Royal Cornwall Hospitals
NHS Trust

Tattoo Placement during Colonoscopy and Flexible Sigmoidoscopy Policy

V2.0

March 2024

Summary

Decision When to tattoo	• Tattooing guides surgical resection and endoscopic surveillance strategies. • Tattooing should be done for lesions > 20mm or suspected malignancy (outside of caecum and rectum). • Don't tattoo in the rectum – this can cause staining of the mesorectum and impact significantly on surgical management.
Technique How to tattoo	Delivery • A potential reason for invisible tattoos is superficial delivery. • It is widespread practice now to raise a saline bleb before switching to tattoo – this ensures the tattoo is placed in the submucosal space (ie not too superficial or deep). Number • Ideally tattoos should be placed in a four-quadrant circumferential method to improve intra-operative visualisation of tattoos. Location • Generally, tattooing 2-5cm distal to a lesion is acceptable. • Tattooing can be performed immediately distal to a lesion margin to aid specific localisation. However, it may be sensible to places tattoos further away to prevent tumour cell seeding. [6] • For lesions that can be endoscopically resected, this also limits the risk of submucosal fibrosis or muscle injury during subsequent resection.
Report How to report tattooing	When reporting tattooing, the following should be documented: • The exact tattoo location should be stated relative to the lesion, including the distance from the lesion. • The exact number of tattoos placed. If more than one set of tattoos, explicit description of relative location to any lesions should be documented.

Summary of best practice recommendations (Source: JAG).

Table of Contents

Data Protection Act 2018 (UK General Data Protection Regulation – GDPR) Legislation.

The Trust has a duty under the Data Protection Act 2018 and UK General Data Protection Regulations 2016/679 to ensure that there is a valid legal basis to process personal and sensitive data. The legal basis for processing must be identified and documented before the processing begins. In many cases we may need consent; this must be explicit, informed, and documented. We cannot rely on opt out, it must be opt in.

Data Protection Act 2018 and UK General Data Protection Regulations 2016/679 is applicable to all staff; this includes those working as contractors and providers of services.

For more information about your obligations under the Data Protection Act 2018 and UK General Data Protection Regulations 2016/679 please see the Information Use Framework Policy or contact the Information Governance Team.

Royal Cornwall Hospital Trust rch-tr.infogov@nhs.net

1. Introduction

1.1. The gold standard tool for diagnosing colorectal cancer is through endoscopy, i.e. colonoscopy or flexible sigmoidoscopy. The goal of early diagnosis is to facilitate curative surgical resection and avoid tumour recurrence. This relies on accurate tumour localisation to guide intraoperative resection which can be achieved via competent tattoo placement. If a lesion is not tattooed or if the tattoo is not visible, this may lead to difficulties with identifying the lesion during surgery or endoscopic resection or identifying the resection site during future surveillance colonoscopy. The UK Key Performance Indicators and Quality Assurance Standards for Colonoscopy guidelines stipulate that all lesions >20mm and/or suspicious cancers outside the caecum and rectum should be tattooed with 100% compliance as a minimal standard, and each trust should have a local policy for tattoo placement.

There have been previous patient safety incidents at The Royal Cornwall Hospital NHS Trust (RCHT) involving colonic tattoos which has led to the resection of the wrong (tumour-free) colonic segment. Inappropriate tattoo placement, e.g. in the rectum, can lead to staining of the mesorectum and can impair surgical planes. Tattoo practice is also highly variable amongst endoscopists (compliance with guidelines, site, number of tattoos, volume, technique, and timing in relation to biopsies).

This document aims to standardise the approach to tattoo placement during colonoscopy and flexible sigmoidoscopy. This document stipulates when tattoos are and are not required, the recommended methodology and technique of tattoo placement, endoscopy reporting documentation in relation to tattoos, and specific intraoperative considerations if localisation is unclear (where there is doubt regarding the tattoo or if the tattoo cannot be found). The methodology for auditing tattoo placement (and exclusion criteria) have also been clearly defined.

Adherence to this trust policy should then be subjected to continuous audit and quality improvement to reduce variations in tattoo practice and to maintain high quality colonoscopy.

1.2. This version supersedes any previous versions of this document.

2. Purpose of this Policy

2.1. Standardised approach to tattooing suspected cancers with the large bowel and lesions >20mm.

2.2. It is essential that all lesions are correctly marked to ascertain an adequate understanding of their actual location. This practice will underpin future interventions, such as:

- Endoscopy – Mark lesions for endoscopic resection and surveillance.
- Surgery – Identify lesion for colonic resection.

3. Scope

3.1. This policy is aimed at Endoscopists carrying out colonoscopies or flexible sigmoidoscopies at The Royal Cornwall Hospital NHS Trust (RCHT).

3.2. This policy does not cover lesions within the upper GI tract or small bowel.

4. Definitions / Glossary

- Anal: relating to the anus.
- Anatomical: pertaining to anatomy or to the structure of the organism.
- Biopsy: removal and examination, usually microscopic, of tissue from the living body.
- BSG: British Society of Gastroenterology.
- Cancer: Its two main characteristics are uncontrolled growth of the cells in the human body and the ability of these cells to migrate from the original site and spread to distant sites. If the spread is not controlled, cancer can result in death.
- Cecum: The cecum, about 6 cm in depth, lying below the terminal ileum, forming the first part of the large intestine.
- Colonoscopy: A procedure whereby a physician inserts a viewing tube (colonoscope) into the rectum for the purpose of inspecting the colon.
- Colonoscope: an instrument for examining the colon, consisting of a flexible lighted tube that is inserted in the colon to look for abnormalities and to remove them or take tissue samples.
- Distal: situated farthest from the centre, median line, or point of attachment. In gastroenterological terms the most distal point in the gut is the anus.
- Flexible sigmoidoscopy: visual examination (with a colonoscope) of the lower third of the colon.
- Lesion: A pathologic change in the tissues.
- Laparoscopic: A minimally invasive surgical or diagnostic procedure that uses a flexible endoscope (laparoscope) to view and operate.
- Photograph: An image, especially a positive print, recorded by exposing a photosensitive surface to light, especially in a camera.
- Quadrants: one fourth of the circumference of a circle.
- Rectum: the distal portion of the large intestine, beginning anterior to the third sacral vertebra as a continuation of the sigmoid and ending at the anal canal.
- Saline 0.9%: This solution of sodium chloride in sterile water (contains 154 mEq/L of Na+ and Cl-) create an oncotic gradient for expanding plasma volume.

- Spot Ex Endoscopic: sterile carbon black suspension for endoscopically tattooing the GI tract.
- Submucosa: A layer of loose connective tissue beneath a mucous membrane.
- Surgery: The performance or procedures of an operation.
- Tattoo: A deliberate decorative implanting or injecting of indelible pigments into the skin or the tinctorial effect of accidental implantation.

5. Ownership and Responsibilities

5.1. Duties within the organisation

The duties of the directors, committees, clinicians, healthcare and administrative staff with responsibility for managing the processes surrounding screening procedures are outlined below:

5.2. Role of the Managers

The following people are responsible for writing, updating and implementation of this policy:

- Clinical Endoscopist, drafted the policy.
- Consultant Gastroenterologist.
- Consultant Colorectal Surgeon, responsible for overseeing the writing and implementation of the policy.
- General Manager Specialist Services and Surgery Care Group General Manager, confirming approval processes.

5.3. Role of the Care group Triumvirate and Governance Manager

The Care Group Triumvirate and Governance Manager are responsible for:

- Quality Assurance, approval and communication of this policy and monitoring compliance and ensuring policy review.

5.4. All Staff members are responsible for:

- Being aware of this policy and any documents referred to within it pertaining to their part in the diagnostic pathway.
- Following the tattooing process as detailed in the summary table at the beginning of this policy and detailed in the Standards and Practice section of this policy.
- Adhering to any requirements described within this policy and documents described in the Standards and Practice section pertaining to their role n the diagnostic pathway.

6. Standards and Practice

6.1. Indications for Tattoo Placement During Colonoscopy

- All lesions ≥20mm and/or suspicious of cancer outside of rectum and caecum should undergo tattoo placement (BSG standard).
- Any lesion <20mm that is left in situ which may be difficult to find on subsequent examination can be considered for tattoo placement.

6.2. When Tattoos are not Required

- In general, lesions in the rectum (defined as <15 cm from the anal verge, or distal to the third valve of Houston) should not be tattooed as this can disrupt surgical dissection planes.
- For rectal lesions that are not tattooed, it is essential that the measurement from the inferior tumour border to the anal verge is carried out accurately and the distance from the anal verge recorded in the endoscopy report.
- Caecal lesions (including appendiceal and ileocaecal valve lesions) do not require tattoo placement, provided that anatomical landmarks have been defined with certainty and supported by photo documentation. A tattoo should be placed if there is doubt or if caecal completion landmarks cannot be clearly visualised.

6.3. Methodology and Technique

- India Ink (e.g. Spot Ex; Diagmed UK) is currently the recommended tattoo agent of choice at RCHT.
- A tattoo must never be injected directly into or underneath a lesion that might be endoscopically removed at a later point in time.
- Tattoos should be placed before suspected cancers are biopsied in order to avoid contamination of the endoscope channel with tumour cells and prevent seeding.
- The following technique is recommended for tattoo placement:
  - Direct the injection needle into the mucosa at an oblique angle (<45-degrees).
  - Create a submucosal bleb using 0.5-1ml of 0.9% saline.
  - Inject 0.5ml-1ml of tattoo ink into the submucosal bleb.
  - Repeat process as needed (for up to 3 tattoos).
- For suspected cancers (including high grade dysplasia), 3 or 4 tattoos should be placed 3-5cm distal (anal side) to the lesion in a four-quadrant circumferential method.

- For endoscopically resectable lesions ≥20mm or smaller lesions at risk of submucosal invasion, place one tattoo (or more if required) 3-5cm distal (anal side) to the lesion, ideally in line with the lesion.

- For endoscopically resectable lesions that are left in situ (including those <20mm), place one tattoo (or more if required) 3-5cm distal (anal side) to the lesion.

- If there is more than one lesion located in the same colonic segment that requires tattoo placement, the tattoo should be placed 3-5cm distal (anal side) to the most distal lesion.

6.4. Endoscopy Reporting Documentation

Endoscopy reporting documentation should include the following:

- For rectal lesions, length of insertion from the anal verge to the suspected lesion.

- The number of tattoos placed.

- Distance from lesion where tattoos have been placed.

- Location of the tattoo relative to the lesion (e.g. distal (or anal) end relative to lesion; same wall or opposite wall).

- Photo documentation of the lesion and tattoos, ideally with an accompanying image of the Scope Guide to localise the lesion.

6.5. Intraoperative Considerations

For surgeons, the following steps should be considered if there is doubt regarding the site of the bowel lesion intra-operatively, i.e. if the tattoo cannot be found, or if there are multiple tattoos:

- For rectal cancers which have not been tattooed, if the cancer is not apparent laparoscopically and not palpable on rectal examination, it may be necessary to perform an intra-operative flexible sigmoidoscopy.

- Intraoperative endoscopic assessment may also be necessary if there are multiple tattoos scattered throughout the colon and if there is uncertainty regarding tumour localisation.

- It may also be necessary to open the specimen and check the tumour has been resected prior to closing the abdomen, if there is uncertainty regarding tumour localisation.

6.6. Exclusions

- Overtly palliative patients, i.e. predefined non-operative candidates, are exempt from requiring tattoos. If in doubt, the policy should be followed.

- Where a tattoo has already been placed for the same lesion during a previous procedure.

7. Dissemination and Implementation

7.1. The policy will be shared at Gastroenterology and Hepatology Business and Governance Meeting and at the Surgical Business and Governance meeting.

- All endoscopists will have the policy emailed to them.
- A copy of the policy will be placed in each endoscopy room.

The endoscopy staff will be made aware of the new policy in a team brief by the endoscopy Sisters.

7.2. This policy has been reviewed and approved by the Bowel Cancer Screening Team at RCHT.

8. Monitoring compliance and effectiveness

Information Category	Detail of process and methodology for monitoring compliance
Element to be monitored	Compliance of tattoo placements according to policy. In previous policy (All elements of the policy required to be monitored).
Lead	Gastroenterology Governance Lead.
Tool	Audit of HICSS flexible sigmoidoscopy and colonoscopy reports that have recorded suspected cancers and polyps ≥20mm. **Numerator**: Number of patients with tattoo placed. **Exclusions:** Patients with overtly palliative intent (known to have extensive metastatic disease at time of colonoscopy). Lesions within the rectum or caecum (to include appendix and ileocaecal valve). Patients with previous tattoo placement for the same lesion. **Denominator:** All patients with cancer and polyps >20mm. **Audit target:** 100% (after exclusions) – BSG target.
Frequency	Initially the audit should be carried out 6 months after introduction of the policy then yearly. A report will be produced after each audit which will be shared at the relevant speciality governance meeting.

Information Category	Detail of process and methodology for monitoring compliance
Reporting arrangements	Any learning or improvement identified from the audit will be shared: • At the Care Board Meeting. • The Senior Management Team (SMT) weekly meeting. • The Gastroenterology and Hepatology Business and Governance meeting. • The General Surgical and Cancer Speciality meeting. • Via endoscopy team briefs.
Acting on recommendations and Lead(s)	According to the new policy, the endoscopy lead will be responsible for providing feedback to endoscopists.
Change in practice and lessons to be shared	The endoscopy lead will be responsible for discussing further training of endoscopist if required.

9. Updating and Review

9.1. This policy will be reviewed after 3 years or if the BSG develop guidelines on the same topic.

9.2. Revisions can be made ahead of the review date when the procedural document requires updating. Where the revisions are significant and the overall policy is changed, the author should ensure the revised document is taken through the standard consultation, approval and dissemination processes.

9.3. Where the revisions are minor, e.g., amended job titles or changes in the organisational structure, approval can be sought from the Executive Director responsible for signatory approval, and can be re-published accordingly without having gone through the full consultation and ratification process.

9.4. Any revision activity is to be recorded in the Version Control Table as part of the document control process.

10. Equality and Diversity

10.1. This document complies with the Royal Cornwall Hospitals NHS Trust service Equality and Diversity statement which can be found in the Equality Diversity And Inclusion Policy or the Equality and Diversity website.

10.2. Equality Impact Assessment

The Initial Equality Impact Assessment Screening Form is at Appendix 2.

Appendix 1. Governance Information

Information Category	Detailed Information
Document Title:	Tattoo Placement during Colonoscopy and Flexible Sigmoidoscopy Policy V2.0.
This document replaces (exact title of previous version):	Tattooing Suspected Cancers within Endoscopy Policy V1.0.
Date Issued / Approved:	December 2023
Date Valid From:	March 2024
Date Valid To:	March 2027
Author / Owner:	Keith Siau, Consultant Gastroenterologist.
Contact details:	07407 261341
Brief summary of contents:	Tattoo placement during colonoscopy.
Suggested Keywords:	Tattoo, Endoscopy.
Target Audience:	**RCHT:** Yes **CFT:** No **CIOS ICB:** No
Executive Director responsible for Policy:	Chief Medical Officer
Approval route for consultation and ratification:	Speciality Governance Meetings.
Manager confirming approval processes:	Roz Davis
Name of Governance Lead confirming consultation and ratification:	Maria Lane.
Links to key external standards:	None required.
Related Documents:	a. Rees CJ, Thomas Gibson S, Rutter MD et al, UK key performance indicators and quality assurance standards for colonoscopy, *Gut* 2016;**65:**1923-1929. b. Medina-Prado L, Hassan C, Dekker E, et al. When and how to use endoscopic tattooing in

Information Category	Detailed Information
	the colon: an international Delphi agreement, Clin Gastroenterol Hepatol. 2021 May;19(5):1038-1050. c. SIGN 126, Diagnosis and management of colorectal cancer, 2011 d. Case of the month: December 2020 - getting inked (thejag.org.uk); Accessed 29th December 2023 e. Backes Y, Seerden TCJ, van Gestel RSFE, et al. Tumor seeding during colonoscopy as a possible cause for metachronous colorectal cancer. Gastroenterology. 2019;157(5):1222-1232.
Training Need Identified:	No.
Publication Location (refer to Policy on Policies – Approvals and Ratification):	Internet and Intranet
Document Library Folder/Sub Folder:	Clinical / Gastroenterology.

Version Control Table

Date	Version Number	Summary of Changes	Changes Made by
April 2020	V1.0	Initial issue	Katharine Todd, Clinical endoscopist
January 2024	V2.0	Title change, Flowchart replaced by summary of recommendation table. Further edits to include polyps <20mm and photo documentation.	Keith Siau, Consultant Gastroenterologist

All or part of this document can be released under the Freedom of Information Act 2000

All Policies, Strategies and Operating Procedures, including Business Plans, are to be kept for the lifetime of the organisation plus 6 years.

This document is only valid on the day of printing.

Controlled Document

This document has been created following the Royal Cornwall Hospitals NHS Trust The

Policy on Policies (Development and Management of Knowledge Procedural and Web Documents Policy). It should not be altered in any way without the express permission of the author or their Line Manager.

Appendix 2. Equality Impact Assessment

Section 1: Equality Impact Assessment (EIA) Form

The EIA process allows the Trust to identify where a policy or service may have a negative impact on an individual or particular group of people.

For guidance please refer to the Equality Impact Assessment Policy (available from the document library) or contact the Equality, Diversity, and Inclusion Team rcht.inclusion@nhs.net

Information Category	Detailed Information
Name of the strategy / policy / proposal / service function to be assessed:	Tattoo Placement during colonoscopy and Flexible Sigmoidoscopy V2.0.
Department and Service Area:	Endoscopy, Specialist Services and Surgery.
Is this a new or existing document?	Existing.
Name of individual completing EIA (Should be completed by an individual with a good understanding of the Service/Policy):	Keith Siau, Consultant Gastroenterologist.
Contact details:	07407 261341

Information Category	Detailed Information
1. Policy Aim - Who is the Policy aimed at? (The Policy is the Strategy, Policy, Proposal or Service Change to be assessed)	Any member of staff that carries out tattooing of lesions during endoscopies.
2. Policy Objectives	Standardised the way in which we Tattoo lesions that are suspected cancers or >20mm.
3. Policy Intended Outcomes	Standardised the way in which we Tattoo lesions that are suspected cancers or >20mm.
4. How will you measure each outcome?	Audit information recorded in Scorpio documents.
5. Who is intended to benefit from the policy?	Patients with suspected cancers in the colon and lesions >20mm.

Information Category	Detailed Information
6a. Who did you consult with? (Please select Yes or No for each category)	• Workforce: Yes • Patients/ visitors: No • Local groups/ system partners: Yes • External organisations: No • Other: No
6b. Please list the individuals/groups who have been consulted about this policy.	**Please record specific names of individuals/ groups:** • Clinical Governance Lead for Gastroenterology. • Consultant Lead for Endoscopy. • Consultant Speciality Lead for Elective Gastrointestinal Surgery (G.I). • Consultant Speciality Lead for 2 Week Wait Cancer Services.
6c. What was the outcome of the consultation?	Approved.
6d. Have you used any of the following to assist your assessment?	**National or local statistics, audits, activity reports, process maps, complaints, staff, or patient surveys:** N/A.

7. The Impact

Following consultation with key groups, has a negative impact been identified for any protected characteristic? Please note that a rationale is required for each one.

Where a negative impact is identified without rationale, the key groups will need to be consulted again.

Protected Characteristic	(Yes or No)	Rationale
Age	No	
Sex (male or female)	No	
Gender reassignment (Transgender, non-binary, gender fluid etc.)	No	
Race	No	
Disability (e.g. physical or cognitive impairment, mental health, long term conditions etc.)	No	

Protected Characteristic	(Yes or No)	Rationale
Religion or belief	No	
Marriage and civil partnership	No	
Pregnancy and maternity	No	
Sexual orientation (e.g. gay, straight, bisexual, lesbian etc.)	No	

A robust rationale must be in place for all protected characteristics. If a negative impact has been identified, please complete section 2. If no negative impact has been identified and if this is not a major service change, you can end the assessment here.

I am confident that section 2 of this EIA does not need completing as there are no highlighted risks of negative impact occurring because of this policy.

Name of person confirming result of initial impact assessment: Keith Siau, Consultant Gastroenterologist.

If a negative impact has been identified above OR this is a major service change, you will need to complete section 2 of the EIA form available here:
Section 2. Full Equality Analysis