 Optimal surveillance intervals

The ideal surveillance interval has not been tested, nor has the impact of co-existing risk factors ever been assessed. Early surveillance programmes included patients with extensive UC who were subjected to biennial colonoscopy. In the St Mark’s series involving 600 patients with extensive UC who underwent 2627 colonoscopies at one to two yearly intervals during 5932 patient years of follow-up, 30 cancers developed of which 16 were “interval” cases. Itzkowitz and Harpaz suggested that surveillance should be conducted annually or biennially provided no dysplasia is found or suspected. Recommendations by the Crohn’s and Colitis Foundation of America (CCFA) state that surveillance intervals depend on initial biopsy findings. If the initial colonoscopy is negative for dysplasia, repeat colonoscopy should be performed every one to two years. After two negative colonoscopies further colonoscopies may be performed every one to three years until IBD has been present for 20 years, at which point surveillance colonoscopies should be repeated every one to two years. In contrast, patients found to have dysplasia on screening or surveillance colonoscopy require colectomy or more aggressive surveillance. Patients with co-existing PSC and IBD require annual surveillance colonoscopies. Although the impact of a family history of CRC on surveillance intervals in IBD has not been evaluated, both American and British guidelines recommend more frequent surveillance when this risk factor is present. The need to intensify surveillance after 20 years has been disputed by the results of the St Mark’s series, which showed a constant cancer incidence for up to 40 years of colitis duration and included a relatively large number of patients.

Practice points:

- A. Annual colonoscopic surveillance is recommended for patients with ulcerative colitis extending proximal to the sigmoid colon or patients with Crohn’s colitis affecting more than one third of the colon and with one or more of the following risk factors:
  - active disease
  - Primary sclerosing cholangitiis
  - Family history of colorectal cancer in first degree relative < 50 years old
  - colonic stricture, patients with multiple inflammatory polyps or shortened colon
  - previous dysplasia

- B. Three yearly colonoscopy is recommended for patients with:
  - inactive ulcerative colitis extending proximal to the sigmoid colon without any of the above risk factors
  - patients with Crohn’s colitis affecting more than one third of the colon without any of the above risk factors
  - IBD patients with a family history of colorectal cancer in a first degree relative > 50 years old

- C. Five yearly colonoscopy recommended for patients in whom two previous colonoscopies that were macroscopically and histologically normal.
4.6 Optimal colonoscopic protocol

Q: What is the recommended technique for surveillance in IBD patients?
Q: What should be the technique of choice if the best technology is not available?

In the past, most cases of dysplasia were thought to be invisible to standard diagnostic instruments, and its detection required extensive mucosal sampling from flat mucosa in each colonic segment, or as targeted biopsies from elevated suspicious lesions. International guidelines have recommended that at least two to four random biopsies should be taken from each colonic segment in order to diagnose dysplasia if it is present. However, clinical evidence shows that random colonic sampling may not necessarily facilitate the detection of all cases of invisible dysplasia. It has been estimated that 64 mucosal biopsies are required to ensure a 95% chance of detecting the highest degree of histological abnormality, but even this approach samples only a very small proportion of total colonic surface, and foci of dysplasia can possibly still escape detection.

During the last decade, studies have shown that most dysplasia in ulcerative colitis is actually visible at colonoscopy, even when standard endoscopic instruments are used. Reports from St Mark’s Hospital, Chicago and Pennsylvania have shown that the proportion of dysplastic lesions that are macroscopically visible to an endoscopist were 77.3%, 58.5%, and 87.9% respectively. When new endoscopic techniques such as chromoendoscopy, endomicroscopy, narrow band imaging or autofluorescence imaging are used, the recognition of dysplastic lesions is increased.

Data from expert centres indicate that the diagnostic yield of detecting dysplasia is greatly enhanced if targeted biopsies were obtained from visible lesions using chromoendoscopy. In a study of 100 patients with chronic extensive ulcerative colitis undergoing cancer surveillance, dysplasia was detected in 0 from 2904 random biopsies and 9 from 157 targeted biopsies. These data have prompted many experts to advocate the use of chromoendoscopy and mucosal sampling of visibly abnormal mucosa as standard practice in IBD surveillance, rather than rely on random mucosal biopsies to detect dysplasia. Other authors believe it is premature to abandon the role of random biopsies entirely until longer follow-up data are available on using chromoendoscopy. There are important practical limitations of chromoendoscopy that limit its sensitivity. The presence of mucosal inflammation or multiple pseudopolyps may affect the interpretation of chromoendoscopy, and in these circumstances, the need for random surveillance biopsies is still justified. Chromoendoscopy requires specific equipment, training and expertise that are not available at every centre. Alternatively, standard white light colonoscopy remains an acceptable and satisfactory means to conduct IBD surveillance provided the colonic mucosa is carefully inspected, and biopsies obtained from each colonic segment or suspicious lesion.

<table>
<thead>
<tr>
<th>Evidence summary</th>
<th>Level of evidence</th>
<th>References</th>
</tr>
</thead>
<tbody>
<tr>
<td>The use of chromoendoscopy enhances the detection of dysplasia in UC patients.</td>
<td>III-2</td>
<td>39, 42, 45</td>
</tr>
<tr>
<td>The detection of dysplasia using standard white light endoscopy requires targeted biopsies to be taken from visibly abnormal sites and at least two to four random biopsies from flat mucosa in each colonic segment.</td>
<td>IV</td>
<td>39-41</td>
</tr>
</tbody>
</table>
Recommendations

If available, the use of chromendoscopy/dye spraying where targeted biopsies are obtained from visibly abnormal lesions or strictures is the preferred means to conduct colonoscopic surveillance in IBD. This is especially true for patients at high risk of colorectal cancer.

Grade C

If chromoendoscopy is unavailable, or if an endoscopist lacks sufficient expertise with this technique, or if the presence of inflammation interferes with the interpretation of chromoendoscopy, an acceptable alternative practice is using standard white light endoscopy with random non-targeted biopsies from each colonic segment and from raised lesions.

Grade D

Practice point:

- When chromoendoscopy is used, random biopsies are required from each colonic segment to establish histological extent and severity of disease. More intensive mucosal sampling from each colonic segment is indicated in patients with a suspicious visible lesion or in situations where chromoendoscopic interpretation is compromised by factors such as active inflammation, inflammatory polyps or poor bowel preparation.

4.7 Surveillance protocol practised in Crohn’s disease, indeterminate colitis and patients with ileo-anal pouches

Q: What should be the follow-up for patients with Crohn’s disease?

On the basis of equivalent CRC risk, current guidelines recommend the same endoscopic protocol in Crohn’s colitis as in ulcerative colitis.4, 5 Patients with more than one third of the colon affected by inflammation, as well as those with complicated ano-rectal disease, colonic strictures or post inflammatory polyps, may be considered for surveillance.4, 5, 31, 46 The recommended starting times and ongoing frequency of colonoscopic surveillance are generally similar to UC, even though these proposals are not supported by evidence. The CRC risk in patients with indeterminate colitis is similar to that of ulcerative colitis. Although guidelines have not generally specified surveillance recommendations in this group, the same level of investigation is appropriate as in UC.4, 5 Individuals who have previously undergone restorative proctocolectomy and ileal pouch anal anastomosis for UC may rarely develop neoplasia in the pouch or anal transition zone. Risk factors include a past history of colorectal neoplasia and PSC. There is no evidence that surveillance is preventative, though guidelines state that it is reasonable to perform an endoscopic examination and biopsy every five years.5

Evidence summary

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<tr>
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<th>Level of evidence</th>
<th>References</th>
</tr>
</thead>
<tbody>
<tr>
<td>Optimal levels of surveillance in Crohn’s disease, indeterminate colitis or ileo-anal pouches have not been defined.</td>
<td>IV</td>
<td>31,46</td>
</tr>
</tbody>
</table>


**Recommendations**

Based on cancer risk, it is recommended that similar colonoscopic surveillance be undertaken for Crohn’s colitis as in ulcerative colitis of equivalent extent, even though supporting evidence is sparse.

Grade D

Specific areas where surveillance is required in Crohn’s disease are patients with colonic strictures or complicated anorectal disease.

Grade D

### 4.8 Management of dysplasia

The management of dysplasia depends on its grade and whether it exists as a macroscopically raised lesion or in flat mucosa.

#### 4.8.1 Elevated dysplastic lesions

Q: What should be the protocol to manage elevated dysplasia in IBD?

Historically, elevated lesions containing dysplasia in IBD were referred to as DALM’s (dysplasia associated lesion or mass). These lesions are highly significant because they are often associated with established or imminent cancer. However, not all elevated dysplastic lesions in IBD are necessarily DALM’s. Raised lesions containing dysplasia in non-inflamed areas are sporadic adenomas that can be managed endoscopically in the same way as in the non-colitis population. Raised lesions containing dysplasia in an area of inflammation may be a sporadic adenoma or dysplastic mass lesion associated with colitis. In the former case, dysplasia is not present elsewhere in the colon. Endoscopically, it can be difficult to distinguish in an inflamed segment a DALM from a sporadic adenoma, or indeed an inflammatory polyp. In practice, all suspicious elevated lesions should be biopsied and if possible removed, and multiple biopsies obtained from flat mucosa in adjacent mucosa and from the other colonic segments. As long as the lesion is entirely removed endoscopically and there is no dysplasia elsewhere in the colon, surgery is not necessarily indicated though close surveillance must be maintained in future. Conversely, if dysplasia is detected elsewhere in the colon, or if the endoscopist is not confident the entire lesion has been removed, surgical intervention is strongly recommended.

<table>
<thead>
<tr>
<th>Evidence summary</th>
<th>Level of evidence</th>
<th>References</th>
</tr>
</thead>
<tbody>
<tr>
<td>Long-term follow up data are reassuring that localised dysplastic lesions in IBD can be treated effectively endoscopically.</td>
<td>IV</td>
<td>49, 52</td>
</tr>
</tbody>
</table>

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Recommendations

Raised lesions containing dysplasia may be treated endoscopically provided the entire lesion is removed and there is no dysplasia in flat mucosa elsewhere in the colon.

Grade D

If a raised dysplastic lesion cannot be completely removed, or if there is dysplasia elsewhere in the colon, surgical intervention is strongly recommended.

Grade D

4.8.2 High grade dysplasia in flat mucosa

Q: What should be the protocol to manage high grade dysplasia in IBD?

If high grade dysplasia (HGD) is diagnosed in flat mucosa and confirmed by a separate pathologist, surgery is usually required. According to a review of 10 dysplasia studies, a finding of high grade dysplasia was accompanied by actual cancer in 42%, and in the rest who underwent surgery, definite dysplasia was usually detected in colectomy specimens. Experience from the 30 year St Mark’s Hospital surveillance programme found that 19/600 (3.2%) developed HGD. Of these, 11 underwent immediate colectomy and five (45%) had cancer in the operative specimen. Eight patients refused immediate surgery, of whom two subsequently developed CRC. In total, 37% of all patients with HGD eventually developed CRC.

<table>
<thead>
<tr>
<th>Evidence summary</th>
<th>Level</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>The predictive value of HGD for imminent or established cancer is high.</td>
<td>II</td>
<td>35, 53</td>
</tr>
</tbody>
</table>

Recommendation

High grade dysplasia in flat mucosa is a strong risk factor for established or imminent carcinoma, and colectomy is usually recommended.

Grade B

4.8.3 Low grade dysplasia in flat mucosa

Q: What should be the protocol to manage low grade dysplasia in IBD?

The significance of low grade dysplasia (LGD) in flat mucosa is controversial. Data from tertiary referral centres have generally shown it is associated with progression to high grade dysplasia or cancer. Of 47 patients who were diagnosed with LGD at St Mark’s Hospital, 20% eventually developed CRC and 39% developed either HGD or cancer. At Mount Sinai Hospital, the rate of progression to higher grades of neoplasia was 53% at five years. These results contrast with other data which show progression from...
LGD to advanced neoplasia is slow, and is not invariable. A meta-analysis of 20 surveillance studies involving 508 cases of low grade dysplasia in flat mucosa or dysplastic mass lesions found the cancer incidence to be 14 per 1000 person years duration, and the incidence of any advanced lesion was 30 per 1000 person years duration. The positive predictive value of LGD for concurrent cancer was 25% and for progression to cancer was 8%.

Because of the uncertainty about the predictive value of LGD in flat mucosa, it is recommended that surgery be considered if it is multifocal. However, patients with LGD in flat mucosa who wish to avoid an operation require repeat colonoscopy at three to six months, preferably with chromoendoscopy, and thereafter at yearly intervals. A finding of unifocal low grade dysplasia in flat mucosa is less likely to be associated with imminent cancer, and follow-up colonoscopy is reasonable within six months in these cases.

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<tr>
<th>Evidence summary</th>
<th>Level</th>
<th>Reference</th>
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</thead>
<tbody>
<tr>
<td>The predictive value of low grade dysplasia in flat mucosa for future cancer is controversial, but probably higher if it is located in multiple synchronous sites.</td>
<td>III-2</td>
<td>35, 54-58</td>
</tr>
</tbody>
</table>

**Recommendations**

Multifocal low grade dysplasia is associated with a sufficiently high risk of future cancer that colectomy is usually recommended. Patients who elect to avoid surgery require follow up surveillance at three months, preferably with chromoendoscopy, and if this examination is normal, annually.

Grade C

Unifocal low grade dysplasia may be followed by ongoing surveillance at six months, and if this examination is normal, annually.

Grade C

4.8.4 Indefinite dysplasia in flat mucosa

Q: What should be the protocol to manage indefinite dysplasia in IBD?

If Indefinite dysplasia (ID) is diagnosed, the rate of progression to a higher grade of dysplasia or carcinoma is unusual. At St Mark’s Hospital, 1/23 patients with ID (4%) eventually developed carcinoma and five (22%) developed LGD after nine years follow-up. In contrast, data from New York showed that the five year rate of progression from indefinite dysplasia to HGD or cancer was 9%. If a biopsy is diagnosed as indefinite for dysplasia by two gastrointestinal pathologists, follow-up surveillance colonoscopy, preferably with chromoendoscopy, at six months is reasonable, and thereafter at annual intervals.
**Evidence summary**

<table>
<thead>
<tr>
<th>Evidence summary</th>
<th>Level of evidence</th>
<th>References</th>
</tr>
</thead>
<tbody>
<tr>
<td>The predictive value of indefinite dysplasia in flat mucosa for imminent cancer is low.</td>
<td>II</td>
<td>35, 59</td>
</tr>
</tbody>
</table>

**Recommendation**

Indefinite dysplasia in flat mucosa does not require surgery, but follow-up colonoscopic surveillance is justified, preferably with chromoendoscopy, at more frequent intervals.

Grade B

### 4.9 Issues requiring more clinical research study:

- Is colonoscopic surveillance in Crohn’s disease using dysplasia as a marker of malignancy justified?

- Are multiple random mucosal biopsies still necessary if chromoendoscopy is used as a tool for colonoscopic surveillance in UC?

- What is the most appropriate time interval for surveillance in IBD patients with a family history of CRC but no other risk factor?

- What is the role of flexible sigmoidoscopy in cancer surveillance for IBD?
References


5 PSYCHOSOCIAL ASPECTS OF SURVEILLANCE COLONOSCOPY AFTER COLORECTAL CANCER RESECTION, POLYPS AND IN INFLAMMATORY BOWEL DISEASE

5.1 Introduction

These guidelines provide recommendations for the surveillance of patients who are included in one of the above three clinical groups. Each patient will require some element of surveillance activity over time. The guideline recommendations are designed to underwrite evidence-based quality care for each individual. Even though the Guidelines have been developed to assist in providing surveillance measures, a number of patients express significant anxiety about the process. The chapter addresses issues relating to community attitudes to colonoscopy as well as individual patient’s anxiety about the procedure as well as compliance with medical advice to undergo the procedure and patient comfort during colonoscopy. Given that, for the vast majority of patients, surveillance colonoscopy entails repeated procedures at regular intervals over decades, these issues assume even greater importance for individuals who have had previous adenomatous polyps removed, who have had resection for colorectal cancer or who have chronic inflammatory bowel disease. The chapter aims to present a range of ways in which their anxieties can be addressed in an evidence based manner.

Patients should be assured of access to appropriate clinicians and facilities during their follow-up. It is suggested that entry to surveillance be facilitated by appropriate instruction from a Multidisciplinary Clinic, together with encouragement to liaise with the Clinic, GP or specialist as required, throughout their ongoing clinical course.

It is expected that each clinician will be thoroughly aware of their responsibilities to their patient and the patient aware that a measure of compliance is expected from their side; their cooperation will be purposefully encouraged.

Patients will usually be made aware that there will be a distinct effort to oversee the milestones they will be expected to meet when under surveillance; on occasions, the recommendations may require endoscopic investigation which will, on most occasions, be colonoscopy. Since almost all patients will have experienced colonoscopy at the commencement of their clinical journey, its further acceptance may be expected to be straightforward. However, some patients remain concerned at the possibility of repeated colonic studies and a very small percentage will continue to have concern before each colonoscopic investigation.

5.2 Community attitude towards colonoscopy

Colonoscopy is no longer a hidden or mysterious “medical thing”. The colonoscope is a widely used diagnostic instrument and, unfortunately, has attracted many disparaging references in the vernacular. Nevertheless, many patients are fearful or anxious of possible pain, discomfort or being hurt during the procedure. Patients may be averse to gastrointestinal endoscopy, which is seen as invasive and possibly embarrassing over and above being discomforting. Information on the subject of colonoscopy is readily available on Google and Wikipedia. It has been referenced in the daily press, more frequently now as patients have been recalled in the National Bowel Cancer Screening Program.

Recently a US financier/philanthropist was in Melbourne to promote a more positive attitude to men’s cancers. The newspaper report noted “he also joked that the most relaxing day in his life, when there are no interruptions from calls or emails is a ‘colonoscopy day’!” “But it is not so relaxing the day before”, Mr Milliken said (Richard Gluyas, Financier floats melanoma mission p6 The Australian, October 26 2010).
While most Australians are fairly accepting of colonoscopy, not all are as relaxed as suggested in this report. It is expected that patients in the categories described in the guidelines will require colonoscopy at some time; however, it is not likely that all will accept it with equanimity. The acceptance level of 80% of patients undergoing repeat colonoscopy in the well-recognised National Polyp Study would appear to be indicative of some element of resistance, anticipation anxiety or distrust of the procedure.

It would appear that while some element of anxiety is not uncommon, as might be expected before colonoscopy, it is more entrenched in some candidates for the procedure than it is for others.

5.3 Colonoscopy and anxiety

Q. What approaches can be incorporated successfully into an efficient surveillance colonoscopy program to minimise anxiety and pain fall out?

While the literature on colonoscopy is very extensive, only a very small percentage addresses the association with anxiety. Clearly, patients in the categories addressed in the recommendations will be drawn from all aspects of society.

Low socioeconomic status (SES) is colloquially believed to be associated with discomfort in relation to medical investigations. One study identified sigmoidoscopy screening for colorectal cancer as a potential stressor. The UK Flexible Sigmoidoscopy (FS) Trial was regarded as an appropriate vehicle to test this view. A subgroup of patients (n=3535) from the trial was assessed regarding psychosocial wellbeing by pre- and post-screening questionnaires. All participants in this trial (n=29804) were sent a questionnaire three months after FS that included measures of distress, anxiety and a single item questionnaire of bowel cancer worry. SES status was coded from the Townsend Index. Worry about bowel cancer and anxiety were higher before screening in low SES patients. After screening, there were reductions in the factors studied but no differences due to SES were involved in the change. Lower SES patients did not show greater adverse reactivity to FS examination than higher SES participants. A key factor observed is that those with reduced education and economic resources are not necessarily more adversely affected by moderately stressful experiences.

5.4 Anxiety level before and during colonoscopy

A cross-sectional study was performed to examine a possible relationship between state anxiety and trait anxiety in endoscopy in an outpatient setting. (Definitions: “Trait Anxiety” indicates the tendency to experience anxiety; it is considered to be a characteristic of personality that endures over time. “State Anxiety” is a temporary uncomfortable experience that occurs when a person feels threatened by a situation.) In effect, trait anxiety is the potential, or tendency to experience state anxiety. These forms of anxiety can be measured by Charles Spielberger’s State-Trait Inventory for Adults. “The use of this inventory clearly differentiates between the temporary condition of “state anxiety” and more general long-standing “trait anxiety”.” Patient response was rated at initial consultation and immediately prior to endoscopy, using the Spielberger State-Trait Anxiety Inventory. A distinct increase in state anxiety was observed before endoscopy (upper gastrointestinal and colonoscopy) but no change was observed in trait anxiety. Females had higher anxiety levels. Overall, anxiety levels were not related to type of endoscopic procedure.

An Australian study, which recognised anxiety as being common in patients undergoing invasive medical procedures, assessed the relationship between coping style of patients, pre-colonoscopy information, anxiety and pain associated with colonoscopy. Coping style was established and patients codified as either information-seekers or information-avoiders. Provision of congruent information in line with coping style was observed to reduce anxiety and ameliorate the patient’s experience of the procedure. There was, however, no effect on dose of sedation or perception of pain.
A questionnaire-based study reviewed the procedural experience of patients undergoing endoscopy. Fifty five (55) consecutive patients undergoing colonoscopy had a three point evaluation of the procedural experience. One week prior to the investigation, they were assessed as to their understanding and their concerns regarding colonoscopy were recorded and rated. The second assessment occurred while awaiting commencement of the procedure and assessed preparation and fasting. The third and final questionnaire was completed 24 to 72 hours after the procedure and after recovery from sedation; it repeated the pre-procedural questionnaire and addressed comfort and social disruption due to the colonoscopy. It was observed that concerns specific to colonoscopy, including anticipation of pain, had impact on acceptance of colonoscopy. This was not improved by experience of the investigation, even if procedural anxiety and pain were reduced. The patient’s pre-procedural views of the investigation should be actively addressed to improve participation in colonoscopy.

While colonoscopy is most frequently performed on adults, it may be used in the diagnostic evaluation of children with colonic disease. Teenagers with inflammatory bowel disease (IBD) will usually require colonoscopy from time to time.

A study designed to compare children aged 10-18 years with either IBD or functional gastrointestinal disease (FGID) undergoing their first colonoscopy recorded the levels of pain or anxiety that they experienced. These levels were assessed by means of a questionnaire recorded immediately before the procedure and through a second questionnaire 48 hours later. While no differences in anxiety were reported, it was noted that higher levels of anxiety accompanied by higher pain scores were experienced by children with IBD at the time of colonoscopy. Children with FGID observe common pain symptoms during colonoscopy and may describe more post-conoscopic pain than those with IBD. It was concluded that anxiety is associated with severity of pain after colonoscopy in children with IBD, while not observed to be a factor in children with FGID.

### 5.5 Compliance with surveillance colonoscopy

All patients being addressed in the recommendations of these guidelines will have a surveillance programme recommended. Not all will approach surveillance colonoscopy with equanimity, even though they will almost certainly have had a previous colonoscopy.

In a cross-sectional study, medical records of patients undergoing excision of colonic polyps in 1997 were reviewed. Patients were excluded from selection using the same criteria used in the National Polyp Study; 333 patients remained for review. Follow up was conducted by telephone interview. Recommendation for follow up was observed in 331 patient records. Compliance status was determined in 211 patients, who had been advised to follow up in three years and all followed up at three years or longer. Where follow up colonoscopy could be determined, compliance was 85%. The 15% of patients who were non-compliant had various reasons; “no time” in 37.5%, 19% stated “they did not know that they needed follow up”, 13% “forgot” that they had had a polyp excised and 19% because of a “bad” experience. Univariate analysis revealed that patients were more compliant if they had had a previous colonoscopy or more than one polyp excised. The authors considered their institution to have established adequacy of follow-up colonoscopy. They opined that the impact on colorectal cancer estimated in the National Polyp Study is achievable and endorsed continual improvement in colorectal cancer awareness and promotion of compliance in the general public as an imperative.

A more recent report covers an update of joint guidelines (American Cancer Society and US Multi-Society Task Force on Colorectal Cancer). This report is based on recommendation for patients who have undergone either polypectomy or colorectal cancer resection. It outlines surveillance requirements and suggest that if adopted they will improve the quality of care in patient groups and will provide facility in shifting available resources “from intensive surveillance to screening and decrease the distress and death of those with colorectal cancer.”
There have been several Australian papers addressing the effect of the Clinical practice guidelines for the prevention, early detection and management of colorectal cancer, which were developed by Clinical Oncological Society of Australia and Australian Cancer Network and approved by NHMRC in 1999.17 to determine their effect on resource usage. Bampton et al18 observed that there was a reduction in the number of surveillance colonoscopies for polyps and colorectal cancer and an appropriate response rising from 63% to 96% in colonoscopies performed on the basis of family history. A study compared clinical practice and the 1999 Guidelines17. Observation was made between two groups undergoing CRC resection 1989-2001 and observed that only 23% of examinations followed the Clinical practice guidelines 199917, leading to the conclusion that surveillance colonoscopies continued to be performed too frequently.19

Development of a coordinated surveillance program SCOOP was funded by the Department of Health and Aged Care in 2001. A clinical nurse was appointed as coordinator, her appointment followed dissemination of the above-mentioned 1999 Guidelines17 education of the public about CRC and integrated hospital aspects of CRC “prevention, (colonoscopy specialist review, identification of family clusters of CRC for genetic screening) within practice in a primary care setting. Patient agreement was required and those over 75 years were excluded. This study aimed at determining compliance. A 98% coincidence with guideline recommendation was achieved in the last four months of the study. This suggested that Guideline improvements could be sustained if appropriately resourced and supported.20

A report21 on Guideline compliance comments on the results of a questionnaire sent to members of the Association of Coloproctology of Great Britain and Ireland (ACPGBI) to determine their response to the Guidelines of members of ACPGBI and the British Society of Gastroenterology (BSG) 196 (49%) responded and although the Guidelines were well established and most physicians accepted them as best practice, the majority did not observe them in relation to various clinical situations and it was reported that only 18% of clinicians observed the Guideline recommendations for surveillance colonoscopy for patients with polyps, CRC and a family history of these conditions.

5.5.1 Will Guidelines for surveillance colonoscopy be effective?

It is speculated that these guidelines, which have been developed in an Australian milieu and addressed scenarios encountered by Australian clinicians should significantly reduce disagreement between clinicians. Optimal distribution of the Guidelines and the Quality Working Group document22, together with a sound educational policy should assist in promoting compliance in clinical groups and alert those patients who have these diseases to the availability of the Guides and they could expect their clinicians to comply with them for universal betterment in care of these conditions.

The implementation measures will require all involved, especially the IT quality component to clearly address the quality of the processes involved. This means providing unobstructed and clear information about patients while simultaneously safeguarding their privacy. The new guidelines and the Quality Working Group22 need to meet these challenges to meet quality standards and to promote and maintain definitive headway in this most important activity.

5.6 Amelioration of anxiety in relation to colonoscopy

State anxiety is moderately increased in patients undergoing outpatient diagnostic endoscopy.4 This increase is not significantly influenced by age, sex, type of procedure or source of referral. The ability of the endoscopist to estimate patient anxiety is generally poor. It is suggested that this is because the increase in state anxiety is usually at a mild level.

An RCT23 explored the view that information provided before interventional clinical procedures should improve knowledge of the procedure and reduce anxiety related to it. The study involved approaching patients a week before colonoscopy, providing an information leaflet on the subject and having them complete a Speilberger State Anxiety Inventory (STAI).11 Patients were randomly
assigned to view or not view an information video before colonoscopy, while all patients completed a second STAI and knowledge test. The study involved 150 patients; 72 video-watchers and 78 non-video-watchers. The groups were generally similar in relation to age, sex, socioeconomic status and initial anxiety score, although female patients had higher baseline STAI scores than those with previous experience. Patients who watched the video were less anxious and achieved a higher score on the knowledge questionnaire than those who did not. Understanding the purpose, procedural details and potential complications of colonoscopy better prepared patients for the procedure. This study is supported in a commentary advocating an information video as a better way to convey information about colonoscopy. It is suggested that the technique may be cost-effective in reducing cost of sedation and post-operative recovery time.

A study of 201 patients undergoing colonoscopy randomised patients into three groups, those provided with pre-procedure information by video plus discussion, video alone or discussion only. All patients answered a thirteen item test of knowledge and all underwent State-Trait Anxiety Inventory. Those patients who were exposed to the video had statistically significant better scores (p<.001) than patients involved only with discussion, but no difference was observed between the video groups. It was concluded that understanding of colonoscopy and its risks and benefits did not increase anxiety. It was considered that the overall approach may save time for the clinician and provide opportunity for more personalised discussion and reassurance of the patient.

Another randomised study included an information video in the pre-procedural activity. Control patients did not view the video. Situational anxiety was measured using the State-Trait Anxiety Inventory (STAI) questionnaire. Patient satisfaction was rated, as was their experience with pain. The colonoscopist and endoscopy nurse were blinded as to which stream a patient had entered and completed a questionnaire as to medication employed, outcome of procedure, its level of tolerance and level of pain experienced. It was reported that midazolam dosage was the same in all patients, but that those who viewed the video used higher doses of fentanyl (p <0.2). Women found the experience to be more painful (p=0.001) and expressed less satisfaction with the procedure. It was observed that there was no impact on tolerability or anxiety among video-observers, but it was suggested that gender differences warranted adjustment of information and medication associated with the procedure.

<table>
<thead>
<tr>
<th>Evidence summary:</th>
<th>Level of evidence</th>
<th>References</th>
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<tbody>
<tr>
<td>Colonoscopy is generally accepted as a useful and non-threatening procedure. It is still, however, regarded with some suspicion and promotes anxiety in a body of people undergoing the procedure.</td>
<td>III-3</td>
<td>8,12</td>
</tr>
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<td></td>
<td>III-3, II</td>
<td>2, 7</td>
</tr>
<tr>
<td>Patients with reduced educational and economic resources are not more adversely affected than those with greater resources by moderately stressful experiences.</td>
<td>III-3</td>
<td>8</td>
</tr>
<tr>
<td>Patients’ pre-procedural view of colonoscopy needs to be actively addressed to improve participation in colonoscopy.</td>
<td>III-3</td>
<td>15, 12</td>
</tr>
<tr>
<td>Previous colonoscopy reduces patient anxiety when the procedure is to be repeated and increases rate of compliance.</td>
<td>II</td>
<td>15, 26, 27</td>
</tr>
<tr>
<td>Provision of congruent information in line with coping style has been observed to ameliorate patient’s experience of the procedure.</td>
<td>III-3</td>
<td>7</td>
</tr>
<tr>
<td>Patients provided with a pre-operative video on colonoscopy were less anxious than those not shown a video.</td>
<td>II</td>
<td>23, 28, 25</td>
</tr>
<tr>
<td>Understanding the purpose, procedural details and potential complications of colonoscopy can better prepare patients for the procedure.</td>
<td>II</td>
<td>23</td>
</tr>
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</table>
**Recommendation**

Pre-colonoscopic advice to patients by means of educational material, video and clinical explanation can assist in improving patient experience with the procedure and in reducing anxiety.

Grade C

### 5.7 Music as an aid to improving comfort of colonoscopy

**Q:** Can music be an additional aid to reduce anxiety, pain etc with surveillance colonoscopy?

A single-blind RCT was used to assess the efficacy of music for patients undergoing colonoscopy. In this study, 109 patients were randomised and fitted with mute or music-delivery headphones. Clinicians were blinded to the trial and sedation was provided if requested. Primary outcome was the measurement of pain and secondary endpoints were recorded as need for sedation, patient satisfaction and willingness to repeat the procedure. Those wearing music headphones recorded statistically significant reduction in pain and in the proportion of patients requiring sedation. Clinicians perceived less difficulty and multivariate analysis confirmed a significant beneficial effect of music. The introduction of music during colonoscopy significantly reduces discomfort.

A meta-analysis of RCTs on the effect of music on patients undergoing colonoscopy, assessed procedure time, dose of sedation, pain scores and willingness to repeat the procedure in the future. Eight studies met the criteria and observed that patients’ overall experience was statistically significantly improved when music was used during the procedure. There were significant differences in pain scores, sedation levels, procedure time and willingness to repeat the procedure. Music was stated to “improve patients’ overall experience with colonoscopy”.

In another randomised study in a US Veterans GI Diagnostic facility, 198 patients were randomised. Ninety-eight (98) comprised a control group, who had 25 minutes of quiet time before endoscopy while the study group (100) had music selected by the investigators, who were nurses, for 25 minutes before having endoscopy. All were evaluated by the State Trait Anxiety Inventory. Both groups experienced reduced anxiety scores but, after controlling for trait anxiety, there was a statistically different outcome between the groups, with those listening to music having a greater reduction in anxiety. It is suggested that music, a non-invasive nursing intervention may reduce anxiety if provided prior to gastrointestinal investigative procedures.

<table>
<thead>
<tr>
<th>Evidence summary:</th>
<th>Level of evidence</th>
<th>References</th>
</tr>
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<tbody>
<tr>
<td>Music played to patients before and during colonoscopy improves their comfort during their experience and improves willingness to repeat the procedure.</td>
<td>I II</td>
<td>30 &lt;br&gt;29, 31</td>
</tr>
</tbody>
</table>

**Recommendation**

Music provided to patients during colonoscopy may reduce their discomfort.

Grade C

### 5.8 Patient comfort and colonoscopy

The pre-colonoscopic preparation of patients assists in lowering anxiety levels and promoting better tolerance of colonoscopy itself.
Sedation or analgesia is important in maintaining patient comfort. However, sedation and monitoring practice across the world is significantly variable. A study in 21 centres in 11 countries was carried out, using a standard questionnaire for each patient. Of 6004 patients undergoing colonoscopy in the study, 53% received conscious/moderate sedation, 30% deep sedation while 17% received no sedation. Most commonly used agents for sedation were midazolam 47%, opioids 33%, an anaesthetist was present in 85% of colonoscopies when deep sedation was involved.

An Australian study of anaesthetists’ practice also failed to reveal a standard practice profile in this country. In this study, the choice of drugs was quite wide but propofol was used by all but one respondent, (200 surveys were sent to Fellows of Australian and New Zealand College of Anaesthetists of whom 113 or 57% responded). However, only 4% used propofol exclusively. Patients undergoing colonoscopy were more likely to receive propofol/midazolam/fentanyl (p<0.001). Pulse oximetry is used in all patients in Australia for deep sedation and an anaesthetist is required to be present during the procedure. This practice of anaesthetist oversight is not necessarily practised overseas.

Most studies on patient satisfaction do not address individual patient satisfaction with sedation directly, but rather satisfaction with the overall procedure. A prospective cohort study reporting 86.6% satisfaction and a literature review reporting 95% early satisfaction with colonoscopy (and 73-100% of patients willing to return for repeat testing) are seen as indicative of acceptance of the procedure. An RCT Phase III study of propofol strongly supported the agent’s use for sedation in colonoscopy. A Cochrane Review supports propofol administration for sedation in colonoscopy for generally healthy individuals and observes that it can shorten recovery times, lead to earlier discharge, meet patient satisfaction and have no increase in side-effects when compared to traditional sedatives, opioids and benzodiazepines. The review suggests that more standardised studies are needed to compare propofol sedation and its administration by anaesthetists and non-anaesthetists. A retrospective survey encourages less highly specialised staff for monitoring sedated patients.

5.9 Elements of clinical care available for patients undergoing colonoscopy

Q: Is a global sedation protocol available for surveillance colonoscopy?

Carefully judged doses of sedation with appropriate monitoring of vital signs and quality technical performance of colonoscopy, provide for a most satisfactory outcome for patients undergoing endoscopy. There are a range of other aids, coping, education and videotapes etc; however, overall, carefully controlled sedation provides patient comfort, satisfaction and successful outcome.

Practice points:
- Controversy continues with regard to choice of drugs for sedation and monitoring patients during colonoscopy.

Conclusions

Sedation for colonoscopy is widely practised and, while a number of drugs are available to assist patient comfort, some services do not choose to use them. There is controversy regarding risks and benefits of available drugs and appropriate monitoring during sedation.

While clinicians appear to be fully cognisant of the relative safety of the drugs and monitoring systems required, controversies remain and a well-designed and -conducted RCT would appear necessary to find whether these variations have an effect on outcomes following colonoscopy.
References


Psychosocial aspects of colonoscopy surveillance after: colorectal cancer, polyps and inflammatory bowel disease


21. Chivers KC, Basnyat PS, Taffinder N. 'How compliant do we want to be with the colonoscopy surveillance guidelines?'. Colorectal Dis 2007;9(9):830-833.


6 SOCIO-ECONOMIC FACTORS ASPECTS THAT MAY IMPACT ON SURVEILLANCE COLONOSCOPY FOLLOWING ADENOMA DETECTION OR CURATIVE RESECTION FOR COLORECTAL CANCER AND IN THE SETTING OF DYSPLASIA SURVEILLANCE IN INFLAMMATORY BOWEL DISEASE

6.1 Introduction

Social and economic circumstances are recognised determinants of access to health care. Those who are less affluent or socially deprived have shorter lives, during which they suffer more illness than those who are more economically favoured. However, economic affluence does not preclude ignorance, which of itself can require special management measures in attempting to assure appropriate outcomes in a surveillance setting.

In preparing clinical management guidelines and recommendations, it is appropriate to consider a range of factors that may impact on patients during their ongoing care. Whilst economic factors are of significance, there are other individual features that, while impacting on economics, are independently of clinical and management importance. Income, education, literacy, occupation or employment, level of interest, place of residence and ethnicity may individually or collectively produce a state of deprivation that can affect patient risk factors and possibly affect access to or compliance with health care services, as well as outcomes of care. The National Health and Medical Research Council has recognised these factors in its Handbook, “Using Socioeconomic evidence in clinical practice guidelines”.

6.2 Impact of socioeconomic factors in the setting of surveillance colonoscopy

Q. What is the impact and nature of SES?

Patients in the three groups who are the subject of these guidelines regarding surveillance colonoscopy are in a position where they will have already received treatment for their underlying condition (in the case of adenoma follow-up or following resection for colorectal cancer) or had a firm diagnosis of their disease (in the case of inflammatory bowel disease). Clearly, all three groups will have accessed the health system and undergone appropriate treatment or assessment.

For the patients involved in these groups, any barriers to health system access and provision of appropriate care have presumably been addressed in the course of initial management, so allowing them to complete their primary treatment. Surveillance in these patients will in large part be fulfilled by following the recommendations in these guidelines. It is expected that patients of low economic status and/or deprivation would have been identified as they were managed through the clinical and social resources of a multidisciplinary clinic and be assured of the best care available in the Australian universal health care system (Medicare). Although Kelsall et al state “despite a universal healthcare system in Australia socioeconomic inequalities in survival from colorectal cancer exist, and an enduring challenge to ensure that improvements in colorectal cancer survival are shared equally across the population”. Alerting clinicians to SES status at all clinical encounters may assist in meeting this enduring challenge sooner rather than later.

6.3 Impact made by socioeconomic factors in the three treatment groups undergoing surveillance colonoscopy

Q: Are there any specific results of lower SES and CRC and Polyps and IBD?

i. SES post curative resection of colorectal cancer

Q. Does lower SES have to result in poorer outcome for curative resection for colonic cancer?
There is significant literature in relation to SES and cancer survival after treatment for colorectal cancer,5, 6, 10, 11, 14-18 Patients with lower SES have been reported consistently to have shorter survival than those with higher SES.7, 8 The determination of SES has been based on a range of criteria, including census, occupational, domiciliary and education data.7,8,9

However, it has been observed in a cohort study that, for patients undergoing consistent type and quality of treatment by the same clinical teams, there is no demonstrable relationship between SES and survival from colorectal cancer19. An RCT20 also noted that, given equal treatment, colorectal cancer outcomes do not appear to depend on SES in England and Wales, the authors suggesting that health system factors may play a part. A cohort study of white and African Americans with advanced lung and colon cancer, who had not had previous chemotherapy, had their socioeconomic and biological data collected prospectively in twelve medical centres in the US Veterans Administration System (1981–1986).21 The essential finding of the study was that lung and colon cancer outcomes ‘may be similar among black and white patients who have equal access to comparable medical care in spite of socioeconomic differences’. This study puts equal access to care as a necessary accompaniment to good clinical care.6, 21 Disparities in treatment and low SES were seen in a case-only study to be a major factor in the explanation of decreased survival of African-Americans.22

These observations, which target both lower SES and deprivation as factors in poorer survival after resection of colorectal cancer, found that if the total of factors that surround treatment are equal in all respects, results are similar. Further research remains to be done, but it seems that if practitioners assist their patients to access best care, they could promote more equality of outcomes. These are special studies and their conclusions have not yet necessarily been accepted. It has been observed in the UK that, although the NHS cancer plan has been implemented, there remains a strong influence of social factors with regard to hospital admission and provision of care.13

The literature searched has not in general provided significant staging, operative or surveillance information. The areas addressed have related to primary treatment and mortality or survival.

In a retrospective review of a health maintenance group’s enrollees who were diagnosed with colorectal cancer between 1993 and 1999, analysis of patients was restricted to those expected to benefit from surveillance for cancer (stages 0, I, II, III AJCC).23 Follow-up times were found to be variable. Survival analysis was used to estimate the cumulative proportion undergoing surveillance and comparison between groups was based on the log rank test.24,25,26 Higher SES and being married were associated with greater utilization. Patients over 80 and those with rectal cancer were less likely to undergo surveillance. There was substantial variation of colonic surveillance examination with clinical socio-demographic factors influencing the likelihood of surveillance.

A qualitative study in the French literature27 evaluated the motivations of people having or not having follow-up after a positive colorectal screening test result. Following semi-directed interviews, it was reported that the doctor-patient relationship had a strong influence on acceptance of colonoscopy. It was also necessary to persuade doctors that colonoscopy and not FOBT was the National Standard.

The frequency of colonoscopy will need to be discussed with all patients, but more specific attention will need to be directed to socio-economically deprived patients. They will benefit by being encouraged to comply with the recommendations of these guidelines.
Evidence summary

<table>
<thead>
<tr>
<th>Evidence summary</th>
<th>Level of evidence</th>
<th>References</th>
</tr>
</thead>
<tbody>
<tr>
<td>There is a body of literature consistently reporting lower cancer survival in patients with low SES.</td>
<td>III-3, IV</td>
<td>5,10,12,13,15,14,16,17,18</td>
</tr>
<tr>
<td>Lower survival rates associated with disparities in care can be improved by eliminating disparities in the management of colorectal cancer.</td>
<td>II, III-3, IV</td>
<td>19,20,21,22</td>
</tr>
</tbody>
</table>

**Recommendation**

Clinicians may assist in improving survival outcomes in curative resection for colorectal cancer patients who are socioeconomically or otherwise disadvantaged by expediting their access to optimal clinical care.

Grade B

**ii. Surveillance after colonic polypectomy**

No studies on post-colonic polypectomy addressed socioeconomic matters. A retrospective review of medical records of patients who had adenomatous polyps in 1997 included only patients who had a clearly successful polypectomy.28

Compliance after polypectomy is reported as being greater than 80%, regardless of age, education and family history (*these observations allow speculation about inclusion of patients with lower SES*). It is noted that the National Polyp Study29 demonstrated that removal of adenomas with a follow-up of at least three years reduced the incidence of colorectal cancer recurrence. The National Polyp Study achieved 80% compliance, but the general population compliance was not known. The study suggests that risk reduction published in the National Polyp Study is achievable through surveillance colonoscopy.

It is hoped that further studies of general population compliance will clearly address SES factors and so assist in developing methods to increase compliance of patients of lower SES.

**iii. Surveillance after diagnosis of inflammatory bowel disease**

A literature search listed 44 papers on colonoscopy in inflammatory bowel disease. One paper addressed socioeconomic factors and involved two studies.30 The paper asserts that the common view is that patients with IBD are of a higher socioeconomic status and a higher level of education. Patients from a population-based IBD database were compared with the general population in respect to employment, education and marital status. Inflammatory bowel disease patients were questioned as to their SES at the time of diagnosis and at the time of the 1995-6 survey. In the second arm of this study, the authors used a database linking health care and census variables in relation to income, occupation and marital status. Their findings concluded that at some time in the course of their illness, those with IBD are more likely to be out of work than the general population. Based on the criteria that had been set, IBD patients were not found to be of higher SES and were equally likely to be married as the general population.

**6.4 Indigenous people (Aboriginal and Torres Strait Islanders)**

The AIHW report Australia’s Health 20084 makes several key points in relation to indigenous people. It reflects that they are usually less healthy, die at younger ages, suffer more disability and the quality of their life is lower than other Australians. The report also states that socially and economically...
disadvantaged groups tend to have worse health across a significant spectrum of conditions, these need to be taken into consideration when addressing indigenous people.

No distinct literature addressing surveillance colonoscopy was located on searching although there have been screening studies in indigenous and ethnic groups.

One publication from North Queensland (Cairns and Townsville Hospitals) addressed colorectal cancer in indigenous people. The study was retrospective and it aimed to better characterise CRC in indigenous people. The authors note difficulties in data collection and report follow-up for a mean of 20.5 months (range 2-51 months). A follow-up programme is reported for the 25 patients treated and it is suggested that approximately 30% of patients estimated to have CRC attended for treatment.

While colonoscopy was offered at one year and at three yearly intervals, compliance is not reported. Authors state the need for difficulty of obtaining accurate information, espouse education of indigenes on CRC and express the opinion that establishing cancer units where there are indigenous liaison officers would facilitate data collection, screening, “family understanding of the disease, increase compliance and ensure more complete follow-up.” These surgeons and health workers give a very useful understanding of services needed in areas of socioeconomic and indigenous care.

6.5 Issues requiring more clinical research study:

- Carefully planned studies are required to specifically address surveillance colonoscopy and colorectal cancer and possibly inflammatory bowel disease in indigenous people.
- Resources will be required to assist in implementation of guideline recommendations in indigenous communities.

References


Clinical Practice Guidelines for Surveillance Colonoscopy - in adenoma follow-up, following curative resection of colorectal cancer, and for cancer surveillance in inflammatory bowel disease


27. de Pauw C. Non-compliance with having a colonoscopy as a follow up to a positive result in colorectal cancer screening: a qualitative study. Sante Publique 2008;20(3):249-257.


7 ECONOMIC CONSIDERATIONS

7.1 Economic burden of colorectal cancer in Australia

In 2007 colorectal cancer was the second most common cancer reported in Australia following prostate cancer in men; in men it was second only to prostate cancer and in women it was second only to breast cancer. The incidence rate of colorectal cancer has increased by 13% from 67 cases per 100,000 to 75 cases per 100,000 in males over the period from 1982 to 2007 but remained relatively stable in females. Colorectal cancer was the second most common cause of cancer deaths in 2007 and was responsible for 10.1% of all cancer deaths.

In 2010, 13% of the cancer disease burden in males was attributable to colorectal cancer and in females, 12% of the cancer disease burden was due to colorectal cancer. Colorectal cancer also accounts for the second highest number of years lost of the total cancer burden due to premature death, and the third highest number of years lost of the total cancer burden due to disease, disability or injury.

The Australian Institute of Health and Welfare has estimated the costs of colorectal cancer at a macro level. In 2000–01 colorectal cancer was estimated to account for 8.17% of total cancer care costs in Australia. It ranked 4th in terms of the most ‘expensive’ cancers in Australia with total health care expenditure on colorectal cancer estimated at $235 million in 2000-01. Colorectal cancer ranks as the most costly cancer for females aged over 65 and the third most costly cancer for males aged over 65. Total treatment costs for per case of colorectal cancer were estimated at $18,246 in 2000-01, which ranks twelfth in terms of the most costly cancer to treat. However, there is relatively little micro-level information available in Australia about treatment patterns and resource use for colorectal cancer.

7.2 Economic evaluation

Economic evaluation is the comparative analysis of the costs and consequences of alternative courses of action. Cost-effectiveness analysis describes economic evaluations where the consequences of interventions are measured in natural units such as life-years gained, complications avoided, or cases correctly diagnosed. While many cost-effectiveness evaluations consider a single measure of output, others present an array of output or outcome measures alongside cost, allowing decision makers to form their own view of the relative importance of each measure.

In a cost-utility analysis (CUA), the consequences of an intervention, procedure or program are adjusted by health-state preference scores or utility weights. This means that the quality of the life years gained can be assessed, which is particularly useful for interventions that extend life at the expense of side effects (such as some chemotherapy for cancer), or produce reductions in morbidity rather than mortality (such as some treatments for chronic conditions, e.g. arthritis). The concept combines life expectancy and quality of life. The cost-benefit analysis assesses all effects, including the health effects in monetary units.

Whatever form of economic evaluation is used, an intervention, procedure or program can be considered efficient relative to the alternatives if it can be shown to produce a given level of benefit for the minimum cost.

Role of economic evidence in the development of guidelines

Two main areas where economic evidence is important in clinical guideline development have been identified by the NHMRC publication “How to compare the costs and benefits: evaluation of the economic evidence”:

• determination of the most cost-effective treatment alternatives
• determination of whether a proposed clinical practice guideline is cost-effective.

In the development of these guidelines, the relevant economic evidence was identified and reviewed and economic analyses were performed. There was limited Australian economic evidence for the costs and cost-effectiveness of alternatives for colonoscopy surveillance. However, a search of the international literature was undertaken and the studies identified were reviewed and summarised. It is important to note that differences in cost structures and reimbursement arrangements mean that the international literature may be of limited relevance to Australia. Differences in the surveillance strategies compared may also limit the value of the economic evidence.

Searches were conducted using Medline and Embase databases, covering the period 1994–2010. In addition, the reference lists of retrieved articles were hand searched. Economic evaluation literature that pre-dates 1994 was considered to be of limited relevance because of changes in technology, cost structures and management practices. The searches were undertaken in three areas:

- Colonoscopic surveillance following surgical resection for colorectal cancer
  - Key words included colorectal cancer, colon cancer, colorectal neoplasms, colorectal surgery, surveillance, colonoscopy, follow-up, cost-effectiveness, cost-benefit analysis, health economics, costs and cost analysis

- Colonoscopic surveillance in people who have had adenomas removed
  - Key words included adenoma, colonic neoplasms, intestinal polyps, colorectal adenoma, colon adenoma, surveillance, colonoscopy, follow-up, health economics, cost-effectiveness, costs and cost analysis

- Colonoscopic surveillance in people with ulcerative colitis
  - Key words included ulcerative colitis, colonoscopy, surveillance, follow-up, health economics, cost-benefit analysis, cost-effectiveness, costs and cost analysis

Articles were included if they were judged to be cost analyses or economic evaluations, that is, if they involved comparison of alternative interventions in terms of costs and consequences. Studies that were reviews of economic evaluations and studies that combined costs of screening and surveillance were not included.

The NHMRC methodology for grading economic evidence has not been applied in reviewing this literature. However, the economic information has been summarised and presented below.

### 7.3 Cost and cost-effectiveness of colonoscopy follow-up strategies after curative resection for colorectal cancer

Eighteen economic studies were found that investigated the cost effectiveness of colonoscopic surveillance for colorectal cancer patients post curative cancer resection. Sixteen of these studies investigated follow-up strategies to detect recurrence of the primary cancer, and have not been described further. The two remaining studies were cost effectiveness studies of colonoscopy surveillance for metachronous lesions and are summarised below and in Table 7.1.

Park and co-workers (2009) compared 8 surveillance strategies, concluding that colonoscopy every three years and colonoscopy every five years was economically feasible. Hassan and co-workers (2009) compared colonoscopy surveillance strategies with or without a 12 month colonoscopy and concluded that the 12 month colonoscopy was clinically efficient and cost effective in terms of cancer detection and cancer specific death prevention.

The two studies reviewed provide some evidence that more frequent or earlier follow-up strategies are cost effective compared to strategies with minimal follow-up. However, the small number of studies precludes a conclusion about which follow-up schedule represents the most cost effective strategy. Further studies are required in this area.
<table>
<thead>
<tr>
<th>Author, year</th>
<th>Country</th>
<th>Study Questions</th>
<th>Conclusion</th>
</tr>
</thead>
</table>
| Park et al 2009 | Korea | **Cost effectiveness analysis**  
Identification of a cost-effective strategy of second primary CRC screening for cancer survivors.  
Comparison of eight screening strategies for a simulated cohort of 50 year old male CRC survivors. | • The ICER for COL3 (colonoscopy every 3 years) in cancer survivors was $US 5593/life-year saved, and did not exceed $ 10,000 life year saved in one way sensitivity analyses.  
• More strict and frequent recommendations for colonoscopy such as COL3 and COL5 (colonoscopy every 5 years) can be considered as economically reasonable second primary CRC strategies. If the risk of CRC in cancer survivors is at least two times higher than in the general population, COL5 had an ICER of less than $10,500 per life-year saved.  
• If the age of cancer survivors starting CRC screening was decreased to 40 years, the ICER of COL5 was less than $7,400 per life-year saved regardless of screening compliance.  
• Direct costs only were expressed in US dollars and the exchange rate was 955 Korean Won for $1 US dollar in 2006. |
| Hassan et al 2009 | USA | **Cost effectiveness analysis**  
Comparison of a strategy of 1 year colonoscopic surveillance versus no early colonoscopic surveillance following resection for CRC. | • The number of early 1 year colonoscopies needed to detect one CRC and to prevent one CRC-related death was 143 and 926, respectively.  
• The incremental cost-effectiveness ratio of the early 1 year colonoscopy as compared to a policy of not performing it was $40,313 (based on direct and indirect costs in $ US 2007) per life-year gained.  
• An early 1 year colonoscopy after resection for CRC is clinically efficient and cost effective in terms of cancer detection and cancer-specific death prevention. |
7.4 Cost and cost-effectiveness of colonoscopy follow-up strategies after removal of adenomas

Eight studies were found that investigated the costs or cost effectiveness of colonoscopic surveillance following polypectomy (summarised in Table 7.2).

Two studies considered only the costs of various surveillance programs: a simulation model of statistical analyses that estimated the cost and procedural burden of colonoscopy surveillance in patients who had had endoscopic removal of adenomas; 20 and an estimation of the total cost of a surveillance program involving flexible sigmoidoscopy and colonoscopy at intervals varying from annually to five yearly. 23 A study by Sieg and Brenner (2007) 24 separately evaluated the costs of surveillance as part of the total costs of screening and surveillance and concluded that the net savings from CRC prevention due to screening would offset screening and surveillance costs.

Four further studies were cost effectiveness analyses. Only one of these analyses compared various colonoscopy surveillance strategies, 25 with a comparison of colonoscopy surveillance at one year versus three years after polypectomy. The one year strategy comparator in the analysis 25 is not a strategy under consideration for the current guidelines therefore the analysis is not considered relevant. Three other cost effectiveness analyses compared therapeutic agents with surveillance colonoscopy 26 27 28.

The remaining study was a cost utility modelling study by Saini and co workers that compared the cost effectiveness of four different surveillance scenarios (no surveillance; three yearly surveillance for all patients; three year surveillance for high risk patients and five year surveillance for low risk patients; three year surveillance for high risk patients and ten year surveillance for low risk patients) for patients diagnosed with adenoma. 29 The authors concluded that surveillance is cost effective as long as intensive (three yearly) surveillance was limited to high risk patients and that intensive follow-up for low risk patients was not cost effective, and even likely to be harmful. On the basis of the results presented, ten yearly surveillance was considered as cost effective for low risk patients.

Only the Saini 29 economic comparison of surveillance colonoscopy strategies following adenoma removal was directly relevant to the current guidelines. There is a need for further economic analyses to be performed in this area.
### Table 7.2 Results of studies investigating costs and cost-effectiveness of follow-up strategies in patients who have undergone adenoma removal

<table>
<thead>
<tr>
<th>Author, year</th>
<th>Country</th>
<th>Study Questions</th>
<th>Conclusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Arguedas et al 2001</td>
<td>USA</td>
<td><strong>Cost effectiveness analysis</strong>&lt;br&gt;Comparison of celecoxib to surveillance colonoscopy on average risk patients with prior polypectomy</td>
<td>- No surveillance was associated with a cost of $US1,016 per patient and colonoscopic surveillance with a cost of $1,813 per patient. Celecoxib use was associated with a total cost of $13,187 (based on 1999 Medicare reimbursement rates).&lt;br&gt;- The incremental cost effectiveness ratio for colonoscopic surveillance vs. no surveillance was $27,970 per life year saved and $27,900 per high grade lesion prevented (discounted).&lt;br&gt;- The incremental cost effectiveness ratio for celecoxib use vs. colonoscopic surveillance was $141,871 per high grade lesion prevented and $1,715,199 per life year saved.&lt;br&gt;- Long-term celecoxib therapy in average risk post-polypectomy patients is not cost effective compared to colonoscopic surveillance.</td>
</tr>
<tr>
<td>Lund et al 2001</td>
<td>UK</td>
<td><strong>Cost analysis</strong>&lt;br&gt;Comparison of costs of adenoma surveillance in a randomised trial of flexible sigmoidoscopy and colonoscopy at one, two and five year intervals.</td>
<td>- In a trial of 776 patients the cost of detecting one adenoma was at least £1,500 and the cost of detecting an adenoma &gt; 1 cm was &gt; £4000 (based on 1998 EUK).&lt;br&gt;- Costs were reported as total procedure costs for the study (£121,008), and one cancer was detected directly by surveillance. It was concluded that this was expensive compared to a cost per cancer detected by faecal occult blood testing a general population of £2000.</td>
</tr>
<tr>
<td>Dupont et al 2007</td>
<td>USA</td>
<td><strong>Cost effectiveness analysis</strong>&lt;br&gt;Comparing aspirin chemoprevention alone and in combination with colonoscopy surveillance in patients with prior adenoma resection</td>
<td>- The incremental cost effectiveness ration of aspirin chemoprevention compared to no intervention was $US87, 609 per life year saved.&lt;br&gt;- The ICER of colonoscopic surveillance compared to aspirin chemoprevention was $78, 226 per life year saved, and the ICER of combined colonoscopy surveillance and aspirin chemotherapy was $60,942.&lt;br&gt;- The incremental cost-effectiveness ratios per case of CRC prevented were $74,615 for colonoscopy, $134,333 for aspirin chemoprevention and $140,167 for the combination strategy.</td>
</tr>
<tr>
<td>Sieg and Brenner 2007</td>
<td>Germany</td>
<td><strong>Cost analysis</strong>&lt;br&gt;of surveillance after polypectomy using online data from the German registry of 109,989 screening colonoscopies.</td>
<td>- Over a 10 year period the discounted cost of surveillance was €7,401,692 (41,881 surveillance colonoscopies in 109,989 individuals; 30,639 without histology and 11,242 with histology/polypectomy)</td>
</tr>
<tr>
<td>Gheorge et al 2008</td>
<td>Romania</td>
<td><strong>Cost estimation</strong>&lt;br&gt;of cost and procedural burden</td>
<td>- Of 466/882 patients scheduled for surveillance colonoscopy:&lt;br&gt;  - 101 had had a polypectomy&lt;br&gt;- The estimated cost for colonoscopy surveillance was:</td>
</tr>
<tr>
<td>Author, year</td>
<td>Country</td>
<td>Study Questions</td>
<td>Conclusion</td>
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</table>
| Hassan et al 2009 | USA/Italy | **Cost effectiveness analysis**  
Comparing early colonoscopy surveillance, one year after polypectomy with colonoscopy three years after polypectomy. | - To detect one cancer and prevent one cancer-related death, 354 and 1,437 early 1 year colonoscopies were needed, respectively. 
- The incremental cost-effectiveness ratio of performing early one-year colonoscopy compared to not performing it was $ US 66,136 per life year gained (based on 2007 $US). 
- Discount not applied as all costs assumed to occur in the year of treatment. |
| Shaukat et al 2009 | USA | **Cost effectiveness analysis**  
Comparison of 4 surveillance strategies for surveillance colonoscopy in a cohort of 50 year old patients post-polypectomy. | Compared with no intervention, Incremental cost effectiveness ratios were: 
- $49,900/ LYG for calcium supplementation (in 2006 $US) 
- $ 20,600/ LYG for surveillance colonoscopy 
- $ 30,300/ LYG for calcium supplementation and surveillance colonoscopy 
Compared to calcium supplementation, incremental cost effectiveness ratios were: 
- $ 15,900/ LYG for surveillance colonoscopy 
- $ 27,200/ LYG for calcium supplementation and surveillance colonoscopy 
Compared to surveillance alone, the incremental cost effectiveness ratio for calcium supplementation and surveillance was $ 3,090,000/ life year gained. |
| Saini et al 2010 | USA | **Cost utility analysis**  
Cost-effectiveness of USA guideline-recommended surveillance by modelling cohort of 50 year old patients with newly diagnosed adenoma until death. | • Compared with no intervention (10/10 strategy), the 3/10 strategy had an ICER of $5,743 (adjusted to 2008 $US) per QALY gained  
• The 3/5 strategy had an ICER of $ 296,226 per additional QALY compared to no intervention.  
• The 3/3 strategy resulted in fewer cancers, cancer-related deaths and fewer QALYs than the less expensive 3/5 strategy  
• 3 year surveillance was cost-effective for high risk patients and 10 year surveillance for low risk patients. |

1. Four surveillance strategies: No intervention; Calcium supplementation (1200mg/day from 50 -80 years); Surveillance colonoscopy from age 50-80 every 5 years (3 years for large adenomas); Calcium supplementation plus surveillance.  
2. 3/3 strategy: patients undergo surveillance colonoscopy every 3 years; 3/5 strategy: high risk patients undergo surveillance colonoscopy at 3 years intervals and low-risk patients at 5 year intervals; 3/10 strategy high risk patients undergo surveillance colonoscopy at 3 years intervals and low-risk patients at 10year intervals; no surveillance
7.5 Costs and cost-effectiveness of colonoscopy follow-up strategies in ulcerative colitis

Six studies were found that investigated the costs or cost effectiveness of colonoscopic surveillance in ulcerative colitis (summarised in Table 7.3). Two studies were cost-utility studies that compared surveillance scenarios, including various follow-up regimes versus no follow up\(^{30}\), and enhanced surveillance versus immediate total colectomy\(^{31}\). A further cost utility study compared surveillance alone and surveillance plus 5-ASA therapy with no surveillance and 5-ASA therapy alone\(^{32}\). One study compared the cost-effectiveness of surveillance for ulcerative colitis with that of other standard endoscopic procedures\(^{33}\). Two further studies were cost analyses; a population-based study that assessed the costs associated with annual surveillance for a small cohort of patients with primary sclerosing cholangitis\(^{34}\) and a simulation model of statistical analyses that estimated the cost and procedural burden of colonoscopy surveillance in patients with inflammatory bowel disease\(^{20}\).

The findings suggest that follow-up for ulcerative colitis is expensive, especially when compared to other endoscopic procedures. However, it was generally concluded that surveillance is effective, particularly when there is a substantial risk of cancer. There is no clear consensus about the timing of surveillance, with annual surveillance being the most effective strategy in two studies\(^{30} \quad 31\), but with a high incremental CER in one study\(^{30}\). The most recent study concluded that immediate colectomy was slightly more cost effective than enhanced surveillance in the management of low-grade dysplasia; however it was acknowledged that patient preference towards the post-colectomy state had a significant influence on its cost effectiveness compared to surveillance\(^{31}\).
Table 7.3. Results of studies investigating costs and cost-effectiveness of follow-up strategies in patients with ulcerative colitis

<table>
<thead>
<tr>
<th>Author, year</th>
<th>Country</th>
<th>Study Questions</th>
<th>Conclusion</th>
</tr>
</thead>
</table>
| Provenzale et al 1998 | USA | **Cost-utility analysis**<br>Comparing no surveillance (colonoscopy for symptoms suggesting cancer and colectomy for high grade dysplasia or cancer) to surveillance<sup>2</sup> with colectomy for low grade dysplasia | Surveillance with colectomy for low grade dysplasia is effective.  
- No surveillance cost $US8,934 and provided 17.4 discounted years of life  
- Yearly surveillance cost $16,000 and provided 17.59 discounted years of life (ICER = $247,700/life year gained)  
- 2 yearly surveillance cost $13,500 and provided 17.59 discounted years of life (ICER = $159,500/life year gained)  
- 3 yearly surveillance cost $11,500 and provided 17.56 discounted years of life (ICER = $111,600/life year gained)  
- 4 yearly surveillance cost $10,400 and provided 17.55 discounted years of life (ICER = $83,700/life year gained)  
- 5 yearly surveillance cost $9,539 and provided 17.54 discounted years of life (ICER = $4,700/life year gained)  
- Variable interval surveillance ICER = $155,400/life year gained  
- Yearly surveillance was the most effective strategy but the incremental CER was expensive compared to mammography breast screening (ICER estimated at $22,000 life years gained). |
| Harewood 2004 | USA | **Cost effectiveness analysis**<br>comparison and ranking of four currently accepted endoscopic procedures (including surveillance of chronic ulcerative colitis) from the payer perspective | Compared to the other endoscopic procedures, surveillance for ulcerative colitis ranked relatively poorly in terms of cost effectiveness.  
Average cost effective ration (CER) :  
- Ulcerative colitis surveillance =$US47,638/case of dysplasia detected (4 biopsy bottles) or $ 14,119/case of dysplasia detected (1 biopsy bottle)  
- Barrett’s surveillance = $ 5,310/case detected  
- Microscopic colitis surveillance = $ 2,447/case detected  
- Small bowel biopsy for Sprue (diarrhoea)= $ 3900/case detected  
- Small bowel biopsy for Sprue (anaemia) = $ 2982/ case detected  
- Small bowel biopsy for Sprue (1st degree relative) = $ 3042/ case detected |
<table>
<thead>
<tr>
<th>Author, year</th>
<th>Country</th>
<th>Study Questions</th>
<th>Conclusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kaplan et al 2007</td>
<td>Canada</td>
<td>Cost analysis of annual surveillance of PSC patients.</td>
<td>The local cost of surveillance colonoscopy for 45 PSC patients in the cohort over 5 years from 2000 and 2005 was $52,990. The direct cost of surveillance to detect 1 additional case of dysplasia in PSC patients was $26,495. Costs reported in Canadian dollars adjusted to the year 2005.</td>
</tr>
<tr>
<td>Gheorge et al 2008</td>
<td>Romania</td>
<td>Cost estimation of the cost and procedural burden of CRC surveillance using colonoscopy in a cohort of patients at higher than average risk for CRC.</td>
<td>Of 466/882 patients that were scheduled for surveillance colonoscopy: - 7 had long lasting ulcerative colitis (average 17.7±3.9 years) - 525 € /6.8 months for surveillance colonoscopies in IBD (costs were not reported separately for Crohn’s disease and ulcerative colitis)</td>
</tr>
<tr>
<td>Rubenstein et al 2009</td>
<td>USA</td>
<td>Cost -utility analysis Comparison of twenty two strategies: natural history (no 5-ASA or surveillance), surveillance without 5-ASA at intervals of 1-10 years, 5-ASA plus surveillance every 1-10 years, and 5-ASA alone using a simulated cohort of 35 year old men with chronic ulcerative colitis followed to 90 years.</td>
<td>Without 5-ASA, annual surveillance was the ideal strategy, preventing 89% of CRC at cost of $ US69,100 per QALY gained compared with surveillance every 2 years (direct costs adjusted to 2007 US$). With 5-ASA, surveillance every 3 years cost $ 63,400 per additional QALY compared with surveillance every 4 years. With patients already taking 5-ASA, endoscopic surveillance might be safely carried out every 2 years or less. Annual endoscopic surveillance for these patients costs nearly $ 1 million per additional QALY gained.</td>
</tr>
<tr>
<td>Nguyen et al 2009</td>
<td>USA</td>
<td>Cost-utility analysis of the relative costs and effectiveness of immediate colectomy and enhanced colonoscopic surveillance for the management of low grade dysplasia (LGD) in ulcerative colitis</td>
<td>The total lifetime cost associated with immediate colectomy was $US 75,900 compared to $83,900 associated with enhanced surveillance based on 2005 $US. For the immediate colectomy cohort the average number of unweighted life-years accrued was 22.5 compared to 22.3 for the enhanced surveillance cohort. Management of LGD with immediate colectomy resulted in 20.1 QALYs compared to 19.9 QALYs for enhanced surveillance. Immediate colectomy was preferable to enhanced surveillance as it was less expensive and produced slightly more QALYs.</td>
</tr>
<tr>
<td>Author, year</td>
<td>Country</td>
<td>Study Questions</td>
<td>Conclusion</td>
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<td>Patient preference toward and perception of the postcolectomy state was the only factor that could potentially make enhanced surveillance cost effective.</td>
</tr>
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</table>

1 Including: a. annual surveillance, b. surveillance every 2 years, c. surveillance every 3 years, d. surveillance every 4 years, e. surveillance every 5 years, f. surveillance every 3 years for the first 20 years, every 2 years for the next 8 years and annually thereafter.

2 The twenty two strategies included: Natural history (the reference strategy; natural history of ulcerative colitis without any 5-ASA or surveillance); Surveillance colonoscopy alone (intervals ranging from one to ten years); 5-ASA alone (with no surveillance); and surveillance plus 5-ASA (intervals ranging from one to ten years).

3 Enhanced surveillance: Colonoscopy repeated at 3 months after the initial detection of LGD and at 6, 12 months and annually thereafter if the 3 month colonoscopy is negative for LGD. If LGD, high grade dysplasia or cancer were detected during the enhanced surveillance period, immediate referral for colectomy resulted.
7.6 Cost-effectiveness Analysis of Proposed Surveillance Guidelines

A summary of the results of the cost-effectiveness analyses undertaken to support surveillance colonoscopy according to the proposed guidelines is presented for

- patients who have undergone curative resection for colorectal cancer
- patients who have had adenoma(s) detected.

This section also includes a summary of the cost of colonoscopy surveillance for patients with ulcerative colitis

A detailed summary of each analysis and costs are provided in the Appendix.

Estimations of the annual incidence of high risk adenoma, low risk adenoma and recurrent colorectal cancer amongst patients having previous curative resection for colorectal cancer who were undergoing colonoscopic surveillance were largely obtained from the literature forming the evidence base that supports the surveillance recommendations in Chapter 3. Estimations of the annual incidence of high risk adenoma and low risk adenoma amongst patients having prior removal of adenoma and who were undergoing colonoscopic surveillance were obtained from the literature forming the evidence base that supports the surveillance recommendations in Chapter 2. Estimations of the proportion of ulcerative colitis patients at high and low risk for colorectal cancer were largely obtained from the literature forming the evidence base that supports the surveillance recommendations in Chapter 4.

Only direct medical costs (2010 Australian dollars) for colonoscopy surveillance from a health services perspective were considered. These include costs associated with bowel preparation and the colonoscopy procedure. The estimated cost for the bowel preparation was approximately $10.00. It was assumed that 30.2% of colonoscopies would be performed in the public sector and 69.8% in the private sector. This was based on the breakdown of separations for AR-DRG version 5.1 or 5.2 for colonoscopy codes G44 (G44A, G44B, G44C) across the public and private sector in 2008–2009. Colonoscopy costs for the public patients were based on costs provided by a Melbourne Teaching hospital. Colonoscopy costs for the private patients were based on costs provided by a major Private Health Insurer.

7.6.1 Cost-effectiveness of colonoscopy surveillance following CRC resection

Using a health service perspective we estimated the costs of surveillance colonoscopies for 14 years following post curative resection for colorectal cancer comparing the surveillance strategy recommended in the 2005 Guidelines for the Prevention, Early Detection and Management of Colorectal Cancer 33 with the surveillance strategy recommended in the proposed new guidelines. The proposed guidelines included a colonoscopy at one year following cancer resection whilst the 2005 guidelines had the first colonoscopy at three years post curative resection.

The analysis was based on a cohort of 7,700 patients who had resection for colorectal cancer and who would be eligible for an initial surveillance colonoscopy at one year (proposed guidelines) or three years (2005 guidelines). For the analysis using the proposed guidelines patients would then be followed by five yearly surveillance if they had a low risk adenoma(s) or normal colonoscopies or at three years if they had a high risk adenoma(s) detected. For the 2005 guidelines patients would then be followed by four yearly surveillance procedures.
surveillance if they had a low risk adenoma(s), normal colonoscopies or high risk adenoma(s). A detailed description of the colonoscopies and costs is presented in Appendix 4.

The estimated cost of surveillance colonoscopy for CRC follow-up with the proposed guidelines which include a one year post resection colonoscopy is $26,690,230 (2010 Aus $) for a cohort of 7700 patients followed over a period of 14 years and $25,617,823 using the 2005 guidelines for the same period (see table below).

Table 7.4: Summary of Colonoscopies and Costs for 7700 patients Post CRC Resection over a 14 year Period

<table>
<thead>
<tr>
<th>Colonoscopies</th>
<th>Total</th>
<th>Recurrent cancer or high risk adenoma(s)</th>
<th>Low risk adenoma(s) or normal colonoscopies (% total)</th>
<th>Total cost for program</th>
</tr>
</thead>
<tbody>
<tr>
<td>Proposed Guideline (1 year post CRC resection)</td>
<td>21697</td>
<td>1578</td>
<td>477 (1.5%)</td>
<td>20119 (93%)</td>
</tr>
<tr>
<td>2005 Guideline (3 years post CRC resection)</td>
<td>20790</td>
<td>2036</td>
<td>881 (2.3%)</td>
<td>18754 (91%)</td>
</tr>
<tr>
<td>Increments*</td>
<td>907</td>
<td>-458</td>
<td>-404</td>
<td>1365</td>
</tr>
<tr>
<td>Incremental cost per additional outcome #</td>
<td>$1,182</td>
<td>-$2,342</td>
<td>-$2,654</td>
<td>$786</td>
</tr>
</tbody>
</table>

On average $55,954 would be spent for every high risk adenoma detected with the proposed surveillance colonoscopy guidelines compared to $29,078 with the 2005 guidelines. With the proposed new guidelines for an additional $2,342 an additional high risk adenoma or recurrent cancer could be avoided or for an additional $2,654 an additional high risk adenoma could be avoided. For an additional $786 an additional low risk adenoma(s) or normal colonoscopy would be detected with the new guidelines.

### 7.6.2 Summary of cost-effectiveness results for colonoscopy surveillance following detection of adenomas

Using a health service perspective costs were estimated for 13 years of follow-up after removal of adenoma(s). All analyses were based on the incidence and distribution of high risk and low risk adenomas that would be expected from a full initial national roll-out of the National Bowel Cancer Screening Program (NBCSP).

For the purposes of this analysis, the total number of people with adenomas detected was rounded to 100,000 (i.e. high risk adenomas and low risk adenomas).
The analyses undertaken for patients diagnosed with adenomas compared the surveillance strategy recommended in the 2005 Guidelines for the Prevention, Early Detection and Management of Colorectal Cancer with one potential new surveillance strategy:

- **Option A (2005 Guidelines)**
  - High risk adenomas - three yearly surveillance; low risk adenomas - five yearly surveillance
  - Subsequent normal colonoscopies – five yearly surveillance

- **Option B:**
  - High risk adenomas – three yearly surveillance; low risk adenomas - five yearly surveillance
  - Subsequent normal colonoscopies – ten yearly surveillance

A detailed description of the number and frequency of the colonoscopies performed and the costs is presented in Appendix 4.

**Option A (2005 Guidelines) vs Option B**

- Over a 13 year period, a higher proportion of patients (4.7% of those patients tested in Option B vs. 4.1% of those patients tested under Option A (2005 Guidelines)) with high risk adenoma would be detected by surveillance colonoscopies performed as per Option B than would be detected from surveillance performed as per Option A (see Table 7.5).
- The cost per high risk adenoma detected over 13 years would be $26,286 with Option B compared to $30,217 with Option A (2005 Guidelines).
- If Option B were adopted the cost of surveillance colonoscopies performed would be less expensive than the current 2005 Guidelines (Option A).
Table 7.5. Summary of Colonoscopies and Costs for 100,000 patients with adenomas over 13 years

<table>
<thead>
<tr>
<th>Guideline Changes</th>
<th>Costs of Guideline Changes</th>
<th>Calculations of Outcomes</th>
<th>Calculations of Incremental Variables</th>
</tr>
</thead>
<tbody>
<tr>
<td>Guideline version</td>
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<tr>
<td>High risk adenoma strategy</td>
<td>Non-high risk adenoma / normal strategy</td>
<td>Total 13 year cost of program</td>
<td>Total number of colonoscopies over 13 years</td>
</tr>
<tr>
<td>2005 Option A</td>
<td>3 yearly</td>
<td>5 yearly</td>
<td>296,070,531</td>
</tr>
<tr>
<td>New option B</td>
<td>3 yearly</td>
<td>Low risk at 5 years; normal colonoscopy at 10 year</td>
<td>214,413,520</td>
</tr>
</tbody>
</table>

*Economic considerations* 90
7.6.3 **Summary of cost results for colonoscopy surveillance in patients with ulcerative colitis**

Since there are no existing guidelines for the management of surveillance for patients with ulcerative colitis, we estimated a 20 year perspective of costs of performing surveillance colonoscopy at intervals recommended in the proposed new guidelines for a cohort of 2,517 people diagnosed with ulcerative colitis. The number of patients in the cohort represents the number of newly diagnosed ulcerative colitis patients expected in Australia in one year based on an incidence of 11.2 per 100,000 \(^{36}\) and the March 2010 Australian population estimates.

Amongst the 2,517 people diagnosed with ulcerative colitis:

**Yr 0-8:**

53.8% (1354) of patients have extensive disease and 46.2% (1163) have limited disease at diagnosis

- Of those with extensive disease, 80 pts (40 with PSC and 40 with a FHx of early CRC) require annual colonoscopy from the time this risk is diagnosed.

- The remaining 1274 pts with extensive disease require no surveillance until Yr 8.

- Of those with initially distal disease, 233 pts would have progressed to develop extensive disease or developed risk factors such as stricture or inflammatory polyps by year 8 and need to start surveillance then. The remaining 930 pts with limited disease do not require any formal surveillance but will follow general population guidelines for colorectal cancer screening.

**By Yr 8:**

There are 1587 pts with extensive disease (1274 plus 80 plus 233) who require surveillance starting at year 8.

Of these 20% (317) will eventually require surgery and need no further surveillance.

This leaves 1270 pts who require surveillance at varying intervals:

- Annual surveillance in a total of 419 pts (33%) who are at high risk due to PSC, family history, active disease, stricture or inflammatory polyps

- Three yearly surveillance in the remaining 67% (851).

The costs for the procedure were based on same day rates of $865.32 in public sector and $1,472 in the private sector with a further $10 added to the cost of each procedure for the cost of the bowel preparation.

Over a period of 20 years of surveillance, a total of 13,486 colonoscopies would be performed in 1,270 people with ulcerative colitis including the following:

- 5106 colonoscopies in 851 people with inactive disease, of which 1,542 would be performed in the public sector at a cost of $1,349,754 and 3,564 would be performed in the private sector at a cost of $5,281,830.
• 8380 colonoscopies in 419 people with active disease, of which 2531 would be performed in the public sector at a cost of $22,152,25 and 5849 would be performed in the private sector at a cost of $8,668,574.

The total cost for of 20 years of surveillance for the 851 people with inactive disease would be $6,631,584 assuming complete physician and patient compliance with three yearly colonoscopy surveillance. For the 419 high risk patients, the total cost of surveillance over 20 years would be $10,833,799, assuming complete compliance with the recommended yearly surveillance regime. The total cost for 20 years of surveillance colonoscopy for a cohort of 2,517 people diagnosed with ulcerative colitis 8 years earlier, where 51.1% of people undergo surveillance according to the new guidelines, would be $17,515,383.

7.6.4 Limitations
In all cases it was assumed that there was total compliance with surveillance recommendations by physician and patients. There are several limitations with the analysis, including the costs being based on charges, lack of data in the literature from longterm follow-up and the use of constant annual rates for adenoma or cancer. In the cost estimations mortality rates, post colonoscopy medical review and complication or perforation rates were not considered. There was no consideration of discounting and no sensitivity analysis was undertaken.

References


Clinical Practice Guidelines for Surveillance Colonoscopy - in adenoma follow-up, following curative resection of colorectal cancer, and for cancer surveillance in inflammatory bowel disease


APPENDIX 1 GUIDELINE DEVELOPMENT PROCESS

A1.1 Introduction

Preamble

In 2006, the Australian Health Ministers Advisory Council (AHMAC) instructed the National Bowel Cancer Screening Program to review colonoscopy services in Australia. The Quality Working Group (QWG) (chaired by Professor James St John) was commissioned to do this. A draft report was issued in June 2008 for public comment and the final report followed in April 2009. The final report was approved by the Australian Screening Committee and then noted by AHMAC in April and referred to the Australian Commission on Safety and Quality in Healthcare. The Commission stated that there was no clash and AHMAC was reassured. AHMAC endorsed the report in early 2010.

The Australian Cancer Network’s “Clinical Practice Guidelines for the prevention, early detection and management of colorectal cancer” 2005 (CPG) included, amongst a large amount of other material, reference to use of colonoscopy and indications for surveillance.

The QWG report recommended that AHMAC endorse guidelines on surveillance colonoscopy as policy and consider linking MBS items to CPG to discourage over-servicing (assuming that the guidelines were contemporary).

It was stressed that guidelines take two to three years to complete and that maintaining the guidelines’ contemporary status can be difficult. This might be addressed by review every three to five years. It was noted that there were no current clinical practice guidelines relating to prevention of bowel cancer development in the setting of inflammatory bowel disease.

It was noted that the US Multi-Society Taskforce report on adenoma and cancer surveillance expressed concern about unrewarding surveillance colonoscopy draining procedural resources away from bowel cancer screening and investigation of patients with symptoms.

The Cancer Council Australia (CCA) was commissioned by the Screening Section of the Department of Health and Ageing (DoHA) to review sections of several chapters of the “Clinical Practice Guidelines for the prevention, early detection and management of colorectal cancer” approved by the NHMRC in 2005 with a specific focus on colonoscopic surveillance. Cancer Council Australia then submitted a proposal to the National Health and Medical Research Council (NHMRC) to develop the Clinical Practice Guidelines for Surveillance Colonoscopy - in adenoma follow-up, following curative resection of colorectal cancer, and for cancer surveillance in inflammatory bowel disease.

A Working Party composed of clinical specialists, a consumer and a Project Officer carried out the work. The Project Officer conducted literature searches, assisted in the critical evaluation of the literature and extracted the relevant data. Funding was provided by the Screening Section of the Department of Health and Ageing.

The development program was designed to meet the standards of scientific rigour required by the NHMRC guideline development process, which is the subject of a series of handbooks on the main stages involved in the development of clinical practice guidelines. The eight NHMRC handbooks have been condensed previously into a single volume—Development of clinical practice guidelines for the management of cutaneous melanoma and melanoma in special sites: a handbook for chapter leaders and expert working groups—which outlines the major steps and expectations involved in developing guidelines and provides a clear path for everyone involved in the project. This handbook provides the definitions and protocols for developing research questions and search strategies, conducting searches and critical appraisal, summarising and assessing the relevant literature and, finally, formulating the recommendations. It includes checklists and templates created to meet NHMRC requirements and designated standards of quality and process. This condensation of all the
NHMRC handbooks has been a most useful aid in the demanding and, for some, new process of developing guidelines.

At its initial meetings the Guidelines Working Party prepared a table of topics and developed questions to address identified clinical needs. The questions were identified with the specific focus of the revision being the role of surveillance colonoscopy in chapters 8, 9, 17, and 23 of the Clinical Practice Guidelines for the prevention, early detection and management of colorectal cancer 2005 and also in a new chapter dealing with surveillance colonoscopy in the management of patients with inflammatory bowel disease (IBD). Subcommittees of the Guidelines Working Party were formed to address topics in their areas of expertise.

Terms of reference

The following points were then discussed and supported by the Working Party:

- A suggestion was made that consideration be given to use of colonoscopy in population screening. While there are trans-Atlantic differences, American Guidelines address individual and not population screening.
- In a comment on funding, it was noted that NHMRC takes no responsibility for funding the current review of surveillance colonoscopy guidelines. The proposed review is QWG-related (as a fundamental aspect of its brief, in direct response to the request from AHMAC that colonoscopy services be reviewed) and will be funded by Department of Health and Ageing (DoHA).
- NHMRC approval of any revisions to the guidelines was to be sought as it was felt to be highly desirable, adding weight to the resulting guidelines. Endorsement by other responsible organisations was felt to be possible if NHMRC approval were not forthcoming.
- ACN/CCA suggested that, while revisions to the CPG might be achieved by 30 June 2010, this timeline was probably optimistic.
- There was a strong need to stick with evidence-based material throughout the guidelines’ development process.
- Relevant new information should be embraced, where possible within the external restrictions imposed, and that new source data that differed from US and European information would need careful review to ensure a good evidence base.
- Areas where evidence was scanty or absent were to be identified.
- Update of research priorities was to be an important part of the development process and funding needs required identification.

A2.1 Steps in preparing the guideline

A clear strategy was developed for every topic and each expert group followed the appropriate steps in preparing the guidelines. While each subcommittee received significant assistance from the Project Officer skilled in methodology, the subcommittees themselves oversaw the synthesis of the evidence and formulation of the recommendations for their topics.

The strategic steps followed are outlined below:

1. Structure the research questions
2. Develop a search strategy
3. Search the literature
4. Select, assess and summarise the literature
5. Critically appraise and summarise each selected article
6. Assess the body of evidence and formulate recommendations
A2.1.1 Structure the research questions

A wide range of questions was proposed for research. The questions focussed on interventions rather than diagnosis or prognosis. All proposed questions were reviewed on the basis of their purpose, scope and clinical importance to the target audience and were structured according to the PICO (populations, interventions, comparisons, outcomes) formulation.

The Guidelines for all three components are designed to answer the question as to how frequently patients require surveillance colonoscopy to achieve maximal protection against the development of colorectal cancer, in their individual circumstances.

The clinical questions asked:

- What are the appropriate intervals between colonoscopies after polypectomy?
- What are the appropriate intervals between colonoscopies after colorectal cancer resection?
- What are the appropriate intervals between colonoscopies in patients diagnosed with inflammatory bowel disease?

A2.1.2 Develop a search strategy

Each research question was submitted to a search strategy based on the PICO formulation.

Most searches were directed to colorectal cancer as a generic base. Searches were limited or widened as necessary, but all maintained the PICO structure. Keywords were selected during the PICO process. Further sources for keywords or MESH and subject terms were derived from evidence-based material, systematically reviewed articles and appropriately relevant literature. A single systematic search strategy was derived from these terms and applied to all included electronic databases.

A2.1.3 Search the literature

NHMRC specifies that clinical practice guidelines should be based on systematic identification and synthesis of the best available scientific evidence. All literature searches were conducted systematically using electronic databases concluding 31 December 2009. Examples include:

- Medline: bibliographic references and abstracts to articles in a range of languages on topics such as clinical medical information and biomedicine, and including the allied health fields, biological and physical sciences
- EMBASE: major pharmacological and biomedical database indexing drug information from 4550 journals published in 70 countries
- Cinahl: bibliographic references and abstracts to journal articles, book chapters, pamphlets, audiovisual materials, software, dissertations, critical paths, and research instruments on topics including nursing and allied health, biomedicine, consumer health, health sciences librarianship, behavioural sciences, management, and education
- Cochrane Library: regularly updated collection of evidence-based medicine databases, including The Cochrane Database of Systematic Reviews
- Psychinfo: Bibliographic references and abstracts to journal articles, book chapters, dissertations and technical reports on psychology; social, clinical, cognitive and neuropsychology; psychiatry, sociology, anthropology and education, with source material from a wide range of languages.

The literature review process of this document includes a systematic search of sites such as PubMed-Medline, Embase, Cinahl and Cochrane to select published guidelines, systematic reviews and primary studies assessing the use of colonoscopy for surveillance after endoscopic resection of colonic polyps and for surveillance after curative-intent resection of colorectal cancer (CRC) for the
years 2003–2009 and inflammatory bowel disease (IBD) for the years 1990–2009. An additional search was done for the years 1990–2002 on surveillance after endoscopic resection of colonic polyps and for surveillance after curative-intent resection of colorectal cancer (CRC) to add relevant articles which were not included in the literature included in the Clinical Practice Guidelines for the prevention, early detection and management of colorectal cancer, approved by the NHMRC in 2005.

Dates searches were performed and the results were as follows:

Embase:

4/11/09: colonoscopy AND (surveillance OR follow up) and colorectal – 27
4/11/09: colonoscopy AND (surveillance OR follow up) AND (colorectal OR bowel cancer – 86
27/1/10: (colorectal OR colon OR rectum) AND (cancer OR neoplasm) AND (surveillance OR follow up) AND (surgery OR resection) – 48
8/5/10: #4'cancer'/exp/mj OR 'neoplasm'/exp/mj AND (colorectal OR 'colon'/exp/mj OR 'rectum'/exp/mj OR 'bowel'/exp/mj) AND (surveillance OR 'follow up'/mj) AND colonoscopy AND [humans]/lim AND [english]/lim AND [1980-2002]/py – 354
8/5/10: articles selected for relevance (omitted articles with no abstract, non-studies, screening and familial cancer) #4'cancer'/exp/mj OR 'neoplasm'/exp/mj AND (colorectal OR 'colon'/exp/mj OR 'rectum'/exp/mj OR 'bowel'/exp/mj) AND (surveillance OR 'follow up'/mj) AND colonoscopy AND [humans]/lim AND [english]/lim AND [1980-2002]/py – 88
17/11/10: 'adenoma'/exp AND ('cost'/exp AND effectiveness OR economic) AND (surveillance OR follow AND up)- 1
17/11/10: (surveillance OR follow AND up) AND ('cost'/exp AND effectiveness OR costing OR 'economics'/exp) AND ('cancer'/exp OR 'neoplasm'/exp) AND (colorectal OR 'colon'/exp OR 'rectum'/exp OR 'bowel'/exp) AND [humans]/lim AND [english]/lim- 27
17/11/10: ulcerative AND 'colitis'/exp/mj) AND('cancer'/exp OR 'neoplasm'/exp) AND (surveillance OR follow AND up) AND(cost'/exp AND effectiveness OR economic)- 2
PubMed:

7/10/09: "Adenoma/diagnosis"[Major]) AND (colonoscopy[Title/Abstract]. visually restricted to 2005 or later. Visually checked for articles relating to rates of diagnosis, failure to diagnose or missed diagnoses – 46


21/10/09: colorectal neoplasms AND diagnosis AND colonoscopy AND (surveillance OR follow-up) for 2003 and 2004. This yielded 226 articles, which were visually reduced to 11 by checking title and/or abstract

21/10/09: chronic inflammatory bowel disease AND colonoscopy AND (surveillance OR follow up) 2003-2009 – 52 articles visually restricted to 8


3/11/09: Search: ("2003"[Publication Date] : "3000"[Publication Date]) AND (((cancer[Title/Abstract]) AND colorectal[Title/Abstract]) AND surveillance[Title/Abstract]) AND "resection"[Title/Abstract]) Limits: Humans, English, Core clinical journals – 13

3/11/09: "2003"[Publication Date] : "3000"[Publication Date]) AND ((polypectomy[Title/Abstract]) AND surveillance[Title/Abstract]) Limits: Humans, English, Core clinical journals – 21


19/11/09: (Inflammatory Bowel Disease) AND neoplasm (Mesh) AND (surveillance OR follow-up) 1990-2009 Humans, English, Clinical journals Original unsorted search which yielded 147 articles

7/1/10: ("barium"[MeSH Terms] OR "barium"[All Fields]) AND ("enema"[MeSH Terms] OR "enema"[All Fields])) AND ("neoplasms"[MeSH Terms] 2004-presentVisually restricted to studies examining methods. Excluded articles dealing with screening only 5


31/12/09: ("2003/01/01"[Publication Date] : "3000"[Publication Date]) AND (Colorectal cancer and multiple adenomas) Limits: Humans, Male, Female, Clinical Trial, Meta-Analysis, Practice Guideline, Randomized Controlled Trial, Review, Comparative Study, Controlled Clinical Trial, Multicenter Study, English, MEDLINE, PubMed Central, All Adult: 19+ years – 32

4/1/10: MYH-associated polyposis and surveillance – 11

4/1/10: Familial adenomatous polyposis (FAP) and polypectomy – 19

4/1/10: ("2003/01/01"[Publication Date] : "3000"[Publication Date]) AND (Surveillance in patients with FAP)) Limits: only items with links to full text, Humans, Clinical Trial, Meta-Analysis, Practice Guideline, Randomized Controlled Trial, Review, Case Reports, Comparative Study, Controlled Clinical Trial, Guideline, English, MEDLINE, PubMed Central, All Child: 0-18 years, All Adult: 19+ years – 32

5/1/10: FAP guidelines – 1
Clinical Practice Guidelines for Surveillance Colonoscopy - in adenoma follow-up, following curative resection of colorectal cancer, and for cancer surveillance in inflammatory bowel disease


13/11/2010: (((#3) AND #4) AND #5) AND #7) #3 Limits: Humans, Clinical Trial, Meta-Analysis, Randomized Controlled Trial, Review, Clinical Trial, Phase I, Clinical Trial, Phase II, Clinical Trial, Phase III, Clinical Trial, Phase IV, Comparative Study, Controlled Clinical Trial, Multicenter Study, English, Core clinical journals, Cancer, MEDLINE, PubMed Central.#4 colorectal OR colon OR rectum OR bowel[Title/Abstract] #5 cancer OR neoplasm[Title/Abstract] #6 surveillance OR follow up[Title/Abstract] #7 economics (Mesh term, includes cost effectiveness)- 41 selected out of 277


Searching on Inflammatory bowel disease instead of ulcerative colitis yielded the same one article.

**CINAHL:**

18/11/09: Inflammatory bowel disease AND colorectal cancer AND surveillance 4 records selected out of – 13

7/5/10: (AB cancer or AB neoplasm) AND (AB colorectal or AB bowel or AB rectum or AB colon) AND (AB surveillance or AB follow up) 1980-2002 Only found one study that seemed useful out of 102 articles

7/5/10: colonoscopy AND (colorectal OR bowel OR colon OR rectum) AND (surveillance OR follow up) 1980-2002 articles selected visually (most on screening, family history or prevention) – 3

**Cochrane Library:**

18/11/09: Inflammatory bowel disease AND colorectal cancer AND surveillance – 3

1/1/10: colonoscopy – 11

1/1/10: CT colonography – 4

7/5/10: (colorectal OR bowel cancer) AND colonoscopy before 2002-24 articles reduces to 4 (most to do with screening and methods of colonoscopy) – 4

13/11/2010: colorectal cancer in Economic evaluations database 12 out of 142- 12

**Additional search was using PubMed which included the following:**

Sessile adenomas and colorectal cancer Limits: Clinical Trial, Meta-Analysis, Practice Guideline, Randomized Controlled Trial, Review, Comparative Study, Controlled Clinical Trial, Government Publications, Guideline, Journal Article, English resulting in 124 records

Colorectal cancer and multiple adenomas Limits: Humans, Male, Female, Clinical Trial, Meta-Analysis, Practice Guideline, Randomized Controlled Trial, Review, Comparative Study, Controlled Clinical Trial, Multicenter Study, English, MEDLINE, PubMed Central, All Adult: 19+ years resulting in 81 records

MYH-associated polyposis and surveillance resulting in 11 records

Surveillance in patients with FAP) Limits: only items with links to full text, Humans, Clinical Trial, Meta-Analysis, Practice Guideline, Randomized Controlled Trial, Review, Case Reports, Comparative Study, Controlled Clinical Trial, Guideline, English, MEDLINE, PubMed Central, All Child: 0-18 years, All Adult: 19+ years resulting in 32 records

Familial adenomatous polyposis (FAP) and polypectomy resulting in 19 records

For each search, the following details were provided in topic- or question-specific reports (available on request from the Cancer Council Australia):

- electronic databases searched
- terms used to search the databases
- search inclusion or exclusion criteria
- language
- study type.

Studies published before 31 December 2009 could be included in the systematic reviews. Studies published after this date could not be included in the evidence base for the recommendations but could be referred to in the text and were described in the Appendices to the topic- or question-specific...
reports (available on request from the Cancer Council Australia). The project team also hand-searched the reference lists of the relevant articles to identify additional articles that had not been detected through searches of the electronic databases. Bi-annual meetings of the guidelines Working Party provided a forum for discussing and sharing overlapping evidence, the discovery of unpublished literature and information from other key organisations or individuals.

**A2.1.4 Select, assess and summarise the literature**

The literature identified by the electronic database searches was assessed for relevance to each question. The following steps were taken to select and sort the literature, with the details and results summarised in topic- or question-specific reports (available on request from the Australian Cancer Network):

1. Define the inclusion criteria:
   The search was limited to English language and to the heading appearing in the title and abstract of articles. Reviews, instructive guidelines, comments and letters are not referred to when critical analyses of the data is performed. These were used to refer the reader to further information and for comparative analyses (for example, international view of guidelines for adenoma and colorectal cancer surveillance). The literature search focussed on diagnoses of colorectal lesions and inflammatory bowel disease at the time of baseline examination and during surveillance colonoscopy. Also, in PubMed searches (dated 1 May 2010), several search strategies were combined to one single search.

   No limitation on date was used when searching databases for articles on cost effectiveness related to colonoscopy surveillance following adenoma resection, CRC resection and IBD diagnosis. Studies for cost effectiveness were selected based on titles and abstracts and omitting any studies that did not deal directly with the topic (eg screening rather than surveillance after cancer, other cancers with colorectal cancer mentioned incidentally, treatment rather than surveillance).

2. Review titles and abstracts of retrieved citations to identify potentially relevant articles
3. Obtain the full text of potentially relevant articles
4. Determine whether the study described in each collected article met the pre-defined inclusion criteria
5. Determine whether systematic reviews accounted for all preceding literature
6. Prepare folders to file searches, background papers and reviewed articles for each question addressed

Two independent assessors then assessed the quality of each of the included studies according to pre-defined criteria for the various study types. Any disagreements were adjudicated by a third reviewer. The quality criteria were:

- **randomised controlled trials (RCTs):** blinding, allocation concealment, follow up and intention-to-treat analysis and mode of randomisation
- **systematic reviews:** search strategy used, the inclusion criteria and their application, study quality assessment, summary descriptive tables, pooling methods and examination of heterogeneity
- **quasi-randomised and cohort studies:** subject selection, group comparability, comparability of outcome measurement, blinding and completeness of follow up.

Criteria for the critical appraisal process are available on the Cancer Council Australia website (www.cancer.org.au).

Summaries of the studies were tabulated in PICO format and the relevant data extracted and summarised in tables. The data extraction was checked by a second assessor. These tables of study
characteristics and evidence are included in the topic- or question-specific reports (available on request from the Cancer Council Australia). The reports also contain lists of collected studies that did not meet the inclusion criteria and the reason for their exclusion.

**A2.1.5 Critical appraisal and summary**

For each clinical question, the included studies and their results were summarised in a template (Template 1 in the Handbook). Each study was submitted to further critical appraisal. The level of the evidence, the quality of evidence as determined above, the size of effect and relevance of the evidence of each included study was documented.

Details of the templates, rating systems, and criteria for the critical appraisal process are available on the Cancer Council Australia website (www.cancer.org.au). Levels of evidence are outlined below.

**Table 1 Designations of levels of evidence for intervention research questions (NHMRC, 2009)**

<table>
<thead>
<tr>
<th>Level</th>
<th>Intervention</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>A systematic review of level II studies</td>
</tr>
<tr>
<td>II</td>
<td>A randomised controlled trial</td>
</tr>
<tr>
<td>III-1</td>
<td>A pseudo-randomised controlled trial (ie alternate allocation or some other method)</td>
</tr>
</tbody>
</table>
| III-2 | A comparative study with concurrent controls:  
  - non-randomised, experimental trial  
  - cohort study  
  - case-control study  
  - interrupted time series with a control group |
| III-3 | A comparative study without concurrent controls:  
  - historical control study  
  - two or more single-arm studies  
  - interrupted time series without a parallel control group |
| IV    | Case series with either post-test or pre-test/post-test outcomes |

**A2.1.6 Assess the body of evidence and formulate recommendations**

The body of literature was assessed by each expert sub-committee in regard to the volume of the evidence, its consistency, clinical impact, generalisability and applicability. These aspects were graded and documented in a second template (Template 2 in the Handbook).

Following grading of the body of evidence, expert sub-committees were asked to formulate a recommendation that related to the summarised body of evidence. This recommendation also had to be graded as follows:

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105 Clinical Practice Guidelines for Surveillance Colonoscopy - in adenoma follow-up, following curative resection of colorectal cancer, and for cancer surveillance in inflammatory bowel disease
<table>
<thead>
<tr>
<th>Grade of recommendation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>Body of evidence can be trusted to guide practice</td>
</tr>
<tr>
<td>B</td>
<td>Body of evidence can be trusted to guide practice in most situations</td>
</tr>
<tr>
<td>C</td>
<td>Body of evidence provides some support for recommendations but care should be taken in its application.</td>
</tr>
<tr>
<td>D</td>
<td>Body of evidence is weak and recommendation must be applied with caution</td>
</tr>
</tbody>
</table>

When no Level I or II evidence was available but there was consensus among the working party members, recommended best practice points have been provided, and can be identified throughout the guideline with the following: Practice Point (PP).

### A2.2 Writing the chapter

All the expert sub-committees were asked to write their guidelines chapter using the following format:

- background
- review of the evidence
- evidence summary with levels of evidence and numbered references
- recommendation(s) and corresponding grade(s)
- references

### A2.3 Review of the chapters

The body of evidence and recommendations for each chapter were reviewed by the Guidelines Working Party and final recommendations agreed to, based on the evidence.

### A2.4 Public consultation

A complete draft of the guidelines was sent out for public consultation in Australia from the period of 21 May to 21 June 2011. The consultation process included soliciting public review of the document through advertisement in a national newspaper, and alerting professional societies and groups and sponsors.

All feedback on the draft received during the consultation period in Australia was reviewed by the Guidelines Working Party. Subsequent changes to the draft were agreed by consensus, based on consideration of the evidence. A final independent review of experts in their fields was conducted before the final draft was submitted to NHMRC.

### A2.5 Dissemination and implementation

The Cancer Council Australia will take the lead in disseminating the guidelines in Australia. This will include a campaign to raise awareness of the new guidelines that incorporates organised media coverage through multiple outlets and an official launch. Cancer Council Australia will distribute the Guidelines directly to relevant professional and other interested groups and through meetings, national conferences, and other CME events. Cancer Council Australia also plans to upload the Guidelines to its Cancer Guideline portal, which is a website using wiki technology. The link to the Cancer Guideline Portal will be available from the Cancer Council Australia website where viewers visiting the website for guidelines will be encouraged to access the wiki site also.

A significant effort will be made to have the Guidelines introduced to senior undergraduate medical students via Cancer Council Australia’s Oncology Education Committee, which has representatives from all the medical schools around Australia. Use of the Guidelines as part of core curriculum in
specialty exams will be encouraged as well as the encouragement of the relevant learned Colleges (surgeons, radiation oncologists and pathologists), to support the Guidelines and to foster their integration into hospital and community practice through resident and registrar education activities.

The scope of implementation activities will depend on the availability of funding. It is recognised that a planned approach is necessary to overcome specific barriers to implementation in particular settings and to identify appropriate incentives to encourage uptake of guideline recommendations. Implementation of the Guidelines will require a combination of effective strategies and may include further CME initiatives and interactive learning, the development and promotion of computer-assisted decision aids and electronic decision-support systems, and the creation of audit and other clinical tools.

References


APPENDIX 2 WORKING PARTY MEMBERS AND CONTRIBUTORS

Surveillance Colonoscopy Working Party to develop Clinical Practice Guidelines for Surveillance Colonoscopy - in adenoma follow-up, following curative resection of colorectal cancer, and for cancer surveillance in inflammatory bowel disease

Dr Cameron Bell (Chair) Gastroenterologist – Royal North Shore Hospital; Director – Bowel Cancer Australia, Sydney NSW

A/Professor Terry Bolin Gastroenterologist - A/Professor Medicine UNSW, Emeritus Consultant - Prince of Wales Hospital, President – Gut Foundation, Sydney NSW

Dr Andrew Clouston Anatomical Pathologist - Envoi Specialist Pathologists, Brisbane QLD

Dr William Connell Gastroenterologist – Chairman, Gastroenterological Society of Australia IBD section, Melbourne VIC

Dr Katie Ellard Gastroenterologist - Royal North Shore Hospital, Sydney NSW

Professor James Kench (NSW) Anatomical Pathologist – Royal Prince Alfred Hospital, Sydney NSW

Dr Orly Lacham Kaplan Project Officer, Working Party, Melbourne VIC

Dr Andrew Luck Colorectal surgeon; President, Colorectal Surgical Society of Australia and New Zealand – Adelaide SA

Professor Finlay Macrae Gastroenterologist – Royal Melbourne Hospital, Melbourne VIC

Professor Ian Olver AM Convenor, Working Party/ CEO, Cancer Council Australia, Sydney NSW

Professor Cameron Platell Colorectal surgeon – Winthrop Professor of Surgery, University of Western Australia, Perth WA

Emeritus Professor Tom Reeve AC CBE Convenor Working Party until 2 July 2010

A/Professor James St John AM Gastroenterologist – Honorary Senior Associate, Cancer Council Victoria; Chair - Quality Working Group, National Bowel Cancer Screening Program, Melbourne VIC

Mr John Stubbs Consumer – Executive Officer, Cancer Voices Australia, Sydney NSW

Ms Christine Vuletich Manager, Clinical Guidelines Network - Cancer Council Australia, Sydney NSW
Chapter subcommittees

1. *Advances in colonoscopy, CT colonography and other methods of investigations*
   
   James St John AM (chapter leader) – Gastroenterologist, VIC
   Gregor Brown – Gastroenterologist, VIC

2. *Management of epithelial polyps: colonoscopic surveillance after polypectomy*
   
   Finlay Macrae (chapter leader) – Gastroenterologist, VIC
   Peter Bampton – Gastroenterologist, SA
   Terry Bolin – Gastroenterologist, NSW
   Gregor Brown – Gastroenterologist, VIC
   Andrew Clouston – Anatomical Pathologist, QLD
   Katie Ellard – Gastroenterologist, NSW
   James Kench – Anatomical Pathologist, NSW
   Barbara Leggett – Gastroenterologist, QLD
   Andrew Luck – Colorectal Surgeon, SA

3. *The role of surveillance colonoscopy after curative resection for colorectal cancer*
   
   Cameron Platell (chapter leader) – Colorectal Surgeon, WA
   Cameron Bell – Gastroenterologist, NSW
   Andrew Luck – Colorectal Surgeon, SA
   James St John AM – Gastroenterologist, VIC

4. *Colonoscopic surveillance and management of dysplasia in inflammatory bowel disease (IBD)*
   
   William Connell (chapter leader) – Gastroenterologist, VIC
   Michael Kamm – Gastroenterologist, VIC
   James Kench - Anatomical Pathologist, NSW
   Rupert Leong - Gastroenterologist, NSW
   Alissa Walsh – Gastroenterologist, NSW

5. *Psychosocial aspects of surveillance colonoscopy after colorectal cancer, polyps and inflammatory bowel disease (IBD)*
   
   Emeritus Professor Tom Reeve AC CBE

6. *Socio-economic factors*
   
   Emeritus Professor Tom Reeve AC CBE

7. *Cost effectiveness*
   
   Professor John McNeil – Epidemiologist, Monash University, VIC
Appendix 1 - Guidelines development process

Dr Cameron Bell  
Dr Orly Lacham Kaplan  
Ms Christine Vuletich

Review panel

Professor Michael Solomon – (Chair) – Colorectal surgeon,  
Associate Professor Robert Eckstein – Anatomical pathologist  
Associate Professor David Hewett – Gastroenterologist  
Dr Paul McMurrick - Colorectal surgeon  
Professor Graeme Young – Gastroenterologist, Chair, World Endoscopy Organization Colorectal Cancer Screening Committee  
Dr Cameron Bell – (Chair, Colonoscopy Surveillance Guidelines Working Party)  
Professor Ian Olver AM – (CEO, Cancer Council Australia/Convenor)

Public consultation from 21 May to 21 June 2011

Consultation submissions received:

<table>
<thead>
<tr>
<th>Name</th>
<th>Address</th>
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<tbody>
<tr>
<td>Julien Wiggins</td>
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</tr>
<tr>
<td></td>
<td>Bowel Cancer Australia</td>
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<td>Honorary Clinical Associate, Cancer Council Victoria</td>
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<td></td>
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<td></td>
<td>CARLTON VIC 3053</td>
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<td>Queensland Bowel Cancer Screening Program (QBCSP)</td>
</tr>
<tr>
<td></td>
<td>Cancer Screening Services Branch</td>
</tr>
<tr>
<td></td>
<td>PO Box 2368</td>
</tr>
<tr>
<td></td>
<td>FORTITUDE VALLEY BC QLD 4006</td>
</tr>
</tbody>
</table>

Acknowledgments

These Guidelines would not have arisen without several driving forces. Many contributors may not have been so willing to participate had the tap on the shoulder not come from Emeritus Professor Tom Reeve AC CBE. The literature search and organisation of material performed by Dr Orly Lacham Kaplan was invaluable as was the continuing encouragement and guidance of Professor Ian Olver AM and the co-ordinating and secretarial support of Ms Christine Vuletich, Cancer Council Australia. The chapter leaders, Professor Finlay Macrae, Professor Cameron Platell, Dr Bill Connell, Associate Professor James St John AM, Emeritus Professor Tom Reeve AC CBE and Professor John McNeil, Andrea Curtis and Lisa Demos, deserve enormous gratitude for the considerable time and effort they invested in developing their respective chapters, as do all of the individual members of the working party and chapter subcommittees, listed in Appendix 2.

Special thanks to:

Ms Philippa Thomson for assisting with the literature searches and the referencing of the chapters.

Professor Jane Young, Professor in Cancer Epidemiology, Public Health, School of Public Health, The University of Sydney, for reviewing evidence summaries in each chapter prior to public consultation.
**APPENDIX 3 CONFLICT OF INTEREST REGISTER AND MANAGEMENT FOR WORKING PARTY MEMBERS OF THE CLINICAL PRACTICE GUIDELINES FOR SURVEILLANCE COLONOSCOPY - IN ADENOMA FOLLOW-UP, FOLLOWING CURATIVE RESECTION OF COLORECTAL CANCER, AND FOR CANCER SURVEILLANCE IN INFLAMMATORY BOWEL DISEASE**

Working Party Members were asked to declare in writing, any interests relevant to the guideline development, prior to commencement. Members were asked to update their information if they became aware of any changes to their interests.

All declarations were added to a register of interests as listed below. The register was made available to the Working Party throughout the development of the guideline, allowing members to take any potential conflicts of interest into consideration during discussions, decision making and formulation of recommendations.

If Working Party Members were identified as having a significant real or perceived conflict of interest, the Chair could decide that the member either leave the discussion whilst the specific area they were conflicted in was discussed or the member could remain present but not participate in the discussion, or decision making on the specific area where they were conflicted. There were no instances where this occurred during the development of this guideline.

<table>
<thead>
<tr>
<th>Name</th>
<th>Conflict of Interest</th>
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<tbody>
<tr>
<td>Dr Cameron Bell (Chair) Gastroenterologist – Royal North Shore Hospital, Sydney NSW</td>
<td>No conflict of interest to declare</td>
</tr>
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<td>A/Professor Terry Bolin Gastroenterologist - A/Professor Medicine UNSW, Emeritus Consultant - Prince of Wales Hospital, President – Gut Foundation, Sydney NSW</td>
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He is involved in clinical trials with  
• Abbott Australasia  
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• ChemoCentryx  
• Endogene Pty Ltd  
• Given Imaging  
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APPENDIX 4: ECONOMIC EVALUATION OF SURVEILLANCE COLONOSCOPIES

INTRODUCTION

Estimation of Costs

Only direct medical costs (2010 Australian dollars) for colonoscopy surveillance were considered. Costs are from a health services perspective. These include costs associated with bowel preparation and the colonoscopy procedure. It was assumed that patients and physicians were compliant with guidelines.

A limitation of this analysis is that the costs were based on charges. In the cost estimations mortality rates, post colonoscopy medical review and complication or perforation rates were not considered.

Bowel preparation and cleansing

Patients are required to ingest oral lavage solutions and/or laxatives prior to undergoing colonoscopy to clear the bowel. The estimated cost for bowel preparation is approximately $10.00 and may include any of the following products: Glycoprep C; Glycoprep and Bisacodyl; ColonLYTELY; PrepKit C; Picolax and a laxative; magnesium citrate with Glycoprep and Bisacodyl.

Colonoscopy Procedure

In the 2009/10 financial year there were 462,375 colonoscopies performed in Australia according to Medicare Australia (colonoscopy item numbers 32090 and 32093).

It was assumed that 30.2% of colonoscopies would be performed in the private sector and 69.8% in the private sector. This was based on the breakdown of separations for AR-DRG version 5.1 or 5.2 for colonoscopy codes G44 (G44A, G44B, G44C) across the public and private sector in 2008–2009. The 2008–09 sample included 262 public hospitals (52% of large public hospitals), 110 participating private hospitals (49% of all private hospitals) and 59 private day hospital facilities (26% of all facilities) with a total of 70,402 patient separations in the Public Sector, 101,945 in the Private Sector and a further 60,714 in Private Day Hospital Facilities.

Public Sector colonoscopy costs were provided by a major Melbourne teaching hospital using Australian Refined Diagnostic Related Groups (AR-DRG) version 6.0. The costs are based on the estimated reimbursements from WIES 17 2010-11 Victorian Cost weights which include the colonoscopy procedure as well as sedation, medical, pathology and other related costs. Chromocolonoscopy was included for Ulcerative colitis patients.

The colonoscopy costs for private sector patients were provided by Medibank Private using AR-DRG 5.1 for the 2010 calendar year. Relevant DRGs include G43 and G44 (i.e. G43Z, G44A, G44B, G44C); these were combined to DRG G48 in AR-DRG version 6. Costs included hospital (Medibank hospital benefits and member hospital out-of-pocket), and medical (Medicare, Medibank and member out-of-pocket) costs.

1. POST COLORECTAL CANCER RESECTION

Using a health service perspective we estimated costs of surveillance colonoscopies for 14 years following post colorectal cancer resection. The total costs of surveillance colonoscopies across this period were compared for the proposed guidelines which included a colonoscopy at one year following cancer resection and the 2005 guidelines which had the first colonoscopy at three years following resection.
Colonoscopy Costs

Public Patients
The estimated reimbursement for a same day colonoscopy procedure in patients with a past history of CRC with no recurrence is $865.32:

- DRG: Z40Z Endoscopy with Diagnoses of other contacts with Health Services
- ACHI Principle Procedure: 32090 fibreoptic colonoscopy to caecum
- ICD-10-AM Principle Diagnosis: Z087 Follow-up examination after combined treatment for malignant neoplasm

The estimated reimbursement for a same day colonoscopy procedure in patients with a past history CRC with recurrence is $1,140.22:

- DRG: G48C Colonoscopy Same day
- ACHI Principle Procedure: 3209001 fibreoptic colonoscopy to caecum with biopsy
- ICD-10-AM Principle Diagnosis: C189 Malignant neoplasm of colon, unspecified part

If patients experiencing a perforation or blood loss but had no recurrence the estimated reimbursement ranged from $1,700.46 for same day discharge, $10,073.52 for an overnight admission to $14,911.55 for a multi-stay admission (i.e. length of stay of 3 days). For patients who experienced a perforation or blood loss and had a recurrence the estimated reimbursement ranged from $5,168.07 where they were discharged on the same day, $6,862.94 when they had an overnight admission and $13,275.90 if they were hospitalised for three days.

Private Patients
The average total cost for a same day patients without a recurrence was $1,365 and $1,387 for all patients (i.e. same day, overnight or multi-stay).

The average total cost for same day patients who had a recurrence was $1,362 and $1,611 for all patients (i.e. same day, overnight or multi-stay)

Incidence Colorectal Cancer
The incidence of bowel cancer in the Australian population aged <80 years was 10,124 in 2005 and 11,102 in 2007. This cost analysis was based on the 2007 population data with 11,202 people newly diagnosed with colorectal cancer.

The distribution of patients by Dukes’ staging was estimated using the proportions provided by Bishop and co-workers (2008) see table below. Approximately 1% of patients in each Dukes’ group were likely to have a total colectomy and would not undergo surveillance. These patients were excluded from the analysis. A further 30% of patients with Dukes’ Stage C and all patients with Dukes’ stage D who would be likely to have advanced cancer and not undergo surveillance were also excluded from the analysis. Therefore 7,700 patients would be eligible for colonoscopy surveillance.

<table>
<thead>
<tr>
<th>Dukes’ stage</th>
<th>Proportion Pts</th>
<th>Total Pts#</th>
<th>Pts -total colectomy (1%)</th>
<th>Pts not having colectomy</th>
<th>Pts eligible for 1y colonoscopy</th>
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</thead>
<tbody>
<tr>
<td>A</td>
<td>0.0910</td>
<td>1010</td>
<td>10</td>
<td>1000</td>
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<td>B</td>
<td>0.2680</td>
<td>2975</td>
<td>30</td>
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<tr>
<td>C</td>
<td>0.4880</td>
<td>5418</td>
<td>54</td>
<td>5364</td>
<td>3755*</td>
</tr>
<tr>
<td>D</td>
<td>0.1540</td>
<td>1710</td>
<td>-</td>
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<td>TOTAL</td>
<td></td>
<td>7700</td>
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</tbody>
</table>

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The distribution of colonoscopies with high risk adenoma(s), low risk adenoma(s) and normal results over the 14 year surveillance period were largely based on the published literature that was used as the evidence base for the recommendations in Chapter 3.

**Incidence and Distribution of CRC Patients using New Guidelines**

The cohort of 7,700 patients who had resection for colorectal cancer would be eligible for an initial surveillance colonoscopy at one year followed by five yearly surveillance if they had a low risk adenomas or normal colonoscopies or three yearly surveillance if they had a high risk adenoma. The distribution of patients and colonoscopies in each category (Figure 1a) was based on the following:

A. At the one year surveillance colonoscopy post CRC resection the estimated number of patients diagnosed with high risk adenomas was 316 based on a weighted mean of 4.1% of patients. 9-12 These patients would then have another colonoscopy in a year.

B. Using a cancer recurrence rate of up to 15% 13-18 it was assumed that 10% of patients (N=770) had a recurrent cancer (local or metastatic) at one year (B1) and a further 5% (N=331) by five years (B2). These patients would no longer be eligible for surveillance colonoscopy.

C. The remaining 6614 patients were assumed to have low risk adenomas or normal colonoscopies at one year (i.e. 7700 - [A+B] or 7700 - [316 +770]). These patients would then have surveillance colonoscopy five yearly unless they had a subsequent diagnosis of high risk adenoma.

D. It was assumed that the rate of high risk adenomas was a 1% per year 10 therefore of the 316 patients with high risk adenomas at one year (A), a further 3% would be diagnosed with high risk adenoma at the next surveillance colonoscopy (4 years post resection) i.e. 9 patients. As this number was small it was assumed that all patients would have had low risk adenomas or normal colonoscopies and would undergo five yearly surveillance colonoscopies thereafter.

E. Of the 316 patients who had high risk adenoma detected at the one year surveillance, the remaining 307 patients had low risk adenomas or normal colonoscopies at 4 years. These patients would then have five yearly surveillance colonoscopy.

F. At the five year surveillance colonoscopy it was assumed that 2.3% 11 of the 6614 patients with normal or low risk adenomas at one year would subsequently be diagnosed with high risk adenomas i.e. 152 patients. These patients would then have a surveillance colonoscopy at three years and then five yearly.

G. At the five year surveillance colonoscopy 6131 had low risk adenomas or normal colonoscopies and continued to have five yearly surveillance colonoscopy (i.e. 6614 - [B2+F])

Assuming total compliance with the proposed guidelines for both physicians and patients a total of 21,700 colonoscopies would be performed over 14 years for patients diagnosed with CRC who had a curative resection and were eligible for a one year surveillance colonoscopy (Table 1a).
Table 1a: Colonoscopies in Post CRC resection Patients eligible for 1 year surveillance colonoscopy

<table>
<thead>
<tr>
<th>Time (years) post CRC Resection</th>
<th>Total colonoscopies</th>
<th>Colonoscopies with recurrent cancer or high risk adenoma</th>
<th>Colonoscopies with low risk adenoma or normal colonoscopy</th>
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<tr>
<td>1</td>
<td>7700</td>
<td>1086</td>
<td>6614</td>
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<td>316</td>
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<td>3</td>
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<tr>
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</tr>
<tr>
<td>14</td>
<td>21697</td>
<td>1578</td>
<td>20119</td>
</tr>
</tbody>
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Assuming that 30.2% of colonoscopies were performed in the public sector and 69.8% in the private sector and using $865.32 for the costs for a same day procedure in the public sector and $1,365 in the private sector for low risk adenoma(s) or normal colonoscopy. For patients with recurrent cancer or high risk adenoma the cost used for the public sector was $1,140.22 for a same day admission and $1,365 in the private sector. A further $10 was added to the procedure costs for the bowel preparation and cleansing.

- For the 1,578 colonoscopies where patients were diagnosed with recurrent cancer or high risk adenoma it was assumed that 477 would be performed in the public sector at a rate of $1,150.22 per procedure and 1,101 in the private sector at a rate of $1,375 per procedure giving a total cost for these colonoscopies of $2,062,630.

- For the 20,119 colonoscopies where patients were diagnosed with low risk adenomas or had normal colonoscopies it was assumed that 6,076 were performed in the public sector at a rate of $875.32 per procedure and 14,043 in the private sector at a rate of $1,375 per procedure. Therefore the cost for these colonoscopies was $24,627,600.

- If all the patients had a same day procedure and there were no complications the total cost for 21,697 surveillance colonoscopies in a cohort of 7,700 patients over a period of 14 years would be $26,690,230.

- The average cost of surveillance over 14 years per patient found to have high risk adenoma or recurrent cancer was $16,914.

**Incidence and Distribution of CRC Patients using 2005 Guidelines**

Using the 2005 guidelines it was assumed that the total cohort of 7700 patients would have a surveillance colonoscopy at three years following cancer resection. The distribution of patients in each category (Figure 1b) was based on the following:
A. An estimated 547 patients were diagnosed with high risk adenomas at four years post resection based on a weighted mean of 7.1% of high risk adenomas at three years (i.e. 4.1% high risk adenoma rate at one year and further 1% per annum). These patients would then have a surveillance colonoscopy in another four years.

B. Using a cancer recurrence rate of 15%, an estimated 1155 patients would have cancer recurrence at the four year surveillance colonoscopy. These patients would no longer be eligible for surveillance.

C. The remaining 5998 patients were assumed to have low risk adenomas or normal colonoscopies at four years (i.e. 7700 - [A+B] or 7700 - [547 +1155]). These patients would then have a surveillance colonoscopy in four years.

D. Of the 547 patients (A) with high risk adenomas at the four year colonoscopy it was assumed that a further 1% of patients would develop an high risk adenoma every year. Therefore at the eight year surveillance colonoscopy 4% or 22 patients would be diagnosed with high risk adenoma(s). As this number was small it was assumed that all patients subsequently had low risk adenoma(s) or normal colonoscopies and thereafter had four yearly surveillance colonoscopy.

E. Of the 547 patients (A) with high risk adenoma(s) at four years the remaining 525 patients had low risk adenomas or normal colonoscopies at eight years (i.e. A-D). These patients would then have four yearly surveillance colonoscopy.

F. Of the 5998 patients (C) who had low risk adenomas or normal colonoscopy at four years a further 5% would subsequently be diagnosed with high risk adenomas at 8 years i.e. 300 patients. These patients would have another surveillance colonoscopy in four years.

G. At 8 years post CRC resection the remaining 5698 of the 5998 patients with normal or low risk adenomas at the four year surveillance colonoscopy would again have low risk adenoma(s) or a normal colonoscopy (C-F). These patients would continue to have four yearly colonoscopies.

H. Of the 300 patients with high risk adenomas at 8 years a further 4% (n=12 patients) would have high risk adenomas at 12 years. As the numbers are small it was assumed that all 12 patients would then have four yearly surveillance colonoscopy.

I. The remaining 288 patients of the 300 patients with high risk adenomas at 8 years had normal or low risk adenomas at 12 years. These patients would then continue to have four yearly colonoscopies.

Assuming total patient and physician compliance with the 2005 guidelines a total of 20,790 colonoscopies would be performed over 14 years for a cohort of 7700 patients diagnosed with CRC who had a curative resection and had their first surveillance colonoscopy at four years post resection (Table 1b).
Table 1b: Colonoscopies in Post CRC resection Patients eligible for 4 year surveillance colonoscopy

<table>
<thead>
<tr>
<th>Time (years) post CRC Resection</th>
<th>Total colonoscopies</th>
<th>Colonoscopies in patients with recurrent cancer or high risk adenoma</th>
<th>Colonoscopies in patients with low risk adenoma or normal colonoscopy</th>
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<tr>
<td>14</td>
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<td></td>
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</tr>
<tr>
<td>Total colonoscopies</td>
<td>20790</td>
<td>2036</td>
<td>18754</td>
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The colonoscopy procedure costs were estimated using the costs described previously for patients in the public and private sectors (proposed guidelines) and a distribution of 30.2% of total colonoscopies in the public sector and 69.8% in the private sector.

- For 2036 colonoscopies where a high risk adenoma or recurrent cancer was detected an estimated 615 were performed in the public sector at a rate of $1,150.22 per procedure and 1,421 in the private sector at a rate of $1,375 per procedure at a total cost of $2,661,260 for these colonoscopies.
- For the 18,754 colonoscopies where a low risk adenoma or normal colonoscopy was diagnosed an estimated 5,664 were performed in the public sector at a rate of $875.32 per procedure and 13,090 in the private sector at a rate of $1,375 per procedure. Therefore the cost for these colonoscopies was $22,956,562.
- If all patients had a same day procedure and no complications the total cost for surveillance colonoscopy over a period of 14 years would be $25,617,823.
- The average cost of surveillance over 14 years for each patient found to have high risk adenoma or recurrent cancer was $12,582.

COSTS EFFECTIVENESS

The estimated cost of surveillance colonoscopy for CRC follow up with the proposed guidelines which include a one year post resection colonoscopy is $26,690,230 (2010 Aus $) for a cohort of 7700 patients followed over a period of 14 years and $25,617,823 using the 2005 guidelines for the same period (see table below).
### Table 1c: Summary of Colonoscopies and Costs for 7700 pts over 14 years

<table>
<thead>
<tr>
<th></th>
<th>Colonoscopies</th>
<th>Total cost for program</th>
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<tbody>
<tr>
<td></td>
<td>Total</td>
<td>Recurrent cancer or high risk adenoma(s)</td>
</tr>
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<td>Proposed Guideline (1 year post CRC resection)</td>
<td>21697</td>
<td>1578</td>
</tr>
<tr>
<td>2005 Guideline (3 years post CRC resection)</td>
<td>20790</td>
<td>2036</td>
</tr>
<tr>
<td>Increments*</td>
<td>907</td>
<td>-458</td>
</tr>
<tr>
<td>Incremental cost per additional outcome #</td>
<td>$1,182</td>
<td>-$2,342</td>
</tr>
</tbody>
</table>

* Increments estimated by subtracting 2005 guidelines from proposed guidelines; # Incremental cost per additional outcome estimated by dividing the increment (total cost for program) by the respective increment

Incremental costs with the proposed surveillance colonoscopy guidelines for patients who have had resection of colorectal cancer: Additional $2,342 per high risk adenoma or recurrent cancer avoided or additional $2,654 per high risk adenoma avoided and $786 per low risk adenoma(s) or normal colonoscopy detected.
Figure 1a: Summary of Post CRC Resection Patients Requiring Colonoscopy Surveillance based on New Guidelines

- **Pts <80 years with CRC**
  - N=11,102 pts

- **Pts advanced cancer/total colectomy (i.e. Stage D, 30% Stage C)**
  - N=3402 pts

**Colonoscopy at 1 year post resection (T=1)**
- N=7700 pts

**A.** High risk adenoma 4.1% or N=316: next colonoscopy at 3 years

**D.** High risk adenoma 1% or N=9 pts: next colonoscopy at 3 year

**E.** N=307 pts Normal/low risk adenoma: go to 5 yearly surveillance colonoscopy

**F.** High risk Adenoma(s) 2.3% or N=152 pts: next colonoscopy at 3 year

**G.** Normal/low risk adenomas(s) N=6131 pts: go to 5 yearly surveillance colonoscopy

**B1.** Recurrent cancer (local or metastatic) 10% or N=770 pts: No further surveillance

**B2.** Recurrent cancer (local or metastatic) 5% or N=331 pts. No further surveillance

**C.** N=6614 pts Normal/low risk adenoma(s): next colonoscopy at 5 years

**N=9 pts**: go to 5 yearly surveillance colonoscopy

**N=152 pts**: Normal/low risk adenoma(s): go to 5 yearly surveillance colonoscopy

**N=6131 pts**: Normal/low risk adenomas(s): go to 5 yearly surveillance colonoscopy

**N=316 pts**: next colonoscopy at 3 years

**N=307 pts**: go to 5 yearly surveillance colonoscopy

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Figure 1b: Summary of Post CRC Resection Patients Requiring Surveillance based on 2005 Guidelines

- **Pts <80 years with CRC**
  - N=11,102 pts

- **Pts advanced cancer/total colectomy (all Stage D, 30% Stage C)**
  - N=3402 pts
  - No surveillance

Colonoscopy at 4 years post CRC resection (T=4) N=7700 pts

- **A. Advanced adenoma(s)**
  - 6.1% or N=547 pts: next colonoscopy in 4 years

- **B. Recurrent cancer**
  - (local or metastatic) 15% or N=1155: No further surveillance

- **C. Normal/non-advanced adenoma(s)**
  - N=5998 pts: next colonoscopy in 4 years

- **D. Advanced adenoma(s)**
  - 4% or N=22 pts: 4 yearly colonoscopy

- **E. Normal/non-advanced adenoma(s)**
  - N=525 pts: go to 4 yearly surveillance colonoscopy

- **F. Advanced Adenoma(s)**
  - 5% or N=300 pts: next colonoscopy in 4 years

- **G. Normal/non-advanced adenoma(s)**
  - N=5698: go to 4 yearly surveillance colonoscopy

- **H. Advanced Adenoma(s)**
  - 4% or N=12 pts: next colonoscopy in 3 years then 4 yearly surveillance

- **I. Normal/non-advanced adenoma(s)**
  - N=288 pts: go to 4 yearly surveillance colonoscopy

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2. ADENOMAS

Surveillance scenario comparisons

The analyses undertaken for patients diagnosed with adenomas compared the surveillance strategy recommended in the 2005 Guidelines for the Prevention, Early Detection and Management of Colorectal Cancer\(^5\) with one potential new surveillance strategy:

- Option A (2005 guidelines)
  - High risk adenomas - three yearly surveillance; low risk adenomas - five yearly surveillance
  - Subsequent normal colonoscopies (no neoplasia) - 5 year surveillance

- Option B:
  - High risk adenomas – three yearly surveillance; low risk adenomas - five year surveillance
  - Subsequent normal colonoscopies (no neoplasia) - 10 year surveillance

Colonoscopy Costs

Public Patients

The estimated reimbursement for a same day colonoscopy procedure in patients with past history of polyps or adenoma(s) and no recurrence is $865.32:

- DRG: \textbf{Z40Z} Endoscopy with Diagnoses of other contacts with Health Services
- ACHI Principle Procedure: \textbf{32090} fibreoptic colonoscopy to caecum
- ICD-10-AM Principle Diagnosis: \textbf{Z090} Follow-up examination after surgery for other conditions

The estimated reimbursement for a same day colonoscopy procedure in patients with a past history polyps or adenoma(s with recurrence is $1,140.22:

- DRG: \textbf{G48C} Colonoscopy Same day
- ACHI Principle Procedure: 32093 fibreoptic colonoscopy to caecum with polypectomy
- ICD-10-AM Principle Diagnosis: \textbf{D010} Carcinoma in situ of colon OR \textbf{K6358} Other polyp of colon

Private Sector

The average total costs for same day patients with past history of polyps or adenoma(s who have not had a recurrence was $1,367 and $1,379 for all patients (i.e. same day, overnight or multistay admissions)

The average total costs for same day patients with past history of polyps or adenoma(s who have had a recurrence was $1,685 and $1,718 for all patients (i.e. same day, overnight or multistay admissions

Incidence and distribution of high risk and low risk adenomas

Baseline distribution of high risk and low risk adenomas

Using a health service perspective costs were estimated for 13 years of follow-up after removal of adenoma(s). All analyses were based on the incidence and distribution of high risk and low risk adenomas that would be expected from a full initial national roll-out of the National Bowel Cancer Screening Program (NBCSP).

The following assumptions were made in these estimations, with eligible population estimates based on June 2010 demographic statistics from the Australian Bureau of Statistics. The rate of participation in the screening program and the distribution of cancer, high risk adenoma and low risk adenoma amongst
people with positive FOBT results undergoing colonoscopy were based on the results of the phase 1 evaluation of the Queensland Bowel Cancer Screening Program. The rate of positive FOBT results (7%) was based on results of the Queensland Bowel Cancer Screening Program reported by the AIHW.

- Full national roll out of the NBCSP for people aged 55-74 years
  - 5,628,882 people eligible for screening
- 45.5% of eligible people participate in the NBCSP
  - 2,555,512 people screened
- 7% of people undergoing screening will return a positive FOBT result
  - 178,886 people return a positive FOBT
- 100% of people with a positive FOBT undergo a baseline colonoscopy
  - 178,886 people undergoing colonoscopy
- Of the 178,886 people undergoing baseline colonoscopy:
  - 5.0% of people will have colorectal cancer detected (8,944)
  - 18.9% of people undergoing colonoscopies will have an high risk adenoma detected (33,809)
  - 33.4% of people undergoing colonoscopies will have low risk adenoma detected (59,748)
  - 93,557 people will have an adenoma detected
- Patients having high risk adenomas were defined as those with ≥2 adenomas, or with adenomas ≥10 mm or with villous/tubulovillous histology or with high grade dysplasia
- Patients having low risk adenomas were defined as those with 1-2 small (<10mm), tubular adenomas.
- Patients with no neoplasia (normal colonoscopy) were those with no adenomatous polyps

For the purposes of this analysis, the total number of people with adenomas detected was rounded to 100,000 (i.e. high risk adenomas and low risk adenomas).

The distribution of colonoscopies with high risk adenoma(s), low risk adenoma(s) and normal results over the 13 year surveillance period were based on the published literature used as the evidence base for the recommendations in Chapter 2.

**Incidence of high risk adenomas at three year surveillance following high risk adenomas at baseline colonoscopy**

The estimated percentage of patients with high risk adenoma at the baseline colonoscopy who were found to have an high risk adenoma at the three year surveillance colonoscopy was based on a weighted mean of 11.1% from four studies that stratified adenoma findings at three year surveillance by the baseline findings.

**Incidence of high risk adenomas at five year surveillance following low risk adenomas at baseline colonoscopy**

The estimated percentage of patients with low risk adenoma at the baseline colonoscopy who had high risk adenoma at the five year surveillance colonoscopy was 2.4% based on Chung et al. 2011.
Incidence of high risk adenomas at six year surveillance following high risk adenomas at three year surveillance colonoscopy

The estimated percentage of patients with high risk adenoma at three year surveillance colonoscopy who had high risk adenoma at the six year surveillance colonoscopy was 18.2% based on Robertson and co-workers\textsuperscript{25} where 8 of 44 (18.2%) patients with high risk findings at the second surveillance examination (mean 37.4 months from baseline) had high risk findings at the third surveillance examination (mean 39.5 months between 2nd and 3rd surveillance examination). All of the 44 patients in the high risk finding stratum at the second surveillance examination also had high risk findings at the baseline examination.

Incidence of high risk adenomas beyond six years surveillance following high risk adenomas at 6 and three year surveillance and baseline colonoscopy

There were no studies with follow-up beyond six years that estimated the percentage of patients with high risk adenoma stratified by previous surveillance findings. Therefore it was assumed that 18.2% of patients undergoing three yearly surveillance for high risk adenomas would have high risk adenomas detected at subsequent colonoscopies.\textsuperscript{25}

For all other surveillance intervals, the numbers of patients with high risk adenomas was calculated using results from Chung et al 2011\textsuperscript{26}.

- For percentages of high risk adenomas detected after 5 years in patients with low risk adenoma or normal colonoscopy at the previous colonoscopy, we used an average percentage of 2.2% calculated from the 5 year percentages of high risk adenomas occurring in patients with normal colonoscopy at baseline and low risk adenomas at baseline (2.0% and 2.4%, respectively).

- To distinguish between colonoscopies that detected low risk adenomas and those with normal results for the Option b analysis, the results from Chung et al 2011\textsuperscript{26} were used (further details in section 2.2).

Due to the lack of data for longer term follow-up, we have extrapolated data on incidence of adenomas at 5\textsuperscript{26} and 6\textsuperscript{25} years to later periods. Accordingly, this is likely to overestimate the incidence of high and low risk adenomas at these periods.

Incidence and distribution of adenomas detected at follow-up surveillance

2.1: Option A (2005 Guidelines)

It was assumed that the total cohort of 100,000 patients with adenomas detected at baseline colonoscopy would undergo surveillance colonoscopy the following intervals:

- Patients with high risk adenoma – surveillance colonoscopy at three yearly intervals
- Patients with low risk adenoma – surveillance colonoscopy at five yearly intervals
- Patients with subsequent low risk/normal colonoscopies – surveillance colonoscopy at five year intervals.

Figures 2.1a and 2.1b show the distribution of patients in each category. The cohort of patients in each category of patients (Figure 2.1a) was based on the following:

A. Total number of people with adenomas at baseline colonoscopy estimated from a full national roll-out of the Bowel Cancer Screening Program for people aged 55-74 years (100,000)
Clinical Practice Guidelines for Surveillance Colonoscopy - in adenoma follow-up, following curative resection of colorectal cancer, and for cancer surveillance in inflammatory bowel disease
Figure 2.1a: Distribution of adenomas over 13 years amongst patients with high risk adenoma(s) at baseline according to Option A (2005 Guidelines)

A. People with adenoma detected at baseline N=100,000

B. T=0
HR=36,000

C. T=3. HR =3,996

D. T=3 LR/N=32,004

E. T=6. HR =727
F. T=6. LR/N =3,269

G. T=8. HR =704

H. T=8. LR/N =31,300

I. T=9 HR =132
J. T=9 LR/N =595
K. T=11. HR =72
L. T=11. LR/N =3,197

M. T=11 HR =70
N. T=11. LR/N =634
O. T=13. HR =689

P. T=13. LR/N =30,611
Q. T=12 HR= 24
R. T=12 LR/N= 108

HR = number of patients with advanced adenoma
LR/NN = number of patients with non-advanced adenoma or no neoplasia
T=surveillance period (years)
Figure 2.1b: Distribution of adenomas over 13 years amongst patients with low risk adenoma(s) at baseline according to Option A (2005 Guidelines)

A. People with adenoma detected at baseline colonoscopy n=100,000

B. T=0 LR=64000

C. T=5. HR =1,536

D. T=5. LR/N = 62,464

E. T=8. HR =154

F. T=8. LR/N= 1,382

G. T=10. HR = 1,499

H. T=10. LR/N = 60,965

I. T=11 HR =15

J. T=11 LR/N=139

K. T=13. HR = 30

L. T=13. LR/N= 1,352

M. T=13. HR =150

N. T=13. LR/N = 1,349

LR = number of patients with low risk adenoma
HR = number of patients with high risk adenoma
LR/N = number of patients with low risk adenoma or normal colonoscopy neoplasia
T=surveillance period (years)
Figure 2.1b shows the distribution of patients in each category which were based on the following:

A. Total number of people with adenomas at baseline colonoscopy estimated from a full national roll-out of the Bowel Cancer Screening Program for people aged 55-74 years (100,000)

B. Total number of people with low risk adenomas at baseline colonoscopy (64,000)

C. \((64,000 \times 2.4\%) = 1,536\): 2007: 2.4% incidence rate for high risk adenomas at 5 year surveillance after low risk adenomas at baseline^26

D. \((64,000 \times 1,536)\): low risk adenoma or normal results

E. \((1,536 \times 10.0\%) = 154\): The number of people with high risk adenomas at 8 year surveillance was based on a three year incidence rate of 10.0% for high risk adenomas in patients with high risk at baseline^26:

F. \((1,536 \times 154) = 1382\): low risk adenoma or normal results

G. \((62,464 \times 2.2\%) = 1499\): The number of people with high risk adenomas at 10 year surveillance was based on an average percentage of 2.2% calculated from the 5 year percentages of high risk adenomas occurring in patients with normal colonoscopy at baseline and low risk adenomas at baseline (2.0% and 2.4%, respectively)^26:

H. \((62,464 \times 1499) = 60,965\): low risk adenoma or normal results

I. \((154 \times 10.0\%) = 15\): The number of people with high risk adenomas at 11 year surveillance was based on a three year incidence rate of 10.0% for high risk adenomas in patients with high risk at baseline^26:

J. \((154 \times 15) = 139\): low risk adenoma or normal results

K. \((1382 \times 2.2\%) = 30\): The number of people with high risk adenomas at 13 year surveillance was based on an average percentage of 2.2% calculated from the 5 year percentages of high risk adenomas occurring in patients with normal colonoscopy at baseline and low risk adenomas at baseline (2.0% and 2.4%, respectively)^26:

L. \((1382 \times 30) = 1352\): low risk adenoma or normal results

M. \((1499 \times 10.0\%) = 150\): The number of people with high risk adenomas at 13 year surveillance was based on three year incidence rate of 10.0% for high risk adenomas in patients with high risk at baseline^26:

N. \((1499 \times 150) = 1349\): low risk adenoma or normal results

Assuming total compliance with the new guidelines a total of 239167 surveillance colonoscopies would be performed over 20 years for patients with adenoma detected at baseline colonoscopy. This includes:

- 9,788 colonoscopies that detect high risk adenomas (combined results from Figure 2.1a and 2.1b)
  - At 3 year surveillance – 3,996 colonoscopies
  - At 5 year surveillance – 1,536 colonoscopies
  - At 6 year surveillance – 727 colonoscopies
  - At 8 year surveillance – 858 colonoscopies
  - At 9 year surveillance – 132 colonoscopies
  - At 10 year surveillance – 1499 colonoscopies
  - At 11 year surveillance – 157 colonoscopies
  - At 12 year surveillance – 24 colonoscopies
  - At 13 year surveillance – 869 colonoscopies

- 382,696 colonoscopies that detect low risk adenomas or no neoplasia (combined results from Figure 2.1a and 2.1b)
  - At 3 year surveillance – 32,004 colonoscopies
  - At 5 year surveillance – 62,464 colonoscopies
  - At 6 year surveillance – 3,269 colonoscopies
Assuming that 30.2% of colonoscopies were performed in the public sector and 69.8% in the private sector and using $865.32 for the costs for a same day colonoscopy reporting low risk adenoma(s) or normal colonoscopy in the public sector and $1,367 in the private sector. For patients who had an high risk adenoma the cost for the colonoscopy in the public sector was $1,140.22 for a same day admission and $1,685 in the private sector. A further $10 was added to the cost of each procedure to account for the cost of the bowel preparation and cleansing.

- Of the 9,788 colonoscopies that detected high risk adenomas, 2,956 were performed in the public sector at a cost of $1,150.22 per procedure and 6,832 in the private sector at a cost of $1,695 per procedure. The total cost for colonoscopies detecting a high risk adenoma was $14,980,290.
- Of the 229,369 colonoscopies that detected low risk adenomas or normal colonoscopies, 69,269 were performed in the public sector at a cost of $875.32 per procedure and 160,100 were performed in the private sector at a cost of $1,377 per procedure. The total cost of these colonoscopies was $281090241.

For a patient cohort of 100,000 patients with adenoma detected at the baseline colonoscopy, the total cost of surveillance over 13 years of follow-up would be $296,070,531 if all patients had a same day procedure and no complications.

A total of 239,167 colonoscopies were performed for $296,070,531 and high risk adenomas were detected in 9,788 patients.

Using a complication rate of 0.1%, in this cohort of patients over 13 years there would be 239 colonoscopies that resulted in perforation or other major complications. The cost of a complication varies from $1700 for a same day discharge to $14,911.55 for a multi stay hospitalisation. Therefore the additional costs for complications from colonoscopies could range from $406,300 to $3,563,860.

2.2 Proposed New guidelines – Option B

It was assumed that the total cohort of 100,000 patients with adenomas detected at baseline colonoscopy would undergo surveillance colonoscopy according to the following intervals:

- Patients with high risk adenoma – surveillance colonoscopy at three year intervals.
- Patients with low risk adenoma – surveillance colonoscopy at five year intervals.

Patients who subsequently had normal colonoscopies would undergo surveillance at 10 year intervals.

Figures 2.2a and 2.2b show the distribution of patients in each category. The cohort of patients in each category of patients (Figure 2.2a) was based on the following:

A. Total number of people with adenomas at baseline colonoscopy estimated from a full national roll-out of the Bowel Cancer Screening Program for people aged 55-74 years (100,000)
B. Total number of people with high risk adenomas at baseline colonoscopy (36,000)
C. (36,000 (B) x 11.1% =3,996): 2007: 11.1% incidence rate for high risk adenomas at 3 year surveillance based on weighted mean from 4 studies
D. [36,000(B) – (3,996(C) + 9720 (E))= 22,284(D)]: normal colonoscopy results
E. \((36,000 \times 27\%) = 9720\) (E): low risk adenoma based on Chung et al 2011 \(^26\)
F. \((3,996 \times 18.2\%) = 727\) (F): based on 18.2 \% incidence rate \(^25\) for high risk adenomas at 6 year surveillance
G. \((3,996 \times (727 + 1079) = 2190\) (G): normal colonoscopy results
H. \((3,996 \times 27\%) = 1079\) (H): low risk adenoma based on Chung et al 2011 \(^26\)
I. \((22,284 \times 2.0\%) = 446\) (I): high risk adenoma based on 2.0 \% incidence rate for people with normal baseline colonoscopy
J. \((22,284 \times 71.3\%) = 15888\) (J): normal colonoscopy results based on Chung et al 2011 \(^26\)
K. \((22,284 \times 26.7\%) = 5950\) (K): low risk colonoscopy results based on Chung et al 2011 \(^26\)
L. \((9720 \times 2.4\%) = 233\) (L): The number of people with high risk adenomas at 8 year surveillance based on 5 year cumulative incidence rate for high risk adenoma of 2.4 \% for people with low risk adenomas at baseline colonoscopy \(^26\).

M. \((9720 \times (233 + 4209) = 5278\) (M):
N. \((9720 \times 43.4\%) = 4209\) (N): low risk adenoma based on Chung et al 2011 \(^26\)
O. \((727 \times 18.2\%) = 132\) (O): based on 18.2 \% incidence rate \(^25\) for high risk adenomas at 6 year surveillance
P. \((727 \times (196 + 132) = 399\) (P): normal colonoscopy results
Q. \((727 \times 27\%) = 196\) (Q): low risk adenoma based on Chung et al 2011 \(^26\)
R. \((1079 \times 2.4\%) = 26\) (R): The number of people with high risk adenomas at 11 year surveillance based on 5 year cumulative incidence rate for high risk adenoma of 2.4 \% for people with low risk adenomas at baseline colonoscopy \(^26\).
S. \((1079 \times 63\%) = 648\) (S): normal colonoscopy results
T. \((1079 \times 43.4\%) = 468\) (T): low risk adenoma based on Chung et al 2011 \(^26\)
U. \((233 \times 10.0\%) = 23\) (U): The number of people with high risk adenomas at 11 year surveillance was based on a three year incidence rate of 10.0 \% for high risk adenomas in patients with high risk at baseline \(^26\):
V. \((233 \times (23 + 63) = 149\) (U): normal colonoscopy results
W. \((233 \times 27\%) = 63\) (W): low risk adenoma based on Chung et al 2011 \(^26\)
X. \((4209 \times 2.4\%) = 101\) (W): The number of people with high risk adenomas at 13 year surveillance based on 5 year cumulative incidence rate for high risk adenoma of 2.4 \% for people with low risk adenomas at baseline colonoscopy \(^26\)
Y. \((4209 \times 100\%) = 4209\) (Y): normal colonoscopy results
Z. \((4209 \times 43.4\%) = 1827\) (Z): low risk adenoma based on Chung et al 2011 \(^26\)
AA. \((132 \times 18.2\%) = 24\) (Aa): based on 18.2 \% incidence rate \(^25\) for high risk adenomas at 12 year surveillance
BB. \((132 \times (24 + 36) = 72\) (Bb): normal colonoscopy results
CC. \((132 \times 27\%) = 36\) (Cc): low risk adenoma based on Chung et al 2011 \(^26\)

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Figure 2.2a: Distribution of adenomas over 13 years amongst patients with high risk adenoma(s) at baseline according to proposed Guidelines- Option B

HR = number of patients with high risk adenoma
N/NN = number of patients with low risk adenoma or no neoplasia
T= surveillance period (years)
CY = colonoscopy

Clinical Practice Guidelines for Surveillance Colonoscopy - in adenoma follow-up, following curative resection of colorectal cancer, and for cancer surveillance in inflammatory bowel disease
Figure 2.2b: Distribution of adenomas over 13 years amongst patients with low risk adenoma(s) at baseline according to proposed Guidelines- Option B

The cohort of patients in each category of patients (Figure 2.2b) was based on the following:

A. Total number of people with adenomas at baseline colonoscopy estimated from a full national roll-out of the Bowel Cancer Screening Program for people aged 55-74 years (100,000)

B. Total number of people with low risk adenomas at baseline colonoscopy (64,000)

C. \((64,000 \times 2.4\%) = 1,536\) (C): Number of people with high risk adenoma at 5 year colonoscopy – based on 5 year cumulative incidence rate for high risk adenoma of 2.4% for people with low risk adenomas at baseline colonoscopy)\(^{26}\).

D. \((64,000 \times 54.2\%) = 34,688\) (D): normal colonoscopy results based on Chung et al 2011 \(^{26}\).

E. \((64,000 \times 43.4\%) = 27,776\) (E): low risk adenoma based on Chung et al 2011 \(^{26}\).

F. \((1,536 \times 10.0\%) = 154\) (F): The number of people with high risk adenomas at 8 year surveillance was based on a three year incidence rate of 10.0% for high risk adenomas in patients with high risk at baseline \(^{26}\).

G. \((1,536 \times 63\%) = 968\) (G): normal colonoscopy results based on Chung et al 2011 \(^{26}\).

H. \((1,536 \times 27\%) = 415\) (H): low risk adenoma based on Chung et al 2011 \(^{26}\).

I. \((27,776 \times 2.4\%) = 667\) (I): The number of people with high risk adenomas at 10 year surveillance based on 5 year cumulative incidence rate for high risk adenoma of 2.4% for people with low risk adenomas at baseline colonoscopy)\(^{26}\).
Assuming total compliance with the new guidelines by physicians and patients a total of 172,931 surveillance colonoscopies would be performed over 13 years for patients with adenoma detected at baseline colonoscopy. This includes:

- **8,157 colonoscopies that detect high risk adenomas (combined results from Part 1 and Part 2)**
  - At 3 year surveillance – 3,996 colonoscopies
  - At 5 year surveillance – 1,536 colonoscopies
  - At 6 year surveillance – 727 colonoscopies
  - At 8 year surveillance – 387 colonoscopies
  - At 9 year surveillance – 132 colonoscopies
  - At 10 years surveillance – 667 colonoscopies
  - At 11 years surveillance – 64 colonoscopies
  - At 12 years surveillance – 24 colonoscopies
  - At 13 years surveillance – 624 colonoscopies

- **164,774 colonoscopies that detect low risk adenomas or no neoplasia (combined results from Part 1 and Part 2)**
  - At 3 year surveillance – 32,004 colonoscopies
  - At 5 year surveillance – 62,464 colonoscopies
  - At 6 year surveillance – 3,269 colonoscopies
  - At 8 year surveillance – 5,328 colonoscopies
  - At 9 year surveillance – 595 colonoscopies
  - At 10 years surveillance – 27,109 colonoscopies
  - At 11 years surveillance – 1,404 colonoscopies
  - At 12 years surveillance – 60 colonoscopies
  - At 13 years surveillance – 26,951 colonoscopies

It was assumed that 30.2% of colonoscopies were performed in the public sector and 69.8% in the private sector and the costs for a same day procedure were $865.32 in the public sector and $1,367 in
the private sector for a patient with a low risk adenoma(s) or normal colonoscopy. For patients with high risk adenoma the cost in the public sector was $1,140.22 for a same day admission and $1,685 in the private sector. A further $10 was added to the cost of each procedure to account for the cost of the bowel preparation.

- Of the 8,157 colonoscopies that detected high risk adenomas, 2,463 were performed in the public sector at a cost of $1,150.22 per procedure and 5,694 were performed in the private sector at a cost of $1,695 per procedure. The total cost of colonoscopies that detected high risk adenoma(s) was $12,484,322.

- Of the 164,774 colonoscopies that detected low risk adenomas or no neoplasia, 49,762 were performed in the public sector at a cost of $875.32 per procedure and 115,012 were performed in the private sector at a cost of $1,377 per procedure. The total cost for these colonoscopies was $201,929,198.

- For this patient cohort of 100,000 patients with adenoma detected at the baseline colonoscopy, the total cost of surveillance over 13 years of follow-up would be $214,413,520 if all patients had a same day procedure and no complications.

- Therefore 172,931 colonoscopies performed in 100,000 patients at a cost of $214,413,520 would detect high risk adenoma(s) in 8,157 patients.

Using a complication rate of 0.1%, in this cohort of patients over 13 years there would be 173 colonoscopies that may result in perforation or other major complications. The cost of a complication varies from $1700 for a same day discharge to $14,911.55 for where there is a multi-stay hospitalisation. Therefore the additional costs for complications from colonoscopies could range from $294,100 to $2,579,698.

**Option A (2005 Guidelines) vs Proposed New Guidelines Option B**

- Over a 13 year period, a higher proportion of patients (4.7% of those patients tested in Option B vs. 4.1% of those patients tested under the 2005 Guidelines - Option A) with high risk adenoma would be detected by surveillance colonoscopies performed as per the new guidelines (option B) than would be detected from surveillance performed as per Option A (2005 guidelines) (see Table 7.5).

- The cost per high risk adenoma detected over 13 years would be $26,286 with the new guidelines Option B compared to $30,217 with the Option A (2005 guidelines).

- If Option B were adopted the cost of surveillance colonoscopies performed would be less than the current 2005 Guidelines (Option A).
Table 7.5. Summary of Colonoscopies and Costs for 100,000 pts with adenomas over 13 years

<table>
<thead>
<tr>
<th>Guideline Changes</th>
<th>Costs of Guideline Changes</th>
<th>Calculations of Outcomes</th>
<th>Calculations of Incremental Variables</th>
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</thead>
<tbody>
<tr>
<td>Guideline version</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>High risk adenoma strategy</td>
<td>Non-high risk adenoma / normal strategy</td>
<td>Total 13 year cost of program</td>
<td>Total number of colonoscopies over 13 years</td>
</tr>
<tr>
<td>2005 Option A</td>
<td>3 yearly</td>
<td>5 yearly</td>
<td>296,070,531</td>
</tr>
<tr>
<td>New option B</td>
<td>3 yearly</td>
<td>Low risk at 5 years; normal colonoscopy at 10 year</td>
<td>214,413,520</td>
</tr>
</tbody>
</table>
3. ULCERATIVE COLITIS

Costs
There are no previous Australian guidelines for surveillance in patients with ulcerative colitis (UC) therefore the economic evaluation is presented as the costs of surveillance for a cohort of UC patients over a period of 20 years as recommended in Chapter 4.

Colonoscopy Costs

Public Patients
The estimated reimbursement for a same day colonoscopy procedure in patients with a past history UC and no recurrence is $865.32
- DRG: G48C Colonoscopy Same day
- ACHI Principle Procedure: 32090 fibreoptic colonoscopy to caecum (ACHI Principle Procedure)
- ICD-10-AM Principle Diagnosis: K519 Ulcerative colitis

The estimated reimbursement for a same day colonoscopy procedure in patients with a past history UC and recurrence is $1,140.22
- DRG: G48C Colonoscopy Same day
- ACHI Principle Procedure: 32090 fibreoptic colonoscopy to caecum (ACHI Principle Procedure)
- ICD-10-AM Principle Diagnosis: K519 Ulcerative colitis

Private Sector
The average total costs for same day patients with UC was $1,472 and $1,552 for all patients (i.e. same day, overnight or multi-stay)

Incidence and Distribution of Patients with Ulcerative Colitis
The incidence of ulcerative colitis (UC) in Australia was based on the recently reported incidence rate of 11.2 per 100,000. The total Australian population in March 2010 was 22,473,489 (Australian Bureau of Statistics) and therefore the estimated number of new cases of UC used in the evaluation was 2,517.

The distribution of patients in each category (Figure 3) was based on the following:
- An estimated 53.8% of ulcerative colitis patients will have extensive disease and the rest would have limited disease. Therefore from a population of 2517 patients with UC (A) a total of 1,354 patients (B) will have extensive UC at diagnosis and 1,163 limited UC (C).
- The mean time from onset of inflammatory bowel disease to PSC is 9 years (range 1.3 to 23 years). Approximately 3% of patients with extensive UC will have PSC i.e. 40 patients (D1). These patients will require yearly surveillance initiated when PSC is diagnosed. It was assumed that all patients with PSC were diagnosed at 8 years.
- A further 3% of UC patients with extensive disease will have a positive family history of CRC i.e. 40 patients (D2). These patients will also require yearly surveillance starting earlier than 8 years.
- The remaining 1,507 patients (E1) with extensive disease will start surveillance at 8 years.
- An estimated 20% of UC patients with limited disease or 233 patients (E2) will progress to extensive UC or inflammatory polyps or stricture and will also require surveillance from 8 years after diagnosis.
The remaining 930 patients with limited disease (F) will follow the general population guidelines for colorectal cancer and are not considered further.

A total of UC 1,587 patients with extensive disease will start surveillance at 8 years (i.e. D + E1 + E2 or 80 + 1507 + 233) (G2).

During the 20 year period it was assumed that 20% of patients with extensive UC starting surveillance or 317 patients (G) will have surgery for cancer, dysplasia or active disease. The remaining 1,270 UC patients (H) will continue to have surveillance colonoscopy for the next 20 years.

A further 33% of patients with extensive disease (n=419) (I) are considered high risk (i.e. inflammatory polyps, past localised dysplasia and will require yearly surveillance. It was assumed that they were diagnosed and commenced surveillance 8 years from UC diagnosis.

It was assumed that the remaining 851 patients (J) with inactive disease would have surveillance colonoscopy every three years over the next 20 years even though a proportion of patients may go to five yearly surveillance if they have had 2 normal colonoscopies (proposed guidelines). These 851 patients would each have an average of 6 colonoscopies over 20 years.

As the cohort of patients with UC ages some patients develop low-grade dysplasia, high-grade dysplasia, or cancer; these have been considered in Figure 3. As there is a wide variability in rates of colorectal cancer mortality in UC patients with five year survival reported between 36% to 100% the evaluation did not adjust for mortality.

The economic evaluation was based on 20 years of follow-up and assumed:

- All 851 patients with low risk (inactive disease) would continue to have three yearly surveillance colonoscopy during this period (see table 3.1).
- All 419 high risk patients (PSC, positive family history, inflammatory polyps, strictures, past localised dysplasia) would have yearly surveillance that commenced from 8 years following UC diagnosis.
- Patients who had surgery for cancer, dysplasia or active disease during the 20 year period were excluded.
- 30.2% of colonoscopies were performed in the public sector and 69.8% colonoscopies were performed in the private sector.
### Table 3.1 Surveillance Colonoscopies in UC Patient Cohort with Extensive UC

<table>
<thead>
<tr>
<th>Time (years)</th>
<th>Patient Cohort</th>
<th>Total Colonoscopies</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Inactive UC</td>
<td>High Risk UC</td>
</tr>
<tr>
<td>1</td>
<td>419</td>
<td>419</td>
</tr>
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*T=0 baseline colonoscopy at 8 years from diagnosis of ulcerative colitis*.  

Costs for procedure were based on $865.32 for a same day procedure in public sector and $1,472 in the private sector with a further $10 added for the cost of the bowel preparation and cleansing.

- If all procedures were same day in patients with inactive UC there would be 1,542 colonoscopies performed in the public sector at a rate of $875.32 and total cost of $1,349,754 and 3,564 colonoscopies in the private sector at a rate of $1,482 with a total cost of $5,281,830. Therefore assuming all 851 patients had three yearly surveillance the cost for this cohort would be $6,631,584 over the 20 years.

- If all procedures were same day in the high risk UC patients there would be 2531 colonoscopies performed in the public sector at a rate of $875.32 and total cost of $2,215,225 and 5849 colonoscopies in the private sector at a rate of $1,482 with a total cost of $8,668,574. Therefore assuming all 419 high risk patients had yearly surveillance over 20 years the cost for this cohort would be $10,883,799.

- The total cost for 20 years of surveillance colonoscopy for a cohort of 2,517 patients diagnosed with ulcerative colitis 8 years earlier would be $17,515,383.
Figure 3. Summary of Ulcerative Colitis Groups Requiring Surveillance Colonoscopy

A. 2517 pts diagnosed with UC

B. Pts with Extensive UC (N=1354 pts)

C. Pts with Limited UC (N=1163 pts)

D. 40 PSC pts (3%), 40 pts +ve family history (3%) – yearly surveillance from diagnosis

E. 1274 pts without PSC or family history start surveillance at 8 years

F. 930 pts limited UC

G. Surgery N=317 pts by 20 years

G2. 1587 pts without PSC or family history start surveillance at 8 years

H. Intact Colon N=1270 pts at 20 years

I. 33% (419) pts at high risk* - yearly surveillance

J. 67% (851) pts without other risk factors - 3 yearly surveillance

Positive family history - follow general population guidelines

Carcinoma/diffuse dysplasia

Active Disease

* other high risk patients includes those with inflammatory polyps, stricture or past localised dysplasia

Clinical Practice Guidelines for Surveillance Colonoscopy - in adenoma follow-up, following curative resection of colorectal cancer, and for cancer surveillance in inflammatory bowel disease
References

6. Australian Institute of Health and Welfare. AIIHW Data Cubes
Clinical Practice Guidelines for Surveillance Colonoscopy - in adenoma follow-up, following curative resection of colorectal cancer, and for cancer surveillance in inflammatory bowel disease


**APPENDIX 5 ABBREVIATIONS**

**Abbreviations**

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
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<tbody>
<tr>
<td>ADRs</td>
<td>Adenoma detection rates</td>
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<tr>
<td>AJCC</td>
<td>American Joint Committee on Cancer</td>
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<tr>
<td>APC</td>
<td>Adenomatous polyposis coli</td>
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<tr>
<td>BMI</td>
<td>Body mass index</td>
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<tr>
<td>C</td>
<td>Chromoendoscopy</td>
</tr>
<tr>
<td>CAM</td>
<td>Complementary and alternative therapies</td>
</tr>
<tr>
<td>CCD</td>
<td>Charge-coupled device</td>
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<tr>
<td>CD</td>
<td>Crohn’s disease</td>
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<tr>
<td>CCFA</td>
<td>Crohn’s and Colitis Foundation of America</td>
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<tr>
<td>CEA</td>
<td>Carcinoembryonic antigen</td>
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<tr>
<td>CI</td>
<td>Confidence interval</td>
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<tr>
<td>CLE</td>
<td>Confocal laser endomicroscopy</td>
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<tr>
<td>CRC</td>
<td>Colorectal Cancer</td>
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<tr>
<td>CT</td>
<td>Computed tomography</td>
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<tr>
<td>CTC</td>
<td>Computed tomographic colonography</td>
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<tr>
<td>DALM</td>
<td>Dysplasia associated lesion or mass</td>
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<td>DCBE</td>
<td>Double contrast barium enema</td>
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<td>EMR</td>
<td>Endoscopic mucosal resection</td>
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<td>EPAGE</td>
<td>European Panel on Appropriateness of Gastrointestinal Endoscopy</td>
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<tr>
<td>ESD</td>
<td>Endoscopic submucosal dissection</td>
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<tr>
<td>FAP</td>
<td>Familial adenomatous polyposis</td>
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<td>FGID</td>
<td>Functional gastrointestinal disease</td>
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<td>FOBT</td>
<td>Faecal occult blood test</td>
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<td>Flexible sigmoidoscopy</td>
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<td>GI</td>
<td>Gastrointestinal</td>
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<td>High definition</td>
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<td>HNPCC</td>
<td>Hereditary non-polyposis colorectal cancer</td>
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<td>Inflammatory bowel disease</td>
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<td>MUTYH</td>
<td>mutY Homolog (E. coli)</td>
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<td>National Bowel Screening Program</td>
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<td>NBI</td>
<td>Narrow band imaging</td>
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<td>OR</td>
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<td>Primary sclerosing cholangitis</td>
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<td>RCT</td>
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<td>Serrated adenomas</td>
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<td>Socioeconomic status</td>
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<td>State-Trait Anxiety Inventory</td>
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<tr>
<td>UC</td>
<td>Ulcerative colitis</td>
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<td>WHO</td>
<td>World Health Organisation</td>
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