

Post Colonoscopy Colorectal Cancer (PCCRC) Audit Frequently Asked Questions

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How will PCCRCs be identified?

The PCCRCs are identified following linkage of HES, bowel cancer screening, and cancer registry datasets. To find the most recent PCCRCs, we are identifying cancers in the registry prior to final sign off.

How will my unit be notified of the audit?

The clinical leads of each unit will be given sign on instructions. It is expected one clinical lead for each trust for the audit will be nominated. This lead can nominate two other individuals to have access to the audit portal.

What if there are several endoscopy units in my Trust?

Cases are identified on a trust, not unit basis but each hospital site will be identified on the portal. If a trust wishes to divide the work between hospital sites up to three users can be registered for each trust. The results, organisational learning and clinical governance issues should be under the auspices of the whole hospital trust.

What is the process?

In the audit portal, there will be a list of patients who have had PCCRCs that had their index colonoscopy in your trust. Selecting one of these cases will launch the audit template. The audit template is based on that recommended by the World Endoscopy Organisation and it has been designed to be self-explanatory with information icons where necessary. In addition, there will be a variety of supporting documents in the portal to help communication and implementation. These documents have been informed by experience in ten pilot sites. They will include explanatory documents, and draft emails and presentations to share with colleagues and the trust information governance team.

A link to a mock example of the portal is here:

https://www.cancerdata.nhs.uk/system/clinical_audit/pccrc2020/edit.htm

Will the audit be time consuming?

The time required to review a case depends on your Trust information systems and whether you have electronic capture of endoscopic images. If you have to review large sets of case notes, and search for Polaroid images, it will take some time to answer all the audit questions. However, once you have all the relevant information, completing the template is quick. The benefit of identifying areas in need of improvement will hugely outweigh the time it takes to review cases. Some of these will be quick wins, but other areas of improvement such as optimising IBD surveillance will be challenging.

What if I have queries about how to enter the data or categorise a case?

We have set up a dedicated email address which members of the team will monitor on a weekly basis at the outset of the audit. We will try and address any concerns within a week of submission. We have created some mock cases which can outline some of the common scenarios but inevitably there will be new problems that arise, and we are keen to help with the decision-making processes.

Email address: leedsth-tr.pccrc@nhs.net (please do not include any patient identifiable information in the email)

What happens if the PCCRC is diagnosed in a different Trust?

We now know that this is a common scenario which is one of the huge benefits of National case identification. When it occurs, the trust where the PCCRC was diagnosed will be notified of the PCCRC first but will not know where the index colonoscopy was performed. They will be asked to provide a limited dataset of the cancer details. Once these have been completed the case will appear on the list of patients on the index colonoscopy trust site. These cancer details should be readily available, and this task should not be at all difficult.

Do I need to seek approval from Information Governance (IG) or Caldicott Guardian?

No. All the necessary approvals have been obtained from the National Disease Registration Service (NDRS) including the NDRS Caldicott Guardian. However, we recommend you inform your trust IG team of the audit. The audit is likely to identify cases that require discharge of Duty of Candour and for this reason, we recommend you also inform and work with your trust patient safety team from the outset of the audit.

Do colonoscopists need to be concerned about the audit?

Virtually all colonoscopists, even the very best, will have PCCRCs if they do enough colonoscopy, especially if they scope patients at high risk of PCCRCs. In many instances, the PCCRC will be considered unavoidable and in others it will not be clear whether the PCCRC arose from poor quality colonoscopy (largely because we don't know the natural history of colorectal cancer). Inevitably, there will be some cases where it will be evident that the procedure was suboptimal and questions might be raised about the competence of individual endoscopists. However, the sample size will be far too small to make any judgements about competence, and as such, individual endoscopists should not be concerned that their competence is being questioned. The case will need to be reviewed in the context of other performance data such as polyp detection rates, caecal intubation rates, withdrawal times, photo-documentation, and decision-making. Individuals should regard PCCRC review as just another source of information about performance.

Is the purpose of the audit to find fault?

No. The purpose of the audit is to be more systematic about finding cases and auditing them against a structured template to identify and prevent causes of PCCRC. The dataset in the audit portal will not be available to anyone outside the trust. However, data from the audit will be aggregated (anonymously) to build an evidence base of why PCCRCs occur in our health setting.

Does the audit replace the requirement of the JAG to identify and review PCCRCs?

The requirement has not changed. The audit is helping endoscopy teams meet the requirement by finding all the cases and providing a structured template to review cases. Having a structured template means that a possible reason for the PCCRC is less likely to be overlooked.

We already have a process in place to meet the JAG requirement why do we have to participate in this audit?

Participating in the PCCRC audit is not mandatory, but it will provide evidence to the JAG and CQC that a process to review PCCRCs is in place at individual trust level, and that the review is being conducted against recommended criteria. Increasingly, the Care Quality Commission will be using proxy evidence to rate trusts and failure to participate in audits, particularly ones like this, will be viewed unfavourably. Furthermore, it will be possible to aggregate data which will provide substantial benefits (see next FAQ). It is hoped that endoscopy teams will appreciate the clear benefit to patients of participation in the audit and that this will be the prime motivation to take part.

Why is aggregated data so important?

Aggregated data from the audit will provide strong evidence of causes of PCCRC, justifying interventions based on the findings to reduce PCCRCs. Unfortunately, individual case series, however well conducted, are too small to justify such interventions. With such evidence it will be possible for professional bodies to make recommendations, and possibly even stipulate requirements designed to reduce the occurrence of PCCRCs. Another bonus of aggregated data will be to provide a reliable estimate of what proportion of PCCRCs are unavoidable and what proportion are falsely attributable to individual trusts because of coding or other data errors. This will help with our 'messaging' within trusts, but more importantly help patients, the wider public and the media understand that even with perfect processes and perfect colonoscopy there will always be PCCRCs. The flip side of this is that we will also be able to predict with more certainty how many PCCRCs are avoidable and be able to set targets for the future. Widespread participation in the audit will send a strong message to the country, and indeed the rest of the world, that England is very serious about improving the quality of colonoscopy services. Finally, we expect all other nations to benefit from what we learn from aggregated data.

We already audit PCCRCs monthly and have robust processes & checks in place which then feedback into our Endoscopy user group. It feels like this national audit is duplicating work.

- a) If you have discussed a case identified by the audit previously then all the work has been done, assuming you have addressed all the relevant questions. You just need to enter the responses – this only takes a few minutes.
- b) The advantage of the audit template is that it ensures all the relevant questions are considered and it is possible you may need to review some of your cases to answer the additional questions.
- c) This audit is not a one off. The intention is to move from the current *ad hoc* review of PCCRCs (which will vary from nothing to a monthly review across trusts) to a consistent, and we hope gold standard approach using the portal.
- d) Using the portal should not interfere with your regular review of cases. It should enhance it with richer information about the case.
- e) There will undoubtedly be cases you have missed in the portal.

The audit requires the GMC/NMC number of the person who did the index colonoscopy. Why is this necessary?

The GMC/NMC number is not a mandatory field. It is possible to complete the dataset without entering a GMC/NMC because there is an 'unknown' option for this field. The sample size required to assess individuals using their PCCRC rate is huge so we will never be able to make judgments on individual competence or find fault with individuals. However, it will be possible using the GMC/NMC number to link the PCCRC dataset to the National Endoscopy Database. This linkage will allow multivariate analysis of the relationship of PCCRCs to the traditional performance metrics of colonoscopy such as volume, caecal intubation rate and polyp detection rate.

Will my data be used?

The organisers of the project have permission from the Office for Data Release to collect and present aggregated data. The intention here is to develop a robust evidence base of factors that lead to PCCRCs. At the moment, there are very small samples of PCCRC review that may not represent the 'real world'. It is anticipated that a large sample from a national audit will provide a high level of confidence of factors that lead to PCCRC, at least in systems like the NHS. As the audit progresses,

the outputs will be shared with all trusts. It is expected they will be of use to other jurisdictions that are not able to collect such data. It is expected that during the process of assessment for the purposes of achieving or maintaining accreditation, the JAG may request sight of key issues arising from the audit and importantly evidence they are being addressed. There will be no sharing of patient or endoscopist level data.

Is the time period 3-years or 4-years after colonoscopy?

For PCCRC rate calculations the time period is 3 years to give an overview of the scale of the issue, track performance over time, and compare jurisdictions using the same metric.

This audit case review delves deeper to find the exact causes for missed or delayed diagnosis. In a perfect world, with no time constraints, this could be anywhere from 0 to 10 years from the colonoscopy. There will clearly be diminishing returns from looking at a very large number of cases from a long period after the colonoscopy so to make the audit process feasible the 6-48 month period is used in line with WEO recommendations. This period may change based on the results of the audit.

I have been using the proforma the JAG recommends. Is the National Audit template different?

The National Audit template has more detail than the JAG proforma. Both are based on the WEO recommendations for determining the most plausible explanation for PCCRCs. The WEO realised that its recommendations for auditing PCCRCs would change as new evidence emerged. New evidence about the cause of PCCRCs has emerged since the WEO publication on PCCRCs and this new information is reflected in the National Audit template. Furthermore, the template has been subject to intense scrutiny by the ten pilot sites and further modifications and simplifications have been made to the template based on their feedback.

We have been told there is a limit of 25 cases/trust. Why has my trust got more cases than this?

Cases are allocated initially to the trust of diagnosis so at the start of the audit some trusts may have more than 25 cases. Ultimately, after reallocation (see below), no trust should have more than 25 cases. For technical reasons, some recently merged trusts have more than 25 cases, but we will be reducing the number in the portal to a maximum of 25 for all trusts.

What is reallocation of cases?

You will notice that if the index colonoscopy occurred in a different trust from the cancer diagnosis, and your trust is the site of cancer diagnosis, we are asking you for the cancer details of these patients. In this instance, once you have completed the cancer details section, the case will be reallocated to the trust of colonoscopy. If this reallocation exercise is done completely then some trusts starting with fewer than 25 cases may end up with more, and those with greater than 25 will end up with 25 or fewer. The cancer details section is very quick to complete (and the information is usually readily available) so we encourage all trusts to check to see how many of their allocated cases are in this category and enter the data as soon as possible.

My Information Governance team has requested further detail on the audit and need responses to several questions in order to approve our involvement. Where can I find further information?

A Data Protection Impact Assessment (DPIA) has been produced for the audit to identify and minimise the data protection risks. This is available in the portal or can be sent out to you by the project team. If there are further IG questions, please contact us.

What is the process for more cases being added into the portal in the future?

We are aiming to update the portal every four months. Updates will take place at the end of January, May and September and will include all newly registered cancers in the cancer registry database that had a colonoscopy in the previous 6-48 months. The next update is January 2022 when there will be five months of new cases because the current cases were identified in August 2021. We do not expect you to have nearly so many cases with each upload. Depending on the size of your colonoscopy service, and the rate of cancer diagnosis by colonoscopy, we expect 95% of sites to have 3-8 cases per upload.

Will colonoscopies performed in the independent sector (IS) for the NHS be included in the audit?

Yes. The aim is to provide access to the audit portal for all independent sites that perform NHS-funded colonoscopies that are coded in HES (we can't yet identify PCCRCs that are not coded in HES). This inclusion of the IS will happen once we are confident the audit is going well in NHS trusts, and when we have agreed with the IS exactly what the process will be. We know that most PCCRCs following colonoscopies done in the IS are subsequently diagnosed in the NHS, and as such the IS sites will not have access to details about the cancer. This means the NHS sites will have to provide this data. Fortunately, the portal has functionality to enable this to happen. The information required about the cancer is minimal, and it should be easy to find and upload.

If you have any questions not answered by the material above please contact leedsth-tr.pccrc@nhs.net