Building a Better Health Service

Quality Assurance and Verification Division

Healthcare Audit Summary Report

Audit of compliance with Section 7.2.3 of the Safety Incident Management Policy (2014) in relation to the decision not to proceed to investigation of serious reportable events (SREs)

Reference Number: QAV002/2017

Title	**Audit of compliance with Section 7.2.3 of the Safety Incident Management Policy (2014) in relation to the decision not to proceed to investigation of serious reportable events (SREs)**	
Number	QAV002/2017	
Timeframe	July 2017 – October 2017	
Team Members	Ms. Petrina Duff, Healthcare Auditor, Quality Assurance and Verification Division (QAVD) (Lead Auditor)	
	Mr. Gerard Gibbons, Healthcare Auditor, QAVD (Co-Auditor)	
	Mr. Cathal Reilly, Healthcare Auditor, QAVD (Co-Auditor)	
Approved by	Ms. Cora McCaughan, Assistant National Director, Healthcare Audit, QAVD	
Source of Evidence	**Type**	**Date**
	Desktop Audit	**Request for Evidence**
	Community Healthcare Organisation (CHO) Area 2	Issued: 24 July 2017 Returned: 01 August 2017
	CHO Area 5	Issued: 24 July 2017 Returned: 26 July 2017
	CHO Area 7	Issued: 24 July 2017 Returned: 01 August 2017
	Dublin Midlands Hospital Group (DMHG)	Issued: 24 July 2017 Returned: 02 August 2017
	Ireland East Hospital Group (IEHG)	Issued: 26 July 2017 Returned: 11 August 2017
	Royal College of Surgeons Ireland Hospital Group (RCSI)	Issued: 27 July 2017 Returned: 14 August 2017
	SAOLTA Hospital Group (SAOLTA)	Issued: 28 July 2017 Returned: 10 August 2017
	South/South West Hospital Group (SSWHG)	Issued: 24 July 2017 Returned: 02 August 2017
	University of Limerick Hospital Group (ULHG)	Issued: 25 July 2017 Returned: 03 August 2017

Final Report Distribution	
Date: 17 January 2018	
Name	**Title**
Mr. Patrick Lynch	National Director, QAVD
Ms. Anne O'Connor	National Director, Mental Health Division
Mr. Liam Woods	National Director, Acute Hospitals Division
Mr. Pat Healy	National Director, Social Care Division
Ms. Cora McCaughan	Assistant National Director, Healthcare Audit, QAVD
Ms. Cornelia Stuart	Assistant National Director, Office of the National Director QAVD
Mr. Gavin Maguire	Assistant National Director, Head of Operations, QAVD
Mr. Tony Canavan	Chief Officer, CHO Area 2
Ms. Aileen Colley	Chief Officer, CHO Area 5
Mr. David Walsh	Chief Officer, CHO Area 7
Dr. Susan O'Reilly	Chief Executive Officer, DMHG
Professor Mary Day	Chief Executive Officer, IEHG
Mr. Ian Carter	Chief Executive Officer, RCSI Hospital Group
Mr. Maurice Power	Chief Executive Officer, SAOLTA Hospital Group
Mr. Gerry O'Dwyer	Chief Executive Officer, SSWHG
Professor Collette Cowan	Chief Executive Officer, ULHG

TABLE OF CONTENTS

ABBREVIATIONS

CHO	Community Healthcare Organisation
DMHG	Dublin Midlands Hospital Group
HG	Hospital Group
IEHG	Ireland East Hospital Group
IIMS	Incident Information Management System
IMF	Incident Management Framework
ND	National Director
NIMS	National Incident Management System
NIRF	National Incident Report Form
QAVD	Quality Assurance and Verification Division
QSC	Quality Safety Committee
RCSI	Royal College of Surgeons Ireland
SAI	Systems Analysis Investigation
SAO	Senior Accountable Officer
SAOLTA	SAOLTA Hospital Group
SCA	State Claims Agency
SICE	Safety Incident Communication/Escalation
SIMP	Safety Incident Management Policy
SRE	Serious Reportable Event
SSWHG	South/South West Hospital Group
ULHG	University of Limerick Hospital Group

1. Background / Rationale

Section 7.2.3 of the HSE Safety Incident Management Policy (SIMP) (2014) outlines the process to be followed in relation to the 'Assessment to determine type of investigation required'. The policy recognises that a decision may be made that no further investigation is required. This occurs in cases where an adverse outcome resulted but where it is immediately evident that there were no "key causal factors[1]" that contributed to the actual adverse outcome, i.e., the incident. When a decision is made at local level that no further investigation is required, paragraph four of section 7.2.3 specifically identifies the actions that local managers must take. In addition, the policy states that if there is any doubt about whether a safety incident was unforeseeable/unavoidable, the first three steps of a systems analysis investigation (SAI) of an incident should be undertaken as follows: organise the investigation and gather the data; complete the incident chronology; and identify key causal factors and incidental findings.

In January 2017, the Office of the National Director (ND) QAVD undertook a review of serious reportable events (SREs) which were reported between January and August 2016 and found that for almost half of these (48% n=121/254) a decision was taken not to conduct a SAI. The ND QAVD acknowledged that whilst there may have been valid reasons not to undertake a SAI, the reasons and supporting documentation were not captured on the internal HSE Incident Information Management System (IIMS).

This audit was requested by the ND QAVD to seek assurance in relation to compliance with the SIMP for SREs that did not proceed to investigation.

2. Aim and Objectives

The aim of this audit was to provide assurance that healthcare providers were compliant with section 7.2.3 of the SIMP in relation to the decision not to proceed to an investigation of a SRE.

The objective of this audit was to examine all relevant documentation to determine if section 7.2.3 of the national policy was adhered to in each case sampled.

3. Methodology

This audit examined a sample of SREs to assess if they were managed in accordance with the requirements of section 7.2.3 of the SIMP. This was carried out using an audit tool and validation of relevant documentary evidence as follows:

- The audit was conducted as a desktop review of a sample of reported SREs from both hospital groups (HGs) and community healthcare organisations (CHOs) and where no investigation was deemed necessary/required.
- A sample of 25 SREs was derived from all SREs noted as not proceeding to investigation on the IIMS and which were reported to the senior accountable officer (SAO) for the service between 01 January and 30 April 2017. Specifically, the final sample included all those SREs rated as extreme (n=5) and major (n=11) according to the HSE Impact Table and reported in the above timeframe. In addition, a random quota selection of nine SREs rated as moderate was selected from the remainder (i.e., 56 SREs of which 52 were rated as moderate and four were rated as minor).

[1] Key causal factors are defined as "Issues that arise in the process of delivering and managing health services which had an effect on the eventual adverse outcome" (SIMP, 2014).

- Copies of the Safety Incident Communication/Escalation (SICE) forms for the sample identified were provided to the audit team by the Office of the ND QAVD prior to commencing contact with the HGs/CHO Areas.
- A request for evidence was developed based upon the specific requirements of paragraph four of section 7.2.3 of the policy, divided into six sections to gather the information required on each SRE and issued to the nominated site liaison at HG/CHO level.

Draft reports were prepared and issued to management and the nominated liaison at each HG and CHO Area for review of factual accuracy, comment and management response to the recommendations made. A level of compliance with section 7.2.3 was provided in these reports, however an opinion on the level of assurance was not provided due to the small sample sizes involved; this is provided in this audit summary report based on the aggregate sample.

4. FINDINGS

Objective: To examine all relevant documentation to determine if section 7.2.3 of the national policy was adhered to in each case sampled.

Based on the documentary evidence reviewed for 25 SREs, the audit team found that the majority of services were substantially compliant with section 7.2.3 of the SIMP. Three healthcare providers, two within the IEHG and one within CHO Area 7, were found to be non-compliant with two specific aspects of the policy as follows:

- No documentary evidence was found that staff and the local QSC (or an equivalent) were informed of the decision not to investigate, and
- No documentary evidence was found that the local QSC (or an equivalent) sought assurance that the decision not to investigate was appropriate.

The main area of non-compliance found was that the majority of the incidents rated as major and extreme included in the audit (c.69% n=11/16) were not notified to the SAO within the 24 hour timeframe stipulated within the SIMP.

When a decision is made at local level that no further investigation is required, paragraph four of section 7.2.3 specifically identifies four actions that managers must take. The following section outlines the findings against these four specific actions. A brief overview of the findings for the 25 SREs included in the audit sample is contained within Appendix A.

Action 1: The data from the incident report form is captured (as per local arrangements) for aggregate review.

In addition to the SICE forms, HGs and CHO Areas were asked to provide copies of the incident report forms for each SRE. Local incident report forms were provided for 21 SREs and the National Incident Reporting Form[2] (NIRF) (for use with the National Incident Management System (NIMS) hosted by the State Claims Agency[3] (SCA)) was provided for four SREs.

[2] A national incident report form aligned to the WHO International Classification of Patient Safety (ICPS).

3 The SCA is responsible for hosting and maintaining the NIMS (formerly STARSweb). During 2015, an upgraded version of the NIMS was rolled out by the HSE in conjunction with the SCA and is regarded as the principal source of national data on incident and claim activity for the Irish health service. It has been designated as the primary system for end-to-end risk management of all incidents (capture, investigations and reporting) both by the Department of Health and the HSE. QAVD of the HSE is responsible for the national implementation of the new system.

Sixteen sites were included in this audit but only four submitted the NIRF as their incident reporting form and of these only one was using the most recent version of the NIRF, i.e., V09 issued 25 January 2017[4]. All 25 SREs had a valid NIMS reference number which confirmed that all services had entered the SREs on the NIMS.

Due to the fact that the majority of sites submitted a local incident report form, the content of the forms was reviewed against Appendix 6 of the SIMP which outlines the expected minimum data set that a local incident report form should contain. On ten local incident forms out of 21, the audit team found certain details that were either missing or did not meet the requirements of the SIMP. The data most often missing was the impact of the incident on the patient (i.e., negligible, minor, moderate, major and extreme as per the HSE Risk Impact Table). In cases where a higher number of data was missing, a recommendation was made within the individual audit reports to ensure that the detail recorded on the local incident report form meets the minimum data set as set out in Appendix 6 of the SIMP (see appendix B of this report for the list of recommendations made in the audit reports).

The above review highlighted that impact details and notification to external agencies for four SREs could not be determined from the NIRF form as it does not contain specific fields to record these details. Section F of the NIRF entitled '*What was the outcome at the time of the incident*' contains a tick box with a list of outcome options, but the classification details listed do not use the same language or colour coding as that recommended by the SIMP, i.e., record impact of incident according to the HSE Risk Impact Table. The audit team was subsequently assured by the Office of the ND QAVD that reports according to impact details can be auto-generated from the NIMS based upon the detail entered into section F of the NIRF. However, services continue to have an obligation to notify specific incidents to external agencies[5] and the current NIRF form does not have a field to note this requirement.

Findings have shown that in practice the majority of sites continued to complete a local incident report form as well as the NIRF. As part of the upgrading of the NIMS, the SCA recognised the need for a national incident report form across all the delegated State Authorities who report into the NIMS. To this end, the NIRF was developed by the SCA in conjunction with all the relevant interested and informed parties, including the HSE. The SIMP recommends that a single form be used to record all incidents and although the SIMP was published in 2014, prior to the rollout of phase one of the NIMS and the introduction of the NIRF in 2015, no reference was found in any subsequent HSE incident reporting policies explicitly stating whether the NIRF is the sole/only incident report form to be used. In addition, the NIRF contains the data field 'Local system reference no.', which would imply that a local incident reference number is generated for each incident using local reporting systems. There is an urgent need for clarity around the duplication in the use of reporting forms and systems.

To summarise, in practice local incident report forms are completed at individual service level and submitted to service level reporting systems. NIRF forms are also completed at service level in order for incidents to be entered onto the NIMS.

Clarity is required across the system as to whether the NIRF is to be used as the mandatory incident report form and the NIMS as the primary reporting system for the HSE and HSE funded

[4] Available at: http://www.hse.ie/eng/about/QAVD/Incident-Management/NIRF-01-V09-Person.pdf. It must be noted that because one of the incidents had occurred in January 2017, this site would not have been expected to be using the January 2017 version of the NIRF, i.e., V09. This incident was submitted on V02 of the NIRF issued in April 2015.

[5] For example, Health Information Quality Authority, Mental Health Commission, Health Products Regulatory Authority, TUSLA, Coroner, Medical Exposure Radiation Unit, etc.

agencies. If this is the case, a communication from the HSE is required in order to remove any confusion and eliminate the current duplication of tasks. In addition, the HSE in collaboration with the SCA should review the NIRF to ensure it meets the requirements of the SIMP, and any future versions of the policy.

Following on from the above findings, the audit team was informed by the Office of the ND QAVD that the system is currently being trained on the new Incident Management Framework (IMF) (the policy to replace the SIMP) and the changes to the NIMS. Specific actions addressing the above findings are now in progress through the implementation of the following: the impending publication of the new HSE IMF; the discontinuance of the SICE form; the introduction of the new NIMS Review Screens; and that the IIMS which will close for new incidents from the 01 January 2018. In addition, in preparation for the new IMF, the audit team was made aware that work with the SCA on the NIRF has been ongoing during the course of this audit and that the new NIRF is due to 'go live' in quarter 1 2018, and that it now includes a field regarding the obligation to report to external agencies.

Action 2: The local manager's decision not to investigate further and the reasoning/factors influencing this decision are noted clearly in documentation and conveyed to all involved, including staff/patients involved in the incident and the local quality and safety committee (QSC) or equivalent, in a manner that respects the rights of all to privacy and confidentiality.

Although this action is concerned with the decision not to investigate and the principle sample criterion for the audit was SREs noted as not proceeding to investigation on the IIMS, for six SREs this was not the case as follows:

- For one SRE, documentary evidence was provided to confirm that a SAI was conducted,
- For one SRE the decision to investigate or not remained 'open', and
- For the remaining four SREs, documentary evidence was provided to verify that investigations were 'pending' or 'to be determined'.

These six SREs did not therefore meet the principle sample criterion, i.e., SREs noted as not proceeding to investigation on the IIMS, and should not have been included in the sample provided to the audit team. Based on the above findings, the audit team initially recommended that a review of the IIMS should be conducted to ensure the accuracy, reliability and validity of the data contained within it. However, the audit team now understand that the IIMS will be closed to all new incidents from the 01 January 2018 and this recommendation is therefore no longer required.

Section 7.2.3 states that the assessment as to whether an investigation is needed or not should occur within 24 hours. For the above four SREs where it was noted that investigations were pending or to be determined, evidence was provided to confirm this assessment had taken place within the 24 hour timeframe as stipulated in the SIMP. However, as no documentary evidence was provided for the SRE noted as 'open', the audit team was unable to determine compliance in this instance.

In all but four SREs, documentary evidence was provided that the local QSC (or an equivalent) was provided with documentation in order for these committees to be assured that an investigation was not required. In addition, sufficient documentary evidence was provided to indicate that the majority of sites informed relevant staff of this decision.

Three sites (4 SREs) were found to be non-compliant with this action as no documentary evidence was found to verify that the above action had taken place. Recommendations were made in the audit reports to the sites regarding this non-compliance issue.

Action 3: A local QSC (or an equivalent) should seek assurance through documentation that a decision not to investigate further is appropriate.

In all but four SREs, documentary evidence was provided that the local QSC (or an equivalent) was provided with documentation in order for these committees to be assured that an investigation was not required.

Three sites (4 SREs) were found to be non-compliant with this action as no documentary evidence was found to verify that the above action had taken place. Recommendations were made in the audit reports to the sites regarding this non-compliance issue.

Action 4: There is appropriate communication with the patient/family.

With regard to informing the patient/family of the decision not to investigate, a review of the documentary evidence found that there was appropriate communication with the family about the incidents themselves and that this had occurred within a timely manner. Evidence also confirmed that family, and patients when possible were informed of the incidents, the causal factors behind the occurrence of the incident, treatment plans and follow-up actions, etc. The audit team acknowledge the good practice at all sites in implementing the culture of open disclosure.

In relation to the above action, there is no guidance within the SIMP regarding what is 'appropriate communication' with family/patients for incidents rated as major and extreme, which did not proceed to investigation and where the key causal factors established that these incidents were unavoidable/unpreventable. This was particularly evident in six SREs (at 3 sites) involving infant deaths/stillbirths. Communication that an investigation would not take place in these cases was viewed as insensitive by one of the sites included.

Actions 2 and 4 of section 7.2.3 were viewed as confusing by the sites with regard to whether there is a requirement to inform the family and patient about the decision not to perform a SAI or any other type of investigation as follows:

- Action 2 states that the local manager's decision not to investigate further and the reasoning/factors influencing this decision are to be noted clearly in documentation and conveyed to all involved; however the 'all' here specifically refers to staff and patients but does not refer to family or next of kin.
- Action 4 simply states that there should be appropriate communication with the patient/family but does not include whether this refers to informing both the family and patient that an investigation is not required.

Clarity is required for services with regard to the requirements around informing family and patients of the decision not to investigate.

Subsequent to the above findings, the audit team was informed by the Office of the ND QAVD that the system is currently being trained on the new IMF, which addresses the issue of communication with family and patients regarding incident investigations.

Additional relevant findings outside the scope of this audit

IIMS Data:

The IIMS is an internal HSE system to record and collate all relevant information regarding serious incidents that are communicated and/or escalated to the Divisional Quality and Patient Safety Lead or to the QAVD National Incident Management and Learning Team. Incidents are entered onto the IIMS using the SICE form.

As mentioned in the methodology section (see page 2), the audit sample was derived from all SREs noted as not proceeding to investigation on the IIMS and which were notified to the SAO for the service between 01 January and 30 April, 2017.

Initially, the audit team selected a sample[6] of 20 SREs which were noted as not proceeding to investigation on the IIMs; and which were notified to the SAO of the service between 01 January and 28 February 2017. A review of the detail on the SICE forms for those 20 SREs found that 6 cases would have to be excluded. As a result, the audit team felt it appropriate to expand the potential sample to include all SRES reported in January and February 2017 (n=59). An analysis of all 59 SICE forms found that 24 SREs (c.41%) in the dataset would have to be excluded from the audit.

Based on these results, the audit team concluded that it was necessary to analyse a further set of data from the IIMS in order to obtain an adequate sample of the data that was the subject of the audit and the potential consequences for the subsequent findings of any report(s) and the integrity and validity of the audit process. The audit team therefore requested details of all SREs that did not proceed to investigation but which were reported in March and April 2017 (n=77). A similar analysis of these SREs was undertaken and the audit team found a further 40 SREs (c.49%) that would have to be excluded from the audit sample.

To summarise, the audit team carried out an analysis of the 136 SREs in order to ensure the validity and reliability of the data and thus the final sample chosen for audit. This exercise revealed that 64 of the 136 SREs (47%) which were reported between January and April 2017 had to be excluded from the potential audit sample for the following reasons:

- 1 incident had occurred in 2015 but was inputted into the IIMS in 2017,
- 1 incident had occurred in 2017 but did not meet the definition of a SRE,
- 1 incident had occurred in 2017 but had a duplicate NIMS reference number,
- 3 incidents had the impact rating noted as '*to be confirmed*' on the IIMS (1 had occurred in 2016 and 2 in 2017),
- 3 incidents had occurred in 2017 but were noted as proceeding to SAI,
- 4 incidents had occurred in 2016 but were notified and inputted into the IIMS in January 2017,
- 14 incidents had occurred and were notified and inputted into the IIMS in 2016 and 3 of these were also noted as proceeding to SAI, and
- 37 incidents had occurred in 2016 but were notified to the SAO on the same date in February 2017 (24.02.2017), all were from Beaumont Hospital, and all related to the Care Management Event 4I, i.e., stage 3 or 4 pressure ulcers.

[6] A quota sampling method was initially used to select the sample for inclusion by SRE code and then reporting division, i.e., acute services and social care area.

- In addition, the audit team found 19 incidents inputted into the March/April dataset which had occurred in either January/February 2017. It was decided these would be included in the final population sample as some of these incidents were rated as major as extreme.

Taking all of the above into account, this left a valid sample population size of 72 SREs from which 25 SREs (c.35%) were selected as the sample for audit.

As mentioned previously, the audit team initially recommended that a review of the IIMS should be conducted to ensure the accuracy, reliability and validity of the data contained within it. However, as the IIMS will be closed to all new incidents from the 01 January 2018, a review is no longer warranted.

Notification to the SAO:

Section 7.2.2.2 of the SIMP states that *"all safety incidents which result in death or serious harm must be reported to the SAO **within 24 hours**. These include incidents categorised as 'major' or 'extreme' on the Impact Table"*. A review of the 25 SICE forms found that 16 SREs were rated as either major (n=11) or extreme (n=5). In 11 of those cases (c.69%), notification to the SAO did not occur within the 24 hour timeframe. The delay in notification to the SAO varied considerably from 1 day to 55 days (the average delay across all 11 SREs was approximately 17 days).

Findings from previous Healthcare Audits of SREs also found high levels of non-compliance with this specific timeline requirement. Taking those previous findings into account and the findings from this audit, it is evident that compliance with this timeline continues to be problematic.

The recently published HIQA National Standards for the Conduct of Reviews of Patient Safety Incidents (October 2017) includes the requirement that serious incidents are notified to the SAO within 24 hours of their identification. This timeline is now a national standard and must be reflected in future versions of the policy.

Falls:

Eleven falls (SRE event 5D) were included in the audit sample and from the documentary evidence reviewed, auditors found that only four patients had an x-ray performed on the same day the fall had occurred. In the remaining seven cases, delays of between 2 and 12 days were found, and in some cases this resulted in a missed diagnosis. The audit team acknowledge that this finding is outside the scope of the audit objective, however, the team felt it was necessary to inform senior management of this finding and for them to decide whether there is a need to further address/review such practices.

5. CONCLUSION

The audit team found that five of the six HGs were substantially compliant with section 7.2.3 of the SIMP. For the CHO Areas included, the audit team found two out of the three Areas to be substantially compliant. One HG and one CHO Area were found to be non-compliant; however this was based upon the review of one SRE in each service respectively.

Based on the documentary evidence reviewed for 25 SREs, the audit team can provide reasonable assurance that the majority of services were substantially compliant with section 7.2.3 of the SIMP. Three healthcare providers were found to be non-compliant with two specific aspects of the policy as follows:

- No documentary evidence was found that staff and the local QSC (or an equivalent) were informed of the decision not to investigate, and
- No documentary evidence was found that the local QSC (or an equivalent) sought assurance that the decision not to investigate was appropriate.

The main area of non-compliance found was that the majority of the incidents rated as major and extreme included in the audit were not notified to the SAO within the 24 hour timeframe stipulated within the SIMP.

Recommendations made in this report, listed hereunder, identify actions that the Office of the ND QAVD must implement in order to ensure compliance with section 7.2.3 of the SIMP.

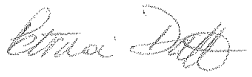
6. RECOMMENDATIONS

The ND QAVD should ensure that a communication is issued/re-issued to all services drawing attention to:

1. The use of the NIRF as the single incident report form and the NIMS as the primary incident reporting system for the HSE and HSE funded agencies.
2. The recently published HIQA National Standards for the Conduct of Reviews of Patient Safety Incidents and the national compliance requirement to notify the SAO within 24 hours of incident occurrence.

Acknowledgements:

The audit team wish to acknowledge the co-operation and goodwill afforded to them by the management and staff at all HGs and CHOs selected for inclusion in this audit.

Lead Auditor	Ms. Petrina Duff
Signature	
Date	20 December 2017
Assistant National Director QAVD	Ms. Cora McCaughan
Signature	
Date	15 January 2018

7. MANAGEMENT RESPONSE TO RECOMMENDATIONS

Management response should be completed by the senior most accountable person with the authority to effect the actions outlined by the recommendations listed.

Recommendation		Management response	Agreed implementation date	Person responsible
1	A communication is issued/re-issued to all services drawing attention to the use of the NIRF as the single incident report form and the NIMS as the primary incident reporting system for the HSE and HSE funded agencies.	The system is currently being trained on the new policy (the IMF) and the changes to NIMS. This will provide the clarity recommended.	Quarter 1 2018	Office of the ND QAVD
2	A communication is issued to all services drawing attention to the recently published HIQA National Standards for the Conduct of Reviews of Patient Safety Incidents and the national compliance requirement to notify the SAO within 24 hours of incident occurrence.			

APPENDIX A: OVERVIEW OF SAMPLE SREs

HG / CHO Area	Location	IIMS Reference Number	Impact Rate	SRE Event Code#	Key Dates 2017			Incident Status as described by Service	SIMP Actions Complied With			
					Occurred	Notified to SAO	Inputted on NIMS		1	2	3	4
CHO 2 **1 SRE**	St Augustine's CNU, Ballina (Social Care)	52221	Major	4I	24.02	24.02	27.02	Closed	Yes	Yes	Yes	Yes
CHO 5 **1 SRE**	St. Otteran's Hospital Waterford (Mental Health)	52311	Major	3C	31.03	**03.04**	04.04	Closed	**No***	Yes	Yes	Yes
CHO 7 **1 SRE**	Baltinglass Community Hospital (Social Care)	52179	Major	5D	09.02	**15.02**	No date	Closed	**No***	**No**	**No**	Yes
DMHG **1 SRE**	The Coombe Women and Infant University Hospital	52319	Extreme	4F(i)	06.02	**29.03**	07.04	Closed	**No****	Yes	Yes	Yes
IEHG **6 SREs**	Midlands Regional Hospital Mullingar	52170	Major	4F(ii)	27.01	**31.01**	15.02	Closed	Yes	**No**	**No**	Yes
	Our Lady's Hospital Navan	52187	Major	4L	10.02	10.02	20.02	**'Open'**	NA	NA	NA	NA
	St. Lukes General Hospital, Kilkenny	52192	Moderate	5D	17.02	23.02	23.02	Closed	Yes	**No**	**No**	Yes
	St. Lukes General Hospital, Kilkenny	52336	Major	5D	04.04	**06.04**	26.04	Closed	Yes	**No**	**No**	Yes
	Mater Misericordiae University Hospital	52205	Major	5D	12.01	**01.02**	02.03	Closed	Yes	Yes	Yes	Yes
	Mater Misericordiae University Hospital	52318	Moderate	4I	11.02	23.03	06.04	Closed	Yes	Yes	Yes	Yes
RCSI HG **7 SREs**	Beaumont Hospital	52173	Major	5D	29.01	**16.02**	16.02	Closed	**No***	Yes	Yes	Yes
	Beaumont Hospital	52175	Major	5D	25.01	**14.02**	03.02	Closed	**No***	Yes	Yes	Yes

	Beaumont Hospital	52184	Moderate	4I	18.01	08.02	08.02	Closed	**No***	Yes	Yes	Yes
	Beaumont Hospital	52273	Moderate	5D	28.02	15.03	16.03	Closed	Yes	Yes	Yes	Yes
	Beaumont Hospital	52282	Extreme	5D	03.03	**21.03**	22.03	**Investigation pending**	Yes	Yes	Yes	Yes
	Beaumont Hospital	52309	Moderate	5D	17.03	31.03	04.04	Closed	Yes	Yes	Yes	Yes
	Connolly Hospital	52338	Moderate	4I	18.04	25.04	27.04	**SAI performed**	**No***	Yes	Yes	Yes
Saolta HG **1 SRE**	Our Lady's Hospital Manorhamilton	52161	Moderate	5D	22.01	24.01	25.01	Closed	Yes	Yes	Yes	Yes
SSWHG **4 SREs**	Cork University Maternity Hospital	52157	Extreme	4F(i)	04.02	**06.02**	06.02	Closed	**No****	Yes	Yes	Yes
	Cork University Maternity Hospital	52181	Extreme	4F(i)	13.02	14.02	14.02	Closed	**No****	Yes	Yes	Yes
	Cork University Hospital	52281	Moderate	5D	07.01	21.03	22.03	Closed	Yes	Yes	Yes	Yes
	University Hospital Kerry	52069	Moderate	4I	03.01	05.01	06.01	**Investigation pending**	Yes	Yes	Yes	Yes
ULHG **3 SREs**	University of Limerick Maternity Hospital	52226	Extreme	4F(i)	09.02	09.02	06.03	**Investigation to be determined**	Yes	Yes	Yes	Yes
	University of Limerick Maternity Hospital	52162	Major	4F(i)	25.01	25.01	25.01	Closed	Yes	Yes	Yes	Yes
	University Hospital Nenagh	52316	Major	4I	25.02	**29.03**	06.04	**Investigation not yet determined**	Yes	Yes	Yes	Yes

No* - Impact details only were missing. Highlighted in audit report but no recommendation made. **No**** - In excess of two missing data fields. Missing details highlighted in audit report and a recommendation made.

The NIRF was submitted by the following sites: St. Otteran's Hospital Waterford (CHO 5), Baltinglass Community Hospital (CHO 7), Midlands Regional Hospital Mullingar (IEHG), and Connolly Hospital (RCSI HG).

SRE Event Code # - Legend	
3	**Patient Protection Events**
3C	All sudden unexplained deaths or injuries which result in serious disability of a person who is an inpatient/resident in a mental healthcare facility.
4	**Care Management Events**
4F(i)	Perinatal death of a neonate occurring in a term infant or an infant weighing more than2,500g.
4F (ii)	Death or encephalopathy of a normally formed neonate occurring in a term infant or an infant weighing more than 2,500g.
4I	Stage 3 or 4 pressure ulcers acquired after admission to a healthcare and social care residential facility.
4L	Diagnostic Error: Death or serious disability associated with a wrong diagnostic result e.g. mislabelled pathology specimen.
5	**Environmental Events**
5D	Patient death or serious disability associated with a fall – a. while being cared for in a healthcare service facility and/or b. during a clinical intervention from a healthcare professional (includes in the community setting, pre-hospital care and the Ambulance Service).

APPENDIX B: SITE SPECIFIC RECOMMENDATIONS

HG/CHO Area	Recommendation
CHO Area 2	None
CHO Area 5	1. The senior most accountable person for CHO Area 5 must ensure that all safety incidents and SREs (rated as major and extreme) are notified to the senior accountable officer within 24 hours of occurrence of the incident.
CHO Area 7	The senior most accountable person for CHO Area 7 must ensure that: 1. All safety incidents and SREs (rated as major and extreme) are notified to the senior accountable officer within 24 hours of occurrence of the incident. 2. Documentary evidence of the local manager's decision not to investigate a serious incident or SRE further and the reasoning/factors influencing this decision is maintained and conveyed to relevant staff and the QSC (or local equivalent). 3. Documentary evidence is maintained to indicate that the QSC (or local equivalent) sought assurance that the decision not to investigate was appropriate.
DMHG	The senior most accountable person for the DMHG must ensure that: 1. The detail recorded on the local incident report form meets the minimum data set as set out in Appendix 6 of the SIMP. 2. All safety incidents and SREs (rated as major and extreme) are notified to the senior accountable officer within 24 hours of occurrence of the incident.
IEHG	The senior most accountable person for the IEHG must ensure that 1. The detail recorded on the local incident report form meets the minimum data set as set out in Appendix 6 of the SIMP. 2. All safety incidents and SREs (rated as major and extreme) are notified to the senior accountable officer within 24 hours of occurrence of the incident. 3. Documentary evidence of the local manager's decision not to investigate a serious incident or SRE further and the reasoning/factors influencing this decision is maintained and conveyed to relevant staff and the QSC (or local equivalent). 4. Documentary evidence is maintained to indicate that the QSC (or local equivalent) sought assurance that the decision not to investigate was appropriate.
RCSI HG	The senior most accountable person for the RCSI HG must ensure that: 1. The detail recorded on the local incident report form meets the minimum data set as set out in Appendix 6 of the SIMP. 2. All safety incidents and SREs (rated as major and extreme) are notified to the senior accountable officer within 24 hours of occurrence of the incident.
SAOLTA HG	None
SSWHG	The senior most accountable person for the SSWHG must ensure that 1. The detail recorded on the local incident report form meets the minimum data set as set out in Appendix 6 of the SIMP. 2. All safety incidents and SREs (rated as major and extreme) are notified to the senior accountable officer within 24 hours of occurrence of the incident.
ULHG	1. The senior most accountable person for the ULHG must ensure that all safety incidents and SREs (rated as major and extreme) are notified to the senior accountable officer within 24 hours of occurrence of the incident.