The WEO Consensus Statements on Post-Colonoscopy and Post-Imaging Colorectal Cancer

BACKGROUND
The story so far...

Definition and taxonomy of interval colorectal cancers: a proposal for standardising nomenclature

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Difference between PCCRCs and interval cancers

• **Interval cancer**
  – A *screening term* – measure of success of screening
  – a “colorectal cancer diagnosed after a colorectal screening examination or test in which no cancer is detected, and before the date of the next recommended exam” (Sanduleanu, Gut 2015)

• **Post-colonoscopy CRC (PCCRC)**
  – A *colonoscopy QA term* - measure of accuracy of the colonoscopy
  – A CRC detected after any colonoscopy – *not screening-specific*
  – Within screening, it *includes* CRC detected at next screening exam
They’re not the same thing

• We need **BOTH** terms:
  – **Interval cancer** for screening programmes (not a *colonoscopy* QA term)
  – **PCCRC** for colonoscopy QA (screening or non-screening)

• Although they’re *often very similar*, they’re **NOT the same** & need to be thought of separately, because they’re purpose is different

• They each need their own **precise definition**

• Risk that if we try to use the same **terminology**, we will add to the confusion
AIMS
Project aims

• To standardize terminology and definitions relating to PCCRC
• To describe the relationship between PCCRC terminology and interval cancer terminology
• To standardize the categorisation of the potential explanations for PCCRC occurrence
• To create colonoscopy, histology and radiology minimum datasets to facilitate PCCRC analysis
Project aims

• To develop a standardized definition for PCCRC rate, allowing benchmarking and comparison between services
• To recommend appropriate action for services upon review of PCCRC cases and rates
• To consider whether the PCCRC concept can be extended to radiological colorectal imaging
• To provide a research manuscript checklist for authors and peer-reviewers of PCCRC papers
Core Members

Project Lead: Matt Rutter

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Additional members:
Han Mo Chiu, Michal Kaminski, Jill Tinmouth, Harminder Singh,
Anna Forsberg, Douglas Corley, Takahisa Matsuda, Jola Gore- Booth (non-voting)
Modified Delphi Process

• All members had equal vote (via email)
• Aiming for 80% agreement (for statement consensus)

• In areas of continuing disagreement
  – A recommendation for or against a particular intervention (compared with a specific alternative) requires both
    • At least 50% of participants in favour
    • No more than 20% preferring the comparator
  – Failure to meet this criterion results in no recommendation
Overview

• Definitions and terminology
  2 statements

• Qualitative review of cases/aetiology attribution
  8 statements

• Quantitative assessment/calculation of PCCRC rate
  7 statements

• Non-colonoscopic imaging of the colon
  4 statements
Terminology
Statement 1

- We recommend that **Post-Colonoscopy Colorectal Cancer (PCCRC)** is the preferred term for cancers appearing after a colonoscopy in which no cancer is diagnosed.
Statement 2

PCCRCs can be sub-categorised into

• **Interval** cancers (where the cancer is identified before the next recommended screening or surveillance examination)

• **Non-interval cancers** (where the cancer is identified at [type A] or after [type B] a recommended screening or surveillance interval, or where no subsequent screening or surveillance interval for repeat examination was recommended [type C], up to 10 years following the colonoscopy)
PCCRC for QA purposes

• Colonoscopy QA applies to non-screening as well as screening

• Many colonoscopies do not result in a recommendation for a further procedure (no “interval”)

• From a screening perspective, a cancer found at a subsequent screening colonoscopy is a screening “success” and not an interval cancer, but may nevertheless indicate a failure of the previous colonoscopy to detect Ca

• Interval cancers may arise from non-colonoscopic aspects of a screening programme (e.g. FOBt).
## Statement 2

<table>
<thead>
<tr>
<th>Interval type</th>
<th>Non-interval type</th>
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<tbody>
<tr>
<td>Detected <strong>prior</strong> to recommended surveillance timepoint</td>
<td>Detected <strong>at</strong> recommended surveillance timepoint</td>
<td><strong>type A</strong></td>
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<tr>
<td></td>
<td>Detected <strong>after</strong> recommended surveillance timepoint</td>
<td><strong>type B</strong></td>
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<tr>
<td></td>
<td>Where no surveillance timepoint had been recommended</td>
<td><strong>type C</strong></td>
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### Examples

<table>
<thead>
<tr>
<th>Interval type</th>
<th>Non-interval type</th>
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<tbody>
<tr>
<td>Detected prior to recommended surveillance timepoint</td>
<td>Detected at recommended surveillance timepoint</td>
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<tr>
<th>Examples</th>
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<tbody>
<tr>
<td>Patient with 2 adenomas (2mm, 4mm) is advised to return in 5 years. Four years later develops anaemia; colonoscopy reveals CRC</td>
<td>Patient with a 15mm adenoma is advised to return for surveillance in 3 years. On surveillance, a CRC is found</td>
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<td></td>
<td>Patient with 3 small adenomas is advised to return for surveillance in 3 years. Patient misses this, returns 4 years later with CRC</td>
</tr>
<tr>
<td></td>
<td>Patient with change in bowel habit – colonoscopy normal. No further investigation advised. 5 years later patient develops symptoms and a colonoscopy reveals CRC.</td>
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<table>
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<tr>
<th>Implications</th>
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<tr>
<td>Was the recommended interval too long?</td>
<td>Was the recommended interval too long?</td>
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Aetiology & Qualitative Assessment
Statement 3

• We recommend that services implement a **formal process** to identify and register PCCRC cases so they can be reviewed for potential causative factors. Ideally this should be on a **prospective** basis, by reviewing whether each newly diagnosed CRC may be a PCCRC. If such methodology is not feasible, then the service should perform an **annual retrospective review** of all CRC cases diagnosed in the last year.
Statement 4

• We recommend that services perform a **Root Cause Analysis** of every PCCRC case identified, to determine the most plausible explanation for the PCCRC, and where appropriate to identify and **implement changes** in practice to improve performance, monitoring them for effectiveness.
Statement 5

• We suggest the use of the term “most plausible explanation” when describing the aetiology of PCCRC cases, given the inherent uncertainties in this process.
Statement 6

• To facilitate the use of a common language when categorising PCCRCs according to their most plausible explanations, we suggest that the following categories should be used:
  a) Possible missed lesion, prior examination adequate
  b) Possible missed lesion, prior examination negative but inadequate
  c) Detected lesion, not resected
  d) Likely incomplete resection of previously identified lesion
  e) Likely new CRC
Statement 6 (cont.)

Disclaimer

• Categorisation of PCCRCs according to their most plausible explanations should be used:
  
  - To facilitate QI work
  
  Example: In the case that a large number of PCCRC cases are diagnosed at the same institution, their categorization forms the basis for review to understand the most plausible explanations and define targeted interventions.

  - To facilitate research
  
  Example: To compare different outcomes between studies a uniform terminology is required.

• This categorisation should **NOT** be used to define accountability at individual level or as a measure to define or support medico-legal decision making.
Statement 6 (cont.)

We suggest that the following descriptors should be used:

a. Most plausible explanation “Possible missed lesion, prior examination adequate”
   – Colonoscopy within the last 4 years that did not detect cancer, where:
     • no advanced adenoma (AA, i.e. >1cm in size and/or villous and/or containing high-grade dysplasia) was identified in the same bowel segment; and
     • there is evidence of caecal intubation; and
     • adequate bowel prep was documented

b. Most plausible explanation “Possible missed lesion, prior examination negative but inadequate”
   – Colonoscopy within the last 4 years that did not detect cancer, where:
     • no AA was identified in the same bowel segment
     • but where either:
       – caecal intubation was not achieved/document; or
       – bowel prep was inadequate
Statement 6 (cont.)

c. Most plausible explanation “Detected lesion, not resected”
   – Colonoscopy within the last 4 years that did not detect cancer, where:
     • AA was identified in the same bowel segment and
     • The lesion was not resected

d. Most plausible explanation “Likely incomplete resection of previously identified lesion”
   – Colonoscopy within the last 4 years that did not detect cancer, where:
     • AA was resected from the same bowel segment and
     • there was no endoscopic/histological confirmation of complete resection

e. Most plausible explanation “Likely new cancer”
   – Last colonoscopy > 4 years prior to CRC detection

• In addition to the above five categories, we suggest adding the modifying statement “deviation from the planned management pathway” when there is clear evidence of deviation from the planned management pathway. For example, where a polyp was identified at colonoscopy, with a plan to remove at a later date, which never happened
Why 4 years??

- microsimulation modelling estimated that the mean dwell time (from normal mucosa to cancer) ranges from 10.6 to 25.8 years
  
  *Kuntz KM et al, Med Decis Making 2011*

- One estimate of the mean sojourn time of preclinical cancer progressing to a detected cancer ranged from 4.5 to 5.8 years
  
  *Brenner H et al, American journal of epidemiology. 2011*
Figure 1. Proposed algorithm for aetiology attribution of PCCRC cases

- Interval from previous procedure >4 years?
  - No
  - Advanced adenoma seen in same bowel segment?
    - Yes
      - Likely new CRC
    - No
      - Was lesion resected?
        - Yes
          - Likely incomplete resection of previously identified lesion
        - No
          - Detected lesion, not resected
  - Yes
    - Caecum intubated & prep good?
      - Yes
        - Possible missed lesion, prior examination inadequate
      - No
        - Possible missed lesion, prior examination negative but inadequate
RCA key elements

• What is the PCCRC subtype? (PCCRC subcategories table)
• What is the most plausible PCCRC aetiology? (aetiology algorithm)
• Any deviation from planned management pathway?
Statement 7

To facilitate attribution of PCCRC aetiology, we recommend that endoscopy/pathology services should collect the following minimum dataset for each procedure:

- Date of colonoscopy
- Patient age
- Patient sex
- Procedure indication (screening, surveillance, symptomatic)
- Predisposing risk factors for CRC (e.g. high-risk cohort such as Ulcerative or Crohn’s colitis or hereditary forms of CRC such as Lynch syndrome and familial adenomatous polyposis)
- Quality of bowel preparation (using a validated score)
- Extent of exam (including photo-documentation of 2 of 3 caecal hallmarks: appendiceal orifice, ileocaecal valve, terminal ileum)
- Location of all visualized polyps
- Estimated size of all visualized polyps
- Paris classification of all visualized polyps by segment of colon
- Type of endoscopic resection (cold snare, cold biopsy, hot biopsy, hot snare, EMR, ESD)
- Completeness of polyp resection, as judged by the endoscopist (not resected, incompletely resected, completely resected). State if the lesion is excised en-bloc or in a piecemeal fashion.
- Completeness of polyp resection, as judged by the histopathologist (not assessed/not assessable, incompletely resected, completely resected) and supported by photo-documentation. State if the lesion is received fragmented or en-bloc
- Other colonic pathology (such as diverticulosis or inflammatory bowel disease)
- Post-procedure management plan
Statement 8

We recommend that other endoscopist-related performance measures, such as caecal intubation rates, adenoma detection rates and caecal withdrawal times, are routinely collected by the endoscopy service, and are used to assist in the review of PCCRC cases.
Statement 9

To facilitate detailed descriptions of PCCRC, we recommend that clinical and pathology services should collect the following minimum dataset for each CRC:

- Was the CRC detected in the context of screening, surveillance or a symptom-driven procedure?
- Date and type of previous colorectal imaging prior to the episode of care in which CRC was detected
- Tumor location
- Macroscopic appearance (e.g. pedunculated, exophytic, ulcerated or diffusely infiltrating)
- Tumor size (horizontal or width in mm)
- Histologic type
- Tumor grade (low/high)
- Microscopic tumor extension (pT)
- Number of regional lymph nodes evaluated/number of positive lymph nodes (pN)
- Vascular lymphatic invasion
- Perineural invasion
- Tumor budding (where recommended, see below)
- Tumor deposits
- Resection margins
Statement 10

We recommend that **MSS/MSI status should be assessed on all PCCRC cases** either by immunohistochemistry or PCR. RAS mutations, BRAF mutations, or other targetable molecular alterations should be determined when indicated.
Performance & Quantitative Assessment
Statement 11

The PCCRC rate is an important performance measure of the ability of colonoscopy to detect and prevent CRC. We recommend that it should be used to monitor the quality of a colonoscopy service.
Statement 12

We recommend that the PCCRC rate should only be used to benchmark services if the required data quality and the necessary databases linkages are available.
Statement 13

We recommend that PCCRC rates should be externally reported at a service level, rather than for individual endoscopists. We recommend that PCCRC rates should be displayed with 95% confidence intervals, and, where appropriate, plotted on a funnel plot to identify outliers more readily.
Sample size calculation

<table>
<thead>
<tr>
<th>Current National PCCRC rate</th>
<th>Unacceptable High PCCRC rate</th>
<th>Number of procedures where cancer found necessary to detect poor performance (alpha, 5% 1-sided)</th>
<th>Number of procedures where cancer found necessary to detect poor performance (alpha, 2.5% 1-sided)</th>
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<tr>
<td></td>
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<td>60% power</td>
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<td>70% power</td>
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<td>80% power</td>
<td>80% power</td>
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<tr>
<td>8.60%</td>
<td>17.20%</td>
<td>42</td>
<td>57</td>
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<td>12.90%</td>
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<td>375</td>
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- Equates to **12,500 colonoscopies**, based on 3% CRC yield at colonoscopy
Statement 14

Whilst for epidemiological and research purposes, there remains a benefit in performing various analyses of PCCRC-related data, we suggest that for quality assurance purposes, a standardised method to calculate an unadjusted PCCRC rate should be used to permit the benchmarking of services. We recommend that this “unadjusted PCCRC rate” is calculated as the number of PCCRCs divided by the total of the number of PCCRCs plus the number of detected cancers, expressed as a percentage.
Statement 15

We recommend that the unadjusted PCCRC rate is calculated based on the date the person had the colonoscopy, with the term “detected cancer” being used to describe cancers diagnosed by the colonoscopy or within 6 months of the date of the colonoscopy, and the term “post-colonoscopy colorectal cancer” (PCCRC) used to describe cancers identified beyond 6 months of the date of the colonoscopy.
Statement 16

We suggest that when the unadjusted PCCRC rate is calculated, the follow-up period since the last colonoscopy is denoted with a suffix –Ny where N refers to the number of years’ follow-up after the last colonoscopy. For consistency and to permit benchmarking, we recommend that as a minimum, all services should report the PCCRC rate for an interval of 3 years (PCCRC-3y)
Example of PCCRC-3y rate calculation for the year 2013

1. Total people with a colonoscopy in 2013
2. Identify those in (1) who were diagnosed with CRC at or within 3 years following their colonoscopy
3. Categorise into detected CRCs and PCCRCs:
   a) CRCs within 6 months of colonoscopy are categorized as “detected CRCs”
   b) Those without a CRC detected at colonoscopy but with a CRC diagnosed 6 to 36 months later are categorized as PCCRCs
4. PCCRC-3y rate = PCCRC/(detected+PCCRC) %
Statement 17

Where exclusions in the population on which PCCRC is calculated are felt to be necessary, these should be stated explicitly in the methodology. However, we recommend that a PCCRC rate involving the entire cohort of adult patients, without exclusions, is also provided.
Non-colonoscopic imaging of the colon
Statement 18

We recommend that in the wider context of all colorectal imaging investigations, Post-Imaging Colorectal Cancer (PICRC) is the preferred term for cancers appearing after a colorectal imaging investigation that is negative for CRC. Similar to PCCRC, PICRC should be used to describe cancers identified beyond 6 months of the date of the imaging procedure.
Statement 19

Whilst it may be possible to calculate PICRC rates across different centres using a particular colonic imaging technique, such as CTC, we suggest that it is potentially misleading to use PICRC rate to compare between different colonic imaging techniques, for example to compare CTC and colonoscopy, unless the populations being investigated are well-matched or randomised. If this is impossible, comprehensive adjustment for all known covariate factors associated with PICRC should be undertaken. The same methodological and sample size considerations described for colonoscopy should also be applied for radiological imaging.
Statement 20

To facilitate adjudication of PICRC case aetiology, we recommend that radiology services should collect the following minimum dataset for all radiology procedures.

— ESSENTIAL:

• Date of procedure
• Type of procedure
• Imaging site name / code
• Indication for colonic testing
• Reason for use of radiological testing rather than colonoscopy
• Bowel cleansing agent used, dose, and quality of cleansing
• Faecal tagging agent used, dose, and quality of tagging
• Gas used for and quality of colonic distension
• Patient positioning during image acquisition
• Findings in each colonic segment
  — Details of polyps/cancers found if applicable (number, size, morphology)
Statement 20 (cont.)

DESIRABLE:

– Details on interpreter(s) of images (name, lifetime experience, number of cases interpreted in previous 24 months)

– CT image acquisition details (slice thickness/reconstruction interval/dose parameters)

– Use of intravenous contrast and antispasmodic

– Mode of interpretation and use of Computer Assisted Detection (CAD)

– Subsequent management recommendations
  • Discharge/repeat test/refer for endoscopy/surgery/other
  • If referral for endoscopy, relevant minimal dataset to be completed
  • If repeat radiology what was the recommended/actual interval
Statement 21

We recommend that if a PICRC is diagnosed, the following data should be sought **retrospectively**, including by review of CTC images.

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**ESSENTIAL**

- Findings in **segment** of colon where PICRC was subsequently found (number, size, morphology and histology of polyps/cancers; presence/absence of diverticular disease; other colonic diagnoses).
- Actual patient **management**, and any difference from that originally recommended at the time of CTC reporting.
- Impression of **the likely nature** of the missed lesion (technical error, perceptual/reader error, non-diagnosable/” invisible” lesion, unknown).

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**DESIRABLE**

- Findings in the **remainder** of the colon (i.e. segments other than where the PICRC was diagnosed).
- Details on **interpreter(s)** of images (positive predictive value over last 24 months, polyp detection rate for proven adenomas 6mm+ over last 24 months).
WHAT NEXT?
What next?

• Submission to Gastroenterology

• Future Research
Research Priorities
• What is the natural history of adenomas and serrated lesions?
• What is the natural history of CRC, including the sojourn time of stages and of the preclinical phase?
• How does natural history of CRC differ in the proximal/distal colon?
• How can the above be used to refine aetiology categorization?
• To what extent do different methodologies for the calculation of PCCRC rates correlate with, add to, or improve on the methodology in this manuscript?
• Can qualitative research of the pathways to the point of CRC diagnosis help refine the current 6-month cut-off between detected CRCs and PCCRCs?
• Validation of the recommended method of reporting a PCCRC rate
• To what extent is a PCCRC-1y rate predictive of a PCCRC-3y rate?
• What are the strengths and weaknesses of different methodologies? What are the most effective interventions to reduce unwarranted variation in PCCRC rates?
• Which screening modalities are most effective at minimizing PCCRC, in particular in relation to the serrated pathway?
DISCUSSION
Aren’t they the same thing?

60 year old

• FOB POSITIVE
• COLONOSCOPY NORMAL

2 years later

• SCREENING
• SUCCESS
• NOT an interval cancer

SCREEN - DETECTED CANCER
Aren’t they the same thing?

- **FOB POSITIVE**
- **COLONOSCOPY NORMAL**

60 year old

- **FOB POSITIVE**
- **COLONOSCOPY NORMAL**

2 years later

- **FOB POSITIVE**
- **COLONOSCOPY CANCER**

SCREENING SUCCESS • NOT an interval cancer
Aren’t they the same thing?

- 60 year old
  - FOB positive
  - Colonoscopy normal

- 2 years later
  - FOB positive
  - Colonoscopy cancer

- Screening detected cancer
  - Screening success
  - Not an interval cancer
Aren’t they the same thing?

60 year old
- FOB POSITIVE
- COLONOSCOPY NORMAL

2 years later
- FOB POSITIVE
- COLONOSCOPY CANCER

PCCRC
- Original colonoscopy failure
- Potential QA issue
Aren’t they the same thing?

- 60 year old
  - FOB POSITIVE
  - COLONOSCOPY NORMAL

- 2 years later
  - FOB POSITIVE
  - COLONOSCOPY CANCER

- PCCRC
  - Original colonoscopy failure
  - Potential QA issue

- So, although a cancer might be a screening success, it can still be a colonoscopy QA failure
- In other words: cancers can be PCCRCs without being interval cancers
Process Outline

• Set up multidisciplinary project team
• Compile list of key questions
• Literature review
• Divide into 2 Working Groups:
  – Aetiology
  – Performance
• Each WG developed evidence-based statements
  – AGREE II tool
  – GRADE methodology
• Consensus (modified Delphi) process
GRADE: quality of evidence

- **High**: RCT
- **Moderate**: Cohort, case control studies
- **Low**: Case series, expert opinion
- **Very low**: All plausible bias would change the effect, Dose-response gradient

Study limitations, Inconsistency of results, Indirectness of evidence, Imprecision, Publication bias, Large magnitude of effect, All plausible bias would change the effect, Dose-response gradient
Examples of implications of strong and weak recommendations

Strong recommendation for intervention
- **For patients**—Most people in this situation would want the recommended course of action and only a small proportion would not
- **For clinicians**—Most people should receive the intervention
- **For quality monitors**—Adherence to this recommendation could be used as a quality criterion or performance indicator. If clinicians choose not to follow such a recommendation, they should document their rationale

Weak recommendation for intervention
- **For patients**—Most people in this situation would want the suggested course of action, but many would not
- **For clinicians**—Examine the evidence or a summary of the evidence yourself and be prepared to discuss that evidence with patients, as well as their values and preferences
- **For quality monitors**—Clinicians’ discussion or consideration of the pros and cons of the intervention, and their documentation of the discussion, could be used as a quality criterion

No specific recommendation
- The advantages and disadvantages are equivalent
- The target population has not been identified
- Insufficient evidence on which to formulate a recommendation
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Aetiology - Key questions

1. What terminology should be used to describe categories?
2. What are risk factors & potential explanations for PCCRC?
3. How to ascribe potential explanations?
4. What should be the minimal histology data set to examine PCCRC?
5. What molecular tests should be performed to examine PCCRC?
6. How to prevent interval CRC in high-risk groups?
Performance - Key questions

1. How should PCCRCs be calculated & reported?
2. How should PCCRC rates be monitored?
3. How should PCCRC papers be peer-reviewed?
   [Checklist]
4. Radiology – can we/how do we extend to post-imaging CRC?
Literature Review

Medline, Cochrane Search terms:
- Colorectal cancer
- Interval cancer
- Healthcare quality assurance

1030 articles

abstract review
feedback from members
removed duplicates

401 articles