

NIMIS '<' SYMBOL INCIDENT <u>Final Report</u>

4th January 2018



EXECUTIVE SUMMARY

This is a report on the management of a technical issue on the NIMIS – National Integrated Medical Imaging System – system that was discovered on 24th July 2017. The issue relates to the 'less than' symbol (<) not being transferred from one component of NIMIS to other downstream applications and therefore omitted on the final report. This omission could lead the physician or surgeon who requested the test to make an incorrect decision in the management of the patient's healthcare condition. It was deemed an incident as it had the potential to cause patient harm.

A Safety Incident Management Team (SIMT) was commissioned by the National Director of the Acute Hospital Divison on 28th July 2017 to manage the incident. The management of this incident was done in accordance with the HSE Safety Incident Management Policy (2014) and informed by the HSE Look-Back Review Process (2015).

A total of 24,275 examination reports, across 33 NIMIS sites, were identified as containing the '<' symbol issue. A specific subset of error examination reports (n=273) had no space between the '<' symbol and the next letter which removed the remaining portion of the sentence. All reports were reviewed in a two-step process: i) comparison of a correct examination report with an incorrect examination report, and ii) determination of patient harm as a result of the misleading error examination report

Each affected hospital was delegated responsibility for managing this incident as it related to the error examination reports that occurred under the governance of that hospital. This included the recall of any patient who was potentially harmed. On 23rd August 2017, all affected hospitals were issued with a procedural pack describing the incident, the recommended methodological approach, and the requirements for completion.

Of the 24,275 error examination reports, there were no instances of patient harm. There was one instance of clinical management error whereby a patient did not receive a 12-month follow-up surveillance scan. The patient was recalled and scanned. There were no adverse findings discovered.

It is the understanding of the SIMT that this is the first instance worldwide of a technical issue of this nature that has affected a national imaging management system. Consequently, the main opportunity for learning, as an outcome of this review, is that there are no established quality assurance procedures for the technical issue that related to this incident. Therefore, the main recommendation of this report is that the NIMIS Project Board should devise and implement a quality assurance procedure for the identification, monitoring, and preliminary risk assessment for this technical issue, and those similar to it, in conjunction with relevant stakeholders. Any quality assurance procedure should have clinical input to support decision-making on whether or not to escalate to a review, and have clear communication channels to the sites which may be affected, in accordance with governance and accountability arrangements. Other recommendations include devising and implementing a permanent 'fix' for this technical issue; and evising and implementing a method to correct all error examination reports to display correctly on all NIMIS report viewing platforms.



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GLOSSARY

Term	Definition			
SIMT	Safety Incident Management Team			
NIMIS	National Integrated Medical Imaging System			
NIMIS NT	NIMIS National Team who undertake a national management role for the NIMIS system			
Reporters	Non-radiology examinations, such as vascular and cardiology studies, are authorised by non-radiologists such as Consultant Vascular Surgeons or Consultant Cardiologists. Non-radiologist reporters are described as 'reporters'.			
Attending Consultant	The attending consultant is the primary physician/surgeon, identified in the selected PAS episode/visit, in whose care the patient was under in the episode of care in which the error occurred.			
RIS	Radiology Information System where radiology examinations are requested, vetted, scheduled, and examination reports are stored			
PACS	Picture Archiving and Communication System where images are viewed and stored. Examination reports are also stored on PACS			
VR	Voice Recognition system for dictating the examination.			
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3-Click	A report creation workflow mainly used by non-radiology imaging areas where a report			
PAS	Patient Administration System			
PeerVue	A radiology quality improvement application			
EPR	Electronic Patient Record			
HealthLink	An electronics communications project which facilitates the transfer of information between primary and secondary care in Ireland.			
Vetted	A NIMIS examination request that has been assessed for justification by a Radiologist or other designated user utilising the NIMIS RIS vetting module and an indicative scheduling priority assigned regarding timeline for its performance.			
Index Case	The first identified case in a group of cases related to a particular incident			
Cardiac Investigations	Non-invasive examinations performed by Cardiology e.g. Holter monitoring, blood pressure monitoring and stress electrocardiogram			
Computed Tomography (CT)	Examinations using X-Rays to produce cross sectional images of body organs			
Cardiac Echo	Examinations utilising sound waves to image the heart and demonstrate its function			



DEXA	Dual Emission X-Ray Absorptiometry - Examinations performed to measure patients bone density utilising X-Rays		
Fluoroscopy Screening	Examinations utilising X-Rays showing 'Real time' images of internal organs		
Interventional Radiology	Examinations performed utilising X-Rays to provide minimally invasive imaging and image guided therapeutic procedures		
Multi-Disciplinary Meeting (MDM)	These examinations are to facilitate sites to record when a patient is discussed at a relevant Multidisciplinary Meeting		
Mammography	Examinations utilising X-Rays to provide images of the breast		
Magnetic Resonance Imaging (MRI)	Examinations utilising magnetic fields and radio waves to produce cross sectional images of body organs		
Nuclear Medicine	Examinations performed using a radioactive substance to demonstrate the function of organs and provide treatments		
Obstetrical Ultrasound	Imaging examinations utilising sound waves performed of the foetus during pregnancy		
Positron Emission Tomography	Examinations utilising radioactive substances to demonstrate the function of organs		
Pulmonary Function Investigations	Examinations performed to investigate patients lung function and related respiratory activities		
Sleep Diagnostic Investigations	Examinations performed to investigate patients exhibiting sleep disorders		
Theatre	Examinations performed in the Operating Theatre that require X-Ray real-time guidance e.g. orthopaedic pinning cases		
Ultrasound	Examinations utilising sound waves to image body organs		
Vascular Ultrasound	Examinations utilising sound waves to image and demonstrate function of body blood vessels i.e. arteries and veins		
General Radiography	Plain X-Ray examinations performed utilising Computed Radiography and Digital Radiography technologies e.g. Chest X-Ray		



INTRODUCTION

This is a report on the management of a technical issue on the NIMIS – National Integrated Medical Imaging System – system that was discovered on 24th July 2017. It was deemed an incident as it had the potential to cause patient harm. The incident relates to the 'less than' symbol (<) not being transferred from its creation on the Voice Recognition (VR) component of NIMIS to other downstream applications and therefore being omitted from the final report. This could lead the attending consultant^{*} to recommend the incorrect management of a healthcare condition to a patient and potentially suffer harm as a result of that mismanagement. The management of this incident was undertaken in accordance with the HSE Safety Incident Management Policy (2014) and is informed by the HSE Look-Back Review Process (2015). A 'Look-Back' review should be considered where a number of people have been potentially exposed to a specific hazard in order to identify if any of those persons exposed have been harmed, and to identify necessary steps to ameliorate that harm (HSE 2015). There are three phases to a 'look-back' review – preliminary risk assessment, audit and recall.

BACKGROUND

NIMIS

NIMIS – National Integrated Medical Imaging System – is a national system implemented to facilitate the requesting of medical imaging examinations; and storage and viewing of associated images and reports. NIMIS allows secure, electronic sharing of images and reports between specialists for faster and improved diagnosis. The increasing use of radiology in clinical medicine is of great benefit to patients and clinicians not only through its enhanced diagnostic capability, but also through its ability to treat patients with minimally invasive interventional procedures.

In 2008, the HSE initiated the NIMIS programme and established a project board to oversee its implementation across respective sites. It is currently under the governance of the Acute Hospitals Division. Sligo Regional Hospital was the first site to 'go-live' with the system in June 2011. Letterkenny University Hospital is the most recent site to 'go-live' in September 2017. To date, the NIMIS platform supports approximately 38,000 users on 1,200 medical device workstations in 63 locations. There are over 22 million imaging records stored on the NIMIS system with 10 million migrated from legacy systems.

There are three primary component parts of the system:

- RIS (Radiology Information System)
 - where radiology examinations are requested, vetted, scheduled, progressed and examination reports are stored
- PACS (Picture Archiving and Communication System)
 - o where images are viewed and stored.
 - examination reports are also stored on PACS
- VR (Voice Recognition) System

^{*} The attending consultant is the primary physician/surgeon, identified in the selected PAS episode/visit, in whose care the patient was under in the episode of care in which the error occurred.



o for dictating the examination

Within the NIMIS suite of applications there are a range of system quality assurance checks that have been configured to ensure a high level of data quality across the system. These include:

- Patients must have a Hospital PAS (Patient Administration System) registration before a radiology request can be generated by a doctor
- Only users with appropriate permissions can request a radiology examination via NIMIS
- Radiology examinations are vetted by a Radiologist, or other designated system user, to determine if they are justified as per the Justification Principle under Irish legislation
- Radiographers review the images for an examination as a validation check before they mark the study as reviewed and ready for reporting by Radiologists
- When a Radiologist is creating an examination report utilizing the VR application they view the text of the report before signing it as final. They also have an opportunity to modify the report during a quarantine window of approximately 4 minutes before it achieves final status
- Once a report achieves final status it can only be modify afterwards by creation of a report addendum with the original signed report remaining intact

Incident

The Acute Hospitals Division of the HSE was informed by the Chair of the NIMIS Project Board on 27th July 2017 that there was a technical issue relating to the NIMIS platform that had the potential for patient harm. Specifically, the 'less than' symbol (<) recorded in a component of NIMIS did not transfer to other downstream applications used by attending consultants to read examination reports. This omission could lead the clinician to recommend to the patient an incorrect management of their healthcare condition through a misinterpretation of the diagnosis, and/or guidance for treatment and/or follow up. The incorrect management of the patient's healthcare condition had the potential to cause harm to the patient. No index cases were identified. An index case is the first case in a group of cases related to a particular incident.

For example, where the RIS report is displaying correctly "There is < 50% stenosis noted in the Internal Carotid Artery" this would display incorrectly on the PACS report as "There is 50% stenosis noted in the Internal Carotid Artery". An incorrect recommendation to undergo surgery could have been made to the patient and possibly suffer harm as a consequence of the surgery.

The following NIMIS system components and downstream report viewing platforms were affected by the "<" issue:

- NIMIS PACS
- PeerVue (a radiology quality improvement application)
- NIMIS examination reports printed from Electronic Patient Record (EPR) systems specific to two NIMIS sites. NIMIS Examination reports printed from NIMIS RIS for other NIMIS sites were not affected



- NIMIS examination results electronic feed to GP's via HealthLink system from one NIMIS site. All other NIMIS sites HealthLink feeds were not affected.
- NIMIS examination report feeds to dedicated ICU systems in three NIMIS sites

Immediate Actions

This technical issue was identified by a Consultant Radiologist in Hospital A who notified the NIMIS programme on 24th July 2017. The Acting NIMIS Programme Lead, together with Change Healthcare, began an initial investigation on 25th July 2017 to estimate the number of affected reports, the possible clinical issues, and the reason why the issue occurred. Approximately 25,000 were deemed affected and dated from the beginning of the NIMIS programme in 2011. As a result, this issue was escalated to the Chair of the NIMIS Project Board on 27th July 2017 who convened a cross-divisional telecall. It was agreed that this technical issue should be deemed an incident as there was a potential for patient harm and that a Safety Incident Management Team (SIMT) would be commissioned by the National Director of the Acute Hospitals Division (AHD). All Hospital Group CEOs were informed of this incident on 27th July 2017 as was the Department of Health, through the National Patient Safety Office.

An email correspondence was issued by NIMIS National Team (NT) on 27th July 2017 to all relevant personnel at each NIMIS site, such as Radiography Services Managers, PACS Managers, RIS Managers, and Consultant Radiologists. All NIMIS reporting users were advised to cease utilising the '<' symbol in the creation of NIMIS examination reports. With regard to Voice Recognition (VR) dictation software, an interim 'fix' was developed, tested and installed on all NIMIS work stations on the 28th July 2017 which converted any instances of the '<' symbol into the text "less than" on the outbound interface from the VR application into NIMIS RIS. Tests were run daily to determine if any new instances of this issue occurred in the immediate aftermath and regularly thereafter.

Safety Incident Management Team

The SIMT was tasked with overseeing the overall management of the incident, including a decision to conduct a 'look-back' review. The terms of reference and membership of the SIMT can be found in Appendix 1. The SIMT focussed on the following areas:

Risk Mitigation

The SIMT sought regular updates from NIMIS NT that no new instances of the '<' symbol occurred after the instalment of the interim 'fix'. NIMIS NT would also provide updates as to the progress of a permanent fix.

Communications

The SIMT acted as a focal point for management of all communications relating to this incident, which included

- Developing a comprehensive response to manage patients' concerns.
- Liaising directly with the Irish College of General Practitioners (ICGP) and the Faculty of Radiologists to describe the incident and listen to concerns
- Contacting the Hospital Groups describing the incident and their responsibilities in managing the incident locally.
- Responding to any media queries, using the opportunity to address patients' concerns.



Preliminary Risk Assessment

A total of 24,275 examination reports, across 33 NIMIS sites, since the NIMIS platform inception, were identified as containing the '<' symbol error. This represents 0.24% of all NIMIS reports. No migrated reports from legacy systems were affected. The SIMT, informed by the Faculty of Radiologists, decided that all examination reports which contained the '<' symbol error would require review as although the possibility for harm was low, the potential harm to a patient was significant. No index cases were reported.

The SIMT established a Clinical Sub-Group to analyse the error examination reports and make recommendations on the methodological approach to the audit and recall, if required, which was approved by the SIMT. The terms of reference of the Clinical Sub-Group can be found in Appendix 2

Table 1: Affected Modalities

Modality	Total Error Examination Reports
Ultrasound	6970
DEXA	6830
СТ	3564
Vascular Ultrasound	2312
General Radiography	1878
Cardiac Investigations	919
MRI	797
Interventional Radiology	470
Nuclear Medicine	146
Mammography	112
Obstetrical Ultrasound	96
Sleep Diagnostic Imaging	49
Fluoroscopy Screening	32
Cardiac Echo	29
Pulmonary Function Tests	33
Positron Emission Tomography	20
Multidisciplinary Team Meeting	14
Theatre	4
Grand Total	24275

Chronology

DATE	OCCURRENCE
24 th July 2017	Issue identified in Hospital A by local consultant radiologist. NIMIS National Team (NT) informed
25 th July 2017	Initial Investigation begun by NIMIS NT and Change Healthcare. Issue escalated to NIMIS Project Board Chair.
27 th July 2017	Cross-divisional meeting held. Decision made to deem as incident and commission a Safety Incident Management Team (SIMT)



	All sites issued with correspondence describing the incident and instructions to mitigate risk in short-term				
	SIMT – Meeting 1.				
28th July 2017	Interim 'fix' installed on NIMIS to prevent further occurrences of this error. Daily checks in place to determine any new instances of this error				
	Hospital Group CEOs issued correspondence describing the incident and instructions to mitigate risk in short-term				
	DoH informed of incident				
3 rd August 2017	Urgent Field Safety Notice issued to all users of the affected software and to the Health Products Regulatory Authority by the software providers. An updated Urgent Field Safety Notice was issued on August 17 th 2017 and published by the HPRA at the following URL:				
	http://www.hpra.ie/docs/default-source/field-safety-notices/september- 2017/v32802_fsn.pdf?sfvrsn=2				
23 rd August 2017	All affected sites issued with a procedural pack on how to complete the review.				
24 th August 2017	All affected sites issued with <alpha by="" copy="" courier<="" hard="" reports="" td=""></alpha>				

METHODOLOGY

The aim of this component of the review was to audit all error examination reports to determine if a patient was harmed due to this incident, and if so, to categorise and describe the harm. All reports were to be reviewed in a two-step process: i) comparison of a correct examination report with an incorrect examination report; and ii) determination of patient harm as a result of the misleading error examination report.

Each affected hospital was delegated responsibility for managing this incident as it related to the error examination reports that occurred under the governance of that hospital. This includes the recall of any patient who was potentially harmed. All affected hospitals were issued with a procedural pack describing the incident, the recommended methodological approach and the requirements for completion on 23rd August 2017 (Appendix 3). There are two different but similar methodologies to audit the error examination reports – Methodology A and Methodology B. Technical and methodological support was offered by NIMIS NT and the SIMT chair.

Methodology A:

Step 1:

Electronic Comparison Tool:

Radiologists/reporters[†] completed this step using a bespoke electronic tool that displayed the correct examination report and the incorrect examination report 'side-by-side'. Radiologists/reporters could then select 'No Significance' or 'Refer for Clinical Impact'.

[†] Non-radiology examination reports, such as vascular and cardiology studies, are authorised by nonradiologists such as Consultant Vascular Surgeons or Consultant Cardiologists. Non-radiologist reporters are described as 'reporters'.



Radiologist/reporters could also complete this step by a letter of exclusion if they were satisfied that these reports would not affect the diagnosis and/or guidance for treatment and/or followup. There were 24,002 error examination reports to be completed on the electronic comparison tool.

<u>3-Click:</u>

There was a particular sub-set of error examination reports identified called "3-Click" examination reports which is a report creation workflow mainly used by non-radiology imaging areas. These reports displayed correctly on the electronic comparison tool as the '<' symbol displayed correctly on RIS, PACS, printed reports, and Healthlink but not on other downstream applications. Sites were contacted directly to explain this and guide them in their completion. There were 3,823 "3-Click" reports.

Findings: Step 1

All of the 24,002 error examination reports for review in Step 1 were completed. This comprised 15,929 on the electronic comparison tool and 8,073 by letter of exclusion. There were 63 reports deemed 'Refer for Clinical Impact'.

Step 2:

On completion of Step 1, all error examination reports deemed 'Refer for Clinical Impact' were forwarded to each affected NIMIS site for review by the attending consultant to determine if the patient was harmed as a result of incorrect management of the patients' healthcare condition due to this error. Any harm was categorised based on the Impact Table of the HSE Risk Assessment Tool. Please see Step 2 in Appendix 3 for further details. The attending consultant could recall patients to determine if there was any harm as a result of this error.

Findings: Step 2

Of the 24,002 error examination reports reviewed, 63 (0.26%) were deemed 'Refer for Clinical Impact' across ten NIMIS sites. There were no instances of harm or clinical management error as a result of the omission of the '<' symbol in downstream reports.

Methodology B

<Alpha:

A specific subset of error examinations reports (<alpha) – where there was no space between the '<' symbol and the next letter and the remaining sentence was removed from the report could not be included in the side-by-side electronic tool. These error examination reports were required to be completed in hard copy by the radiologist/reporter in the first instance, and then by the attending consultant if the error examination report was deemed 'Refer for Clinical Impact'. All NIMIS system and downstream report viewing applications were affected by this issue. There were 273 <alpha error examination reports. Each hospital was issued with their hard copies by courier on 24th August 2017.

Findings: <Alpha

All 273 error examination reports were reviewed and all data collection tools were returned by each affected hospital. There were no instances of harm and one instance of clinical management error.



Table 2: Findings

Hospital	Total Error Examination Reports	Not Significant	Refer for Clinical Impact	Not Harmful	Harmful
Beaumont Hospital	4048	4048			
Cappagh National Orthopaedic Hospital	3	3			
Cavan - Monaghan General Hospitals	1411	1411			
Connolly Hospital Blanchardstown	614	610	4	4	0
Coombe Women's & Infants University Hospital	1988	1988			
Our Lady's Children's Hospital, Crumlin	246	246			
Our Lady of Lourdes Hospital Drogheda	783	781	2	2	0
Ennis Hospital	43	43			
St. John's Hospital	25	25			
University Hospital Kerry	663	663			
University Hospital, Limerick	1522	1519	3	3	0
Louth County Hospital	13	13			
Mater Misericordiae University Hospital	3899	3894	5	5	0
Mayo University Hospital	141	140	1	1	0
Midland Regional Hospital Mullingar	2908	2908			
Naas General Hospital	12	12			
Our Lady's Hospital Navan	219	216	3	3	0
Nenagh Hospital	34	34			
National Rehabilitation Hospital	3	3			
Portiuncula University Hospital	260	260			
Midland Regional Hospital Portlaoise	528	527	1	1	0
Rotunda Hospital	31	31			
Royal Victoria Eye and Ear Hospital	7	7			
South Infirmary/Victoria University Hospital Cork	45	45			
St. James's Hospital	1875	1875			
Sligo University Hospital	664	664			
St. Columcille's Hospital	48	48			
St Luke's Hospital Kilkenny	269	266	3	3	0
St. Luke's Radiation Oncology Network	15	15			
South Tipperary General Hospital	134	134			
AMNCH, Tallaght	923	918	5	5	0
Midland Regional Hospital Tullamore	42	42			
University Hospital Waterford	501	465	36	36	0
Wexford General Hospital	358	358			
Grand Total	24275	24212	63	63	0

Recall Stage

If a patient had been harmed, or potentially harmed, as a result of this error, then the patient must be recalled. Of primary importance was that the patient received a correct diagnosis; further investigations, if required; and commenced on the correct management plan as soon as possible. Each hospital was responsible for the recall stage of the review. Hospitals were offered guidance in the 'Communication Plan' of the procedural pack and were also advised



to follow Section 7.8 of the *Guideline for the Implementation of a Look-Back Review Process in the HSE* (2015). All instances of patient harm were to be logged on the National Incident Management System (NIMS) by the hospital, as per HSE Safety Incident Management Policy (2014), or local equivalent policy.

PATIENT OUTCOME

Of all 24,275 error examination reports reviewed there were no instances of patient harm as a result of the omission of the '<' symbol in downstream reports. There was one (n=1) instance of error in the clinical management of a patient as a result of the omission of the '<' symbol from an examination report in the '<alpha' subset of error examination reports. This patient was recalled and scanned. There were no adverse findings discovered.

LEARNING POINT

It is the understanding of the SIMT that this is the first worldwide instance of a technical issue of this nature that has affected a national imaging management system which has the potential to cause patient harm. Consequently, there are no established quality assurance procedures currently in place within the HSE for the type of error, or similar, that occurred in this incident. There is now an opportunity to learn from this review. In particular, identification of the type and number of possible technical issues which could affect NIMIS and its component and third-party applications and its impact on patient safety; methods to monitor the potential impact on patients and clinical business processes from those technical issues; development of procedures for preliminary risk assessment; and decision-making processes to escalate, or not, to a review. Any quality assurance procedure should have clinical input to support decision making on whether or not to escalate to a review, and have clear communication channels to the sites that may be affected, in accordance with governance and accountability arrangements. Such learning would seek to build upon and link with current established regulatory practices related to monitoring of certified medical devices.

The methodological approach developed during this review, in consultation and partnership with the Faculty of Radiology, can serve as a template and learning opportunity for future radiology related reviews or incidents. The health service must carefully evaluate the degree of risk whenever such errors are uncovered and decide on the appropriateness of progressing to a fuller review. This particular review demonstrates that in the area of radiology, where a technical error was present for a significant period of time, any risk associated with the error was offset by the availability of additional clinical information on the patient's condition and by the judgement of the consultant reviewing the report in a wider clinical context. This judgement comes into play particularly when decisions of significant consequence face the clinician and it is clear that the radiology report alone is but one component of the process of decision-making

CONCLUSION

This review is now complete. There were no instances of patient harm as a result of this error. This review should inform any future incident relating to a diagnostic imaging technical issue.



RECOMMENDATIONS

- The NIMIS Project Board should devise and implement a quality assurance procedure for the technical issue, or similar, that caused this incident in conjunction with relevant stakeholders.
- The NIMIS Project Board should devise and implement a permanent software 'fix' for the technical issue that caused this incident in conjunction with relevant stakeholders.
- The NIMIS Project Board should devise and implement a method to correct all error examination reports to display correctly on all NIMIS report viewing platforms in conjunction with relevant stakeholders.



ACKNOWLEDGEMENT

The HSE wishes to acknowledge any undue concern or upset that resulted from this incident.

The HSE would also like to acknowledge the time, effort and support of the many stakeholders who worked together to identify the presence of any harm to a patient as a result of this error. In particular, we acknowledge the frontline staff, such as administrative staff, PACS and RIS Managers, QPS Advisors, Radiologists (including Consultant A who first identified this issue), other reporting clinicians, and attending consultants, who coordinated and completed the investigation locally. We acknowledge the NIMIS National Team for their expert knowledge the software service provider, Change Healthcare, for their technical support throughout the process. Also, we acknowledge the hospital management and Clinical Directors for their timely and efficient cooperation and diligence in bringing this issue to a close. Finally, we acknowledge the National Clinical Programme for Radiology and Faculty of Radiology for their clinical expertise, and for their collaboration with the SIMT throughout the investigation.

REFERENCES

Guideline for the Implementation of a Look Back Review Process in the HSE 2015

HSE Safety Incident Management Policy 2014



APPENDICES

Appendix I SIMT Terms of Reference

Terms of Reference

Safety Incident Management Team (SIMT)

Introduction

On 24thJuly 2017, a potential patient safety issue was identified and reported to AHD on 27th July regarding clinical reporting on outboard reports and interfaces within the National Integrated Medical Imaging System (NIMIS) across the healthcare system. This issue is under investigation by Change Healthcare and the NIMIS National Team.

Purpose

- 1. Oversee the overall management of the incident
- 2. Ensure appropriate investigation/review of the incident is conducted as per HSE Incident Management Polices & Guidelines
- 3. Facilitate sourcing of experts as deemed necessary as per HSE Incident Management Polices & Guidelines
- 4. Managing communications with relevant stakeholders as required

Membership

Ms. Margaret Brennan (Chair)	Assistant National Director, AHD, HSE
Dr. Colm Henry	National Clinical Advisor and Group Lead, AHD, HSE
Dr. Peter Kavanagh	National Clinical Programme for Radiology, Clinical Lead
Dr. Ciaran Brown	General Manager, AHD, HSE
Mr. Keith Morrissey	Acting NIMIS Programme Lead
Ms. Ann Martin	Communications, HSE
Ms. Mary Donnellan-O'Brien	General Manager, Diagnostics Directorate, UHL
Mr. Fran Thompson	Assistant National Director, OCIO, HSE
Ms. Deirdre Carey	Risk & Incident Officer, AHD, HSE



Appendix 2 Clinical Sub-Group Terms of Reference

Terms of Reference

Safety Incident Management Team - Clinical Sub-Group

Introduction

The HSE has identified technical issues with clinical reporting within the NIMIS solution which has potential patient safety implications. Specifically, the "<" symbol is not being passed to outbound reports and interfaces.

This is the terms of reference for an investigation sub-group of the Safety Incident Management Team convened to coordinate the response to this potential patient safety issue.

Purpose

The purpose of the sub-group is to

- Recommend to the SIMT for approval, a methodology for a 'look-back' at the affected reports to determine level of potential patient harm. This will include all requirements needed to complete the review of reports and recall of patients as required.
- Coordinate the review of the reports and recall; collate and analyse the findings; and present a report to the SIMT.

Membership

Dr. Colm Henry	National Clinical Advisor and Group Lead, AHD, HSE
Dr. Peter Kavanagh	National Clinical Programme for Radiology, Clinical Lead
Mr. Gareth Clifford	Quality Standards & Compliance Office, AHD, HSE



Appendix 3 Procedural Pack

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NIMIS '<' SYMBOL ISSUE

HSE Safety Incident Management Team: Recommended Approach to Review of all Incidents Relating to this Error

Safety Incident Management Team

- Ms. Margaret Brennan (Chair); Assistant National Director, AHD, HSE
- Dr. Colm Henry; National Clinical Advisor and Group Lead, AHD, HSE
- Dr. Peter Kavanagh; National Clinical Programme for Radiology, Clinical Lead
- Dr. Ciaran Browne; General Manager, AHD, HSE
- Mr. Keith Morrissey; Acting NIMIS Programme Lead
- Ms. Ann Martin; Communications, HSE
- Ms. Mary Donnellan-O'Brien; General Manager, Diagnostics Directorate, UHL
- Mr. Fran Thompson; Assistant National Director, OCIO, HSE
- Ms. Deirdre Carey; Risk & Incident Officer, AHD, HSE

Clinical Sub-Group

- Dr. Colm Henry; National Clinical Advisor and Group Lead, AHD, HSE
- Dr. Peter Kavanagh; National Clinical Programme for Radiology, Clinical Lead
- Mr. Gareth Clifford; Quality Standards & Compliance Officer, AHD, HSE



NIMIS '<' SYMBOL ISSUE: REVIEW METHODOLOGY

The aim of this review is to determine if a patient was harmed due to an incorrect clinical management decision of the patient by the 'attending' clinician^{*} due to this technical error.

There are two different, but similar, methodologies recommended to address two specific issues identified by the HSE in relation to the '<' symbol.

- A) The '<' symbol is omitted, and therefore not visible when a report is viewed electronically within PACS - though the '<' is visible on the original report. There are 24,002 reports affected by this issue across 33 different NIMIS sites. Please see Methodology A.
- B) When a report contains a '<' symbol which is immediately followed by text (i.e. no space between '<' and the next letter - '<alpha') then the remainder of the sentence is omitted. There are 273 reports affected by this issue across 29 different NIMIS sites. Please see Methodology B.

Methodology A

Data

The dataset for your hospital can be found on NIMIS Report File. Please see the Report File Spreadsheet, which was sent with this document, for the link to your data. Each dataset will have the following worksheets:

- Complete Raw Dataset
- **Pivot Table**
- Breakdown by Modality
- Breakdown by Examination Type
- Breakdown by 'Signer'[†]
- Breakdown by Patient Class
- Breakdown by Attending Clinician

Approach to Review

All error examination reports will be reviewed to determine the potential for patient harm. Each of the affected hospitals will be sent a dataset of their error examination reports categorised by modality, examination type, 'signer', patient class, and attending clinician.

 $^{^{*}}$ The attending clinician (a NIMIS nomenclature) is the primary physician/surgeon in whose care the patient was under in the episode of care in which the error occurred.

[†] A 'signer' is the radiologist/reporter who authorises an examination report.



The Consultant Radiologists, and the departments responsible for reporting of non-radiological examination types, of each hospital can decide to exclude from the review one or more examination types or reports based on 'signer'. The radiologist/reporter must be satisfied that the omission of the '<' symbol in those reports does not change the diagnostic information conveyed to the attending clinician and does not alter the guidance for treatment given to the attending clinician.

If there is a decision to exclude a number of examination types and/or exclude reports based on 'signer' this must be confirmed in writing to the SIMT, signed by the Lead Consultant Radiologist/Clinical Director of Radiology (Appendix 1), or Clinical Director for the department responsible for reporting of non-radiological types (Appendix 2).

Review Process

The review will be a two-step process.

- Comparison of master reports with exported reports
- Determination of patient harm as a result of misleading error reports

Step 1

All hospitals will be sent a dataset with a breakdown of their affected reports. The Hospital CEOs/General Managers are responsible for ensuring that appropriately trained radiologists/reporters are available.

Radiologists/reporters are encouraged to review this breakdown to determine if there are any error examination reports that may be excluded from the side-by-side review, based on examination type and/or reports based on 'signer', as described above.

Of the remaining error examination reports to be reviewed, an electronic tool for side-by-side comparison of reports has been installed on your workstations. The '<' symbol is highlighted in the master report for ease of identification. The electronic tool will be able to filter by modality, examination type and 'signer'. A guidance document on the tool has been developed radiologist/reporters to use (a document entitled 'Report Comparison Utility' has been sent along with this document).

The Lead Consultant Radiologist will nominate radiologists to review error examination reports. Speciality radiology examination type lists (e.g. US Hip Dynamic) should preferably be reviewed by the original signer, or if that is not possible, by another Radiologist in the Department with similar expertise.

Non-radiology examination type lists (e.g. VUS Carotid Vertebral Arteries, PFT Overnight Oximetry, and CI Holter Monitor) should be reviewed by the original 'signer' or if that is not possible, by another reporter in that department with similar expertise. Non-radiological examination reports are not under the governance of the radiology department.



On reviewing the master report and exported report side-by-side, the radiologist/reporter will decide if the error was '*Not Significant*' or '*Refer for Clinical Impact*', and select the corresponding button on the same 'side-by-side' page. The next report will then come onto the screen.

Change Healthcare will automatically collect this data, and will collate and forward it daily to the SIMT.

Step 2

Once Step 1 of the review is complete, all error examination reports deemed '*Refer for Clinical Impact*' need to be reviewed by the attending clinician to determine if there was any patient harm as a result of this error.

To facilitate this process, Change Healthcare will

- Print the correct master copy and incorrect error copy
- Highlight the '<' symbol
- Sort by attending clinician and then alphabetically by patient name (Surname, First Name).
- Print Data Collection Tool A (Appendix 3)
- Print Header Letter
- Staple
- Deliver to all hospital CEOs/General Managers by courier

The attending clinician will need to review the error examination report and correct examination report, together with the patient's healthcare record. The hospital is responsible for ensuring that each of these patients' healthcare record is available for the attending clinician.

The attending clinician will need to decide if there was any patient harm as a result of this error. The attending clinician may wish to recall the patient to determine if there was any harm as a result of this error. Please see 'Recall Stage' below.

- If there was no harm, the no further action is required.
- If there was harm as a result of the error, the attending clinician is to:
 - Describe the incorrect management/plan of care; and
 - o Categorise it as Wrong Treatment, Under Treatment, or Over-Treatment
 - Describe the harm; and
 - \circ $\;$ Categorise it as Negligible, Minor, Moderate, Major or Extreme
 - Categorisation must be based on the Impact Table (Injury) of the <u>HSE Risk</u> <u>Assessment Tool</u>. The hospital's QPS Advisor will support the attending clinician in determining the category of harm.

Data Collection Tool A should be completed, and signed, by the attending clinician. Hospitals are required to send all Data Collection Tools back to this office by courier.

When the complete 'look-back' process is completed, the hospitals should shred both the correct and incorrect examination reports.





<u>Recall Stage</u>

If a patient has been harmed as a result of this error, or if there is a potential that harm has occurred, then the patient must be recalled. Please note that this review uses the 'Look-Back' definition of 'Recall Stage'. This does **not** mean that all patients who are recalled will require repeat radiological/non-radiological examinations. This will be at the discretion of the attending clinician. Of primary importance is that the patient receives a correct diagnosis; further investigations, if required; and commenced on the correct management plan as soon as possible.

Please find guidance in the 'Communication Plan' below. Hospitals are also advised to follow Section 7.8 of the *Guideline for the Implementation of a Look-Back Review Process in the HSE* (2015).

All instances of patient harm must be logged on the National Incident Management System (NIMS) by the hospital, as per HSE Safety Incident Management Policy (2014), or local equivalent policy.

Methodology B

These reports are treated differently as they cannot be compared electronically and must be reviewed in hard copy. All affected hospitals will be sent these reports in hard copy by courier.

<u>Data</u>

The dataset for your hospital can be found on NIMIS Report File. Please see the Report File Spreadsheet, which was sent with this document, for the link to your data. Each dataset will have the following worksheets:

- Complete Raw Dataset
- Pivot Table
- Breakdown by Modality
- Breakdown by Examination Type
- Breakdown by 'Signer'[‡]
- Breakdown by Patient Class
- Breakdown by Attending Clinician[§]

Approach to Review

All error examination reports must be reviewed to determine the potential for patient harm. Each of the affected hospitals will be sent a dataset of their error examination reports categorised by modality, examination type, 'signer', patient class, and attending clinician.

^{*} A 'signer' is the radiologist/reporter who authorises an examination report.

[§] The attending clinician (a NIMIS nomenclature) is the primary physician/surgeon in whose care the patient was under in the episode of care in which the error occurred.



Review Process

The review will be a two-step process.

- Comparison of master reports with exported reports
- Determination of patient harm as a result of misleading error reports

Step 1

All hospitals will be sent a dataset with a breakdown of their affected reports. The Hospital CEOs/General Managers are responsible for ensuring that appropriately trained radiologists/reporters are available.

Change Healthcare will

- Print the correct master copy and incorrect error copy
- Highlight the '<' symbol
- Sort by attending clinician and then alphabetically by patient name (Surname, First Name).
- Print Data Collection Tool B (Appendix 4)
- Print Header Letter
- Staple
- Deliver to all hospital CEOs/General Managers by courier

The Lead Consultant Radiologist will nominate radiologists to review error examination reports. Speciality radiology examination type lists (e.g. US Hip Dynamic) should preferably be reviewed by the original signer, or if that is not possible, by another Radiologist in the Department with similar expertise.

Non-radiology examination type lists (e.g. VUS Carotid Vertebral Arteries, PFT Overnight Oximetry, and CI Holter Monitor) should be reviewed by the original 'signer' or if that is not possible, by another reporter in that department with similar expertise. Non-radiological examination reports are not under the governance of the radiology department.

On reviewing the master report and exported report side-by-side, the radiologist/reporter will decide if the error was '*Not Significant*' or '*Refer for Clinical Impact*'. The radiologist/reporter is required to complete the first part of Data Collection Tool B.

STEP 2

Once Step 1 of the review is complete, all error examination reports deemed '*Refer for Clinical Impact*' need to be reviewed by the attending clinician to determine if there was any patient harm as a result of this error.



The attending clinician will need to review the error examination report and correct examination report, together with the patient's healthcare record. The hospital is responsible for ensuring that each of these patients' healthcare record is available for the attending clinician.

The attending clinician will need to decide if there was any patient harm as a result of this error. The attending clinician may wish to recall the patient to determine if there was any harm as a result of this error. Please see 'Recall Stage' below.

- If there was no harm, the no further action is required.
- If there was harm as a result of the error, the attending clinician is to:
 - \circ $\;$ Describe the incorrect management/plan of care; and
 - o Categorise it as Wrong Treatment, Under Treatment, or Over-Treatment
 - Describe the harm; and
 - o Categorise it as Negligible, Minor, Moderate, Major or Extreme
 - Categorisation must be based on the Impact Table (Injury) of the <u>HSE Risk</u> <u>Assessment Tool</u>. The hospital's QPS Advisor will support the attending clinician in determining the category of harm.

Data Collection Tool B should be completed, and signed, by the attending clinician. Hospitals are required to send all Data Collection Tools back to this office by courier.

When the complete 'look-back' process is completed, the hospitals should shred both the correct and incorrect examination reports.

<u>Recall Stage</u>

If a patient has been harmed as a result of this error, or if there is a potential that harm has occurred, then the patient must be recalled. Please note that this review uses the 'Look-Back' definition of 'Recall Stage'. This does **not** mean that all patients who are recalled will require repeat radiological/non-radiological examinations. This will be at the discretion of the attending clinician. Of primary importance is that the patient receives a correct diagnosis; further investigations, if required; and commenced on the correct management plan as soon as possible.

Please find guidance in the 'Communication Plan' below. Hospitals are also advised to follow Section 7.8 of the *Guideline for the Implementation of a Look-Back Review Process in the HSE* (2015).

All instances of patient harm must be logged on the National Incident Management System (NIMS) by the hospital, as per HSE Safety Incident Management Policy (2014), or local equivalent policy.

TIMELINE FOR COMPLETION

Data Collection Tools (A & B) must be returned to the SIMT by 29th September 2017

A preliminary report will be completed and submitted to the SIMT by 10th October 2017

The final report will be submitted to the SIMT by 27th October 2017



NIMIS '<' SYMBOL ISSUE: INFORMATION GOVERNANCE PROTOCOL

Introduction

As healthcare professionals we are often privy to personal, confidential, and in many instances, extremely sensitive information. To work successfully, we need to be able to gather, obtain and share this information with those of us who really need to know.

As custodians of personal information each of us has responsibilities. Most notably, we must make every effort to keep personal information confidential and secure. The principles of confidentiality and data protection are part of our legal and ethical duties. Although, certain information is considered especially sensitive, all information about someone's health and the care they are given must be treated with regard to confidentiality at all times.

The aim of this protocol is to ensure all staff working on the NIMIS '<' symbol issue are aware of their responsibilities with regard to good Information Governance. Engagement with Change Healthcare is through the NIMIS programme, HSE

Why do we need Information Governance?

Information Governance provides a framework for handling information in a confidential and secure manner to appropriate ethical and quality standards. We need information to assist us in managing this incident. We must manage this information securely, efficiently and effectively, so we need a suitable policy to create a solid governance framework for how we handle the information we need to collect.

Good Information Governance will help patients:

- To be more confident in how the HSE handles their information.
- Be sure that information about them will only be shared with those who need to know
- Share information so they receive the best service and care.

Confidentiality

Information, especially if patient specific gained through work on the NIMIS '<' symbol issue, is strictly confidential <u>and must not be discussed with any third party that is unauthorised to receive</u> <u>the information</u>.

- All Media Communications must filter through the HSE nominated spokesperson.
- All management documentation related to the NIMIS '<' symbol issue is to be stored in one file location. This includes agendas, minutes, communications, briefings and any other suite of information that could be requested under Freedom of Information.
- All personal information related to the incident must be locked away when not personally attended. Care should be taken to ensure that documentation related to the incident is not placed in any public place or where it may be viewed or accessed by an inappropriate person





who has no need to be privy to this information. Always lock your laptop/computer when you have to leave it unattended. This will prevent unauthorised persons from viewing your private or confidential data. To lock your laptop/computer – you can press the *Ctrl, Alt* and *Delete* keys together and select *Lock Computer*.

- Any documentation from the incident containing personal information should be sent under confidential cover by courier only and the contents should be similarly labelled as confidential. Letters to individual patients regarding scheduled appointments can be sent under normal post but every effort must be made to ensure that the patient address is correct and that the patient has not deceased.
- Only use HSE approved encrypted USB memory sticks.
- At a minimum, all electronic files related to this incident must be password protected and/or encrypted using HSE approved content encryption software (if available on your PC) when transmitting via e-mail.
- Care and vigilance are required at all times in the management of the incident database of files and patients to be reviewed / recalled. These should be password protected. Regular updating of the databases is essential to ensure accurate and timely information to inform the local safety incident management team, or equivalent.

Follow links for further guidance on: HSE ICT Policies http://hsenet.hse.ie/CIO/Policies and Procedures/ HSE ICT Security Standards http://hsenet.hse.ie/CIO/Security and Standards/Security/ HSE Data Protection http://www.hse.ie/eng/services/list/3/hospitals/ulh/staff/resources/pppgs/dp/DPstaff guide.pdf

Data Collation Tool

Patient/service user's personal information must be treated in the strictest confidence. Patient personal information may be entered on to the data collation tool if access to the data collation tool is strictly limited to the healthcare team who would ordinarily have the right to access the patient/service user's personal information as part of the delivery of healthcare.

Electronic means of sending and storing information

The use of electronic means for sending and storing this information must be done in compliance with the Health Service Executive's Information & Communication Technology Policies for the use of Information Technology (I.T.) Resources.

Sensitive documentation should not be transmitted via email, where possible. If it is deemed absolutely necessary to use email the following guidance is recommended:

- Sensitive and confidential information should only be sent to an email address which ends in: @hse.ie (or for HSE funded services, this information should only be sent within the



organisation's internal email structure).

- In exceptional circumstances where it is necessary to send sensitive and confidential documents to an email address that is not within the HSE domain, the documents must be encrypted. The transfer of such information outside of the HSE domain must be authorised by a HSE line manager (at Grade 8 level or above).
- Emails containing sensitive information should be tracked and monitored.
- Emails should be addressed to named individuals and should not be copied or accessed by an authorised recipients' support staff or personal assistant.
- Recipients should be asked to confirm secure receipt of sensitive and confidential information sent via email, as advised in the HSE Electronic Communications Policy. Passwords should not be communicated to recipients via the same medium used to send the confidential and sensitive information. Passwords should comply with the HSE Passwords Standards Policy.
- It is preferable for passwords to be communicated via a personal telephone call to the authorised recipient.

In particular the following HSE National policies are most relevant to electronically held and transmitted information:

- Information Security Policy
 <u>http://hsenet.hse.ie/HSE_Central/Commercial_and_Support_Services/ICT/Policies</u>
 <u>and_Procedures/Policies/HSE_I_T_Security_Policy.pdf</u>
- I.T. Acceptable Usage Policy
 <u>http://hsenet.hse.ie/HSE_Central/Commercial_and_Support_Services/ICT/Policies</u>
 <u>and_Procedures/Policies/HSE_I_T_Acceptable_Use_Policy.pdf</u>
- Electronic Communications Policy
 <u>http://hsenet.hse.ie/HSE_Central/Commercial_and_Support_Services/ICT/Policies</u>
 <u>and_Procedures/Policies/HSE_Electronic_Communications_Policy.pdf</u>
- Encryption Policy
 <u>http://hsenet.hse.ie/HSE_Central/Commercial_and_Support_Services/ICT/Policies</u>
 <u>and_Procedures/Policies/HSE_Encryption_Policy.pdf</u>
- Password Standard Policy <u>http://hsenet.hse.ie/HSE_Central/Commercial_and_Support_Services/ICT/Policies_and_Procedures/Policies/HSE_Password_Policy.pdf</u>

In summary, the information gathered as part of a Look-back Review Process should not be held outside of HSE offices and must be adequately protected and stored while in the possession of the HSE.



NIMIS '<' SYMBOL ISSUE: COMMUNICATION PLAN

A Look-back Review Process is implemented as a matter of urgency where a number of people have potentially been exposed to a specific hazard in order to identify if any of those exposed have been harmed^{**} and to identify the necessary steps to ameliorate the harm. There are a number of reasons for considering a Look-back Review Process one of which includes the following: equipment found to be defective in a manner that may have put people at risk of harm.

If a patient has been harmed as a result of this error, or if there is a potential that harm has occurred, then the patient must be recalled. Please use the below guidance. Hospitals are also advised to follow Section 7.8 of the *Guideline for the Implementation of a Look-Back Review Process in the HSE* (2015).

Communicating with patients

In most instances, the patients for inclusion in the review/recall of the Look-back Review Process should be notified by letter, signed by a named senior member of staff and preferably the lead clinician. However, in incidents involving smaller numbers (or for particular subgroups of those being included for review / recall stage) telephone or face to face contact may be appropriate, written information should also be provided in such circumstances.

Where potentially serious adverse outcomes are suspected, or the team suspects that a person affected may be in a vulnerable state, the GP for the person affected should be consulted regarding how best to communicate with the person affected. In exceptional circumstances it may be appropriate to communicate with the person affected via their GP or next of kin. This will be determined by the local Safety Incident Management Team, or equivalent, on a case by case basis.

See sample letters as follows:

- Letter to all persons affected who are to be included in the Look-back Review Process (Appendix 5)
- Letter to General Practitioners/other referrers to the service (Appendix 6)

Special attention should be given to the interdependent timing of communications to persons affected and possible media communications.

The principle behind all communication should be to balance reassurance with absolute disclosure.

Letters should be sent in an envelope marked *Private and Confidential -To be opened by addressee* only and *If undelivered return to a designated PO Box number*. It is not advisable to use registered post as this may increase the likelihood of mail not being delivered in a timely manner (due to requirement for the recipient to sign for receipt of mail). The letter should provide the persons

^{**} Harm to a person: Any physical or psychological injury or damage to the health of a person, including both temporary and permanent injury





affected with the option to indicate if they do not wish to be included as part of the Look-back Review Process.

The replies should be recorded on the data collation tool so that people do not receive unwelcome further information. Their details should be carefully segregated and highlighted on the data collation tool.

Depending on the scope of the Look-back Review Process, the service may need to identify vulnerable groups, those without capacity, minors, parents who are minors etc., in order to ensure that appropriate contact is made and support is provided in relation to their inclusion in the Look-back Review process. At all times the principles of the HSE Consent Policy must be adhered to. Every reasonable effort should be made to contact all persons affected identified for inclusion in the Recall stage. People may have moved out of the area, or moved abroad.



Appendix 1. Letter from Hospital - Radiological

Dear Ms. Brennan,

The Department of Radiology in XXXXX hospital has completed its initial review of the entire sample of affected error examinations reports for this hospital sent to us by the Safety Incident Management Team. The department is aware this review is not due to an issue of competence on the part of any radiologist but rather a technical issue on NIMIS which may have the potential for patient harm.

The Department of Radiology has determined that the below examination report type(s) and reports signed by radiologist(s)

Does NOT change the diagnostic information conveyed to the attending clinician
 Does NOT alter guidance for treatment

Excluded Examination Type

- (List examination type(s) here)

Excluded Reports Signed by Radiologist

- (List radiologist(s) here)

(NOTE: You may also print the entire list of excluded examinations types and/or reports signed by radiologists from the Data Extract sent to you on NIMIS. Please countersign each page. Thank you)

Print Name

Signature

Medical Council Number

Consultant Radiologist Department of Radiology Lead



Appendix 2. Letter from Hospital – Non-Radiological

Dear Ms. Brennan,

The Department of XXXXX in XXXXX hospital has completed its initial review of the entire sample of affected error examinations reports for this hospital sent to us by the Safety Incident Management Team. The department is aware this review is not due to an issue of competence on the part of any reporters but rather a technical issue on NIMIS which may have the potential for patient harm.

The Department of XXXXX has determined that the below examination report type(s) and reports signed by reporters(s) under their clinical governance.

- Does NOT change the diagnostic information conveyed to the attending clinician
- Does NOT alter guidance for treatment

Excluded Examination Type

- (List examination type(s) here)

Excluded Reports Signed by Radiologist

- (List radiologist(s) here)

(NOTE: You may also print the entire list of excluded examinations types and/or reports signed by radiologists from the Data Extract sent to you on NIMIS. Please countersign each page. Thank you)

Print Name

Signature

Medical Council Number

Clinical Director



Appendix 3. Data Collection Tool A

NIMIS '<' Symbol Issue Data Collection Tool

NB: To be completed by the Physician/Surgeon in whose care the patient was under during the episode of care where the error occurred.

PATIENT DETAILS

Patient Name: Prepopulated by CH	Patient MRN: Prepopulated by CH	
Patient DOB: Prepopulated by CH	Accession No.: Prepopulated by CH	
Modality: Prepopulated by CH	Examination Type: Prepopulated by CH	
Date of Examination: Prepopulated by CH	Hospital Site: Prepopulated by CH	

		Yes Vo	•	
If no, please con	npl <mark>ete your d</mark> eta	ils below. If yes	, please comple	te th <mark>e following:</mark>
Categorise the in	ncorrect manag	ement / plan of care	:	
Wrong Treatmen	nt 🖸	Under Treatment	2	Over Treatment
Categorise* the	harm that occur	red:		
Categorise* the Negligible 🛯	harm that occur Minor 🗖	red: Moderate 🖬	Major 🗖	Extreme 🛛
Categorise* the Negligible 🗖 "Harm is based on th	harm that occur Minor 🗖 te Impoct Table (Inju	red: Moderate 🗆 ry) of the HSE Risk Assessme	Major 🗖	Extreme 🗖
Categorise* the Negligible 🖬 "Harm is based on th Describe the har	harm that occur Minor 🖬 re Import Table (Inju rm that occurred	red: Moderate 🖬 ny) of the HSE Risk Assessme i:	Major 🗖	Extreme
Categorise* the Negligible 🖬 "Harm is based on th Describe the har	harm that occur Minor me Impoct Table (Inju rm that occurred	redi: Moderate 🖬 ny) of the HSE Risk Assessme 1:	Major 🖬 ent Tool	Extreme 🛛

PHYSICIAN/SURGEON DETAILS

Name:	Signature:	
Date:	Medical Council Number:	

For Office Use: Data Collection Tool A



Appendix 4. Data Collection Tool B

NIMIS '<' Symbol Issue Data Collection Tool

NB: To be completed by the Radiologist/Reporter: Who should determine if the error has 'No Significance' or should 'Refer for Clinical Impact'

If 'Refer for Clinical Impact' the remainder of the tool should be completed by the Physician/Surgeon in whose care the patient was under during the episode of care where the error occurred

C P		 -	1.25

Patient Name: Prepopulated by CH	Patient MRN: Prepopulated by CH	
Patient DOB: Prepopulated by CH	Accession No.: Prepopulated by CH	
Modality: Prepopulated by CH	Examination Type: Prepopulated by CH	
Date of Examination: Prepopulated by CH	Hospital Site: Prepopulated by CH	

RADIOLOGIST/REPORTER

Not Significant	Refer for Clinical Impact			
Name:	Signature:	Signature:		
Date:	Medical Council Number:	Medical Council Number:		

INSTRUCTIONS IF REFER FOR CUNICAL IMPACT

If no, please comple	te your deta	ils below.	If yes, p	lease complet	te the following:	
Categorise the inco	rrect manag	ement / plan	n of care:			
Wrong Treatment		Under Treatment 🛛			Over Treatment	
Describe the incorre	ct manager	nent / plan o	of care:			
Categorise* the har Negligible 🛛	m th a t occur Minor 🗖	red: Moder	rate 🗖	Major 🗖	Extreme 🛛	
"Harm is based on the Im	pact Table (Inju	ry) of the HSE R	sk Assessment	Tool		
Describe the harm t	hat occurred	i:				
HYSICIAN/SURGEON	DETAILS					
Name: Sig			gnature:			

For Office Use: Data Collection Tool B



Appendix 5. Letter to Patient - Informing them of their inclusion in the Review/Recall Stage of the 'Look-Back' Process

Note: This is a sample letter only and may be amended as required to reflect individual persons affected and look-back review process requirements.



Patient name & address

Dear [name of person affected],

You had a [test/x-ray/investigation/procedure] completed in [Location] on [Date].

We have reviewed your [test/x-ray/investigation/procedure] undertaken at the [Location] in [Date(s)/Year(s)] as part of a quality assurance process in relation to the recent issue identified with the 'less than' symbol (<) on radiology examinations.

I am writing to you because your file has been reviewed as part of this process and our clinical team would like to meet with you to check that your procedure was satisfactory and you have no concerns in this regard.

An appointment has been made for you at (Time) on (Date) in the (Location)

The (Location) is situated (Directions)

On arrival please report to (Location) where some details will be taken. You are asked to bring the following with you:

- Contact telephone number
- List of current medications (name and dose)
- Medical card, if you are the holder of one

I apologise for any anxiety this might cause but wish to reassure you that this is a precautionary measure to ensure your care is of the highest possible standard. If this time or date above does not suit you, please contact (Name liaison person and contact details)

Yours sincerely,

Consultant



Appendix 6. Letter to General Practitioner - Informing them of the inclusion of their patient(s) in the Review/Recall Stage of the 'Look-Back' Process

Note: This is a sample letter only and may be amended as required to reflect individual persons affected and look-back review process requirements.



Patient name & address

Dear (Doctor Name),

(Service Name) recently reviewed (test/x-ray/ investigation/procedure) undertaken at the hospital in (Date(s)/Year(s)). This review was part of a quality assurance process in relation to the recent issue identified with the 'less than' symbol (<) on radiology examinations.

Our records show that your patient (Name) previously attended (name of location) for (name of procedure). We have written to your patient to advise them that their file was reviewed as part of this process and to offer them an outpatient appointment.

If you have any queries about this letter, please contact (Name person and contact details)

Yours Sincerely,

Consultant