



Isle of Man
Government

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Department of Health and Social Care

Rbeynn Slaynt as Kiarail y Theay

Audit Advisory Division, The Treasury

Endoscopy Service Review

Final Report

Noble's Hospital

Isle of Man Department of Health and Social Care

Confidential

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MIAA
Advisory Services

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Acknowledgement

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1. Introduction and background

- 1.1 Endoscopy is a regularly used medical procedure where the inside of the body is examined using an instrument called an endoscope; a long thin flexible tube that has a light source and camera at one end. Images from the camera are relayed to a television screen and can be recorded. Gastrointestinal endoscopy can be used to diagnose, take samples of and treat various conditions of the gullet, stomach and bowel. Similar instruments can help with the management of conditions of the bladder, womb and lungs.¹
- 1.2 As part of work carried out during late April and early May 2017, in preparation for the publication of Isle of Man Department of Health and Social Care (DHSC) waiting times, it was found that a number of people who ought to have been given appointments for follow-up endoscopies during the period 2014-2017 had not in fact been given their appointments. This finding constituted a significant patient safety risk, in that the failure to monitor conditions in accordance with generally accepted guidelines could mean that the progression of or appearance of disease had been missed and so may not have been treated.
- 1.3 MIAA Advisory services provides access to a diverse range of products and professional specialists. It operates independently of internal audit and other assurance functions to enable provision of expert independent advice to management.
- 1.4 The Director of Audit Advisory (The Treasury, Isle of Man Government) requested MIAA advisory support to provide independent expert input to complete this review. This was to evaluate the endoscopy systems by design and as operated in respect of the administration of the complete pathway for endoscopy tests (including identification of those requiring test, booking arrangements, monitoring of waiting list attendance and post attendance action(s)). The review was to identify the root causes which contributed to the risk described at 1.2 and to make recommendations as to any further action required.

2. Objectives

- 2.1.1 The principal objective was to ascertain as far as practicable the circumstances surrounding the healthcare risk incident including:
 - a) providing a detailed description of the endoscopy appointment system;
 - b) providing endoscopy service demand data for the financial years 2014/15, 2015/16, 2016/17 and 2017/18 (actual, year to date – projected, full year); and;
 - c) providing endoscopy service capacity data for the same periods as set out in 2.1.1b, to include comment on facilities, equipment and trained personnel.

¹ Source DHSC TOR

2.1.2 Regarding the healthcare risk incident:

- a) make an assessment of the most likely causative factor(s);
- b) review and document any evidence that alerts had been raised in the past (say, 10 years) in respect of endoscopy service waiting times, the appointment system or, specifically, the recall of patients requiring follow-up tests; and,
- c) If evidence is found that alerts had been raised as set out in 2.1.2b, review and document any action plans which followed the alerts and the outcomes of those action plans.

2.1.3 Recommend any actions which the DHSC should take as a result of this review.

2.2 The following sub-objectives apply:

- Review the endoscopy systems by design and as operated during the period 2014-17 in respect of the administration of the complete pathway for endoscopy tests (including identification of those requiring test, booking arrangements, monitoring of waiting list attendance and post attendance action(s));
- Consider service performance in the context of available demand and capacity data for the period under review i.e. 2014 to 2017; and,
- Review and document service governance and risk management arrangements, including any evidence that alerts had been raised in recent years in respect of endoscopy service waiting times, the appointment system or, specifically, the recall of patients requiring follow-up tests.

3. Scope and Terminology

Review Period. Documentation and researched evidence base relating to the period 2014 to 2017.

Endoscopy. *'... the use of a light, flexible instrument to view the interior of a body cavity with use of a camera. Endoscopies can be used for a number of reasons. For diagnostic purposes the endoscope will be used to determine the nature of a disease (includes biopsy etc.) and for therapeutic purposes an endoscope may be used to administer some form of treatment to a disease...'*²

Screening. *'The process of identifying healthy people who may have an increased chance of a disease or condition. The screening provider then offers information, further tests and treatment. This is to reduce associated problems or complications.*

*'...review of a population to identify possible presence of an as yet undiagnosed disease in individuals without signs or symptoms...'*³

² PGCS10: Coding endoscopy procedures; National Clinical Coding Standards OPCS.4 Reference Book (2017)

³ <https://www.nhs.uk/conditions/endoscopy>

Surveillance activity. '...The follow up of individuals at increased risk of disease in line with recommended clinical intervals...'

4. Approach

- 4.1 Prior to MIAA involvement, initial work had been undertaken by Audit Advisory Division, The Treasury, Isle of Man Government, including the collation of correspondence and summaries of meetings with a limited number of individuals with knowledge of the service. Support to complete the review was requested from MIAA.
- 4.2 The MIAA review has focused principally on corporate arrangements, systems and processes rather than the role of any individual(s). It has not sought to enquire into individual responsibility or to attribute blame and does not intentionally make any inferences or statements relating to an individual or group of individuals whether professional, managerial or administrative.
- 4.3 In order to provide an evidence base in support of the overall objective, the following aspects have been undertaken:
- Collation of extensive detailed document files and copies of many emails to and from numerous different individuals at different levels of the organisation and DHSC.
 - MIAA undertook interviews with a selection of clinical and non-clinical staff at different levels across the organisation. This included engagement with Endoscopy Service representatives, wider Nobles Surgical Division staff and senior Nobles Hospital representatives.
 - MIAA met with a range of personnel in relevant posts at Nobles (2017) to gain their insight of issues relevant to the incident; Members of Nobles Executive Team (NET), Clinical Leads, Divisional Manager (Surgical), Divisional Lead. Interviews took place with a standard structure to provide consistency of approach to collate feedback relevant to the review objectives; to establish as far as practicable the systems operating and changes to them since the risk event; to capture personal perspective on relevant factors and to collate evidence offered to support comments made. Each person interviewed also had opportunity to offer any additional comment, which they considered relevant. All written detail was subject to review and agreement by each person interviewed.
 - In addition, wider discussion took place to detail structures, processes and systems as designed and in operation to deliver the Endoscopy Service during the relevant period i.e. Endoscopy Management Leads, Endoscopy Booking Service (EBS), Patient Informatics Centre (PIC), Nobles Information Lead.
 - MIAA requested available data-sets relevant to service demand and capacity, (including service waiting times) i.e. available and/or generated during the relevant time frame and those that had been compiled subsequently.

5. Structure of the report

5.1 The following report is constructed to present facts ascertained, system evaluation and evidence based opinion in respect of each objective set out in section 2. It comprises the following;

| | | |
|--------------|---|--|
| Section 6. | Executive Summary. | A high level commentary of key themes arising from the review relevant to each of the objectives |
| Sections 7-9 | Findings. | Factual detail ascertained to address the review objectives. |
| Appendix A. | Action Plan | Comprehensive listing of actions relevant to period of the incident and further system enhancement |
| Appendix B. | Endoscopy Pathway: Summary Overview | Diagram of referral routes, decision points and actions. |



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6. Executive Summary

- 6.1 This review confirms weaknesses in both the design and operating effectiveness of controls in place for the Endoscopy Service during the critical 2014-2017 period of review. These were compounded by performance datasets not being sufficiently comprehensive to provide a complete picture of service demand and capacity during this time.
- 6.2 MIAA has confirmed a series of alerts to potential patient safety risks via a deteriorating position in respect of service capacity not being able to meet demand, including for surveillance procedures, during the critical 2014-17 period. These alerts did not trigger an appropriate response via corporate risk management systems. The organisation has established clinical governance arrangements. A reporting software operated and clinical governance meetings took place on a routine basis. It is clear that despite such arrangements, corporate risk and assurance measures require thorough review and enhancement to ensure a consistent and robust approach to:
- The identification, recording and assessment of the significance of risk;
 - Clarity and understanding of thresholds and routes of escalation throughout the organisation;
 - Ensure review measures are applied routinely to provide corporate assurance of risk being effectively managed and mitigated within agreed tolerances;
 - Clarity in the Terms of Reference for all governance committees which link to strategic risks to be explored and monitored.

In the absence of a robust 'assurance framework' there is a lack of an evidence base on which to determine whether known risks were adequately discussed and if so what rationale/tolerance threshold was applied.

6.3 **Endoscopy Appointment system: system description and evaluation.**

- 6.3.1 **Software application(s)**, which were available (Medway and Unisoft), were not fully understood/implemented and did not form a prime basis for effective management, monitoring and reporting of the complete Endoscopy pathway. Aspects of referral, appointment, procedures and surveillance are fundamental elements of the software application. This review does not establish evidence of a universal approach to populating systems for each of these aspects. However, there has been no reference to any reports being generated from established systems for service monitoring or reporting. Of particular relevance to the healthcare incident, the recording of surveillance activity on Medway would have presented a basis for greater prominence of increasing surveillance backlogs (Medway software application has only been used to capture surveillance activity since mid-2017).

- 6.3.2 **Procedures and Protocols.** Across the various disciplines relevant to the Endoscopy Service, there was an incomplete set of coherent procedures and protocols. The Endoscopy Service has an existing operational policy covering key areas including appointments, referrals, procedures results and surveillance arrangements. Procedure notes exist however, they are out of date. They do not reflect the service consolidation to Nobles in 2017 and lack detail in key areas, including surveillance management.
- 6.3.3 **Referral Stage.** A clearly defined, complete referral pathway is required to help ensure access at the earliest opportunity to the most appropriate endoscopy service.
- 6.3.4 **Referral Prioritisation.** Referrals were/are graded across priority levels with surveillance requests included in the lowest 'routine' priority. The Endoscopy Service informed us that there was awareness of a surveillance backlog during the critical 2014-17 period and that demand pressures resulted in the vast majority of available appointments being allocated to 'higher priority' activity (2 week wait and urgent cases). This led to surveillance activity not being given distinct a profile or a risk based prioritisation.
- 6.3.5 **Waiting Times.** A definition of 'waiting times' is required. Endoscopy Service patient waiting times were/are measured from the date a referral is input to the Medway patient management system by the Endoscopy Bookings Team i.e. the 'clock start' is the input date to the Medway system. Waiting times do not therefore measure the timeline of previous relevant activity including an initial request for an endoscopy procedure (eg from primary care) and any subsequent outpatient clinic attendance in advance of a consultant referral to Endoscopy. There is a risk that the true length of the referral pathway is not being measured, with waiting times being potentially understated. System procedures should include a defined waiting time measurement methodology which incorporates all key pathway stages (including surveillance) and acceptable waiting time performance targets.
- 6.3.6 **Surveillance System.** The lack of a standardised approach to notify surveillance requests to the Endoscopy Bookings Team remains to date. System procedures should include greater detail relevant to surveillance i.e. roles, responsibilities, accountability and procedures to ensure surveillance requests are consistently captured on a timely basis, with waiting times subject to robust monitoring.
- 6.3.7 **Surveillance system recording and reporting.** There was a lack of visibility/prominence of overdue surveillance due to the use of various forms of handwritten annotated notes to capture surveillance requests. It is reasonable to suggest that the service response to meeting immediate challenges in respect of demand for higher priority activity (2 week cancer wait and urgent cases), combined with reliance on a manual paper based system to record surveillance requests (until mid-2017), resulted in relatively less focus on overdue surveillance.

6.4 **Service Demand and Capacity.**

- 6.4.1 Service datasets were not sufficiently comprehensive to provide a complete picture of service waiting times, activity and quality performance during the critical 2014-17 period. The absence of meaningful measurement of demand and capacity has fundamental impact on effective service management.
- 6.4.2 Datasets presented to MIAA do not combine to allow a full assessment of service performance in the context of evaluation of demand and capacity during the critical period from 2014 to 2017. There is a corresponding lack of key information including on waiting times and surveillance activity. Limited service level information shared with MIAA (referrals, activity completed and waiting times) does not derive from a defined dataset. It is understood to have been collated from a variety of sources and does not provide an evidence based profile of service performance in the context of evaluation of demand (including waiting times), capacity and quality during the critical time period from 2014-2017. Information presented to the Executive Team and incorporated into Business Cases does however indicate increasing demand and increased waiting times.
- 6.4.3 The lack of regular performance information generated from effective patient administration system(s) contributes to a lack of awareness of Endoscopy Service demand and activity, including the surveillance position.
- 6.4.4 MIAA could not obtain current information to confirm how levels of service demand combined with recent increased capacity (since summer 2017) are impacting service waiting times, including waiting time trajectories going forward and arrangements to manage waiting time backlogs.
- 6.4.5 Data sets requested to support comment on facilities, equipment and trained personnel have not been available.

6.5 **Regarding the healthcare risk incident: Assessment of the most likely causative factor(s).**

- 6.5.1 The outcome of work completed presents a complex iteration of causative factors which led to the scenario which was the subject of 'significant incident – at risk review' (July 2017). Collectively, these contributed to increased pressure for the service with the consequence of it becoming, over a prolonged period, a situation of unacceptable risk to patient care.

- 6.5.2 **The service faced major development challenges during the period.** The service was undertaking a process of transformation during the period of business case and investment justification processes (e.g. centralisation of the service). Reference has been made to changing protocols and clinical advances (e.g. new and changes to NICE guidance), new national screening initiatives and challenges in recruitment of staff (especially clinical). These challenges required energy and attention, which may have been a cause of distraction to the importance of day to day operational needs e.g. performance, the surveillance system.
- 6.5.3 **Issues were raised regarding a lack of clear and coherent leadership of the service.** Clinicians and Managers told us that they were unclear about leadership of the service. In addition, there had been a number of different interim appointments during the period which led to a lack of consistency and coherence of direction. Clinical leadership was undertaken via the Surgical Directorate and was described as being unclear.
- 6.5.4 **Departmental awareness of surveillance arrangements.** There are differences of opinion as to the actual administration of the surveillance scheme. Some thought that this was fully computerised and automated, whereas others thought it to be paper based or a combination of the two.
- 6.5.5 **Policies, protocols and procedures** (clinical and operational) were incomplete.
- 6.5.6 **Service datasets were not sufficiently comprehensive** to provide a complete picture of service waiting times, activity and quality performance during the critical 2014-17 period.
- 6.5.7 **A serious risk to patients materialised.** The Endoscopy Service was under pressure for a prolonged period and concerns were being expressed. The actual risks to patients were not formally reported/identified until 2017 despite corporate governance and reporting systems being in place. This would suggest that these systems were/are weak or not being regarded or used as intended.
- 6.5.8 **There is evidence of knowledge** across the health and social care economy during the period to indicate that it was known that the service was struggling for a variety of reasons (including minutes of meetings, emails confirming increasing demand and pressures and the reasons why).
- 6.5.9 **Business Case Management.** Business Cases for additional funding via the Treasury were presented to address a number of high level issues. Whilst these did highlight increasing demand they did not clearly and very specifically articulate risks to patients, including implications of not undertaking surveillance in a timely and/or risk assessed manner.

Several references were made with regard to Business Cases that had been collated. They referred to differences in approach and variation in the scope of detail and emphasis requested. Some told us that certain aspects had been excluded in order to ease the process of approval and acceptability. Others felt they were all-consuming in how they were collated and presented. Queries were raised on how business cases progress through the organisation in terms of decisions being made at an appropriate level and subsequently communicated to key stakeholders.

6.6 Regarding the healthcare risk incident and evidence that alerts had been raised in the past.

6.6.1 There are differences in the versions of the same events relating to causative factors, the level at which alerts were raised and even what actual discussions took place. This review does not focus on individuals. That said, versions of events conveyed to MIAA as to who said what and when do not reconcile. These differences are stark in some instances. This position adds to the notion of weaknesses in corporate governance systems and escalation processes.

6.6.2 It is clear that numerous concerns (some of a desperate nature), were expressed via emails, throughout the period, by different individuals in various roles.

6.6.3 Emails expressing concerns are numerous and widespread across Nobles and the Health and Social Care community. They raise obvious alarm bells. They involve clinicians and managers. They present missed opportunities to delve deeper or ask searching questions to establish the position and actual risks to patients.

6.6.4

| Timeframe | Extract of communication |
|--------------|--|
| October 2013 | '...we are at crisis regarding the waiting lists ...' |
| June 2014 | '... I hope this comes over as desperate as I am about it...This is a desperate situation ...' |
| August 2015 | '... We are saddened and disappointed as we know that the current waiting times are very long ...' |
| April 2016 | '... waiting list figure which is 980, however this excludes planned surveillance procedures, of which there are 740 patients booked as far ahead as 2023 ...' |
| May 2016 | '... I am really worried about the length of the waiting list ...' |

| Timeframe | Extract of communication |
|------------|---|
| July 2016 | '... make sure that no precise information is passed to patients regarding their waiting list for endoscopy. In particular, we should avoid giving them false hope or generating panic. I have just received a letter of a patient who was due to have a surveillance colonoscopy who apparently has been told the "repeat procedures were all being automatically deferred for at least one year". This generates anxiety and panic. I would prefer a more general statement such as "you are in the waiting list and your priority is routine"..."' |
| March 2017 | ' ... I am taking the liberty to email once again...highlight my concerns and solicit very urgent action. ...We have many patientswith very high risk for cancer who are not receiving any endoscopy surveillance ...' |

- 6.6.5 A number of individuals are firmly of the opinion that concerns expressed during the period both formally and informally had not been acted upon. Individuals told MIAA that they had little confidence in the system to act when expressing concerns.
- 6.6.6 Reference was made to what was regarded as a lack of response to issues contained in the West Midlands Quality Review (2014) that clearly pointed towards service workload issues and potentially insufficient capacity at that time.
- 6.6.7 There is no evidence of any action plan(s) having been formally compiled, communicated or progressed to address concerns referenced which may be deemed fundamental to the incident.
- 6.7 In constructing this report, and associated Executive Summary, MIAA remains concerned that not all dimensions and evidence has been fully exposed or explored. The complexity, wide ranging evidence and weight of papers presents a complicated, multi-dimensional picture. To provide full exposure and assurance would require more detailed evaluation, requiring time and organisation commitment. Observations which relate to the response instigated June 2017, though strictly outside the scope of this review, present certain issues for further consideration/action must be referenced. The action points in Appendix A will provide the opportunity to assess priority and impact.

7. System Description and Evaluation

This section presents detail of the system as operating during the period of the risk incident. Recommendations to address risks directly relevant to the circumstances of the incident are captured at Appendix A, which also offers additional recommendations to enhance future administration of systems.

An operational policy (September 2014, reviewed September 2015, May 2016 and April 2017) exists for the Endoscopy Service. It covers key areas; appointments, referrals, procedures, results and surveillance arrangements. An overview summary of the service pathway is presented at [Appendix B](#).

7.1 The Endoscopy Appointment System

Medway is the key patient administration system for managing patient referrals, listings and appointments.

7.1.1 Clinical Assessment of need for treatment (Referrals)

An 'Endoscopy Booking Service' exists. It comprises a Bookings Manager and clerical support. Referrals were/are received from a number of sources including GP requests, consultants referring from clinics and inpatient wards.

Referrals to the Endoscopy booking team were/are via e mail or post and in a variety of formats; including bespoke referral forms, request letters from GPs annotated by consultants to denote urgency of need for an endoscopy procedure.

7.1.2 **Emergency patients.** Over and above patients subject to prioritising of scheduled activity an emergency endoscopy rota applied/applies. Emergency patients generally went/go straight to theatre rather than to the endoscopy suite. An agreed communication procedure has been in place from June 2017 whereby theatre staff confirm the Endoscopy Bookings Team that endoscopy procedures have been performed.

7.1.3 **General Practice referrals.** On receipt of a request from a GP, the Patient Information Centre (PIC) updates the Medway appointment system prior to a consultant reviewing the request (the referral waiting list clock does not start at this stage). The consultant did/may request an endoscopy procedure at this stage, although the majority of patients will first be asked to attend a consultant clinic (including all 2 week wait patients) before any endoscopy referral. Consultants did/may determine at clinic if an endoscopy procedure is actually required and make a referral to the 'Endoscopy Booking Team', usually via medical secretaries. The Endoscopy booking team updated/will update the referral on Medway on receipt, at which point the original GP request recorded by PIC on Medway was/is 'cancelled'. Referral information captured by the booking team included/includes hospital number, procedures to be undertaken and priority level.



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7.1.4 **Consultant led Review** of all referrals (from GP and Noble's Consultants) to identify if the requested procedure is clinically appropriate took/takes place to reduce inappropriate referrals. Consultants also/will also confirm a priority level of referral.

Four priority categories existed (in order of decreasing priority);

- The highest priority level is for a '2 week wait' for a suspected cancer case;
- 'Urgent';
- 'Soon' priority classification between urgent and routine was possible until July 2015 (no longer used);
- 'Routine' priority. (Surveillance activity was/is given a 'routine' priority level).

7.1.5 **Scheduling of all referrals received**

Referrals received into the service were/are processed according to priority level assigned. Each was/is transposed to patient lists by the Endoscopy Booking team, with bookings made in line with priority levels.

7.1.6 **Private Patients.** 1-2 patient list slots were/are reserved for private patients, although NHS patients were/may be moved into such if available. Arrangements for private patients are agreed separately through a 'Private Patients Committee'.

7.1.7 **Bronchial procedures and bowel screening.** Separate patient lists are maintained which are not managed by the Endoscopy Bookings Manager. However, it has been stated that staff managing these listings did/will co-ordinate with the Endoscopy Bookings Manager to ensure available slots were/can be reallocated to the Endoscopy team as and when possible.

7.2 **Appointments: Endoscopy (excluding surveillance)**

7.2.1 For certain procedures e.g. a colonoscopy, patients required/require a 'pre-assessment' appointment to determine patient's suitability for the procedure. For such patients, two appointments were/will be booked; one for a pre-assessment and another for the procedure. A 7-10-day gap occurred/occurs between each. An Endoscopy Nurse led/leads the pre-assessment appointment.

7.2.2 Once the respective dates were/are allocated to a patient, a letter was/is generated by the Medway system detailing pre-assessment (as applicable) and procedure appointments. It is understood that when a patient failed to confirm acceptance of appointment detail, the Endoscopy Booking Team may have made/makes contact with them by phone to confirm appointments. Medway was/is updated once appointments were/are confirmed; patient requests to rearrange appointments are managed on a priority basis. Where appointments were/are cancelled to due circumstances arising at the hospital (e.g. lack of Endoscopist availability), patients are offered the next available appointment. Reasons for cancelled appointments could/can be recorded on Medway.

7.3 Endoscopy Procedures

- 7.3.1 UNISOFT is the prime system to capture clinical outcomes and record recommendation for appropriate next action(s).
- 7.3.2 Following an Endoscopy procedure, the consultant updated/updates key results on UNISOFT. A standard procedure report facility existed/exists on UNISOFT, which could/can share information with key stakeholders including the patient's GP. At the time of the procedure, the consultant made/makes a judgement of need for additional pathology testing based on visual examination. Where pathology was/is considered necessary and requested, it has been stated that there is generally a 2-week turnaround period for results being available to the consultant who initiated the pathology request.
- 7.3.3 When physical examination or pathology indicated/indicates potential cancer cases, the endoscopy consultant directly liaised/will liaise with the Multi-Disciplinary Team (MDT) to agree next step(s) of the care pathway.
- 7.3.4 Endoscopy procedures sometimes resulted/result in an outpatient Endoscopy clinic appointment with the consultant being required. It would have been/is arranged via the Patient Information Centre.

7.4 Surveillance requests:

- 7.4.1 Guidance issued by 'NICE' and 'The British School of Gastroenterology' sets out recommended timeframes for surveillance specific to clinical conditions. This informs requests made by consultants to the Endoscopy Booking Team to administer surveillance follow up.
- 7.4.2 Surveillance requests arose/may arise in the following circumstances:
- On the day of an endoscopy procedure or following receipt of subsequent pathology results (2 weeks after the procedure);
 - Following an outpatient clinic or an assessment while an inpatient.
- 7.4.3 Surveillance requests to date are not routinely captured on any system, including UNISOFT which is used to record results of endoscopy procedures. There was/is absolute reliance on clinicians forwarding each surveillance request in a timely manner. Methods to request surveillance include patient information sheets (proforma), annotation on referral forms and annotated UNISOFT reports. Such requests were placed on a lever arch file. Risks are that a surveillance request does not reach the Endoscopy booking team, that it is received but not actioned and/or the request is not received by the booking team (or acted upon) in a timely manner. Should such risk manifest, it would only be highlighted by a patient or a representative making direct contact to follow up a delay in surveillance appointment.

7.5 Surveillance recording and reporting

- 7.5.1 On receipt of surveillance requests, the 'Endoscopy Booking Team' schedules each surveillance procedure in line with the date requested by the consultant.

- 7.5.2 Medway, the key system for hospital appointment management was not used for surveillance requests until mid-2017.
- 7.5.3 A paper-based system was utilised to manage surveillance requests until mid-2017. Three lever arch files, labelled by consultant contained planned surveillance activity by procedure, year and month. Each file was/is updated on receipt of new requests by the 'Endoscopy Booking Team'. Consultants were/are reliant on the Endoscopy Booking Team allocating listed patients in line with the time period stipulated. The reliance on a manual paper system was partly due to a lack of Endoscopy booking team expertise on how to record and report planned surveillance activity on the Medway system. Since mid-2017, the paper system has been used in parallel with Medway to manage surveillance requests.
- 7.6 **Surveillance: Monitoring of 'Aged Profile'**. A lack of visibility and prominence of overdue surveillance will have resulted from use of a 'stand-alone paper-based' system. During the critical 2014-17 period, there was no defined approach to ensure regular review and re-scheduling of delayed cases within the increasing surveillance backlog i.e. a single aged waiting list profile did not exist.

7.7 **Waiting time measurement**

- 7.7.1 Patient waiting times are currently measured from the date a referral is input to the Medway system by the Endoscopy bookings team.
- 7.7.2 The 'referral pathway clock' starts at date of entry of referral as captured in Medway, which may not necessarily be the date the referral is received by the Endoscopy bookings team.
- 7.7.3 Discussion with consultant and 'Endoscopy Booking Team' established that, under current arrangements, every patient on a 2 week wait, subsequently referred into the service is required to attend consultant clinics before an endoscopy procedure referral is made. The initial request for a procedure (e.g. by a GP), any subsequent outpatient clinic attendance and consultant referral date are not currently incorporated in waiting time performance. Whilst an initial endoscopy request from primary care will be logged on Medway by the PIC and then forwarded to consultant for 'grading' (for a decision on clinic and/or endoscopy referral), the initial logged request is not deemed an official 'clock start' and therefore not routinely followed up and monitored.

Clinicians have cited need to reassess if each step is necessary i.e. consultant review of referral detail may be sufficient basis on which to make decision as to whether endoscopy procedure is appropriate (without the need for a patient to first attend an outpatient clinic).

| Initiated | PIC | Review | Clinic | Referral | Booking | Medway |
|---------------------------------------|--------------------------|--------------------------------------|--|-------------|---|---|
| GP | Log of request on Medway | Consultant review of written request | Need for endoscopy confirmed/prioritised | Manual Form | Referral Processed – Endoscopy Booking Team | Booking input |
| Ward | | | | | | 2 week / Urgent / Routine 'Waiting List Clock' triggered. |
| Waiting List Start Point? | | | | | | |

7.7.4 There is a risk that the Endoscopy service is not measuring true length of the referral pathway and waiting times may be understated and/or inconsistently reported.

7.8 Service Centralisation

7.8.1 The Endoscopy Service operated across two sites, Nobles and Ramsey, until mid-2017. Operating across two sites raised a number of challenges including interaction between staff, cross-cover and implementation of service efficiencies.

7.8.2 Following an options appraisal of possible solutions to provide an effective and safe Endoscopy service at Nobles hospital, a purpose built Endoscopy Suite was officially opened at Nobles in 2016.

7.8.3 A subsequent decision was made that a centralised service at this location would provide an improved service through better communication, system efficiencies and a dedicated clinical environment which is not shared with other services, thus helping to maintain privacy and dignity.

7.8.4 Ramsey Endoscopy services were transferred to Nobles from June 2017. The location of all staff at Nobles has presented the opportunity to provide extra Endoscopy capacity through four additional weekly patient lists without any additional outlay on staff. These additional lists have been implemented since July 2017 and have been fundamental to managing backlog surveillance.

8. Demand and Capacity

8.1 A key objective of this MIAA review was to consider service performance in the context of available demand and capacity data for the period under review i.e. 2014-2017. MIAA requested the following key data-sets at the commencement of the review to progress this objective:

- Endoscopy referral information for the period 2014-17;
- Endoscopy procedures completed (again for 2014-17); and,

- Service waiting times for 2014-17, including analysis of waiting time breaches for surveillance patients and waiting time backlog reduction plans.
- 8.2 A request was made for this information (22nd November 2017) and further follow up discussions took place with the Divisional Manager for Surgery and the Informatics Lead (6th December 2017). The Informatics lead subsequently confirmed that he could not envisage the data being available from the established patient administration systems (Medway and UNISOFT) to compile the activity information as defined above.
- 8.3 No routine system (Medway / UNISOFT) generated data sets relating to planned, pending and completed activity (including surveillance) existed at the time of the incident. MIAA understands that no data sets have been developed or implemented since.
- 8.4 This review has established that reports re Surgical Division 'performance' were received by the Nobles Executive Team on a quarterly basis. Key aspects presented specific to the Endoscopy service included 'Cancer Waits' statistics relating to 'Colorectal and Upper GI'; all of which are classified as '2 weeks' (refer 7.1.4). This is a sub set of total Endoscopy activity. The reports do not present wider Endoscopy referrals, activity (procedures completed) or waiting times.
- 8.5 In the absence of any data-sets from prime source i.e. established systems (Medway/Unisoft), detail contained in hard copy correspondence and documents presented to support this review have been considered. These provide some limited context; however, the following limitations are relevant in that information provided:
- was not derived from reports generated directly from established patient administration systems (Medway/Unisoft)
 - does not cover activity for the entire 2014-17 period under review
 - cannot be disaggregated to patient level (and therefore cannot be validated against established patient information systems).
 - does not allow establishment of the surveillance position for referrals, procedures or waiting times
 - does not provide a clear indication of trends in service waiting times;
 - does not include a documented plan showing a trajectory of how overdue procedures across the service will be managed over the short / medium term.
- 8.6 In such context, we have used available data to provide some insight to service demand and capacity as per points set out below. It should be emphasised that MIAA has not been able to validate observations below to established systems.
- 8.6.1 **Referrals:**
- Referrals to the service (the prime indicator of demand) have been increasing in recent years (*source: Endoscopy Booking Team – Referral Analysis*);

- During the period 2015-17, the majority of referrals to the Upper GI and Colorectal specialisms were for suspected cancer 2 week waits, with a relatively low number of (lower priority) 'routine referrals'. It is not clear if these routine referrals included surveillance requests (*source: extracts from Surgical Division monthly reports*).

8.6.2 Activity (Procedures).

- 85% increase in endoscopy procedures over the 10-year period 2006 to 2016 (*source: paper summary of IOM Endoscopy procedures – 2006/07 and 2016/17*)
- 3,063 patients received 3,317 procedures across the two locations during 2016-17 (*source: paper summary of lists, patients and procedures – Nobles & Ramsey – 2016/17*)

8.6.3 Waiting times

- During the period August – December 2017 (following the introduction of 4 additional patient lists) the service had capacity to manage levels of demand during the same period (setting aside any waiting list backlog) (*source: Endoscopy Central Booking Team – Referral and Procedure analysis*)
- There was a widening gap between demand and capacity i.e. an increasing 'waiting list' backlog from 2012-2016 (*source: Surgical Division Performance report April 2016*)
- At June 17, 'Cancer 2 Week Wait' referrals were taking 8 weeks to be seen i.e. waiting time targets were being breached by 6 weeks; there is also reference to a 33 week wait for a routine endoscopy appointment at June 2017 (*source: Departmental emails shared with MIAA*).

8.7 Analysis at 8.5 – 8.6 above confirms data-sets presented do not combine to allow a full assessment of service performance in the context of evaluation of demand and capacity during the critical 2014-17 time period.



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9. The Healthcare Risk Incident

9.1 Most likely causative factors and Knowledge of the Service

MIAA's approach involved both reviewing extensive documentation of case files and exchanges of emails at levels throughout the organisation and beyond.

Comments contained in those emails have been collated by MIAA. Some convey very clear concerns (see examples in Table at 6.6.5) and signal organisational knowledge of the issue over a prolonged period. Documentation reviewed by MIAA would have presented numerous opportunities to proactively ask for further clarification or more information about the actual impact on patients.

9.1.1 The considerable difference in perspectives around what happened, who knew what and when they became aware, does lead to a confused picture of the service operationally and managerially. There were differences between clinical and non-clinical staff about the service being provided; leadership of the service and especially about accountability. Such was this position, MIAA considers these as a major contributory factor leading to actual significant patient safety risk.

9.1.2 There is also differences of opinion with regard to communication and willingness to listen to comments felt to be of a constructive nature. These were conveyed by and about system leadership. We were told that this had led to disillusionment and reluctance to speak up. Other related observations made related to lack of clarity in communications between staff "on the shop floor" and the Executive Team/Board. Opposed to this was a clear intention and willingness by those in leadership to operate openly and receptively.

9.1.3 MIAA was told about the service being managed by a number of different interim and permanent staff during the period. Whilst that may have been necessary from an on-going management perspective, it did not help continuity or in the development or teamwork or building relationships i.e. it appears to have added confusion.

MIAA asked specifically about the recall of patients within the service. Again, some thought this was happening whereas others didn't know. Again, there were differences of opinion with regard to the arrangements in place. Differences of opinion include:

- Whether increasing delays in booking appointments (for surveillance) were specifically escalated.
- Whether "surveillance" activity was included in data contained in Business Cases seeking investment in the service.
- Whether or not surveillance data actually formed part of non-urgent waiting list activity or not.
- Whether the surveillance system was fully computerised or paper based.



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- 9.1.4 The West Midlands Quality Review and references it made to the service was highlighted to MIAA. MIAA has (deliberately) not considered the Review Outcomes as part of the process so as not to be influenced by what is said. Individuals referred to extracts and felt that what was said which relates to the service had not been acted upon. The workload of the colorectal CNS was so high that an individual stated they *'...did not have the time to fulfil the role of key worker and provide holistic care for patients with colorectal cancer...'* It is not clear from detail presented whether sufficient capacity was available to meet the expected patient pathway timescales. IOM DHSC should reflect on the West Midlands review and add to the recommendations at Appendix A as applicable.
- 9.1.5 Waiting times for endoscopy were a major contributor to the patient pathway delays. A new unit was planned for spring 2015, but additional staffing had not been identified for the unit, and plans to reduce endoscopy waiting times were not evident.
- 9.1.6 *'...Bowel screening had been introduced but it was not clear that the team had the capacity to cope with the resulting workload. Reviewers suggested that a capacity and demand study may be helpful, taking account of all pressures on the workload of the team...'*
- 9.1.7 Moreover, whilst not part its remit, MIAA was told that similar issues (to the Endoscopy Service) were actually present in others e.g. MRI waiting times, stroke thrombolysis. This has been referenced as a prompt to IOM DHSC to consider this report's findings across other clinical settings.

9.2 Business Case Management and Development of the Service

- 9.2.1 The service was undoubtedly facing major change and transformation during the period. These will have presented significant challenge both operationally, for business continuity and managerially. These related to:
- Centralisation of the service
 - Recruitment of the right people with the right qualifications
 - Provision of fit for purpose equipment.
 - Have a modern building able to cope with increasing demand and advance in clinical techniques.
- 9.2.2 Addressing such service critical issues will have taken time and energy. Not unreasonably these may have been the focus of attention during the period to the detriment of operational matters such as the surveillance scheme. Individuals confirmed that this was highly likely. Additionally, some individuals felt that the service was being designed and driven with an emphasis dominated by financial strategies (constraints) rather than quality of care. The two appeared to have become separate but were clearly linked as one had an impact on the other.

9.2.3 There were a number of Business Cases submitted seeking new additional investment; business cases reference that the service was struggling to cope with current and projected demand.

One submission was seeking a purpose-built endoscopy unit, submitted to the Department of Health in March 2013 but did not include additional staffing costs. Individuals made reference that this was to ease the submission process despite concerns that the new facility would not be staffed adequately. Increased capacity was therefore created in terms of facilities, but personnel requirements appeared to be out of scope. Reference is made to an increase in referrals and a backlog in planned surveillance procedures (Dec 15) but no specific/explicit reference is made to a critical failure in undertaking follow-up care i.e. the surveillance issue.

9.2.4 In April 2016 a (further) business case to increase endoscopy staff following the move to a new unit and 'tripling in size'. MIAA could not identify reference to additional staff to ensure full utilisation of increased unit capacity.



| Theme | Issue | Risk | Recommendation | System Risk Ranking | Direct contributory factor to healthcare incident? |
|---|---|--|--|---------------------|---|
| Policies and Procedures. Endoscopy Operational Policy | There is an existing endoscopy operational policy (Sep 14, reviewed on Sep 15, May 16 and April 17) covering key areas including appointments, referrals, procedures, results and surveillance arrangements. This lacks detail in key areas and is out of date in that it does not reflect the service consolidation to Nobles in 2017. | Relevant risks are: <ul style="list-style-type: none"> • Policy does not reflect latest consolidated working arrangements; • There is a lack of detail on key areas including surveillance management - see recommendation aside | As part of a full review of protocols and procedures within the service (clinical and administrative) to ensure that they are fit for purpose, the current operational policy would benefit from being revisited, including documentation of: <ul style="list-style-type: none"> • Bespoke arrangements implemented following the consolidation of the service at a single location (Nobles); • a standardised referral pathway; • Clear accountability for managing surveillance; • Clear procedural mechanisms with regard to the collation, reporting and management of waiting list information, including surveillance waiting list performance information; • a standardised system which will ensure surveillance requests are captured and transferred on timely, consistent basis; • Defined risk escalation mechanism; • Arrangements for joint working with bowel screening and other users of endoscopy capacity (respiratory / screening) to ensure efficient use of service capacity. | High Risk | Lack of defined, detailed arrangements to manage patient surveillance |
| Policies and Procedures. Referral Pathway | Referrals to the Endoscopy booking team are in a variety of formats; including bespoke referral forms and request letters from GPs annotated by consultants. | Relevant risks are: <ul style="list-style-type: none"> • Relevant referral information on procedures and urgency may not be complete; | The service would benefit from a standard referral pathway including: <ul style="list-style-type: none"> • a standardised referral form to be used across the service; this should be 'self-vetting' to ensure complete information is captured and should direct referring clinicians to the most appropriate test(s); | Medium Risk | - |

| Theme | Issue | Risk | Recommendation | System Risk Ranking | Direct contributory factor to healthcare incident? |
|--|--|--|---|---------------------|--|
| | | <ul style="list-style-type: none"> Referrals are not directed to correct recipients, potentially creating delay Referral to treatment waiting time targets are not effectively defined and monitored | <ul style="list-style-type: none"> instructions on how referrals should be directed to the Patient Information Centre or Endoscopy booking team as applicable; instructions for prompt and complete capture of referral information on Medway; Defined referral to treatment waiting time measurement methodology and targets – item 3 below reporting arrangements for (Medway) referral information as a key aspect of waiting time performance management; | | |
| <p>Policies and Procedures. Waiting Times</p> | <p>Endoscopy Service patient waiting times were/are measured from the date a referral is input to the Medway patient management system by the Endoscopy Bookings Team i.e. the 'clock start' is the input date to the Medway system. Waiting times do therefore not measure the timeline of previous relevant activity including an initial request for an endoscopy procedure (for example from primary care) and any subsequent outpatient clinic attendance in advance of a consultant referral to Endoscopy.</p> | <p>There is a risk that the Endoscopy service is not measuring true length of referral pathway (including outpatient clinic attendance) and therefore waiting times may be understated.</p> | <p>The following additional information should be captured on Medway to allow measurement of the full referral pathway:</p> <ul style="list-style-type: none"> Date of initial endoscopy request by a clinician, including requests from primary care Date of PIC logging of initial request (this is currently captured on Medway but cancelled on receipt of a consultant referral) Date of consultant review / vetting of request (including where a consultant determines that a procedure is not appropriate) Date of consultant outpatient clinic (as applicable) Date of consultant referral for endoscopy procedure Date referral received by Endoscopy Booking team Date of entry of referral to Medway by Endoscopy Booking team | <p>High Risk</p> | <p>-</p> |

| Theme | Issue | Risk | Recommendation | System Risk Ranking | Direct contributory factor to healthcare incident? |
|--|---|---|---|---------------------|--|
| | | | The above detail should be incorporated within defined waiting time measurement methodology and performance waiting time targets in the referral pathway. | | |
| Policies and Procedures. Waiting Times | Clinicians have cited need to reassess if each step in current Endoscopy pathway is necessary i.e. consultant review of referral detail may be sufficient basis on which to make decision as to whether endoscopy procedure is appropriate (without the need for a patient to first attend an outpatient clinic). | Requirement for outpatient clinic attendance before an Endoscopy referral is made may create unnecessary delay in patient referral to treatment pathway. | Department to reassess if each step in current Endoscopy pathway is necessary and / or if consultant judgement should determine if, following receipt of initial referral, an outpatient clinic attendance is required in advance of an Endoscopy procedure. | High Risk | - |
| Surveillance System. Requests for Surveillance | Surveillance requests are not routinely captured on any system, including UNISOFT which is used to record results of endoscopy procedures. There was/is absolute reliance on clinicians forwarding each surveillance request to the Endoscopy Booking Team in a timely manner. Methods to request surveillance include patent information sheets (pro-forma), annotation on referral forms and annotated UNISOFT reports. | There is the risk that a surveillance request does not reach the Endoscopy Booking team and / or the request is not received by the Booking team on a timely basis. | There is need for a standardised system which will ensure surveillance requests are captured and transferred to the Endoscopy Booking team on timely, consistent basis. Endoscopy team to consider: <ul style="list-style-type: none"> Surveillance requests to be routinely captured on UNISOFT at point at which consultant completes post procedure report. Endoscopy Booking Team could access this information for subsequent action; As an interim measure, Endoscopy Booking team to receive copies of all relevant patient correspondence post procedure which would include reference to requested surveillance procedures. | High Risk | Surveillance requests to Endoscopy Booking Team may not have been received and / or delayed. |
| Surveillance System. | During the critical 2014-17 period, there was no defined approach to ensure regular review and re-scheduling of delayed cases | Lack of a defined approach to review / re-schedule delayed surveillance cases will have | <ul style="list-style-type: none"> Defined policy for surveillance management should be adopted to ensure regular review and re-scheduling of delayed cases | High Risk | Lack of defined approach to review / re-schedule |

| Theme | Issue | Risk | Recommendation | System Risk Ranking | Direct contributory factor to healthcare incident? |
|---|--|---|--|---------------------|--|
| Backlog Management | within the increasing surveillance backlog i.e. a single aged waiting list profile did not exist. | contributed to lack of proactive management of the increasing backlog. | | | backlog surveillance |
| Performance Management. General Framework | <p>There was a lack of routine performance management information on Endoscopy Service through the critical 2014-17 period, including patient surveillance arrangements.</p> <p><i>[Datasets presented to MIAA do not allow a full consideration of service performance in the context of evaluation of demand and capacity over the critical time period from 2014-2017].</i></p> | <p>Lack of assurance that service objectives are being met; adverse performance not identified and addressed in a timely manner.</p> <p>A lack of datasets confirming service demand / capacity pressures during this period will have contributed to lack of decision maker visibility and awareness of the backlog endoscopy surveillance position.</p> | <p>Clear processes to manage current and future performance to include:</p> <ul style="list-style-type: none"> • Data sets should be defined and implemented to ensure appropriate, accurate and timely information to facilitate proactive review of planned, pending or completed Endoscopy activity, including surveillance. • Medway reporting functionality should be fully explored. A suite of reports should be defined and generated routinely to monitor and inform the management of service performance. [Medway offers functionality which should enable the production of bespoke reports on activity and waiting times across the service. System should contain sufficient data to populate datasets to include referral, appointment and procedure information]. • Performance to be scrutinised at service level in first instance with routine assurance / risk escalation to Divisional and Corporate levels. • Performance issues to be escalated to and via the designated Committees and Board through clear designated structures and processes. • Performance framework to include quality measures which should be given sufficient coverage in relevant meetings at all levels | High Risk | lack of visibility and prominence of increasing surveillance backlog |

| Theme | Issue | Risk | Recommendation | System Risk Ranking | Direct contributory factor to healthcare incident? |
|---|--|---|--|---------------------|--|
| Performance Management. Surveillance Requests | A paper-based system was utilised to manage and monitor surveillance requests until mid-2017. Three lever arch files, labelled by consultant, contained planned surveillance activity by procedure, year and month. Each file was/is updated by the Endoscopy Booking Team on receipt of new requests. | Lack of visibility and prominence of overdue surveillance will have resulted from use of a manual paper based system and corresponding lack of available Medway reports highlighting that target times were not being met during the critical 2014-17 period under review | <ul style="list-style-type: none"> Medway reports of performance against planned surveillance dates should be routinely produced to provide assurance to those charged with governance that surveillance procedures are being completed in line with target dates. | High Risk | Lack of visibility and prominence of increasing surveillance backlog |
| Governance. Risk Management | A series of alerts over a sustained time period that endoscopy demand was exceeding capacity are evidenced. Position was known and understood across the organisation at numerous levels and wider health and social care system. | These alerts did not trigger an appropriate response in corporate risk management systems in that potential patient safety risks were not managed effectively. | <p>The following key components of risk management to be considered and developed:</p> <ul style="list-style-type: none"> Consistent mechanism to identify, record and assess the significance of risks; Formal reporting protocols to be established/reaffirmed to ensure escalation thresholds are understood by all and mechanisms are accessible to all. Mechanism to manage risks through action planning, monitoring and reporting at appropriate governance forums; action plans to be standing agenda items – covering actions to date, residual risk exposure, and follow up required Ongoing evaluation of risks as part of an established corporate assurance framework. Review of status of any risk registers relevant to service / issues and the process followed and how staff (and | High Risk | Alerts, including on surveillance backlog, did not trigger an appropriate Divisional / Departmental response |

| Theme | Issue | Risk | Recommendation | System Risk Ranking | Direct contributory factor to healthcare incident? |
|--|--|--|---|---------------------|--|
| | | | <p>patients via comments and complaints) can be assured that alerts / issues of concern will be considered properly and formally within an organisationally understood and accepted procedure</p> <ul style="list-style-type: none"> • Clarity in the Terms of Reference for all governance committees which link to strategic risks to be explored and monitored; • Articulation of Departmental appetite for risk i.e. principles on how the Department intends to accept or mitigate risks; | | |
| <p>Governance. Business Case Management</p> | <p>The following observations apply:</p> <ul style="list-style-type: none"> • Original Business Case to support new Endoscopy unit (and thereby increase theatre capacity) did not include additional staff resources; • Subsequent Business Case to request additional staff to meet wider service demand was not progressed; similarly other interim options to increase capacity were not progressed. Raises issues around lack of transparency on decision making post business case submission. | <p>Relevant risks are:</p> <ul style="list-style-type: none"> • Business case quality - did not capture full resource and capacity implications of intended revised working arrangements; • Lack of clarity in respect of business case decision making and communicating decisions made | <p>Areas to consider:</p> <ul style="list-style-type: none"> • Service developments and efficiency changes proposed to be developed and assessed with input from clinicians so that impact on resources and the quality of care is understood. • The need for a robust quality assurance of business cases to ensure these capture a full assessment of service demand, capacity, quality, risk and resource implications • Business Cases to include Clinical and Quality Risk/Impact Assessment routinely in addition to Financial and Operational context • There is a need to ensure business case decisions are made at an appropriate level (in line with schedule of reservation and delegation) and that decisions are communicated to key stakeholders | <p>Medium Risk</p> | <p>-</p> |

| Theme | Issue | Risk | Recommendation | System Risk Ranking | Direct contributory factor to healthcare incident? |
|---|--|--|--|---------------------|--|
| <p>Governance. Endoscopy Service Leadership, Communication and Culture</p> | <p>Clinicians and Managers told us that they were unclear about leadership of the service during the critical 2014-17 period. In addition, there had been a number of different interim appointments during the period – the staff view was that this had led to a lack of communication, consistency and coherence of direction. Clinical leadership undertaken by the Surgical Directorate and was described as being ‘unclear’.</p> | <p>Relevant risks are:</p> <ul style="list-style-type: none"> • Service objectives may not be achieved • Accountabilities are not defined • Lack of co-ordination and communication • Impact on staff morale • Confused picture of service, both operationally and managerially | <ul style="list-style-type: none"> • Surgical Division to ensure Endoscopy Service operational and clinical leadership roles and responsibilities are defined, communicated and agreed. • To develop a system and culture of open communication that encourages constructive challenge. This should mean that: <ul style="list-style-type: none"> ○ Staff adequately informed and updated about what’s going on in the organisation, its vision and values. ○ Regular interaction, or opportunities for interaction with staff, especially at service level. ○ Clinicians and non-clinicians work and meet together as part of normal service review/development. ○ Staff feel that they are listened to and their comments considered with a system that includes feedback about concerns expressed. ○ Ensure there is organisational knowledge of improvement methods and the skills to use them. ○ Make full use of internal and external reviews, and learning is shared (and used to make improvements). | High Risk | Yes – service accountabilities not clear |
| <p>Governance. Knowledge of Endoscopy Service</p> | <p>MIAA discussions noted differences of opinion with regard to the arrangements in place. Differences of opinion included:</p> | <ul style="list-style-type: none"> • Confused picture of surveillance arrangements likely to have contributed to lack | <ul style="list-style-type: none"> • Policies and procedures to incorporate detailed surveillance management arrangements (as referenced above); these should be communicated to key stakeholders. | High Risk | Yes – lack of clarity on surveillance arrangements |

| Theme | Issue | Risk | Recommendation | System Risk Ranking | Direct contributory factor to healthcare incident? |
|---|---|--|--|---------------------|--|
| Surveillance Arrangements | <ul style="list-style-type: none"> Whether increasing delays in booking appointments (for surveillance) were specifically escalated. Whether surveillance activity was included in data contained in Business Cases seeking investment in the service. Whether or not surveillance data actually formed part of non-urgent waiting list activity or not. Whether the surveillance system was fully computerised or paper based. | of effective surveillance management | | | |
| Governance. Departmental Response to Surveillance Backlog | Once concerns were formally highlighted to address the surveillance appointment backlog, prompt action was taken during 2017 to review medical case files and offer procedures to those patients categorized as potentially at risk. Working papers to support the Departmental led exercise were provided to MIAA. We were not able to establish a complete evidence base to support actions taken. | Lack of consolidated evidence base to confirm that all patients identified to be at "at risk" received appropriate follow up care or elected to withdraw from process. | A closure report should be compiled setting out corporate response instigated in June 2017 i.e. issues, approach, results and underlying evidence sources in respect of completeness of patient listings; confirmation of patient attendance and results; and, assurance that data is consistent with appointment, procedure and results information recorded in key hospital IMT systems. This measure should provide a single point of reference to evidence the corporate response and to provide assurance that all that could and should have been done has been effectively completed. | Medium Risk | - |
| Capacity Management | Service performance data shared with MIAA indicates a widening gap between demand and capacity i.e. an increasing 'waiting list' backlog from 2012-2016. | Service demand exceeding capacity over an extended time period results in | The Endoscopy Service should explore the following areas as components of a review of capacity management: <ul style="list-style-type: none"> Changes to working patterns e.g. extended days, 3 session days, weekend working; | Medium Risk | - |

| Theme | Issue | Risk | Recommendation | System Risk Ranking | Direct contributory factor to healthcare incident? |
|-------|-------|----------------------------------|--|---------------------|--|
| | | increased patient waiting times. | <ul style="list-style-type: none"> • Use of 'nurse endoscopists'; • Establishment of a list of patients willing to attend at short notice – to help ensure optimum use made of existing capacity; • An opt in system for referrals (the service noted numerous examples where a patient was offered an appointment and was not aware that a referral had been made and they were on a waiting list); • Service to make full use of new endoscopy suite in use since 2016 – it is reported that there is still one unit without equipment and personnel; • Analysis of points allocated under Joint Advisory Group on Gastrointestinal Endoscopy (JAG) Global Rating scale which is a useful tool to analyse capacity utilisation. The IOM Endoscopy Service allocates a total of 8 points per patient list in a 3.5 hour time period which is considered maximum possible to keep lists on schedule; to note UK comparator is in the range 10-12. Whilst acknowledging that there are some factors hindering direct comparison (e.g. IOM does not include 'hidden activity' such as sedation), further analysis / comparison might identify achievable service efficiencies. <p><i>[To note changes to contracts/job plans and negotiation may be required for some of items above]</i></p> | | |

