A report evaluating the risk of unintended exposures at SBUHB using voluntarily reported radiotherapy errors

By Daniel North BSc

Contents

List of Abbreviations

CF – Contributory Factor

CFT – Causative Factor Taxonomy

DoL – Development of Learning

ESB – Effective Safety Barrier

FSB – Failed Safety Barrier

IR(ME)R – Ionising Radiation (Medical Exposure) Regulations

NHS – National Health Service

NRLS – National Reporting and Learning System

PHE – Public Health England

PSI – Patient Safety Incident

RC – Root Cause

RT – Radiotherapy

RTE – Radiotherapy Error

SB – Safety Barrier

SBUHB – Swansea Bay University Health Board

TSRT – Towards Safer Radiotherapy

Acknowledgements

I'd like to thank my project supervisors, Dr. Ryan Lewis (Head of Radiotherapy Physics Services) for suggesting this investigation and Nicki Davies (Quality, Risk & Governance Lead Radiographer) for all her help in gathering the data and finding the answers to any question.

I'd also like to thank the Datix Radiotherapy Incident Report Team for all of their work investigating and submitting these reports to the NRLS, and both the Radiotherapy Department and Radiotherapy Physics Department for voluntarily reporting all of these incidents and helping to improve the safety of radiotherapy.

1. Summary

This analysis has been carried out on behalf of the Swansea Bay University Health Board (SBUHB) on radiotherapy errors (RTE) that were voluntarily reported by the provider. All reports submitted during the previous year (December 2019 – November 2020) were requested for this analysis; the year was offset by a month so that this report would be synchronised with the release of triannual reports from Public Health England (PHE).

The aim of this report is to demonstrate the ability to perform simple and repeatable analysis on the RTE reports submitted at SBUHB, following the methods and guidance outlined by the PHE through their various radiotherapy publications. This report has therefore been structured so that it may be used to easily cross-reference the reports published by PHE. By performing the same analyses as PHE it will enable the data reported by SBUHB to be benchmarked against the national data consistently, quickly, and over any period.

The data gathered in this report will be used to perform a data informed risk analysis, based on the RTEs reported at SBUHB. This risk analysis will investigate the risk of unintended or accidental exposures at SBUHB by using the analysis on the most frequent errors that occur.

2. Data

2.1. Source of Data

The data included in this report was sourced from two locations, Swansea Bay University Health Board (SBUHB) and Public Health England (PHE); both sets of data originate from the National Reporting and Learning System (NRLS). The SBUHB data was provided by the Radiotherapy Incident Report Team at the provider, who carry out the investigations on all radiotherapy errors (RTEs). The team were able to provide the reports submitted in the same format in which they had been submitted to the NRLS. The PHE data was scrubbed from the "triannual analyses" released by PHE during the year investigated (Public Health England, Safer Radiotherapy - Triannual RTE analysis and learning report (December 2019 to March 2020), 2020) (Public Health England, Safer Radiotherapy - Triannual RTE analysis and learning report (April to July 2020), 2020) (Public Health England, Safer Radiotherapy - Triannual RTE analysis and learning report (August to November 2020), 2020). This data originated from the voluntary reports submitted to the NRLS from radiotherapy providers across the UK, it has undergone consistency checking and analysis by PHE before it was published.

All reports obtained from SBUHB were fully anonymised before they were shared for analysis, there is no risk of patients being identified from the information contained in this report. SBUHB currently owns all the data it has shared for analysis, however the ownership of all NHS data in Wales is being transitioned to NHS Wales.

As the reports investigated in this analysis are all submitted on a voluntary basis, the data can only represent the incidents that were reported by the provider and does not necessarily represent the actual frequency of incidents at the provider. Any interpretations of the data in this analysis must follow this reasoning and be carefully considered.

The SBUHB data was contained within a Microsoft Excel spreadsheet, this data was then imported into IBM SPSS so that it may be analysed. As all the coding contained within the reports was within a text field, this had was transcribed by hand into variable fields; this process was double checked within SPSS and compared with Excel to ensure the accuracy of the data. The PHE data taken primarily from the triannual analyses performed between December 2019 – November 2020 were also stored within an Excel spreadsheet and imported to SPPS as required.

2.2. Case Studies

PHE regularly performs consistency checks on many of the reports submitted, to help ensure that it's analysis of the process codes is carried out with consistency on their usage. Unlike consistency checking performed by PHE, this report has not attempted to recode any of the reports submitted and was only looking for any inconsistencies present. Once the data had been transferred into SPSS a preliminary investigation for consistency was carried out; three cases were discovered where the coding was suspected to have been incorrectly applied. These are laid out in the case studies below.

2.2.1.

TSRT9 / Level 4 / 4a / 5a / 6b / 7f / 13cc / CF1c / CF1d / CF2c

An oncologist for an in-patient at the hospital completed an e-booking form late at night to request emergency radiotherapy treatment for the patient. The patient ID on the booking form was incorrect in both name and NHS number. This was remedied the next morning by the on-call SPR, who completed a new booking form with the correct details.

The patient was then booked in for a CT scan and treatment the following day, coming by non-emergency transport. However, the next morning a message was received that the patient was now too ill to transfer and in a lot of pain, so the CT scan was cancelled. Later that day the patient arrived unexpectedly via emergency transport and was sent for urgent radiological investigation due to severe pain. The patient was able to be scanned, however their medical history was unclear so they were not treated as this would first need to be established to correctly prescribe radiotherapy.

Later the patient was scheduled for 5 daily treatments as an in-patient at Singleton Hospital, but no provisions were made for their admission. Both the ward and surgical admissions unit were unaware of the patient resulting in a staff nurse having to stay late to administer any required medications. Staff were also making many phone calls as there were no available beds for the patient; as radiotherapy is an out-patient department, with appointments between 08:00 and 18:00 only, it would not be possible or safe for a patient to remain after hours if hospital admission was no possible.

Finally, the senior manager on-call for SBUHB was able to be contacted and the patient's admission was arranged to the medical admissions unit for 18:00.

An investigation of this RTE found the root cause to be failure to follow the correct procedures. While the e-booking form was initially completed incorrectly, this was remedied before the booking was cancelled due to the patient's health. However, upon emergency transport to Singleton Hospital no new e-booking was completed resulting in staff being unaware of the patient's arrival; this was in part due to a lack of communication between hospitals.

In response a training session was scheduled where this Datix report could be highlighted for a shared learning experience from error reporting. In addition, the correct procedure to exercise when completing an e-booking form for the radiotherapy referral pathway is now included in the training for new Specialist Registrars.

This RTE demonstrates the use of many pathway codes for a widespread incident over several days. Each of the pathway codes included are being utilised correctly, and the reason for each codes' usage is specified within the incident description; though the coding could be included within the description to clarify, on this occasion it is sufficiently clear. This is close to a perfectly coded RTE as outlined by PHE in Development of

Learning (DoL), with one exception (Public Health England, Development of learning from radiotherapy errors - Supplementary guidance series, 2016).

While the root cause was specified in the description of this event as a failure to adhere to protocol (which would fall under CF2c), the order of coding does not conform to that requested in DoL, where the root cause should be the first causative factor listed. By ensuring the investigations of these RTEs are finalised and coded correctly before submission, the subsequent analysis may be performed more efficiently and confidently. This could be done with the use of final QC checks of investigations before submission.

Additionally, this could be built into the spreadsheet so that codes are given separate fields, outside of the description, which could make the data analysis far quicker and standardised to pull straight from the source, with no need for transcribing.

2.2.2.

> **TSRT9 / Level 5 / 13i / 13cc / CF3a**
>
> An unforeseen breakdown of a LINAC Treatment Unit resulted in an inability to treat 16 patients. This caused a delay in the progression of all patients along the RT pathway until the machine had been repaired. No harm came from the delay, and all patients were treated as planned once the machine became operational.
>
> Upon investigation it was found the ionisation chamber was faulty and had to be repaired by electronics engineers. Following repairs, the treatment unit underwent QC checks by radiotherapy physics staff before it could return to clinical use. This particular LINAC is already on the risk register due to its age; additionally, it is no longer supported by the manufacturer.

This RTE is far less involved than the previous case, however it succinctly describes the incident that occurred. As a non-conformance due to equipment failures a less thorough write-up may be expected. Again, all codes are backed up by the event description, which provides conformation that the coding is correct or at least as intended, an important factor for PHE to consider in their analyses.

However, there is an issue with the coding in this case. While 13cc has been correctly applied for the management of unexpected errors, 13i has been used incorrectly as a code for equipment malfunction. According to PHE 13i is commonly used inappropriately in this context but should be used for carrying out on-set imaging against protocol only, the correct code for an equipment malfunction such as this would be 13z (Good practice in radiotherapy error and near miss reporting: On-set imaging, 2020).

2.2.3.

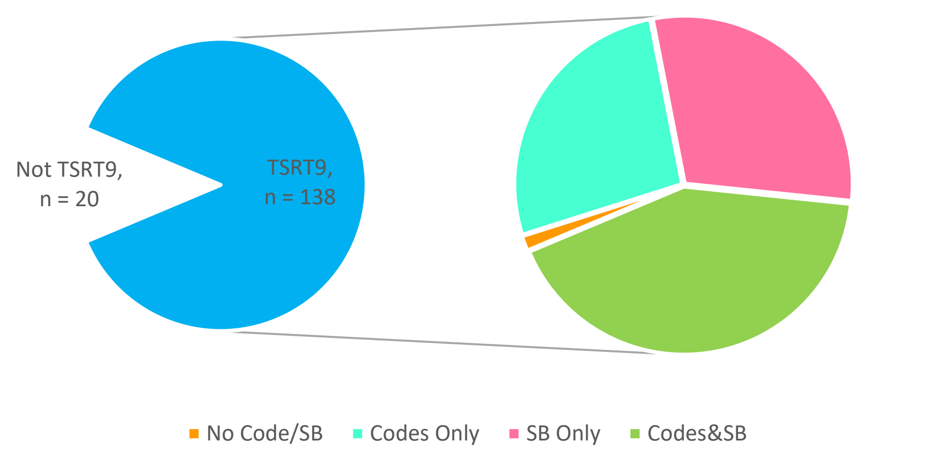
> **TSRT9 / Level 1 / CF7a**
>
> During a CT simulation scan it was noticed by radiographers that the bolus had slipped away from the surface of the patient's skin. The impact of this was queried with a consultant and the decision to arrange a re-scan for the patient was made. The bolus would need to be firmly attached to the skin surface to obtain images for an accurate treatment to be planned. The investigation of this incident found that no harm had come to the patient during this RTE, and no issues or failures by staff or procedures had occurred. Following this investigation further measures were put into place to avoid any re-occurrences of this incident.

As this was the sole Level 1 report submitted by SBUHB, it was a clear anomaly. Upon reading the report thoroughly it seemed clear that a mistake was made in reporting. A Level 1 report is reserved for reportable radiation incidents, which a repeat CT scan resulting in no harm to the staff or patient is not. This anomaly was questioned in a meeting with RT staff at the provider, who were able to confirm that this incident had been incorrectly coded as a Level 1 and was likely a Level 5. This was later confirmed via email.

However, as this report has made no other efforts in recoding anomalous reports, this RTE has been removed from further analysis. This decision was made for this miscoding but not the previous case study above on the basis that a) it was a confirmed error in reporting by the staff of SBUHB, and b) as the only Level 1 report it could be conveniently dropped from further analysis without significant effect on later figures.

2.3. Data Selection

Figure 1. Breakdown of coding included in each report



From data provided by SBUHB, there were 23,735 attendances by patients to the radiotherapy department at SBUHB between December 2019 to November 2020. The Datix reports submitted by RT staff at the provider were requested for this period. A total of 158 reports were submitted from SBUHB during this time, resulting in an error reporting rate of 7 per 1000 of all attendances for this period. This figure is on par with the national reporting rates seen by PHE.

When PHE pulls data for analysis from the NRLS it does so through use of a trigger code; patient safety incidents (PSI) that are not also RTEs are not investigated by the PHE as part of the RTE analysis. Of these 158 reports submitted by SBUHB, 87.3% (n = 138) were reported using the TSRT9 trigger code.

In this analysis only reports using the trigger code were investigated, as these contain the relevant level and pathway coding; whether they are solely PSIs or also RTEs, all 20 reports without the trigger code contain only descriptions of the incident and the following investigation. This report has made no attempts to recode or perform consistency checking on reports, so these will be left out of further analysis.

100% (n = 138) of TSRT9 reports submitted include the level (i.e. the severity of the incident and whether it is reportable as determined by TSRT) and the requested Causative Factor Taxonomy. The majority of reports using the trigger code included error coding at 98.6% (n = 136), with only one Level 4 report missing all coding as well as the incorrect Level 1 report seen in the case study. Of these coded reports 71.7% (n = 99) specified the safety barriers, and 68.8% (n = 95) included other RTE process subcodes.

Statistical analysis was performed across aspects of the data to verify the validity of reports. The SPSS software was used for this purpose as it allowed for a simple import of all the data from Excel (the format the data was received). The Chi-squared test was employed to analyse the multiple response sets in which the various codings had been stored.

3. Results

3.1. Levels

Figure 2. **Number of TSRT9 reports submitted per level** (n = 137)

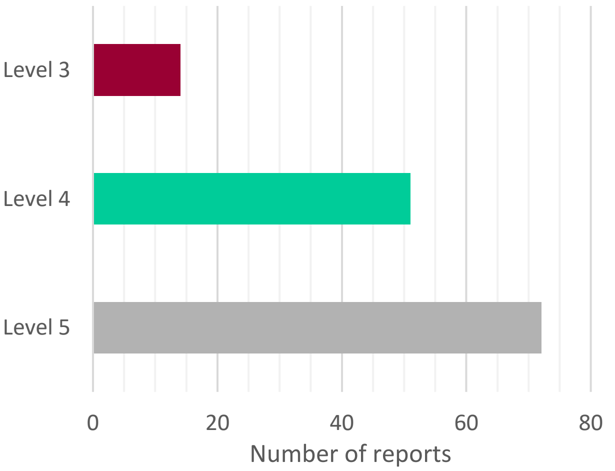
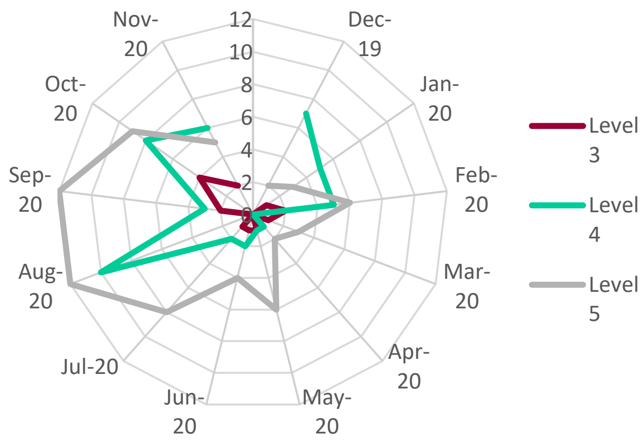


Figure 3. **Number of reports submitted each month per level** (n = 137)



Breaking down the TSRT9 reports by level, 89.8% (n = 123) were 'near misses' (Level 4) or 'other non-conformances' (Level 5). Of those remaining 10.2% (n = 14) were 'minor radiation incidents', there were no reportable (Level 1) or non-reportable (Level 2) radiation incidents reported during the period investigated (as discussed in the case study the level 1 incident reported was miscoded and will not be included in further analysis). This does not confirm that no high level incidents occurred, as it is possible some reports were re-coded by PHE during consistency checking, or at worst they were unreported.

However, within the same reporting period PHE reported that a total of 126 reportable and non-reportable radiation incidents had occurred nationally, a consistent ~20 of each per triannual analysis. With over 60 RT providers in the UK, and SBUHB being an average sized provider, it is likely that level 1 and 2 incidents would not be yearly occurrences at a provider of this size (Appendicies).

Inspectorate data shows that providers have a tendency to overestimate the severity of reports, between January 2018 and December 2019 15.7% (n = 47) of level 1 and 2 reports submitted by providers would be recoded as level 2 and 3 reports by the inspectorate (Public Health England, Safer Radiotherapy - Biennial radiotherapy error data analysis and learning report (January 2018 to December 2019), 2020). This is consistent with the findings by a PHE survey (Safer Radiotherapy Newsletter - January 2019, 2019) which indicated that high-level incidents (Levels 1 – 3) were more likely to be reported by providers than low-level incidents (though a higher volume of lower-level incidents (Levels 3 – 5) are expected to be reported according to the biennial report).

While the total number of reports submitted by this provider is on par with PHE estimates, there are a far greater number of 'near misses' and 'other non-conformances' reported than 'minor radiation incidents'. This is contrary to the findings of PHE, where 'minor radiation incidents' are usually the most numerous of reports.

In SPSS the report levels were cross-tabulated with the pathway processes specified in the reports. To successfully employ the Chi-squared test the empty unreported processes were removed from the tabulation. The prediction was that the level of each report would be dependent on the processes specified within it, significance between the variables was found ($p = 0.047$).

3.2. Triannual Periods

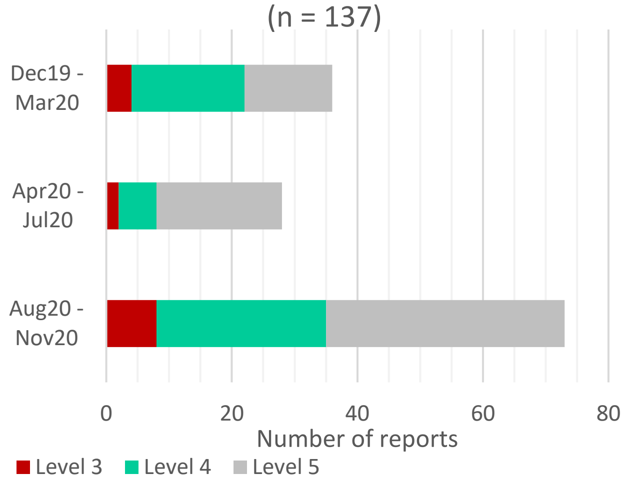


Figure 4. **Number of reports per triannual period, divided by level** (n = 137)

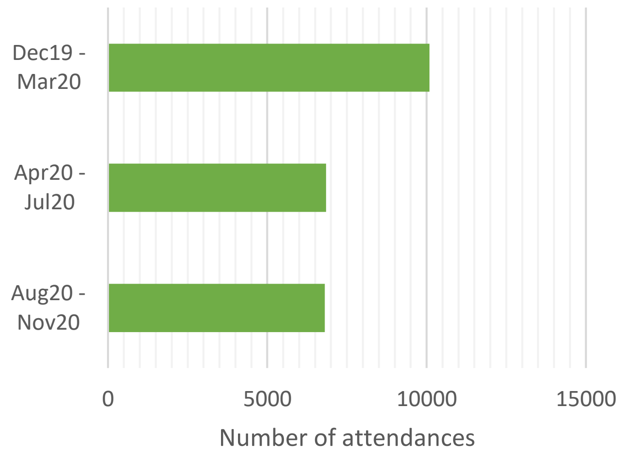


Figure 5. **Number of attendances per triannual period** (n = 23,735)

The number of attendances and the number of reports submitted by this this provider each month during the period investigated have been included to help understand the effect of COVID-19 on the service at this provider. Alongside a month-by-month breakdown of the reports submitted, the data has also been split into triannual periods which coincide with the dates of triannual analyses released by PHE. This has been done so that this data may be easily cross referenced with the national analyses of these time periods.

In future annual analyses by SBUHB a monthly breakdown may be unnecessary as it is too short a timeframe in which few reports are submitted; it may be more helpful to compare with previous years than over only a few months. However, given the circumstances of the pandemic and this reports' focus on the past year of data, it is a useful comparison to make.

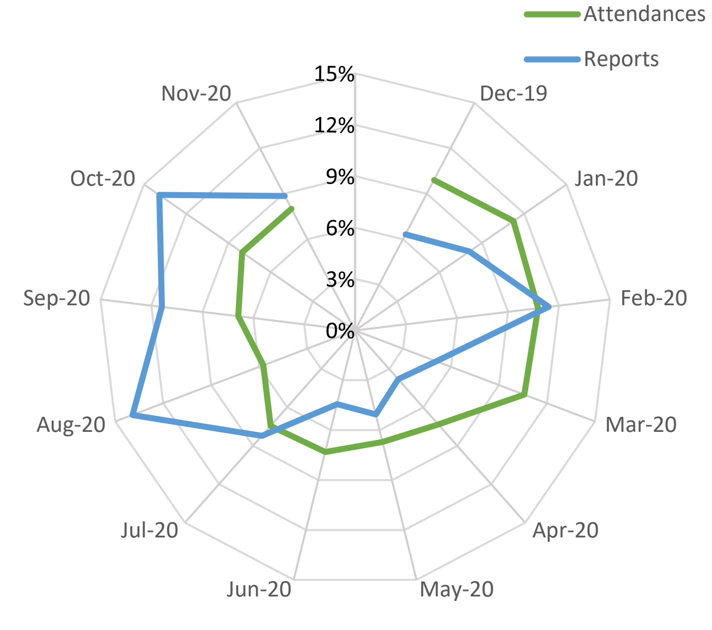
It is worth noting that the dates shown correspond to the date that the incident was reported and not the submission to the NRLS. The lag time between reporting and submission is dependent on the investigation of the incident and can vary dramatically. At SBUHB 41.1% (n = 65) of reports were submitted with a fortnight of the incident, 77.2% (n = 122) were submitted within a month of the incident. There were four instances where reports took over three months to be submitted, with the longest lag time of 109 days; it is likely that these reports would therefore not be included in the triannual analyses performed by PHE, as they are published approximately four months after the period they investigate. There was difficulty in confirming the exact delay in PHE's data gathering for their analyses; meaning the tri-annual analyses in this report may not perfectly align with those done by PHE.

In their biennial reports PHE have investigated the lag time between an incident and the submission of reports to the NRLS. They found a maximum lag time of over 1,200 days for some RT providers, and an average of 515 days overall.

The National Cancer Research Institute (NCRI) is carrying out a study on the impact of the Covid-19 pandemic on radiotherapy in the UK. According to them there has been "a substantial reduction in new cancer referrals" as well as “the pausing or cancelling of screening programmes” and “the omission, delay, and/or instances of patient refusal of radiotherapy” (UK wide COVID-19 radiotherapy initiative | COVID RT, 2020). These unfortunate knock-on effects have to be expected when social distancing and rigorous cleaning protocols are put into place, not only in RT departments, but in hospitals, GP surgeries, care homes and emergency services. Every step along a patients journey to treatment became increasingly difficult and time consuming.

In reviewing the national data between December 2019 – March 2020 PHE found that the pandemic had “no obvious impact on RTE trends for this reporting period” (Safer Radiotherapy e-Bulletin (June 2020), 2020). It was also noted that no RTE directly associated with Covid 19 had been identified. The period that PHE are investigating here is likely before the full effect of the pandemic was being felt in RT, with patients already awaiting/completing treatments, the decrease in referrals found by NCRI had not yet impacted the departments.

Figure 6. **Percentage of total attedances/reports each month**



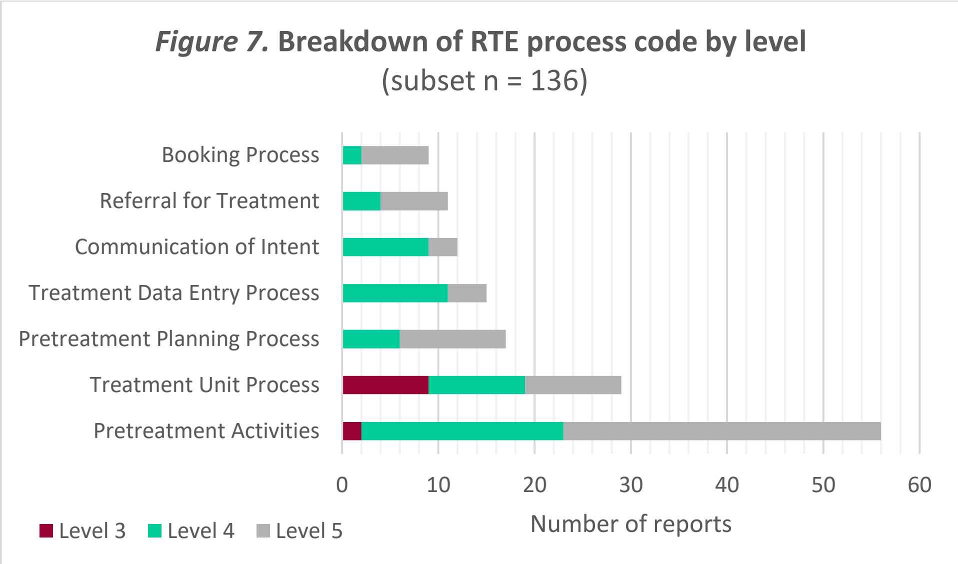
As can be seen above the productivity of submitting reports was already low at the beginning of the year, with the number of RTEs reported at less than 4 per 1000 attendances, before the initial 2020 lockdowns were introduced across the UK. By looking at the attendance over the year it is clear that a drop in the number of attendances doesn’t occur until April, which does coincide with the initial onset of lockdowns in the UK, there is also a more significant drop in the number of reports submitted in the following months.

A radial diagram included below demonstrates how the two sets of data appear to follow quite different trends. While the number of attendances throughout the year certainly decreases once the lockdowns are implemented, it undergoes a smoother transition than is seen in the reporting, before beginning to recover later in the year. However, the number of reports submitted drastically drops after February, before lockdowns are introduced, and remains low until August; where the reporting reached a high of 16 reports per 1000 attendances, while the number of attendances was at its lowest.

While this data may seem in disagreement it is worth noting that the highest number of reports submitted within a month was 22, where there were at most 2670 attendances; this disparity could explain the sudden shifts seen in reports as it is a far sparser data set.

SPSS was used to cross-tabulate the pathway processes specified in the reports with the "triannual period" defined. In order to successfully employ the Chi-squared test the empty processes were again removed from the tabulation. The prediction was that the processes specified in each report should not be significantly related with when the report was submitted, though the validity of this prediction was unknown. The test found there was no significance between the variables (p = 0.251).

3.3. Process Codes



All RTE coding on the reports were combined into each process along the RT pathway according to DoL, so that the areas of work with the greatest error could be found. Reports that span multiple subcodes of the RT pathway processes were combined into each process and contribute toward each. As can be seen in *figure 7* the majority of RTEs reported were associated with 'pretreatment activities' with 40.8% (n = 56) of reports having cited codes from that process.

Reports were spread over 14 of the 21 process codes, only the 7 most frequently reported processes were included above. The processes where an RTE was not reported to have occurred were Infrastructure, New Equipment, ~~Brachytherapy~~, End of Treatment Process, Follow Up Process, Document Management and Staff Management (Brachytherapy is not a treatment provided at SBUHB and therefore not of concern).

As is clear above 'pretreatment activities' contains the majority of level 4 and level 5 reports, with most level 3 reports instead occurring within the 'treatment unit process'. The 'treatment unit process' was associated with 21.2% (n = 29) of all reports.

3.4. Process Subcodes

Figure 8. **Breakdown of most frequently reported RTE process subcodes by level** (subset n = 136)

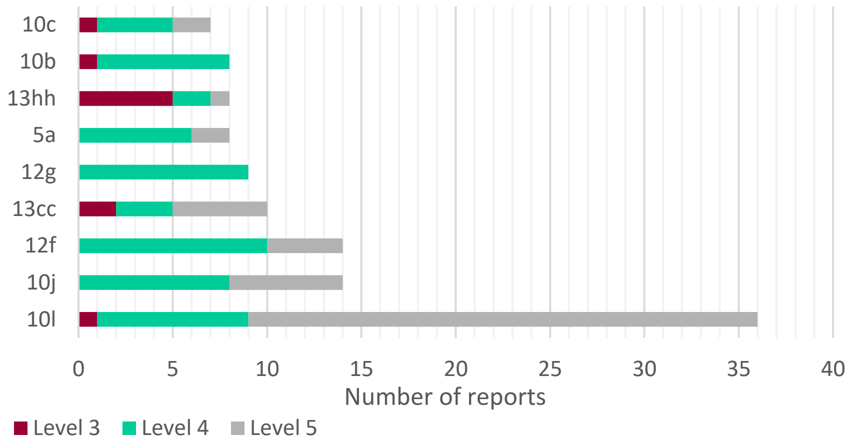
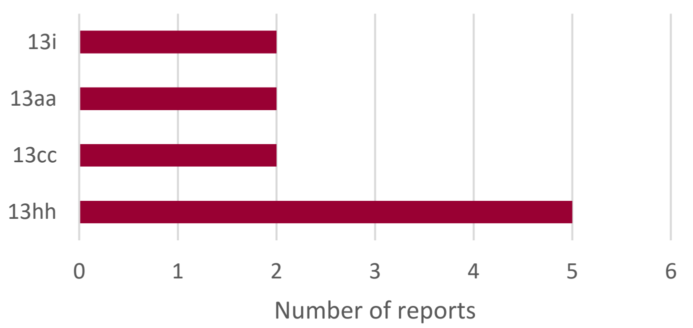


Figure 8 contains the most frequently reported RTE process sub-codes as contained in reports, these subcodes also contain the safety barriers coded into each report. By far the most common subcode reported was 10l 'End of process checks' as part of the 'pretreatment activities' process, which was included in 26.3% (n = 36) of all reports. Of this subset of data 75% (n = 27) of reports were categorised as 'other non-conformances' (level 5), with 22.2% (n = 8) being 'near misses' (level 4) and only a single 'minor radiation incident' (level 3) using this code.

The next most populous subcode is shared by 10j 'Documentation of instructions/information' and 12f 'Accuracy of data entry', subcodes of the processes 'pretreatment activities' and 'treatment data entry' respectively. Each of these codes were included in 10.2% (n = 14) of all reports and were more frequently used for 'near misses' over 'other non-conformances'. Neither of these subcodes were employed by 'minor radiation incident' reports.

Level 3 – Minor Radiation Incidents

Figure 9. **Most frequently reported codes on level 3 reports** (subset n = 14)



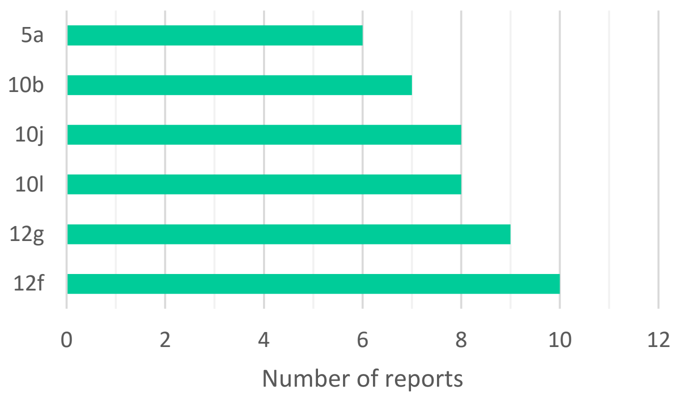
Breaking down the subcodes of level 3 reports only, it is shown in figure that the most frequently used subcodes (n > 2) were all within the 'treatment unit process' of the RT pathway. Of these 13hh 'End of process checks' was most commonly used, appearing on 35.7% (n = 5 / 14) of all Level 3 reports.

All the above codes are routinely amongst the most commonly reported nationally, especially for higher level instances though they are used in reports of all levels. However, 13hh is reported the least nationally, more often used as a secondary safety barrier (Public Health England, Safer Radiotherapy - Biennial radiotherapy error data analysis and learning report (January 2018 to December 2019), 2020). The most frequently used code for Level 3 reports in the national data is 13z 'On-set imaging: production process', which was not used by SBUHB in this reporting period.

A further 14 subcodes were used only once within all level 3 reports, with five of these also belonging to the 'treatment unit process'.

Level 4 - Near Misses

Figure 10. **Most frequently reported codes on level 4 reports** (subset n = 50)



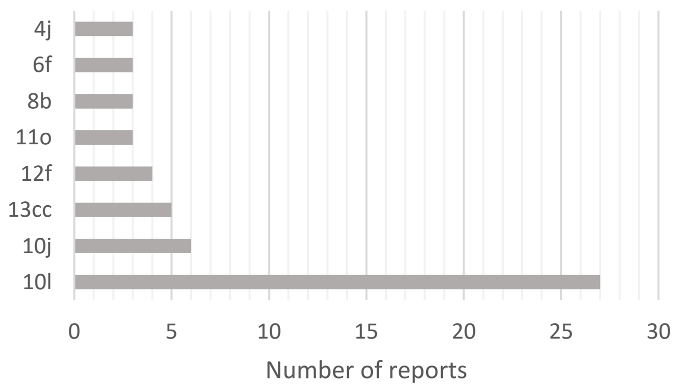
Level 4 reports are the most normally distributed between different subcodes. While 42.0% of level 4 reports are attributed to Pretreatment Activities (n = 21), the most frequent subcodes are 12f 'Accuracy of data entry' and 12g 'End of process checks', though only 22% (n = 11) of reports are attributed to the 'treatment data entry process'. These two subcodes are the most common pairing of codes found in this data, with 12f and 12g being used together on 18% (n = 9) of level 4 reports. Additionally, 12g was reported exclusively with 'near-misses' during this period, making these nine pairings its only occurrences.

Similarly, 10j 'Documentation of instructions/information' and 10l 'End of process checks' are the second most frequent pairing in this analysis; however, they are split across levels 4 and 5, with four shared instances each (8% (n = 4 / 50) and 6% (n = 4 / 72) respectively).

Level 4 reports use 45 process subcodes over 50 reports.

Level 5 – Other Non-Conformances

Figure 11. **Most frequently reported codes on level 5 reports** (subset n = 72)



The Level 5 codes are also well distributed between different codes and processes along the RT pathway. Yet there is a clear abundance of the code 10l 'End of process checks', with 37.5% (n = 27) of reports having used it. For a large number of reports this is a potentially concerning statistic.

10l is specified along with other codes in 37.0% (n = 10 / 27) of its occurrences, and most frequently with 10j in 14.8% (n = 4 / 27) of reports, however in 92.6% (n = 25 / 27) reports it is the only safety barrier quoted.

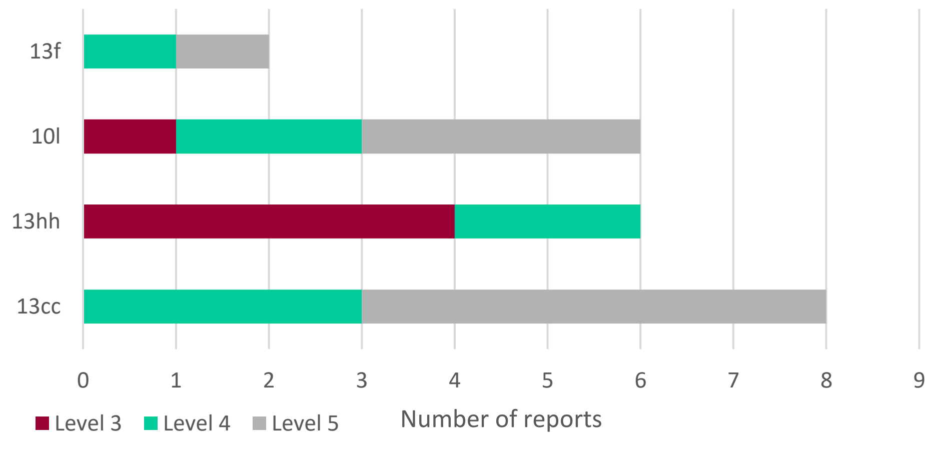
Level 5 reports use 52 process subcodes across 72 reports.

3.5. Safety Barriers

Safety barriers are included as part of the RTE pathway coding, they are specified as safety barriers within the codes. When PHE perform consistency checking they discern from each report which safety barriers were included, which ones failed, and which were effective at catching an error. This process is heavily dependent on the descriptions and investigation outcomes provided by the RTE staff that submit their reports. For this analysis each report was carefully read over, and the effective/failed safety barriers noted, this was then repeated without checking the initial run. This was done to ensure consistency in the understanding of the report, for any reports where failed/effective SBs were in disagreement the entire process was repeated. This section of the analysis is dependent on the understanding of the RT pathway and subjective understanding of submitted reports.

Effective Safety Barriers

Figure 12. **Breakdown of effective safety barriers by level** (subset n = 22 / 32)



The safety barrier subcodes within the ‘treatment unit process’ appear to be the most effective in catching any errors; as previously indicated this is largely the last opportunity in which errors may be discovered. The most frequent effective safety barrier was 13cc ‘Management of variations/unexpected events/errors’, which was the effective safety barrier in 25% (n = 8 / 32) of reports that specified effective barriers, but 8.1% (n = 8 / 99) of all reports that included safety barriers.

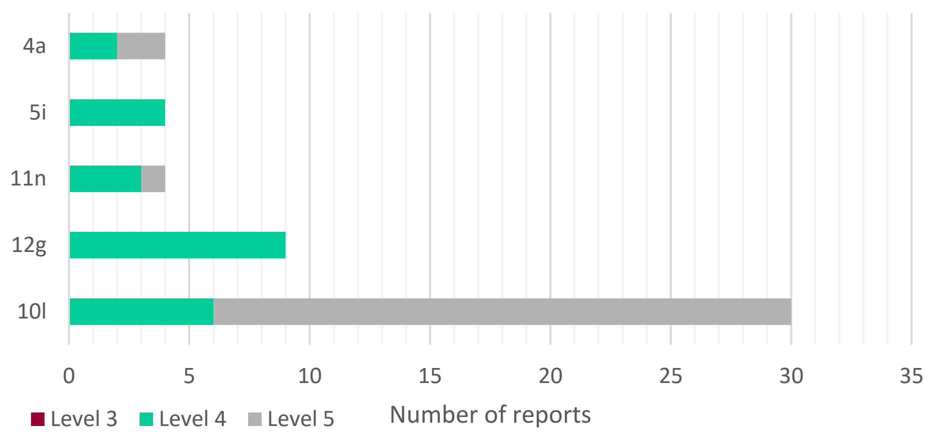
‘End of process checks’ subcodes for two processes appear within the four most frequent effective safety barriers, 13hh and 10l, which belong to the processes ‘pretreatment activities’ and ‘treatment unit process’ respectively. 13hh and 10l share an equal number of instances with each an effective safety barrier in 19% (n = 6 / 32) of reports that specified effective barriers, 6.1% (n = 6 / 99) of all reports that included safety barriers. As ‘end of process checks’ is the final opportunity for an error to be discovered before it progresses through the pathway, the primary goal of these safety barriers is to catch any error that may progress to the next process.

As all errors reported are identified at some point within the pathway, it would be beneficial to see more effective safety barriers clarified within reports. PHE has found the same trend nationally, where the failed safety barriers are reported more often than those which were effective.

With six level 3 reports containing effective safety barriers, there is a marginal increase in the percentage of level 3 reports included over other breakdowns in this report, which may suggest that level 3 reports are more likely to specify the safety barriers than those of less severe incidents.

Failed Safety Barriers

Figure 13. **Breakdown of failed safety barriers by level**
(subset n = 51 / 74)



There are almost twice as many reports containing failed safety barriers than there are for effective safety barriers, however almost half of these reports (43%, n = 30) are attributed to the code 10l “End of process checks” for ‘pretreatment activities’. This is reported to be the failed safety barrier significantly more than any other code, with the following four most frequent codes each making up 6% (n = 4) of failed barriers. Of the 10l reports 80% (n = 24) are level 5 non-conformances. As there are only 36 reports in total that contain the code 10l, then it is the FSB in 83.3% of its occurrences.

The failed safety barriers associated with level 3 reports are not any of the most frequently reported failed safety barriers. The most frequently reported FSBs contain no level 3 incidences which may indicate that they are less prone to causing serious RTE.

10l is overwhelmingly the FSB most frequently reported for level 5 RTEs, accounting for 61.5% (n = 24) of FSBs.

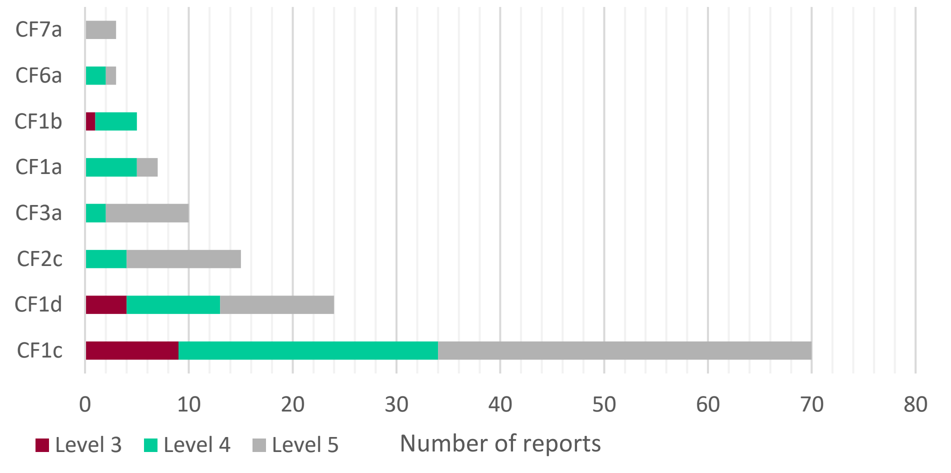
3.6. Causative Factors

Root Cause

Causative Factors reported are broken into two groups, the root cause, and contributory factors. The frequency with which root causes were reported appears to overwhelmingly agree with the national averages, with the top 3 reported factors being in the same order for this institution, and additionally in similar ratio. The two most frequently reported root causes, CF1c and CF1d, are the most frequently reported for both each level individually and overall. This holds true for the most reported contributory factor too, CF2c. This is believable as the CFs are not as specific as the error coding, the broader cause of the incident is more likely to fall into a pattern.

Only 8 of the 24 causative factors were cited as the root cause across all reports, these are all included in the root causes table below. A total of 15 causative factors were included as contributory factors.

Figure 14. **Root Cause frequency in reports by level** (subset n = 137)



The most frequent root cause is CF1c ‘Slips and lapses’ which is cited as the primary causative factor in 51.1% (n = 70) of reports. This is the primary root cause cited for incidents of all levels. In both level 4 and 5 reports there appears a particularly large usage of this code, with it used at approximately three times the frequency of any other code. This pattern is not observed nationally where the most frequently reported RC codes share similar levels of usage.

The second most frequent RC for all Levels observed is CF1d ‘Communication’, which has been used in 17.5% (n = 24) of reports. This is also one of the most frequently reported RCs in the national findings

In level 4 incidents the root cause is primarily within the CF1 category, which concurs with the national findings. A broader range of causative factors are cited in these instances.

Figure 15. **RC of RTE in pretreatment activities process by level** (subset n = 56)

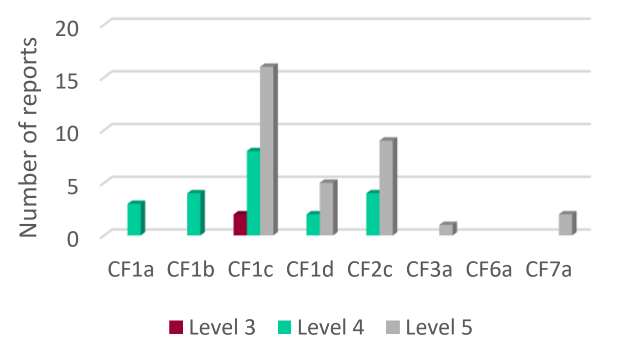
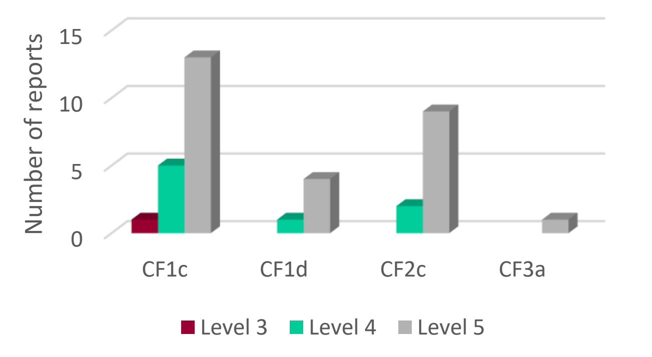
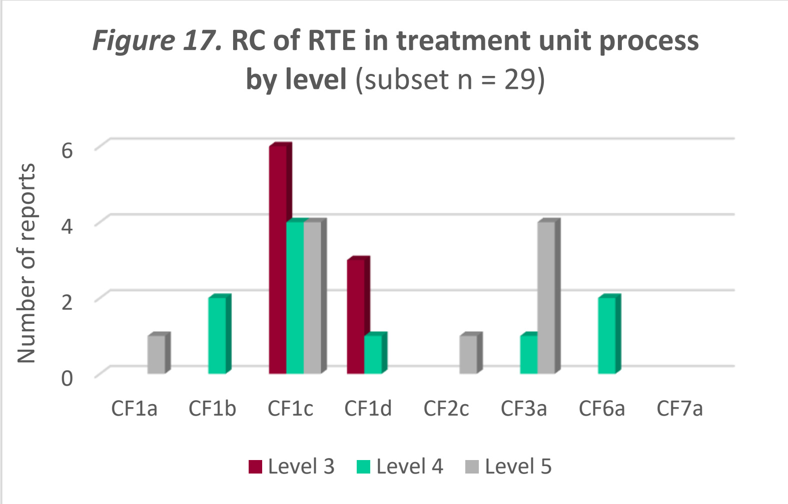


Figure 16. **RC of subcode 10l "End of Process Checks" by level** (subset n = 36)

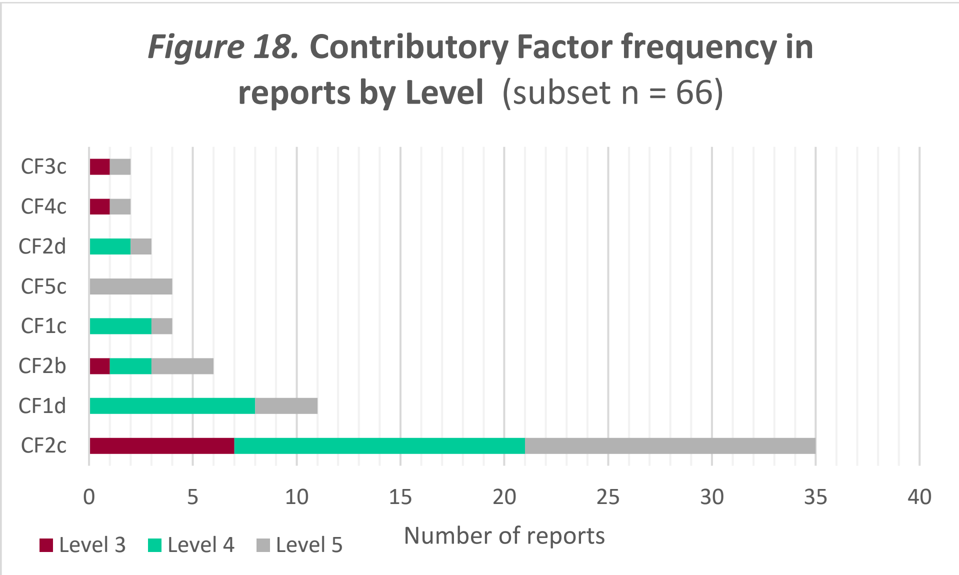


The root causes have been separated here into the most frequent pathway processes; ‘pretreatment activities’ and ‘treatment unit process’. The most frequent subcode 10l ‘End of process checks’ has also been broken down by root causes. It can be observed through this that almost all reports in the ‘pretreatment activities’ process that have specified the root cause CF1c contain the subcode 10l (n = 19), therefor slips and lapses are responsible for over half of the incidents that included 10l in the report.

The causative factor CF3a is used far more often in the ‘treatment unit process’ than in ‘pretreatment activities’, which suggests that IT failures are a far more common occurrence on treatment units than they are on CT scanners.



Contributory Factors



Contributory factors are used to define any additional causes that led to an incident, but which are not the root cause. As with the primary RTE coding as many contributory factors as needed may be attributed to each RTE, though in practice only 48% of reports contained multiple CFs.

The most frequently included CF was CF2c "Adherence to procedures/protocols" (54%, n = 35), which is reported slightly more often than it has been nationally where it rose to 45.8% in 2019 having increased from 35.1% in 2017 (Public Health England, Safer Radiotherapy - Biennial radiotherapy error data analysis and learning report (January 2018 to December 2019), 2020). It would appear the reporting here is consistent with that nationally, where the frequency of this CF is increasing yearly. The reasoning behind this could be linked to the increasing complexity of RT procedures, where adherence to procedures is increasingly important. Or it's possible that the addition of safety barriers and other protocols along the RT pathway results in the observation of more slips and lapses.

In the national findings CF1c and CF1d are reported as contributory factors in relatively equal amounts every year, however CF1d appears a more prevalent CF in SBUHB data.

4. Risk Analysis

The primary aim of performing a risk analysis in this report is to remain IR(ME)R compliant by performing an analysis into the risk of unintended or accidental exposures, as is now required as of IR(ME)R 2017 (Ionising Radiation (Medical Exposure) Regulations, 2017).

The severity of an event has been defined in the table below. This table has been informed by the guidance materials. Despite the suggestions put forward in the guidance materials, this investigation will not take any financial risks for the organization into account.

It would be unwise to solely define the severity of an incident by the events that have previously occurred, therefore the severity of an error has been determined through a combination of the levels of previous RTEs and the harm they caused, along with how far they progressed through the pathway where available and their potential to become a 'reportable radiation incident' (level 1).

SEVERITY				
Risk Score	Severity	Staff Impact	Organization Impact	Patient Impact
1	No Harm	No injury Harm prevented	No risk to organization	No issues for patients
2	Low	Minor injury	Minimal risk to organization	Minor injury Minor correction to treatment
3	Moderate	Injury causing temporary incapacity Additional treatment needed	Moderate risk to organization Minor breach of patient confidentiality Potential for adverse publicity	Injury causing temporary incapacity Additional treatment needed Litigation possible Breach of legal or authoritative guidance
4	Severe	Injury causing permanent incapacity Injury requiring major intervention or ITU admission SUI (Serious Untoward Incident)	High risk to organization Service restriction/closure Severe breach of patient confidentiality Probable adverse publicity	Injury causing permanent incapacity Injury requiring major intervention or ITU admission SI (Serious Incident) Litigation expected / Prosecution risk
5	Catastrophic	Incident causing death SUI	Extreme risk to organisation Major disruption to service Major breach of patient confidentiality Significant adverse publicity	Incident causing death SI Prosecution risk

The likelihood of an RTE was estimated from the SBUHB data only, i.e. the likelihood of events occurring is taken solely from whether that event was reported within the past year. As this report focuses on only a year of data, no events have been given a likelihood score of 1. This may incur an over exaggeration of risk to the provider, but that is preferable to an ill-informed simplification. In further annual reports performed within the provider, a more robust risk analysis may be carried out based on the data of many years of service.

LIKELIHOOD		
Likelihood Score	Chance of occurring	Description
1	Rare	Very good control Almost no occurrence
2	Unlikely	Good control ~ 1 a year
3	Likely	Limited effective control ~1 in 6 months
4	Somewhat likely	Weak control ~1 in 2 months
5	Very likely	No effective control >1 a month

The final risk scores as suggested by the guidance material should be calculated for both the initial risk and also following mitigation. This report was not intended to suggest specific alterations to the systems in place, only to highlight the possible areas of failure within those systems. Consequently, no attempt has been made to suggest mitigation or to calculate an improved risk score.

The types of risk below are those suggested by the IR(ME)R Guidance, with the addition of 'documentation errors' and 'treatment process errors', which were discovered to be necessary additions to categorise some RTEs (Institute of Physics and Engineering in Medicine, Society and College of Radiographers, & Royal College of Radiologists, 2020). The areas of risks were determined by evaluating the reports submitted and grouping them into repeat RTEs.

a) Positional and Geographic errors

Area of risk by coding	Consequence	Likelihood	Risk Score
Incorrect set-up guidance	3	4	12
Plan movements missing or incorrect	2	5	10
Mould inaccuracies	2	3	6
Set-up procedure followed incorrectly	3	3	9

There were several reports detailing discrepancies between the patient set-up sheet and the laser level / tattoo locations / the patient (n = 8). These cases mainly occurred within 'pretreatment activities' or the 'treatment data entry process' and were discovered before propagating into the 'treatment unit process'. However, there were exceptions where RT staff continued with treatment as per protocol as the set-up sheet was unclear. This could lead to a patient receiving a significant dose in the wrong location, though no harm came from any of these instances.

The most numerous areas of risk is the movements included in the Mosaiq plan were either missing or incorrect (n = 11). This often resulted in an impossible position for the treatment couch. There were no cases of harm to the patient or RT staff, and these errors were quickly noticed and often solved while the patient waited. They do appear to happen on a monthly basis.

Mould inaccuracies refers to RTEs where the mould was not able to be correctly positioned due to the restrictions of the machine itself (n = 2). These are minor errors that can potentially delay a patient's progression significantly.

Incorrectly following the set-up procedure has the potential to be as damaging as incorrect guidance, there were only two reported incidents of this. Both RTEs reported were reported to have the RC 'CF1d – Communication' as the set-up guidance in both cases was unclear on off-protocol procedures being carried out. Steps have already been taken and stickers implemented to make the documentation clearer.

b) Target volume errors

Area of risk by coding	Consequence	Likelihood	Risk Score
Scan length too short for planning	2	4	8
PTV not localised correctly	3	3	9
Treatment field passes through couch	2	2	4

A repeat RTE for CT is the scan length being too short for planning (n = 6), where the scans were mostly carried out as instructed. This can result in a secondary scan being necessary, this shouldn't have much impact on the patient, but they are being subjected to additional and unnecessary radiation. As with treatment any off-protocol scans should be clearly marked and flagged on booking forms.

The repeat issue with PTV (Planning Target Volume) localisation was that it had not been grown properly as to protocol, resulting in a PTV that was too small (n = 3). These occurred within the 'treatment planning process' and were quickly discovered before any treatment was carried out. However, should an RTE have propagated all the way through to the 'treatment unit process' then a far more serious incident may have occurred, as an incorrectly localised PTV could have significant effects on the rest of planning and the dose administered.

The treatment field passing through couch (n = 3) was a repeat error in a short timeframe, so its likelihood has been reduced. This was repeatedly due to a thorax board of index 0 causing the field to pass through the metal insert of the couch. Though no harm came from these errors had the error not been discovered the dose received by the patient would have been affected.

c) Equipment related errors

Area of risk by coding	Consequence	Likelihood	Risk Score
Machine breakdown due to environmental effects	2	3	6
Faults likely due to age of machine	2	3	6
Other unforeseen equipment faults	1	4	4
No daily QA performed on treatment unit	4	2	8

There were many RTEs reporting breakdowns of treatment units (n = 5) during the year, due to environmental effects such as water leaks or power cuts. These are largely unavoidable errors and very much dependent on the location and structure of RT provider. The RTEs appear contained to a few weeks of power cuts occurring repeatedly and a single water leak which effected several treatment units. The water leak took one LINAC out of use for several weeks which has a great impact on delaying patients and their progression trough the pathway. If these were continuous issues it would be advisable to take steps to improve the infrastructure and mitigate the problem.

Faults due to the age of machines (n = 3) may be similarly unavoidable but repeat errors should be taken seriously by hospital management and possibility of newer replacement machines investigated. While no faults caused direct harm to a patient, one RTE did take the affected CT planner offline for several days which caused delays to patients across South Wales.

There were many other unforeseen faults with treatment or scanning equipment, which do not fit into the other categories (n = 6). These include computer glitches and equipment breakages, which caused no direct harm to patients but were responsible for minor delays as staff tried to solve the problem. Incidents such as these cannot be predicted, however awareness of these errors can lead to quicker resolutions as staff can focus on the solution instead of trying to diagnose the problem.

There was a single report detailing that no daily QA had been performed on a treatment unit, this was discovered after a patient had received their treatment. It was discovered after treatment that QA had not been performed on the 4MeV electron beam, which was used for treatment, this QA hadn't been performed for two days when the patient had been treated on both. This is an especially risky RTE when treatments continue to be carried out on the machine. Once the QA was carried out it was found that all parameters were within tolerance levels and that no harm had come to the patient. This RTE should have been discovered on the first day of treatment, ideally before treatment commenced, it was however allowed to propagate along until after the patient received a second dose. It would be advisable for RT staff to perform a check of whether daily QAs have been completed before commencing treatment.

d) Incorrect referral

Area of risk by coding	Consequence	Likelihood	Risk Score
Incorrect patient information on booking form	2	3	6
Incorrect treatment request on booking	3	3	9
Lack of communication with booking	2	4	8

Mistakes with patient referral were found to be quite common at SBUHB. Incorrect patient information (n = 4) is usually quite harmless as many SBs are in place to catch this over the RT pathway, and the incorrect patient is very unlikely to receive treatment. However, this can cause delays for patients awaiting treatment, and cause stress or confusion to patients/families that are mistakenly contacted in regards to another patient.

A booking request by a clinician for the incorrect treatment could have significant outcomes on the patients' health and wellbeing. These errors (n = 4) have a combination of the root causes CF1c 'Slips and lapses' and CF1d 'Communication', with the clinician often being unclear or contradictory on the booking request form. Some treatments were carried out not as intended by the clinician, which thankfully on these occasions led to no serious harm, with one patient receiving the correct overall dose in fewer fractions. At best RTEs of this nature can cause patient delays if discovered during the treatment planning process, causing a new plan to be developed.

There were many cases where an in-patient at Singleton Hospital or another local hospital was booked in for RT without any communication (n = 7). This can cause a wide range of issues for the patient stemming from no available beds to no available staff. There were multiple cases where a patient was transferred while the CT scanner was under maintenance. Lack of communication therefore leads to unnecessary complications such as staff staying behind, additional workload in identifying patient, or a waste of time for patient. These events cause no significant harm but are a large waste of time and energy for all involved, they were also common occurrences. The importance of communication should be stressed to all staff.

e) Documentation Slips

Area of risk by coding	Consequence	Likelihood	Risk Score
Incorrect QCL completed or completed incorrectly	2	4	8
QCL not completed/exported	2	4	8
Wrong name, DOB or NHS ID	2	4	8
Wrong consent form	3	3	9

Completing the wrong QCL or incorrectly completing a QCL (n = 7) may have a variety of impacts on the patient's progression along the radiotherapy pathway. The most common process where QCL errors occur is 'pretreatment activities', and most of these are picked up during 'pretreatment planning process'. The fact that these slips are so commonly reported here, without mention in RTEs further along the radiotherapy pathway would suggest that the safety barriers in place within the 'pretreatment planning process' are sufficient to catch the few errors that slip through previous barriers. With the relatively low frequency of reports this does not seem a cause for concern.

Incomplete QCLs or QCLs that do not get exported (n = 9) have a more significant impact on the patients progression along the radiotherapy pathway. In three reported incidents the patient was missed and therefor did not progress along the pathway for over 10 days. These events did not result in any harm to these patients and their treatments were planned as prescribed following the delay. This is a point of concern however, as delays in beginning treatment could result in long term health effects for the patient.

On many occasions documentation progresses through the pathway with incorrect details (n = 8). There are several instances reported for each of the following; incorrect name, incorrect date of birth, incorrect NHS number. These details are often mixed up (i.e. surname and given name reversed) and often belong to another patient. There appears to be no clear process where these errors are made or discovered. While it is beneficial for staff to be reminded of the importance of these steps, it is also clear that slips and lapses will occasionally occur. These reports had no significant impact on the patients effected. An effort to reduce the transcribing of data could prove beneficial in reducing the number of these errors, however without efficient safety barriers an initial error will still progress through the pathway.

The uploading of an incorrect consent form (n = 4) could have a more significant impact if the patient in question has not signed a consent form themselves. It is imperative that consent for treatment is received from the patient prior to treatment commencing, and had these mistakes not been discovered early in the pathway then a larger incident could have occurred.

f) Treatment process errors

Area of risk by coding	Consequence	Likelihood	Risk Score
Delay in treatment due to communication (x6)	2	4	8
Incorrect dose in plan (x2)	3	3	9
Incorrect treatment procedures carried out (x6)	4	4	16
Treatment equipment not used (x2)	4	3	12

A delay in the patients' treatment once it has commenced has the potential to be very impactful on the treatment plan (n = 6). Most delays caused to patient treatment were due to either a lack of communication between departments and staff, or a lack of understanding of the importance of regimen to the radiotherapy pathway. Of the six reports, two belonged to one patient who saw an 11-day gap in treatment due to unexpectedly receiving dialysis before being discharged, where the other four patients were delayed for shorter periods.

An incorrect dose calculation in the treatment plan (n = 2) could cause significant detriment to the patient, however both errors were spotted before treatment commenced. One of these was detected by the treatment unit which could not deliver >1000MU in a single field.

RT staff on occasion have carried out the incorrect treatment procedures (n = 6) or carried out a procedure without the required equipment (n = 2) such as a bolus. These were often minor errors to the treatment procedure, such as failing to remove patient jewellery, which should not cause any significant harm to the patient. However, on several occasions on-treatment checks and scans were missed over several fractions of a patient's treatment. While no harm came from these instances it is essential that checks are performed over the course of treatment so that the patient's health, size of tumour etc. may be closely monitored.

5. Discussion

5.1. Breakdown of Levels

The quantity of reports of each level observed at this provider would suggest it is opposing the reporting culture evidenced in the PHE survey (Safer Radiotherapy Newsletter - January 2019, 2019). As seen in section 3.1. there are a far greater number of low-level incidents reported by SBUHB than those of greater severity. It is possible that the more serious incidents are either unreported or underestimated in the investigations carried out at SBUHB. However, no evidence of this was observed in the case studies or data analysis

Given the number of reports to cite various 'End process checks' as a SB, which are more often used on low-level reports, it is unlikely that these are more severe events. It is likely that only a few 'minor radiation incidents' (level 3) occurred at this provider, however a strong reporting culture leads to many more level 4 and 5 reports than the national average.

5.2. Breakdown over time

As can be seen in section 3.2. that the productivity of submitting reports was already low at the beginning of the year, with the number of RTEs reported at less than 4 per 1000 attendances, before the initial 2020 lockdowns were introduced across the UK. With many patients admitted for coronavirus over the winter holiday the NHS was already under pressure at this time. It seems reasonable that the department was overworked and finalising fewer reports at this time. By looking at the attendance over the same period it is clear that a drop in the number of attendances doesn't occur until April, which coincides with the initial onset of lockdowns in the UK, there is also a more significant drop in the number of reports submitted in the following months.

A radial diagram included demonstrates the divergence between reports and attendances throughout the year. The number of attendances certainly decreases once the lockdowns are implemented, but undergoes a smoother transition before beginning to recover later in the year. This is reasonable as a crucial service such as RT cannot simply cease all ongoing treatment, even if social distancing guidelines and other safety measures must be followed; this would explain why PHE had seen "no obvious impact" at the beginning of the year (Safer Radiotherapy e-Bulletin (June 2020), 2020). Over time the number of referrals would be expected to decline as less people are attending doctors' appointments, as described by NCRI (UK wide COVID-19 radiotherapy initiative | COVID RT, 2020).

However, the number of reports submitted drastically drops after February, before lockdowns are introduced, and remains low until August, where through the end summer the number of reports submitted doubles. While this data may seem in disagreement it is worth noting that the highest number of reports submitted within a month was 22, where there were at most 2670 attendances.

It would appear that during the first half of 2020 when the pandemic was at it's potential worst, the consistency in reporting within SBUHB understandably began to suffer. In what was possibly an attempt to reverse this trend the reporting over summer reached a high of 16 reports per 1000 attendances in August, while the number of attendances was at it's lowest. This may help explain the prevalence of 'near misses' and 'other non-conformances' reported in the final triannual period.

5.3. Breakdown of process codes

The frequency of the Treatment Unit Process within Level 3 reports agrees with findings by PHE, where this process contains the majority of all higher-level reports, but especially ‘minor radiation incidents’ as they are far more numerous. This is likely because this is the final opportunity for errors to be spotted and hopefully corrected before treatment is completed. This may indicate that would be level 3 errors are noticed and corrected earlier within the RT pathway, leading to less severe incidents reported at SBUHB.

The prevalence of ‘pretreatment activities’ cited among reports is to be expected given the lower than expected use of ‘treatment unit process’. This process is commonly the most frequent among lower-level reports in PHE findings. Many of the reports using these subcodes are the result of ‘slips and lapses’ regarding documentation, such as the completion of QCLs; the greatest cause for concern among these reports is the delay in patient propagation along the pathway.

5.4. Breakdown of subcodes and safety barriers

In the national data the most prevalent code reported with level 3 incidents is 13z ‘On-set imaging: production process’, which did not appear at all within the SBUHB data. As noted in the case study, at least one report was potentially miscoded as 13i instead of 13z, a common mistake found by PHE in the reports submitted. There were four reports using the code 13i submitted by SBUHB, two of which were also ‘minor radiation incidents’. This would explain the absence of this commonly used code.

The code used most frequently by SBUHB on level 3 reports was 13hh ‘End of process checks’ (n = 5), with 80% of these occurrences it was the effective safety barrier. Its use as a FSB was restricted to the health and safety of staff and the patient was not at any risk. This code also features significantly as an ESB/FSB in analyses by PHE. The reports that used this code were attributed primarily to CF1c ‘Slips and lapses’ and CF2c ‘Adherence to protocols/procedures’ and weren’t RTEs that had propagated through the pathway. Many of the earlier subcodes in the process are used primarily for lower-level incidents. This SB therefor appears to be functioning as intended and catching any errors which occur within the ‘treatment unit process’.

Some codes were used in conjunction far more frequently than all others, these were contained to ‘near misses’ and ‘other non-conformities’. The most frequently paired codes 12f ‘Accuracy of data entry’ and 12g ‘End of process checks’ are used together on 18% (n = 9) of ‘near misses’ reported. These were the only instances where 12g was reported and it was always as a failed safety barrier. The root cause of these reports was primarily CF1c ‘Slips and lapses’ followed by CF1a ‘Failure to recognize hazard’. Most instances of an RTE during the ‘treatment data entry process’ were found to have propagated further along the pathway, causing delays for the treatment unit. This SB does not appear effective in stopping RTEs from progressing, as in at least 64% (n = 9 / 14) of reports citing 12f the inaccurate data entry did progress to the next process.

The second most frequent pairing was 10j ‘Documentation of instructions/information’ and 10l ‘End of process checks’ which were divided between level 4 and 5 reports. While reported together almost as frequently as 12f and 12g, the SB 10l is reported far more frequently so the pairing only comprises 22% (n = 8 / 36) of reports containing 10l.

10l is the most frequently used code overall, and the most frequent for ‘other non-conformances’ where it included in 38% (n = 27) of reports, totalling 75% of its uses. With ‘pretreatment activities’ the RTE process included in over 40% of reports this is reasonable but demonstrates the prevalence with which 10l is reported for the ‘pretreatment activities’ process. In 93% (n = 25) of level 5 reports 10l was the sole SB included, and other codes were only added in 37% (n = 10) of reports. It is also the most reported failed safety barrier, though it is successful in 17% (n = 6) of reports, including the single ‘minor radiation incident’ (level 3) to use the code.

Based on this it would seem unlikely that these RTEs have been misreported, with 10l being the appropriate code to have used. There is potentially a concerning number of ‘slips and lapses’ not being discovered during the ‘end process checks’ for ‘pretreatment activities’, many end up propagating through the pathway and causing disruptions and delays for the RT planning staff and patients. However, many of these RTEs are minor issues that cause no significant harm to the patient, and the SB was sufficient to stop a level 3 RTE from continuing further. The commonality of this code being the SB responsible may explain its prevalence as the only code or safety barrier used in many reports; it's possible that the use of this code leads to a less thorough investigation or specificity in a report.

It is worth noting that determining whether a SB was effective or failed is dependent on the correct interpretation of events. While this may be achievable while performing an investigation, to improve this section of the analysis in the future it would be advantageous to include relevant coding within the description of the incident. This was previously suggested in DoL and would help to make each report explicitly clear in what safety barrier was effective in discovering the error (Public Health England, Development of learning from radiotherapy errors - Supplementary guidance series, 2016).

5.5. Breakdown of Causative Factors

The only root causes reported for level 3 events were all categorised as CF1 'Individual' RTEs. This suggests that the more serious incidents occurring at the provider are caused only by human error. This is largely in agreement with PHE which finds that the root cause of most level 3 events to be CF1c, however a significant portion of level 3 incidents routinely cite CF3a 'Equipment or IT network failure' as a leading root cause in the national findings. This is reversed in the reports submitted at this provider, where this code is used more frequently the lower the level. With several large equipment failures in the past year this is a potential point of concern should the severity of these instances be underreported; but as these instances only caused the delay of patients through the RT pathway, they appear to be coded appropriately.

In both level 4 and 5 reports there appears a particularly large usage of the code CF1c, with approximately three times the frequency of any other code. This pattern is not observed nationally where the most frequently reported RC codes share similar levels of usage. This could indicate an overreliance on this code while investigating incidents. Alternatively, this is evidence for a reporting culture where individual slips and lapses are quickly reported when discovered.

5.6. Breakdown of Risk Analysis

The risk analysis found the most severe areas of risk to occur during the treatment unit process due to procedures being followed incorrectly. These errors occurred bimonthly on average making them a likely RTE to occur in the future. The root cause was primarily 'slips and lapses' with the most common contributory factor being 'adherence to protocols/procedures', meaning these were fundamentally human errors stemming from a lack of concentration/attention to carrying out the procedure as intended. It is highly advised that steps are implemented to reduce the number of these errors occurring, as there will always be the possibility that severe harm could come to the patient from a mishap like this.

Another area of high risk was patient set up, where the set-up guidance was often found to be incorrect or incomplete, which hindered the patient being set-up correctly and caused delays to treatment. Similar errors were found in the plan movements on Mosaiq, leading to similar disruptions for patients and staff. The risk here is largely due to the frequency of these errors, which can occur multiple times a month. These RTEs may be of minor concern to patent safety as they are often discovered before any harm was done, however they cause unnecessary stress for both staff and patients while delaying treatment until the issue is resolved.

There were some cases of set-up being performed incorrectly. Thanks to the safety barriers already in place the majority of these RTEs were discovered before treatment commenced.

Equipment related errors will always be an issue in any department that is reliant on such complex machinery. Approximately half of the RTEs related to equipment failures weren't caused by the equipment itself but rather environmental or human related error. While faults that are clearly related to the age of the machine do occur, these are the minority of equipment errors.

There are many reports that describe minor documentation slips that propagate through the pathway but cause no harm to the patient. It is important to be mindful of how easy it is for this type of error to occur, especially in processes where transcribing is still necessary. Staff should be encouraged to double check names and NHS numbers on all forms they use as a patient progresses through the pathway. Otherwise, these errors are unlikely to be spotted until flagged by software, or some error occurs. These RTEs are unlikely to cause direct harm to a patient, but there is the possibility of contacting the wrong patient.

6. Conclusions

To facilitate quick analyses such as this in the future, there are some improvements that could be made to the reports themselves. To allow the data to be quickly used within Excel or importing to SPSS, it would be beneficial for the coding to be easily and consistently extractable. To do this the reports could be improved by consistently placing the trigger code first, followed by the coding separated by spaces and backslashes, with a line break to separate this from the detailed description of the report.

The reporting culture at SBUHB appears strong, with most reports being low-level incidents that were caused by individual ‘slips and lapses’. This demonstrates a safety conscious workforce that regularly voluntarily report near misses and other non-conformances at rates higher than the national average. The number of these low-level reports explains the prevalence of ‘pretreatment activities’ as the most frequently reported process, as it largely contains reports of this type in both sets of data.

However, many of these RTEs do propagate further along the pathway, and it appears that the SB 10l ‘end of process checks’ is commonly used as the sole descriptor. Many of these reports deal with incomplete/incorrect QCLs, which do propagate if not caught by the final SB in the process. At three reports a month on average 10l has become commonplace, its effectiveness should be revaluated.

Few minor radiation incidents have occurred in this period, and they are in agreement with the national data from belonging to the treatment unit process to the frequency with which they occur (0.6 per 100 attendances). Many of these errors were successfully caught by SBs within the process without progressing along the pathway. The risk analysis found several RTEs where incorrect procedures were carried out during the ‘treatment unit process’, some of these resulted in level 3 reports as the patient was treated incorrectly. These are ‘slips and lapses’ and were caught before treatment concluded, they do not appear to be a cause for concern.

7. References

British Institute of Radiology, Institute of Physics and Engineering in Medicine, National Patient Safety Agency, Society and College of Radiographers, & The Royal College of Radiologsists. (2008). *Towards Safer Radiotherapy.* Retrieved from papers2://publication/uuid/982D69AB-9050-4038-9709-22C6CC07D01A

Institute of Physics and Engineering in Medicine, Society and College of Radiographers, & Royal College of Radiologists. (2020). *Ionising Radiation (Medical Exposure) Regulations: Implications for clinical practice in radiotherapy. Guidance from the Radiotherapy Board.* Retrieved from https://www.rcr.ac.uk/sites/default/files/guidance-on-irmer-implications-for-clinical-practice-in-radiotherapy.pdf

Public Health England. (2016). *Development of learning from radiotherapy errors - Supplementary guidance series.*

Public Health England. (2020). *Safer Radiotherapy - Biennial radiotherapy error data analysis and learning report (January 2018 to December 2019).*

Public Health England. (2020). *Safer Radiotherapy - Triannual RTE analysis and learning report (April to July 2020).*

Public Health England. (2020). *Safer Radiotherapy - Triannual RTE analysis and learning report (August to November 2020).*

Public Health England. (2020). *Safer Radiotherapy - Triannual RTE analysis and learning report (December 2019 to March 2020).*

Public Health England. (2020). *Safer Radiotherapy - e-Bulletin (June 2020).*

Public Health England. (2019). *Safer Radiotherapy Newsletter - January 2019*

Laurence, R. (2020, April 28). UK wide COVID-19 radiotherapy initiative | COVID RT. National Cancer Research Institute. Retrieved from https://www.ncri.org.uk/covid19-radiotherapy-initiative/

8. Appendices

These charts displaying the number of reports submitted voluntarily by each RT provider have been reprinted here with the permission of PHE. A bracket has been added to show where SBUHB stands in relation to other providers. It was tempting to be specific and pinpoint the specific bar that corresponds to SBUHB, however the number of alterations by PHE while consistency checking is not known.