NHS England

Optical Diagnosis with Resect & Discard Guidance – September 2024 Version 4.0

Purpose

This operational guidance is to support providers of the NHS Bowel Cancer Screening Programme (BCSP) to safely implement the use of Optical Diagnosis (OD) for diminutive polyps (small polyps of ≤5mm) with a Resect and Discard (R&D) strategy – where polyps that fit a strict criterion can be discarded rather than being sent to histopathology.

The document provides information about the following areas:

- Background
- Role of OD Champion
- Accreditation process to perform OD within BCSP
- Re-accreditation process
- Timeline for implementation
- Implementation of OD within BCSP
    - Patient selection
    - Polyp selection
    - Equipment requirements
    - Photo documentation
    - Patient communication
    - Changes to BCSS to accommodate OD
- Quality Assurance
- Appendix 1 – Financial worksheet for business cases
- Appendix 2 – Slides from SSP/SP implementation of OD workshop

Background to Optical Diagnosis with Resect and Discard

Optical Diagnosis (OD) with a resect and discard (R&D) strategy involves a colonoscopist making an optical diagnosis of small diminutive polyps (≤5mm) with high confidence. They are required to record with photographic documentation of the polyps, using both white and blue light imaging (e.g. narrow band imaging (NBI)) and then discarding the resected polyps rather than sending them to histopathology.

The DISCARD3 study reported a detailed evaluation of this approach within bowel cancer screening and showed that the surveillance intervals achieved using this approach met the threshold for safe implementation and evaluated a quality assurance process to confirm clinical safety. The study also demonstrated OD with a R&D strategy is feasible and acceptable to both clinicians and patients.

Small diminutive polyps ≤5mm in 2023 represented 50 - 60% of all polyps resected in the NHS Bowel Cancer Screening Programme (BCSP).

Adopting OD should: -

- significantly reduce the burden on histopathology services (which in turn should allow extra capacity for faster turnaround for other histology sent to the laboratory).
- promote green endoscopy by substantially reducing use of consumables.
- offer cost-savings (both for histopathology and with reduction in consumables) at a screening centre and national level.

Role of OD Champion

Each screening centre is required to appoint an OD Champion before commencing to implement OD within the BCSP.

To become an OD champion this clinician will: -

- be an accredited bowel cancer screening colonoscopist working in the programme.
- have completed training about OD – face to face or via e-learning (in development – due for release on Q3 of 24/25). If the OD champion is completing the e-learning training format, it is strongly advised that they gain the support of another OD champion in the form of a “buddy”. Buddy’s can be identified by QA – requests should be made via england.nationalbowelhub.nhs.net
- successfully achieve ≥85% accuracy for polyps diagnosed with high confidence (high level of certainty of type and size) in the post training test. The test will be completed at the end of the training.
- on successful completion of the post-training test - perform 20 high confidence polyp diagnoses and provide photographic evidence to be reviewed and approved as per figure 1.
- have dedicated time allocated (suggested 0.25 PA’s per week (planned activities – 1.0 PA is 4 hours of time or ½ day, hence 0.25 = 1 hour) for every 500,000 population cover by the screening centre) to manage the implementation and management of optical diagnosis with a R&D strategy within their screening centre.

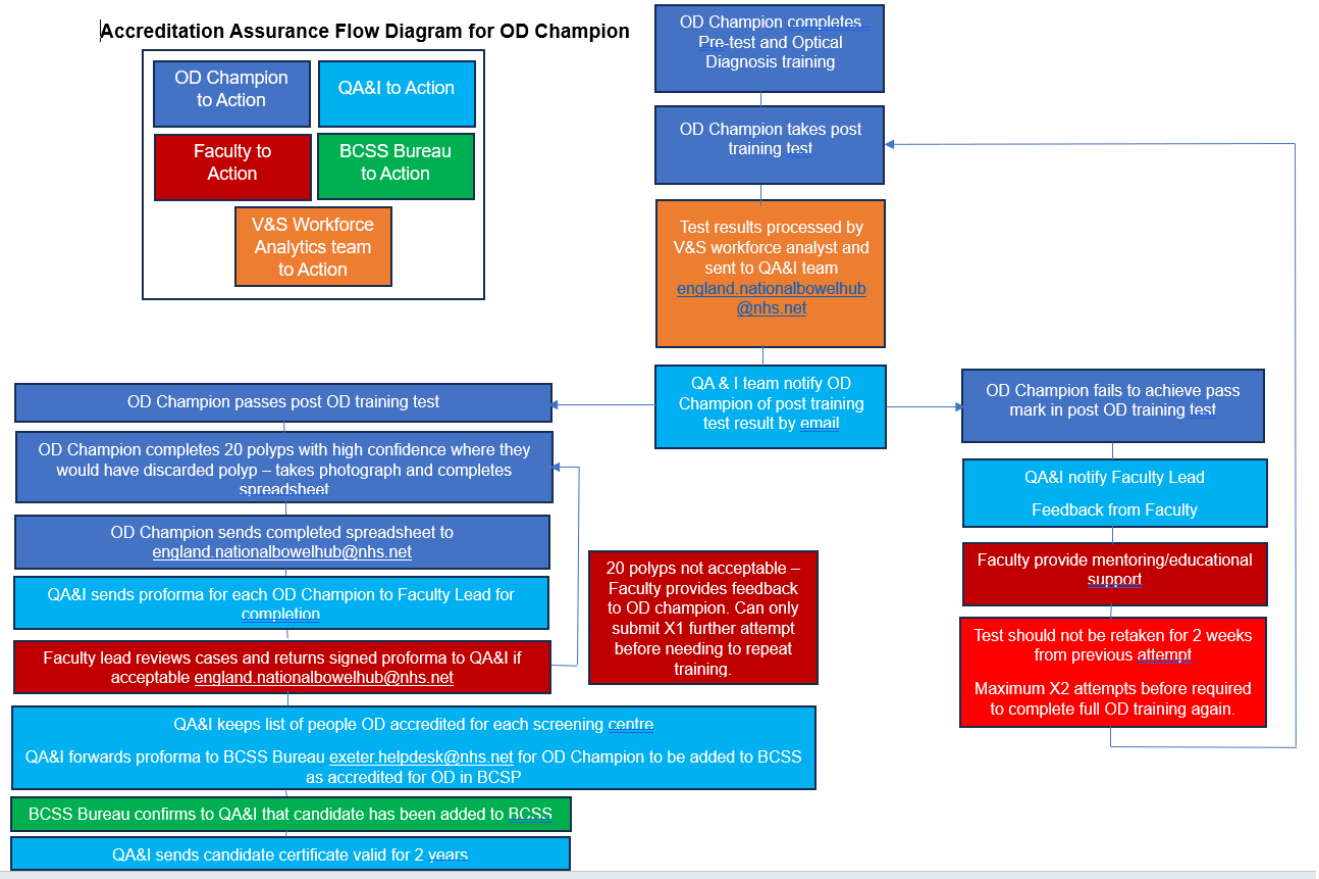
As an OD champion they will: -

- ensure audit and quality assurance is maintained in the screening centre with regards to OD. This should include an annual check of quality of photo documentation and an annual check/audit of labelling of polyps.
- have an important role as an advocate for OD within their Centre, supporting colleagues to adopt OD and being responsible for local accreditation of colleagues for OD practice (reviewing the 20 polyp cases) once they have successfully completed the relevant training and post training test.

Job description for role of Optical Diagnosis Champion

Role description OD Champion Jan 2024.d

Figure 1: OD champion accreditation process.



Accreditation process to perform OD with R&D within BCSP for screening colonoscopists.

The screening colonoscopist will be required to: -

- complete training on OD – either face to face or via e-learning (in development – due for release on Q3 of 24/25).

- successfully achieve ≥85% accuracy for polyps diagnosed with high confidence (high level of certainty of type and size) in the post training test. The test will be completed at the end of the training.

- following successful completion of the post-training test - perform 20 high confidence polyp diagnoses with provide photographic evidence to be reviewed and approved by local OD champion as per figure 2. The polyps for assessment can be from patients in the symptomatic service, as all histology needs to be sent to histopathology until full accreditation is awarded. Accreditation will only give permission for OD to be performed within the bowel cancer screening programme and not in the symptomatic service.

Figure 2: OD with R&D accreditation process in BCSP

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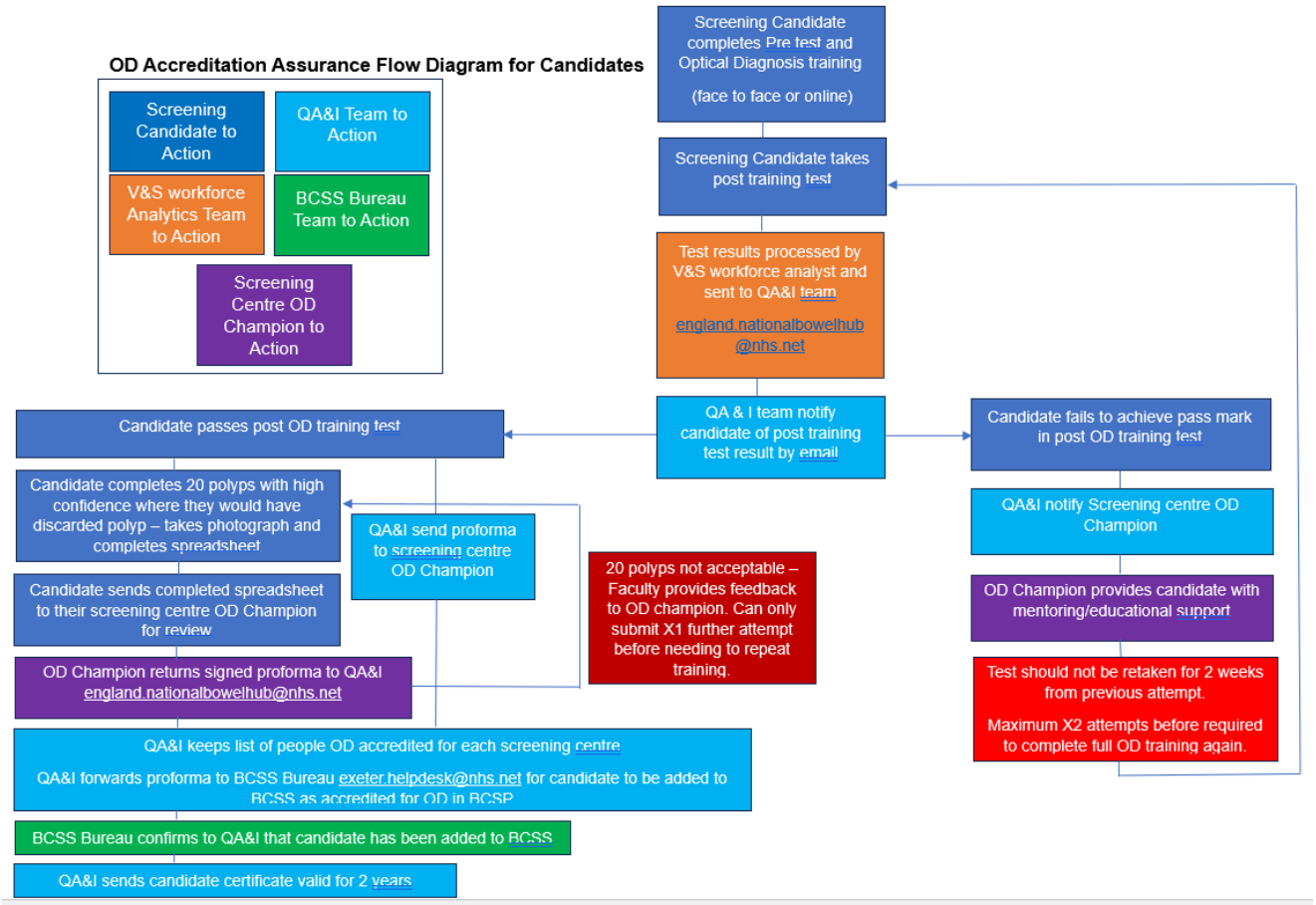
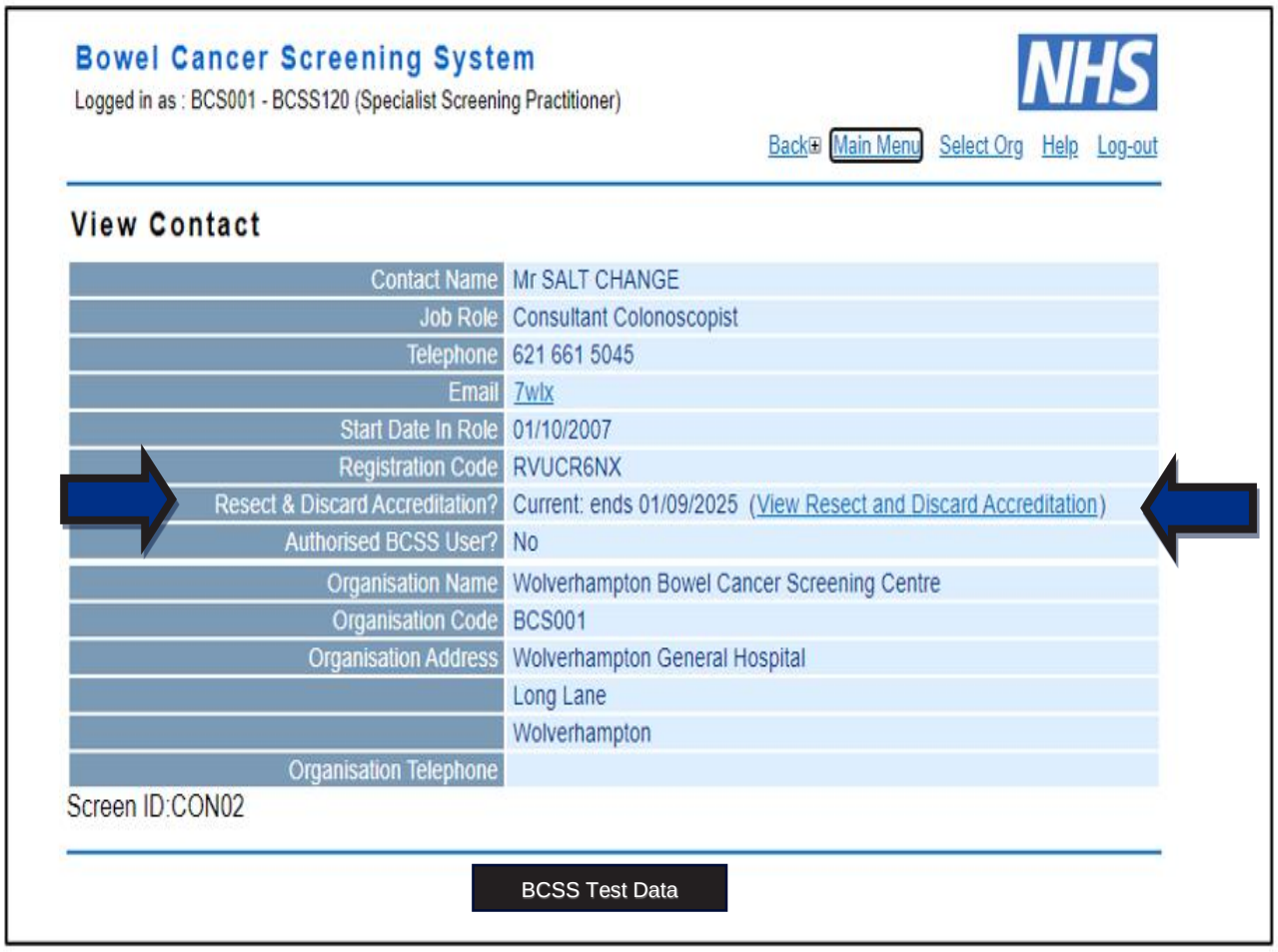


Once both parts (post-test and 20 polyps) have been successfully completed, the national Quality Assurance (QA) team will notify the BCSS Bureau to update the colonoscopists records.

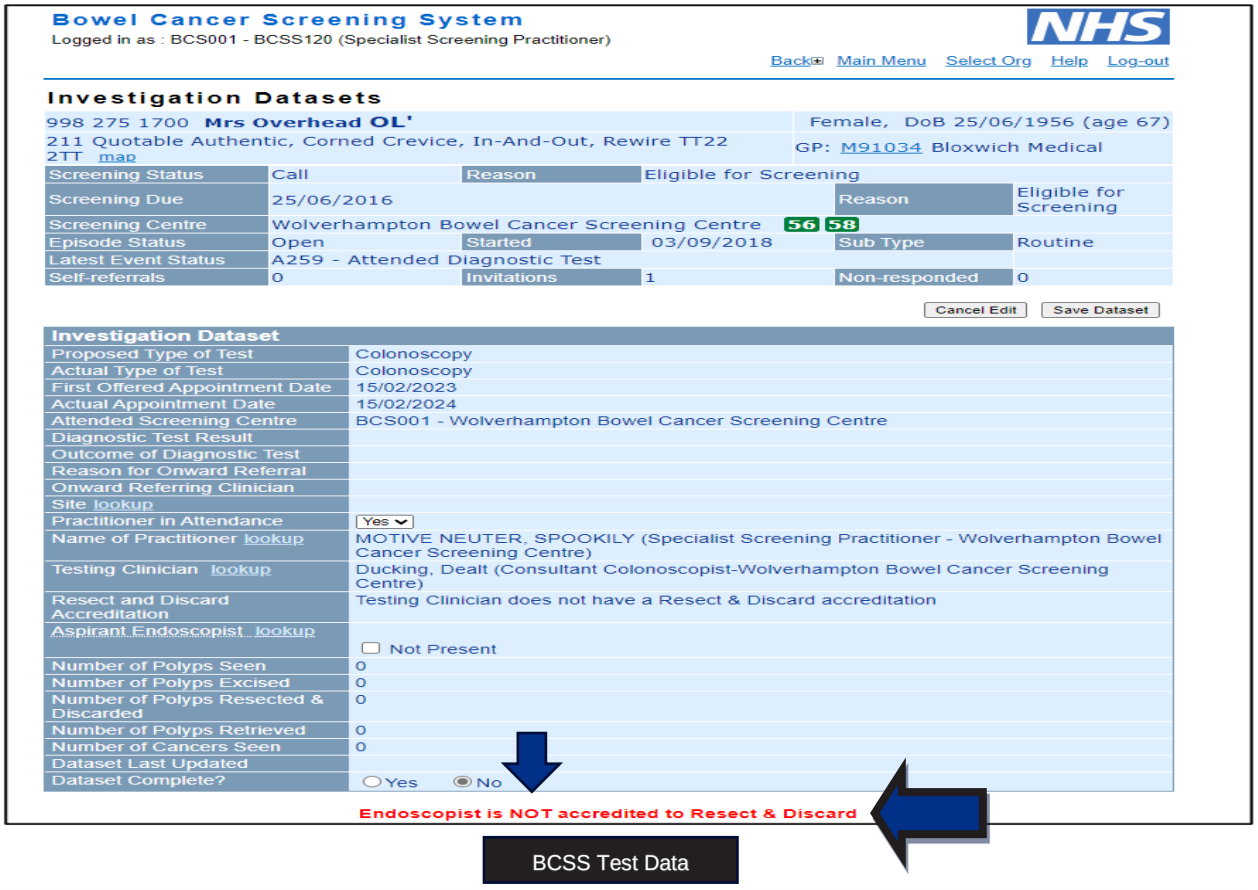
This will show in BCSS as “current” on the contact screen (see screenshots on page 7) and provides an end date for when reaccreditation is required.

The endoscopist **must not** commence resect and discard until BCSS has been updated.

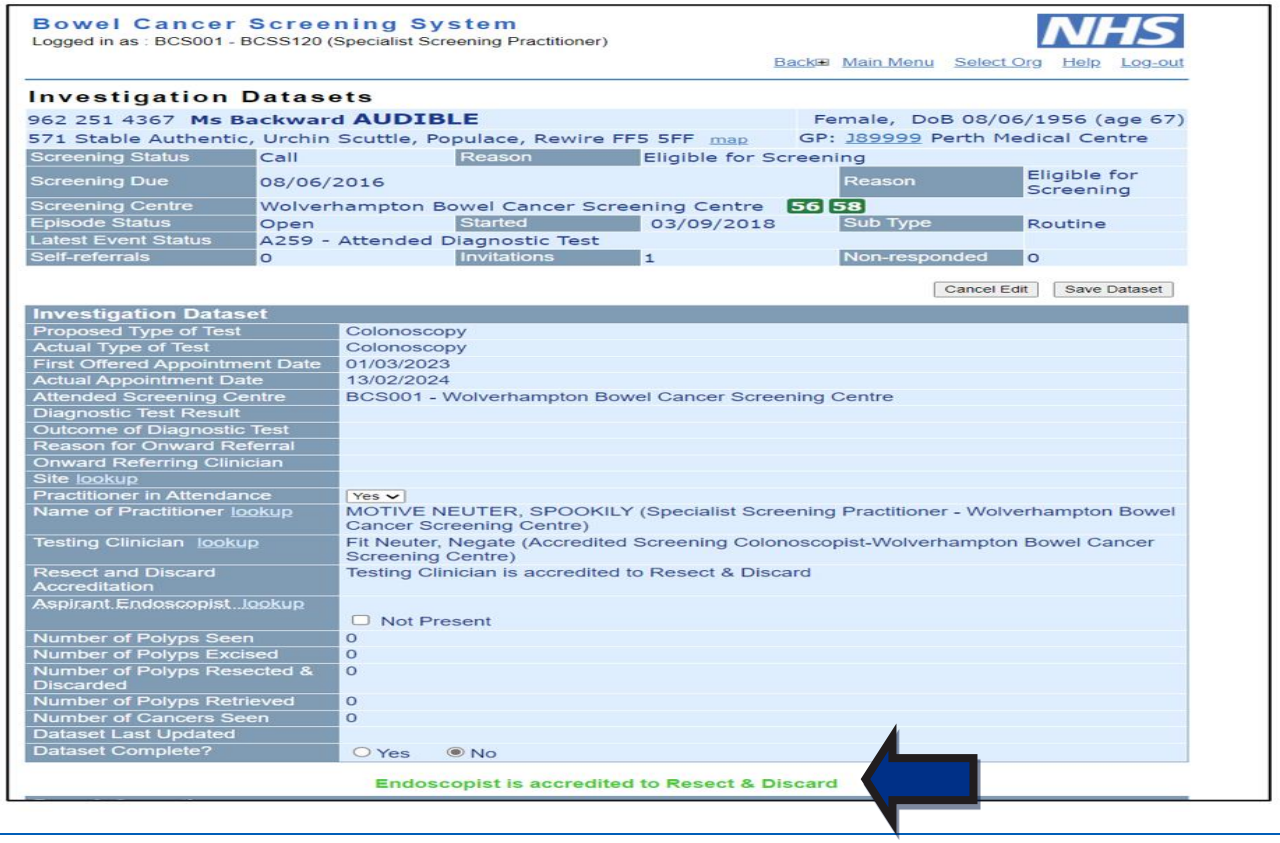
The added accreditation is now shown on the endoscopist's contact record.



BCSS has been built to alert the person (SSP or SP) working in the procedure room as to whether the colonoscopist is or isn't accredited to perform OD. This is highlighted by a red or green banner at the bottom of the investigation data set. For people who are unable to identify certain colours, the red banner has NOT in capitals whereas the green banner where a person can perform OD is in lower case.



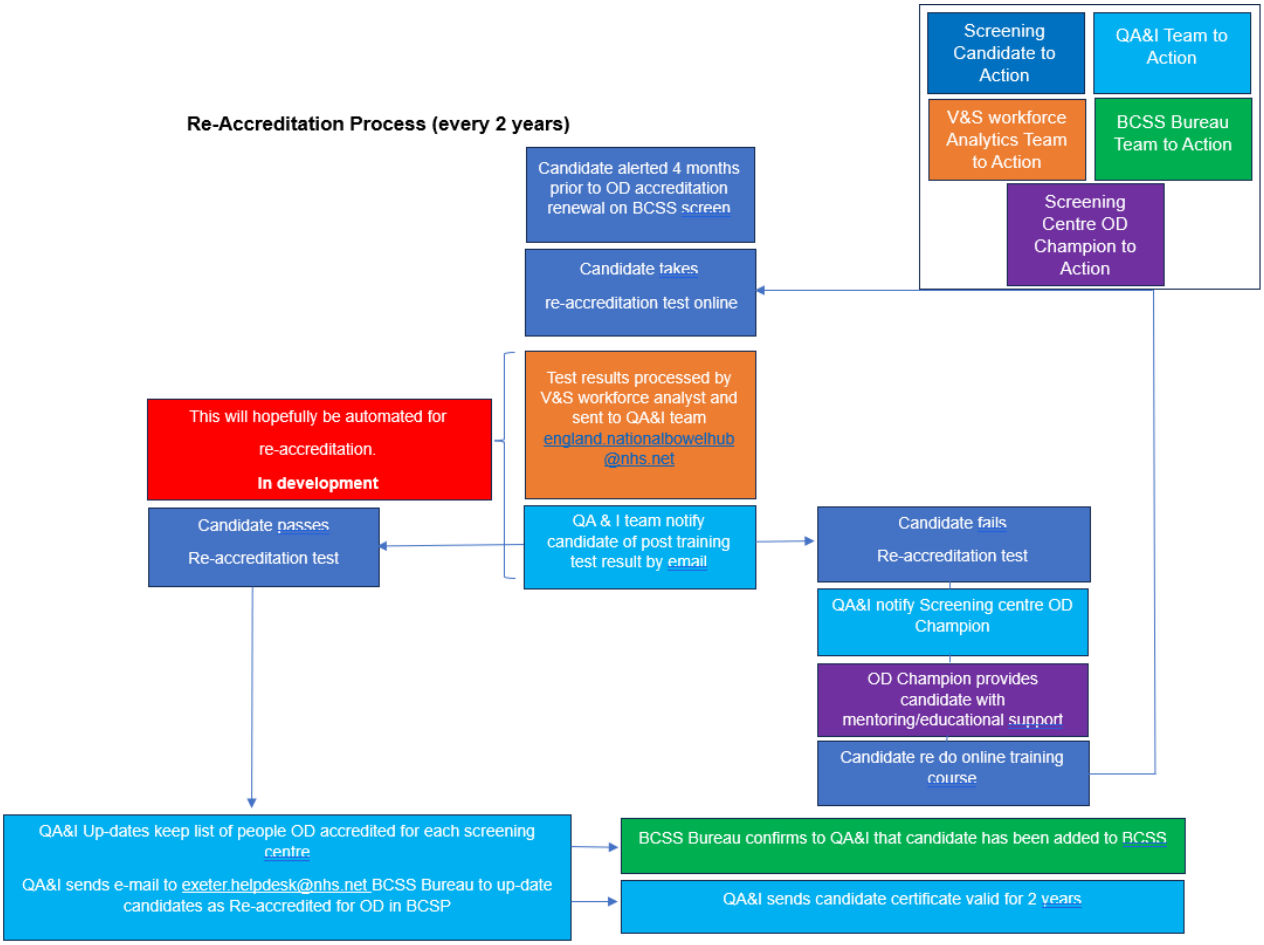
BCSS Test Data

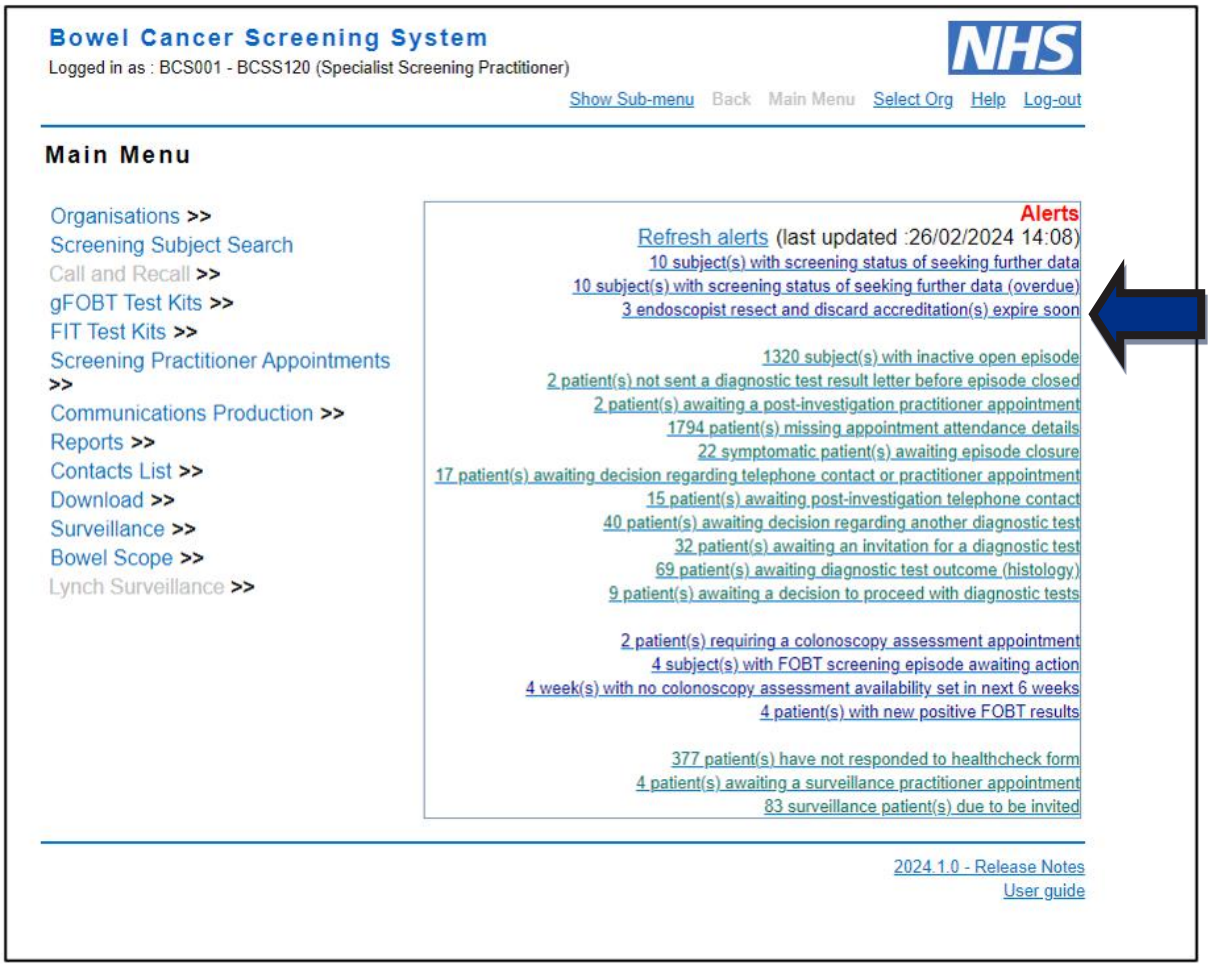


Re-accreditation process

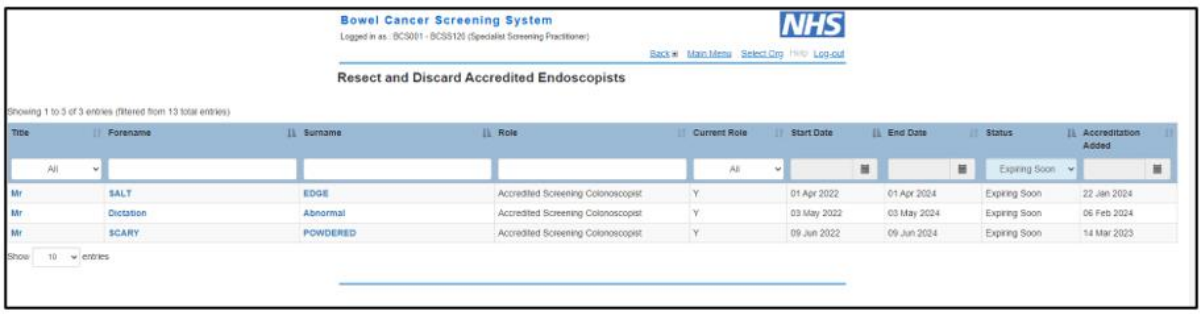
All OD clinicians need to complete a re-accreditation online test every 2 years. BCSS will alert the need for re-accreditation 4 months before it is due – this is on the screening centre alerts page (see screen shot on page 10) and can be viewed by the screening centre manager or SSP roles on BCSS. If the clinician does not revalidate before the expiry date, they should **not** continue to perform OD. BCSS will automatically change the status to alert people working in the procedure room that the clinician should not perform OD until a new date is entered into the system. If a person does discard a polyp when they are not accredited, it will need to be recorded as lost.

Figure 3: OD re-accreditation process





The alert takes the user to a version of the Resect and Discard Accredited Endoscopists report which is filtered to show those “Expiring Soon”.



Timeline for implementation

All screening centres will be expected to engage with OD and look to accredit all current screening colonoscopists with ≥ 1 year of BCSP experience for OD within three years (by May 2027).

Newly accredited BCSP colonoscopists can choose to do the OD training and accredit as soon as they become a screener, but some may wish to have a period of consolidation into BCSP practice. Once a person has completed their first year (or 120 index procedures) they must then move on to accredit for OD.

Implementation of OD into the BCSP

Inclusion criteria

Patient Selection

- All patients within the NHS BCSP FIT pathway are eligible for OD. This includes both index and surveillance procedures.

Polyp Selection

Polyps selected for OD with R&D must meet the following criteria:

- a resect and discard strategy should only be used for adenomas and serrated polyps diagnosed with high confidence
- polyp size ≤5 mm
- polyp location is within colon
- the endoscopist has high confidence (high level of certainty about size, type etc) about the polyp following OD. The endoscopist must be comfortable that the position of the polyp allows high quality photographic evidence with both white and blue light.

Exclusion criteria

- All patients on Lynch syndrome surveillance are **NOT** eligible for OD with R&D strategy, as the approach has not been validated in this cohort and the NHS BCSP needs to gather consistent data on outcomes and histopathology. This includes people with Lynch syndrome who have chosen to withdraw from Lynch syndrome surveillance but wish to continue to receive a screening FIT kit and then require further investigations. All patients with Lynch syndrome should not be included for OD with R&D.

- OD should not be performed in cases where the endoscopy equipment or the endoscopy reporting system (ERS) is unable to support high quality photo documentation and labelling of polyps. In these cases, all polyps must be sent to histopathology.

- Anal canal polyps
- Rectal polyps - management varies according to sub-type and is covered in the next section.

Management of diminutive rectal polyps

- Diminutive rectal adenomas diagnosed with high confidence should be resected and discarded (as they would be if located in any other part of the colon).

- Diminutive rectal hyperplastic polyps diagnosed with high confidence should be left in situ. The BCSP data shows that of 90% of diminutive rectal polyps resected prove to be simple hyperplastic polyps which do not influence surveillance, whereas 10% are other sub-types of the serrated family which do drive surveillance.

- All other diminutive rectal polyps (eg those diagnosed with low confidence or polyps of other serrated sub-types) should be sent be resected and sent to histology.

Equipment Requirements

Colonoscopes should be high definition (at least 290 series or equivalent) with blue light imaging capability and the ability to photodocument.

Blue light imaging capability is similar across brands:

- Olympus - narrow band imaging (NBI)
- Fujifilm - blue light imaging (BLI)
- Pentax - i-scan 3

Endoscopy Reporting Systems (ERS) need to allow a text label to be applied to photos in real-time or immediately after the procedure.

Photo documentation

Screening colonoscopists are responsible and must ensure that good quality images of all polyps selected for R&D following high confidence OD are: -

- recorded with white/blue light (such as narrow band imaging (NBI).
- identified and labelled either within the endoscopy reporting system (ERS) or as part of the formal endoscopy report.

In a resect and discard strategy, polyp photos are the only polyp record so must be sufficient quality for review.

- If the photo is not of adequate quality, even if the clinician has high confidence in the optical diagnosis, the confidence level must be assigned as low confidence and the polyp sent to histology.
- High quality polyp photo documentation is important to allow auditing and review of cases where polyps are resected and discarded.

Poor photo issues

- stool covering polyp surface
- too far away from the polyp
- majority of polyp not visible
- blurred photo
- no blue light photo
- poor photo labelling

Photos should be: -

- Clean mucosa (no obscured views)
- Complete view (majority of polyp visible)
- Correct focus (sharp surface)

If equipment is not of sufficient quality or breaks down and a photo cannot be taken, all polyps must be sent to histology as is current practice.

The method of recording will vary according to the endoscopy equipment and ERS used within the endoscopy unit and should be described in a centre standard operating procedure (SOP) document.

The BCSP OD task and finish group are working with the Joint Advisory Group (JAG) and National Endoscopy Database (NED) teams to encourage ERS system manufacturers to create a standard approach to polyp image capture to support OD with R&D in future.

Labelling polyp photos

- Polyp photos should be labelled during the procedure or immediately after.
- The label is a number corresponding to the order in which the polyp was photo documented and resected.
- Both a white light and blue light photo is required for each polyp – they should have the same ID label.
- The polyp label will be recorded on BCSS and the endoscopy reporting software.
- Once photo documented, the polyp should be resected immediately to avoid confusion.
- Avoid multiple polyps in a single photo if possible. Otherwise, the central most polyp will be considered the polyp of interest.
- Practicalities of labelling will vary between endoscopy reporting software providers. There must be an SOP for each screening centre, developed in collaboration with the endoscopists, to ensure the process works for all the team.

- Labelling should be consecutive to match BCSS and therefore it may be helpful when some polyps are discarded to make it clear on the histopathology request that they have been optically diagnosed and discarded and as a result not all polyps are being sent to pathology. i.e polyps 1, 2, 5, 6 are being sent to pathology but 3 and 4 have been optically diagnosed and discarded. It will be helpful for the pathologists, so they don't think they are missing polyps.

Patient Communication

Following feedback from patients the term "Optical Diagnosis" is preferred to "Resect and Discard" when speaking to a patient. This provides reassurance that the polyp has been viewed, assessed by an expert, carefully considered, photographed and documented before being discarded.

Communication in procedure room

Communication between the SSP/SP and endoscopist in the room is vital to ensure: -

- information is accurately collected.
- polyps discarded are those appropriate.
- guidance is followed.

SSP/SPs should be asking these questions for **all** polyps and for **all** patients: -

- What is the size of the polyp?
- What is your optical diagnosis?
- Do you have high/low confidence?

The polyp can be discarded if it meets the inclusion criteria above.

If a clinician decides to discard a polyp that is outside of guidance – for example 6mm, please record this accurately. BCSS will allow you to record outside of guidance.

Changes to BCSS to accommodate OD/R&D

Several changes have been made to the BCSS to accommodate OD/R&D.

Key points to note are as follows:

- the datasets for OD with R&D will only be available to OD-accredited colonoscopists. You will be able to identify who is OD accredited through BCSS (screenshots on pages 7&8).
- polyp descriptors for OD will include adenoma, serrated (including hyperplastic) and other.
- the system will not allow OD with R&D for patients undergoing Lynch syndrome surveillance colonoscopy.
- the system has alerts on the main alert page to highlight the requirement for a screener to re-accredit 4 months ahead of due date.

Training has been provided on the changes to the BCSS – included are the slides.

Resect & Discard BCSS training v0.3.pp

Quality Assurance (QA)

Quality assurance (QA) in any screening programme is essential to minimise harm and maximise benefits. The national and regional QA teams will monitor both the training and accreditation requirement as well as clinical key performance indicators (KPIs) to ensure delivery of an effective, equitable, safe and high-quality pathway continues for individuals within the BCSP where changes to the pathway are implemented.

The number of colonoscopists per site, accreditation and re-accreditation will be monitored by the quality assurance teams.

Quality standards and KPIs will continue to be monitored for all colonoscopists. The data collated for the following current BCSP standards have been amended to reflect optical diagnosis:

- BCSP-S09: referral: pathology turnaround time
- BCSP-S12: intervention or treatment: adenoma detection rate (FOBt)
- BCSP-S15: intervention or treatment: polyp retrieval rate

OD Champions will be required to perform annual audits of the quality of photo documentation of polyps discarded and polyp labelling, and these will need to be submitted to the regional quality assurance teams.

Roles and responsibilities

- Maintain records of OD champions in each screening centre (national QA team)
- Maintain a record of screening colonoscopists trained and accredited to do optical diagnosis and ensure they are added to the bowel screening system (BCSS) to enable a record to be completed (national QA team)
- Ensure all services and sites are using appropriate equipment (national with support from regional teams)
    - Images are recorded with both white and blue light (OD Champion and QA teams)
    - Images can be labelled and identified within the endoscopy reporting system (OD Champion and QA teams)
- Annual check of quality of photo documentation carried out by OD champion (regional QA team as part of annual prioritisation/assessment)
- Annual check/audit of labelling of polyps carried out by OD champion (regional QA team as part of annual prioritisation/assessment)
- Clinical KPIs and outcomes will be monitored as well as number of polyps, size and confidence. (national QA team)

Appendix 1
Financial information workshop

Text and financial table for OD Business

Appendix 2
Slides from SSP Implementation

Workshop to support SSPs in the implemen