Welsh Risk Pool Radiology Review

CIRCULATION	Swansea Bay UHB; WRP Committee
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TITLE OF REPORT
Radiology Review - Abertawe Bro Morgannwg University Health Board 2019 (now Swansea Bay UHB)

PURPOSE OF REPORT
An assurance review of standards to ensure that abnormal unexpected findings identified during image reporting are acted upon in a timely manner.

THIS IS A DRAFT REPORT FOR REVIEW
BY THE WELSH RISK POOL AND SWANSEA BAY UNIVERSITY HEALTH BOARD

This Review has been led by the Welsh Risk Pool and forms part of an all-Wales review into the management of unexpected findings in radiological investigations

Review of the management of unexpected findings in radiological investigations

Report Version Draft .*August 2019*

01 Executive Summary

01.01 This review was carried out in March 2019, prior to the boundary changes related to the health boards that took place in April. The hospitals reviewed were Morriston Hospital, now part of Swansea Bay UHB and Princess of Wales Hospital, now under the remit of Cwm Taf Morgannwg UHB.

01.02 Radiological diagnostic imaging represents a significant and increasing part of modern medicine. Maskell (2017) highlights that the advances in medical imaging over the past few decades are often cited as being among some of the most important achievements of modern medicine, and that the diagnostic possibilities afforded by new imaging modalities have driven an explosion in demand for scans of all types.

01.03 The Welsh Risk Pool analyses the learning and improvement interventions for all claims presented for reimbursement. With the increasing availability and complexity of diagnostic imaging, it is perhaps not surprising that issues in relation to radiology services, and the use of information by from radiology in all specialties, are seen in claims. The Welsh Risk Pool Committee has requested this review be carried out into the assurance of systems and processes to reduce harm arising from radiology services and the information provided to all clinical specialties.

01.04 Site visits as part of the review were undertaken during March 2019, which included visits to all the acute sites in the organisation, which was then Abertawe Bro Morgannwg University Health Board (ABMU). These site visits were followed up with additional meetings and discussions and liaison with NHS Wales Informatics Service (NWIS) in relation to potential solutions.

01.05 A theme identified in claim cases is the failure to appropriately act, intervene or follow up a patient when radiology reports indicate an unexpected significant finding. This issue is not new and has been the subject of safety alerts and standards for well over a decade. Events continue to occur which result in the avoidable death or severe harm to patients and significant pressure

is placed on to the risk pooling scheme from reimbursing claims. The review therefore seeks to consider the steps taken in relation to abnormal findings and how assured the Health Board can be in respect of findings being acted upon when reported.

01.06 Historically, issues have been seen in relation to patients treated in an Emergency Department where abnormal findings are reported at a later time by a radiologist and there is a failure to ensure the appropriate follow up is in place. However, almost all clinical specialities and types of diagnostic imaging are implicated in these issues. The review has therefore commenced at each health locality with the Emergency Department (ED) but does consider all specialties served by the diagnostic imaging function. Staff in both ED and Radiology Departments provided information, evidence and verbal input.

01.07 An additional issue highlighted in claim and inquest cases involve concerns regarding the access to, transferability and portability of diagnostic images and reports. The review also provides analysis of the assurance that the Health Board can take in relation to images being transferred to specialist tertiary centres or other providers, both inside and outside of NHS Wales.

01.08 A further, and unfortunately, relatively frequent occurrence is the finding of a clinical abnormality which was present, or indicating that the patient needs further review, at a previous scan or image - but was not reported in the first image report. These are described by the Royal College of Radiologists as ‘discrepancies’ and Brady (2017) highlights that they present in between 3% and 5% of all radiology reports. Standards have been established for discrepancy meetings and how organisations should learn and improve as a result of holding these. The review therefore considers the assurance that the Health Board can take in respect of learning and improvement from the discrepancy review process.

01.09 There are processes and procedures in place at each of the sites for the management of unexpected findings in radiological investigations. Some existing and emerging good practice was noted, however there are some

inconsistencies in the procedures at the different sites. The detail of these findings is set out in the body of the report below, and recommendations have been made in respect of risk and areas for improvement.

01.10 Abertawe Bro Morgannwg University Health Board is clearly a complex and geographically spread organisation, with radiology services provided over the sites and servicing a diverse range of clinical specialties and community based services, along with liaison with (and provision of) tertiary and specialist services within Wales.

01.11 In services through the whole Health Board, there is **substantial assurance** that a process is in place whereby if a critical or emergency finding is identified and included on a diagnostic imaging report it will be notified to requesting clinicians and support provided in determining the appropriate clinical pathway or treatment.

01.12 In relation to abnormal findings, there are **reasonable assurance** levels across the sites that such results will be communicated.

01.13 For the radiology services based at both sites there is **reasonable assurance** that a process is in place whereby if an urgent finding is identified and included on a diagnostic imaging report it will be highlighted to the requesting clinician and appropriate action taken.

01.14 Failures in ensuring that requesting clinicians are appropriately sighted and appropriate action has been taken in these types of case, have led to incidents of avoidable death and significant harm to patients and to associated high value clinical negligence claims. Whilst all parties must recognise that the requesting clinician carries a responsibility to review the report provided by a diagnostic imaging service and to take appropriate action, it is simply not acceptable for radiology services to ignore the unique position that they are in to highlight unexpected and abnormal findings and to assist in managing the human factors risk. The WRP Assessors therefore assert that a robust quality improvement plan is implemented to ensure that improvements are made.

01.15 A number of reviews and studies highlight that electronic flagging, alerting and auditing tools can be used with electronic radiology services. These solutions can provide a definitive solution to the problem of failure by the requesting clinician to recognise and act if an abnormal unexpected finding is reported, and places a real-time tool to reduce patient safety risks arising from this issue. Through exploration of potential opportunities with the existing RADIS software used in the majority of NHS Wales organisations, the WRP Assessors have identified that there is some limited functionality which can assist with this activity, but reports indicate that this functionality has not been activated due to a lack of consensus on how it should be coded and operate. The NHS Wales Informatics Service (NWIS) has some responsibility for the RADIS systems, although the current model is that each organisation has separate instances of this software operating locally.

01.16 It is therefore recommended that as a matter of urgency the NWIS lead for RADIS explores the options and makes a recommendation for an all-Wales solution.

01.17 The RADIS solution does not offer a long term solution and a more bespoke intervention will be necessary to provide a more robust assurance against the risk of failure to act. Whilst recommendations other than electronic solutions have been made in the past, and there has been attempt at implementing non electronic solutions in many services, the installation of an electronic solution is considered by the study authors to be the only cost-effective measure which will provide an increased assurance in this area of risk. Therefore, a recommendation is made on a national basis that Welsh Government should consider options for an all-Wales electronic flagging and alert tool to support all organisations in managing the human factors risks associated with this issue.

01.18 The review has noted previous patient safety reports in this area and a recent Welsh Audit Office Report into Radiology Services in Wales.

02 Introduction

02.01 The Welsh Risk Pool reviews all requests for reimbursement in relation to negligence claims made against member health bodies. Where themes and trends are identified, further intervention is necessary and a claims review may be commissioned by the Welsh Risk Pool Committee.

02.02 Cases in relation to the reporting, communication and actions taken in respect of radiological investigation report are periodically seen by the Welsh Risk Pool Committee and this review has been requested, to focus primarily on the assurance of mechanisms to follow up abnormal unexpected findings and the assurance of discrepancy review processes within health bodies in NHS Wales.

02.03 Cases in relation to the transfer of images to other care centres, both inside and outside of NHS Wales, have also highlighted concern. A recent Regulation 28 Preventing Future Deaths notice, served on NHS Wales health bodies, raised concerns regarding the ability of clinicians to share images between sites of different organisations and between NHS Wales systems and those of receiving teams in NHS England Trusts.

Failure to follow up abnormal unexpected findings

02.04 A theme identified in case reports is the failure to follow up a patient where an abnormal unexpected finding is identified on radiology image reports. Investigations have established that these incidents have resulted in significant harm to patients, including avoidable death, along with claims of significant financial value.

02.05 Two examples of the failure to follow up an abnormal unexpected finding are provided here in this review report for illustrative purposes. Neither of these examples is directly related to an individual patient or health body, but formed a combination of the circumstances and finding from a number of cases which have been reviewed.

Example case 1

An example of a failure to follow-up an abnormal, unexpected radiology finding incident is a 41 year old smoker who has an x-ray for a suspected clavicle, which is confirmed and treated appropriately.

The radiologist reporting the chest x-ray image taken during the episode of care identifies a solid, non calcified 7mm nodule within the lung tissue and notes it in the report. This is not considered a critical finding (which might necessitate intervention within a short timescale) but is considered to be an abnormal unexpected finding.

In the example case, the clinical team treating the patient do not refer the patient to the respiratory service or for further investigations. The patient is discharged and, as they have no other co-morbidities, does not have any further clinical contact.

Clinical guidelines (BTS 2015) in such cases would indicate that a staging scan or further imaging would be necessary in relation to a nodule of this size. This would lead to monitoring and if the nodule becomes larger, or is risk assessed as potentially malignant, further intervention such as biopsy or excision would be recommended.

In the example case, the patient and clinical teams are unaware of the need for CT surveillance and the patient re-presents to the primary care service 3 years later with a history of several weeks of non-productive cough. Investigations establish that the patient has malignant lung cancer which is unsuitable for surgery. Following palliative treatment, the patient dies.

The case investigation identifies that if the patient had CT imaging and a referral to the respiratory service at the time of the original nodule being noted on the chest x-ray report, then on the balance of probabilities, the patient would have had curative treatment.

The estate of the deceased patient brings a claim against the health body, which is settled at a total value (including damages and costs) of £750,000.

Example case 2

A further example of a failure to follow-up an abnormal, unexpected radiology finding incident is a 45 year old construction worker who attends hospital following a fall, complaining of wrist and arm pain. X-rays do not identify any bony injury and the patient is given advice to self-care with rest and cold compresses and to mobilise the wrist gradually.

The radiologist reporting the x-ray identifies concerns that follow up x-rays (known as a scaphoid series) or an MRI scan is required. This is noted in the x-ray report and is passed to the clinician who requested the original x-ray.

In the example case, the clinician who requested the original x-ray leaves the department for another post and no other clinician reviews the case – resulting in the patient being unaware of the need for further follow-up. College of Emergency Medicine guidelines indicate that appropriate treatment would be immobilising the joint and referral to a specialist service.

The patient continues to experience pain and continues to mobilise the wrist, until after two months attends his GP who re-refers the patient to the orthopaedic service and they are seen after a further month. At clinic, a mal-union of a fractured scaphoid is diagnosed and surgery is necessary. Following surgery and intensive physiotherapy, the patient is able to recommence work but is determined to have a 20% loss of mobility and is unable to continue a manually intensive job.

The case investigation determines that surgery would not have been necessary if the wrist had been immobilised and follow-up had been arranged within the first two weeks of the injury.

The patient brings a clinical negligence claim, which is settled at a total value (including damages and costs) of £400,000.

02.06 These illustrative examples highlight the potential harm and financial costs associated with cases where there is a failure to follow up an abnormal unexpected radiological findings and this is the main focus of this review.

02.07 The issue of failure to take action following an abnormal unexpected radiological finding has been a challenge within the patient safety sector for a number of years. Following concerns about reported serious incidents in both England and Wales, NPSA (2007) issued Safer Practice Note 16, which remains a valid standard. Whilst some of the challenges identified in this alert are no longer a challenge (for example reliance at that time on printed radiological reports as the communication between clinicians – whereas in 2019, the main method is predominantly via electronic communication), many of the issues covered in the alert remain a challenge to the modern NHS. The alert identified that effective two-way communication systems were important to act as 'safety-netting' in the event that failures occurred.

02.08 The Royal College of Radiologists has recognised the challenges in relation to the communication of diagnostic imaging findings and in 2012 released its second edition of standards for communicating in the event of unexpected findings.

02.09 Both the Royal College and the NPSA alert recognise that the primary duty for acting on the results of diagnostic imaging reports lies with the requester of the image, whilst it is the clear duty of radiologists and other healthcare professionals who provide reporting services (such as reporting radiographers or sonographers) to provide timely and clear reports which outline the implications of what has been found.

02.10 Welsh Risk Pool case reviews appear to indicate that the focus of the problem is often where intervention or action by an alternative specialty is required – such as an image requested by cardiology needing an intervention by a respiratory service.

02.11 As part of the standards for the communication of unexpected findings, the Royal College standards place an expectation onto organisations:

> *"to ensure that the designated pathways between radiology departments and referrers are designed to minimise the risk of*

> *serious harm to patients by significant imaging findings being overlooked – even though they have been correctly reported"*
>
> RCR (2012, pp11)

02.12 The Welsh Scientific Advisory Committee considered this issue and published "Standards for reporting critical, untoward, urgent or unexpected radiological findings" in 2014. This recognised, as with the NPSA alert and Royal College standards, three levels of priority in relation to the urgency of the response required to the findings. The three levels are: Critical and / or Emergency, Urgent and Red Star.

> *<u>Critical and / or Emergency findings</u> are those which need an immediate clinical intervention – such as a tension pneumothorax.*
>
> *<u>Urgent findings</u> are those which need a clinical intervention within 24 hours – with the example of a cerebral tumour given*
>
> *<u>Red Star findings</u> are those which are unexpected but do not necessarily require immediate or urgent clinical intervention. Examples given include renal cell carcinoma seen on an ultrasound scan which is looking for gallstones.*

02.13 It is clear that red-star findings will be the most numerate of abnormal unexpected findings. The cases presented to the Welsh Risk Pool suggest that the existing safety-nets are not effective at ensuring red-star findings are acted upon appropriately. There is no clear evidence that critical / emergency or urgent findings have the same level of difficulty, with previous claim reviews achieving strong assurance in relation to these findings.

02.14 The Welsh Scientific Advisory Committee (2014) established standards for ensuring effective communication of Red-Star reports:

- *The reporter will fax or email the report to the requesting clinician and copy to the MDT if appropriate*
- *The referring clinician should acknowledge receipt of the report*

- *Monthly audits will be used to ensure that red star findings have been acted upon*

The Welsh Risk Pool will therefore focus on the performance against these standards.

02.15 The Welsh Scientific Advisory Committee (2014) also recognised the importance of an IT-based solution for this issue

> *"...it is recognised that an IT-based acknowledgement system that flags reports of high priority, logs when reports have been read by the referrers and documents actions, would add further strength to the process and should be a goal for future development"*
>
> WSAC (2014, pp1)

The Welsh Risk Pool will also consider the availability of a suitable ICT solution for NHS Wales as part of this review.

Discrepancy Management

02.16 Diagnostic imaging is a constantly evolving and growing field of medicine, utilised by almost all clinical specialties to inform, advise and determine appropriate treatment.

02.17 It is recognised as a service under considerable pressure, with difficulties recruiting radiologists in some fields and locations.

02.18 Examples of discrepancies within radiological reports are seen in cases reviewed by the Welsh Risk Pool, where a case is re-reviewed by another radiologist or re-reviewed with the benefit of knowing a patient diagnosis, and it is clear that something on an earlier image could have been utilised to determine or inform treatment.

02.19 Brady (2016) highlights that the number of errors and discrepancies within radiology reporting are noted to be between 3% and 5% of all reports – with variation between locations and types of image. The inevitable link to clinical negligence claims arising from discrepancies is clear, although Brady

(2016) and RCR (2014) highlight that radiology reporting is, like most fields of medicine, about the opinion of the reporter based on the image and information available at the time. There is, therefore, an acknowledgement that there will be a level of discrepancy within image reports and the Royal College of Radiologists set out standards for organisations to hold learning from discrepancy meetings as an improvement task.

02.20 When the Welsh Risk Pool reviews cases where a radiological discrepancy forms part of the breach of duty, assurance is often provided that discrepancy meetings are held locally and that learning is shared. It is not so clear that learning is shared more widely across different radiology teams within an organisation or nationally across NHS Wales.

Transmission and accessibility of radiological images

02.21 Within modern healthcare, some specialties are not provided at each health locality and the model of providing some services on a regional basis or in specialist tertiary centres is known to provide better outcomes for patients in some instances. As the regionalisation, and indeed nationalisation across Wales, of some services increases the need for transferability and portability of diagnostic imaging is increasingly important.

02.22 An inquest held within Wales heard evidence that it was not possible to transmit CT images to a hospital outside of Wales, which resulted in a delay to treatment of a patient with a subarachnoid haemorrhage:

> *"The inquest heard that commissioning of software required for transfer of radiology images is Wales based, thus while images could be transferred between Welsh hospital for neurosurgical review they could not be sent across the border for review by non-Welsh hospitals"*
>
> PFD SW (2018,pp2)

02.23 This resulted in the Coroner issuing a Preventing Future Death notices (PFD) in respect of the case. In response to the issued Preventing Future Death

notice, the Coroner received information that images could be transferred outside of Wales.

02.24 WAO (2018) considered the ICT infrastructure of imaging systems across NHS Wales and highlighted that the information relating to a diagnostic image within Wales is held in different systems – predominantly RADIS and PACS. The report of the image is stored on RADIS and the scan image is stored on PACS - together comprising the clinical record of the image. The WAO report did find challenges with access to information in the system and different ICT instances of the RADIS databases.

02.25 The PFD was served on the Director of Legal & Risk Services in additional to health bodies in Wales and it was agreed that the Welsh Risk Pool Radiology Review would seek clarification of the position in all organisations regarding the transferability and portability of images and / or reports.

Ensuring the review is effective

02.26 The review involved the WRP Assessors visiting the acute hospital sites across the Health Board and looking at the systems and processes in place in both the Radiology and Emergency Departments (ED).

02.27 The Assessors spoke to a number of staff in all the Radiology and Emergency Departments at the Health Board, including medical and nursing staff, radiologists and radiographers and administrative staff. The Assessors then spoke to staff from a range of other clinical specialties.

02.28 The Assessors also considered national developments, particularly in relation ICT based solutions and contacted the NHS Wales Informatics Service for information. Consideration was also given to potential ICT solutions available within the marketplace.

03 Scope of review

03.01 The review has been considered to consider aspects of the communication between services and radiology services, along with the effectiveness of discrepancy review processes.

Appropriate management of abnormal unexpected findings

03.02 The review focussed on situations where a reporting radiographer or radiologist identified an unexpected abnormal finding on the requested diagnostic image.

Discrepancy Management

03.03 The review focussed on the processes within the radiology services and health bodies reviewed in respect of meetings held to review discrepancies and to share learning.

Accessibility, Transferability and Portability of Reports & Images

03.04 The review focussed on the ICT access to radiological images and reports for a range of clinicians:

- clinicians who requested the investigation
- other clinicians in the same specialty or locality
- other clinicians more widely in the health body
- all clinicians across NHS Wales
- specialist clinical teams outside of NHS Wales

04 Review Standards

04.01 Having completed analysis of claim reviews, claim cases, previous studies, available literature and relevant standards, protocols and guidelines for the sector, a series of Review Standards were developed by the review team. These are used to provide a grading analysis against for the Health Board and to assist in the development of a quality improvement plan in response to the report.

Abnormal Unexpected Findings

04.02 Assurance that the Health Board has effective safety-net systems to ensure that urgent &red-star findings on radiology reports are acted upon in a timely manner

RCR (2012)	Evidence of designated pathways between radiology department and referrers, designed to minimise the risk of serious harm to patients due to significant findings being overlook even though they are reported correctly
WSAC (2014)	Electronic copy of report sent to requesting clinician
NPSA (2007)	Documented radiology department safety-net procedures
WSAC (2014)	Copy of report is sent to MDT if appropriate
WSAC (2014)	Referring clinician acknowledges report
WSAC (2014)	Monthly audits are undertaken to ensure red-star findings are acted upon
NPSA (2007)	If a patient's radiology imaging report is not available at the time of accident and emergency attendance, in-patient discharge or out-patient consultation, check the results as soon as possible and ensure the patient is informed of them. Patients may be informed through standard letters, phone calls or other appropriate means.

Discrepancy Management

04.03 Assurance that the Health Board has effective Learning from Discrepancy Meetings, which are held frequently, capture appropriate cases which are categorised and assessed (and escalated where necessary) for patient harm, and learning outcomes are shared widely.

RCR (2014)	There is a clear process for discrepancy cases which are collected to be discussed at meetings
RCR (2014)	Images being discussed are considered whether the discrepancy has resulted in any patient harm
RCR (2014)	The focus of discrepancy meetings is learning and the convenor guides the discussions with anonymity of the original reporters as far as possible
RCR (2014)	Meetings should be held on the frequency of at least one meeting every two months
RCR (2014)	Discrepancies discussed should be categorised using the Royal College of Radiologists scale
RCR (2014)	Minutes of the discrepancy meetings should be taken and shared with local and senior leadership teams or committees

Accessibility, Transferability and Portability of Reports & Images

04.04 Assurance that the Health Board has appropriate systems to permit smooth and timely transfer or access of images and reports to alternative care centres or teams when required

Best Practice	Images should be able to be viewed by specialist clinicians with whom the health body has clinical agreements to provide services
Best Practice	Reports should be able to be viewed by specialist clinicians with whom the health body has clinical agreements to provide services
Best Practice	Images & Reports should be able to be accessed by all clinicians within a health body, including those in alternative specialties or health localities
Best Practice	Images & Reports should be able to be access by all clinicians within NHS Wales

05 Methodology

05.01 The review was conducted by a group of staff from the Safety & Learning Team within the Welsh Risk Pool.

05.02 Analysis of claims data was undertaken prior to the review, to identify the common themes and trends in respect of radiology related claim cases.

05.03 Review of UK and Wales studies, alerts, guidelines and standards in respect of radiology reporting was undertaken prior to the review – to determine the expected requirements of radiology services and clinical specialties.

05.04 Standards for the review to consider Health Board services against were then established and agreed at the Safety & Learning Team Meeting.

05.05 Consideration of existing Health Board policies and Standard Operating Procedure documents was undertaken prior to the commencement of site visits.

05.06 The review consisted of a visit commencing at each of the Emergency Department of the Health Board – at Morriston and Princess of Wales Hospitals. Clinical cases were tracked through their lifecycle of requesting, to imaging, reporting and follow up.

05.07 Interviews with a range of staff within the Emergency Department and radiology service were held.

05.08 Discussions were held with the radiology service in respect of specialties other than ED. Discussions were then held with cardiology and respiratory staff.

05.09 Consideration of the ICT software systems in place within the Health Board will be undertaken and comparison made to the available systems across NHS Wales. This will be continued in conjunction with NHS Wales Informatics Service (NWIS).

05.10 Consideration was made of additional ICT functionality which could be accessed by Health Boards in Wales.

05.11 A review panel discussion was then held to ensure that the findings were triangulated from the information gathered in policies and discussions.

05.12 An assurance table, using the standard NHS Wales Internal Audit assurance grading (Substantial Assurance, Reasonable Assurance, Limited Assurance, No Assurance) was then generated.

06 Review Participants

06.01 A team of clinical and non-clinical safety & learning advisors were drawn to form the review panel for this study.

Review Team Leader

06.02 Sue Derbyshire, *WRP Clinical Assessor and Safety & Learning Advisor*

Sue is the lead assessor for the review project across all Health Boards in NHS Wales and is the lead author of this report.

Review Team

06.03 Isobel Smith, *WRP Clinical Assessor and Safety & Learning Advisor*

Gethin Bateman, *Safety & Learning Advisor*

The review team participated in the planning of the review, analysis of information and conduct of site visits.

Responsible Head of Service

06.04 Jonathan Webb, *Head of Safety & Learning*

Jonathan provided oversight for the review and agreed the terms of reference and review standards.

07 Review Findings

07.01 The assessors were supported in accessing information and were able to locate (using the HB intranet system) the identified policies, guidelines and SOP's referred to by those involved in the meeting.

07.02 The Emergency Departments' (ED) and Radiology Departments' staff at Morriston Hospital involved in the reviews had prepared comprehensive evidence to confirm systems and processes in place and had worked well together on the task. Staff from all departments were able to describe and demonstrate the processes in place. Policies appeared to be in place within the local areas.

07.03 Systems and processes are in place at Princess of Wales Hospital and evidence was provided in support of local policies in place within the Radiology and Emergency departments.

07.04 There was little evidence to confirm that policies were standardised across the health board. However, at each location communication between radiology and emergency departments appeared to be good. Policies and protocols are in place to guide staff and the emergency and radiology departments are working towards shared policies and protocols so that all staff work more seamlessly together. These policies are local to each of the two hospitals but as structural geographic changes are imminent this will not be counterproductive. Handbooks are available to guide staff in pertinent subjects, including requesting images and managing results.

08 Systems & processes to manage unexpected diagnostic results

08.01 A lung cancer pathway is in place at both sites. If a suspicion of a lung cancer is noted the result is highlighted to a Radiologist who arranges a CT scan for the same day. If the incidental finding is noted later then the patient is recalled for the CT scan. The result of the scan will be forwarded to the initial requester with the recommendation for further action and specialist referral. The process is outlined in a protocol.

08.02 A red star flagging process is in place to highlight abnormal results and is communicated with the report or sooner depending on the level of urgency.

09 Image reporting processes

09.01 There is no electronic system that includes confirmation of receipt and necessary action by the referrer at either of the sites. Reports can be accessed via the RADIS system and clinicians can also access them via the Welsh Clinical Portal.

09.02 Reporting timescales were discussed. At Morriston Hospital ED images are prioritised and as CT scans taken on ED patients are urgent cases the reports are returned in a short time frame. There is, however, no 'hot reporting' system and so delays of several days may occur in plain x-ray reporting.

Strategic planning is taking place at both sites with the aim of introducing faster reporting timescales and consideration of such initiatives. There is a growing cohort of reporting radiographers being trained and a workforce review is in progress, with the aim of recruiting more staff on a flexible, rolling recruitment plan.

09.03 In both hospitals there is a written criteria which states which plain x-rays will not be formally reported by the Radiologist unless a request is made by the referrer. These are known as 'canned reports' and is normal practice across the NHS in Wales. The exclusions include paediatric images, dental x-rays and those requested in Trauma and Orthopaedics (other than chest, abdominal, bone age and skeletal survey views).

09.04 At Morriston Hospital reporting for CT scans is outsourced during the night hours (from 11pm-8am) but no plain x-rays are reported by these contactors. In house Radiologists continue to take on call shifts overnight and requesters need to obtain agreement to undertaking body scans during the out of hours period. In Princess of Wales Hospital image reporting is outsourced to the external contractors (Everlight) from 5pm-8am. This was considered to be a good service by staff interviewed as part of the review.

09.05 A leaflet is in place in Morriston Hospital to inform patients who have been referred for imaging by their GP of the process for obtaining results. This leaflet states that the results should be with the GP in approximately one week.

09.06 At Princess of Wales Hospital patients referred for imaging by their GP are verbally advised of the timescales and process for obtaining their results. Reports sent to GPs by email include the facility to confirm receipt (by use of the 'voting' facility integral to the email). Any abnormal or unexpected result will be red starred in the usual manner. It was reported that this system is then cross referenced by Radiology Secretaries to ensure that abnormal results have been received. This is perceived as good practice. However, it was also reported that although some GP practices have embraced this system and all

Practice Managers are in favour of its use, some GPs are adamant that they will not participate.

10 IT functionality for transferring and transporting images & reports

10.01 The image sharing process was described and demonstrated. Protocols are in place to guide staff and those interviewed across both sites were confident that there are few problems in sharing images in Wales or other parts of the UK. For patients from other countries the images are burned to CD and given to the patient. It was noted, however, that image sharing can be a slow process where there are many images or groups of images (e.g. in cardiac cases). It was also stated that NWIS, who provide IT support for the RADIS system can be delayed, apparently due to resource problems within the service. The delays and issues are noted within the risk register.

11 General IT functionality & compliance

11.01 Image Reports can be seen prior to the issue of the hard copy on the PACS electronic imaging system.

11.02 Staff interviewed in Princess of Wales Hospital as part of the Radiology review discussed how an electronic system that could provide image reports and include the facility to record receipt and action taken on any anomalies would greatly reduce the risk of abnormal and/or incidental results being overlooked and not actioned.

12 Activity levels and staffing

12.01 There is currently a shortfall of five Radiologists at Morriston Hospital, with four posts out to advert at this time. The department has agreed a flexible working model that aims to accommodate the needs of the service and also its staff.

12.02 The Radiology Department at Princess of Wales Hospital has a shortfall of three radiologists and sonographers. Recruitment adverts are currently in place and initiatives such as the employment of a locum midwife to perform obstetric scans has proved a success. In addition, a CT colon radiographer reports the scan results and has won awards for the initiative. This member of staff is now assisting Health Inspectorate Wales in developing a training programme to enable the process to develop across the country. It was demonstrated that retention of staff is good and that the in house training programme has facilitated a full complement of Band 6 and 7 radiographers.

12.03 Reporting radiographer numbers are increasing and there is an enthusiasm for undertaking the training by team members. Radiology staff are available to support ED staff in interpretation of images and are located within easy reach of the departments

13 Cross checking results from diagnostic investigations in ED

13.01 In Morriston Hospital when formal reports are generated within the Radiology Department they are forwarded in hard copy to the ED. Clerical staff take out all the reports that state that the image is completely normal. All other reports are forwarded to the ED Consultant on a daily basis. A check is made whether the patient was admitted to hospital or provided with an outpatient appointment e.g. to fracture clinic. If the patient has been admitted to a speciality and the abnormal or incidental finding does not relate to that specialism then the Consultant will communicate the result. This process was discussed at length and it was noted that it takes a protracted amount of time and can be postponed on the occasions when the ED is working at or beyond capacity, which is a regular occurrence. Where there is pressure on the department the Consultant allocated to clinical administration duties may be needed in the department to manage patients and maintain safety. There is currently an under-establishment of Consultant numbers in the ED, which means others have to take on extra shifts and on call duties. The ED

Consultants cover day shifts from 8am to 11 pm, often reportedly staying on much later into the night hours.

13.02 At Princess of Wales Hospital the process for validating diagnostic results against the individual patient's treatment plan and outcome is underpinned by protocol. An initiative to record the review is facilitated by specific documentation that is routinely printed on the back of the x-ray request form. This contains areas to record the date of the validation check, any action taken plus follow up or recall that has been arranged. Treatment provided is included and any necessary information provided to onward care givers. The form is then scanned in to the patient's records. This can be seen as good practice that could be usefully adopted across Wales.

13.03 No filtering of reports is undertaken in the Radiology Department at Princess of Wales Hospital, all are forwarded to the ED. Medical secretaries then remove only those that relate to no other comment than 'normal'. All others are forwarded to the designated ED Consultant who then filters out those not needing any further review. Those needing further analysis are then reviewed and any appropriate action taken and recorded. Feedback is provided to individuals and to their Educational Supervisors. Any unusual or interesting cases or themes noted are incorporated into teaching sessions. It was discussed at the site visit that timescales for reporting can vary and it was demonstrated that a delay of up to four weeks had recently been highlighted. It was stressed, however, that stringent efforts are made to reduce such backlogs when they occur.

13.04 Audits e.g. on missed fractures are undertaken regularly and a database kept of any such missed injuries. The ED and Radiology Departments cooperate on the audits and share the results across both areas. Any themes are picked up and acted upon.

14 Staff training, competence and support

14.01 Junior doctors on both sites are taught x-ray interpretation at induction training and as part of their weekly (protected time) teaching sessions.

14.02 Emergency Nurse Practitioners at both sites learn x-ray interpretation within the scope of their practice (limb images) and have medical, radiologist and Advanced Nurse Practitioner support on both an individual level and in teaching provision. Proformas are in place for specific injuries and include imaging requesting advice.

14.03 At Princess of Wales Hospital a junior doctors handbook is available electronically to all clinical staff and is regularly reviewed. This handbook is an up to date and comprehensive guide to policies, protocols and specific condition management. It also includes guidance on image requesting and results management. This resource could be usefully shared across other emergency departments.

14.04 Discrepancy meetings take place within the Radiology Departments and it was reported that the emergency departments discuss any issues relating to x-rays within the department. At Princess of Wales Hospital radiology staff would attend any such meetings.

15 Conclusions

15.01 whilst policies and protocols were, in the main, local to each hospital radiology and emergency departments (rather than health board wide) they were appropriate and regularly reviewed. As there were boundary changes initiated shortly after the review took place this is less relevant at Swansea Bay UHB.

15.02 Systems are in place to manage unexpected diagnostic results in both hospitals. Assurance levels are outlined at 17.03 in the table below.

15.03 There is no electronic system that includes confirmation of receipt and necessary action at either of the sites. Staff would appreciate the development of such a system.

15.04 Reporting timescales can vary and efforts to reduce delays being made.

15.05 Sharing and transfer of images to other NHS organisations in Wales and the wider UK are reportedly unproblematic.

15.06 There is a shortfall in the number of radiologists in post at each hospital.

15.07 Reporting and specialist radiographer numbers have increased and award winning initiatives put in place.

15.08 Diagnostic results are validated within the emergency departments, although it was noted that these can be very time consuming.

15.09 Audits of missed fractures take place in both emergency departments, supported by radiology staff.

15.10 X-ray interpretation training is provided to referring clinicians and at Princess of Wales Hospital ED a comprehensive electronic handbook is available to support clinical staff.

15.11 Discrepancy meetings take place within the radiology departments and learning is shared. Emergency departments are supported by radiology staff and any issues relating to x-rays are highlighted and discussed at departmental meetings.

16 Recommendations

It is recommended that:

16.01 Timeliness of formal reporting is crucial to enable prompt and appropriate treatment provision and planning. It is appreciated that current resources make attainment of target times a challenge. It is recommended that every effort be put in to obtaining and managing sufficient resources to enable prompt turnaround timescales.

16.02 IT functionality - The introduction of software that could support an electronic system to acknowledge receipt of formal reporting and confirm that appropriate action has been taken would be welcomed by staff. It is recommended that consideration at senior levels is given to this subject.

A number of reviews and studies highlight that electronic flagging, alerting and auditing tools can be used with electronic radiology services. These solutions can provide a definitive solution to the problem of failure by the requesting clinician to recognise and act if an abnormal unexpected finding is reported, and places a real-time tool to reduce patient safety risks arising from this issue. Through exploration of potential opportunities with the existing RADIS software used in the majority of NHS Wales organisations, the WRP Assessors have identified that there is some limited functionality which can assist with this activity, but reports indicate that this functionality has not been activated due to a lack of consensus on how it should be coded and operated. The NHS Wales Informatics Service (NWIS) has some responsibility for the RADIS systems, although the current model is that each organisation has separate instances of this software operating locally.

It is therefore recommended that as a matter of urgency the NWIS lead for RADIS explores the options and makes a recommendation for an all-Wales solution.

The RADIS solution does not offer a long term solution and a more bespoke intervention will be necessary to provide a more robust assurance against the

risk of failure to act. Whilst recommendations other than an electronic solutions have been made in the past, and there has been attempt at implementing non electronic solutions in many services, the installation of an electronic solution is considered by the study authors to be the only cost-effective measure which will provide an increased assurance in this area of risk. Therefore, a recommendation is made on a national basis that Welsh Government should consider options for an all-Wales electronic flagging and alert tool to support all organisations in managing the human factors risks associated with this issue.

16.03 Consistent protocol - It is recommended that GP practices are encouraged to use the email system 'voting' facility to confirm receipt of formal reports. WRP will report this issue to the Welsh Risk Pool Committee, who may wish to investigate this further to ensure that GP practices, now covered by WRP indemnity, ensure that all reasonable action is taken to minimise the risk of diagnostic results being missed.

16.04 Culture - Audit results presented demonstrated that there can be some misinterpretation between the definition of what should be reported as 'urgent' and that under the 'red star' criteria. It is recommended that clarity and consistence is achieved in this regard and that the process is audited for compliance .

17 Assurance Map

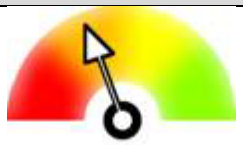
17.01 The Welsh Risk Pool adopts the same assurance tools and terminology as the NHS Wales Internal Audit team – I order to provide consistency and enhanced readability for reports, outcomes and recommendations.

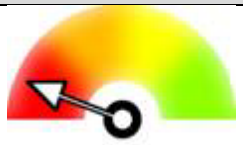
17.02 There a four levels of assurance, which are each linked to related definition and indicator.

RATING	INDICATOR	DEFINITION

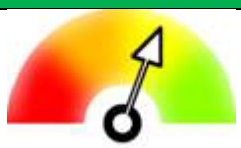
Substantial assurance		The organisation can take **substantial assurance** that arrangements to ensure an appropriate and timely response to diagnostic imaging reports are in place. Few matters require attention and are compliance or advisory in nature with **low impact on residual risk** exposure.

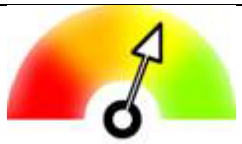
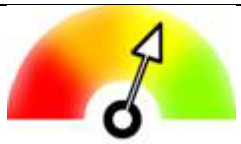
RATING	INDICATOR	DEFINITION
Reasonable assurance		The organisation can take **reasonable** that arrangements to ensure an appropriate and timely response to diagnostic imaging reports are in place. Some matters require management attention in control design or compliance with **low to moderate impact on residual risk** exposure until resolved.

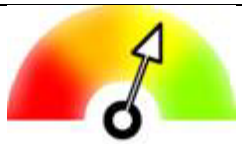
RATING	INDICATOR	DEFINITION
Limited assurance		The organisation can take **limited assurance** that arrangements to ensure an appropriate and timely response to diagnostic imaging reports are in place. More significant matters require management attention with **moderate impact on residual risk** exposure until resolved.

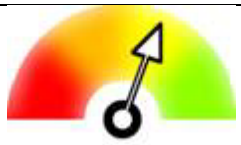
RATING	INDICATOR	DEFINITION
No assurance		The organisation has **no assurance** that arrangements to ensure an appropriate and timely response to diagnostic imaging reports are in place. Action is required to address the whole control framework in this area with **high impact on residual risk** exposure until resolved

17.03 The assurance findings are outlined here and have been separated for each of the two services within the Health Board.

Abnormal unexpected findings are appropriately highlighted to requesting clinicians and acknowledged, with appropriate action taken			
	Morriston Hospital	Princess of Wales Hospital	
Critical/Emergency findings			
	Substantial Assurance	Substantial Assurance	
Urgent or Red Star findings			
	Reasonable Assurance	Reasonable Assurance	

Validation of actions taken by ED in response to red star or other urgent or critical finding			
	Morriston Hospital	Princess of Wales Hospital	
Validation by ED			
	Reasonable Assurance	Reasonable Assurance	

Discrepancy management within radiology services- assurance that issues are highlighted, reviewed and monitored			
	Morriston Hospital	Princess of Wales Hospital	
Discrepancy Monitoring and review			
	Reasonable Assurance	Reasonable Assurance	

Assurance that images can be downloaded, transported or transferred to other clinical centres over the 24/7 period			
	Morriston Hospital	Princess of Wales Hospital	
Transfer, Download and Transportability of Images 24/7			
	Reasonable Assurance	Reasonable Assurance	

18 Acknowledgements

18.01 The Welsh Risk Pool review team wish to thank staff in the Emergency Departments at Radiology Services at Morriston and Princess of Wales Hospitals.

18.02 This draft report is presented to the Health Board for the purposes of factual accuracy checking and to help establish the development of an action plan in response to the findings of the review. Members of the review team

would be very happy to meet with members of the Health Board leadership team to explore this further.

18.03 This draft report is also presented to the RADIS lead within NWIS as a key recommendation rests with this service. Members of the review team would be very happy to meet with the RADIS lead or other NWIS staff to progress the issues highlighted.

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