Oxford University Hospitals
NHS Foundation Trust

Cover Sheet

Public Trust Board Meeting: Wednesday 10 November 2021

TB2021.90

Title: An Annual Review of the Serious Incidents Requiring Investigation (SIRI) and Never Events reported during Financial Year 2020/21

Status:	**For Discussion**
History:	**A summary paper presented to the Committee**

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Confidential:	**No**
Key Purpose:	**Assurance**

Executive Summary

1. This report presents a review of the serious incidents requiring investigation (SIRI) during the financial year (FY) April 2020-March 2021. It considers trends over time in incident reporting and themes that arise from review of all the investigations with descriptions of actions taken to prevent recurrence of adverse events and to support good practice.
2. 84 Serious incidents requiring investigation (SIRI) were declared during the FY April 2020-March 2021 (compared with 71 in FY 2019/20 and 109 in FY2018/19 (excluding those reclassified[1]). 28 SIRIs were subsequently reclassified leaving 56 SIRIs for review in this report. *All data in this report is based on these 56 SIRIs*.
3. As with the last financial year, COVID-19 has continued to have an impact on reporting especially during the pandemic 'waves'. March 2020 (from the previous FY 2019/20), going into April 2020 (This FY 2020/21) saw a large decrease in reporting due to the COVID-19 pandemic. Reporting rates have now returned to levels seen before the pandemic and have also increased to the highest levels seen by at the Trust. Incidents with Moderate or greater harm continue to increase with an average of 44 incidents per month for this FY compared to 39 FY 2019/20 and 17 for FY 2018/19. This may reflect the change in the approach to more consistent impact grading instigated in early 2019 and also the education around the reporting of moderate impact incidents such as unexpected transfer to a higher level of care.
4. The top three SIRI themes which occurred most frequently were
    - Diagnostic related (10)
    - Unexpected patient deterioration/death (9)
    - Lost to follow up (9)

    Trends and actions within this top 3 list are presented in detail in sections 4, 5, & 6.

    Additional information is supplied with respect to incidents where deaths occurred in the same admission and incidents that were investigated as Never Events.
5. Future plans for further improvements to the SIRI process and overall quality and safety are described.
6. **Recommendations**

    The Board is asked to note and discuss the content of this report.

[1] The use of the word downgrade has been reviewed in an attempt to clarify any misunderstanding of the reason why a level of investigation may have been changed. Changing a level of investigation is not carried out because it becomes less important or valuable but using the word 'downgrade' in some situations may be inferred as implying a hierarchy of importance for investigation types. We now use the phrase 'or reclassified or recategorised' instead.
To note the word downgrade is still used for impact changes

Contents

An Annual Review of the Serious Incidents Requiring Investigation (SIRI) and Never Events reported during Financial Year 2020/21

1. Purpose

1.1 The purpose of this paper is to inform the Board of the trends in reported Serious Incidents during FY April 2020-March 2021. The paper provides information to The Board on actions taken to prevent recurrence of these types of incident and ongoing work to further embed a culture of both safety and duty of candour across the Trust.

1.2 The Appendices have been used for additional information about the SIRI forum process, NHS survey and training. This report focuses on the themes and actions arising from the SIRIs in FY 2020/21.

2. Review of numbers of Incidents and SIRIs

2.1 During the FY 2020/21 84 SIRIs were declared by the Trust via the Strategic Executive Information System (STEIS), NHS England's web-based serious incident management system.

2.2 Twenty-Eight of these SIRIs were reclassified (previously described as downgrades) on STEIS (with agreement from Oxfordshire Clinical Commissioning Group (OCCG)) during the financial year, leaving 56 SIRIs in 2020/21. This is a decrease of 15 from the previous financial year, and below the mean for the past three years (77).

Table 1: SIRIs by FY

FY	SIRIs excluding reclassifications
1617	106
1718	91
1819	109
1920	71
2021	56

2.3 The reduction in number of SIRIs also reflects that 22 of the 28 cases added to STEIS as SIRIs (at that time) and later reclassified relate to patients who have died as a result of probable or definite nosocomial transmission of COVID-19. If these were included in the figures the number would be 74 which is in line with 1920. These COVID-19 related

incidents were originally called as individual SIRIs, but later, updated national guidance suggested that a single STEIS reference should be used to cover all nosocomial infections. Ultimately 58 individual cases were associated with this over-arching COVID-19 SIRI and have been followed up fortnightly in a COVID-19 nosocomial meeting chaired by the Director of Safety and Effectiveness.

2.4 The number of clinical incidents reported March-May 2020 was notably below the mean (see Graph 2, below) which may reflect that, during the height of COVID-19 wave one, there was a significant reduction in elective and out-patient treatment as part of the response to the pandemic and that a reduced amount of clinical activity, especially a large amount of surgery, has resulted in a reduction in incidents, and subsequently a reduction in SIRIs.

2.5 In 2020/21 2.4% of patient-related incidents involved moderate or greater impact, which is in line with the 2019/20 figure of 2.0%. Previous financial years had seen a lower percentage (2018/19 0.9%, 2017/18 0.5%). This increase is associated with the change of approach to more consistent actual-impact grading that began in January 2019.

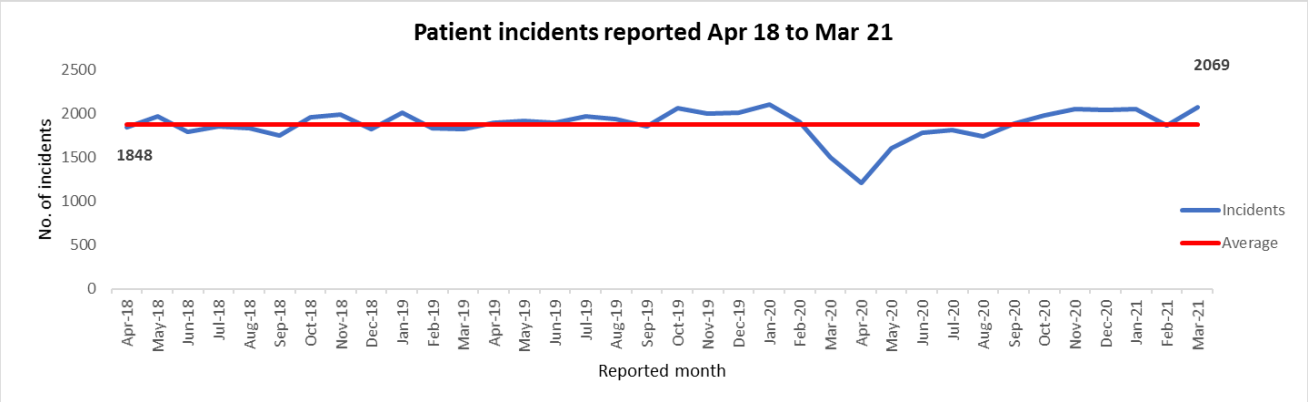
2.6 Graph 2 shows all patient related incidents at Oxford University Hospitals NHS Foundation Trust (OUH) between April 2017 and March 2021. This demonstrates the overall incident reporting culture in the Trust over this period.

2.7 Table 2 shows the average monthly incident reporting rates by financial year. In June 2020 the Trust moved governance systems from Datix to Ulysses. This move has not had a negative effect on incident reporting within the Trust as we are currently seeing the highest reporting rates of incidents during the current financial year.

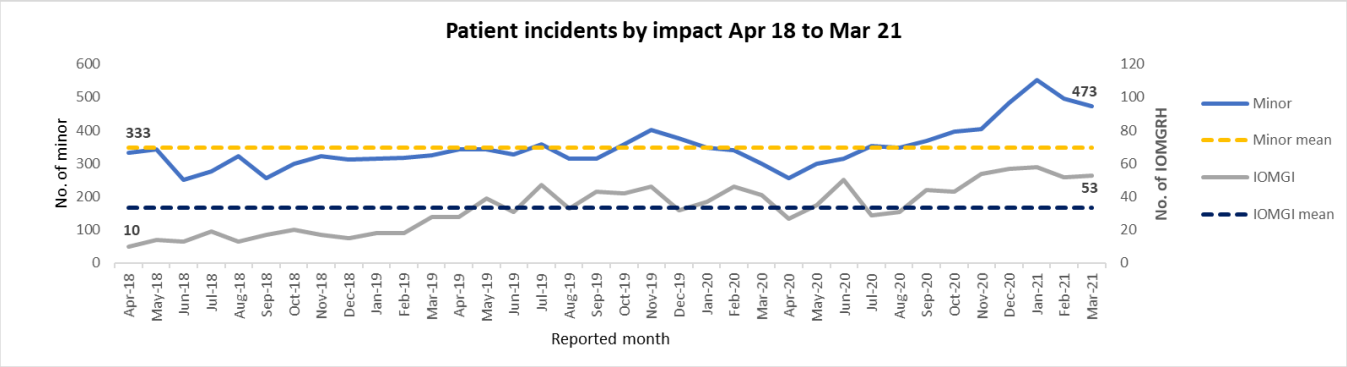
Table 2: Average monthly reporting rates by financial year.

Financial Year	Number of reported patient incidents	Total number of incidents reported
17/18	1869	2220
18/19	1875	2243
19/20	1919	2318
20/21	1841	2273
21/22 (Apr to Sep)	2157	2718

Graph 2: Incident reporting trend data for patient safety incidents April 2018-March 2021

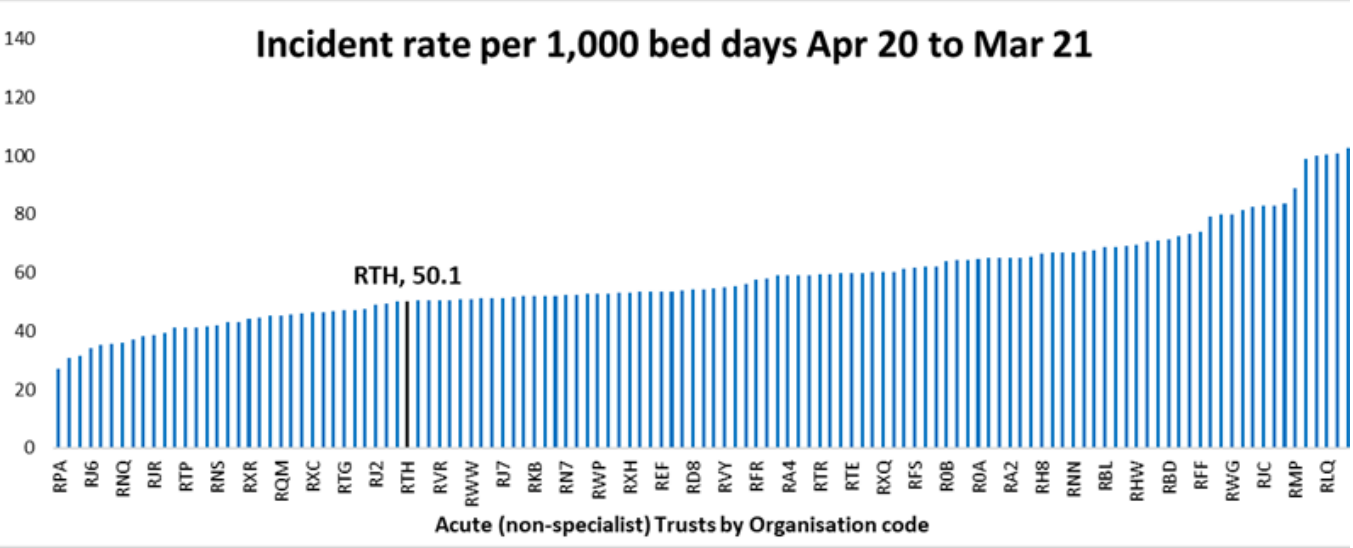


Graph 3: Trends in number of patient safety incidents showing incidents of minor impact and incidents of moderate and greater Impact (IOMGI) from April 2018 to March 2021



2.8 Graph 3. The reason for the spike in minor impact incidents from December 2020-March 2021 is not known but reflects a period of both COVID-19 and ongoing elective activity. The monthly figures for quarter 1 of 2021/22 all showed a reduction during the second COVID-19 wave.

Graph 4 The rate of incidents reported per 1,000 bed days between April 2020 and March 2021 by acute (non-specialist) organisations. Each vertical line is an acute provider. OUH is depicted by the black line.



Graph 4 shows a decrease in the rate the incidents are reported per 1,000 bed days, from 51.8 in FY 2019/20 to 50.1 in FY 2020/21

2.9 The reason for the decrease is that in June 2020 the Trust introduced a new incident management system called Ulysses and time was taken by the team to help the Trust transition from Datix over to Ulysses, consequently incidents were not manually uploaded to the National Reporting and learning System (NRLS) in real time and there was a backlog of uploading onto the NRLS. This backlog is in the process of being cleared and it is expected to be fully cleared by late November 2021.

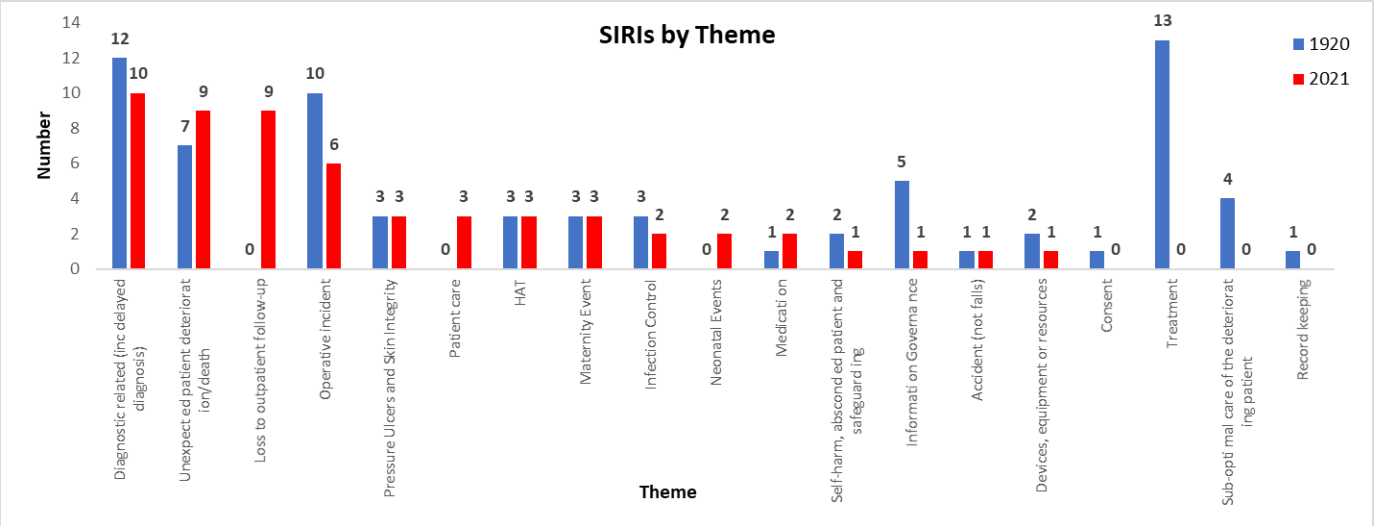
2.10 Graph 2 and table 2 demonstrates reassuring data that the incident reporting rate (apart from during the COVID-19 pandemic peaks) has remained at a relatively constant rate or even slightly above the monthly mean.

2.11 This data used to be released monthly but has now moved to yearly. The next graph to be published, including data from April 2021 to March 2022, should show a truer reflection of incidents reported to the NRLS.

2.12 In FY 2020/21 14,259 incidents were reported to NRLS, this is a decrease from 18,181 (3922 incidents) reported in FY 2019/20 but explanations above provide a rationale for this and table 2 shows the live data on incident reporting within the Trust (sees section 2.7).

3. SIRIs by Theme

Graph 10: provides an overview of the SIRIs (excluding reclassifications) reported in the past two years by theme.



3.1 These themes have been developed considering both the natures of the incidents and the causes. Whilst those themes based on specific outcomes (e.g. hospital acquired thrombosis (HAT), pressure damage) are relatively homogenous, others encompass a more wide-ranging group of incidents which could fit into numerous themes but the most prominent theme and reason for it being a SIRI is chosen by the PST. For example, a patient who developed pressure damage because of an omission of information about a turning regime might be recorded under pressure ulcer & skin integrity or documentation. The themes are chosen based on the knowledge of the case available when the SIRI is originally identified, and with the intention to maximise comparison over the years.

3.2 For FY 2020/21 some of these themes were amended to reflect a more accurate description of the SIRI. The following themes were amended

- Falls and Fractures changed to Slips, Trips and Falls
- Medical equipment and Devices changed to Devices, Equipment and Resources
- Sub-optimal care of the deteriorating patient changed to patient care
- Themes removed were treatment and record keeping
- Loss to Outpatient follow up was added
- Due to some of these changes it is difficult to compare some themes like for like.

3.3 The greatest number of SIRIs reported in 2020/21 were diagnostic (which includes delayed diagnosis) of which there were 10. This is a reduction compared to 12 in 2019/20, and 17 in 2018/19.

3.4 This was closely followed by unexpected patient deterioration (9) this is a slight increase compared to 7 in 2019/20 and 10 in 2018/19.

3.5 Loss to outpatient follow up equalises the above with 9 and is a newly introduced category as we were finding more SIRIs that fit into this category that would have previously been dispersed in other more generic categories in previous FY's.

3.6 Three of the top four incident categories have not changed compared to the last FY but the treatment theme, which was in the top four in the last 2 FY's, has now been removed and SIRIs that would have previously been in this category has been distributed to other themes.

3.7 The only increase in any theme for this FY is unexpected patient deterioration, as mentioned above, and neonatal events with 0 in FY 2019/20 and 2 in FY2020/21; the two SIRIs are unrelated, and they do not reflect any perceived trend in care.

3.8 Pressure ulcer and skin integrity, Hospital acquired pressure thrombosis, maternity events and accidents (not falls) remain equal compared to FY 2019/20.

3.9 Information governance (IG) and operative incidents can be compared like for like as these themes have not changed and these have decreased compared to FY 2019/20. IG had 1 SIRI in FY 2020/21 compared to 5 the previous FY (80% decrease) and operative incidents reduced from 10 to 6 (40% decrease).

3.10 As Sub-optimal care of the deteriorating patient was changed to patient care it can be compared and shows 1 less SIRI called this FY compared to FY 2019/20.

3.11 Slips, trips and falls, security and radiation do not feature on graph 12 as there have been no SIRIs declared for the past 2 FYs with this as the main theme.

3.12 Detailed analysis of the most common categories of SIRI is presented below.

4. Diagnostic incidents

4.1. There were 10 incidents in the category diagnostic incidents, which occurred in a range of departments, across all sites and all Divisions. There are three separate themes within this group.

4.1.1. There are six incidents related to a diagnostic delay. NB An issue relating to endorsement of results has been identified in multiple SIRIs, under various themes, which is discussed below in section 7.

4.1.2. There are three SIRIs relating to diagnostic screening.

4.1.3. One incident is related to an incidental finding not being acted upon

Trustwide actions arising from these SIRIs

4.2. The Trustwide actions below are not exhaustive, but represent the primary approaches taken in response to these incidents.

4.2.1. Internal communication about patient care should be done via Message Centre on EPR. This has been communicated within local and Trust level governance meetings. A safety message is being written to communicate this information to all Trust employees.

4.2.2. All clinicians should be aware of the role and remit of specialist MDTs and how to make a referral. A Trustwide safety message is being written, these issues have also been discussed at SIRI forums and OCCG closure meetings and within local governance meetings. The work surrounding MDT's and the referrals process is ongoing and being actively managed.

4.2.3. All MDTs should have a referral proforma to capture essential information and ensure there is a clear clinical question. This is currently being produced, the need for MDT referral proformas has been highlighted at the SIRI forum and locally.

4.2.4. Robust electronic systems should be in place to streamline and remove delays in processes if staff are working across sites and at home. Remove reliance on paper copies of documentation. Urology is to be part of this pilot to move procedure booking forms onto EPR, this will include specific mandatory fields or clinical information and an audit trail.

4.2.5. Amend the affected CareSets to remove the incorrect blood test and add the correct blood tests. This was completed within 48 hours of the incident.

4.2.6. Identify the patients affected by the incorrect test within the CareSet and review each case to see whether a patient needs be recalled and further screening completed. A list of patients was compiled and sent to the Divisions to review. To date no further issues have been reported

4.2.7. When any clinician leaves the Trust temporarily or permanently, the correct leavers process must be adhered to by the department including proxying into their inbox to pick up results, an out of office message should also be set up for their EPR message centre. A safety message is being drafted to disseminate to all Trust staff and emails have been circulated internally where the incident occurred. The Chief Clinical Informatics Officer brought a revised staff leaving

process to Clinical Governance Committee, with a plan to engineer a Trustwide roll-out.

4.2.8. Raise awareness of the urgent and unexpected procedure and highlight the difference between EPR and paper requests and OUH compared with tertiary referrals.

4.2.9. Share OUH 'Adult blunt chest wall injury pathway' with GP's and OCCG. The OCCG agreed to publish in their local GP bulletin – This has been completed.

4.2.10. A safety message is to be produced to highlight staff on the team to use the Resuscitation Event Record and ensure drugs are prescribed on EPR. This message has been composed and sent to all OUH emails.

4.2.11. All of these actions and learning points are highlighted at the Clinical Governance Committee meeting with a bi-monthly NE/SIRI report.

5. Unexpected patient deterioration

There were 9 incidents in the category of operative incidents. These incidents covered a range of theatre and non-theatre environments, in all Divisions and within either the JR or Churchill hospital

5.1. Two incidents occurred on the ward

5.2. Six incidents related to an intra/post procedure-surgery

5.3. One incident occurred at home

5.4. **Trustwide actions arising from these SIRIs** The Trustwide actions below are not exhaustive, but represent the primary approaches taken in response to these incidents.

5.4.1. A collaborative cross-divisional project (including the OUH Airway Group and the Resuscitation Department) to determine site of front of neck access (FONA) kits across the OUH. The introduction of the Difficult Airway Response Protocol (DART) team has been successful, FONA kits have been placed on all relevant resuscitation trolleys

5.4.2. Regular, "low dose high frequency training" for FONA should be offered to staff who may be involved in emergency airway management. This has been delayed due to social distancing but will resume as soon as practicable.

5.4.3. An agreed red flag checklist is to be available at the bedside of all patients with recent neck surgery so that escalation can begin as early as required. The checklist is now being used at bedsides.

5.4.4. Concurrent insertion of more than one central venous catheter should be considered a higher risk procedure for arterial puncture, this is to be added to the relevant LocSSIP.

5.4.5. The Corporate Bed Management Policy will be updated, with a particular focus on outlying of patients outside specialties. A proforma has been introduced to aid this and the corporate bed management policy is being reviewed.

6. Loss to outpatient follow-up

There were 9 incidents in the category of loss to outpatient follow up. These incidents covered all Divisions with the exception of Clinical support service (CSS) Division and occurred on all hospital sites.

6.1. Eight incidents relate to a delay in cancer diagnosis/treatment

6.2. One incident relates to urology stents

Trustwide actions arising from these SIRIs

6.1. The Trustwide actions below are not exhaustive, but represent the primary approaches taken in response to these incidents.

6.1.1. Education and guidance to be given to junior doctors that all diagnostic test results should be endorsed and acted on appropriately by the referral team in line with OUH Trust Policy (this is a recommendation in 3 of the above SIRIs). In addition to communication and discussion of this requirement in various forums, the junior doctor handbook has been updated to detail the correct pathway for abnormal results.

6.1.2. There should be adequate infrastructure available at the Manor Hospital so that OUH staff have access to EPR and label printers for histology requesting on NHS patients (when NHS patients are being treated at the Manor hospital). A temporary pathway for Pathology referrals in the Manor has been created whilst the extension of the network to the Manor is explored.

6.1.3. The correct process for referring patients to the Gynaecology-oncology MDT was clarified and emphasised to all clinical staff at the Gynaecology Clinical Governance meeting.

6.1.4. Create an SOP for referral of patients from acute settings to cancer services, which will include the need to refer to a named clinician

within the specialist service to take responsibility for the patient's ongoing care.

6.1.5. All paediatric orthopaedic patient scan results should be given to the patients or their parents by the clinician rather than the administrative staff. This has been added to the handbook for paediatric orthopaedic registrars two weeks after the completion of the investigation.

6.1.6. The importance of acting on abnormal radiology results was discussed during safety huddles and in governance meetings across the Trust.

6.1.7. Information Management and Technology Team with EPR to explore how results awaiting endorsement can be flagged to the referrer or a staff member viewing the patient record. The feasibility of pop-up windows for unendorsed results is being considered.

6.1.8. When an outcome action is required by a clinician or practitioner not present at an MDT, they should be notified with a message into their EPR Inbox, instead of by email. A SOP has been created and supplied to all MDT chairs following a discussion at the MDT Chairs meeting.

7. Main issues identified throughout the SIRI reports in FY 2020/21

7.1. The themes above are allocated when the SIRI is declared and therefore based around the nature of the incident. After an investigation further causative/incidental issues may be identified.

7.2. The two main issues identified are below

Endorsement of results (This includes some in lost to follow-up group above)

7.3. There are 5 SIRIs identified where endorsement is one of the main issues.

7.4. There are several measures in place to try to mitigate these result endorsement issues. Some have already been mentioned above. The others are as follows:

7.4.1. The endorsement rates are monitored in CGC and will continue to do so with emphasis on orbit data being collected for each Division down to department within the Divisional reports so that it can be clearly seen what progress is being made.

7.4.2. Learning from areas that have improved their endorsement rates should be shared. For example, gynaecology.

7.4.3. Safety messages have been issued about the importance of endorsing results and how this should be achieved, and a repeat message will be sent.
7.4.4. Ribbon banner reminders were set up for a week to go to all computers to remind staff to undertake results endorsement each day.
7.4.5. Safety huddles are used as a reminder to endorse results.
7.4.6. Training within certain areas as described in the actions above.
7.4.7. IT solutions are being worked on within the digital team.
7.4.8. Safety summit will be designed to include the importance of result endorsement as part of patient safety.
7.4.9. Learning from other similar Trusts, for example how endorsement is achieved within the Shelford group.
7.4.10. Ways in which these can be improved is continually being reviewed with the OCCG.

Referrals process (this includes MDT and incidental findings)

7.5. To note some of the learning from these SIRIs identified will have already been documented above within the themes.

7.6. There are 12 SIRIs identified with referral as an issue.

7.7. There are several measures in place to try to mitigate these issues. Some have already been mentioned above. The others are as follows:

7.7.1. Safety messages about best practice for consultant-to-consultant referrals, and referrals to MDTs.

7.7.2. An SOP created for the 2WW cancer pathway from ED

Monitoring some aspects of these with the OCCG through the OCCG SIRI closure meetings.

8. SIRIs in which the patient died

8.1. 19 SIRIs involved patients who died. In 14 cases the impact of the incident was the death of the patient. There were 5 cases where the patient died but the incident which was the subject of the investigation may not have impacted on the eventual outcome.

8.2. Of these 14 SIRIs there were 6 cases related to unexpected patient deterioration, 2 intrauterine/neonatal deaths, 1 hospital acquired thrombosis (HAT), 1 operative incident, 1 maternity event, 1 relating to self-harm, 1 related to devices, equipment, or resources and 1 related to infection control (see point 9.3).

8.3. There is one Trust level investigation into all probable and definite Oxford University Hospitals NHS Foundation Trust (OUH) nosocomial probable and/or definite COVID-19 transmissions resulting in death or serious harm.

8.4. Cases of SIRIs involving a death also have a structured judgement mortality review in accordance with national guidance. SIRIs involving deaths are presented to the Mortality Review Group (MRG) by the investigator to facilitate Trust wide learning. MRG has consultant representation from all divisions.

Table 5: SIRIs involving patient deaths 2018/19, 2019/20 and 2020/21:

Year	2018/19	2019/20	2020/21
Total number of SIRIs involving a death	14	14	19
Impact of the incident was the death of the patient.	6	12	14
Incident categories			
Diagnosis and treatment	6	0	0
Unexpected patient deterioration/suboptimal care of the deteriorating patient	4	9	6
Devices, equipment or resources	0	1	1
Accident (not falls)	0	1	0
Operative incident	0	1	1
Infection control	0	1	1
Maternity event	0	1	1
Hospital acquired thrombosis	2	0	1
Intrauterine and neonatal death	1	0	2
Fall	1	0	0
Chemotherapy management	0	0	0
Equipment and environment	0	0	0
Self-harm	0	0	1
Learning and action themes			
Review of practice and procedures	✓	✓	✓
Training and Education	✓	✓	✓
Documentation and the electronic patient record	✓	✓	✓
Multidisciplinary team working	-	✓	✓
Clinical audits and service evaluation	-	✓	✓

In comparison with 2019/20 death related SIRIs we can observe:

8.5. The number of SIRIs involving deaths has increased from 14 in 2019/20 to 19 in 2020/21. These cases have been reviewed by the Clinical

Outcomes Manager, and this increase is not felt to be indicative of any trend.

8.6. The number of cases where the impact of the incident recorded on Ulysses was Death has increased from last year from 12 to 14.

8.7. Unexpected patient deterioration/suboptimal care of the deteriorating patient remains a common incident category theme.

8.8. Out of the 6 identified for this FY, these cases had a SIRI report discussed at MRG, no death was felt to have been avoidable (more than 50% probability). Many of the cases were complex with no clear link between the incident and the patient death.

8.9. Whilst the common learning and action themes have remained review of practice and procedures, training and education and documentation and the EPR the individual actions under these themes are different to those from last year.

The themes for learning and actions in SIRIs involving patient deaths were:

8.10. Review of practice and procedures

8.11. Safety huddles to be utilised to discuss care of patients that are experiencing challenges such as delirium with focus on the question ‘what risks are there today that need mitigation?’

8.12. Review and update of both the enhanced observations policy and the missing persons policy.

8.13. Update OUH Hypertension in Pregnancy guideline to: Clearly state blood pressure thresholds for further monitoring and action. Include a section on the diagnosis of chronic hypertension in pregnancy. State that blood pressure should be measured at every antenatal appointment including in the first trimester.

8.14. Ensure that related Maternity Guidelines align with Revised Hypertension in Pregnancy guidelines: Review and update OUH Antenatal Care guideline to include explicit thresholds for diagnosis of hypertension and action thresholds. Review and update OUH Maternity Assessment Unit guideline to make blood pressure thresholds for diagnosis of hypertension and onward action more explicit.

8.15. Review out of hours emergency airway cover for OUH sites performing neck surgery and associated surgical emergency teams responses.

8.16. Consideration of the Trust to introduce a Family Liaison Officer to adequately support families who are involved in a patient safety investigation.

8.17. Review of pharmacy staffing and clear process for urgent time critical medicines collection.

8.18. Standardisation of airway trolleys and equipment across OUH adult critical care areas, including the use of 'Glidescope' video laryngoscopes which are now being implemented in all theatre areas, thus increasing standardisation of airway management across OUH.

8.19. The Corporate Bed Management Policy should be updated, with a particular focus on outlying of patients outside specialties.

8.20. A review of respiratory capacity should be undertaken in line with Get it Right First Time (GIRFT) recommendations.

Training and Education

8.21. Improve awareness of the inpatient Alcohol team and how they can support patients and staff.

8.22. Consistent awareness and understanding of capacity and its management.

8.23. Increase awareness within the Trust of the requirement to contact the obstetric team within 1 hour of arrival for pregnant patients and patients in the puerperium.

8.24. Raising awareness of the sepsis 6 care bundle.

8.25. Raise awareness of micro guide to nursing staff.

8.26. Introduction of a regular CTCC multi-disciplinary educational programme, including simulation, involving medical, nursing and allied health professional staff as recommended in Guidelines for Provision of Intensive Care Services 2020 with focus on enhancing patient safety through improving inter-disciplinary working and use of standard operating procedures.

8.27. Documentation and the EPR

8.27.1. EPR and the standard for OUH record keeping must be maintained in order to provide safe patient care.

8.27.2. Produce an OUH safety message regarding accurate documentation.

8.27.3. To create a flag on the EPR system that notifies staff in a non-obstetric setting that a patient is either currently pregnant or is within the puerperium. To also include a reminder to contact the obstetric team for review.

8.27.4. To introduce the OUH AICU Airway Passport on CTCC. This incorporates multiple safety checklists, including assessment of

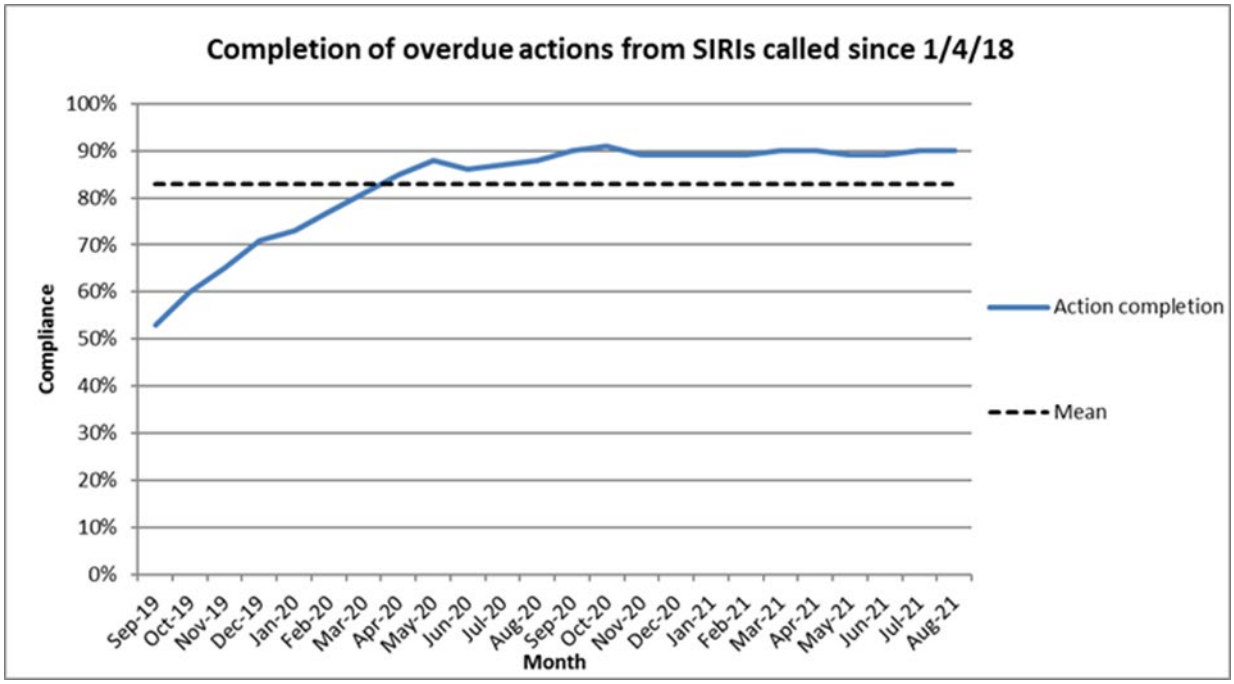
airway difficulty, intubation, extubation, re-intubation and space for documentation of airway management and difficulties.

9. SIRI Actions

The SIG meetings have been collating monthly data on the completion of actions identified in SIRI investigations since September 2019.

9.1. Graph 11 demonstrates that there has been an upward trajectory which continued in the beginning of this FY at 85 % compliance. It has then plateaued but remained above the mean with the highest compliance being 91% in October 2020. This is excellent work considering the operational demands due to the ongoing COVID-19 pandemic during this period.

Graph 11: provides monthly completion rates for overdue actions from SIRIs called since 1 April 2018



9.2. The Trust recognises that actions identified at the point of an investigation may not prove feasible in the longer term or may require more time than originally predicted. SIG gives Divisions the opportunity to table actions that have proven challenging for discussion. As an example, actions relating to staff training were extended because the COVID-19 pandemic meant that classroom teaching was not possibly for much of 2020, and interim communications to staff to reinforce required practice were agreed,

9.3. Since 1 April 2020, the Trust's 'new' incident management software, Ulysses has now been implemented to manage actions from SIRIs or Divisionals called. This has allowed Divisional and central governance oversight of evidence and allow targeted reports on action compliance to be produced.

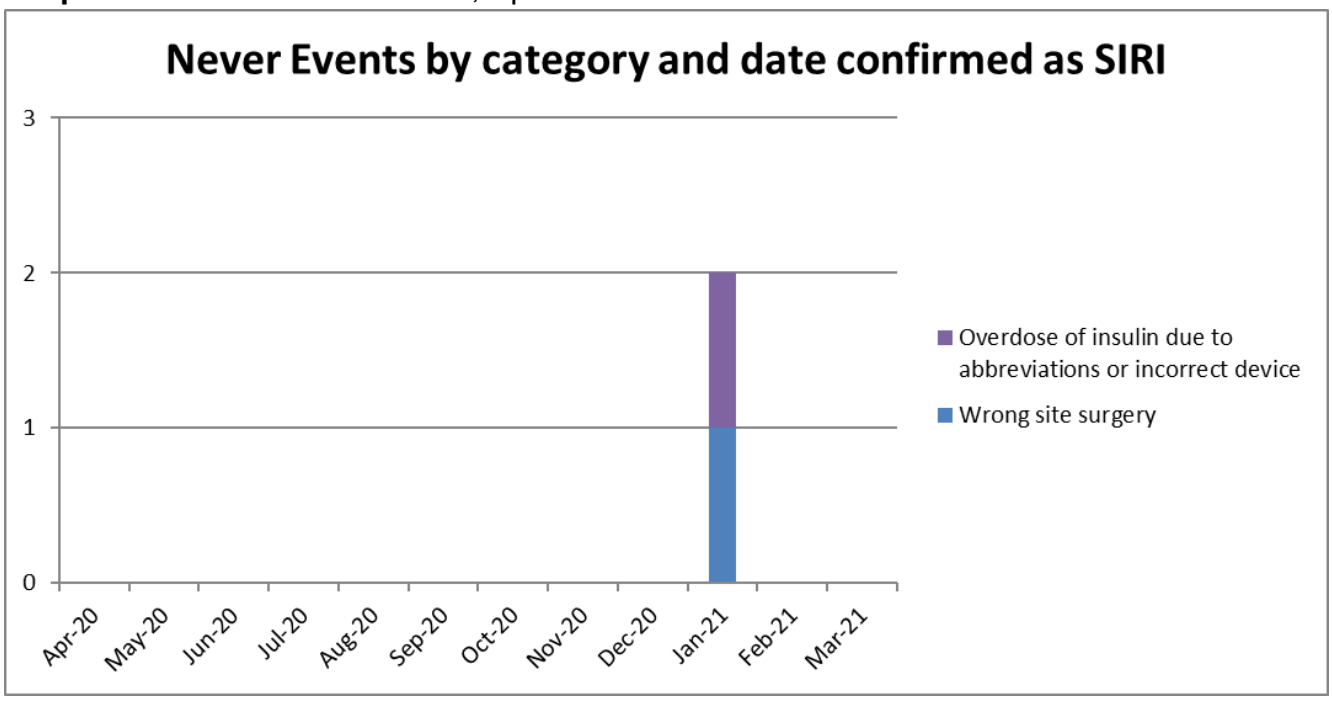
10. Never Events

10.1. In 2020/21 There were 2 Never Events reported in OUH compared to 7 in 2019/20, 11 in 2018/19 and 9 in 2017/18. The Never Events in 2020/21 were as follows:

10.1.1. One wrong site surgery case

10.1.2. One overdose of insulin due to abbreviations or incorrect device

Graph 12: Never Events at OUH, April 2020 to March 2021



10.1.3. The first Never Event was a wrong site/side surgery A CT-guided biopsy was taken from the right lung of a patient listed for a biopsy from the left lung, this was carried out at the Churchill hospital.

10.1.4. The second Never Event occurred in an interim high dependency Unit (HDU) which had been converted during the peak of the COVID-19 pandemic within 24 hours within the Emergency Assessment Unit (EAU). A patient received an overdose of insulin administered using the incorrect type of syringe.

10.1.5. The Never Events comes under the theme of Operative Incident and Medication, respectively. The actions for these Never Event are as follows

10.2. Wrong site surgery

10.2.1. Human factors training was organised for all staff involved with CT interventional procedures.

10.2.2. Education/induction programme for nursing and medical staff to include reading CRIS request out at time of WHO checklist in line with the current specific question of “confirm the following has been checked: clinical request and consent form consistency”.

10.2.3. Monthly audits of the WHO safety checklist.

10.3. The overdose of insulin administered using the incorrect type of syringe Never Event.

10.3.1. To produce a ‘repurposing areas checklist’ for areas throughout the Trust inclusive of the use of unfamiliar staff.

10.3.2. Look into the feasibility of insulin syringes being stored with insulin vials and the check to be added to the daily checklist.

10.3.3. Safety message to be written about the use of insulin syringes when drawing up insulin from a vial.

10.4. In 2020/21, learning from Never Events has been shared at all levels in the organisation and externally as follows

10.5. Internally:

10.5.1. The learning has been reported at committees within the Trust. This includes the Patient Safety and Clinical Risk Committee, Clinical Governance Committee and Integrated Assurance Committee.

10.5.2. The Never Events reports have been discussed within departments, for example local morbidity and mortality meetings, Directorate and Divisional Governance meetings and departmental staff meetings.

10.5.3. In 2019 a new process was adopted by which all Never Event investigations are presented to the CEO, Chief Medical Officer and Chief Nursing Officer following completion. The investigation team summarises the incident and main findings, and the Divisional and local management discusses progress against the action plan, and further learning. Clinicians involved in the Never Events also attend,

and positive feedback concerning the process has been received from all sides.

10.5.4. All SIRI root cause analysis reports are uploaded to the Trust intranet on completion and available to all staff.

10.5.5. Safety messages were sent globally in response to both the Never Events identified in 20201-21, relating to the correct syringes for insulin administration, and essential information required for interventional radiology requests.

10.6. Externally:

10.6.1. The CQC and NHS Improvement are informed of a Never Event when it occurs and a 72-hour report is sent to them for information which includes any immediate remedial actions.

10.6.2. Oxfordshire Clinical Commissioning Group (OCCG) review all completed root cause analysis reports. Prior to the pandemic they would complete assurance visits once action plans were complete to ensure that learning had been sufficiently embedded. At present time the PST are collecting evidence of all completed actions and sending them to the OCCG where they make a decision on closing the Never Event and closing the incident on STEIS.

11. Future Plans

11.1. A Weekly patient safety message will continue to be sent to all staff.

11.2. The National Patient Safety Strategy (NPSS) was launched July 2019 and an introductory version of a Patient Safety incident Response Framework (to replace the current Serious Incident Framework) was published in March 2020. Although the timetable for national release of the final version of this framework is not concrete, three current employees have been identified to cover the Patient Safety Specialist role mandated by the NPSS to support the development of a patient safety culture, safety systems and improvement activity.

11.3. The PSS team will continue to meet regularly and report progress to the Clinical Governance Committee as required, including the creation of a Patient Safety Improvement Response Plan (pending further guidance form the national leads) to describe the local strategic and operational arrangements for a proportionate and co-ordinated response to patient safety incidents. Training for PSS team members in the National Patient Safety Syllabus is expected to be made available in FY 2021/22.

11.4. Implementation of the Learn from Patient Safety Events Service, which will replace the National Reporting and Learning System, is also expected in 2021/22. The PSS team is working with the Clinical Governance Informatics Lead to address this, and concerns have been fed back to the national leads about required amendments to the Trust's incident reporting system.

11.5. Work will also continue in FY 2021/22 to meet the requirements of the Framework for Involving Patients in Patient Safety. The central requirements are to include patient representation in primary governance meetings, and to expand the incident investigation process to achieve greater input from patients and families.

11.6. Until the new framework is instigated the Trust will continue to regularly train RCA investigators.

11.7. Specialised 72-hour reports are continuing to be developed within Ulysses.

11.8. DoC and how it is interpretated alongside the understanding of moderate impact continues to be reviewed.

11.9. The action plan module within Ulysses went live in December 2020 and continues to be used for SIRI action plans and is available for Divisions to monitor Divisional level investigations.

11.10. A Safety Summit is to be organised which will have a focus on result endorsement with an aim to improve these rates consistently across the OUH.

12. Quality Priorities

12.1. Two of the Trust's 8 quality priorities for 2021/22 are particularly relevant to issues raised above:

12.1.1. Safety Huddles priority has continued from 2020/21 which now also includes a sub-set of focussed huddles i.e Recognising Acutely Ill and Deteriorating Patients (RAID) huddles, overseen by the RAID committee.

12.1.2. Introduction of triangulation of complaints, claims, incidents and inquests which allows communication between the relevant OUH departments about the nature of these issues allows for optimal efficiency in addressing the issues, and a combined approach to patient and relative responses, investigations, and systemic improvements.

12.2. The process for setting quality priorities begins in the preceding financial year, so although the Trust's incident profile will have informed the final selection, along with many other drivers such as patient satisfaction surveys, the full information contained in all SIRI root cause analysis reports will not have been available.

13. Recommendations

13.1. The Board is asked to note and discuss the content of this report.

14. Appendices

Appendix 1 - The SIRI process including Duty of Candour

Appendix 2 - SIRI overview, including extensions, reclassifications and SIRIs by site and Division

Appendix 3 - NHS survey

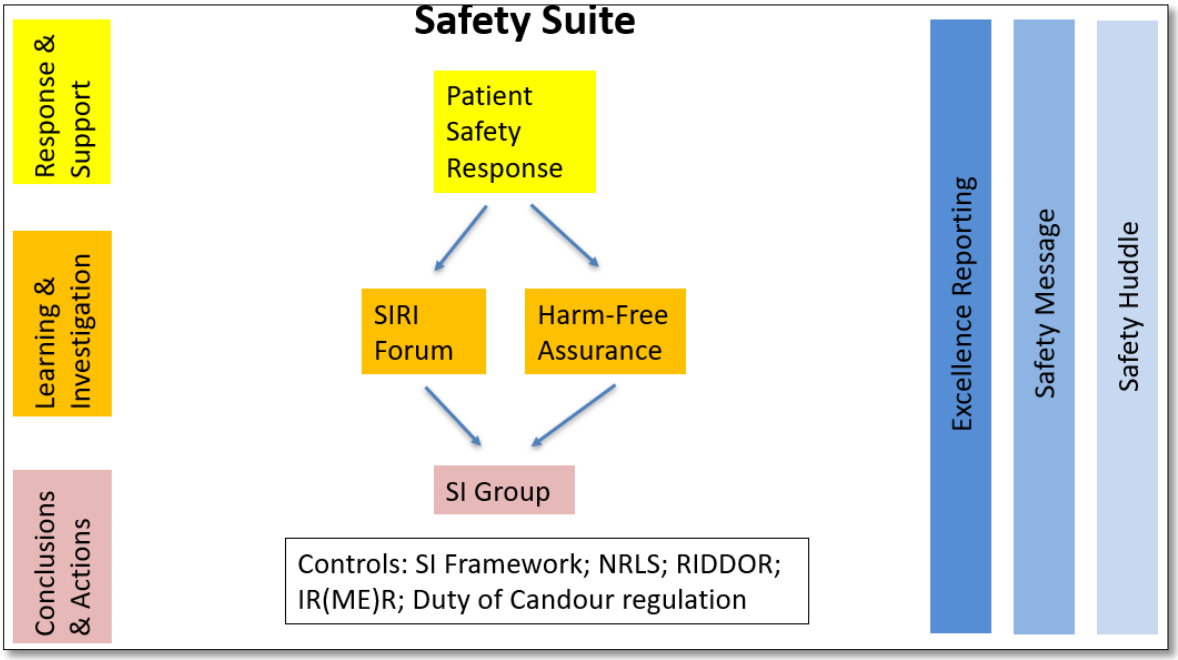
Appendix 4 - Additional training

Appendix 1 - The SIRI process including Duty of Candour

15. The Safety Suite

15.1. These are multiple processes to help streamline incident management and learning from incidents. Diagram one below demonstrates how these processes interact.

Diagram 1



15.3. In 2020/21's meetings 1103 incidents were discussed, of which 111 were reclassified. In 18 cases, departments were visited by a delegation from the PSR meeting, to ensure that patients and staff were suitably supported. This is a lower figure than in previous years because working practices during the first and second waves of COVID-19 made visits to many departments difficult or inadvisable. Attendees at the forum during the last FY included CMO, CNO and their deputies, Divisional Medical

Directors, Clinical Directors, Consultants from multiple disciplines; Matrons and nursing/midwifery staff; Allied health care professionals, and advisors from corporate teams.

15.4. The SIRI forum is a weekly meeting where incidents are presented and the level of investigation and level of impact is agreed by a multi-disciplinary team with departments and divisional managers encouraged to attend and to take ownership of decisions made about levels of investigation. It is a forum founded on Just Culture and mutual respect. This meeting is also attended by subject matter experts such as the Chief Clinical Information Officer, Information Governance (IG), human factors leads and the thrombosis lead as required.

15.5. All incidents reported are screened by the central Patient Safety Team (PST) which meets weekly with the Director of Safety & Effectiveness and Head of Clinical Governance with a provisional list of incidents that may meet the criteria for a SIRI or Divisional or have important cross-Divisional shared learning.

15.6. Following on from a CQC inspection related to incidents reportable under the Ionising Radiation (Medical Exposure) Regulations (IRMER) it was agreed that the SIRI forum would be an effective place to monitor these incidents. Consequently, Medical Physics review all incidents categorised as Radiation Incidents and inform central PST which incidents are CQC reported IRMER reportable incidents. These are then presented at the SIRI forum to raise awareness of issues and actions needed.

15.7. The Tissue Viability team (TV) reviews all hospital-acquired category 2, 3 and 4 pressure damage incidents with the local manager, to identify investigation levels. Where a SIRI or Divisional is proposed, this is also agreed with Divisional management. These decisions are noted at the SIRI Forum, with discussion only required where a consensus decision has not been feasible. This process is overseen by the Harm Free Assurance group chaired by the Chief Nursing Officer.

15.8. An identical process occurs under the aegis of the Harm Free Assurance group for falls resulting in moderate or greater impact.

15.9. Any incident reporting a hospital-acquired thrombosis (HAT) is reviewed by the Thromboprophylaxis team (TP) and a HAT screen is completed to ascertain whether it was potentially preventable. TP informs the central PST when there is a potentially preventable HAT that requires inclusion on the SIRI forum agenda.

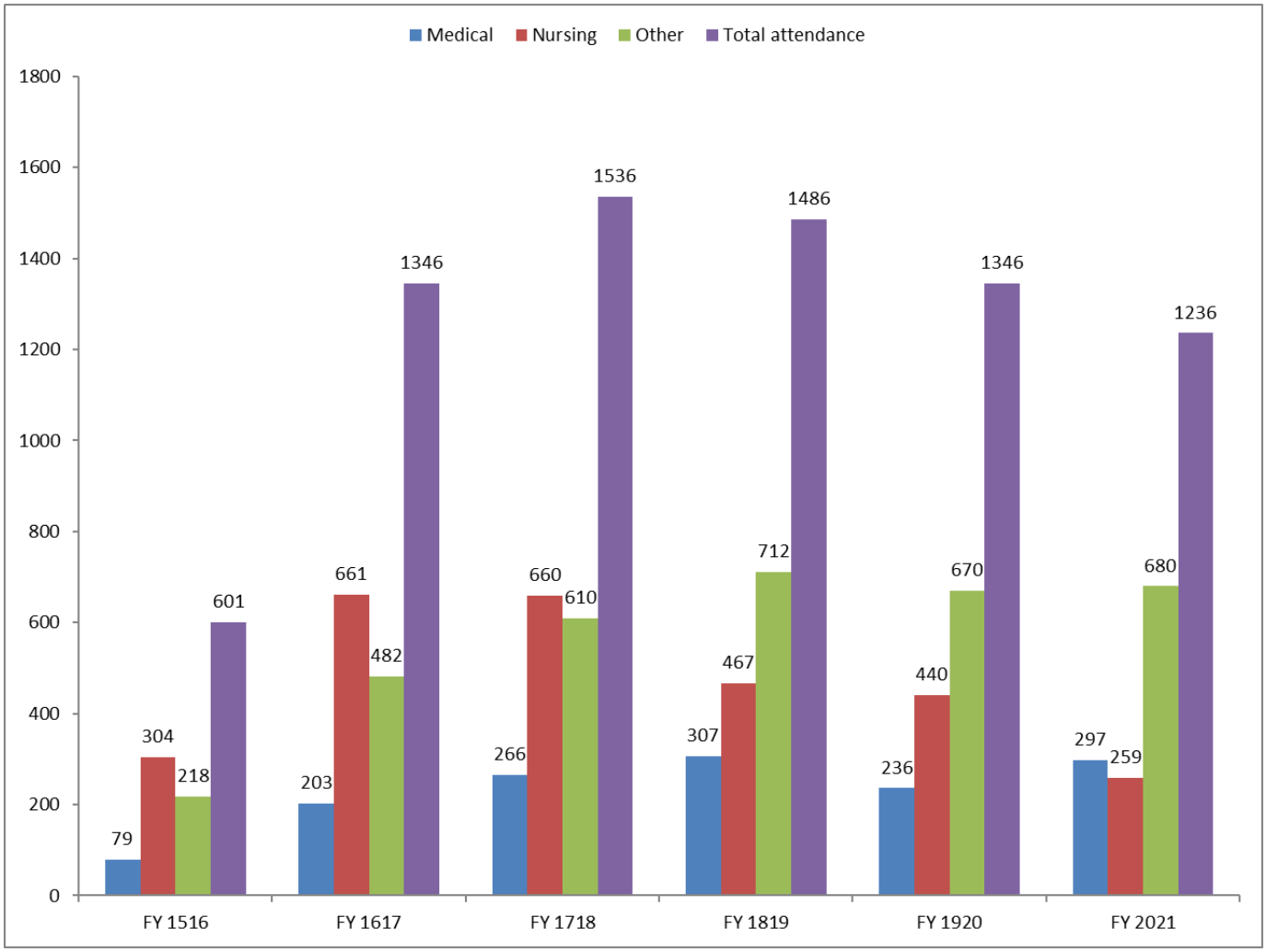
15.10. The Health & Safety team (H&S) reports any patient harm incidents resulting from a fall to the Health and Safety Executive, when these

incidents fit the criteria under the Reporting of Injures and Dangerous Occurrences Regulations (RIDDOR) report. To aid the process of identifying any such incidents, the SIRI forum was identified as a place where minutes can reflect H&S's advice on whether incidents meet these RIDDOR criteria.

15.11. Monthly meetings occur between central PST and the Trust's Legal team to review all open inquests. Any inquest that may meet the criteria for a SIRI is cross-checked with the incident management system and a review by the Division is requested. This is an extra safety net for identifying potential SIRIs. There is also an opportunity of issues relating to inquests, claims or complaints to be discussed at the weekly Serious Incident Group (SIG) meetings, and a monthly review of any red-graded legal cases.

15.12. At SIG, SIRIs and specified Divisional and local investigations are presented roughly halfway through their investigation period. This enables any early learning and action to be shared across the Senior Divisional representatives, identify any blockers to progress, further suggestions made by the group as well as to discuss any issues faced by the investigator.

Graph 5: SIRI Forum attendance by staff group showing the number of nursing staff, medical staff and other staff who have attended. The 'others' category includes clinical risk expertise, Information Governance, Pharmacy and laboratory staff, H&S, and observers such as trainee nurses or medics. (NB the forum began in June 2015, so FY 1516 only covers 10 months).



15.13. This FY was unusual, the requirement to lock down on 23 March 2020 meant that we had to adapt to how we carried out the meetings and familiarise ourselves with Microsoft Teams. A majority of attendees worked clinically at times, and this meant that for all of April 2020 five meetings were not held in person or virtually but via email. Outcomes were in a smaller multi-disciplinary (MDT) and sent out via email asking for any objections or opinions about the incidents; the Duty of Candour (DoC) was also monitored this way.

15.14. In addition, a further 3 meetings were cancelled due to the second wave of the pandemic and dealt with as described above, and there were 2 meetings when the SIRI forum first started out on Microsoft Teams (MST) and attendees were not minuted.

15.15. Consequently, there were 12 potential meetings without a recorded of attendance. Considering this, attendance remains very good, and the move to virtual meetings since the start of this financial year means that attendance is not limited.

15.16. The use of MST for SIRI Forum during 2021 has facilitated clinicians with knowledge of the incidents to attend before or after clinical duties and from other OUH sites which was not always possible when attendance was required in person. This is reflected in the rise of medical staff attending. This has been a very positive aspect of a virtual meeting.

15.17. The nursing staff attending has reduced; this could be for a number of reasons, a) they have been working clinically throughout the pandemic b) HAPU and falls are on by a case-by-case basis through the harm free process (as explained above) c) nursing staff used to attend on behalf of consultants who were unable to attend but now, following the reasons explained above, they no longer need to deputise.

15.18. Overall SIRI forum attendance fell by 8% (110) from 2019/20 figures. However, there were only 41 meetings this FY compared to 48 meetings in 2019/20 and 52 in 2018/19, but if worked out by average attendance per meeting this is increased from 28 attendees per meeting in 2109/20 to 30 this FY.

Duty of Candour (DoC)

15.19. The legal, professional and regulatory DoC has been embedded into the Trust's day to day governance processes within the Divisions with weekly monitoring via the SIRI Forum (table 3).

15.20. The PST updates incidents as a failsafe system following each SIRI forum's discussion to ensure that it accurately reflects actions relating to the DoC.

15.21. The Divisional Clinical Governance and Risk Practitioners (CGRPs)upload the written evidence of DoC onto each incident record. The SIRI forum's agenda and minutes remind staff that updates, and evidence should also be added to the patients' notes.

Table 3: DoC compliance from FY 2020/21 by quarter which shows that Duty of Candour was addressed for all patient incidents reported as moderate impact or above

Quarter 2021	DoC verbal compliance	DoC written compliance
1	100% (113/113)	100% (113/113)
2	100% (103/103)	100% (103/103)
3	100% (154/154)	100% (154/154)
4	100% (163/163)	100% (163/163)

15.22. There can be complications relating to Duty of Candour, such as a patient's contact details being out of date, which can delay the completion of one or both elements. All cases requiring Duty of Candour are managed in the Trust's weekly SIRI Forum and Divisional representatives supply updates on progress to confirm that these cases are being actively managed, and report when the obligations have finally been addressed.

15.23. In situations where DoC cannot be completed or there are complications; it is discussed in either SIG or the SIRI forum where it is confirmed if there are other ways in which the DoC can be achieved. If agreed it is not appropriate or all avenues have been exhausted the rationale is documented on the Ulysses incident form. In these cases it is considered that DoC has been addressed.

Weekly Safety Messages

15.24. Since February 2019 the Patient Safety Team has sent a weekly Safety Message email to all staff. Topics from the 52 messages sent in 2020/21 include positive patient identification in blood transfusion, Never Events and insulin syringes, administration of oral liquid medication, tissue viability and device related pressure damage, documenting side and site of procedure/surgery, discharge summaries, reporting COVID-19 cases on Ulysses, results endorsement and nasogastric tube safety for patients with COVID-19.

Patient Safety Alerts

15.25. Three patient safety alerts were created and added to the front page of the Trust intranet in 2020/21. Patient safety alerts are raised in response to some SIRIs, however, with the introduction of the weekly Safety Messages patient safety alerts are becoming less prevalent.

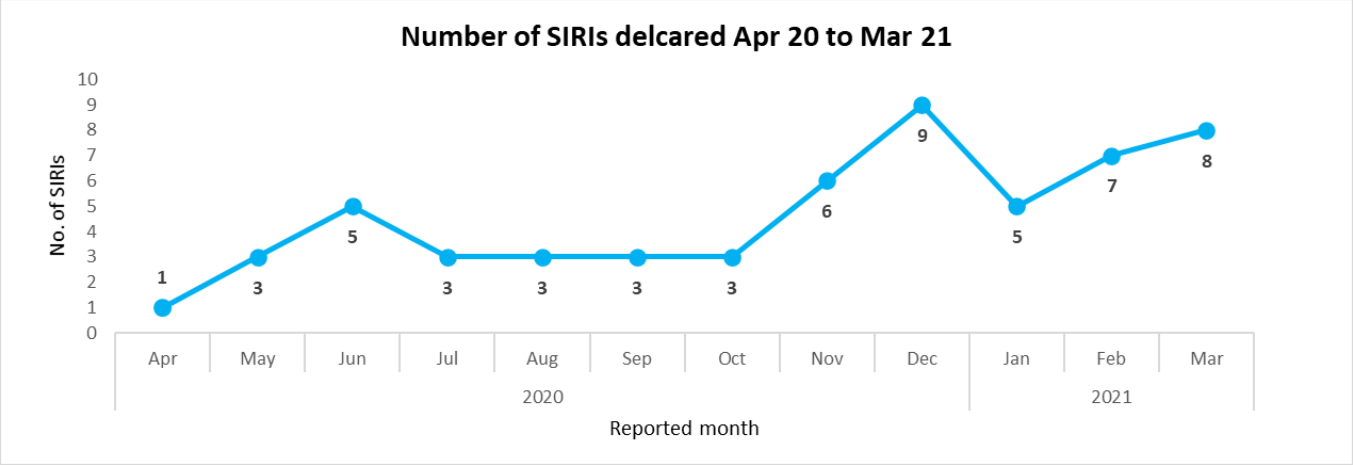
Appendix 2 – SIRI overview, including extensions, reclassifications and SIRIs by site and Division

16. SIRI overview

16.1. This year has seen a drop in the number of SIRIs declared per month with an increase from November 2020 onwards. There is no definitive explanation for the reduced numbers at the beginning of the FY but COVID-19 has played a role in the reduced number of incidents reported and consequently the number of SIRIs declared. (see 2.3 above).

16.2. Graph 6 shows the number of SIRIs of all types declared during FY 2020-21, excluding those subsequently reclassified.

Graph 6: 56 SIRIs declared, which excludes subsequent reclassification



16.3. As in the previous three financial years, there were no delays in completing SIRI reports beyond the national guidance time scale of 60 working days or of an agreed extension from the OCCG. However, 37% of 2020/21 SIRI investigations required an agreed extension request (see Graph 7 below). This is compared to 25% in FY 2019/20 and 26% in FY 2018/19. The primary reason for extensions this FY is due to the impact of COVID-19 and the pressures on staff. Some governance staff who also help to facilitate the investigations were moved to work clinically. NHSEI and OCCG agreed that extensions should and would be granted without question during this period of time. Some extensions have also been requested repeatedly, these include HSIB investigations which the Trust do not have any control over.

16.4. Whilst the Trust would prefer to request fewer extensions, the instigation of the Serious Incident Group, in July 2019, allows a colleague from OCCG to witness the progress of the investigation over its duration,

and to hear justifications for any extensions, which gives them assurance that extensions are because of challenges near the end of the investigation process and in order to gain more robust action plans or deeper levels of investigation, rather than failure to engage with it in a timely fashion.

Graph 7: SIRIs extension rates

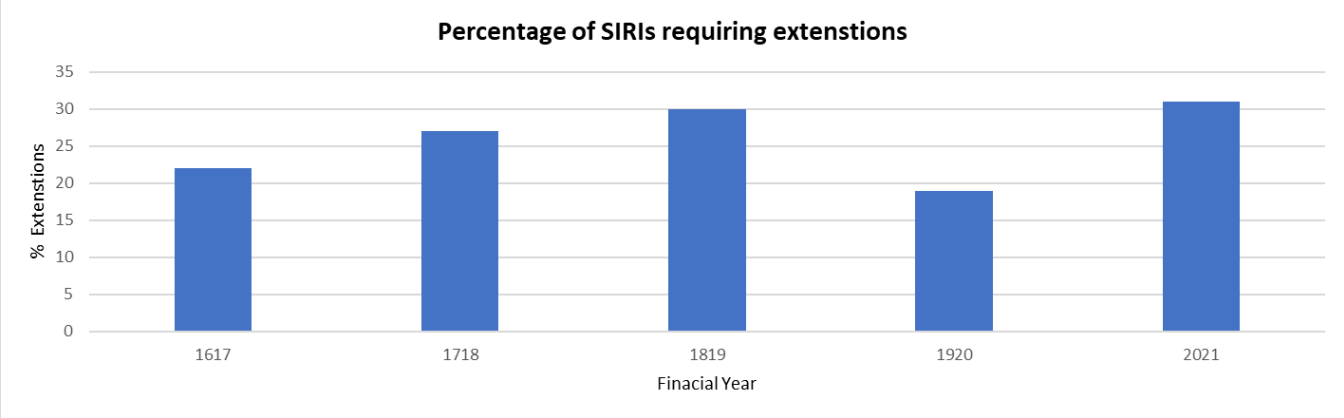
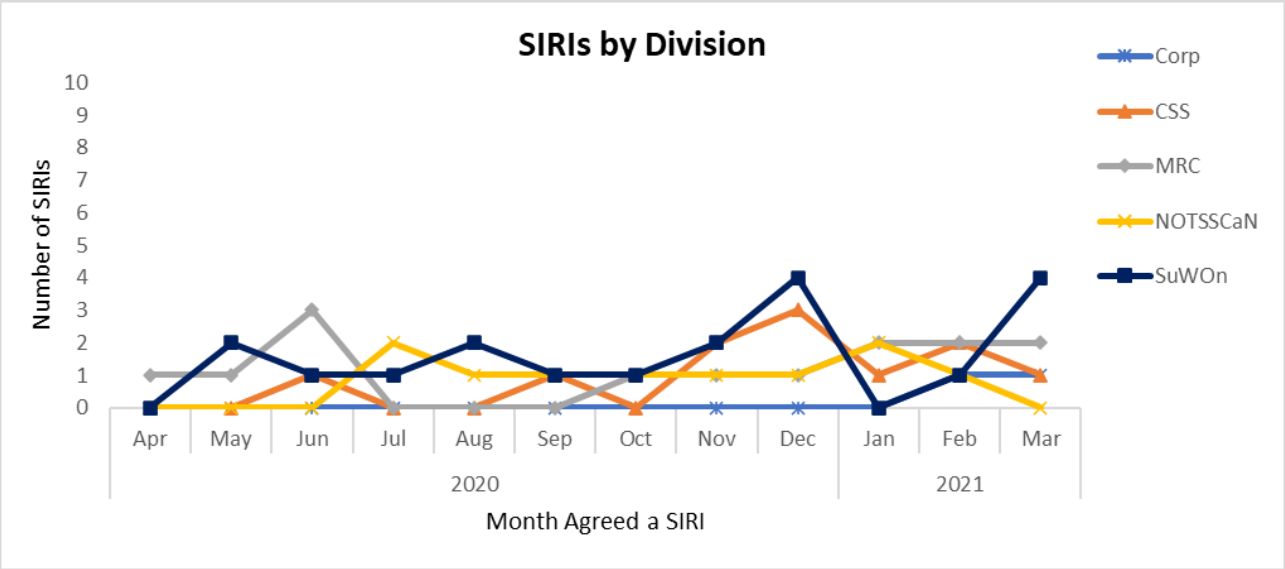


Table 4 shows the number of SIRIs investigated per Division, excluding reclassification.

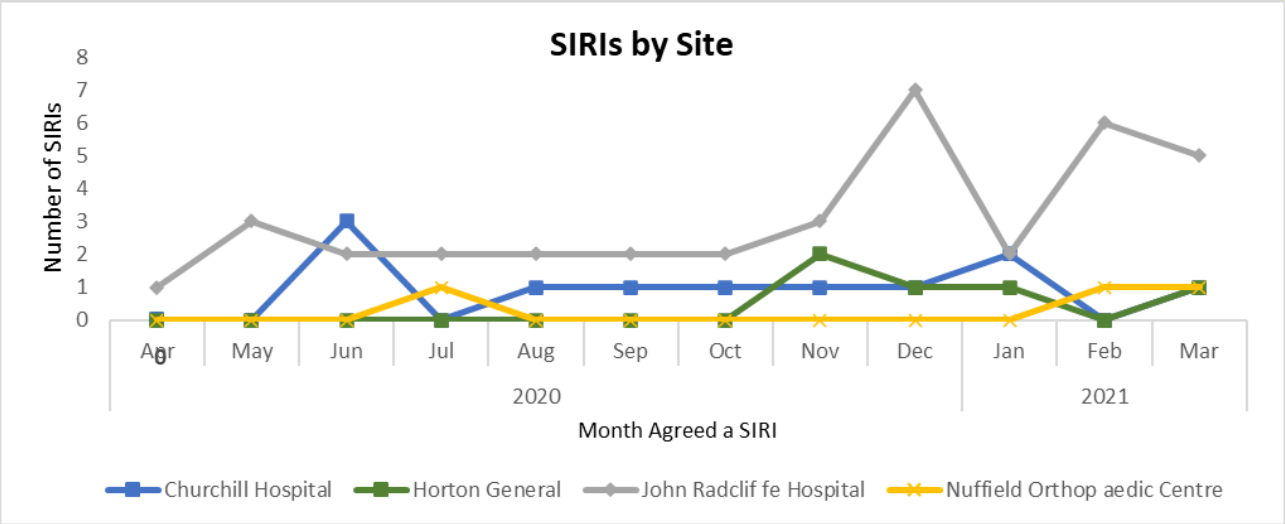
Division	SIRIs declared 2018/19	SIRIs declared 2019/20	SIRIs declared 2020/21
CSS	10	11	11
MRC	23	13	14
NOTSSCaN	33	17	10
SuWOn	41	27	19
Corporate	2	3	2
Totals	109	71	56

16.5. Some SIRIs require cross-Divisional input; table 4 shows the lead Division who will investigate but other Divisions may have had equal input into the findings and conclusions of the report.

Graph 8: shows the number of SIRIs declared by Division



Graph 9: shows the number of SIRIs by site. The John Radcliffe (JR) consistently reported the most SIRIs, which reflects the fact that it hosts the greatest amount of patient activity.



Reclassification of SIRIs

16.6. Reclassifications are proposed by the Trust and require agreement by OCCG or NHSE/I.

16.7. 28 SIRIs out of the 84 SIRIs (33%) originally reported on STEIS were reclassified. This was a unique circumstance due to the new and emerging guidance around nosocomial COVID -19 deaths and declaration of SIRIs at that time. Initially the Trust declared SIRIs for each individual nosocomial death where COVID-19 was confirmed 'probable' (positive specimen date 8-14 days after hospital admission) or 'definite' (positive specimen date 15 or more days after hospital

admission) and is cited on any part of the death certificate. Discussions with NHSE/I and OCCG later confirmed that one SIRI could be declared, and all other confirmed cases (as described above) could sit under this 'umbrella' SIRI. Because of this, 22 previously declared were reclassified. Subsequent nosocomial SIRIs fitting the above criteria were thereafter added to the main overarching SIRI.

16.8. The remaining 6 SIRIs were reclassified into 5 local investigations (with 2 being re-instated to SIRIs) and 1 OCCG systemwide SIRI.

The following SIRIs were reclassified to local investigations:

16.8.1. 2021-009- A patient was delivered midazolam for tranquillisation, the possibility that a higher strength solution than intended was delivered could not be ruled out. This was initially declared as a Never Event and investigated fully. After completion of the report the OCCG and NHSE/I agreed that this did not meet the criteria for a Never Event and therefore did not meet the SIRI criteria because the midazolam strengths were risk assessed as appropriate for the area for which they are stored in Emergency assessment Unit (EAU) and Emergency Department (ED).

16.8.2. 2021-015- A notebook containing patient identifiable information has been reported missing. This was initially declared based on specific criteria set by the Information Commissioner's Office (ICO). The agreed OUH process is that information governance team inform PST when an incident fits this criteria and should be declared as a SIRI. Following further investigations the ICO decided that as the notebook was lost within OUH rather than the community this no longer met their requirements of a SIRI and was reclassified.

16.8.3. 2021-023- A patient died following a potential anaphylaxis reaction. Following a discussion in SIG it was agreed that this did not meet the criteria of a SIRI as the investigator could not find any evidence that this incident (which is extremely rare) could have been anticipated or avoided.

16.9. The following 2 SIRIs were reclassified and then re-established as SIRIs in FY 2021/22:

16.9.1. 2021-032- This was a patient who had several patient safety incidents during their admission and there was a concern of moderate impact from a medication incident. A SIRI was thought the best mechanism to investigate robustly. During SIG the finding were discussed, and the group decided that this did not meet the criteria for a SIRI. It was reclassified. The family members complained about the reclassification and after it was reviewed by a different

expert within the OUH and re discussed in SIG it was agreed that it would be investigated as a SIRI as the best mechanism to address the families questions. The original SIRI number was reopened on STEIS. To date this remains an on-going investigation.

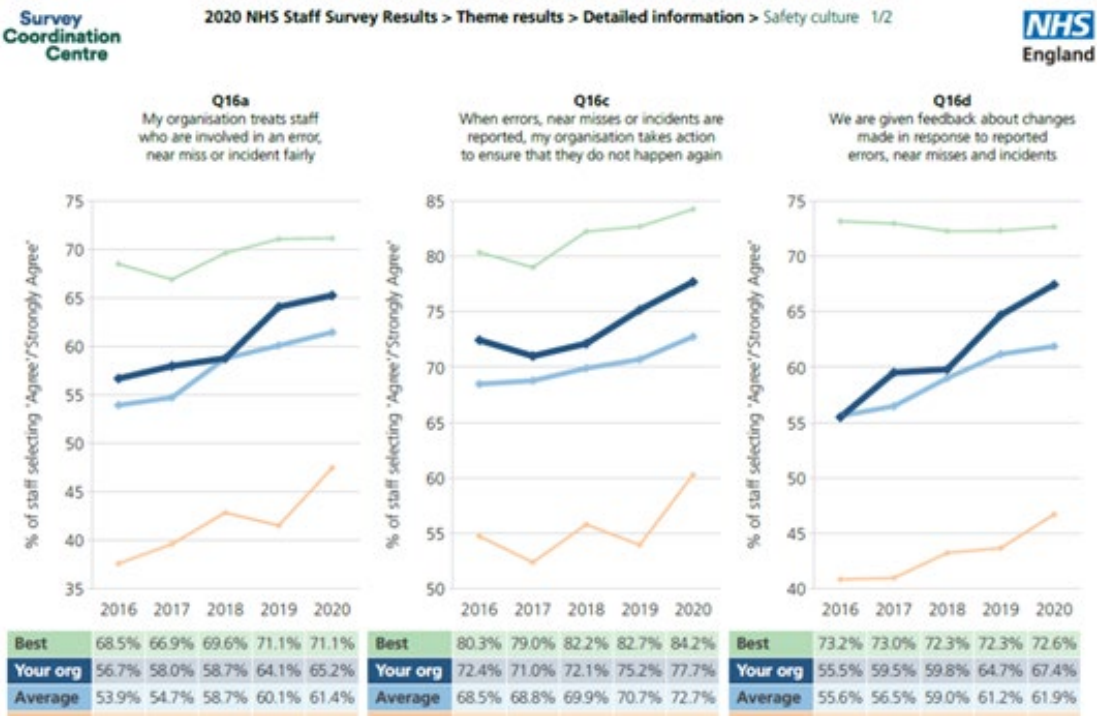
16.9.2. 2021-077- A patient was anaesthetised without a signed written consent form and was woken and required a second anaesthetic. This was originally declared as a SIRI and then reclassified to a Divisional investigation in FY 2020/21 as it was initially believed to be human/individual rather than a system error . It was presented at SIG in May 2021 where further investigation had identified that system errors were involved and it was reclassified back to a SIRI investigation with the original SIRI number from FY 2020/21. The potential to reclassify incidents at SIG allows a further level of scrutiny for incidents such as this case.

16.10. 2021-012 was reclassified as a systemwide SIRI under the management of OCCG, instigated when there are several agencies involved- A patient presented as an emergency to the gynaecology ward and was found to have a cervical rhabdomyosarcoma. It was stated in a clinic letter they underwent a speculum examination at another hospital in February, but reportedly this did not take place. This was reclassified to an OCCG system wide SIRI.

Appendix 3- NHS Staff survey

The results of the 2020 national NHS Staff Survey provide positive assurance regarding the Trust's approach to incident reporting and management. Questions relating to the treatment of staff involved in incidents, taking remedial actions in response to incidents, and communicating of these with staff, all showed an increase on responses from the past three years, and all were above the national average.

Graph 13: Incident management questions from the national staff survey



Appendix 4 - Additional training and communication activities

These include-

- Training by the Patient Safety Academy continued to be funded across the Thames Valley region by Health Education England. Courses were offered to OUH staff on human factors, incident analysis and quality improvement
- A root cause analysis (RCA) training course has been delivered by PST once per month since September 2018. 34 staff members were trained in 2020/21. This is a smaller number than in previous years, because the influence of COVID-19 meant that sessions did not take place between March and September 2020. All staff are welcome to attend, with special emphasis on consultants who may lead SIRI investigations.
- Over the course of the past year the pandemic presented significant challenges and OxSTaR worked closely with our infection prevention and control team and with educators across the OUH to deliver innovative training to support changing work practices. Simulation and other educational technologies allowed rapid upskilling of staff and dissemination of knowledge on electronic platforms which could be accessed at any time using any device. A wide range of teaching materials, including videos, webinars and training in the safe use of personal protective equipment and intubation and proning drills for patients with COVID were provided. Sixteen new patient pathways and 15 new checklists were designed (some of which were adopted nationally) and improvements in staff confidence and capability were evident from quantitative and qualitative feedback.