

Safety Incident Management Team Report for NIMLT Case 50796

Final Report
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Feidhmeannacht na Seirbhíse Sláinte
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1. Introduction

This is a report on the management of a patient safety incident involving BowelScreen and symptomatic colonoscopy services at Wexford General Hospital (WGH). The patient safety incident relates to the work of a Consultant Endoscopist (referred to as Clinician Y) employed by WGH who undertook screening colonoscopies on behalf of the BowelScreen Programme since the commencement of the screening programme in WGH in March 2013. Clinician Y also performed non-screening colonoscopies for the diagnosis of symptomatic patients as part of routine surgical service provision at WGH.

The management of the patient safety incident was in accordance with the HSE Safety Incident Management Policy with particular reference to the HSE Guidelines for the Implementation a Look-back Review Process in the HSE (1-3).

Current guidance outlines a three phase approach to the conduct of a look-back; i.e. risk assessment; audit of records to identify those potentially affected; and patient recall. HSE Safety Incident Management Policy also provides for systems analysis investigation of incidents to establish the factual circumstances leading up to the incident and identify the key causal and contributory factors associated with it.

2. Background

2.1 Colonoscopy Services in Ireland

Endoscopy is a minimally invasive procedure which involves examining the inside of a person's body using a medical device known as an endoscope. An endoscope is a long thin fibre-optic tube which has a light and video camera at the end and transmits images to a screen. There are multiple types of endoscopy depending on which part of the body is being examined. Colonoscopy is used for examination of the colon, otherwise known as the large or lower intestine.

A screening colonoscopy is a preventive test for people who do not have any symptoms or family history of colorectal cancer. Diagnostic colonoscopy is a diagnostic test for people who have symptoms or a strong family history of colorectal cancer.

Both the screening and diagnostic colonoscopy services use the term surveillance colonoscopy. A surveillance colonoscopy is performed on patients who do not have signs or symptom of disease but who do have a personal history of colon cancer/ polyps and other gastrointestinal diseases. A surveillance colonoscopy can be performed on patients of varying ages and intervals based on the patient's history.

In Ireland, screening colonoscopy accounts for 3-4% of colonoscopies undertaken in HSE/HSE funded hospitals.

2.2 National Screening Service and BowelScreen Programme

The National Screening Service (NSS) is the national service responsible for the planning and delivery of screening services in Ireland. The National Screening Service (NSS) encompasses BreastCheck - The National Breast Screening Programme, CervicalCheck - The National Cervical Screening Programme, BowelScreen – The National Bowel Screening Programme and Diabetic RetinaScreen – The National Diabetic Retinal Screening Programme.

The introduction of colorectal screening (the BowelScreen programme) has been a major advance in the management of colorectal cancer in Ireland. Between 2013 and August 2016, the BowelScreen programme had invited 611,135 people for screening and 251,865 had completed home testing. 9,045 index screening colonoscopies had been conducted and 13,424 people had adenomas removed and 410 people were diagnosed with colon or rectal cancer.

2.3 Screening Process

A home test (Immunochemical Faecal Occult Blood (FIT) test kit) is offered to women and men aged 60 to 69 every two years. This test can detect minute levels of blood in the stool and is therefore used to select the group of patients who may be at a higher risk of pre-cancerous growths and cancers in the colon. Patients with positive FIT tests are then sent to one of 14 screening colonoscopy units to undergo a screening colonoscopy. The BowelScreen programme is the first population based screening programme to use the FIT test.

Colonoscopy is the main diagnostic test used to identify colorectal cancer. The quality standards of colonoscopy practice include key performance indicators (KPIs) such as caecal intubation rate (CIR), adenoma detection rate (ADR) and post-colonoscopy colorectal cancer (PCCRC).

A colonoscopy is not 100% accurate. Some individuals may undergo a colonoscopy which is negative for cancer but subsequently be diagnosed with cancer, i.e. Post-colonoscopy Colorectal Cancer (PCCRC). These are sometimes referred to as interval cancers in the context of screening programmes. The colorectal screening committee of the World Endoscopy Organisation has proposed a definition of an interval cancer as a "*colorectal cancer diagnosed after a screening or surveillance exam in which no cancer is detected, and before the date of the next recommended exam*" (4). It is acknowledged that "*Colorectal cancers (CRCs) diagnosed within a few years after an index colonoscopy can arise from missed lesions or the development of a new tumour*" (5).

2.4 Wexford General Hospital and BowelScreen

Wexford General Hospital (WGH) is a 242-bed Model 3 hospital which provides acute hospital services to the population of Wexford and parts of Waterford and Wicklow. Ely Hospital, formerly a private hospital, is a small satellite hospital which is under the direct governance and management of WGH and located approximately 3 km from WGH. Endoscopy services at WGH are bi-located with one endoscopy suite each at the WGH and Ely sites. In accordance with

BowelScreen requirements, it is internationally accredited; having been assessed and approved by the UK based Joint Advisory Group on GI Endoscopy (JAG).

Following their acceptance as a screening site by the NSS, a Memorandum of Understanding (MOU) (Appendix 1) was developed and agreed between BowelScreen and WGH before screening commenced at that site. The MOU contains a number of Key Performance Indicators (KPIs) based *Guidelines for Quality Assurance in Colorectal Screening First Edition* (6) which were published prior to programme establishment. The first screening colonoscopies were carried out in WGH on the 5th of March 2013.

2.5 Incident

The BowelScreen programme was informed on October 8th 2014 of a recently diagnosed case of caecal cancer, who had undergone a screening colonoscopy in April 2013 at WGH. The notification was made by the Consultant Surgeon, not attached to WGH, who had performed the cancer surgery. In accordance with the MOU between WGH and BowelScreen, WGH were informed of the case and requested to undertake an immediate case review¹.

A second case of caecal cancer in a patient screened in June 2013 was notified by the BowelScreen Clinical Lead at WGH to management there on October 22nd 2014. The WGH BowelScreen Clinical Lead also informed the BowelScreen programme at that time. He performed cancer surgery on that patient in October 2014. BowelScreen then requested WGH to undertake a second case review.

BowelScreen also reviewed KPIs for WGH at that time and found them to be acceptable. The adenoma detection rate at WGH was 35.3% which exceeded the upper limit of the BowelScreen quality assurance (QA) standard of 25-35%. All screening units in the country exceeded the QA standard which ranged from 35.3% to 65.1% when analysed in November 2014 at a time when numbers screened permitted such analysis.

¹ Standard MOU in place for all BowelScreen screening sites.

Both patients had been screened by the same endoscopist (Clinician Y). Clinician Y's adenoma detection rate was 26.56%; this was within the BowelScreen quality assurance (QA) standard of 25-35%. Agreement was reached between WGH, BowelScreen and Clinician Y on November 13th 2014 that Clinician Y would cease performing BowelScreen colonoscopies until the reviews of the cases were undertaken and completed. Clinical governance arrangements were put in place by WGH and Clinician Y continued to perform colonoscopy on symptomatic patients under clinical supervision.

In agreement with BowelScreen, the BowelScreen Clinical Lead at WGH also reviewed all BowelScreen colonoscopy reports since the programme commenced. This was completed in December 2014 and revealed the absence of evidence (i.e. photograph) that the caecum was reached in approximately 30% of Clinician Y's screening colonoscopies. The colonoscopy records of the two cancer cases that prompted the review did not contain a photograph of the caecum either. No issues were detected with the work of other endoscopists at WGH. BowelScreen was informed of these findings on December 16th 2014. A repeat (validation) audit of the same records was completed by the BowelScreen Clinical Director on 7th and 8th of January 2015 and the findings were consistent.

Clinician Y does not accept these findings and has reported a caecal intubation rate of 91%, from data gathered in WGH in 2013.

The SIMT does not accept this rate because when the BowelScreen colonoscopies were reviewed following the notification of two cancers, the caecal intubation rate for Clinician Y's BowelScreen colonoscopies was calculated to be 71%. Two independent reviewers arrived at this rate, on the basis that either photos were not taken, or were not adequate in 118 patients' records.

2.6 Risk Assessment

The two case reviews and the findings of the audit of BowelScreen colonoscopy records were reviewed by the BowelScreen Clinical Advisory Group² on January 5th 2015. They advised that all BowelScreen patients scoped by Clinician Y whose records did not contain evidence that the caecum was visualised ought to be recalled for a precautionary repeat colonoscopy. This recommendation was endorsed by the BowelScreen Executive Management Team (EMT)³ on January 8th 2015.

2.7 Safety Incident Management Team (SIMT)

The incident was escalated to the National Incident Management and Learning Team (NIMLT) of the HSE on Friday 16th January 2015. A cross-divisional meeting of senior management was held on Tuesday 20th January to discuss the incident and a look-back authorised.

A Safety Incident Management Team (SIMT) was jointly commissioned by the National Directors of Health & Wellbeing and Acute Services on Friday 23rd January 2015 and an investigation ensued in accordance with the HSE Safety Incident Management Policy (1-3).

The Terms of Reference (TOR) (Appendix 2), SIMT and sub-group membership (Appendix 3) were agreed and procedural guidance developed to ensure a consistent approach for the appropriate conduct of the recall (Appendix 4). The SIMT and clinical sub-group meeting schedule is appended (Appendix 5).

² Membership of the BowelScreen Clinical Advisory Group: Prof Diarmuid O'Donoghue, Prof Padraic MacMathuna, Mr Richard Stephens, Dr Alan Smith, Dr Martina Morrin (not in attendance on that day), Prof Kieran Sheahan (not in attendance on that day).

³ Membership of the Executive Management Team (EMT): Ms Majella Byrne, Mr Simon Murtagh, Ms Sheila Caulfield, Ms Gillian O'Connor, Prof Diarmuid O'Donoghue, Dr Alan Smith.

3. Look-back Review Methodology

Once established the SIMT sought assurance on all other⁴ colonoscopies performed by Clinician Y. Management at WGH therefore commissioned a peer-review audit of charts of symptomatic patients who had undergone colonoscopy. The methodology was based on that employed by BowelScreen for the earlier audit of BowelScreen colonoscopies.

Patients (along with their families and treating clinicians) whose cases were being reviewed were informed about the review before any other external communication issued (3). In accordance with HSE look-back guidance, the SIMT deferred posting recall letters to BowelScreen patients until the audit (of charts of Clinician Y's symptomatic patients who had undergone colonoscopy) was completed and all those affected by the incident could be identified and recalled together. The SIMT received clinical advice that the time period involved would not compromise the clinical management of patients.

Throughout the look-back review process every effort was made to ensure sensitive and clear communication with patients, and to provide sufficient funding and expert support to optimise the patient experience.

The two index cases were met with for open disclosure in advance of the look-back. Their permission was also sought to conduct systems analysis investigation of their cases.

3.1 Peer-review Audit of Charts of Clinician Y's Symptomatic Patients who had undergone Colonoscopy and NCHD colonoscopies

A peer review audit of charts of Clinician Y's symptomatic patients who had undergone colonoscopy was undertaken on February 4th and 5th 2015 and the report was made available on Tuesday 10th 2015. The audit was conducted by two Consultant Colo-rectal Surgeons from another hospital. The auditors

⁴ In addition to BowelScreen colonoscopies already reviewed.

recommended recall of 163 patients to the outpatients department (OPD) to determine which patients would require repeat colonoscopy⁵.

Clinician Y was informed of the audit but he was not invited to review the audit findings before they were provided to the SIMT in advance of patient recall.

3.2 Phase 1 Recall

Phase 1 recall letters were posted on Friday February 13th 2015. Pre-assessment phone calls for colonoscopy commenced on February 16th 2015. Colonoscopy appointments were offered from February 23rd 2015 onwards. OPD appointments were scheduled between February 18th 2015 and March 6th 2015⁶. Ultimately scheduling was determined by patients' personal preference and availability. OPD and colonoscopy appointments were available to all patients within a three week time period. 77% of BowelScreen patients had their recall colonoscopy within one month of contact (Figure 1).

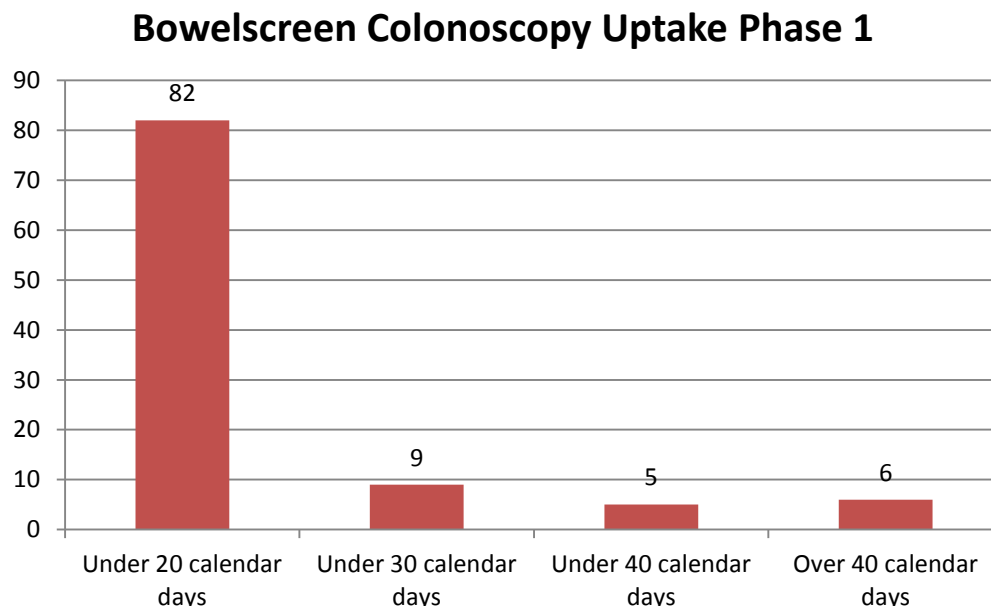


Figure 1: BowelScreen Colonoscopy Appointment Uptake Phase 1⁷

⁵ 6 patients were recommended for individualised follow-up plans outside OPD follow-up.

⁶ Appointments were offered to those unable to attend at short notice for up to six weeks.

⁷ Based on 86% uptake of phase one offer of colonoscopy.

Over the course of phase 1 of the recall it was confirmed that Clinician Y was responsible for the supervision of a small number of endoscopies performed by Non-Consultant Hospital Doctors (NCHDs)⁸. The files of 55 patients in which Clinician Y was the secondary endoscopist (i.e. trainer /supervisor of an NCHD, trainee endoscopist) were also included in the audit by the team that completed the audit of charts of Clinician Y's symptomatic patients who had undergone colonoscopy. The SIMT instructed that these patients were recalled to OPD simultaneously with all other Phase 1 patients.

3.3 Phase 1 Recall Findings

Phase one patients were selected for recall because, like the index cases, their endoscopy records did not contain a photograph to demonstrate that the caecum had been visualised at colonoscopy. These patients were therefore thought to be at risk of having an unidentified caecal cancer.

There were no cancers identified among the Clinician Y's symptomatic patients who had undergone colonoscopy and were recalled (n=165). However, four cancers were identified among the BowelScreen cohort of patients (n=118) during Phase 1 of the recall. All four of the cancers identified were anatomically located outside the caecum.

The Chair of the SIMT requested the clinical sub-group of the SIMT (which included some members of the BowelScreen Clinical Advisory Group) to review the risk assessment in the context of four non-caecal bowel cancers having been diagnosed during phase 1 of the recall.

3.4 Revised Risk Assessment

The clinical sub-group of the SIMT met on March 31st 2015 to review interim recall findings and revise the risk assessment. They recommended repeat colonoscopy for all BowelScreen patients who had a BowelScreen colonoscopy performed by Clinician Y who had not already been recalled (see Table 1). Likewise, the team

⁸ Cohort identification was based on the electronic endoscopy patient management system. This initially only identified colonoscopies in which Clinician Y was the primary endoscopist.

that completed the audit of charts of Clinician Y’s symptomatic patients who had undergone colonoscopy agreed that NCHD and symptomatic cases who had not been recalled because there was evidence that the caecum had been visualised, should now also be offered OPD appointments (see Table 1).

The SIMT met on April 2nd 2015 to plan Phase 2 of the recall on foot of those recommendations.

3.5 Phase 2 Recall

Recall letters issued to Phase 2 patients and their GPs on Friday April 24th 2015. Liaison nurses began pre-assessment telephone calls for colonoscopy on Tuesday April 28th 2015 to schedule appointments from May 5th 2015 onwards. Earlier appointments were available on request. Based on clinical advice, a four to six week target was set, for completion of Phase 2 of the recall. 79% of patients had their recall colonoscopy within one month of contact (Figure 2). Scheduling of Phase 2 of the recall was also determined by patients’ personal preference and availability.

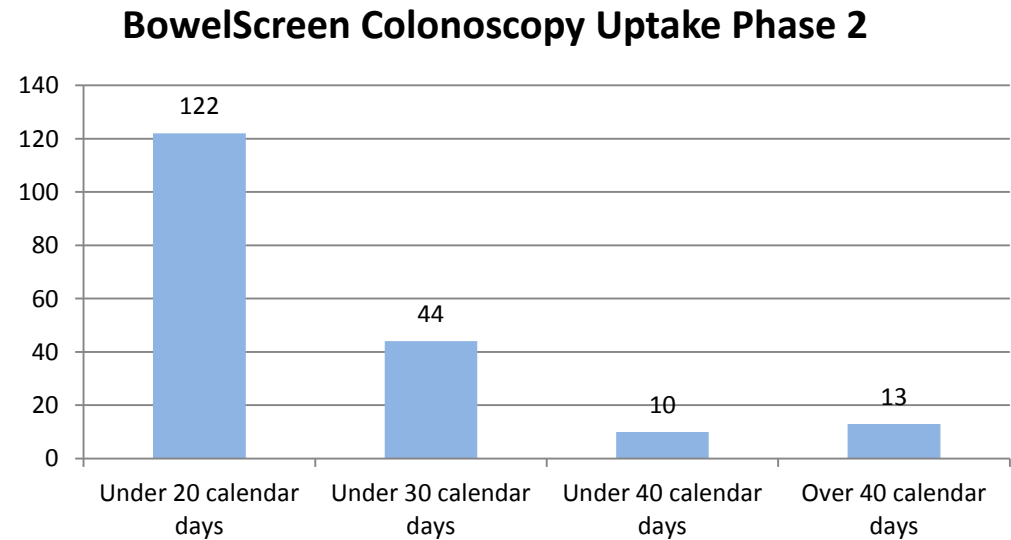


Figure 2: BowelScreen Colonoscopy Uptake Phase 2⁹

⁹ Based on 90% uptake of phase 2 offer of colonoscopy.

3.6 Recall Summary

The incident involved a look-back review process and the recall of 615 patients either for repeat colonoscopy or an outpatient's appointment. The number of patients recalled in each phase, including colonoscopy attendance, is detailed in Table 1, while the chronology of the incident is summarised in Table 2.

Table 1: Recall Summary

	Audit Cohort	Recall OPD	Recall Colonoscopy
Phase 1: Screening (n=118)	384	N/A	118
Phase 1: Symptomatic	320	165	49/165
Phase 1: NCHD	55	30	10/30
Phase 2: Screening (n=211)	Audited pre Phase 1 (i.e. n=384)	N/A	211
Phase 2: Symptomatic	Audited pre Phase 1 (i.e. n=320)	68	13/91
Phase 2: NCHD	Audited pre Phase 1 (i.e. n=55)	23	
PATIENTS RECALLED	615		
COLONOSCOPY RECALL	401		
DNA COLONOSCOPY	37		
ATTENDED COLONOSCOPY	364		

Table 2: Look-back Chronology

Date	Event	Phase	Team
October 8 th 2014	Notification of Cancer Case No 1		NSS/WGH
October 22 nd 2014	Notification of Cancer Case No 2		NSS/WGH
October 2014	NSS Request WGH to review cases as per MOU		NSS/WGH
13 th November 2014	Clinician Y agreed to stand down from BowelScreen		NSS/WGH
16 th December 2014	WGH inform NSS of problems re documentation of completion of colonoscopy	Preliminary Risk Assessment	NSS/WGH
5 th Jan 2015	BowelScreen Clinical Advisory Group (CAG) Recommends Recall		NSS
8 th Jan 2015	BowelScreen Executive Management Team (EMT) endorses recall		NSS
8 th & 9 th Jan 2015	NSS Independent Review of Colonoscopy records		NSS
15 th Jan 2015	BowelScreen EMT review status, agree recall required and escalation required.		
16 th January 2015	NIMLT escalation		NSS/ H&WB
23 rd January 2015	SIMT Commissioned		H&WB/AH
26 th January 2015	Systems Analysis for index cases 1 & 2 requested at first SIMT meeting		SIMT
4 th & 5 th Feb 2015	Audit of charts of Clinician Y's symptomatic colonoscopy patients	Phase 1 Recall	Commissioned Experts
11 th & 18 th Feb 2015	Open Disclosure with index cases and permission for Systems Analysis		WGH
13 th Feb 2015	Recall letters Issued		SIMT NSS/WGH
16 th Feb 2015	Colonoscopy Pre-assessment Start Date & Clinician Y ceases all colonoscopy		NSS
23 rd Feb-13 th March 2015	BowelScreen recall colonoscopies		Ireland East Hospital Group
18 th Feb- 6 th March 2015	Symptomatic Patient's OPD		WGH
18 th March 2015	NCHD Audit		Commissioned Experts
1 st & 8 th March 2015	NCHD OPD		WGH & Commissioned Experts
Priority Apts Post OPD	NCHD recall colonoscopies		WGH
31 st March 2015	Revised Risk Assessment		Clinical sub-group/ Commissioned Experts
3 April 2015	Validation of all remaining screening records of Clinician Y commenced		NSS
23 rd April 2015	Notification to Medical Council		Executive Management WGH
24 th April 2015	Phase 2 Recall letters Issued		SIMT NSS/WGH
28 th April 2015	Colonoscopy Pre-assessment Start Date	Phase 2 Recall	NSS
May 5 th – June 12 th 2015	BowelScreen recall colonoscopies		Ireland East Hospital Group
May 6 th 2015	NCHD/Symptomatic Patients OPD		WGH & Commissioned Experts
July 2015	98% Recall Completion		
March 2016	100% Recall Completion		
Sept 2016	First Draft SIMT Report		
Oct 2016- Jan 2017	SIMT Report Completion following due process		
December 2016	Systems Analysis Completion following due process		
January 2017	Report Publication		

4. Outcomes

4.1 Adverse Events

In the management of this incident, 13 cancers were detected in a population of 384 patients who had their first screening colonoscopy performed by Clinician Y during the period March 5th 2013 to November 7th 2014, Two cases prompted the recall, four cases were identified in phase 1, two cases presented independently during phase 1, four cases were identified in phase 2 and one case was identified at a planned surveillance colonoscopy of a high risk patient¹⁰ (Table 3). The clinical sub-group has categorised all 13 post-colonoscopy colorectal cancers (PCCRC) as presumed missed cancers.

Table 3: Adverse Outcomes

Project Code	Gender	Months between Screening and Recall Colonoscopy or Diagnosis ¹¹	Site of CRC
IC No 1	M	16	Right Colon
IC No 2	M	15	Right Colon
Phase 1/ No 3	M	24	Rectal
Phase 1/ No 4	F	17	Rectal
Phase 1/ No 5	M	22	Transverse colon
Phase 1/ No 6	F	23	Descending Colon
IC/ No 7	M	3	Splenic Flexure
IC/ No 8	M	23	Rectal
Phase 2/ No 9	M	22	Transverse colon
Phase 2/ No 10	F	14	Right Colon
Phase 2/ No 11	M	8	Descending Colon
Phase 2/ No 12	M	14	Sigmoid colon
IC/ No 13	F	13	Sigmoid colon

¹⁰ The patient was put on annual surveillance by Clinician Y after the first screening colonoscopy.

¹¹ IC1, IC2, IC7, IC/8 and IC/13 were not part of the recall cohort.

Nomenclature

Interval Cancer = IC

Original two index interval cancer cases notified to BowelScreen
Cancer cases detected during phase 1 of recall (n=118)
Two further interval cases notified to BowelScreen simultaneously with phase 1 (n=118) but outside that element of the recall
Cancer cases detected during phase 2 of the recall (n= 211)
Interval Cancer detected at a scheduled 1 year recall of a high risk patient

4.2 Altered Treatment Plans

In addition to those patients diagnosed with cancer, a number of patients were referred for surgical removal of polyps (subsequently found to be benign on histology) or were placed on appropriate surveillance determined by the number and size of adenomas removed during their recall colonoscopy.

In the conduct of phases 1 and 2 of the recall; 67 BowelScreen patients were placed on colonoscopy surveillance or had their surveillance status altered.

None of the patients from the NCHD and symptomatic cohorts were diagnosed with cancer; however, in the conduct of phases 1 and 2 of the recall, 61 patients from the NCHD and symptomatic cohorts were placed on colonoscopy surveillance or had their surveillance status altered.

5. Clinician Y

Clinician Y is employed at WGH as a full-time permanent consultant and is on the specialist register of the Irish Medical Council. Since his entry on the Specialist Register he has attended a number of specialist training sessions and has been involved in the clinical governance of the endoscopy unit at WGH; e.g. development of guidelines for JAG accreditation.

Agreement was reached between WGH, BowelScreen and Clinician Y on November 13th 2014 that Clinician Y would cease performing BowelScreen colonoscopies until the first two case reviews were completed. Clinical governance

arrangements were put in place by WGH and Clinician Y continued to perform colonoscopy on symptomatic patients under clinical supervision. Clinician Y agreed to stand down from all colonoscopy work on Monday February 16th 2015. This was by mutual agreement between WGH management and Clinician Y. Clinician Y voluntarily remained on leave during the investigation process and has participated and co-operated with all personnel involved in the management of this incident.

Clinician Y was supported by an independent expert in providing feedback to this report. Clinician Y has drawn attention to international literature regarding Interval cancers and post colonoscopy colorectal cancers (PCCRC) and the technical difficulties associated with detection of bowel cancers depending on factors such as size, and anatomical location of tumours. The SIMT is in agreement that PCCRC are a feature of bowel screening and endoscopy services internationally. In the context of a screening programme *“Interval cancers are those that occur following a negative screening episode, in the interval before the next invitation to screening is due”* (7).

Studies have shown that rates vary depending on the methods employed and the population studied (4). The SIMT also acknowledges that a PCCRC rate had not been calculated for the Irish population at the time of this incident, as the incident occurred in the first round of the BowelScreen programme, at which stage there was insufficient data to perform such an analysis. The clinical sub-group of the SIMT in collaboration with a Consultant Gastroenterologist from the UK undertook a statistical modelling exercise in April 2015, as the recall progressed to Phase 2; i.e. seven cancers amongst screening colonoscopies performed, to estimate the number of colonoscopies that would need to be performed to generate the number of cancers at the level identified in this incident (Appendix 6).

The clinical sub-group considered both the level and nature of the cancers being identified and notwithstanding methodological limitations, concluded that *“Even under the circumstances of the highest PCCRC rate [for the population] of 8.6% modelled here, a total of 7 missed cancers ... is significantly higher than would be expected”* (Appendix 6).

These findings were conveyed to management at WGH who notified the Medical Council of the incident on April 23rd 2015.

The analysis was updated in September 2015 (Appendix 6). Based on the identification of 13 cancers it was estimated that over 3,000 screening colonoscopies would need to have been undertaken. Clinician Y undertook 384 screening colonoscopies.

Clinician Y does not accept this analysis. He has referred to his cancer detection rate of 2.54% which was within the Key Performance Indicator range of 2. ->/=5 per 1000 screened. Clinician Y has also stated that his PCCRC falls within acceptable limits. The SIMT has considered this matter. The purpose of the statistical modelling exercise employed in this incident was first and foremost to assist the Clinical Advisory Group in answering the question “how often should the programme incur one missed cancer (PCCRC) amongst BowelScreen colonoscopists given two known fixed variables (1) the cancer detection rate in BowelScreen colonoscopies (4.2% at time of analysis) and (2) internationally published PCCRC rates ranging from 2.5% to 8.6% The SIMT is satisfied that the calculation methods are accurate and justify the Clinical Advisory Groups opinion that PCCRCs exceed what would be typically expected.

6. Incident Management; Logistical Challenges and Learning Points

Look-backs of their nature pose logistical challenges. Several features of this look-back added to its complexity:

- It involved cancer diagnosis which is of major clinical significance
- The recall process involved additional invasive tests which required accurate identification of patient, clinical/screening record validation followed by telephone pre-assessment and scheduling of procedure
- It involved a high volume of patients

- Endoscopy is a high-demand service and is closely monitored for exceedances in waiting times for urgent and non-urgent colonoscopies for symptomatic patients
- Governance of the incident crossed two HSE directorates and a newly established hospital group.

Consequently, there are many important learning points that arise from the management of this look-back in regard to administrative, investigative and clinical processes required for effective incident management.

6.1 Assessing Performance

BowelScreen quality assurance guidelines state: *“A process for dealing with suboptimal performance and mechanisms will be in place for the screening programme. The local clinical lead/director will be the individual managing compliance with QA guidelines for all colonoscopists and will, in the first instance, address non-compliance issues. Endoscopists who fail to achieve agreed standards after an implementation plan has been agreed will have their practice reviewed by the hospital clinical governance risk committee/endoscopy lead clinician and the NCSS as appropriate” (6)*¹².

Endoscopist performance varies and consequently so too do patient outcomes (8-11). The difficulty in linking true patient outcomes and individual performance is acknowledged in European guidelines for quality assurance in colorectal cancer screening (7). However, those guidelines also specify that if there are concerns about performance, or if there is a desire to assess competence prior to participation in a screening programme, it is possible to assess knowledge and skills-based competencies in addition to reviewing key performance indicators (7, 12)¹³. To that end the UK Bowel Cancer Screening Programme introduced an accreditation process an objective of which is *“to ensure that patient safety is paramount and the continued high standards of the Bowel Cancer Screening Programme are maintained” ... Aspirant screening colonoscopists undertake a summative assessment of knowledge and skills to test their competencies. A*

¹² Pp49 Section 5.5 Failure to meet agreed quality standards.

¹³ Pp166.

failure by an accredited BCSP colonoscopist to reach national standards, or provide the required data returns, may result in a series of possible sanctions”(13).

There is a need to strengthen the clinical and executive governance structures to assess, monitor and manage performance endoscopy services in Ireland including BowelScreen.

The International Peer Review Panel Report of Quality Assurance Standards published in March 2011 considered the generic issue of accreditation of endoscopists to be beyond the remit of the screening service (14). The panel stated that:

- The endoscopy service in association with professional bodies must develop a competency framework/mechanism.
- The Royal College of Physicians of Ireland and the Royal College of Surgeons of Ireland should play a central and leading role in developing such a framework.
- A number of challenges will arise including identifying an appropriate accreditation test, defining how the process will work and critically dealing with poor performance(14)¹⁴.

The recently established HSE Acute Hospital Division (AHD) Endoscopy Programme is progressing matters in regard to clinical governance of endoscopy services and endoscopy training in Ireland (see 6.12 Wider Endoscopy Services).

6.2 Adenoma Detection Rate

BowelScreen in the first population based screening programme to use FIT testing, therefore, there was not an international benchmark against which the ADR could be set. BowelScreen set the quality assurance (QA) standard for ADR at 25-35%, based on expert analysis of the literature and available data.

The BowelScreen adenoma detection rate at WGH was 35.3% and just exceeded the BowelScreen QA standard of 25-35%. All screening units in the country exceeded the QA standard which ranged from 35.3% to 65.1% when analysed in

¹⁴ Pp8, Section 3.8.

November 2014. Clinician Y's adenoma detection rate was 26.56%, this was within the normal range.

At the onset of this incident, BowelScreen calculated the ADR for each unit. Information on individual ADR performance is being calculated as a KPI by BowelScreen since December 2014.

6.3 Notification of Interval Cancers

The first cancer case in this incident was notified to BowelScreen by a surgeon operating in a private hospital and the second was notified to the BowelScreen Clinical Lead at WGH by a surgeon operating in a HSE hospital. Publicity surrounding the incident prompted a surgeon in another HSE hospital to notify a third cancer case in a BowelScreen patient to a clinical colleague in WGH¹⁵.

Following this incident BowelScreen wrote to designated cancers centres alerting them to the possibility of cancers being diagnosed through the symptomatic service in 60-69 year olds who may have participated in BowelScreen. Cancer centres and specifically members of Gastro Intestinal (GI) Cancer Multi-disciplinary Meetings (MDM) have been asked to check if newly diagnosed colorectal cancer cases have participated in the BowelScreen programme and to notify BowelScreen of any suspected interval cancers. In such circumstances the Clinician should seek the consent of the patient to contact BowelScreen and obtain the screening record. BowelScreen believed that alerting Cancer Centres to the possibility of an interval cancer would supplement the cancer registry/BowelScreen data linkage for the reporting of interval cancers.

In the context of a cancer screening programme; an interval cancer is 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 (4). These can include cases missed at the original screening test, they may be not visible at the screening test or they may have become both detectable and symptomatic after the screening test.

¹⁵ This case is included in the statistics quoted in this report.

BowelScreen quality assurance guidelines state “... *Cancers detected following a negative screening colonoscopy may represent missed lesions and qualitative concerns. However, some cancers may be a facet of aggressive tumour biology. No standard has been set but the goal is to minimise the number of interval cancers. Once monitoring processes have been established, it is anticipated that monitoring interval cancers will become an important component of quality assurance*”(6)¹⁶.

International best practice includes the ascertainment of interval cancers as a key component of the quality assurance of screening programmes. In 2010 the European guidelines for quality assurance in colorectal cancer screening and diagnosis stated:

“The ascertainment of interval cancers represents a key component of the evaluation of a screening programme. The documentation and evaluation process requires forward planning and linkage between screening registries and cancer registries, including data on causes of death, with no losses to follow-up. Data collection and reporting should cover all cancers appearing in the target population. Methods of ascertainment and follow-up may differ across countries and screening programmes depending on the availability and accessibility of data and of existing data sources: cancer/pathology registries, clinical or pathology records or death records/registries”(7).

A distinction needs to be made between the detection and monitoring of interval cancers as a long-term quality assurance and evaluation measure in a screening programme (which is often in arrears because of the time required to fully validate cancer registry data) and the real-time monitoring of interval cancers as a measure of patient safety especially in the early stages of a screening programme.

It is important that all reasonable means be employed to detect interval cancers and that the requisite processes are put in place to support notification to BowelScreen by clinicians and the NCR. To that end there is a requirement to extend the request to notify interval cancers to other HSE and private facilities as

¹⁶ Pp49 Section 5.4.3 Surveillance interval cancer.

well as designated HSE cancer centres. Furthermore, agreement could be reached with the NCR to monitor and report interval cancers. The NCR receives information on histologically confirmed cancer cases within weeks of diagnosis. It would therefore be possible to match these cases to BowelScreen cases, were lists of BowelScreen participants sent to the NCR. This would be similar to a process already agreed between the NCR and other screening programmes.

6.4 Investigation of Interval Cancers

An immediate case review was undertaken by WGH upon notification of each of the first two cancer cases and a full investigation of BowelScreen colonoscopies instituted upon notification of the second cancer case. Neither case could be classified at that time as an adverse event which would have triggered a systems analysis investigation under HSE Safety Incident Management Policy (2, 3). Further investigation was required, i.e. an audit of colonoscopy records at the unit, before these cases were categorised as “*probable missed cancers*” by the SIMT on advice of the clinical sub-group in January 2015.

In June 2015 the BowelScreen programme produced a revised *Standard Operating Procedure (SOP): Response to the notification of a post-colonoscopy colorectal cancer (interval cancer)* (Appendix 7). The SOP provides for the management of such notification under the local colonoscopy units’ clinical governance and risk management structures and the referral of any performance or quality issues to the Hospital Group CEO and HSE Acute Hospitals Division. It also provides for case review by the NSS, which in some instances could lead to further investigation.

HSE Safety incident Management policy states that: “*The following considerations influence the decision to escalate a safety incident for additional support:*

- *The safety incident involves more than one division, care group or hospital group which makes the incident management or investigation problematic for the local service.*

- *The local area has issues with capacity or capability to manage and investigate the safety incident according to HSE Safety Incident Management Policy (2014) and related guidelines.*
- *The HSE Investigator(s) deem that external input to the investigation is required.*
- *Where the assessment of a safety incident indicates that a look back review is required.*
- *If there is a significant risk to public confidence in services” (3)¹⁷.*

In this case the incident was escalated when it was evident that look-back was required.

The classification of safety incident as an adverse event within a screening programme is problematic. NHS England and NHS Screening Programmes recently produced guidance on managing safety incidents in NHS screening programmes which state *“In distinguishing between a screening safety incident and a serious incident, consideration should be given to whether individuals, the public or staff would suffer avoidable severe harm or death if the root cause is unresolved; or the likelihood of significant damage to the reputation of the organisations involved”* (15).

In addition to existing HSE guidance, the NSS should revise its guidance on the investigation and management of patient safety incidents in screening programmes to reflect the difference between a diagnostic and a screening test, and the governance arrangements under which screening services are provided. This guidance should be consistent with existing HSE incident notification and management requirements.

6.5 Post-colonoscopy Colorectal Cancer Rates (PCCRC)

PCCRC is a key quality indicator of colonoscopy. Several studies have sought to quantify the occurrence of PCCRCs and determine what factors predispose to their development (8, 16-26) . Across these studies PCCRCs were consistently

¹⁷ Pp15

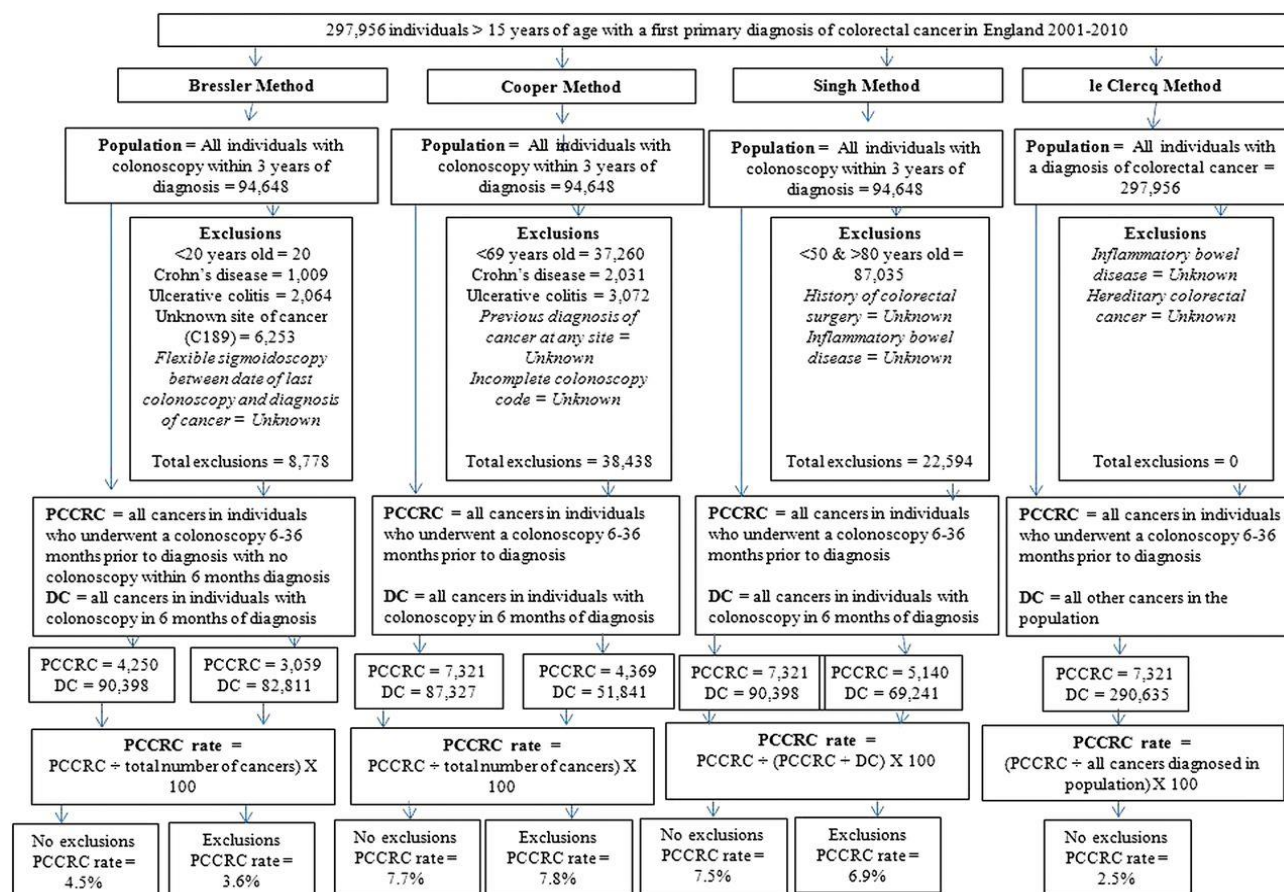
seen to be more common in older age groups, in women, in the proximal bowel and following colonoscopies undertaken by non-specialist endoscopists.

The reported rates in the literature of PCCRC have varied considerably from 2.5% to 8.6%. Although this could be due to differences in the quality of colonoscopy services across the populations considered, it may also be a reflection of the different datasets and methods used to calculate the rates. Several methods for the calculation of PCCRC have been published, the methods for which were summarised in a recent publication (27)¹⁸. All studies were based on population level data and the methods used cannot be applied to individual practitioners who undertake low numbers of procedures¹⁹.

¹⁸ Figure 1 Pp1250.

¹⁹ When assessing the observed rate of interval cancers in this incident the clinical subgroup undertook a modelling exercise comparing various background rates of PCCRC for the screening population.

Application and results of four previously published methods for determining post-colonoscopy colorectal cancer (PCCRC).



Eva J A Morris et al. Gut 2015;64:1248-1256



The calculation of a BowelScreen PCCRC rate (also known as an interval cancer rate in a screening programme) will be calculated in the coming years subject to a sufficient number of colonoscopies having been undertaken to allow meaningful statistical analysis and cross-referencing and validation of data by the National Cancer Registry (NCR) and BowelScreen.

6.6 Endoscopy

The endoscopy resources necessary to conduct both phases of the recall were provided by Ireland East Hospital Group, for both phases of the recall. To that end St Vincent's University Hospital and the Mater Misericordiae Hospital each provided endoscopy slots including Saturday appointments. WGH conducted all OPD appointments and a smaller number of colonoscopies. Sufficient endoscopy capacity was provided at these sites to offer a colonoscopy to patients over a three week period in the case of Phase 1 patients and a four to six week period in the case of Phase 2 patients. The quality of the recall colonoscopies was of upmost importance and a decision was taken that the recall would utilise JAG accredited units only. The conduct of the recall within the Ireland East Hospital Group afforded close linkages between NSS and endoscopy units necessary to track patients throughout the process.

The process was onerous given the demands already made on colonoscopy services which are closely monitored for exceedances in waiting times for urgent and non-urgent colonoscopies for symptomatic patients. Clinical services had to be maintained within endoscopy services but recall patients were regarded as urgent cases and additional clinics were scheduled (as noted above to include Saturday clinics).

The SIMT advocated for the shortest recall scheduling regime possible arguing in favour of additional weekend and out of hour's clinics to expedite the process. The timelines were dictated by the feasibility of conducting the recall while maintaining normal day to day work. The timelines agreed were to the satisfaction of the clinical sub-group of the SIMT and Gastroenterologists in the acute hospital

endoscopy services. 88% of patients had a colonoscopy within 30 calendar days of their pre-assessment phone call.

6.7 Administration

Look-backs entail a high administrative burden. Databases were created at the NSS and WGH. These databases had to be crosschecked with each other and validated against other sources to identify deceased patients or patients in the care of other acute services. In addition to routine administrative tasks databases had to be updated continually as the recall progressed to track patients and provide accurate, timely information required by the SIMT. An option to enlist an outside team of administrators unfamiliar with the screening and recall process was balanced against dedicating fewer personnel with expertise from within the service.

In BowelScreen three liaison nurses were assigned to the recall to conduct pre-assessment and scheduling of patients. In WGH a liaison nurse and senior administrator were assigned to work on the incident. The Endoscopy Clinical Nurse Specialist (CNS) and CNMIII with responsibility for the unit were also assigned to work on the incident as required.

The assignment of dedicated liaison personnel at both sites provided expertise, continuity of care and consistency in approach during the review. These nurses and administrators became very familiar with the process; acted as the primary liaison point and developed a relationship with patients and endoscopy units alike.

6.8 Revision of Risk Assessment

In evaluating the recall, the risk assessment merits consideration. At all times the risk assessment was based on the clinical information available. It was only after a number of cancers were detected, histologically confirmed and categorised as probable missed lesions in anatomical locations outside the caecum that it was possible to determine whether a risk existed among patients who were not

included in Phase 1. Once identified, this risk was acted upon immediately and the remaining patients recalled.

6.9 Patient Advocacy

Membership of the SIMT included a patient advocate from the patient representative organisation Patient Focus. As a team member the patient advocate attended meetings and reviewed documentation. The patient advocate was asked to comment specifically on matters such as patient letters, media statements, appointment scheduling and open disclosure meetings. The patient advocate was a valued team member and provided important insight and assurance over the course of the look-back. While the majority of complaints and queries were handled at the relevant HSE sites, Patient Focus and the patient advocate member of the SIMT fulfilled an important liaison role also.

6.10 Communications

Patients and their GPs were written to advising them of the recall and inviting them to attend for a repeat colonoscopy/OPD appointment in advance of public communication of the incident. The letters included contact details for the NSS in the case of BowelScreen patients and WGH for all other patients. Patients received pre-assessment telephone calls from the NSS and calls to confirm OPD appointments from WGH as necessary.

In both phases of the recall letters to patients and their GPs were posted on a Friday for delivery on the following Monday or Tuesday. This approach was advantageous for the following reasons:

- Liaison personnel were available in the NSS and at WGH, to deal with patients' queries for the full working week following receipt of letters. Given the high volume of patients involved this optimised the chance of addressing patient concerns and allaying fears.
- In the case of BowelScreen patients it provided for efficient scheduling, as the same personnel also conducted the colonoscopy pre-assessment.

Patients were encouraged to take the follow-up appointments being offered promptly.

In accordance with HSE guidance, timely accurate communication with those affected was prioritised over public media communication. To that end, every effort was made to identify and engage with the patients affected in advance of any public communication. Media statements and interviews contained sufficient detail to serve the public interest without divulging sensitive clinical information on patients already diagnosed or cause un-necessary distress to patients who were still within the recall process.

The *HSE Infoline* was used to deal with any queries from the general public following media publicity. Patients affected by the recall were referred to the dedicated services at the NSS and WGH.

6.11 Open Disclosure

The patients whose cases prompted the look-back process had received open disclosure and were informed of the recall in advance of the recall. All other cases were aware of their diagnosis in the context of the recall at the time of their diagnosis. As each new case was identified contact was established with the patient / family to invite them to attend a formal open disclosure meeting in WGH.

Open disclosure is a matter of extreme sensitivity and the system imperative to communicate in a timely and honest manner and to balance this with each individual patient's clinical condition and readiness to participate in the process. Two patients complained about being contacted by the hospital to attend formal open disclosure meetings in WGH as they had already discussed their diagnosis with their clinical teams elsewhere and been fully aware that the diagnosis was made as part of a look-back.

6.12 Wider Endoscopy Services

The Conjoint Board in Ireland of the Royal College of Physicians (RCPI) and Royal College of Surgeons (RCSI) in conjunction with the Quality Improvement Directorate of the HSE have developed a Quality Improvement Programme in GI Endoscopy and the HSE Acute Hospital Division (AHD) has also established an Endoscopy Programme. A National Clinical Lead has been appointed. The work of the programme is coordinated through a working group and reports to the HSE Acute Hospitals Division Endoscopy Steering Group and BowelScreen is closely involved in this process also.

The programme objectives include:

- Strengthen clinical governance for endoscopy services across Hospital Groups
- Increase the capacity of endoscopy services to meet current and future demand
- Establish a national training programme for endoscopy
- Design a systematic approach to validation and scheduling of endoscopy procedures
- Develop a national referral pathway
- Develop a national quality assurance framework for endoscopy services
- Support the development and expansion of BowelScreen in public hospitals.

6.13 JAG Accreditation

14 (of 37 adult endoscopy units) are accredited by the UK Joint Advisory Group on Gastrointestinal Endoscopy (JAG). It is expected that specific standards for paediatric endoscopy will be published by JAG in Q1 2017. The HSE Acute Hospital Division Endoscopy Programme is working closely with JAG to examine the currently JAG assessment criteria and support additional units to achieve accreditation. An increased in the number of JAG accredited units would also increase the number of sites that could perform services on behalf of BowelScreen.

7. Conclusion

The look-back is now complete. All patients who required recall have been offered follow-up appointments and in the majority of cases accepted clinical follow-up.

Taking into consideration the issue of hindsight bias and outcome bias including references to the fact that the endoscopists undertaking recall colonoscopies were aware that the recall was instigated on foot of concern regarding the quality of initial screening colonoscopies; this review has found a higher than acceptable rate of interval cancers in the cohort of patients screened by Clinician Y.

This look-back was complex, it involved multiple phases, patient cohorts and services; therefore, minor delays experienced in each element were cumulative. There were critical junctures along the trajectory of the management of this incident where alternate action may have expedited identification and management of this incident; e.g. earlier notification of index cases or earlier audit of symptomatic patients. Notwithstanding these issues, the cohort affected was identified in a timely manner and the recall was not unduly delayed.

8. Recommendations

1. The rollout of the National Quality Improvement Programme for Endoscopy should be completed and proceed to mandatory participation for all HSE and HSE funded units
2. Bowel Screen should continue to undertake ongoing revision to the Quality Assurance Guidelines and should ensure that the next revision takes into account the findings of this review.
3. The endoscopy service in association with professional bodies must develop a competency framework/mechanism.
 - The Royal College of Physicians of Ireland the Royal College of Surgeons of Ireland and BowelScreen should play a central and leading role in developing such a framework.
 - Until an appropriate national framework has been agreed, BowelScreen should continually review/update appropriate methods

of assurance regarding competency in endoscopy from individual endoscopists before participation in the BowelScreen programme, in addition to the existing requirements in regard to, training the trainer, adenoma detection rates and volume of activity.

4. The quality of BowelScreen and symptomatic endoscopy activity should be audited at unit and individual endoscopist level. Each unit should be held accountable for local audits. The National Quality Improvement Programme for Endoscopy should have oversight of all endoscopy services but the NSS should also have oversight of BowelScreen audits.
5. The adenoma detection threshold levels should be reviewed in light of this incident
6. Processes should be put in place to ensure timely notification of colorectal cancer in patients who have undergone a screening colonoscopy; this should include a request to all HSE/HSE funded and private facilities to notify cases and the establishment of an interval cancer reporting process with the NCR.
7. The PCCRC rate for both the screening and general population of Ireland should be determined.
8. The NSS should develop a specific policy for managing safety incidents in the context of screening services, which is also in line with overarching HSE safety incident management policy.
9. The governance of patient and public communication should be clarified by the SIMT from the outset and adhered to throughout the incident management process, particularly where incidents span different accountability units within the health service.
10. All HSE service providers should be continually updated on adverse incident management, notification and escalation processes in order to ensure dissemination of learning from incidents such as this.

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Appendices

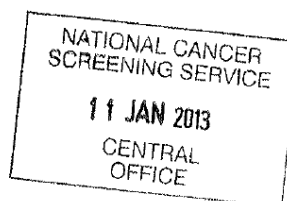
Appendix 1: Memorandum of Understanding 01/01/2013– 31/12/2013

National Cancer Screening Service
MEMORANDUM OF UNDERSTANDING (MOU)

National Cancer Screening Service (NCSS); AND

Wexford & Ely General Hospital

MOU THAT THE ABOVE NAMED HOSPITAL WILL PERFORM CERTAIN
FUNCTIONS IN RESPECT OF THE PROVISION OF ENDOSCOPY AND RELATED
SERVICES ON BEHALF OF THE NATIONAL COLORECTAL SCREENING
PROGRAMME OF THE NATIONAL CANCER SCREENING SERVICE



THIS MEMORANDUM OF UNDERSTANDING (MOU) IS MADE ON 21 DECEMBER 2012.

Between

1. The National Cancer Screening Service (NCSS) of 4th Floor, King's Inns House, 200 Parnell Street, Dublin 1 as part of the Health Service Executive (HSE)

And

2. Wexford & Ely General Hospital

BACKGROUND

The NCSS is part of the HSE National Cancer Control Programme (NCCP), it encompasses BreastCheck – The National Breast Screening Programme, CervicalCheck – The National Cervical Screening Programme and BowelScreen – The National Colorectal Cancer Screening Programme, and preparations for the roll out of diabetic retinopathy screening are underway.

The NCSS is obliged to carry out and arrange to carry out a national colorectal screening programme for the early diagnosis of colorectal cancer to reduce mortality from colorectal cancer among the target population.

SCOPE AND PURPOSE OF AGREEMENT

The purpose of this agreement is to specify the manner in which the Hospital will perform and deliver the relevant services in consideration for the fee, as set out in Schedule 2.

The performance of the services will be monitored against the Key Performance Indicators as set out in Schedule 1.

PRINCIPLES

The service will be delivered in line with the NCSS – Guidelines for Quality Assurance in Colorectal Screening. The Hospital will be furnished with a copy. The Guidelines identify the relevant Key Performance Indicators (KPIs) for the service.

The Hospital agrees to have available between 10 and 15 screening colonoscopy slots per week. Any agreement to carry out additional screening colonoscopies will be agreed by both parties in advance.

The actual number of screening colonoscopies carried out will be dependant on a number of factors including programme uptake and level of FIT test positivity. Therefore the NCSS is not in a position to confirm or guarantee actual numbers, however the NCSS will liaise with the Hospital on an ongoing basis in order to plan capacity required.

WEXFORD & ELY GENERAL HOSPITAL

The Hospital will ensure all screening client data related to pre-assessment, admission, procedures etc. is captured on the COR database in an accurate and timely manner.

OBLIGATIONS OF THE NCSS

The NCSS undertakes to notify the Hospital's screening colonoscopy unit within 5 working days of a positive result being received from the FIT screening laboratory of those screening clients requiring a colonoscopy in the Hospital's endoscopy unit.

The NCSS shall provide information to enable reporting on KPIs to the relevant department manager in the Hospital.

The NCSS will provide the Hospital's screening colonoscopy unit with access to the NCSS COR database to be used in the administration of screening clients.

The NCSS will provide, as a point of contact, a designated colorectal coordinator/s to each colonoscopy screening unit.

QUALIFICATION AS A SCREENING COLONOSCOPY UNIT

The Hospital agrees to the following in order to retain their status as a screening colonoscopy unit:

- NHS JAG Accreditation
- Endoscopy Reporting System (with amended data file)
- Demonstrated management of symptomatic waiting list in line with national targets
- Current MOU with the NCSS

The NCSS reserves the right to withdraw screening unit status from the Hospital in the event that any of the above conditions are not maintained.

The NCSS reserves the right upon the failure of the Hospital to adhere to the KPIs in a consecutive two month period to suspend the Hospital unit from the screening programme until such a time as the Hospital can demonstrate its ability to rectify and resolve the issues.

SERVICE DELIVERY

PRE-ASSESSMENT

The Hospital will carry out the pre-assessment of the screening client over the phone and will complete the pre-assessment form on the COR system. Screening clients may require a face to face assessment which is to be organised by the Hospital.

BOWEL PREPARATION

It is the responsibility of the Hospital to provide the screening client with the appropriate bowel preparation entirely free of charge. It is not permitted to provide the screening client with a prescription for bowel preparation.

The particular bowel preparation used can be determined by the screening colonoscopy unit. However, all bowel preparations used for screening clients must contain a P.E.G compound.

PATIENT CENTRED SERVICE

The Hospital will provide the screening client with clear, objective, full and prompt information on their diagnosis. Special and minority needs shall be catered for.

The Hospital shall endeavour not to cancel screening client appointments unnecessarily and will notify the screening client of the cancellation at the earliest practicable date.

In the event of the Hospital cancelling an appointment arrangements should be made to accommodate the screening client at the next available date.

All standard communication issued by the screening unit will be approved by the NCSS.

The Hospital will provide a 24 hour contact number for screening clients following colonoscopy.

The Hospital will operate a clear policy on management of screening client complaints and concerns, in compliance with HSE complaints policy.

The Hospital will ensure all screening colonoscopies are carried out within the NHS JAG accredited endoscopy unit and not any other location.

PATIENT PATHWAY

The Hospital undertakes to refer screening clients diagnosed with cancer to the relevant associated HSE designated cancer centre and should have robust arrangements in place to effectively manage the patient pathway.

The pathway for all screening clients who attend Wexford & Ely General Hospital has been established and follows the NCSS Quality Assurance Guidelines for Colorectal Screening. All histology will take place at Waterford Regional Hospital and a Memorandum of Understanding will be in place with Waterford Regional Hospital for this purpose. Waterford Regional Hospital is the referral pathway for all subsequent surgery and treatment. Screening clients will be discussed at relevant Waterford Regional Hospital MDMs.

INTERDISCIPLINARY PATHWAY

The Hospital agrees that screening clients following screening colonoscopy found with extra-colonic conditions shall be referred to the appropriate service within the Hospital and the Hospital undertakes to co-ordinate the screening client referral to the appropriate service.

DATA / INFORMATION REQUIREMENTS

The Hospital agrees to the required system amendments to the Endoscopy Reporting System (ERS) in order to ensure the NCSS is provided with the information required to identify a screening client.

The Hospital shall be responsible for the management of clinical information generated or stored in the Hospital in accordance with relevant standards and legislation. Detailed documentation of activity will be recorded in each centre so that clinical and administrative audit can be undertaken if necessary.

The Hospital shall ensure that all data is logged on the COR database in an accurate and timely manner.

ADVERSE/POTENTIAL INCIDENT REPORTING

The Hospital shall report to the NCSS without delay all clinically significant adverse incidents impacting on screening client care.

All 30 day mortality should be reported immediately to the NCSS and accurately recorded on the COR database.

The Hospital will continue to manage and record 'near miss' incidents as part of its internal quality assurance and comprehensive risk management system.

The Hospital shall be able to deal with the complications that may occur and (i) provide emergency admission with general surgical service and operating theatre availability; (ii) cross match and provide blood for transfusion; and (iii) provide emergency angiographic and radiology services.

HISTOPATHOLOGY SERVICES

The Hospital is responsible to direct all histopathology arising from screening colonoscopies from the screening colonoscopy unit to the designated HSE cancer centre histopathology service.

It is the responsibility of the Hospital to transport and provide these samples to the designated histopathology service in a timely manner.

All histology for Wexford & Ely General Hospital will take place in Waterford Regional Hospital.

QUALITY STANDARDS

The Hospital will adhere to the Guidelines for Quality Assurance in Colorectal Screening. A process for dealing with suboptimal performance will be in place.

WEXFORD & ELY GENERAL HOSPITAL

The Hospital should identify and nominate a clinical lead who will be responsible for managing compliance with QA guidelines for all endoscopists carrying out screening colonoscopies and will, in the first instance, address non-compliance issues.

Endoscopists carrying out screening colonoscopies who fail to achieve agreed standards after an implementation plan has been agreed will have their practice reviewed by the clinical governance risk committee/endoscopy lead clinician and the NCSS as appropriate.

TRAIN THE TRAINER

Those identified as clinical trainers must undergo appropriate 'train the trainer' courses within six months of commencement as a screening unit. All other endoscopists involved in carrying out screening colonoscopies are expected to have the course completed within 18 months. Failure to do so may result in the withdrawal of screening unit status from the Hospital.

PERFORMANCE MONITORING

This agreement shall be reviewed at an annual review meeting and may be amended, if necessary, to reflect and address any issues arising during the year. If any changes are to be made to the agreement following the review, a new MOU will be drafted and should be signed and dated by both parties.

Review meetings may consider, but not limited to, any of the following:

- Activity Data
- Human Resources and staffing issues
- Review of KPIs
- Service user feedback
- Any reports received by the NCSS indicating areas of concern or serious incidents

A discussion will take place between the two parties in the event of non-compliance with the KPIs in two consecutive months.

The Hospital agrees to adhere to the standards outlined in the Guidelines for Quality Assurance in Colorectal Screening. Failure to do so may result in the loss of screening unit status.

Quarterly meetings will be scheduled throughout the year with the NCSS on dates agreed by both parties.

DISPUTE RESOLUTION

The parties to this agreement agree to avoid disputes and deal with issues as they arise, through direct discussion.

Unexpected disputes which could potentially have an effect on the safety and quality of screening patients will be resolved in a timely manner. In the event of an urgent dispute, the parties will meet within 7 days to endeavour to resolve the issue within a further 14 days.

TERMINATION OF MOU

WEXFORD & ELY GENERAL HOSPITAL

If the NCSS deem that the Hospital has not carried out the services in line with the agreed KPIs or has failed to engage with the NCSS in good faith to agree a plan of action and timetable, the NCSS reserves the right to issue a termination notice of this MOU in writing to the Hospital and if within four months the Hospital does not take action to rectify the breach the NCSS reserves the right to terminate this MOU.

This MOU may be terminated by mutual consent of the parties. Either party may terminate this MOU upon one month written notice to the other.

ACCREDITATION

NHS JAG ACCREDITATION

The Hospital must ensure that Level 2 NHS JAG accreditation is achieved 12 months following the date of accreditation.

The Hospital agrees to a reassessment visit every five years and with an Annual Report Card submission in the interim years in line with NHS JAG accreditation pathway.

In the event of failure to maintain accreditation standards NHS JAG may withdraw accreditation status temporarily until issues have been resolved satisfactorily. This will result in the withdrawal of screening unit status to the Hospital until the issues identified have been resolved.

GLOBAL RATING SCALES (GRS) CENSUS

GRS Census returns must be completed bi-annually by the Hospital within the specified time frame indicated on the GRS website.

SCHEDULE 1 - KEY PERFORMANCE INDICATORS

Key performance indicator	Minimum standard	Achievable standard
Proportion of clients offered colonoscopy within 4 weeks from when deemed clinically suitable following pre-assessment	≥90%	100%
Minimum number of colonoscopies undertaken annually by each screening endoscopist <ul style="list-style-type: none"> Colonoscopies (symptomatic & screening) per annum Screening colonoscopies (auditable after programme is running at full capacity) 	<ul style="list-style-type: none"> >300 >150 	
Unadjusted caecal intubation rate (CIR) with photographic evidence	≥90%	≥95%
Perforation rate of colonoscopy	<1 per 1,000 colonoscopies	
Post-polypectomy perforation rate	<2 per 1,000 colonoscopies where polypectomy is performed	
Post-polypectomy bleeding requiring transfusion (PPB)	<1% colonoscopies where polypectomy is performed	
Percentage of individuals scheduled for surveillance colonoscopy who undergo that procedure within 3 months of scheduled date	>85%	>90%
Cancer detection rate	≥2 per 1,000 screened	≥5 per 1,000 screened
Adenoma detection rate (ADR)	25% of colonoscopies	35% of colonoscopies
Median number of lymph nodes retrieved in non-neoadjuvant treated cases	>12	
Proportion of lesions reported as high-grade dysplasia	≤10%	
Proportion of polyp cancer identified as poor differentiation	≤20%	
Proportion of histopathological biopsy reports authorised and relayed to referrer within 5 working days of receipt of specimen in laboratory	≥90%	100%
Proportion of colon cancer referrals to a designated cancer centre taken place within 10 working days of histological diagnosis	≥90%	100%

OTHER MEASURABLE STANDARDS

The colorectal screening programme will also monitor other measurable standards that are included in the Quality guidelines. While these may not be KPIs, they will have an impact on the overall performance of the programme.

Standard	Minimum standard	Achievable standard
Bowel cleanliness at colonoscopy: excellent or adequate	≥90%	≥95%
Colonoscopic comfort	Auditable outcome	
Medication used for comfort during lower gastrointestinal (GI) endoscopy	Auditable outcome	
Use of reversal agents	Auditable outcome	
Colonoscopic cancer detection rate	≥11 per 100 colonoscopies	
Colonoscope withdrawal time	≥6 mins inspection time on withdrawal ≥90% of negative procedures	≥6 mins inspection time on withdrawal ≥95% of negative procedures
Retrieval rate of polypectomy specimens for histological analysis	≥90%	≥95%
Other adverse events of colonoscopy	Auditable outcome	
Referral rates for CT colonography referred for colonoscopy following a positive FIT	≤10%	
Proportion of polyp cancers with double reporting	100%	

SCHEDULE 2 - FEE

TOTAL FEE

The fee (inclusive of all taxes, expenses and other costs associated with or incurred in the performance of the service) to be paid by the NCSS in consideration of the performance of the services shall be in EUR.

The fee payable for each screening colonoscopy performed will be 550EUR.

PAYMENT OF THE FEE

The fee in respect of the services shall be payable by the NCSS via the HSE budgeting system (Rosetta).

Fee payments will be made quarterly in arrears (based on colonoscopies reported on the COR database).

UNFUNDED SERVICES

The Fee is payable for the provision of screening colonoscopies only. Any other services provided by the Hospital that have not been authorised in advance in writing by the NCSS shall be outside the scope of this MOU.

The costs of the Unfunded Services and all responsibilities, obligations and liabilities relating to or arising in connection with the Unfunded Services shall be the sole responsibility of the Hospital.

WEXFORD & ELY GENERAL HOSPITAL

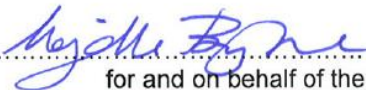
SCHEDULE 3 – PROCESS FLOWS

WEXFORD & ELY GENERAL HOSPITAL


IN WITNESS WHEREOF this MOU is executed by the parties as follows:-

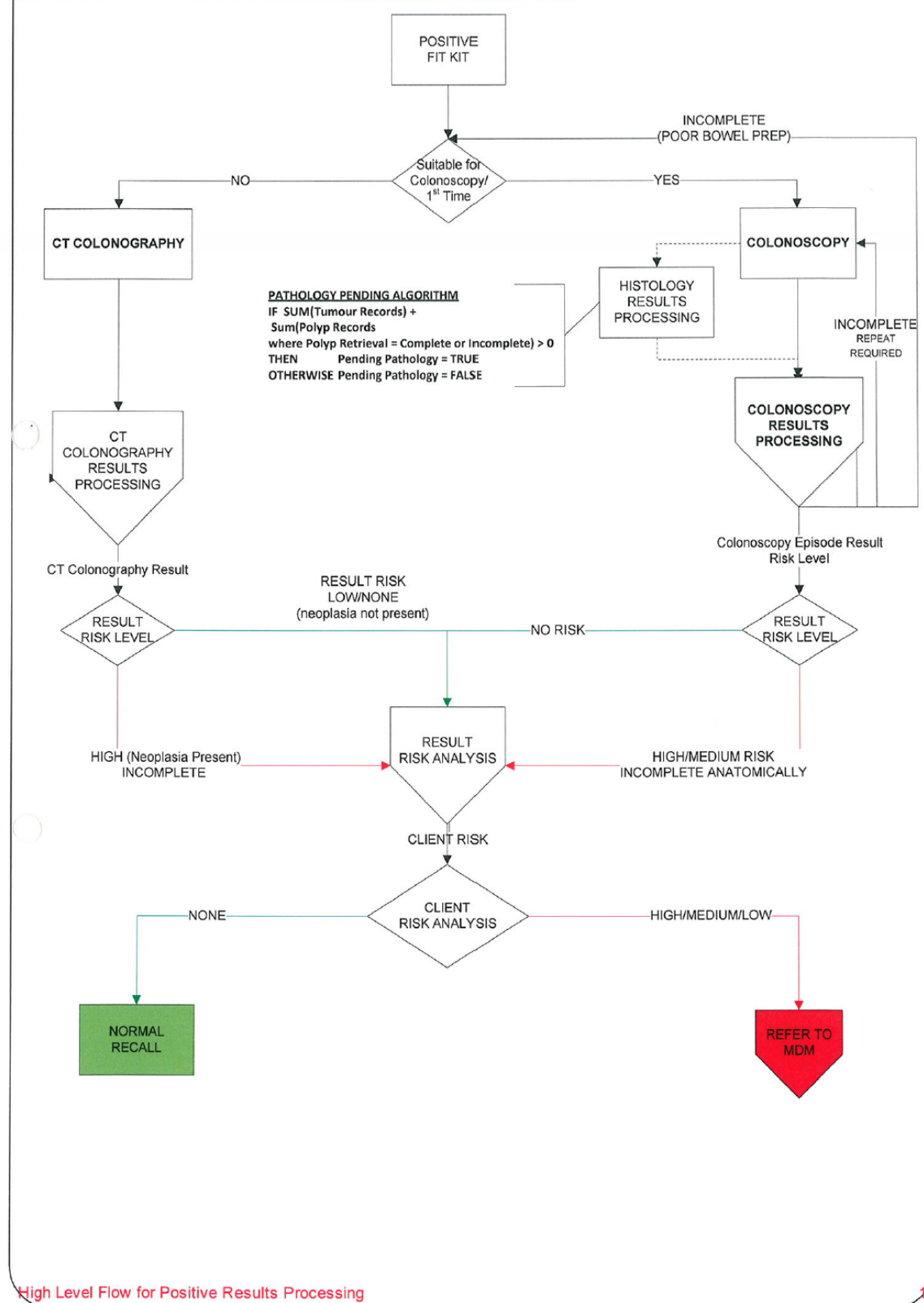
DATED: 14/1/13

Signed by

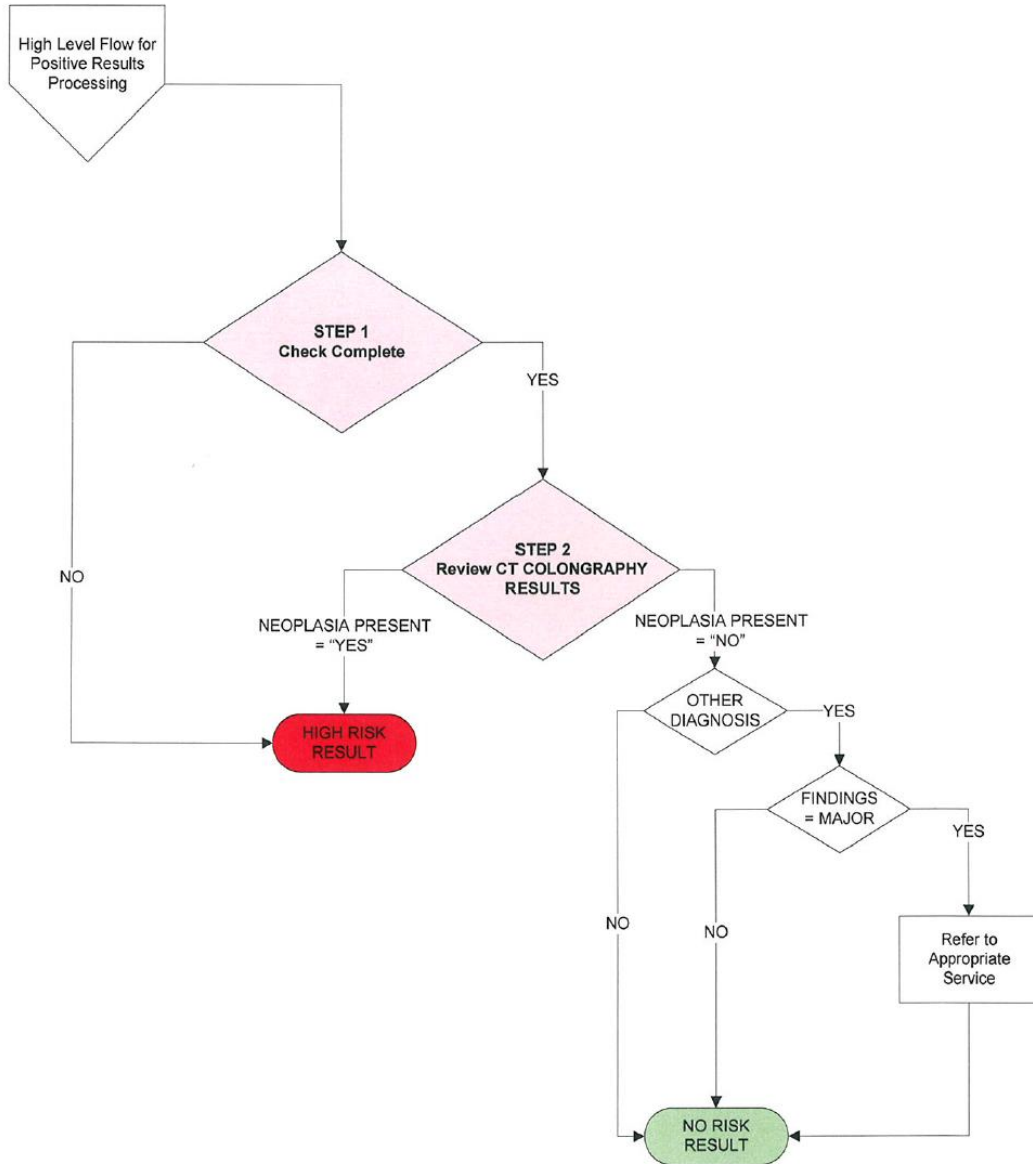

for and on behalf of the
NATIONAL CANCER SCREENING SERVICE

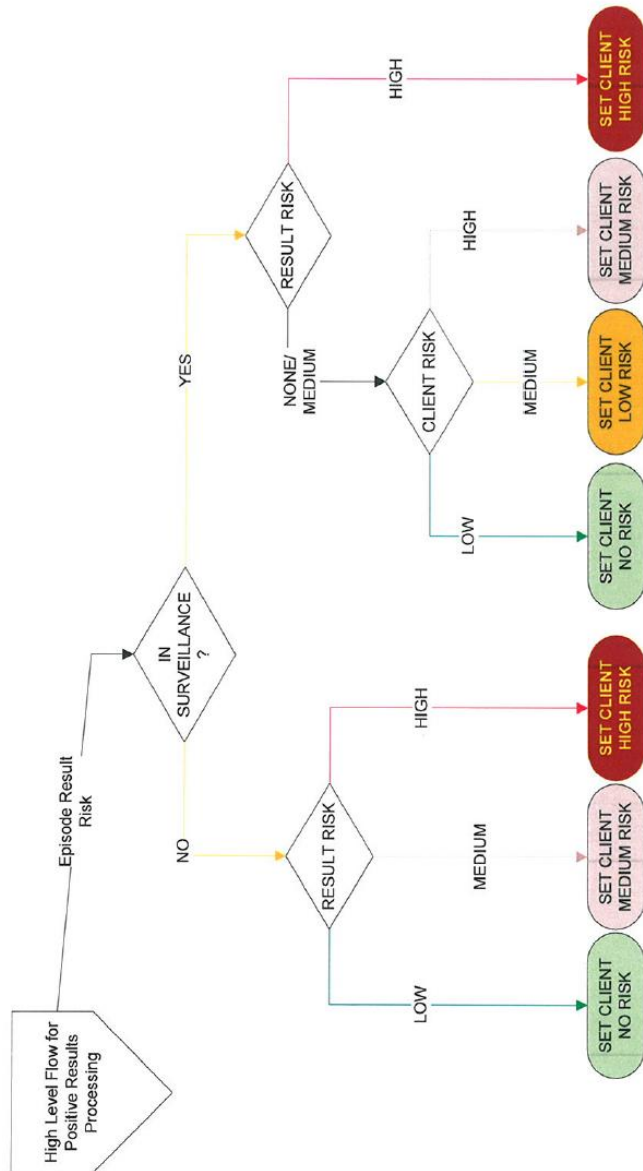
Signed by

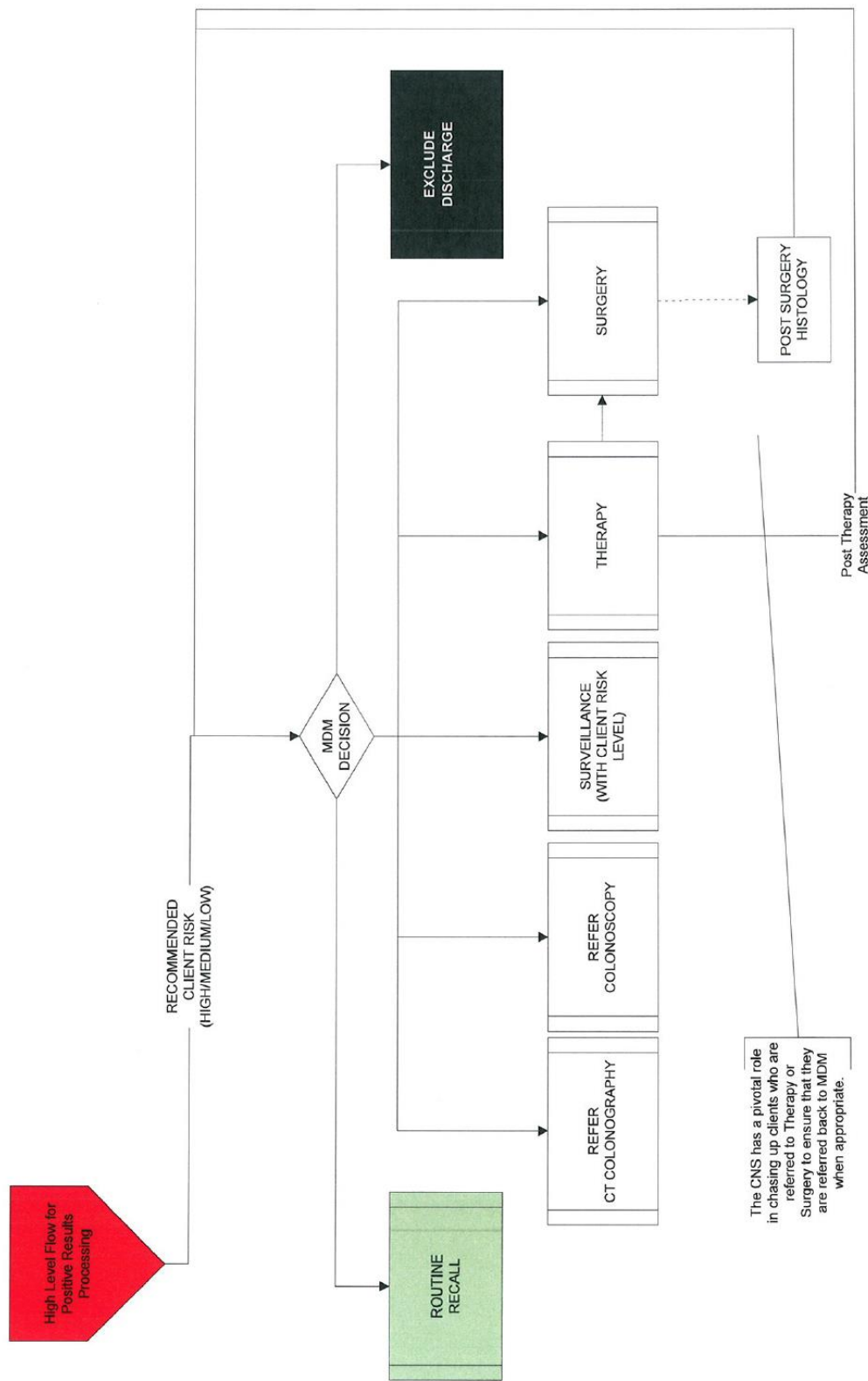

for and on behalf of
HOSPITAL
9/1/13.

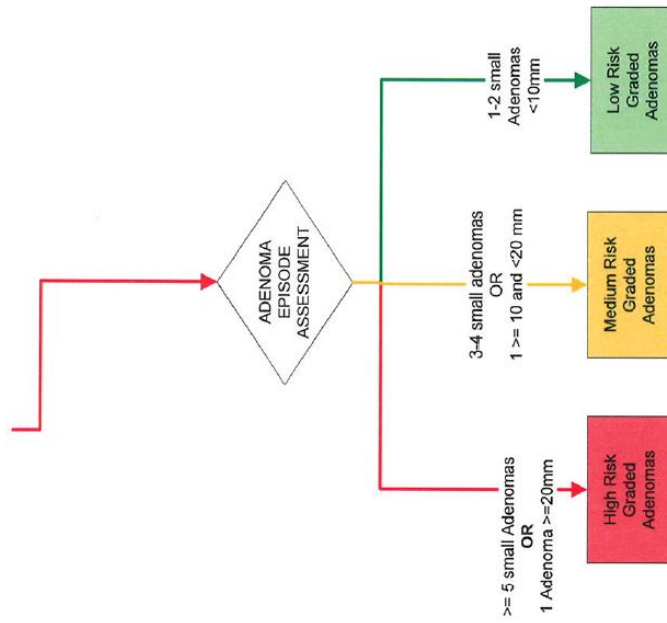












Appendix 2: Memorandum of Understanding 01/01/2014– 31/12/2014

**National Cancer Screening Service
MEMORANDUM OF UNDERSTANDING (MOU)**

National Cancer Screening Service (NCSS)

AND

Wexford General Hospital

**MOU THAT THE ABOVE NAMED HOSPITAL WILL PERFORM CERTAIN
FUNCTIONS IN RESPECT OF THE PROVISION OF ENDOSCOPY AND RELATED
SERVICES ON BEHALF OF BOWELSCREEN - THE NATIONAL COLORECTAL
SCREENING PROGRAMME OF THE NATIONAL CANCER SCREENING
SERVICE**

THIS MEMORANDUM OF UNDERSTANDING (MOU) IS MADE 7 FEBRUARY 2014

Between

1. The National Cancer Screening Service (NCSS) of 4th Floor, King's Inns House, 200 Parnell Street, Dublin 1 as part of the Health Service Executive (HSE)

And

2. Wexford General Hospital

COVERING THE PERIOD

1 January 2014 to 31 December 2014 inclusive.

1. BACKGROUND

- (a) The NCSS is part of the Health Service Executive. It encompasses BreastCheck – The National Breast Screening Programme, CervicalCheck – The National Cervical Screening Programme, BowelScreen – The National Colorectal Cancer Screening Programme, and Diabetic RetinaScreen – The National Diabetic Retinal Screening Programme.

2. SCOPE AND PURPOSE OF AGREEMENT

- (a) The purpose of this agreement is to specify the manner in which the Hospital will take on the role of a Screening Colonoscopy Unit and deliver the specified services in consideration for the fee, as set out in Schedule 1.
- (b) This MOU supersedes all previous MOUs and undertakings.

3. PRINCIPLES

- (a) The service will be delivered in line with the NCSS – Guidelines for Quality Assurance in Colorectal Screening and is available at www.cancerscreening.ie. The Guidelines identify the relevant Key Performance Indicators (KPIs) for the national programme.

4. OBLIGATIONS OF THE NCSS

- (a) The NCSS undertakes to notify the Hospital's screening colonoscopy unit within 5 working days of a FIT positive result being received from the laboratory for those clients who will require a screening colonoscopy in the Hospital's endoscopy unit
- (b) The NCSS will provide the Hospital's screening colonoscopy unit with access to the NCSS COR database to be used for the collection and recording of data related to screening clients

- (c) The NCSS will provide, as a point of contact, a designated BowelScreen Endoscopy Coordinator.
- (d) The NCSS will modulate the invitation process with the aim of ensuring that the number of screening colonoscopies will not exceed the capacity specified in 5 (a) over the quarterly payment period.

5. OBLIGATIONS OF THE SCREENING COLONOSCOPY UNIT

- (a) To undertake **10** screening colonoscopies (i.e. 10 clients) per week for a minimum period of 46 weeks per annum.
 - 1. Any agreement to carry out additional screening colonoscopies will be agreed by both parties in advance.
- (b) Ensure that the outcome of all screening colonoscopies are entered onto the hospital's endoscopy reporting system (ERS) according to the Standard Operating Procedure (SOP) developed by the Conjoint Board in Ireland of the Royal College of Physicians and Royal College of Surgeons and BowelScreen – The National Colorectal Screening Programme. A copy has been given to The Hospital.
- (c) To maintain symptomatic waiting times for routine GI endoscopy ≤ 13 weeks
- (d) Continue to support the training needs of the Clinical Nurse Specialist (CNS)
 - 1. Access to appropriate resources
 - 2. Contingency to cover the CNS's pre-assessment and booking roles during periods of annual leave & sick leave which will also ensure that the Hospital's obligation under 5 (a) can be met
- (e) Adhere to current and future BowelScreen Programme Operational Protocols.
 - 1. *Protocol for the discussion of polyps post endoscopy*
 - 2. *Protocol for the prescribing and issue of bowel preparation*
 - 3. *Colonoscopic surveillance following adenoma removal*
- (f) Maintain NHS Joint Advisory Group on Gastroenterology (JAG) accreditation including the completion of twice yearly GRS Ireland Census returns
- (g) In the context of 5.a the frequency of the referenced endoscopy/histopathology polyp conference should be no less than every two weeks
- (h) Participate in a regular Performance Management meeting with the NCSS
- (i) Participate in all performance improvement initiatives initiated by the NCSS in the context of BowelScreen
- (j) In the context of all communications from the NCSS and 5 (h), provide the names and contact details of the following:
 - 1. **Clinical Lead**
 - 2. **Trainer/Mentor for the CNS**
 - 3. **Nurse Lead** (ADON/equivalent) or other with delegated authority of ADON
 - 4. **Managerial Lead**

6. SERVICE DELIVERY

- (a) The Hospital will provide the screening client with clear, objective, full and prompt information on the outcome of their colonoscopy as per any patient attending the endoscopy unit. Special and minority needs shall be catered for.
- (b) The Hospital shall endeavour not to cancel screening client appointments unnecessarily and will notify the screening client of the cancellation at the earliest practicable date.
- (c) In the event of the Hospital cancelling an appointment arrangement should be made to accommodate the screening client at the next available date.
- (d) The Hospital will provide a 24 hour contact number for screening clients following colonoscopy.
- (e) The Hospital will operate a clear policy on management of screening client complaints and concerns, in compliance with HSE Complaints Policy.
- (f) The Hospital will ensure all screening colonoscopies are carried out within the NHS JAG accredited endoscopy unit.
 - 1. Any deviation from 6 (f) will be agreed by both parties in advance.

7. PRE-ASSESSMENT

- (a) The Hospital will carry out the pre-assessment of the screening client over the phone and will complete the pre-assessment fields on the BowelScreen COR system. Screening clients may require a face to face assessment which is to be organised by the Hospital.

8. BOWEL PREPARATION

- (a) It is the responsibility of the Hospital to provide the screening client with the appropriate bowel preparation entirely free of charge. Please see '*Protocol for the prescribing and issue of bowel preparation*'
- (b) The particular bowel preparation used can be determined by the screening colonoscopy unit. However, all bowel preparations used for screening clients must contain a polyethylene glycol (PEG) compound.

9. HISTOPATHOLOGY SERVICES

- (a) The Hospital is responsible to direct all histopathology arising from screening colonoscopies from the screening colonoscopy unit to the designated HSE Cancer Centre histopathology service.
- (b) It is the responsibility of the Hospital to transport and provide these samples to the designated histopathology service in a timely manner.
- (c) All histopathology for Wexford General Hospital will take place in Waterford Regional Hospital

- (d) The frequency of Endoscopy – Histopathology polyp conferences should be held no less than every two weeks and in accordance with the *Protocol for the discussion of polyps post endoscopy*

10. CT COLONOGRAPHY

- (a) The Hospital is responsible to refer screening clients to a HSE designated Cancer Centre providing CT Colonography services in accordance with the BowelScreen CT Colonography pathway.

11. SURGICAL CANCER SERVICES

- (a) The Hospital undertakes to refer clients diagnosed with a screen detected colon or rectal cancer to a HSE designated Cancer Centre and should have robust arrangements in place to effectively manage the patient care transfer/pathway.

12. OTHER CLINICAL SERVICES

- (a) The Hospital agrees that BowelScreen clients diagnosed with a condition, other than cancer, and requiring symptomatic follow up shall be referred to the appropriate service within the Hospital or appropriate local hospital and the Hospital undertakes to arrange the referral in a timely fashion as per standard clinical practice.

13. DATA / INFORMATION REQUIREMENTS

- (a) The Hospital agrees to the required system amendments to the Endoscopy Reporting System (ERS) in order to ensure the NCSS is provided with the information required to safely and accurately identify a screening client.
- (b) The Hospital shall be responsible for the management of clinical information generated or stored in the Hospital in accordance with relevant standards and legislation. Detailed documentation of activity will be recorded in each centre so that clinical and administrative audit can be undertaken if necessary.
- (c) The Hospital shall ensure that all data is logged on the COR database in an accurate and timely manner.

14. ADVERSE/POTENTIAL INCIDENT REPORTING

- (a) The Hospital shall report to the NCSS without delay all adverse incidents related to BowelScreen clients.
- (b) The Hospital will continue to manage and record 'near miss' incidents as part of its internal quality assurance and comprehensive risk management system.

15. QUALITY STANDARDS

- (a) The Hospital agrees to adhere to the Guidelines for Quality Assurance in Colorectal Screening. The Key Performance Indicators are set out in Schedule 2.
- (b) The Hospital should have an appropriate governance structure in place for managing compliance with QA guidelines for all endoscopists carrying out screening colonoscopies and will, in the first instance, address non-compliance issues.

- (c) The NCSS reserves the right to seek a review meeting with the Hospital should it become aware of or have concerns about deviation from the Guidelines for Quality Assurance in Colorectal Screening.

16. TRAIN THE TRAINER

- (a) Those identified as clinical trainers or mentors must undergo appropriate 'train the trainer' courses within six months of commencement as a screening colonoscopy unit.

17. PERFORMANCE MANAGEMENT

- (a) As per 5(h) meetings will be scheduled throughout the year with the NCSS on dates agreed by both parties.
- (b) The NCSS reserves the right to conduct more frequent performance review meetings with no less than 4 weeks notice given to the Hospital
- (c) Performance Management meetings may consider, but not limited to, any of the following:
 - 1. Obligations 5(a)-(e)
 - 2. Review of KPIs
 - 3. Adverse incidents
 - 4. Any data or reports received by the NCSS requiring further clarification

18. DISPUTE RESOLUTION

- (a) The parties to this agreement agree to avoid disputes and deal with issues as they arise, through direct discussion.
- (b) Unexpected disputes which could potentially have an effect on the safety and quality of screening clients will be resolved in a timely manner. In the event of an urgent dispute, the parties will meet within 7 days to endeavour to resolve the issue within a further 14 days.

19. SCREENING COLONOSCOPY UNIT STATUS

- (a) Retention of BowelScreen Screening Colonoscopy Unit status is dependent on adherence to the contents of this MOU. The NCSS reserves the right to withdraw Screening Colonoscopy Unit status from the Hospital upon the failure of the Hospital to adhere to the service provision in line with the contents of this MOU.

19. TERMINATION OF MOU

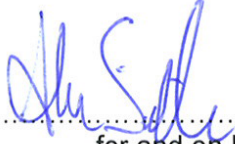
- (a) If during the course of 2014 the NCSS deem that the Hospital has not carried out the services in line with the contents of the MOU, the NCSS reserves the right to issue a termination notice of this MOU in writing to the Hospital and if within two months the Hospital does not take action to rectify the breach the NCSS reserves the right to terminate this MOU.
- (b) This MOU may be terminated by mutual consent of the parties. Either party may terminate this MOU upon one month written notice to the other.

IN WITNESS WHEREOF this MOU is executed by the parties as follows:-


Wexford General Hospital

DATED: 14/2/14

Name: Dr Alan Smith
Position: Medical Director – Screening Policy
Signed by


.....
for and on behalf of the
NATIONAL CANCER SCREENING SERVICE

Name Lily Byrnes
Position General Manager
Signed by


.....
for and on behalf of
HOSPITAL
14/2/14

SCHEDULE 1 - FEE

1. TOTAL FEE

- (a) The fee (inclusive of all taxes, expenses and other costs associated with or incurred in the performance of the service) to be paid by the NCSS in consideration of the performance of the services shall be in EUR.
- (b) The fee payable for each screening colonoscopy performed (including surveillance colonoscopies) will be 550EUR.
- (c) The payment of the fee of 550EUR for each screening colonoscopy will be dependent on adherence to Obligations 5(a), 5(b) and 5(c) listed above

2. PAYMENT OF THE FEE

- (a) The fee in respect of the services shall be payable by the NCSS via the HSE budgeting system (Rosetta).
- (b) Fee payments will be made quarterly in arrears
- (c) In the context of Obligation 5(a) there will be a **10% deduction** from the total fee payable for failure to adhere to $\geq 90\%$ of committed colonoscopies over the previous quarter¹

Working Example

- A Screening Colonoscopy Unit agrees to 10 colonoscopies per week
- This equates to 120 colonoscopies over a 12 week quarterly period
- 90% of $120 = 108$
- Full payment to the unit is guaranteed on completion of ≥ 108 colonoscopies i.e. ≥ 108 colonoscopies achieved means €550 per screening colonoscopy
- 10% payment deduction from total fee on < 108 completed colonoscopies i.e. < 108 colonoscopies achieved means €495 per screening colonoscopy

- (d) In the context of Obligation 5(b) the total fee payable will be calculated based on the number of colonoscopies reported on the COR database
- (e) In the context of Obligation 5(e) there will be a **10% deduction** in the fee payable in the event of two successive months of having ≥ 30 symptomatic patients waiting > 13 weeks for a GI endoscopy. This will be based on waiting list data returned to the NTPF.

3. UNFUNDED SERVICES

- (a) The Fee is payable for the provision of screening colonoscopies only. Any other services provided by the Hospital that have not been authorised in advance in writing by the NCSS shall be outside the scope of this MOU.
- (b) The costs of the Unfunded Services and all responsibilities, obligations and liabilities relating to or arising in connection with the Unfunded Services shall be the sole responsibility of the Hospital.

¹ This performance metric will only apply once the BowelScreen invitation process generates the agreed referral colonoscopies in 5 (a). Each unit will be notified when this point i.e. commencement date is reached for their unit.

SCHEDULE 2 - KEY PERFORMANCE INDICATORS

Key performance indicator	Minimum standard	Achievable standard
Proportion of clients offered colonoscopy within 4 weeks from when deemed clinically suitable following pre-assessment	≥90%	100%
Minimum number of colonoscopies undertaken annually by each screening endoscopist <ul style="list-style-type: none"> Colonoscopies (symptomatic & screening) per annum Screening colonoscopies (auditable after programme is running at full capacity) 	<ul style="list-style-type: none"> >300 >150 	
Unadjusted caecal intubation rate (CIR) with photographic evidence	≥90%	≥95%
Perforation rate of colonoscopy	<1 per 1,000 colonoscopies	
Post-polypectomy perforation rate	<2 per 1,000 colonoscopies where polypectomy is performed	
Post-polypectomy bleeding requiring transfusion (PPB)	<1% colonoscopies where polypectomy is performed	
Percentage of individuals scheduled for surveillance colonoscopy who undergo that procedure within 3 months of scheduled date	>85%	>90%
Cancer detection rate	≥2 per 1,000 screened	≥5 per 1,000 screened
Adenoma detection rate (ADR)	25% of colonoscopies	35% of colonoscopies
Median number of lymph nodes retrieved in non-neoadjuvant treated cases	>12	
Proportion of lesions reported as high-grade dysplasia	≤10%	
Proportion of polyp cancer identified as poor differentiation	≤20%	
Proportion of histopathological biopsy reports authorised and relayed to referrer within 5 working days of receipt of specimen in laboratory	≥90%	100%
Proportion of colon cancer referrals to a designated cancer centre taken place within 10 working days of histological diagnosis	≥90%	100%

OTHER MEASURABLE STANDARDS

The colorectal screening programme will also monitor other measurable standards that are included in the Quality guidelines. While these may not be KPIs, they will have an impact on the overall performance of the programme.

Standard	Minimum standard	Achievable standard
Bowel cleanliness at colonoscopy: excellent or adequate	≥90%	≥95%
Colonoscopic comfort	Auditable outcome	
Medication used for comfort during lower gastrointestinal (GI) endoscopy	Auditable outcome	
Use of reversal agents	Auditable outcome	
Colonoscopic cancer detection rate	≥11 per 100 colonoscopies	
Colonoscope withdrawal time	≥6 mins inspection time on withdrawal ≥90% of negative procedures	≥6 mins inspection time on withdrawal ≥95% of negative procedures
Retrieval rate of polypectomy specimens for histological analysis	≥90%	≥95%
Other adverse events of colonoscopy	Auditable outcome	
Referral rates for CT colonography referred for colonoscopy following a positive FIT	≤10%	
Proportion of polyp cancers with double reporting	100%	

Appendix 3: SIMT TOR

Terms of Reference for the Safety Incident Management Team

NIMT 50796

The Terms of Reference for this Safety Incident Management Team are set out in the Safety Incident Management Policy as follows:

1. Oversee the management of the incident including caring for those harmed, ensuring that the source of the harm is addressed so the risk of further harm arising is eliminated or reduced as far as is reasonably practicable and contingency plans for service continuity if required.
2. Ensure an appropriate investigation of the incident is conducted as per HSE Incident Management Policies and Guidelines
3. Facilitate sourcing of external independent experts to the look back review and/or related systems analysis investigations if the need for this is identified by competent HSE investigators
4. Manage communication with service users, staff, the public, internal and
5. External agencies as required linking with National Communication Representatives as necessary
6. Inform the recommendations arising out of investigations (if appropriate)
7. Arrange for expeditious implementation of recommendations of investigation as part of the organization's risk management work if appropriate (The respective divisions would be responsible for ensuring this)

The members of the Safety Incident Management Team include:

- Dr Orla Healy, Specialist in Public Health Medicine

Acute Hospitals Division

- Senior Hospital Group Representative Clinical/Administrative
- HR Representation
- Ms Angie O'Brien Communications Department
- Administrative support

Health & Wellbeing Division

- Majella Byrne Head of Screening NSS

- Dr Alan Smith Medical Director - Screening Policy
- NCSS Communications

As required local Clinical/ Administrative input. It is envisaged that the hospital team link and communicate with the Hospital Group Representative.

Through the Chairperson, the investigation team will:

Be afforded the assistance of all relevant staff and other relevant personnel. Should immediate safety concerns arise, the Chair of the safety incident Management team will convey the details of these safety concerns to the Commissioner as soon as possible.

7. Communication Strategy

A communication strategy will be determined.

Reference:

Safety Incident Management Policy, HSE, May 2014

Appendix 4: SIMT Membership

SAFETY INCIDENT MANAGEMENT TEAM Team Membership

Final Team Membership

Dr Orla Healy (Chair)	NIMLT
Ms Deirdre O’Keeffe	Interim Head of QPS, Acute Hospitals Division
Ms Mary Day²⁰	Group CEO, Ireland East Hospitals Group
Prof Diarmuid O’Donoghue	Clinical Director, BowelScreen
Mr Kevin O’Malley	Chief Clinical Director, Ireland East Hospitals Group
Dr Alan Smith²¹	Medical Director – Screening Policy, Interim Operations Director, BowelScreen BowelScreen
Ms Lily Byrnes²²	General Manager, WGH
Patient Advocate²³	Sheila O’Connor
Communications²⁴	Ms Angie O Brien and Ms Sheila Caulfield

Subgroups

Clinical	Mr Ken Mealy, Consultant Surgeon and BowelScreen Clinical Lead at WGH Prof Diarmuid O’Donoghue, Clinical Director, BowelScreen Mr Kevin O’Malley ,Chief Clinical Director, Ireland East Hospitals Group Medical Dr Alan Smith, Medical Director – Screening Policy, Interim Operations Director, BowelScreen, BowelScreen
Communications	Ms Sheila Caulfield, Head of Communications, NSS Ms Angie O’Brien, Area Communications Manager, HSE South
NSS	Ms Majella Byrne ,Head of Screening Service, NSS Ms Sheila Caulfield, Head of Communications, NSS Dr Alan Smith, Medical Director – Screening Policy, Interim Operations Director, BowelScreen BowelScreen Prof Diarmuid O’Donoghue, Clinical Director, BowelScreen
WGH	Ms Lily Byrnes, General Manager, WGH Ms Patricia Hackett, Services Manager Clinical Directorate, WGH Mr Ken Mealy, Consultant Surgeon and BowelScreen Clinical Lead at WGH Ms Eleanor Carpenter, Acting Clinical Risk Manager, WGH

²⁰ Alternate Mr Kilian Mc Grane, Deputy CEO

²¹ Alternate Ms Majella Byrne Head, National Screening Service

²² Alternate Ms Patricia Hackett Services Manager WGH

²³ Replaced by Ms Brigid Doherty Patient Focus

²⁴ Alternate Mr Fiachra O’Ceilleachair

Appendix 5: Procedural Guidelines for Patient Recall

NIMLT 50796 Patient Recall Procedural Guidelines 2015

HSE Policy Context

This incident is being managed in accordance with the following HSE Policies, Procedures and Guidelines.

- Draft Guideline for Conducting a Look-back Review (January 2015)
- QPSD-D-060-1.1: HSE Safety Incident Management Policy (2014).
- QPSD-GL-53_1: HSE Guideline for Systems Analysis Investigation of Incidents and Complaints (2015)
- Open Disclosure: National Guidelines (2013)
- Supporting Staff Following and Adverse Event: The Assist Me Model (HSE/SCA, 2013).
- Integrated Risk Management Policy (2011).
- Developing and Populating a Risk Register Best Practice Guidance (2009).
- HSE Information Security Policy
http://hsenet.hse.ie/HSE_Central/Commercial_and_Support_Services/ICT/Policies_and_Procedures/Policies/HSE_I_T_Security_Policy.pdf
- HSE I.T. Acceptable Usage Policy
http://hsenet.hse.ie/HSE_Central/Commercial_and_Support_Services/ICT/Policies_and_Procedures/Policies/HSE_I_T_Acceptable_Use_Policy.pdf
- HSE Electronic Communications Policy
http://hsenet.hse.ie/HSE_Central/Commercial_and_Support_Services/ICT/Policies_and_Procedures/Policies/HSE_Electronic_Communications_Policy.pdf
- HSE Encryption Policy
http://hsenet.hse.ie/HSE_Central/Commercial_and_Support_Services/ICT/Policies_and_Procedures/Policies/HSE_Encryption_Policy.pdf
- HSE Password Standard Policy
 - http://hsenet.hse.ie/HSE_Central/Commercial_and_Support_Services/ICT/Policies_and_Procedures/Policies/HSE_Password_Policy.pdf

Information Governance Protocol NIMLT 50796

1. Introduction

As healthcare professionals we are often privy to personal, confidential and in many instances extremely sensitive information. To work effectively, we need to be able to gather and share this information with those of us who really need to know.

As custodians of personal information each of us has responsibilities. Most notably - we must make every effort to keep personal information confidential and secure. The principles of confidentiality and data protection are part of our legal and ethical duties. Although, certain information is considered especially sensitive, all information about someone's health and the care they are given must be treated with regard to confidentiality at all times.

The aim of this protocol is to ensure that all staff working on the NIMLT 50796 Safety Incident is aware of their responsibilities with regard to good Information Governance.

2. Why do we need Information Governance

Information Governance provides a framework for handling information in a confidential and secure manner to appropriate ethical and quality standards. We need information to assist us in managing this incident. We must manage this information securely, efficiently and effectively, so we need a suitable policy to create a solid governance framework for how we handle the information we need to collect.

Good Information Governance will help patients:

- To be more confident in how the HSE handles their information.
- Be sure that information about them will only be shared with those who need to know and
- Share information so they receive the best service and care.

3. Confidentiality

Information especially if patient specific gained through work on the NIMLT 50796 Safety Incident is strictly confidential **and must not be discussed with any third party that is unauthorised to receive the information.**

All Media Communications must filter through the HSE nominated spokesperson.

- All management documentation related to the NIMLT 50796 incident is to be stored in one file location. This includes agendas, minutes, communications, briefings and any other suite of information that could be requested under Freedom of Information.
- When printing reports, avoid the use of identifiers, unless this is essential for the purpose of the report.
- All personal information related to the incident must be locked away when not personally attended. Care should be taken to ensure that documentation

related to the incident is not placed in any public place or where it may be viewed or accessed by an inappropriate person who has no need to be privy to this information. Always lock your laptop/computer when you have to leave it unattended. This will prevent unauthorised persons from viewing your private or confidential data. To lock your laptop/computer – you can press the *Ctrl, Alt* and *Delete* keys together and select *Lock Computer*.

- Any documentation from the incident containing personal information should be sent under confidential cover **by registered post only** and the contents should be similarly labelled as confidential. Letters to individual patients regarding scheduled appointments can be sent under normal post but every effort must be made to ensure that the patient address is correct and that the patient has not deceased.
- Only use HSE approved encrypted USB memory sticks.
- At a minimum, all electronic files related to this SI must be password protected and/or encrypted using HSE approved content encryption software (if available on your PC) when transmitting via e-mail.
- Care and vigilance are required at all times in the management of the incident database of audited files and patients to be recalled across both locations in WGH and NSS. These should be password protected. Regular updating of the databases is essential to ensure accurate and timely information to inform the safety incident management team.

Follow links for further guidance on

HSE ICT Policies - http://hsenet.hse.ie/CIO/Policies_and_Procedures/

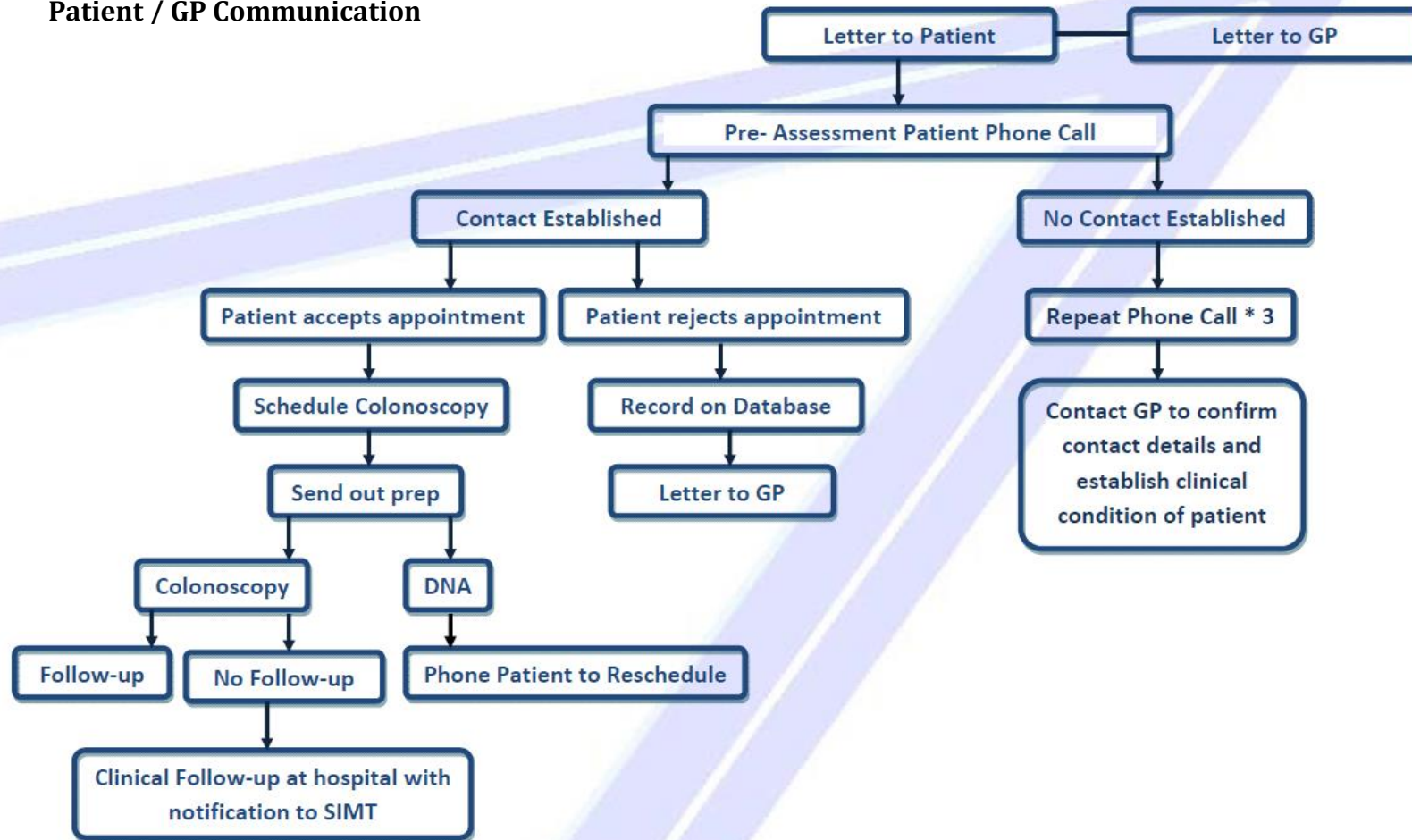
HSE ICT Security Standards -

http://hsenet.hse.ie/CIO/Security_and_Standards/Security/

HSE Data Protection -

http://www.hse.ie/eng/services/list/3/hospitals/ulh/staff/resources/pppgs/dp/DPstaff_guide.pdf

Patient / GP Communication



NB: Each step in process must be recorded on database assigned to liaison with responsibility for that case

SIMT 03/02/2015

Public Communication

All public communication will be conducted via the SIMT. Media queries should be directed to the Communications Subgroup. Special attention will be given to the interdependent timing of patient / service user, staff and media communications. The timing and nature of public communication is in accordance with HSE look-back guidance, i.e.

The principle behind all communication should balance reassurance with absolute disclosure. The following principles apply to all communications during a look-back review process:-

- **People are informed of their inclusion in the Recall Stage of the Look-back Review Process before the Recall Stage is commenced**
- Information on the Look-back Review Process is first given to the people whose care is being reviewed by the Recall Team
- Information subsequently given to media or others should not exceed what is shared with the people concerned
- The media should be provided with the FAQ document
- Patient confidentiality should be respected and maintained in all media communications
- The media should be educated on the communications process and its rationale

Appendix 6: Schedule of Meetings

Meeting 1	Safety Incident Management Team	26 th January 2016
Meeting 2	Safety Incident Management Team	28 th January 2015
Meeting 3	Safety Incident Management Team	2 nd February 2015
Meeting 4	Safety Incident Management Team	4 th February 2015
Meeting 5	Safety Incident Management Team	5 th February 2015
Meeting 6	Safety Incident Management Team	10 th February 2015
Meeting 7	Safety Incident Management Team	12 th February 2015
Meeting 8	Safety Incident Management Team	18 th February 2015
Meeting 9	Safety Incident Management Team	20 th February 2015
Meeting 10	Safety Incident Management Team	25 th February 2015
Sub-group Meeting	Clinical Sub-group Meeting	03th March 2015
Meeting 11	Safety Incident Management Team	05 th March 2015
Sub-group Meeting	Clinical Sub-group Meeting	11th March 2015
Meeting 12	Safety Incident Management Team	12 th March 2015
Meeting 13	Safety Incident Management Team	19 th March 2015
Meeting 14	Safety Incident Management Team	26 th March 2015
Sub-group Meeting	Clinical Sub-group Meeting	31st March 2015

Meeting 15	Safety Incident Management Team	02 nd April 2015
Sub-group Meeting	Clinical Sub-group Meeting	13th April 2015
Meeting 16	Safety Incident Management Team	09 th April 2015
Meeting 17	Safety Incident Management Team	16 th April 2015
Meeting 18	Safety Incident Management Team	22 nd April 2015
Meeting 19	Safety Incident Management Team	27 th April 2015
Meeting 20	Safety Incident Management Team	07 th May 2015
Meeting 21	Safety Incident Management Team	14 th May 2015
Meeting 22	Safety Incident Management Team	21 st May 2015
Meeting 23	Safety Incident Management Team	28 th May 2015
Meeting 24	Safety Incident Management Team	11 th June 2015
Meeting 25	Safety Incident Management Team	19 th June 2015
Meeting 26	Safety Incident Management Team	02 nd July 2015
Meeting 27	Safety Incident Management Team	20 th July 2015
Meeting 28	Safety Incident Management Team	24 th August 2015
Meeting 29	Safety Incident Management Team	27 th November 2015
Meeting 30	Safety Incident Management Team	16 th February 2016

Sub-group Meeting	Clinical Sub-group Meeting	13th April 2016
Meeting 31	Safety Incident Management Team	31 st August 2016
Sub-group Meeting	Clinical Sub-group Meeting	11 th November 2016
Meeting 32	Safety Incident Management Team	14 th November 2016
Meeting 33	Safety Incident Management Team	16 th December 2016
Meeting 34	Safety Incident Management Team	12 th January 2017

Appendix 7: BowelScreen Report April & Sept 2015

BowelScreen Frequency of Post Colonoscopy Colorectal Cancers (PCCR)

Dr Alan Smith on behalf of the Clinical Subgroup of the Safety Incident Management Team
(NIMLT Case Ref 5076)

27 April 2015

1. Background and terminology

- 1.1 The aim of BowelScreen is to detect colorectal cancers at an early stage or to prevent colorectal cancer by removing adenomas.
- 1.2 If a cancer or an adenoma is present but is not detected by colonoscopy it constitutes a *missed* lesion.
 - 1.2.1 Missed lesions only become apparent if the patient becomes symptomatic and requires a repeat investigation (for symptoms) or other reason or if a lesion is found during a surveillance colonoscopy within a timeframe such that it was likely to have been present during the previous investigation.
 - 1.2.2 These cancers are collectively termed **post-colonoscopy colorectal cancers (PCCRC)** ¹. PCCRC is often defined as the proportion of persons with CRC who underwent a colonoscopy up to 36 months prior to the diagnosis of CRC ².
 - 1.2.3 *Interval cancer* is a type of PCCRC and is a term used in population based cancer screening programmes. They refer to lesions detected between screening rounds or following a screening test in a previous round.

2. PCCRC as a quality indicator

- 2.1 PCCRC is a key quality indicator of colonoscopy. Several studies have sought to quantify the occurrence of PCCRCs and determine what factors predispose to their development ³⁻¹⁵. Across these studies PCCRCs were consistently seen to be more common in older age groups, in women, in the proximal bowel and following colonoscopies undertaken by non-specialist endoscopists.
 - 2.1.1 The reported rates in the literature of PCCRC have varied considerably from 2.5% to 7.5%. Although this could be due to differences in the quality of colonoscopic services across the populations considered, it may also be a reflection of the different datasets and methods used to calculate the rates.
 - 2.1.2 Most recently, in November 2014 a retrospective observational population based study involving all individuals with a first primary diagnosis of colorectal cancer made between 2001 and 2010 and treated in the English NHS was published. This reported an 8.6% PCCRC rate across the English NHS ¹⁶.
- 2.2 As it is likely that these cases will be relatively rare, the calculation of a BowelScreen PCCRC rate (interval cancer rate will take many years (rounds) to accumulate. Each reported or notified case requires a systematic and comprehensive case by case review to identify potentially correctible factors and learning points.

3. Wexford and Clinician Y incident (1 Oct 2014-27 April 2015)

3.1 A total of 7 confirmed cancers and 1 suspected cancer have been detected in a population of 395 patients who had their index screening colonoscopy¹ performed by Clinician Y during the period 5 March 2013-7 November 2014. See Table 1 below.

3.2 Clinical Subgroup met as the recall of 118 patients was nearing completion, to review clinical findings and to advise SIMT on necessary follow-up action

Table 1 Summary of Confirmed and Suspected Cancer Cases (to date)

COR ID	Project Code	Gender	Date of initial BowelScreen colonoscopy	Date and location of repeat colonoscopy	Site of CRC	Histology Confirmed Y/N
196847	IC 1	M	23 April 2013	02 October 2014	Caecum	Yes
147884	IC 2	M	25 June 2013	01 October 2014	Caecum	Yes
342123	P118/3	M	12 March 2013	05 March 2015	Rectal	Yes
817892	P118/4	F	29 October 2013	10 March 2015	Rectal lesion 10cm	Yes
182921	P118/5	M	14 May 2013	13 March 2015	Transverse Colon	No Large 18mm lesion. Clinicians suspect CRC. Await surgery and post surgery histopathology
633452	P118/6	F	16 April 2013	1. 23 February 2015 2. 31 March 2015	Biopsy confirmed adenocarcinoma from descending colon in 31 March colonoscopy	Yes
508117	IC/7	M	29 January 2014	17 April 2014	Colon - splenic flexure	Yes
17415	IC/8	M	01 April 2013	26 March 2015	Rectal 10CM	Yes
Nomenclature						
Interval Cancer = IC						
Project 118 = P 118						
	Original two index cases notified to BowelScreen					
	Cancer cases detected during recall of 118					
	Clinically suspected case detected during recall of 118					
	Two further interval cancers cases notified to BowelScreen outside of recall of 118					

¹ All 395 patients were invited to participate in BowelScreen and had a positive faecal immunochemical test (FIT) thereby requiring a colonoscopy.

- 3.3 The Clinical Subgroup are treating all 7 confirmed cases as post colonoscopy colorectal cancers and are treating all 7 confirmed cases as presumed missed.
- 3.4 To date no other PCCRC (interval) cancer cases have been reported/ notified to the BowelScreen programme from any source.

4. Quantitative evaluation of 7 missed cancers

- 4.1 On 13 April 2015 the Clinical Subgroup undertook to assess this performance i.e. 7 missed cancers amongst 395 screening colonoscopies performed.
- 4.2 Professor Roland Valori assisted the Clinical Subgroup in its discussions.
- 4.3 The performance was assessed using the following known/fixed variables (up to 13 April 2015)
- 5,925 colonoscopies performed in BowelScreen
 - 252 cancers provisionally diagnosed ² in BowelScreen
 - Cancer detection rate of 4.25 per 100 screening colonoscopies (95% CI 3.7-4.7)
 - Number of screening colonoscopies performed by Consultant Y = 395
 - Number of presumed missed cancers in this incident = 7
- 4.4 The performance was assessed under five reported PCCRC rates in the literature ¹⁶
- PCCRC rates of 2.5%, 4.5%, 7.5%, 7.7% and 8.6%

4.5 Results

- 4.5.1 Assuming a PCCRC rate of 8.6% an endoscopist would be expected to perform 1,938 screening colonoscopies to miss 7 cancers (95% CI 1,238 - 3,704).
- 4.5.2 Assuming a PCCRC rate of 7.7% an endoscopist would be expected to perform 2,165 screening colonoscopies to miss 7 cancers (95% CI 1,357-4,290)
- 4.5.3 Assuming a PCCRC rate of 7.5% an endoscopist would be expected to perform 2,222 screening colonoscopies to miss 7 cancers (95% CI 1,387-4,498)
- 4.5.4 Assuming a PCCRC rate of 4.5% an endoscopist would be expected to perform 3,704 screening colonoscopies to miss 7 cancers (95% CI 2,132-9,941)
- 4.5.5 Assuming a PCCRC rate of 2.5% an endoscopist would be expected to perform 6,667 screening colonoscopies to miss 7 cancers (95% CI 3,385-31,506)

² Figure is considered provisional until all data is validated and confirmed after the end of the screening round

Conclusion

- It is the view of the Clinical Subgroup that the PCCRC rate in BowelScreen is likely to be closer to 2.5% than 8.6%. This view is currently based on the high adenoma detection rates reported in BowelScreen screening colonoscopy units.
- Even under the circumstances of the highest PCCRC rate of 8.6% modelled here, a total of 7 missed cancers in 395 screening colonoscopies is significantly higher than would be expected. See Table 2.

Table 2 Output of PCCRC Model using a PCCRC rate of 8.6%

Post Colonoscopy Colorectal Cancer Scenario			
Model assumption 1	Cancer Rate % in BowelScreen colonoscopies	4.2	
	A total of	23.8	screening colonoscopies are done to detect 1 cancer
Model assumption 2	Post Colonoscopy Colorectal Cancer Rate % (PCCRC)	8.6	
	One cancer missed for every	11.6	cancers detected
Model assumption 3	Number of suspected PCCRC cancers	7	← INSERT NUMBER OF PCCRC HERE
	How many BowelScreen colonoscopies would you typically expect to do in clinical practice to see 7 PCCRC cancers under model assumptions 1 and 2	1,938	

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BowelScreen

Frequency of Post-colonoscopy Colorectal Cancers (PCCR)

Dr Alan Smith

(NIMLT Case Ref 5076)

14 September 2015

Background and terminology

The aim of BowelScreen is to detect colorectal cancers at an early stage or to prevent colorectal cancer by removing adenomas.

If a cancer or an adenoma is present but is not detected by colonoscopy it constitutes a *missed* lesion.

Missed lesions only become apparent if the patient becomes symptomatic and requires a repeat investigation (for symptoms) or other reason or if a lesion is found during a surveillance colonoscopy within a timeframe such that it was likely to have been present during the previous investigation.

These cancers are collectively termed **post-colonoscopy colorectal cancers (PCCRC)** Error! Reference source not found.. PCCRC is often defined as the proportion of persons with CRC who underwent a colonoscopy up to 36 months prior to the diagnosis of CRC Error! Reference source not found..

Interval cancer is a type of PCCRC and is a term used in population based cancer screening programmes. They refer to lesions detected between screening rounds or following a screening test in a previous round.

PCCRC as a quality indicator

PCCRC is a key quality indicator of colonoscopy. Several studies have sought to quantify the occurrence of PCCRCs and determine what factors predispose to their development Error! Reference source not found.. Error! Reference source not found. Across these studies PCCRCs were consistently seen to be more common in older age groups, in women, in the proximal bowel and following colonoscopies undertaken by non-specialist endoscopists.

The reported rates in the literature of PCCRC have varied considerably from 2.5% to 7.5%. Although this could be due to differences in the quality of colonoscopic services across the populations considered, it may also be a reflection of the different datasets and methods used to calculate the rates.

Most recently, in November 2014 a retrospective observational population based study involving all individuals with a first primary diagnosis of colorectal cancer made between 2001 and 2010 and treated in the English NHS was published. This reported an 8.6% PCCRC rate across the English NHS **Error! Reference source not found.**

As it is likely that these cases will be relatively rare, the calculation of a BowelScreen PCCRC rate (interval cancer rate will take many years (rounds) to accumulate. Each reported or notified case requires a systematic and comprehensive case by case review to identify potentially correctable factors and learning points.

Wexford and Clinician Y incident (1 Oct 2014-14 September 2015)

A total of **13 confirmed cancers** have been detected in a population of 384 patients who had their index screening colonoscopy²⁵ performed by Clinician Y during the period 5 March 2013-7 November 2014. See Table 4 below.

Table 4 Summary of Confirmed Cancer Cases (to date)

Project Code	Gender	Date of initial BowelScreen colonoscopy	Date of repeat colonoscopy	Site of CRC	Histology Confirmed Y/N
C 1	M	23/04/2013	02/10/2014	Caecum	Yes
C 2	M	25/06/2013	01/10/2014	Caecum	Yes
P118/3	M	12/03/2013	05/03/2015	Rectal	Yes
P118/4	F	29/10/2013	10/03/2015	Rectal	Yes
P118/5	M	14/05/2013	13/03/2015	pT1 (transverse colon)	Yes
P118/6	F	16/04/2013	1. 23 February 2015 2. 31 March 2015	Biopsy confirmed adenocarcinoma from descending colon in 31 March colonoscopy	Yes
C/7	M	29/01/2014	17/04/2014	Colon - splenic flexure	Yes
C/8	M	01/04/2013	26/03/2015	Rectal	Yes
P211/9	M	30/07/2013	23/05/2015	Transverse colon	Yes
P211/10	F	08/04/2014	13/06/2015	Ascending colon	Yes
P211/11	M	28/10/2014	13/06/2015	pT1 (descending colon)	Yes
P211/12	M	29/04/2014	13/06/2015	pT1 (sigmoid colon)	Yes
C/13	F	01/04/2014	26/05/2015	Sigmoid colon	Yes

Nomenclature

Interval Cancer = IC

Project 118 = P 118

Project 211=P 211

	Original two index interval cancer cases notified to BowelScreen
	Cancer cases detected during recall of 118
	Two further interval cancers cases notified to BowelScreen outside of recall of 118
	Cancer cases detected during recall of 211
	Interval Cancer detected at a scheduled 1 year recall of a high risk patient

The clinical sub-group are treating all 13 confirmed cases as post colonoscopy colorectal cancers and are treating all as presumed missed.

Quantitative evaluation of 13 missed cancers

The figures presented in this report reflect the figure of 13 presumed missed cancers and are an update to the report of the incident clinical sub-group report of 27 April 2015.

The performance was assessed using the following known/fixed variables (up to 11 September 2015):

- 6,254 colonoscopies performed in BowelScreen
- 317 cancers provisionally diagnosed²⁶ in BowelScreen
- Cancer detection of 5.01 per 100 screening colonoscopies (95% CI 4.5-5.5)

²⁵ All 384 patients were invited to participate in BowelScreen and had a positive faecal immunochemical test (FIT) thereby requiring a colonoscopy.

²⁶ Figure is considered provisional until all data is validated and confirmed after the end of the screening round

- Number of [index] screening colonoscopies performed by Consultant Y = 384²⁷
- Number of presumed missed cancers in this incident = 13
- The performance was assessed under five reported PCCRC rates in the literature¹⁶ PCCRC rates of 2.5%, 4.5%, 7.5%, 7.7% and 8.6%

Results

Assuming a PCCRC rate of 8.6% an endoscopist would be expected to perform 3,017 screening colonoscopies to miss 13 cancers (95% CI 2,020-5,253).

Assuming a PCCRC rate of 7.7% an endoscopist would be expected to perform 3,370 screening colonoscopies to miss 13 cancers (95% CI 2,230-6,147)

Assuming a PCCRC rate of 7.5% an endoscopist would be expected to perform 3,460 screening colonoscopies to miss 13 cancers (95% CI 2,273-6,280)

Assuming a PCCRC rate of 4.5% an endoscopist would be expected to perform 5,766 screening colonoscopies to miss 13 cancers (95% CI 3,476-13,131)

Assuming a PCCRC rate of 2.5% an endoscopist would be expected to perform 10,379 screening colonoscopies to miss 13 cancers (95% CI 5,601-37,037)

Conclusion

It is the view of the clinical sub-group that the PCCRC rate in BowelScreen is likely to be closer to 2.5% than 8.6%. This view is currently based on a national adenoma detection rate of 50.2% (at 31 July 2015) in BowelScreen screening colonoscopy units.

Even under the circumstances of the highest PCCRC rate of 8.6% modelled here, a total of 13 missed cancers in 384 index screening colonoscopies is significantly higher than would be expected. See Table 5.

Table 5 Output of PCCRC Model using a PCCRC rate of 8.6%

Post Colonoscopy Colorectal Cancer Scenario			
Model assumption 1	Cancer Rate % in BowelScreen colonoscopies	5.01	←INSERT CANCER RATE IN BOWELSCREEN HERE
	A total of	20.0	screening colonoscopies are done to detect 1 cancer
Model assumption 2	Post Colonoscopy Colorectal Cancer Rate % (PCCRC)	8.6	←INSERT PCCRC RATE HERE
	One cancer missed for every	11.6	cancers detected
Model assumption 3	Number of suspected PCCRC cancers	13	←INSERT NUMBER OF PCCRC HERE
	How many BowelScreen colonoscopies would you typically expect to do in clinical practice to see [model assumption 3] PCCRC cancers under model assumptions 1 and 2	3,017	

²⁷ There were a further 11 cases in which Clinician Y did a repeat procedure but these 11 patients had their index screening colonoscopy performed by another Clinician.

Appendix 8: BowelScreen SOP following Notification of Interval Cancer

	Title; Response to the notification of a post-colonoscopy colorectal cancer (interval cancer)
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Written /Revised By (Title)	Name	Signature	Date
Interim Operations Director BowelScreen Medical Director - Screening Policy NSS	Dr Alan Smith		
Approved By (Title)	Name	Signature	Date
Interim Operations Director BowelScreen Medical Director - Screening Policy NSS	Dr Alan Smith		
Clinical Director & Chair of CR Clinical Advisory Group	Prof Diarmuid O'Donoghue		

Document Revision History			
Rev	Change Details	Revised By	Date Effective
1	Initial Release	N/A	8/6/15
2			
3			
4			

Purpose & Scope (including Quality Standards)

To outline the actions following the notification of a post-colonoscopy colorectal cancer (interval cancer)

Responsibility

Responsibility for Implementation of document: Operations Director and Clinical Director.

Responsibility for Upkeep of document: Operations Director

References:

HSE Open Disclosure Policy

National Cancer Screening Service Guidelines for Quality Assurance in
Colorectal Screening

CR-QP-002 Appendix BowelScreen Interval Cancer Case Report Format
Method

Confirm colorectal cancer diagnosis, along with clinical details available (site, stage, treatment plan).

Confirm screening pathway from invitation through to screening colonoscopy, reported findings and clinical management decision

Notify the screening colonoscopy unit involved via Clinical Lead and General Manager/CEO

Request screening colonoscopy unit to manage the notification under its own clinical governance and risk management structures.

This should include a review of the screening colonoscopy endoscopy record, any histopathology and the clinical management decision to determine if there are potential explanatory variables, correctable factors or quality issues of concern.

Screening colonoscopy unit to refer any performance or quality issues to the relevant Hospital Group CEO and HSE Acute Hospitals Directorate

BowelScreen to review clinician's adenoma detection rate (objective data) and caecal intubation rate (unit audit data) and a sequential series of 50 photos of the caecum confirming completion

BowelScreen to review screening colonoscopy units twice yearly Global Rating Scale census returns to JAG

BowelScreen CAG to review case documentation and to classify case notification as either (1) colonoscopy interval cancer (non-surveillance) or (2) surveillance interval cancer

BowelScreen CAG to make recommendation of either (1) 'interval cancer – no further investigation required' or (2) 'interval cancer – further investigation required'.

Complete case notification report

BowelScreen Executive Management Team to review and approve case notification report

BowelScreen to send a copy of the case notification report to the relevant screening colonoscopy unit

In the event of an interval cancer – further investigation required the NSS Head of Screening to notify National Director, Health and Wellbeing Division

Open disclosure remains responsibility of screening colonoscopy unit

Timing and manner of 'open disclosure' will be dependent on notification, clinical circumstances, treating Consultant, wishes of affected patient.

Quality Control & Audit

N/A