

EXTERNAL REVIEW OF NIMLT CASE 50796

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EXECUTIVE SUMMARY

This review has been carried out to assess the governance and management of the look back process that occurred in relation to the Wexford Screening incidents where two post screening colonoscopy colorectal cancers were identified in October 2014. In addition, the review has examined the current governance arrangements pertaining to Quality Assurance (QA) between BowelScreen and those hospitals providing services for BowelScreen.

The conclusions of this review are that:

1. The look back process was carried out in a timely and efficient manner, and to the highest possible standards.
2. There were missed early opportunities to identify shortcomings in the performance of the colonoscopist responsible for the incident, but that there were significant mitigating circumstances surrounding this.
3. Current QA governance arrangements between BowelScreen and its provider units are appropriate.

The recommendations from this review are:

- That the recommendations made in the Safety Incident Management Team (SIMT) final report are followed.

In addition:

- That there should be a regular programme of revision of Quality Assurance Guidelines and the tolerance limits set by these Guidelines.
- That the quality of screening colonoscopy be audited both at Unit and individual endoscopy level, and that findings should be fed back to the provider unit in the form of confidential comparative audit, whereby the provider unit can assess its performance against other units.
- That a robust statistical approach to the analysis of KPIs using funnel plots be considered in order to assist with the identification of outliers.
- That BowelScreen develops SOPs for the investigation of outlying units and endoscopists.

- That the reporting of post colonoscopy colorectal cancers is formalised and optimised, and whenever this occurs to ensure that the colonoscopist concerned is informed and that his or her performance as assessed by the KPIs is satisfactory.
- That the collection and audit of Key Performance Indicators for the National Colonoscopy Service and BowelScreen are harmonised so that the data only has to be collected once and BowelScreen can avail itself of a comprehensive national database.
- That consideration should be given to individual accreditation of all colonoscopists utilising the direct observation of procedural skills (DOPS) methodology *at the end of training*
- That consideration should be given to the development of a formal process for expressing concerns such as that provided by the National Clinical Assessment Service (NCAS) in the United Kingdom.
- That when a SIMT report and Systems Analysis reports are required for the same incident the processes are linked to avoid inconsistencies and delays

SCOPE OF REVIEW

This review was commissioned by the National Director, Health and Wellbeing and the National Director, Acute Hospitals Division, HSE, and, in accordance with the terms of reference is divided into two parts:

1. Review of the governance and management of the look back process that occurred in relation to the Wexford Screening incidents
2. Review of the current governance arrangements pertaining to Quality Assurance (QA) between BowelScreen and those hospitals providing services for BowelScreen

In part 1 (Review of the governance and management of the look back process that occurred in relation to the Wexford Screening incidents), the review will

- a. Investigate the governance, accountability and authority at each level involved in the incident with particular reference to the roles of
 - The Commissioners
 - SIMT
 - Endoscopy Units
 - The Hospital Group (Ireland East)
 - Wexford General Hospital
- b. Consider if, overall, the incident was completed in a timely manner, appropriate to the clinical risk the incident posed to patients with particular reference to the timelines of the following crucial elements of the incident:
 - Pre-escalation
 - Escalation
 - Risk Assessment
 - Audit Phases
 - Recall Phases
 - Systems analysis and related decisions
 - Open disclosure
 - Communications
 - Report finalisation and close out of SIMT
- c. Make recommendations on the following:
 - The conduct of the BowelScreen Programme
 - The conduct of future look backs
 - Hospital Level management and governance of endoscopy services

In part 2 (Review of the current governance arrangements pertaining to Quality Assurance (QA) between BowelScreen and those hospital providing services for BowelScreen), the review will:

- a. Examine the governance procedures of the Quality Assurance (QA) process in place between BowelScreen and those hospitals providing services for BowelScreen.
- b. Examine the current Quality Assurance process in place between BowelScreen and its providers and consider possible additional enhanced measures that might be put in place to ensure the QA standards are robustly implemented
- c. Make recommendations to support further learning and improvement regarding how to assure and support the purchasing of safe and effective quality assuring services.

SOURCES

This report was compiled from the following sources:

1. Papers supplied by BowelScreen including;
 - a. The Safety Incident Management Team (SIMT) Final Report on the Incident dated 17th January 2017,
 - b. The Systems Analysis Reports on the Incident (one for each index case) dated 30th November 2016
 - c. Minutes of all relevant meetings leading up to the Final Report.
 - d. Extensive correspondence and further documentation related to the incident
2. Interviews with the Following:
 - a. Dr Stephanie O’Keeffe, National Director, Health and Wellbeing, HSE (Commissioner of Final SIMT Report)
 - b. Mr Liam Woods, National Director, Acute Hospitals Division, HSE (Commissioner of Final SIMT Report)
 - c. Dr Orla Healy, Chair of SIMT and author of final report
 - d. Dr Alan Smith, Former Programme Director, BowelScreen, National Screening Service (NSS)
 - e. Prof Diarmuid O’Donoghue, Clinical Lead, BowelScreen, NSS
 - f. Ms Lily Byrnes, General Manager
 - g. Mr Ken Mealy Clinical Lead, Wexford General Hospital
 - h. Patrick Lynch, National Director, Quality Assurance and Verification Division, HSE
 - i. Charles O’Hanlon, Head of Services, NSS
 - j. Mr Tom O’Brien, BowelScreen Programme Manager, NSS
 - k. Dr Chris Steele, National Clinical Lead for Endoscopy, HSE
 - l. Staff member, Wexford General Hospital

THE BOWEL SCREENING PROCESS IN IRELAND

Basic Process

The population Bowel Screening Programme in the Republic of Ireland, termed BowelScreen, is offered to all men and women between the ages of 60 and 69 with a long-term plan to expand this age range to 55 to 74. The screening test is a Faecal Immunochemical Test (FIT) and the current threshold for triggering a colonoscopy invitation is 45mcg of haemoglobin per gram of faeces. The programme has a dedicated IT system that is populated by key performance indicators (KPIs). The data are entered by clinical nurse specialists and monitored monthly by a BowelScreen Clinical Advisory Group. There is also a random annual audit completed in each hospital by the Clinical Lead for BowelScreen.

Commissioning

Colonoscopy is commissioned by BowelScreen and a memorandum of understanding is created between BowelScreen and the colonoscopy provider units. The details of this memorandum of understanding are included as an appendix to the SIMT Final Report but the key issues in this context are as follows:

- Colonoscopy will be delivered in line with the guidelines for Quality Assurance in Colorectal Screening produced for the Irish Programme.
- The screening programme provides the hospital screening colonoscopy unit with access to a database to be used for the collection and recording of screening data.
- A designated BowelScreen Endoscopy Co-ordinator is provided for each Unit as a point of contact.
- The outcome of all screening colonoscopies are entered on to the hospital's endoscopy reporting system.
- The Unit must maintain NHS Joint Advisory Group on Gastroenterology (JAG) accreditation including the completion of twice yearly global rating scores (GRS) returns.
- The Unit will provide the names and contact details of:
 1. A Clinical Lead
 2. A Trainer/Mentor for the Clinical Nurse Specialists
 3. A Nurse Lead
 4. A Managerial Lead
- The Unit will provide adequate bowel preparation for the screening colonoscopies.
- Detailed documentation of activity will be recorded in each Centre to allow clinical and administrative audit when necessary.
- All data is logged onto the screening database in an accurate and timely manner.

- The hospital report to the screening service any adverse incidents related to Bowel Screening clients without delay.
- The unit agrees to adhere to the Guidelines for Quality Assurance in Colorectal Screening.
- The unit will have an appropriate governance structure for managing compliance with QA Guidelines for all endoscopists carrying out screening colonoscopy, and will in the first instance address non-compliance issues themselves.
- The screening service reserves the right to seek a review meeting with the unit should it become aware or have concerns about deviation from the guidelines.
- Those identified as Clinical Trainers or Mentors must undergo appropriate Train the Trainer Courses within 6 months of commencement of a screening colonoscopy unit.
- The screening service reserves the right to conduct more frequent performance review meetings with no less than 4 weeks' notice given to the unit.
- The screening service reserves the right to withdraw screening colonoscopy unit status from the unit and issue the termination notice of an MOU should the unit fail to adhere to the service provision in line with the contents of the MOU.
- The fee payable for each screening colonoscopy performed is €550.

Key Performance Indicators

The key performance indicators (KPIs) relating to colonoscopy and relevant to this review are as follows

- The minimum number of colonoscopies undertaken annually by each screening colonoscopist must be over 300 of which at least 150 should be screening colonoscopies.
- The unadjusted caecal intubation rate with photographic evidence should be greater than 90%.
- The adenoma detection rate should be greater than 25% of colonoscopies. (This is a minimum standard and the achievable standard stated in the KPIs is 35%).

Other measureable standards which may not be KPIs but which are included in the Quality Guidelines are as follows

- Bowel cleanliness at colonoscopy excellent or adequate in over 90% of cases.
- Colonoscopy withdrawal time equal to or greater than 6 minutes in over 90% of negative procedures.

CHRONOLOGY OF THE INCIDENT AND ITS MANAGEMENT

In September 2014 a patient who had undergone a screening colonoscopy in April 2013 at Wexford General Hospital (WGH) was diagnosed at colonoscopy to have a caecal cancer. The BowelScreen Service was informed of this on October the 8th 2014 by the Consultant Surgeon, not employed at Wexford General Hospital (WGH), who had performed the cancer surgery for this patient.

In keeping with the memorandum of understanding between Wexford General Hospital (WGH) and BowelScreen, WGH were requested to undertake an immediate case review.

On October 27th 2014 the BowelScreen Programme was informed of a second case of caecal cancer diagnosed in a previously screened patient. This patient was notified by the BowelScreen Clinical Lead at WGH who also performed this patient's cancer surgery in October 2014. This patient had undergone screening colonoscopy at WGH in June 2013.

Both of these patients had had their screening colonoscopy performed by the same clinician (Clinician Y) at WGH.

Relevant to these two incidents, it was reported that, in March/April 2013, soon after the commencement of screening colonoscopies at WGH, a HSE employee had expressed concern to Clinician Y about his completion of colonoscopy. The staff member went on to express these concerns in May 2013 to BowelScreen by telephone and was reassured that the concerns would be communicated to the Clinical Lead at WGH. A conversation took place between the Clinical Lead at BowelScreen and the Clinical Lead of WGH, but when the employee saw no improvement in Clinician Y's performance, the employee went back to the Clinical Lead at WGH and communicated concerns verbally in June 2013. The Clinical Lead at WGH then spoke to other staff who did not raise concerns about any of the colonoscopists. In addition, Clinician Y's self-reported completion rate was over 90% and his adenoma detection rate (ADR) was within the accepted range for BowelScreen. In September 2013, after a further conversation between the employee and the Clinical Lead at WGH, the Clinical Lead sent a recently published article to all members of the Multidisciplinary Team which emphasised the need to reach the caecum during colonoscopy. In December 2013, the employee suggested an audit of the caecal photographs that the endoscopists had been requested by BowelScreen to take at each colonoscopy. The provision of these photographs was required in the BowelScreen QA guidelines, but was a self-reported measure by each endoscopist.

The employee was asked in March 2014 to document the concerns by management. In April 2014, the Clinical Lead at WGH discussed these concerns with BowelScreen and was informed that it was the responsibility of WGH to deal with them as detailed in the MoU between BowelScreen and WGH. Around this time, the Clinical Lead at WGH carried out an informal review of clinician Y's colonoscopy contemporary reports and photographs which he found to be satisfactory. He also issued a memo to all endoscopists to the effect that: 1. Colonoscopy

completion must be documented by a caecal photograph, 2. A formal audit of these photographs be performed and 3. Team agreement (i.e. between endoscopist and nurses) of caecal intubation should be reached in all cases. It was agreed that the aforementioned audit (which was a joint decision between the Clinical Lead at WGH and BowelScreen) should start in the Autumn of 2014. BowelScreen made a routine site visit to WGH in May 2014 during which the professional discord between the staff member of the HSE and the colonoscopist in question was noted. The required KPIs were being monitored and were noted to be currently satisfactory. At this meeting it was agreed that the BowelScreen Clinical Advisory Group (CAG) colonoscopy audit template was to be circulated to all screening colonoscopy units before end of June 2014. On 8th October 2014, the first PCCRC was reported.

It should be noted that the team who carried out the systems analysis reviews recorded that several staff observed that there was professional discord between the employee and Clinician Y. However it should also be noted that the employee received a firm endorsement as a highly competent professional from a manager. These observations were also made at interview by the author of this report.

After notification of the second post-colonoscopy colorectal cancer BowelScreen requested WGH to undertake a second case review and at the same time they again reviewed the key performance indicators for WGH. The adenoma detection rate at WGH was at 35.3% (exceeding the BowelScreen Quality Assurance Standard of 25% to 35%). Clinician Y's adenoma detection rate was 26.33% falling within the acceptable quality assurance range. However, it should be noted that all screening units in the country exceeded the QA Standard ranging from 35.3% to 65.1% when this was analysed in November 2014.

It was agreed between BowelScreen, WGH and Clinician Y on November the 13th 2014 that Clinician Y would stop carrying out screening colonoscopies, at least until the case reviews were completed. It was agreed, however, that Clinician Y should continue to perform colonoscopy on symptomatic patients under clinical supervision.

The BowelScreen Clinical Lead at WGH then went on to review all screening colonoscopy reports since the programme commenced. This process was completed by December 2014 and it was found that an adequate photograph of the caecum (a QA requirement of BowelScreen) was missing in approximately 30% of Clinician Y's screening colonoscopy reports. It was noted that the colonoscopy reports of the two patients who had prompted the review were not accompanied by an adequate photograph of the caecum. The work of the other endoscopists at WGH did not give rise to concern.

These findings were transmitted to BowelScreen on December the 16th 2014.

A subsequent validation audit of the same records was carried out by the BowelScreen Clinical Director on the 7th and 8th of January 2015 and the findings were found to be consistent.

On the 15th of January 2015 the BowelScreen Clinical Advisory Group recommended that all screening patients who had undergone colonoscopy by Clinician Y, whose colonoscopy reports did not contain an adequate photograph of the caecum, should be recalled for a repeat colonoscopy.

The following day (16th of January 2015) this incident was escalated to the National Incident Management and Learning Team (NIMLT) and a Cross Divisional Senior Management Meeting was held on the 20th January 2015 to discuss the incident. Consequently a Safety Incident Management Team (SIMT) was commissioned by the National Director of Health and Wellbeing and Acute Services on the 23rd January 2015, and this team held their first meeting on the 26th of January 2015.

Subsequent to these meetings, Clinician Y's *symptomatic* colonoscopy work underwent a peer review audit by two Consultant Colorectal Surgeons on February the 4th and 5th 2015 and the report was made available on February 10th 2015. The recommendation was for recall of 163 patients to the outpatient department to determine who would require repeat colonoscopy.

In addition to this the clinical files of 55 patients, where Clinician Y had been the secondary endoscopist (i.e. supervising another colonoscopist), were reviewed on March the 18th 2015 and as a result 30 patients were immediately phoned and recalled for outpatient appointments.

Clinician Y ceased all colonoscopy work on February the 16th 2015 by mutual agreement between WGH and Clinician Y. This was because it was agreed that the level of supervision required to ensure that he did not undertake colonoscopy independently was putting too great demands on consultant colleagues. Clinician Y subsequently went on leave and remained on leave during the investigation process. He has subsequently undergone retraining in colonoscopy, but has not returned to work.

On March the 31st 2015 the Clinical Sub Group of the SIMT reviewed the interim recall findings, and because cancers identified amongst the cohort of patients who were having repeat colonoscopy were anatomically located outside the caecum it was recommended that repeat colonoscopy should be performed for all patients who had had a screening colonoscopy performed by Clinician Y (and not just those in whom a photograph of the caecum was missing).

Thus there are two recall phases to this look back process:

1. Only screening patients in whom the caecum had not been adequately photographed and the selected symptomatic cohort.
2. All the other screening patients and further symptomatic patients colonoscoped by Clinician Y or under his supervision.

Phase 1 Recall

Process

Recall letters for phase 1 were posted on 13th February 2015 and phone calls for pre-assessment for colonoscopy started on the 16th February 2015. Subsequently colonoscopy appointments were offered from 23rd February 2015 and outpatient department appointments between 18th February 2015 and 6th March 2015. Appointments for both outpatient consultation and colonoscopy were made available to all patients within 3 weeks and within 1 month of initial contact 77% of the screening patients had had their recall colonoscopy. During phase 1 it was appreciated that Clinician Y had supervised 55 colonoscopies performed by non-Consultant hospital doctors (NCHD) in a training capacity. These were included in the audit of Clinician Y's symptomatic patients who had undergone colonoscopy and on the instruction of the SIMT these patients were given outpatient appointments with all other phase 1 patients.

Phase 1 Findings

Four cancers were identified among the cohort of screening patients but it was noted that all four of these cancers were anatomically located outside the caecum and it was appreciated that, in this instance, photographic evidence of the caecum was not sufficient to guarantee the quality of the colonoscopy. There were no cancers diagnosed among Clinician Y's symptomatic patients.

Phase 2 Recall

Process

Owing to the discovery that cancers in the screening patients had been located outside of the caecum a decision was taken by SIMT to recommend repeat colonoscopy for all screening patients who had undergone colonoscopy by Clinician Y. The phase 2 recall letters were issued on 24th April 2015 and pre-assessment telephone calls commenced on 28th April 2015 in order to organise appointments from the 5th May 2015, although earlier appointments could be requested. Recall colonoscopy in phase 2 was carried in 79% of individuals within one month of contact.

Phase 2 Findings

In phase 2 a further 4 cases of colorectal cancer were identified (again all of them outside of the caecum).

Summary of Phase 1 and Phase 2

In total this look back process involved the recall of 615 individuals either for an outpatient appointment or for repeat colonoscopy. The audit cohort consisted of 384 screening

individuals, 320 symptomatic individuals and 55 individuals undergoing colonoscopy by an NCHD under supervision by Clinician Y.

In phase 1, 118 screening patients (where evaluable photographs of the caecum were not available) underwent a recall colonoscopy. Of the 320 symptomatic patients 165 were recalled to the outpatients department and 49 underwent a further colonoscopy. Of the 55 NCHD patients, 30 were seen at outpatients and 10 underwent a further colonoscopy.

In phase 2, 211 screening patients underwent recall colonoscopy, 68 symptomatic patients and 23 NCHD patients were seen at outpatients, and of these 91 patients, 13 had a further colonoscopy. Thus in total 615 patients were recalled, 401 were recalled for colonoscopy, 37 did not attend so that a total of 364 attended colonoscopy.

Out of the population of 384 patients who underwent their first screening colonoscopy by Clinician Y between 5th March 2013 to 7th November 2014, 13 cancers were detected in individuals who had an initial screening colonoscopy that had been reported to be normal. Two of these cases prompted the recall, 4 cases were identified in phase 1, and 2 cases presented independently during the phase 1 period. Four cases were identified in phase 2 and 1 case was identified at the planned surveillance colonoscopy of a high risk patient. Thus 13 post colonoscopy colorectal cancers out of 384 colonoscopies were identified.

Owing to patient preference it was not possible to carry out every out-patient appointment or colonoscopy expeditiously but recall was complete in the 98% by July 2015 and 100% by March 2016.

Notification of Post Colonoscopy Cancers

In this particular incident the first cancer was notified to BowelScreen by the surgeon who operated on the patient in a private hospital and the second was notified to BowelScreen by the Clinical Lead at WGH by a surgeon operating in an HSE hospital. Because of the publicity created by this incident another surgeon in another HSE hospital notified a third cancer case in a BowelScreen patient to a clinical colleague in WGH. It appears that, prior to this incident, there was no formal method of identifying post colonoscopy cases despite there being a requirement for them to be reported.

Following the incident BowelScreen alerted all designated cancer centres to the possibility that cancers diagnosed through the symptomatic route in 60 to 69 year olds may have participated in BowelScreen and should be reported to the centre. Multi-disciplinary Teams (MDTs) were asked to check newly diagnosed colorectal cancers had participated in the BowelScreen Programme and to notify BowelScreen of any suspected interval cancers. It should be noted that a linkage between the Cancer Registry and the BowelScreen Data exists for the reporting of interval cancers.

It is recognised by BowelScreen that a distinction has to be made between the detection and monitoring of interval cancers after a positive screening test as a long-term quality assurance and evaluation measure in the screening programme and the real-time monitoring of interval cancer after colonoscopy as a measure of patient safety. In order to maximise the detection of post colonoscopy cancers there is a requirement to extend the request to notify such cancers to other HSE and private facilities as well as designated HSE Cancer Centres.

As the National Cancer Registry receives information and histological confirmed cancers within weeks of diagnosis it would be possible to match these cases to BowelScreening cases but this would require lists of BowelScreening participants to be sent to the National Cancer Registry. It is understood that a similar process has already been agreed between the National Cancer Registry and other screening programmes.

Investigation of Post Colonoscopy Cancers

At the time of this incident the initial cases that triggered the investigation could have been classified as an adverse event under the HSE Safety Incident Management Policy. However, in June 2015 the BowelScreen Programme produced a revised Standard Operating Procedure. This SOP provides for the management of such notifications under the local colonoscopy units' clinical governance and risk management structures and any performance or quality issues should be referred to the hospital group CEO and HSE Acute Hospitals Division. It also provides for case review by the National Screening Service which could lead to further investigation.

Assessment of Colonoscopy Units and Performance

The Quality Assurance Guidelines of BowelScreen indicate that the local Clinical Lead is the individual managing compliance with the QA Guidelines for all colonoscopists and will be the first port of call for addressing non-compliance issues. Individual endoscopists are not required to be specifically accredited to operate within the BowelScreen Programme.

An International Peer Review Panel Report of Quality Assurance Standards was published in March 2011. This report stated that the generic issue of accredited of colonoscopists was beyond the remit of the screening service and the panel stated that

1. The endoscopy service should develop a competency framework mechanism in association with professional bodies.
2. The Royal College of Physicians of Ireland and the Royal College of Surgeons of Ireland should play a central, meaningful role in developing this framework.
3. The challenges identified included identifying the appropriate accreditation test, defining how the process would work and how to deal with poor performance.

The Conjoint Board in Ireland of RCPI and RCSI in conjunction with the Quality Improvement Director of HSE have developed a quality improvement programme in GI endoscopy and the HSE Acute Hospital Division has established an endoscopy programme. A National Clinical Lead has been appointed for this work. The objectives of this programme include

1. Strengthening clinical governance for endoscopy services across the country.
2. Increasing the capacity of endoscopy services.
3. Establishing the national training programme.
4. Designing a systematic approach to validation and scheduling of endoscopy procedures.
5. Developing a national referral pathway.
6. Developing a national quality assurance framework for endoscopy services.
7. Supporting the development and expansion of BowelScreen in a public hospital.

MANAGEMENT OF THE INCIDENT

Process

The process of the management of this incident is described above and it should be appreciated that this entailed considerable pressure on the colonoscopy services which was managed expeditiously and it incurred a high administrative burden involving creation and cross checking of databases. In BowelScreen, three liaison nurses were assigned to the recall to conduct pre-assessment and scheduling of patients. In WGH a senior administrator and a liaison nurse were assigned to work on the incident, in addition to the Endoscopy Clinical Nurse Specialist and the CNMIII with responsibility for the unit.

Clinician Y

There can be no doubt that Clinician Y was under performing as it was accepted that even under the circumstances of the highest acceptable post-colonoscopy cancer rate (8.6%) it was estimated that over 3,000 screening colonoscopies would need to have been undertaken for 13 post colonoscopy cancers to result. Clinician Y only undertook 384 screening colonoscopies. It is interesting to note that both the cancer detection rate and the adenoma detection rate of Clinician Y were within the Key Performance Indicator range although both were at the lower limit. This calls into question the validity of using predetermined clinical standards rather than ongoing comparative audit of performance. Clinician Y appears to have been managed appropriately, given that he ceased performing BowelScreening colonoscopies in November 2014 and stood down from all colonoscopy work on February 16th 2015. It is clear that Clinician Y has participated and cooperated with everyone working on the management of this incident.

SIMT RECOMMENDATIONS

The following recommendations have been made by the Safety Incident Management Team:

1. That roll-out of the National Quality Improvement Programme for Endoscopy be completed and mandate participation for all HSE and HSE-funded units.
2. BowelScreen should continue revising the Quality Assurance Guidelines and ensure that the next revision takes into account the findings of this review.
3. The Endoscopy Service along with the professional bodies should develop a competency framework mechanism as indicated in the section on the assessment of colonoscopy units and performance.
4. That the quality of both bowel screening and symptomatic endoscopy should be audited both at unit and individual endoscopist level and that each unit should be held accountable for the audits. To oversee this the National Quality Improvement Programme for Endoscopy should have oversight of all endoscopy services, but the NSS should also receive information on the BowelScreen audits.
5. Adenoma detection threshold levels should be reviewed.
6. That processes should be established to optimise notification of colorectal cancer in patients who have undergone a screening colonoscopy. This to include a request to all HSE, HSE-funded and private facilities who notify cases and the establishment of an interval cancer reporting process with the National Cancer Registry.
7. That the post colonoscopy colorectal cancer rate for both screening and the general population of Ireland should be determined.
8. The NSS should develop a specific policy in line with the overarching HSE Safety Incident Management Policy for instances that occur within the context of a screening service.
9. The governance of patient and public communication should be clarified by the SMIT at the outset of any incident management process.
10. That HSE service providers should be updated on adverse incidence management whenever it occurs in order to disseminate learning from incidents such as this.

FINDINGS OF THE REVIEW

The findings of this review are structured according to the terms of reference (see above).

Part 1 Review of the governance and management of the look back process that occurred in relation to the Wexford Screening incidents.

Governance, accountability and authority at each level involved in the incident with particular reference to the following roles.

- *The Commissioners*

The National Director Health and Wellbeing and the National Director Acute Hospitals Division HSE very properly commissioned a Safety Incident Management Team (SIMT) in order to conduct the review and look back process on the 23rd January 2015 and the degrees of their authority and accountability were entirely appropriate.

- *SIMT*

The SIMT first met on the 26th of January 2015 and they conducted the management of the look back process in a timely and appropriate manner. It is noted that the recall process took part in two phases. In phase 1 only those screening patients in whom an adequate photograph of the caecum had not been available were recalled. Phase 2 was initiated when it was recognised that the cancers diagnosed by the look back process were not located in the caecum and therefore positive identification of the caecum could not be taken as evidence of an adequate colonoscopy. The initial decision only to recall those without an adequate photograph of the caecum was entirely reasonable and phase 2 was initiated very rapidly and did not delay investigation of the entire cohort of patients. The process followed by the SIMT to bring the look back to a conclusion were exemplary and the governance and lines of accountability and authority were entirely clear.

- *Endoscopy Units*

The endoscopy units involved in the management of the look back process were entirely cooperative with the look back process, providing a prompt and efficient service, especially considering the concurrent service demands placed upon them.

- *The Hospital Group (Ireland East)*

For the recall process endoscopies were provided by the Ireland East Hospital Group. St Vincent's Hospital and the Mater Misericordiae Hospital each provided endoscopy slots and WGH conducted all outpatient appointments and a smaller

number of colonoscopies. This ensured that sufficient endoscopy capacity was provided, and, in order to ensure a high quality of colonoscopy, the recall only utilised JAG accredited units. Thus the Ireland East Hospital Group functioned extremely well during this process and the lines of accountability were very clear.

- *Wexford General Hospital*

All staff at the Wexford General Hospital cooperated with the look back process in an exemplary fashion.

Summary

This review concludes that there were no issues of governance, accountability or authority at any of the above mentioned levels involved with the incident.

Was the incident was completed in a timely manner, appropriate to the clinical risk the incident posed to patients with particular reference to the timelines of the following crucial elements of the incident?

- *Pre-escalation*

The first index case was notified to BowelScreen on October the 8th 2014 and the second on October the 27th 2014. Escalation to the National Incident and Management and Learning Team occurred on the 16th of January 2015. It could be argued that this time interval could have been shorter but the diagnosis of a post colonoscopy colorectal cancer is not an unheard of event and may occur in up to 8.6% of screening colonoscopies. It took a finite amount of time to appreciate that the both the index cases had been colonoscoped by the same colonoscopist and when this connection had been made it was noted that the colonoscopist's performance in terms of adenoma detection rate and cancer detection rate (KPIs for bowel screening) were within the then current tolerance limits. It was, however, agreed that the colonoscopist would stop carrying out screening colonoscopies on November the 13th 2014 (less than a month after the notification of the second index case), and it was only when the audit of caecal photographs had been complete was it fully appreciated that the colonoscopist's work had been substandard. The Bowel Screening Clinical Advisory Group recommended a recall process for all individuals who had been colonoscoped, and in whom an adequate photograph of the caecum was not available on the 15th of January 2015, and escalation occurred immediately thereafter. Thus, although the pre-escalation phase could have been a little shorter, there are a number of extenuating circumstances and the Christmas Holiday period would have introduced further inevitable delays. This review therefore concludes that the length of the pre-escalation phase was quite

reasonable and the fact that the colonoscopist was restricted to performing colonoscopy under supervision at an early stage of the process is commendable.

- *Escalation*

Validation of the audit of caecal photographs was carried out by the BowelScreen Clinical Director on the 7 & 8th January 2015 and the BowelScreen Clinical Advisory Group made their recall recommendation on the 15th January 2015. Escalation was then extremely rapid with the SIMT being commissioned on the 23rd January 2015 and holding their first meeting on the 26th of January. The first recall letters were issued on the 13th of February and the first colonoscopy appointments were offered from the 23rd February 2015. Thus, given the complexity of the arrangements that had to be made this review concludes that escalation was carried out in a timely manner and appropriate to the degree of clinical risk.

- *Risk Assessment*

It is clear that the risk posed to the individuals who has been colonoscoped by the colonoscopist in question was recognised at a very early stage after the reporting of the two index cases. This is indicated by the rapidity with which he was put under supervision and subsequently stopped from colonoscoping all together on February 16th 2015. This review concludes that risk assessment was carried out in a timely fashion and acted upon rapidly.

- *Audit Phases*

The first phase of the audit was to look at the colonoscopist's performance against the standards set by BowelScreen, and this was done immediately after notification of the second index case and it is notable that the colonoscopist's adenoma detection rate and cancer detection rate were within the agreed tolerance limits. The second audit phase consisted of a review of all screening colonoscopy reports at WGH since the programme commenced by the Clinical Lead at WGH and this process was completed by December 2014. This was the first clear evidence of inadequate performance by the colonoscopist and was followed by a validation audit of the same records carried out by the BowelScreen Clinical Lead on the 7th & 8th of January 2015. A further audit of the colonoscopists symptomatic colonoscopy work was carried out by two Consultant Colorectal Surgeons on February 4th & 5th 2015 and their report recommending the recall of 163 patients to the out-patient department was made on February the 10th 2015. The last part of the audit was a review of the clinical files of 55 patients where the colonoscopist had been the supervising colonoscopist and this was carried out on March the 18th 2015 and resulted in the recall of 30 patients for out-patients appointments. This review concludes

that these audits were all carried out as expeditiously as could be reasonably expected by appropriate people and to an appropriate standard.

- *Recall Phases*

The process and timelines for phase 1 and phase 2 recall are detailed in the section on the chronology of the incident and the look back process (pp10-12). Given the considerable pressure that all endoscopy units are under, particularly with escalating demand for colonoscopy in symptomatic patients, this review concludes that the recall was carried as expeditiously as possible. Although recall was not complete until March 2016 it should be noted that it was 98% complete by July 2015 and most of the delay was occasioned by patient preference.

- *Systems analysis and related decisions*

In February 2015 investigations into the care and treatment of the index patients were commissioned by the General Manager at Wexford General Hospital, and these investigations were carried out by a team consisting of two Consultant Colorectal Surgeons, the Clinical Risk Manager at St Luke's General Hospital Kilkenny and the Acting Clinical Risk Manager at Wexford General Hospital. This investigation resulted in two system analysis reports which were accepted by the Commissioner in January 2017. This was confirmed to the colonoscopist on the 18th of January 2017. Both of the index patients have received copies of these reports but as they relate to specific patients it is not HSE policy to publish these reports. They have, however, been uploaded to the National Incident Management System and will be included in the 2016 aggregate report of system analysis and investigations. Anonymised reports have been made available to appropriate personnel within HSE. The Chief Medical Officer, the Director of the National Patient Safety Office and other staff of the Department of Health were informed at a briefing in the Department of Health on the 17th January 2017. The systems analysis reports conclude that

1. There was failure of the colonoscopist to adhere to the required standards for screening colonoscopy.
2. There were missed opportunities by local and national governance structures to prevent, detect and address substandard performance by the colonoscopist.

While it is clear from both the system analysis reports and the SIMT final report that the colonoscopist was not performing to the standard required by BowelScreen it is only within the systems analysis report that the missed opportunities by local and national governance structures to identify a problem with the standard of the colonoscopist's work are documented. On the face of

it, this is appropriate as the SIMT final report was intended as a report of the management of the look back process and not as a root cause analysis. However, as discussed in the section below on report finalisation and close out of SIMT, it would have been ideal had the systems analysis reports been available in time to inform the final SIMT report.

The events leading up to the discovery of the two index post colonoscopy colorectal cancers are summarised in the fifth paragraph of the Chronology of the Incident and its Management (pp8-9). In retrospect, had the concerns of the staff member working at Wexford General Hospital been acted upon promptly, the effect of the incident could have been ameliorated. However, there are a number of mitigating circumstances as follows:

1. The colonoscopist in question had a good reputation as a reliable endoscopist and indeed had documentary evidence of completing a Training the Colonoscopy Trainers Course at St Mark's Hospital in October 2011 and having attended a training day for colonoscopic polypectomy, again at St Mark's Hospital, in June 2011.
2. The colonoscopist in question had a self-reported caecal intubation rate of 90% and his adenoma detection rate was within the then current tolerance limits set by BowelScreen.
3. There is clear evidence of frequent communication between the Clinical Lead at WGH and BowelScreen.
4. In terms of BowelScreen's responsibility a memorandum of understanding between WGH and BowelScreen placed the responsibility of governance for colonoscopy with WGH.
5. The Clinical Lead at WGH informed the whole endoscopy team on two occasions about the need for caecal intubation and its adequate documentation, and on the second occasion it was agreed that team agreement in the endoscopy room should be reached on caecal intubation.
6. The Clinical Lead carried out an early informal review of a small sample of the colonoscopist's caecal photographs and found them to be satisfactory.
7. The Clinical Lead at WGH had spoken to relevant employees and none of them reported a problem with the colonoscopist's ability to reach the caecum.
8. It was recognised within WGH and by BowelScreen when they visited in May 2014 that there was professional discord between the staff member of the HSE and the colonoscopist in question.

Having said this, an opportunity was missed and a formal process for addressing the employee's concerns may have corrected this issue.

- *Open disclosure*

Every effort was made to identify and communicate with the patients before public communication was commenced. Following media publicity the HSE information line was used to handle questions from the general public. The original patients whose cases initiated the look back received open disclosure and have been provided with copies of the systems analysis reports. On identification of each new case of colorectal cancer identified by the look back process, contact with the patient and their family was made to invite them for formal open disclosure meetings in WGH. This review concludes that disclosure was handled in an appropriate and timely manner.

- *Communications*

A patient advocate formed part of the membership of the SIMT and this advocate was a valued team member providing important insight and assurance throughout the look back process. All patients and their GPs were written to in order to inform them of their recall and to invite them for either an out-patient appointment or a repeat colonoscopy before the incident was open to public communication. All letters were posted on a Friday so that they were delivered on the following Monday or Tuesday for two main reasons;

1. So that liaison personnel were available in both NSS and WGH to deal with queries
2. For the BowelScreen patients, this provided more efficient scheduling.

This review concludes that communication was handled in a timely and appropriate fashion.

- *Report finalisation and close out of SIMT*

The SIMT report is a clear, well written and comprehensive document that lays out the management of the look back process in an exemplary fashion. It is unfortunate, however, that the Systems Analysis Reports (SARs) were not made available in time for the final report. Upon investigation, however, it is clear that the SARs were held up by legal injunction and as it became urgent to issue the final SIMT report, a decision was taken in September 2016 that the SIMT report would have to be finalised without these SARs. Given the uncertainty around if and when the SARs were to be available, this review concludes that the SIMT acted appropriately in issuing the final report without waiting for the systems analysis reports.

Part 2 Review of the current governance arrangements pertaining to Quality Assurance (QA) between BowelScreen and those hospital providing services for BowelScreen

The governance procedures of the Quality Assurance (QA) process in place between BowelScreen and those hospitals providing services for BowelScreen.

The Quality Assurance processes in place between BowelScreen and Hospitals providing services for BowelScreen were appropriate for the time but in retrospect it was clear that the tolerance limits set for the Key Performance Indicators of adenoma detection rate and cancer detection rate were set too low and are being revised. The Quality Assurance measure of caecal intubation verified by caecal photographs is entirely appropriate but at the outset the governance procedures surrounding this Quality Assurance measure were not adequate in that regular audits were not being performed either by the provider units or by BowelScreen. This has been addressed. In mitigation, it has to be appreciated that BowelScreen was rolled out at a time when there were significant financial pressures on the Health Service and as with all new Health Service Developments everyone involved in BowelScreen was going through a steep learning curve.

The current Quality Assurance process in place between BowelScreen and its providers and consider possible additional enhanced measures that might be put in place to ensure the QA standards are robustly implemented

The current Quality Assurance process in place between BowelScreen and its providers is now greatly enhanced and individual colonoscopy data is now collected by BowelScreen on a regular basis. The performance statistics are now given to the provider units so that they can compare their performance with other units. This review concludes that the Quality Assurance measures in place are appropriate but that the analysis of performance data might benefit from a more robust statistical approach incorporating a statistical reporting tool such as funnel plots that would rapidly identify outliers. It would also be helpful to have a standard operating procedure (SOP) for the rapid investigation of outliers.

RECOMMENDATIONS AND CONCLUSIONS

Recommendations

- *The conduct of the BowelScreen Programme*

This report concludes that the BowelScreen Programme has learnt a great deal from the look back process and recommendations would be as follows

1. That there should be a regular programme of revision of Quality Assurance Guidelines and the tolerance limits set by these Guidelines.
2. That the quality of screening colonoscopy be audited both at Unit and individual endoscopy level, and that findings should be fed back to the provider unit in the form of confidential comparative audit, whereby the provider unit can assess its performance against other units.
3. That a robust statistical approach to the analysis of KPIs using e.g. funnel plots be considered in order to assist with the identification of outliers.
4. That BowelScreen develops SOPs for the investigation of outlying units and endoscopists.

- *The conduct of future look backs*

This particular look back was carried out in a very appropriate manner and, given the learning that has occurred and measures that have been put in place, it is unlikely that a look back of this magnitude would be necessary in the future. If it were, it is recommended that, as was the case in this instance, the investigation of patients at risk of harm should be prioritised. The other recommendation to be made concerning the look back process is to formalise and optimise the reporting of post colonoscopy colorectal cancers and whenever this occurs to ensure that the colonoscopist concerned is informed and that his or her performance as assessed by the KPIs is satisfactory.

- *Hospital Level management and governance of endoscopy services*

The appointment of a National Clinical Lead for endoscopy is a major step forward in this area and clearly major progress is being made in developing an audit system for all colonoscopy. Recommendations would be as follows

1. To harmonise the collection and audit of Key Performance Indicators for the National Colonoscopy Service and BowelScreen. Thus data would only have to be collected once and BowelScreen could avail itself of a national database. This would result in quality improvement across the whole colonoscopy service.
2. Consideration should be given to individual accreditation of colonoscopists utilising the direct observation of procedural skills (DOPS) methodology

employed by the English Bowel Screening Programme. It is appreciated that this would *not be practical* for all colonoscopists working within BowelScreen as it would undoubtedly impact severely on the ability to deliver a service. However, consideration should be given to robust accreditation for trainees before they pursue individual practice. This could be introduced as a staged process, such that accreditation of advanced skills could follow accreditation for diagnostic colonoscopy.

- *Supporting further learning and improvement regarding how to assure and support the purchasing of safe and effective quality assurance services.*

It is clear that a great deal of learning has already occurred as a result of this incident but the recommendation would be to ensure that learning from all adverse incidence is disseminated as widely and efficiently as possible.

Overall Conclusions

- This review concludes that from the initial recognition of the two index post-polypectomy colorectal cancers the incident was managed in a timely and efficient manner.
- There were some deficiencies in reacting to early concerns raised about the colonoscopist's competence, although there are significant mitigating factors.
- A formal process for expressing concerns such as that provided by the National Clinical Assessment Service (NCAS) in the United Kingdom might be usefully considered.
- The process of having a separate SIMT final report and SARs did not in this instance produce a comprehensive final product. There is no one to blame for this but consideration should be given to harmonising these processes to avoid a similar situation occurring in the future.
- Finally, the recommendations given in the SIMT final report are firmly endorsed by this review.