



Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

Special Report

September 2015

Serious Reportable Events

Thursday 26th November 2015

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1. Summary

Providing quality and safe care where patients and service users are at the centre of that care, is fundamental to the provision of healthcare services. It always needs to be remembered that when things go wrong there is a person, a family and often a wider community whose lives are deeply affected, sometimes irreparably. In addressing what are serious events in the lives of individuals, it is incumbent on all healthcare staff and managers to understand what went wrong, to learn from it and to respond openly and compassionately to those affected.

While there will always be risks in the delivery of healthcare it is essential that all safety incidents are reported, managed, and investigated. The HSE's Safety Incident Management policy (2014) describes how these responsibilities should be undertaken.

Serious Reportable Events (SREs) are a defined list of serious incidents, many of which may result in death or serious harm.

- Some SRE categories are considered to be largely preventable patient safety incidents that should not occur if the available preventative measures have been implemented by the healthcare providers concerned (e.g. wrong site surgery).
- Others are serious incidents that may not have been preventable or predictable but which need to be examined to determine if in these areas, safety was compromised or can be improved. (e.g. patient falls).

The decision to establish a Framework for the Reporting SREs was introduced in March 2014 and the defined list of SREs and associated guidance for 2015 was published in January 2015.

There is evidence that SREs are being reported at local level and while there is a good history of reporting incidents across many services, the level of national reporting of SREs varies. The data informing this Report shows that some services have reported no SREs nationally. This may be a product of the fact that the implementation of the new SRE reporting system is an ongoing process.

Reporting is however improving each month. Until there is greater confidence about the levels of reporting, individual service areas with higher numbers of reported SREs **should not** be interpreted as these services having higher numbers of serious safety incidents.

In the 19 months between March 2014 and September 2015 **233** SREs were reported.

Division	Acute Hospitals	Mental Health	Social Care	Other	Health & Wellbeing	Total
Total	174	28	30	1	0	233

These SREs are reported under 6 broad categories:

Category	Surgical	Product Device	Patient Protection	Care Management	Environment	Criminal	Total
Total	23	8	21	103	57	21	233

In 100 of the 233 SREs reported it was confirmed that a person had died. It is important to say however that while the HSE records SREs where a death has also occurred, this **does not** mean necessarily that the death resulted from the incident concerned as it may result from other factors including patient co-morbidities. It is only after clinical review or investigation that such conclusions can be drawn.

2. Introduction

2.1 Context

Every year the health service has millions of interactions with patients and service users. In public acute hospitals almost 1.4 million people receive either inpatient or day case treatment annually. There are a further 3.2 million attendances at hospital outpatient departments, 1.2 million attendances in emergency departments and 68,000 babies born in the country's maternity units. Social care services provide services to approximately 70,000 people annually. This includes the disability sector which provides residential care to nearly 9,000 people in over 900 units and services for Older People which delivers public residential care to nearly 6,000 people in 129 units as well as home care to over 55,000 people.

These interventions are often complex, delivered in high-pressure environments and involve multiple professionals working in multidisciplinary teams. Excellent care and outcomes are most often the result, but modern health care also carries significant risks and, at times, things do not go to plan. Adverse events and patient harm can and do occur.

Creating a culture of open disclosure and learning from the things that go wrong is the bedrock of making systems safer.

2.2 Serious Reportable Events (SREs)

While there will always be risks in the delivery of healthcare it is essential that all safety incidents are reported, managed, and investigated. The HSE's Safety Incident Management policy (2014) describes how these responsibilities should be undertaken.

Serious Reportable Events (SREs), are a defined list of serious incidents, many of which may result in death or serious harm.

- Some SRE categories are considered to be largely preventable patient safety incidents that should not occur if the available preventative measures have been implemented by the healthcare providers concerned (e.g. wrong site surgery).
- Others are serious incidents that may not have been preventable or predictable but which need to be examined to determine if in these areas, safety was compromised or can be improved. (e.g. patient falls).

The decision to establish a Framework for the Reporting SREs was introduced in March 2014 and the defined list of SREs and associated guidance for 2015 was published in January 2015.

Since January 2015, the number of SREs reported has been published on www.hse.ie as part of the HSE's monthly Performance Report. This Special Report has been prepared to provide some additional analysis in relation to SREs reported in the 19 months between March 2014 and September 2015.

3. Establishing the SRE framework

3.1 Why the SRE reporting Framework has been developed

The publication of data in relation to serious safety incidents varies from country to country. In publishing national data on Serious Reportable Events (SREs), Ireland will be in line with international best practice for public reporting on patient safety.

The Health Information and Patient Safety Bill, the general scheme of which was published recently, will once enacted make it mandatory to report a prescribed set of events which result in serious harm or death.

Any health service information system must have the confidence of the public, patients, service users and of the front line staff, clinicians and managers that use it. This means the data must be accurate, structured and directly comparable over time. A new system must therefore be introduced in a planned and systematic way and must ensure the quality and correct interpretation of what is being reported. For this reason the HSE has placed a significant focus to the implementation of the new reporting requirement across what is a large complex system.

It is expected that the quality of reporting will improve over time and public reporting will in itself promote both the comprehensiveness and quality of reporting.

3.2 Approach to implementing the SRE reporting system

Defining SREs

The Schedule of SREs for 2015 was produced following;

- Consideration of serious incident classifications used in other jurisdictions.
- Development of a national schedule for SREs by the SRE Governance Group which includes clinical experts in each of the areas covered by the Schedule.

In light of the first full year of operation, further work is currently underway to refine the reporting system for SREs in 2016. One key element of this work will involve continued improvements to the definitions and guidance for SREs.

Reporting process

One of the priorities for the HSE is to promote improvement in the reporting of SREs to ensure that safety issues are recognised, understood, addressed and learned from across the health and social care system.

The primary purpose of reporting is to ensure that individual incidents are appropriately reviewed to determine if there were there were any potentially avoidable causes that led to the incident and to ensure that any underlying safety issues are addressed.

National level reporting also allows the HSE to review aggregated data as a means of assessing patient safety across the health and social care system.

Implementation of this new SRE Framework has involved a significant programme of work during 2015. In particular this has meant;

- Communicating the new requirements across the health and social care system.

- Putting systems in place to ensure the standardised reporting of SREs. This includes developing the capacity of each new Hospital Group, Community Healthcare Organisation (CHO) and the National Ambulance Service to collect information on SREs from across multiple service units.
- Improving the comprehensiveness of SREs reported.
- Validating the quality of data reported.

The HSE has also decided that SREs will be subject to public reporting. The phases for reporting are.

Phase 1: From January 2015 SRE numbers are reported publicly in the HSE's monthly Performance Report.

Phase 2: Publication of the first special report on SREs for the period March 2014 to September 2015.

Phase 3: Ongoing publication of reports on SREs.

In parallel to the SRE reporting process, the new National Incident Management System (NIMS) has been rolled out as a joint initiative with the State Claims Agency. This system will become the source of information in relation to SREs and will over time provide significant additional analysis in relation to all adverse events and other safety incidents.

Management process

The monitoring and review of SREs is undertaken on a monthly basis at National, Hospital Group, Community Healthcare Organisation (CHO) and National Ambulance Service levels.

3.3 Open Disclosure

In addition to reporting SREs, each service is required to ensure they promote an open, timely and consistent approach to communicating with service users and their families when things go wrong. This is called open disclosure. The HSE has together with the State Claims Agency developed a national policy and guidelines on open disclosure. This policy continues to be implemented across the health system.

4. Analysis of SREs reported

4.1 Total number of SREs reported

The total number of SREs reported in the 19 months between March 2014 and September 2015 was **233**.

While there is a good history of reporting incidents across many services and evidence that SREs are being reported at local level, the level of national reporting of SREs varies. The data informing this Report shows that some services have reported no SREs nationally. This may be a product of the fact that the implementation of the new SRE reporting system is an ongoing process.

Reporting is however improving each month. Until there is greater confidence about the levels of reporting, individual service areas with higher numbers of reported SREs **should not** be interpreted as these services having higher numbers of serious safety incidents.

The breakdown of SREs by HSE service Division is set out in the table below.

Division	Acute Hospitals	Mental Health	Social Care	Other	Health & Wellbeing	Total
Total	174	28	30	1	0	233
% of total	75%	12%	13%	<1%	0%	

4.2 SREs by category (Detail by Division)

	Acute Hospitals	Mental Health	Social Care	Other	Health & Wellbeing	Total
Surgical	23					23
Product / Device	4		3	1		8
Patient Protection	3	17	1			21
Care Management	98	2	3			103
Environmental	41		16			57
Criminal	5	9	7			21
Total	174	28	30	1	0	233

4.3 Number of SREs where a death has also occurred

Note: While the HSE records SREs where a death has also occurred, this **does not** mean necessarily that the death resulted from the incident concerned as it may result from other factors including patient co-morbidities. It is only after clinical review or investigation that such conclusions can be drawn.

Division	Acute	Mental Health	Social Care	Other	Health & Wellbeing	Total
Where a death has occurred	72	18	9	1	0	100

4.4 SREs reported by year of notification

Year	2014	2015	Total
Number of SREs	74	159	233

4.5 SRE reporting by service area

Note: Comparison of the number of SREs reported nationally across services ***does not*** mean that these services have more SREs. The HSE is working with services to improve reporting and lower numbers may indicate lower reporting levels rather than lower rates of occurrence.

Hospital Group	Hospitals with reported SREs	Hospitals with no reported SREs	Total SREs
Ireland East Hospital Group	7	4	51
Dublin Midlands Hospital Group	6	1	19
RCSI Hospitals Group	5	1	43
South/South West Hospital Group	6	4	37
University of Limerick Hospital Group	4	2	7
Saolta University Health Care Group	6	0	15
Children's Hospital Group	1	1	2
Sub total	35	13	174

Community Healthcare Organisations (CHOs)	CHOs with reported SREs	CHOs with no reported SREs	Total SREs
	9	0	59
Sub total	9	0	59

Total			233
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4.6 SRE Categories

Serious Reportable Events are defined under 6 broad categories:

- Surgical,
- Product / Device,
- Patient Protection,
- Care Management,
- Environmental
- Criminal Events.

SREs are by definition serious incidents, many of which can result in serious harm or death. This analysis reports 100 deaths associated with the SREs reported. While it is acknowledged that where a person has died this may not have been the result of a failure in care, it is still nevertheless a devastating event for the families and friends of those concerned. For this reason it is incumbent on clinicians, managers and other front line workers to respond to these events with care and compassion and also to understand what led to the event and to be open about this with those concerned.

Care Management Events

- Care Management Events account for the highest number (**n=103 / 45%**) of all SREs reported.

27 (27%) of the Care Management events relate to Category 4F(i) *the perinatal death of a neonate occurring in a term infant or an infant weighing more than 2,500g or death.*

- **28 (27%)** of the care management events relate to category 4F(ii) *death or encephalopathy of a normally formed neonate occurring in a **term infant or an infant weighing more than 2,500g.***

In **16** of these cases it was confirmed that a baby had died.

- **20 (19%)** of the **103** care management events reported relate to category 4i *a Stage 3 or Stage 4 pressure ulcer acquired after admission to a healthcare and social care residential facility.*

In **3** cases it was confirmed that a person had died.

Environmental Events

- Environmental Event SREs consist of 4 sub categories which account for **57 (24%)** of all SREs reported.

- **54 (95%)** of the **57** events relate to Category 5d *a patient death or serious disability associated with a fall.*

In **18** cases it was confirmed that a person had died.

Criminal Events

- Criminal Events consist of 4 sub categories which account for **21 (9%)** of all Serious Reportable Events reported.

- **12** cases related to Category 6c *a sexual assault on a patient or other person within or on the grounds of a healthcare service facility.* (The majority of alleged sexual assaults recorded were alleged peer to peer assaults).

Surgical Events;

- **14 (61%)** surgical event SREs relate to Category 1d *the unintended retention of foreign objects in an enclosed body cavity in a patient after surgery or other procedure performed by a healthcare service provider.*

In all cases, the foreign object was identified and corrective action was taken.

- **4 (17%)** surgical event SREs relate to Category 1e *an intra-operative or immediate postoperative death in a patient with no known medical problems occurring after surgery or other interventional procedure performed by a healthcare service provider.*

Patient Protection Events

- Patient Protection Events account for **21 (9%)** of all SREs reported.

- **16** out of the **21** events relate to Category 3c *a sudden unexplained death or injury resulting in serious disability of a person who is an inpatient or a resident in a mental healthcare facility.*

In **15** cases it was confirmed that a person had also died.

- **5** of the **21** events relate to Category 3b *a patient death or serious disability associated with a patient absconding from a healthcare service facility but excluding where a patient advises the healthcare service provider that he or she is leaving against medical advice.*

In **4** cases it was confirmed that a person had also died.

Product / Device Events

- **8 (3%)** Product or Medical Device event SREs have been reported.
- Of these **8** events, **6** fell under Category 2b related to *a patient death or serious disability associated with the use or function of a medical device.*

It was confirmed in **2** cases that a person had also died.

Summary table

SRE Category	Number of SREs reported	% of SREs per Category	SREs where a death has also occurred
Care Management Events	103	45%	56
Environmental Events	57	24%	18
Criminal Events	21	9%	1
Surgical Events	23	10%	4
Patient Protection Events	21	9%	19
Product / Device Events	8	3%	2
Total	233	100%	100

4.7 Ranking of SREs by sub category

The top 5 SREs (n148) account for 64% of all events reported.

Ranking	Category	Sub category	Number
1	Environmental Event	Patient fall	54
2	Care Management	Death or encephalopathy of a normally formed neonate	28
3	Care Management	Perinatal death of a neonate occurring in a term infant	27
4	Care Management	Stage 3 or 4 Pressure ulcer acquired after admission	20
5	Care Management	Diagnostic Error	19
6	Patient Protection	Unexplained Death / Injury of inpatient / resident in a mental health Facility	16
7	Surgical Event	Unintended retention of foreign object in a patient post surgery	14
8	Criminal	Sexual Assault	12
9	Criminal	Physical Assault	7
10	Product	Medical Device	6
11	Care Management	Maternal Death	6
12	Patient Protection	Patient absconding	5
13	Surgical Event	Intra-operative / postoperative death	4
14	Environmental Event	Patient death or serious disability associated with a burn incurred within a healthcare service facility	3
15	Care Management	Medication Error	3
16	Surgical Event	Surgery performed on wrong Body Part	3
17	Criminal	Impersonating a healthcare professional	1
18	Criminal	Abduction of patient	1
19	Surgical Event	Surgery performed on the wrong Patient	1
20	Surgical Event	Wrong surgical procedure performed	1
21	Product	contaminated medications, medical devices or biologics	1
22	Product	Intravascular air embolism	1
Total			233

5. Compliance with Investigation timelines

The HSE's National Safety Incident Management Policy sets out the steps to be taken if and when an investigation is required. It has been developed in line with international best practice in patient / service user safety and risk management. While an investigation process can be time consuming due to its rigour, complexity and the need to work with all those concerned including the people who have been affected, the HSE is seeking to improve the timeliness of investigations. The completion of investigations within a 4 month timeframe is a target set out in the HSE's National Service Plan 2015 and the achievement of this target is monitored as part of the HSE's monthly performance monitoring process.

At the time of reporting, 78% of investigations are currently outside the national target of four months.

6. Where to from here?

The HSE acknowledges that the reporting of serious reportable events is still a new process and work will continue to embed the reporting and learning from adverse events into the overall approach to improving patient safety. While it is not yet possible to establish trends or draw any general conclusions from the data, this first report does provide some understanding of adverse events across the health and social care system. Public reporting on the number and types of SREs is an important step in this journey.

There are a number of actions being taken by the HSE to improve the reporting of and learning from SREs and to improve the quality of services across the health and social care system. These include;

Reporting

- The continued implementation of the National Incident Management System (NIMS) together with the State Claims Agency. NIMS will provide significant additional information and analysis of adverse events that will support the improvement of safety across our health services.
- SREs will continue to be reported publicly as part of the HSE's monthly Performance Report.

Management processes

- The monitoring of reported SREs will continue through the monthly performance oversight meetings with the HSE's National Divisions and with each Hospital Group and Community Healthcare Organisation and the National Ambulance Service.
- This report has been provided to each HSE service Division, Hospital Group, Community Healthcare Organisation and the National Ambulance Service to review the analysis as part of their formal Management Team processes. The purpose of this review will be to determine whether there is a requirement to implement improvements as part of their overall quality, safety and risk programme.

Audit

- A formal audit of compliance with the policy for reporting SREs will be undertaken in early 2016.

Development of SRE process

- Following the first full year of operating the new reporting SRE Framework, further development of the SRE schedule and its definitions will be undertaken by the SRE Governance Group.

Capacity building

- A Programme of Safety Incident Management and Systems Analysis Investigation training continues to be rolled out across the health service.
- The HSE's Open Disclosure policy will continue to be rolled out across the health system.

Quality improvements

- A range of Quality Improvement initiatives are being implemented across the health system. These include;
 - Implementation of the National Clinical Programmes,
 - The development of Patient Safety Statements for each of the country's hospitals which will bring together key quality and safety indicators for acute hospitals that will be used by management and clinicians to monitor quality and safety across these hospitals.
 - The continued roll out of the 'Pressure Ulcers to Zero' improvement collaborative.
 - The ongoing implementation of the National Policy and Procedure for Safe Surgery.
 - Establishment of the HSE's National Women and Infants Programme.
 - The development of the Irish Audit of Surgical Mortality in collaboration with the Royal College of Surgeons in Ireland.
 - Continued implementation of the HSE's Safeguarding Policy.
 - Promoting the role of the HSE's Confidential Recipient.
 - Implementing the system wide change programme across social care services.
 - Implementing suicide prevention initiatives outlined in 'Connecting for Life' the National Strategy to reduce suicide.

Appendix 1: SRE Categories (detailed)

1.	SURGICAL EVENTS	NUMBER
1A.	Surgery performed on the wrong body part by a healthcare service provider.	3
1B.	Surgery performed on the wrong patient by a healthcare service provider.	1
1C.	Wrong surgical procedure performed on patient by a healthcare service provider.	1
1D.	Unintended retention of a foreign object in an enclosed body cavity in a patient after surgery or other procedure performed by a healthcare service provider.	14
1E.	Intra-operative or immediately postoperative death in a patient with no known medical problems (ASA Class I) occurring after surgery or other interventional procedure performed by a healthcare service provider.	4
Total		23 (10%)

2.	PRODUCT OR DEVICE EVENTS	NUMBER
2A.	Patient death or serious disability associated with the use of contaminated medications, medical devices, or biologics provided by the healthcare service provider.	1
2B.	Patient death or serious disability associated with the use or function of a medical device in which the medical device is used or functions other than as intended or anticipated in the care of a patient provided by the healthcare service provider.	6
2C.	Patient death or serious disability associated with intravascular air embolism that occurs while being cared for by a healthcare service provider but excluding death or serious disability associated with certain neurosurgical procedures or cardiac procedures known to present a high risk of intravascular air embolism.	1
Total		8 (3%)

3.	PATIENT PROTECTION EVENTS	NUMBER
3A.	Child or other dependent person discharged to the wrong person by a healthcare service provider.	0
3B.	Patient death or serious disability associated with a patient absconding from a healthcare service facility but excluding where a patient advises the healthcare service provider that he or she is leaving against medical advice.	5
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.	16
Total		21 (9%)

4.	CARE MANAGEMENT EVENTS	NUMBER
4A.	Patient death or serious disability associated with a medication error by the healthcare service provider but excluding reasonable differences in clinical judgment involving drug selection and/or dose.	3
4B.	Wrong formulation/route administration of chemotherapy by a healthcare service provider.	0
4C.	Intravenous administration of mis-selected concentrated potassium chloride by a healthcare service provider.	0
4D.	Patient death or serious disability due to the administration of incompatible blood or blood products by a healthcare service provider.	0
4E.	Maternal Death for whom the hospital has accepted medical responsibility, registered with an independent midwife for pregnancy care/ registered with a maternity hospital-during pregnancy or within	6

4.	CARE MANAGEMENT EVENTS	NUMBER
	<i>six weeks of delivery</i> (whether in the hospital or not).	
4F(i)	<i>Perinatal death of a neonate</i> occurring in a <i>term infant or an infant weighing more than 2,500g</i> .	27
4F(ii)	<i>Death or encephalopathy of a normally formed neonate</i> occurring in a <i>term infant or an infant weighing more than 2,500g</i> .	28
4G	<i>Patient death or serious disability</i> associated with <i>severe hypoglycaemia</i> (excluding neonates), the onset of which occurs while the patient is being cared for in a healthcare service facility.	0
4H	<i>Death or serious disability (kernicterus)</i> associated with <i>non detection</i> by a healthcare service provider to identify and treat <i>Hyperbilirubinemia in neonates within the first 28 days of life</i> .	0
4I	<i>Stage 3 or 4 pressure ulcers</i> acquired <i>after admission</i> to a healthcare and social care residential facility.	20
4J	<i>Patient death or serious disability</i> due to <i>spinal manipulative therapy</i> by a healthcare service provider.	0
4K	<i>Patient death or serious disability</i> resulting from or associated with the use of <i>restrictive interventions such as physical, mechanical, manual or environmental restraint (e.g. seclusion)</i> to a patient while being cared for in a healthcare service facility.	0
4L	<i>Diagnostic Error</i> . Death or serious disability associated with a wrong diagnostic result e.g. mislabelled pathology specimen.	19
4M	The <i>non utilisation of a donor organ</i> deemed suitable for transplantation.	0
4N	<i>Death of a living organ donor</i> .	0
Total		103 (45%)

5	ENVIRONMENTAL EVENTS	NUMBER
5A	<i>Patient death or serious disability</i> associated with an <i>electric shock</i> while being cared for in a healthcare service facility but excluding events involving planned treatments such as cardioversion.	0
5B	An incident in which a <i>line designated for oxygen or other gas</i> to be delivered to a patient while being cared for by a healthcare service provider <i>contains the wrong gas or is contaminated by toxic substances</i> .	0
5C	<i>Patient death or serious disability</i> associated with a <i>burn incurred</i> within a healthcare service facility.	3
5D	<i>Patient death or serious disability</i> associated with a <i>fall</i> – 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).	54
Total		57 (24%)

6	CRIMINAL EVENTS	NUMBER
6A	Any instance of care ordered by or provided by someone <i>impersonating a healthcare professional</i> .	1
6B	<i>Abduction of a patient</i> of any age while being cared for in a healthcare service facility.	1
6C	<i>Sexual assault</i> on a patient or other person within or on the grounds of a healthcare service facility.	12
6D	<i>Death or serious injury/disability</i> of a patient or other person resulting from a <i>physical assault</i> that occurs within or on the grounds of a healthcare service facility.	7
Total		21 (9%)

Appendix 2: Analysis of SREs by service areas

Number of Serious Reportable Events (by Hospital)

Ireland East Hospital Group	Number of SREs Reported
Sub total	51
Dublin Midlands Hospital Group	Number of SREs Reported
Sub total	19
RCSI Hospitals Group	Number of SREs Reported
Sub total	43
South / South West Hospital Group	Number of SREs Reported
Sub total	37
University of Limerick Hospital Group	Number of SREs Reported
Sub total	7
Saolta University Health Care Group	Number of SREs Reported
Sub total	15
Children's Hospital Group	Number of SREs Reported
Acute Hospitals Total	2
Acute Hospitals Total	174

Serious Reportable Events by CHO and Division

Region		Mental Health	Social Care	Other	Total by CHO
CHO 1	Donegal, Sligo, Leitrim, West Cavan and Cavan / Monaghan	1	6		7
CHO 2	Galway, Roscommon, Mayo	5	5		10
CHO 3	Clare, Limerick, North Tipperary, East Limerick	0	4		4
CHO 4	Kerry, North Cork, North Lee, South Lee and West Cork	1	5		6
CHO 5	South Tipperary, Carlow, Kilkenny, Waterford, Wexford	5	0		5
CHO 6	Wicklow, Dun Laoghaire, Dublin South East	0	3		3
CHO 7	Kildare, West Wicklow, Dublin West, Dublin South City, Dublin South West	7	3		10
CHO 8	Laois, Offaly, Longford, Westmeath, Louth and Meath	4	1		5
CHO 9	Dublin North, Dublin North Central and Dublin North West	4	3		7
National Division		1		1	2
Total		28	30	1	59