# NATIONAL CLINICAL INCIDENTS, CLAIMS AND COSTS REPORT

## Lessons learned, a five year review: 2010-2014

Gníomhaireacht Bainistíochta an Chisteáin Náisiúnta
National Treasury Management Agency

An Ghníomhaireacht Stáit um Éilimh
State Claims Agency

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# iii. Abbreviations

| | |
|---|---|
| **CHO:** | Community Healthcare Organisation |
| **CIS:** | Clinical Indemnity Scheme |
| **CTG:** | Cardiotocography |
| **ERPC:** | Evacuation of Retained Products of Conception |
| **EHR:** | Electronic Healthcare Record |
| **HIE:** | Hypoxic Ischaemic Encephalopathy |
| **HIQA:** | Health Information and Quality Authority |
| **HSE:** | Health Service Executive |
| **HQIP:** | Healthcare Quality Improvement Partnership |
| **ICU:** | Intensive Care Unit |
| **IUCD:** | Intrauterine Contraceptive Device |
| **NCHD:** | Non Consultant Hospital Doctor |
| **NHS:** | National Health Service |
| **NHS LA:** | National Health Service Litigation Authority |
| **NIMS:** | National Incident Management System |
| **NNTP:** | National Neonatal Transport Programme |
| **NPSA:** | National Patient Safety Agency |
| **PPO:** | Periodic Payment Order |
| **SCA:** | State Claims Agency |
| **SCBU:** | Special Care Baby Unit |
| **SRE:** | Serious Reportable Event |

# iv. Definitions

**National Incident Management System (NIMS):**

**Incidents** (which include claims), are reported to the State Claims Agency (SCA) using the "National Incident Management System" (previously known as STARSWeb). This is hosted by the SCA for the HSE, other healthcare enterprises and State Authorities. The NIMS is the principal source of national data on incident and claims activity for the Irish Health Service. It is an end to end risk management web based system. Its purpose includes the capture of incidents (including Serious Reportable Events); the management of investigations; recording of investigation conclusions and recommendations; management of the claims and litigation processes; management of reserving transactional and payment processes, and provision of a level of actuarial analysis and functionality.

**Incident:** An incident is an unplanned, unexpected or uncontrolled occurrence, which causes (or has the potential to cause) injury, ill-health, and/or damage. An incident can be a harmful incident (adverse event), a no harm incident, a near miss, dangerous occurrence (reportable circumstance) or complaint.

**Clinical Incident:**

A clinical incident on the NIMS is one which falls under the incident hazard category of clinical care. This category includes incidents relating to clinical procedures, birth specific procedures, medication incidents, nutrition or blood related incidents and the provision of treatment and services of a diagnostic or palliative nature.

A reference to "clinical incident" in this report refers to the date that such a clinical incident is alleged to have occurred and reflects the data set analysed for this report.

**Clinical incident rate:**

The clinical incident rate for any one year is the number of clinical incidents which occurred in that year per 100,000 population in the Republic of Ireland. This figure was obtained by dividing the total number of clinical incidents by the total population nationally.

The rate is reported as the number of clinical incidents per 100,000 population.

General Incident:
A general incident on the NIMS is one which falls outside of the clinical care incident hazard category. This includes all incidents relating to exposure to physical hazards, exposure to psychological hazards, exposure to chemical hazards, exposure to biological hazards, crashes/collisions, property damage/loss (non-crash collision), dangerous occurrences and informal complaints.

Claim created:
A claim refers to notification of intention to seek compensation for personal injury and/or property damage where it is alleged the State was negligent. The application may be in the form of a letter of claim, an InjuriesBoard.ie application, or a written or oral request.

**Clinical claim rate:**

The clinical claim rate for any one year is the total number of clinical claims created nationally, reported on the NIMS per 100,000 population in the Republic of Ireland. This figure was obtained by dividing the total number of clinical claims created in a year by the total population nationally.

The rate is reported as number of clinical claims created per 100,000 population.

Finalised Claim:
A finalised claim is a claim in which all matters associated with the claim have been agreed e.g. costs. Some associated payments and reimbursements may still be outstanding on finalised claims.

Legacy data:
Legacy data refers to incidents (which include claims) whereby the specific category was not available prior to the introduction of the NIMS.

Please specify field:
This field was used for analysis of data in this document. It is a combination of incident types and problem causes which were entered on the old STARS Web system. Since 2015, the WHO taxonomy used by the NIMS facilitates for more accurate reporting.

**Severity Rating using STARSWeb:**

When reporting incidents on STARSWeb, the severity rating was decided by the healthcare service. It was not a mandatory field. The severity rating was based on the impact of the incident multiplied by the likelihood of recurrence, in conjunction with the HSE risk matrix.

**Severity Rating using the NIMS:**

These severity ratings, assigned by the NIMS are based on the outcome of the injury at the time of the incident, as listed in the table below. This is modelled on the HSE Risk Impact Table as outlined in the HSE National Safety Incident Management Policy.

| Outcome at the time of incident reporting | Severity Rating |
|---|---|
| 1 No adverse outcome | Negligible |
| 2 Injury not requiring first aid | Negligible |
| 3 Injury or illness, requiring first aid | Minor |
| 4 Injury requiring medical treatment | Moderate |
| 5 Long-term disability/incapacity (incl. psychosocial) | Major |
| 6 Permanent incapacity (incl. psychosocial) | Extreme |
| 7 Death | Extreme |

**Monetary values and percentages** in this report may be rounded.

The data for this report was run on 30/11/2015 for claims and incidents and on 31/12/2015 for the costs by the Data Services team.

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# 1.0 FOREWORD

The overarching aim of this report is to help improve patient safety by analysing and interrogating national data on clinical incidents, claims and costs.

The most common clinical incidents and claims nationally have been identified and tracked over a 5 year period for services and medical specialities providing a holistic picture. Data is contextualised with international, published data where appropriate. Practical risk management suggestions have been offered.

This evidence based, national information identifies high risk areas so that key stakeholders can provide targeted interventions, specific education and training and focused research. Collaboration with all stakeholders nationally including front-line staff, the public, the HSE, the Department of Health, the postgraduate training bodies, universities, clinical research facilities and research funders, together with their equivalent bodies internationally is important.

Data analysis and interrogation, regular audit and review of results of interventions and swift implementation of interventions and research that lead to improvement, is key to developing a "learning health system" that provides safer care.

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# 2. EXECUTIVE SUMMARY

## 1. Aims

The aims of this report are:

- to provide evidence based national data on clinical incidents, clinical claims, costs and finalised claims so as to
- improve patient safety and quality of care
- identify high risk areas for targeted interventions
- highlight key areas that require focused training and educational input
- contextualise national data with international data, where appropriate
- provide practical risk management suggestions
- encourage further collaboration with key stakeholders nationally and internationally to provide proactive, cohesive solutions
- improve quality and standardisation of clinical incident reporting nationally
- provide guidance regarding potential future research areas

## 2. Background

The State Claims Agency (SCA) is unique in international terms in that it analyses data pertaining to national clinical incidents, claims and costs. Therefore, it is in a position to follow a clinical incident from the time of its reporting, to settlement or resolution of the later clinical claim. Internationally, other State indemnifiers have data pertaining to claims and costs but not incidents. This "beginning to end" perspective enables the SCA to obtain a holistic view of how healthcare services function. It provides a service from risk management and suggestions regarding incident prevention through to claim management and resolution. Interrogation of data regarding clinical incidents, claims and costs is valuable to provide an overall picture of high risk areas in healthcare, which may be targeted from a clinical, educational, training and research perspective. This five years of data (2010-2014 inclusive) was reported to the SCA on the STARSWeb system, mapped over to the NIMS and analysed using the NIMS. This data includes data from public healthcare enterprises (acute hospitals; Community Healthcare Organisations; the National Ambulance Service and other support services) but does not include data from private healthcare enterprises or qualified general practitioners.

## 3. Incidents

Nationally, clinical incident rates were reviewed: the clinical incident rate increased from 883 in 2010 to 1,014 in 2014 per 100,000 population. An increase in clinical incident reporting, by a healthcare service across the spectrum of severity of injury, is considered nationally and internationally to be indicative of development of a strong patient safety culture.

The most common category of clinical incident nationally was *"other"*, where the incident did not fall into one of the particularised categories (Table 1).This category has reduced over time given the much wider range of categories, pick list options, mandatory fields and automation offered by the NIMS, which has replaced STARSWeb. This category was followed by incidents pertaining to delay or failure to treat leading to an adverse outcome. Medication incidents were prominent and included incorrect dose, missed medication and incorrect medication on admission, transfer or discharge. Incidents pertaining to failure or faulty medical device or equipment, serious soft tissue damage and clinical records missing or misplaced were common. Incidents related to Maternity services including post-partum haemorrhage and perineal tears (3rd and 4th degree including breakdown of the perineum), ranked in the ten most common incidents nationally which were reported to the SCA, 2010-2014 inclusive.

Medicine, Maternity, Surgery, Disability and Older Persons were the most common services, in decreasing order, in which clinical incidents were identified (Table 1). Each service was analysed in detail and the ten most common clinical incidents were highlighted. Suggestions to prevent common clinical incidents were outlined.

| Most Common Clinical Incidents nationally, 2010-2014 | Medicine | Maternity Services | Surgery | Disability Services | Older Persons |
|---|---|---|---|---|---|
| Other | 17942 | 8828 | 7049 | 14061 | 5297 |
| Delay / Failure to Treat - Adverse Outcome | 5477 | 617 | 1474 | 80 | 232 |
| Failure/Faulty Medical Device/ Equipment | 2339 | 667 | 1797 | 208 | 240 |
| Incorrect Dosage | 4048 | 276 | 830 | 576 | 221 |
| Missed Medication | 2351 | 296 | 505 | 1636 | 284 |
| Serious Soft Tissue Damage | 3824 | 42 | 977 | 35 | 352 |
| Clinical Records Missing / Misplaced | 2212 | 930 | 1794 | 14 | 12 |
| Medication on admission/transfer/ discharge incorrect or not reconciled | 3288 | 8 | 876 | 83 | 31 |
| Post-partum Haemorrhage | 1 | 4276 | 6 | 0 | 0 |
| Perineal Tear (3rd & 4th Degree, incl. breakdown of perineum) | 0 | 3676 | 1 | 0 | 0 |
| Ten Most Common Incidents | 41482 | 19616 | 15309 | 16693 | 6669 |
| Overall Total | 68983 | 46692 | 27371 | 19812 | 7992 |

**Table 1: Ten most common clinical incidents, nationally 2010-2014 inclusive and the most common services in which clinical incidents were identified, categorised by the *please specify* field.**

## 4. Opportunities for improvement and suggestions

Many clinical incidents were common to multiple services.

### i. Systems problems

Most clinical incidents are related to a series of *"systems' problems"* [Swiss cheese effect] rather than to one individual or person. Resolving systems' problems often has resource implications.

### ii. Quality and standardisation of clinical incident reporting

The quality of clinical incident reporting has been, at times, suboptimal and must be improved. The State Claims Agency has been working assiduously with healthcare enterprises to increase standardisation and reduce variation regarding the modes, patterns and quality of clinical incident reporting to the SCA using the NIMS. A large body of work has taken place as part of the NIMS implementation project, which has been led by the HSE in partnership with the SCA, to improve the quality of incident data being reported.

### iii. Prevention of delay or failure to treat leading to an adverse outcome

Causes of delay or failure to treat may be multifactorial and may include communication, waiting time for investigation and/or procedure, review by an appropriate expert and delay in receipt of investigation results.

#### Suggestions:

- **Reduction in waiting lists** has resource implications and includes consideration of options such as the provision of direct access for GPs to certain investigations e.g. echocardiogram, computerised tomography [CT] scans and/or consideration given to a seven day week for elective lists for diagnostics
- Introduction of an **Electronic Healthcare Record, which would work seamlessly between hospitals and community,** with GP and patient portals
- Implementation of the National Clinical Effectiveness Committee [NCEC] **Clinical Handover** [Communication] and Early Warning System guidelines nationally

### iv. Prevention of Medication incidents

Medication incidents were identified as an issue across multiple services nationally and are a recognised international issue.

#### Suggestions:

- Implementation of a **clinical pharmacy service** in all hospitals.
- **Medication reconciliation** at time of patient transfer.
- Implementation of a multidisciplinary, **multi phasic, specific training and education programme** for doctors and nurses and audit outcomes.
- Implementation of the **Electronic Healthcare Record with Clinical Decision Support** and Computerised Physician Order Entry.
- **Introduction of a national drug kardex** in all hospitals and healthcare services so that when doctors, nurses and pharmacists in training move hospital, there is a standardised, national drug kardex.

- **Empowerment of patients and carers** regarding knowledge of medications; institute a *"know your medications"* programme. Empowerment of the patient/carers and/or family to become a more active participant(s) in the multidisciplinary care team, particularly at transitions of care, which are the times of high risk.

## v. Repair or replace faulty or failed medical devices and equipment and perform regular checks

There is an increasing number and complexity of medical equipment and devices used in health care with an escalating cost of replacement.

### Suggestions:

Failed medical devices or equipment should be replaced. Consideration should be given to hiring / leasing equipment, which may be more economical than purchasing. Central procurement should be employed where possible, facilitating trade discount and standardisation of medical devices and equipment, nationally. Ensure regular checks of medical devices and equipment prior to use. While this affects all services, Surgery is particularly susceptible due to the high number of procedures performed. Additionally the Older Persons service is vulnerable due to the amount of specialised equipment used.

These incidents may be either clinical or related to a faulty product and therefore may be covered by the clinical or the general indemnity scheme respectively at the SCA or, by the manufacturers of the medical device or equipment.

## vi. Prevention of serious soft tissue damage

Care of skin and soft tissue is important for all patients but particularly for vulnerable groups such as older persons, those with mobility difficulties and children. Prevention is key. In the event of skin or soft tissue damage, early, targeted treatment is required. The HSE's Quality Improvement Division (QID) has performed significant work in this area regarding its "Pressure Ulcer's to Zero Improvement Collaborative".

## vii. Prevention of missing or misplaced clinical records

Missing or misplaced clinical records was an incident common to multiple services. The introduction of the Electronic Healthcare Record in Ireland with Clinical Decision Support and Computerised Physician Order Entry, with a seamless communication between hospital and community, (including GP, community pharmacy, and other community services), together with patient portals, will reduce the occurrence of this incident type. The unique patient identifier number will assist in the tracking of healthcare records and investigation results.

## viii. Prevention of post partum haemorrhage and prevention of 3rd and 4th degree perineal tear (including breakdown of the perineum).

Specific guidance regarding prevention of these Maternity service related clinical incidents has previously been published nationally and internationally and should be followed.

### ix Clinical incidents identified nationally are similar to those identified internationally

Many clinical incidents identified nationally are similar to those identified across healthcare systems internationally. Collaboration and sharing of knowledge, skills and quality improvement projects by centres of excellence nationally and internationally is valuable.

## 5 Claims and cost

### i. Claims

The Clinical Indemnity Scheme (CIS) was established on July 1st 2002, to provide clinical malpractice indemnity to non-consultant hospital doctors (NCHDs), nurses, midwives and allied healthcare professionals. The scope of the CIS was broadened in February 2004 when consultants, working in public hospitals, were included in the scheme, in respect of clinical incidents occurring on or after February 1st 2004. The CIS, therefore, is still considered an *"immature"* indemnity scheme, actuarially speaking. The volume and costs of claims will continue to grow, as the scheme matures, eventually plateauing sometime around 2020.

The clinical claim rate nationally increased from 10 to 13 per 100,000 population, between 2010 and 2014. A peak in 2012 of 17 per 100,000 is largely explained by mass actions including DePuy hip replacement, the Lourdes Redress scheme (hysterectomies) and symphysiotomies. An increase in the number of new clinical negligence claims reported was identified in England by the NHS Litigation Authority between 2010/11 to 2014/15.

The ten most common clinical claims created nationally, 2010-2014 inclusive were identified and included *"other"* where the claims did not fall into one of the particularised categories (Table 2). Claims related to *"diagnosis"*, including the categories of delayed diagnosis and failure to diagnose, were relatively frequent and combined, accounted for 19.0% of the ten most common clinical claims. Claims related to failure or faulty medical device or equipment were common and, in the main, were accounted for by the DePuy hip replacement mass action. Similarly, unnecessary surgery or procedure and wrong procedure or operation were largely accounted for by the mass actions in respect of symphysiotomies and hysterectomies (The Lourdes Redress Scheme). Claims pertaining to unexpected complications in the categories of "during" and "following" a procedure were relatively frequent (the combined figure accounting for 10.1% of the ten most common clinical claims 2010-2014 inclusive). Claims pertaining to *"delays"*, including delay or failure to treat, leading to an adverse outcome featured in the ten most common claims nationally for this 5 year period.

Hospital-related deaths, reported to the Coroner, represent a small but relevant proportion of clinical claims in some specialities reviewed, namely, Emergency Medicine, Cardiology, Gastroenterology and Respiratory Medicine. Practitioners in these specialties should note that they may be called by Coroners to give evidence to the Coroners' Courts in these instances.

Surgery, Medicine, Maternity, Gynaecology and Other, in decreasing order, were the most common services, in which clinical claims were created, 2010-2014 inclusive (Table 2). These high risk services were analysed and the most common clinical claims created in each service identified. National data was compared to international, peer reviewed, published studies of closed claims in the same services for *"lessons learned"* purposes.

| Most Common Clinical Claims Created Nationally, 2010-2014 | Surgery | Medicine | Maternity Services | Gynaecology | Other Services |
|---|---|---|---|---|---|
| Other | 295 | 234 | 99 | 30 | 85 |
| Failure/Faulty Medical Device/ Equipment | 292 | 2 | 2 | 3 | 1 |
| Failure to Diagnose | 35 | 150 | 10 | 4 | 4 |
| Delayed Diagnosis | 50 | 95 | 10 | 9 | 1 |
| Unexpected Complications Following Operation / Procedure | 119 | 7 | 11 | 15 | 0 |
| Delay / Failure to Treat - Adverse Outcome | 54 | 63 | 14 | 6 | 3 |
| Unnecessary Surgery / Procedure | 6 | 0 | 121 | 4 | 0 |
| Wrong Operation / Procedure | 3 | 0 | 0 | 100 | 0 |
| Unexpected Complications During Operation / Procedure | 33 | 5 | 11 | 8 | 0 |
| Unintentional Punch / Laceration to Organ | 22 | 2 | 6 | 12 | 0 |
| Ten Most Common Claims | 909 | 558 | 284 | 191 | 94 |
| Overall Total | 1100 | 730 | 713 | 229 | 101 |

**Table 2: Ten most common clinical claims created nationally 2010-2014 inclusive and the most common services in which clinical claims were created during this 5 year period, categorised by the *please specify* field.**

### ii. Cost

Overall, the total number of clinical claims finalised annually 2010-2014 inclusive increased and therefore the associated cost increased. This is largely explained by mass action claims. The total cost of clinical claims finalised during this 5 year period was €288,796,591 of which awards/settlements amounted to €177,479,000, legal fees for the plaintiff to €65,473,645, legal fees for the SCA to €40,810,885 and "others", which includes expert fees, amounted to €5,033,061. Total legal fees, expressed as a percentage of awards/settlements, was 59.9% for this five year period. Total legal fees, expressed as a percentage of awards/settlements was 62.1% in 2010 and reduced to 51.0 % in 2014. The average cost per clinical claim finalised, inclusive of compensation and all costs (legal fees for the plaintiff, legal fees for the SCA, expert costs etc.) reduced from €152,329 in 2010 to €141,813 in 2014.

## 6. Specialities

Eight areas of Medicine were analysed in detail from a clinical incidents, claims and costs viewpoint over the five year period 2010-2014 inclusive, namely, Emergency Medicine, Mental Health, Radiology, Cardiology, Respiratory, Gastroenterology, Neurology and Infectious Diseases. This analysis will enable specialists, and their multi-disciplinary teams, to review their specialities at a national level from a clinical incidents, claims and costs viewpoint.

## 7. Finalised claims

Finalised claims from six areas were analysed clinically for "lessons learned" including Emergency Medicine, Paediatrics, Mental Health, Gynaecology and Slips, Trips and Falls. Risk management suggestions were offered. A finalised claim is a claim in which all matters associated with the claim have been agreed e.g. costs. Some associated payments and reimbursements may still be outstanding on finalised claims.

## 8. Future initiatives

Future initiatives include more rapid analysis of real time data, increased targeted education, further focused training and more research in specific areas of concern to help provide risk management suggestions to reduce clinical incidents and promote patient safety. Collaboration between institutions, nationally and internationally is critical to success.

# 3.0 INTRODUCTION

This report analyses five years of national data from a clinical incidents, clinical claims and costs perspective to identify high risk areas in Medicine so they may be targeted for intervention and improvement. It provides risk management suggestions to help prevent occurrence and recurrence of clinical incidents and assist in the promotion of patient safety.

It analyses the five services in which the most clinical incidents were reported to the SCA, including Medicine, Maternity, Surgery, Disability and Older Persons. The ten most common clinical incidents in each of these services were identified and suggestions made to help prevent their recurrence.

It interrogates clinical claims and costs for the most common services in which claims were created: Surgery, Medicine, Maternity, Gynaecology and Other. The ten most common clinical claims in each of these high risk services were identified and results compared to international, peer reviewed, published data.

Specific areas of Medicine including Emergency Medicine, Mental Health, Radiology, Cardiology, Respiratory, Gastroenterology, Neurology and Infectious Diseases were reviewed from a clinical incidents, claims and costs perspective. This comprehensive review enables specialists and multidisciplinary care teams to review specific areas of interest nationally across the life cycle of a clinical incident: from occurrence of clinical incident to resolution of the later clinical claim. Data is contextualised by comparison with international data where appropriate.

Finalised claims were analysed across multiple areas of Medicine to identify *"lessons learned"* and provide risk management suggestions in Emergency Medicine, Paediatrics, Mental Health and Gynaecology services, (pertaining to retained foreign bodies) and in Slips, Trips and Falls.

From 1st February 2004, the Clinical Indemnity Scheme (CIS) incepted cover for consultant doctors, working in the public health sector, but only in respect of incidents occurring on or after that date. The CIS is still *"immature" i*n terms of its development as a clinical negligence scheme, from an actuarial viewpoint, by virtue of its early years post development. Knowing that clinical claims generally take a number of years to evolve, it is timely that a five year review has now been undertaken.

# 4.0 INCIDENTS

## 4.1 Clinical incident number, 2010-2014 inclusive

The total number of clinical incidents reported by healthcare services nationally to the SCA, 2010-2014 inclusive, was reviewed. There has been an increase in the number of clinical incidents during this five year period. It is acknowledged nationally and internationally that health care services which report a high number of clinical incidents across the spectrum of severity of injury are generally associated with a strong patient safety culture. During this five year period, clinical incidents increased by 6,521 (which equates to a 16.2% increase) (Figure 1). This may be related to changes in pattern of clinical incident reporting, changes in clinical care or a combination of both. In parallel, general (i.e. non clinical) incidents increased by 6,910 (which represents a 13.0% increase).

Regarding severity rating, in total over the five year period, there were 206,717 clinical incidents identified of which 2,870 (1.4%) were classified by the healthcare services as extreme; 131 (0.1%) as major; 34,817 (16.8%) as moderate; 33,953 (16.4%) as minor and 26,730 (12.9%) as negligible. The remaining 108,215 (52.3%) were not classified from a severity rating viewpoint by healthcare services.

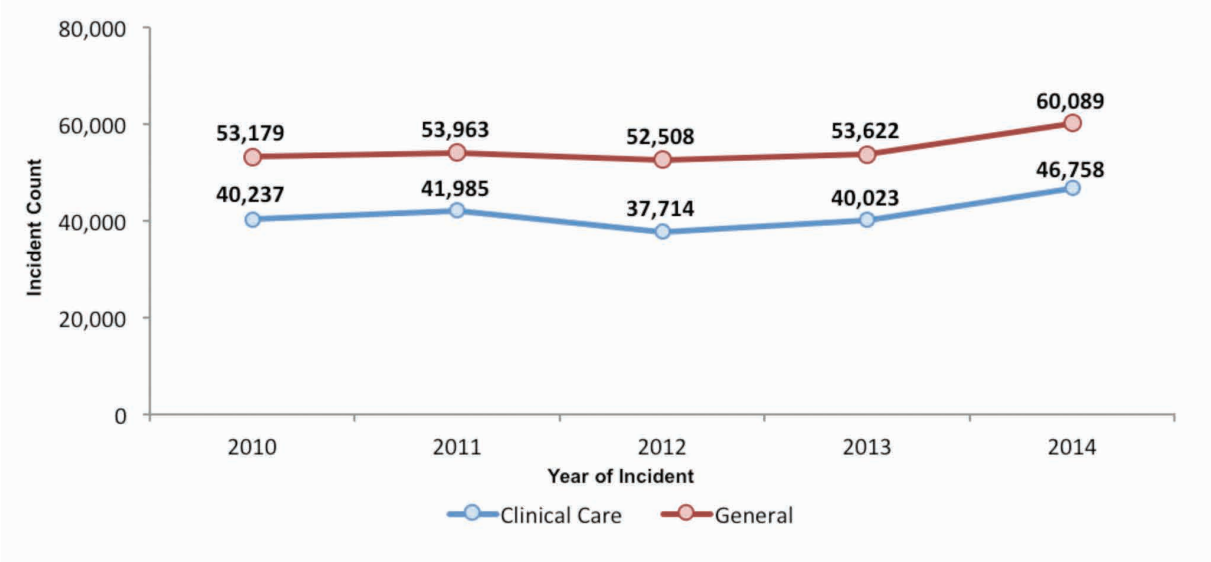


**Figure 1: Clinical and General incident count nationally, 2010-2014 inclusive**

Adjusted for increases in the national population, using data from the Central Statistics Office,[1] an increase in the clinical incident rate was identified: from 883 in 2010 to 1,014 in 2014, per 100,000 population (Figure 2).

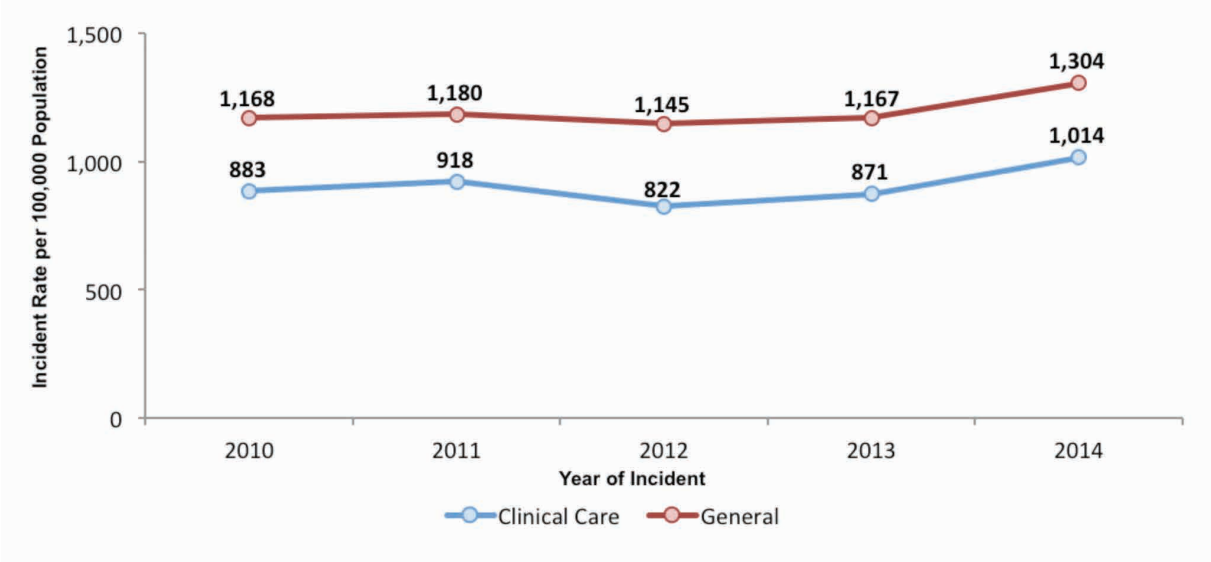


**Figure 2: Clinical and General incident rate per 100,000 population, 2010-2014 inclusive**

## 4.2 Analysis of clinical incidents by service

The five most common services in which clinical incidents were identified by the SCA, 2010-2014 inclusive, were Medicine (n=68,983), Maternity (n=46,692), Surgery (n=27,371), Disability (n=19,812) and Older Persons (n=7,992). Further detailed analysis was performed on these from a clinical viewpoint.

## 4.3 Most common clinical incidents nationally, 2010-2014 inclusive

The most common clinical incidents identified nationally, 2010 to 2014 inclusive were analysed using the *"please specify"* field on the NIMS. The subgroup *"other"* (n=66,716, 32.3%), where the incident did not fall into one of the particularised categories, was most common. This subgroup is reducing with the use of the NIMS which offers new and expanded incident categories and picklists from which to choose. This subgroup was followed by incidents that related to delay or failure to treat leading to an adverse outcome (n=9,681, 4.7%) and then incidents related to failure or faulty medical device or equipment (n=7,916, 3.8%). Medication-related incidents, which included incorrect dosage, missed medication and incorrect or not reconciled medication on admission/transfer/discharge, when combined, accounted for 14.7% (n=17,830) of the ten most common clinical incidents (Table 3).

| Ten Most common Clinical incidents nationally 2010-2014 inclusive | Total Incidents (n) | Percentage (%) |
|---|---|---|
| Other | 66,716 | 32.3% |
| Delay/Failure to treat - Adverse Outcome | 9,681 | 4.7% |
| Failure/Faulty Medical Device/Equipment | 7,916 | 3.8% |
| Incorrect Dosage | 7,215 | 3.5% |
| Missed Medication | 6,168 | 3.0% |
| Serious Soft Tissue Damage | 5,675 | 2.7% |
| Clinical Records Missing/Misplaced | 5,671 | 2.7% |
| Medication on admission/transfer/discharge incorrect or not reconciled | 4,447 | 2.2% |
| Post-partum Haemorrhage | 4,337 | 2.1% |
| Perineal Tear (3rd & 4th degree including breakdown of perineum) | 3,694 | 1.8% |
| Ten Most Common Incidents | 121,520 | 58.8% |
| Overall Total | 206,717 | 100.00% |

**Table 3: Ten most common clinical incidents identified nationally, categorised by the *please specify* field 2010-2014 inclusive**

## 4.4 Medicine

### 4.4.1 Clinical incidents in Medicine nationally, 2010-2014 inclusive

There has been an increase of 461 (3.2%) in the number of clinical incidents identified in Medicine nationally, 2010-2014 inclusive (Figure 3). This may reflect changes in patterns of clinical incident reporting, (possibly related to increased training and education in this area), may relate to changes in clinical care or a combination of both.

Regarding severity rating, in total over the five year period there were 68,983 clinical incidents identified pertaining to Medicine of which the healthcare services rated 934 (1.4%) as extreme; 33 (0.05%) as major; 14,061 (20.4%) as moderate; 13,740 (19.9%) as minor and 9356 (13.6%) as negligible. The remaining 30,859 (44.7%) clinical incidents did not receive a severity rating from the healthcare services.

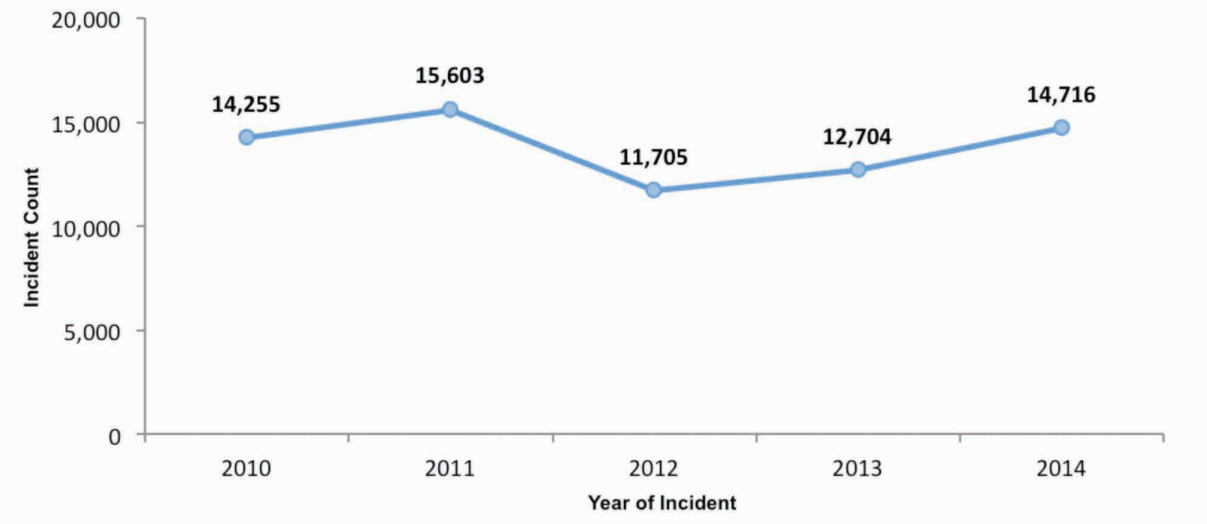


**Figure 3: Clinical incidents identified in Medicine nationally, 2010-2014 inclusive**

### 4.4.2 Ten most common clinical incidents in Medicine, nationally, 2010-2014 inclusive

The ten most common clinical incidents identified in Medicine 2010-2014 inclusive were analysed using the *"please specify"* field in the NIMS (Table 4). They accounted for 66.4% (n=45,804) of the total clinical incidents in Medicine for this time period. After the subgroup *"other"* (n=17,941, 26.0%), incidents related to delay or failure to treat leading to an adverse outcome were the second most common (n=5,477, 7.9%), followed by incorrect dosage (n=4,048, 5.9%) and serious soft tissue damage, (n=3,824, 5.5%). When combining incidents related to medication, including incorrect dosage, incorrect or not reconciled medication on admission/transfer/discharge and missed medication, they accounted for a significant proportion (n=9,687, 21.1%) of the top ten clinical incidents in Medicine during this 5 year period.

| Ten Most common Clinical incidents in Medicine 2010-2014 inclusive | Incident number (n) | Percentage (%) |
|---|---|---|
| Other | 17,941 | 26.0% |
| Delay / Failure to Treat - Adverse Outcome | 5,477 | 7.9% |
| Incorrect Dosage | 4,048 | 5.9% |
| Serious Soft Tissue Damage | 3,824 | 5.5% |
| Medication on admission/transfer/discharge incorrect or not reconciled | 3,288 | 4.8% |
| Missed Medication | 2,351 | 3.4% |
| Failure/Faulty Medical Device/Equipment | 2,339 | 3.4% |
| Injury Arising from Donation | 2,298 | 3.3% |
| Clinical Records Missing / Misplaced | 2,212 | 3.2% |
| Inappropriate Admission/transfer | 2,026 | 2.9% |
| **Ten Most Common Incidents** | **45,804** | **66.4%** |
| **Overall Total** | **68,983** | **100.0%** |

**Table 4: Ten most common clinical incidents identified in Medicine nationally, categorised by the *please specify* field, 2010-2014 inclusive**

### 4.4.3 Most common clinical incidents in Medicine, tracked, 2010-2014 inclusive

The most common clinical incidents identified in Medicine during this 5 year period were tracked, (excluding the subgroup *"other"*), to help identify trends (Figure 4). During this period, a reduction in incidents related to incorrect medication on admission/transfer or discharge, missed medication and incorrect dosage was documented. The latter had a spike in 2011, which was largely accounted for by an increase in incidents from one hospital. Incidents pertaining to incorrect dosage decreased in 2012, below the 2010 figure, and have remained relatively stable at this level. A significant increase (doubling) in incidents related to serious soft tissue damage was documented in addition to an increase in delay or failure to treat leading to an adverse outcome.

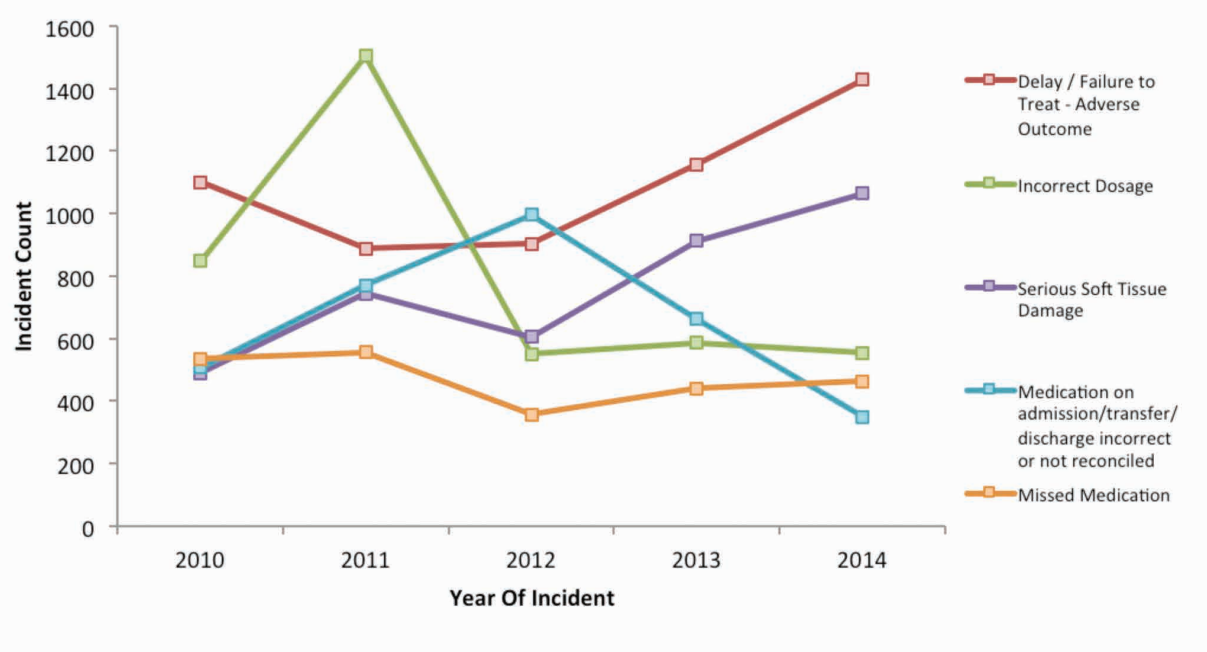


**Figure 4: Most common clinical incidents in Medicine nationally, categorised by the *please specify* field, tracked 2010-2014 inclusive, excluding "other"**

### 4.4.4 Suggestions

#### i. Medication reconciliation

Medication reconciliation is particularly important at times of patient transfer: e.g. on admission from primary to secondary/tertiary care, on discharge from hospital to community or when moving ward within a hospital. Use of an Electronic Healthcare Record with portals for general practitioners (GPs) and community services (e.g. pharmacy) would help ensure medication reconciliation and reduce medication errors. While awaiting the national roll out of an Electronic Health Care Record, the linking of IT systems between the hospital and the community and GP (e.g. via Healthlink) from a medication viewpoint would be useful.

### ii. Specific training and education programme

A specific training and education programme for doctors and nurses regarding medication incidents including identification, potential consequences, prevention and management of medication incidents, would be useful. Consideration should be given to whether this might become mandatory over time with the provision of continuous professional development (CPD) points. Outcomes from the implementation of training programmes should be audited regularly to ensure effectiveness. Results of audits may be presented and published within the hospital, hospital group and nationally to increase awareness among staff and the public.

### iii. Clinical pharmacy service

Availability of a clinical pharmacy service in all hospitals would reduce medication errors. This service would ensure pharmacists perform ward rounds with the medical/surgical teams to provide medication advices including medication side effects, drug interactions, correct doses and promote generic prescribing. A clinical pharmacy service would ensure regular review of the drug kardex with appropriate discontinuation and commencement of medications.

### iv. Introduction of a national drug kardex

Introduction of a national drug kardex would reduce variation and promote standardisation across hospitals nationwide. Currently, each hospital has a different drug kardex which each health care professional has to learn how to use correctly when they change their location of employment. Standardisation of a drug kardex, and its use would assist doctors, nurses, and pharmacists in training as they rotate employment through hospitals nationally. This should help decrease errors in prescribing and documentation of allergy status. The current variation that exists nationally between all hospitals regarding the format of the drug kardex is potentially confusing.

### v. Electronic Health Care Record with Clinical Decision Support

The introduction across the public health sector of an Electronic Healthcare Record with Clinical Decision Support and Computerised Physician Order Entry will help reduce medication errors, as documented in other countries[2]. Pop-up alerts, advising doctors of drug to drug interactions, correct doses, recommended antibiotic choices, based on clinical guidelines or standards, and electronic prescriptions, all assist in reduction of medication incidents. A standardised, certified Electronic Healthcare Record with portals for the GP and community services (e.g. community pharmacist) would reduce errors. Adequate training of staff on the correct use of the Electronic Healthcare Record is critical. In the USA, financial incentives were given to doctors who proved *"meaningful use"* of the Electronic Healthcare Record. Avoidance of *"alert fatigue"* is important where there are too many alerts and doctors "over-ride" them. The Electronic Healthcare Record was rolled out in Q4 of 2016 to some Maternity Services (Phase I) nationally.

### vi. Empowerment of the patient or carer regarding knowledge of his/her medications

Empowerment of the patient or carer to become a more active member of the multidisciplinary care team is recommended. Similar to the banking and airline services, individuals/patients should become more actively involved in their personal healthcare. Patients are the single constant member of the multi-disciplinary team and this is particularly important when patient healthcare traverses both hospital and community sites and when communication may be suboptimal. It is suggested that it would be helpful if patients/carers know, carry a list, or have a photograph on their mobile phones of their most up-to-date prescription medication or use medication apps where possible. In time, the Electronic Healthcare Record and unique identifier number, linking hospital and community services, will resolve many medication incidents.

### vii. Review of "donation incidents"

All the "donation incidents" reported to the SCA were related to haematology. A review of donation incidents from a blood and blood product viewpoint would be useful to identify causes, severity and implications of clinical incidents. Subsequently, targeted processes to reduce or prevent these incidents from recurring could be implemented.

### viii. Medical equipment or devices

Faulty or failed medical equipment or devices should be fixed or replaced, respectively. Consideration should potentially be given to hiring equipment from companies, with full service included, as an alternative option to the purchase of equipment which often has to be replaced every few years (generally every seven years) because it is deemed *"out of date"* by the manufacturer. Medical equipment and devices should continue to be regularly checked in accordance with the manufacturer's guidance. Between 2012 and 2016 inclusive, it is understood the HSE spent €154.4 million on the Equipment Replacement Programme with an additional €35 million allocated for 2017 (personal correspondence to author).

### ix. Improved quality of clinical incident reporting

Significant education and training has been provided by the clinical risk team of the SCA to healthcare services nationally at hospital and CHO level. This together with refining new categories and picklists offered by the NIMS is helping to reduce the subgroup *"other"* over time.

## 4.5 Maternity services

### 4.5.1 Clinical incidents in Maternity services nationally, 2010-2014 inclusive

A dedicated report *Clinical incidents and claims report in Maternity and Gynaecology services: a five year review, 2010-2014*[3] was recently published by the SCA in which significant detail is available related to this topic. Slight differences in numbers exist between this report and the previous one because the data was re-run on a different date: the changes are explained by on-going quality improvement initiatives combined with the fact that further incidents have been uploaded on the NIMS during the intervening period. Data is run based on the "date the incident occurred" and not the "date the incident was reported to the NIMS".

Maternity was the second most common service which reported clinical incidents to the SCA 2010-2014 inclusive. The total number of clinical incidents in Maternity services identified by the SCA has reduced from 9,504 in 2010 to 9,406 in 2014 (n=98, 1.0%). This may be due to changes in clinical care, more accurate reporting of clinical incidents or a combination of both (Figure 5). Total clinical incidents nationally, increased over the same time period.

The total number of clinical incidents in Maternity services during this five year period was 46,692 of which 405 (0.9%) were rated extreme; 20 (0.04%) major; 5,513 (11.8%) moderate, 3,351 (7.2%) minor; 2,546 (5.5%) negligible and the remaining 34,836 (74.6%) did not receive a severity rating from the healthcare services.

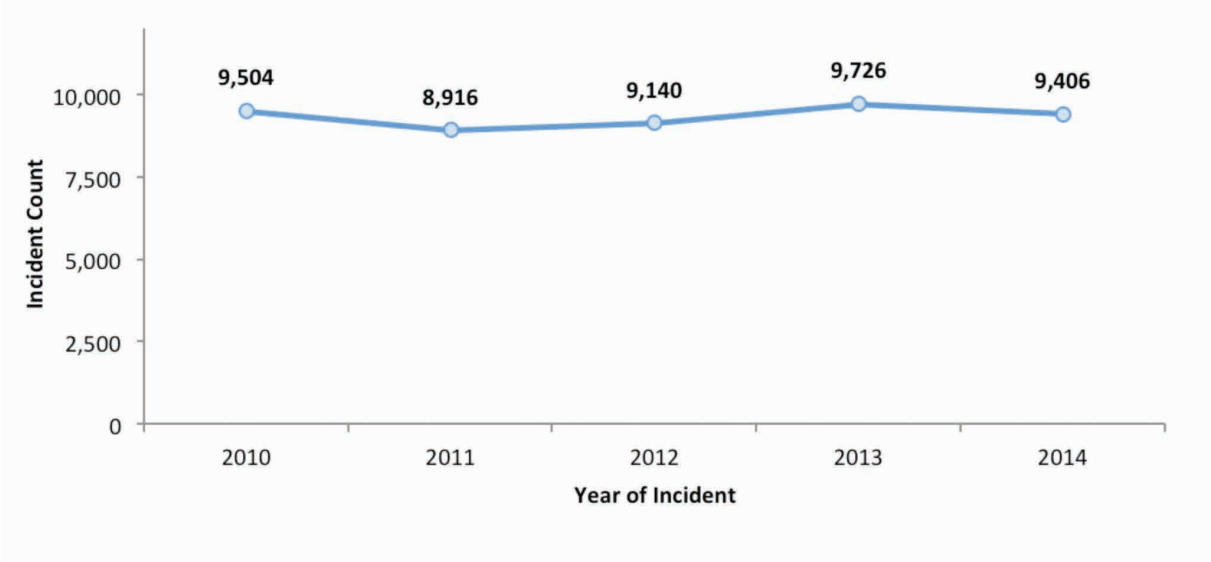


**Figure 5: Clinical incidents identified in Maternity services nationally, 2010-2014 inclusive**

### 4.5.2 Ten most common clinical incidents in Maternity services nationally, 2010-2014 inclusive

Clinical incidents in Maternity services 2010-2014, inclusive, categorised by the *"please specify"* field were analysed (Table 5). The most common incident was the subgroup *"other"* (n= 8,827, 18.9%), followed by postpartum haemorrhage (n=4,276, 9.2%), perineal tear (3rd and 4th degree including breakdown of the perineum, n=3,676, 7.9%) and Apgar score <5 at 1 minute, 7 at 5 minutes, cord base excess <12 and cord pH < 7.2 (n=3,522, 7.5%), (Table 5).

| Clinical Incidents Identified in Maternity Services, 2010-2014 inclusive | Incident number (n) | Percentage (%) |
|---|---|---|
| Other | 8,827 | 18.9% |
| Post-partum Haemorrhage | 4,276 | 9.2% |
| Perineal Tear (3rd & 4th Degree, incl. breakdown of perineum) | 3,676 | 7.9% |
| Apgar <5@1, 7@5, cord BE <12, pH<7.2 | 3,522 | 7.5% |
| Unexpected transfer to SCBU/NICU | 3,221 | 6.9% |
| Unplanned re-attendance | 1,918 | 4.1% |
| Shoulder Dystocia | 1,912 | 4.1% |
| Complication leading to transfer to operating room post 2nd stage | 1,379 | 3.0% |
| Clinical Records Missing / Misplaced | 930 | 2.0% |
| Incomplete Records | 877 | 1.9% |
| Ten Most Common Incidents | 30,538 | 65.4% |
| Overall Total | 46,692 | 100% |

**Table 5: Ten most common clinical incidents identified in Maternity services nationally, categorised by the *please specify* field, 2010-2014 inclusive**

### 4.5.3 Most common clinical incidents in Maternity services nationally, tracked, 2010-2014 inclusive

The most common clinical incidents identified in Maternity services, 2010-2014, inclusive, excluding the subgroup *"other"* and mass actions were tracked and analysed, to help identify trends using the *"please specify"* field (Figure 6). This analysis demonstrated that incidents related to post-partum haemorrhage (PPH) and unplanned re-attendance have significantly increased in number, while incidents related to perineal tear (3rd and 4th degree), unexpected transfer to the SCBU or NICU have remained relatively stable. Incidents related to low Apgar score and low cord pH have almost halved in number during this 5 year period. Overall, for the common clinical incidents in Maternity services, incidents rates in Ireland compared favourably with international, published, incident rates.[3]

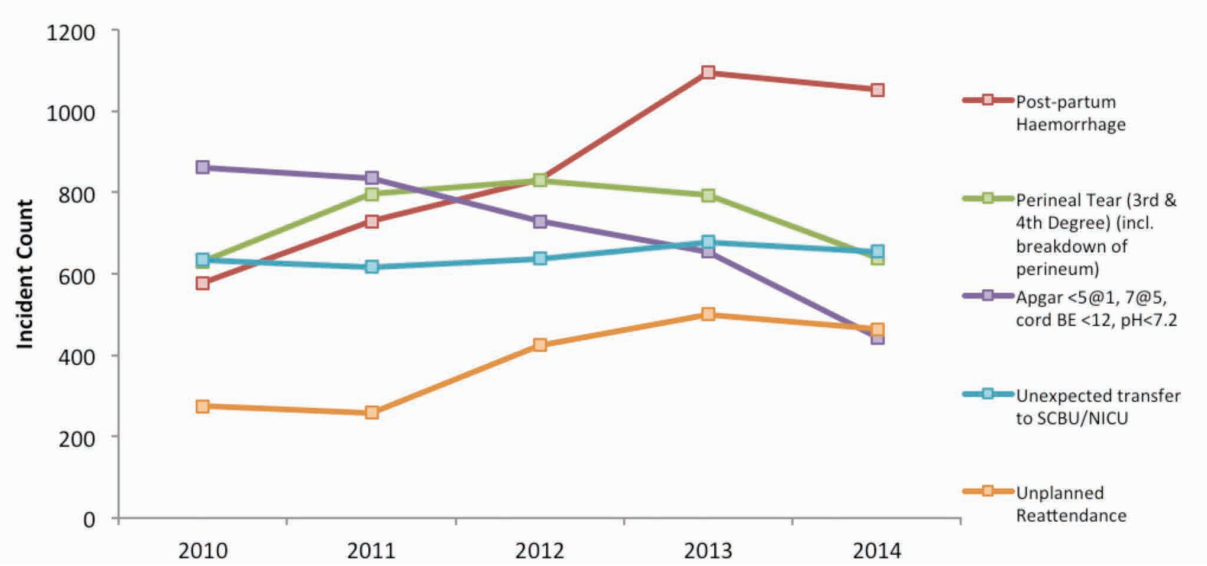


**Figure 6: Most common clinical incidents identified in Maternity services nationally, tracked, categorised by the *please specify* field, 2010-2014 inclusive, excluding "other"**

### 4.5.4 Suggestions

The recent detailed *"Clinical incidents and claims report in Maternity & Gynaecology Services – a five year review, 2010-2014"*[3] suggests that national and international guidance should be followed regarding management of common incidents in Maternity services and this guidance is discussed.

## 4.6 Surgery

### 4.6.1 Clinical incidents in Surgery nationally, 2010-2014 inclusive

Surgery was the third most common service which reported clinical incidents to the SCA 2010-2014 inclusive. There was a 6.6% (n=360) increase in clinical incidents identified in Surgery during this time period (Figure 7). This increase may be explained by changes in pattern of clinical incident reporting in Surgery, changes in clinical care or a combination of both.

Regarding severity rating, of the total number of clinical incidents (n= 27,371) identified in Surgery over this five year period, 413 (1.5%) were rated extreme; 27 (0.1%) major; 6,678 (24.4%) moderate; 5,326 (19.5%) minor; 3,877 (14.2%) negligible and the remaining 11,049 (40.4%) did not receive a severity rating from the healthcare services.

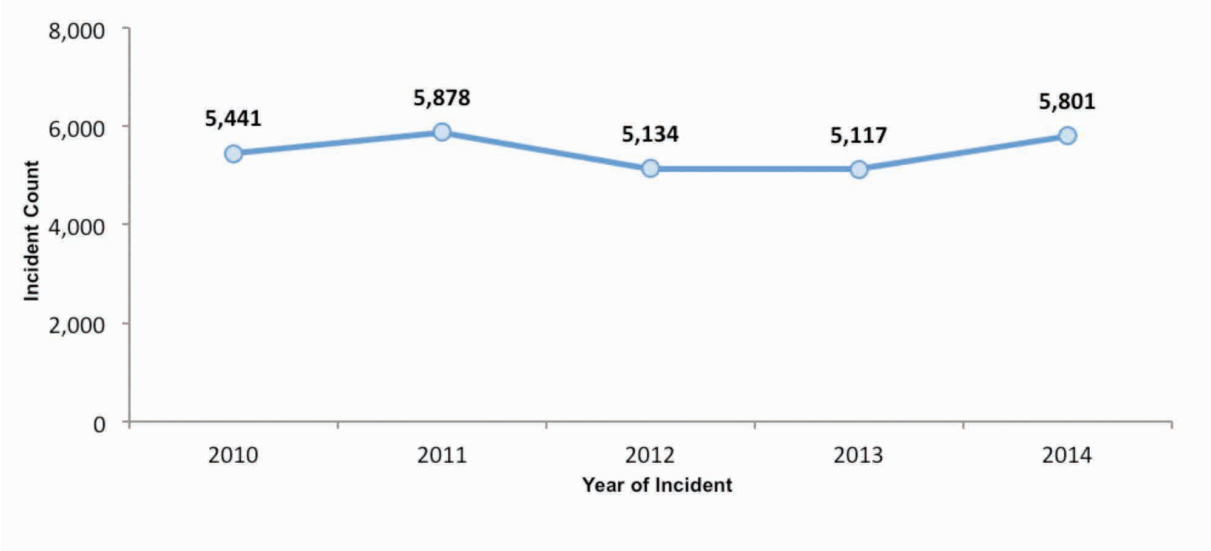


**Figure 7: Clinical incidents identified in Surgery nationally, 2010-2014 inclusive**

## 4.6.2 Ten most common clinical incidents in Surgery, 2010-2014 inclusive

Data was analysed in further detail to identify the ten most common clinical incidents in Surgery over this five year period using the *"please specify"* field (Table 6). The subgroup *"other"* was the most common incident identified (n=7,049, 25.8%). Not surprisingly, in a service dominated by procedures/operations, incidents pertaining to failure or faulty medical device or equipment (n=1,797, 6.6%) ranked high. Incidents related to *"records"*, including missing or misplaced clinical records and wrong medical records applied to a patient, were relatively common, and when combined, accounted for 14.6% (n=2,455) of the ten most common clinical incidents in Surgery, nationally, during this time period. Similarly, though less common, were incidents related to medication which included incorrect medication or non reconciled medication on admission/transfer/discharge and incorrect dosage which, combined, accounted for 10.1% (n=1,706) of the ten most common clinical incidents identified in Surgery during this five year period.

| Ten Most Common Clinical Incidents in Surgery, 2010-2014 inclusive | Incident number (n) | Percentage (%) |
|---|---|---|
| Other | 7,049 | 25.8% |
| Failure/Faulty Medical Device/Equipment | 1,797 | 6.6% |
| Clinical Records Missing / Misplaced | 1,794 | 6.6% |
| Delay / Failure to Treat - Adverse Outcome | 1,474 | 5.4% |
| Serious Soft Tissue Damage | 977 | 3.6% |
| Medication on admission/transfer/discharge incorrect or not reconciled | 876 | 3.2% |
| Incorrect Dosage | 830 | 3.0% |
| Delayed / Cancelled surgery - Result Patient Harm | 776 | 2.8% |
| Wrong Medical Records Applied to Patient | 661 | 2.4% |
| Incorrect data | 629 | 2.3% |
| Ten Most Common Incidents | 16,863 | 61.6% |
| Overall Total | 27,371 | 100.0% |

**Table 6: Ten most common clinical incidents identified in Surgery nationally, categorised by the *please specify* field, 2010-2014 inclusive**

### 4.6.3 Most common clinical incidents in Surgery nationally, tracked, 2010-2014 inclusive

The most common clinical incidents identified in Surgery, excluding the subgroup *"other"*, were tracked over a five year period to help identify trends, using the *"please specify"* field (Figure 8). More than a doubling of clinical Incidents related to serious soft tissue damage and delay or failure to treat leading to an adverse outcome was documented. A relatively small increase in incidents related to failure or faulty medical device or equipment was identified. A significant (fivefold) reduction in incidents pertaining to incorrect medication or medication not reconciled on admission/transfer/ discharge was documented while a reduction in incidents pertaining to missing or misplaced clinical records was identified.

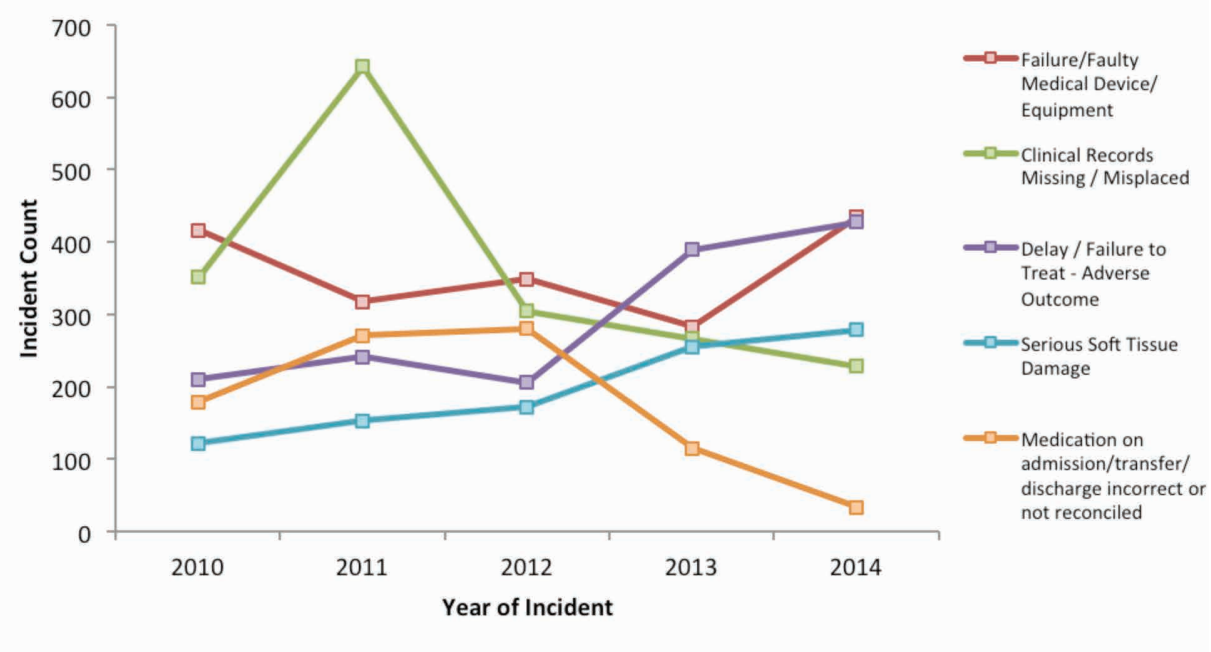


**Figure 8: Most common clinical incidents in Surgery nationally, tracked, categorised by the *please specify* field, 2010-2014 inclusive, excluding "other"**

### 4.6.4 Suggestions

#### i. Failed or faulty medical devices and equipment should be replaced or fixed respectively

Failed or faulty medical device or equipment is a more common incident in Surgery than other services because this service is based on surgical procedures and interventions utilising medical devices and equipment. Replacement of medical devices or equipment deemed 'out of date' by the manufacturer has significant implications for capital investment nationally. The possibility of hiring medical devices and equipment using a central procurement process, and availing of trade discount instead of purchasing, is one worth considering and one which has worked in other jurisdictions. All medical devices and equipment should undergo thorough, regular checks and should be checked prior to use.

#### ii. Electronic Healthcare Record with clinical decision support should reduce missing or misplaced health care records and medication errors

Introduction of an Electronic Health Record reduces the risk of missing healthcare records. The USA has introduced Electronic Healthcare Records with Clinical Decision Support across all states. Ireland launched phase 1 of the Electronic Healthcare Record in Maternity services in the last quarter of 2016.

Studies have identified that the Electronic Healthcare Record with Clinical Decision Support and Computerised Physician Order Entry reduced both turnaround time and medication errors.[2]

The Electronic Healthcare Record system has been shown to facilitate patient safety and quality improvement through use of checklists, alerts and predictive tools; embedded clinical guidelines that promote standardised evidence-based practices; electronic prescribing and test ordering that reduces errors and duplication of tests.[4]

Studies have identified that medication orders/prescriptions not using Computerised Physician Order Entry were approximately 8 times more likely to require pharmacist involvement, with the majority of pharmacist interventions performed to prevent medication errors. The overall mean turnaround time for medication orders/prescriptions was significantly shorter in the Computerised Physician Order Entry group in comparison with the hand-written group.[5]

#### iii. Attempt to reduce waiting times

Delay in treatment or failure to treat is an area that has received significant attention in the media nationally and internationally. Long waiting times for Surgery may be related to staffing levels with specific expertise (medical and nursing), availability of operating theatre time or postoperative intensive care units' beds. This is both a national and international issue. The National Treatment Purchase Fund has been used as an initiative to reduce specific waiting lists. The NHS has partnered with private health care providers for some elective surgical procedures e.g. endoscopies, colonoscopies to reduce waiting lists as has the HSE e.g. haemodialysis.

#### iv. Improve quality of clinical incident reporting

Detailed education and training on how to report clinical incidents and to categorise them has been undertaken by the SCA in both acute hospitals and CHOs nationwide.

## 4.7 Disability services

### 4.7.1 Clinical incidents in Disability services nationally, 2010-2014 inclusive

Disability services were the fourth most common services in which clinical incidents were identified, 2010-2014 inclusive. A significant increase (n=2,927) in the number of clinical incidents in Disability services was documented during this time period, which equates to a 91.2% increase. This may be accounted for by changes in patterns of incident reporting in Disability services, (related to education and training in this important area), changes in clinical care, changes in IT capability to report, or a combination of all of the above (Figure 9). The finalised Residential Care Standards became available January 2013 of which risk management was an important component. Two healthcare centres significantly increased reporting in 2014. Additionally, Disability services nationally are caring for a population that has complex care needs (intellectual and physical disability) and is ageing.

Regarding severity rating, of the total (n=19,812) clinical incidents identified in Disability services during this five year period, 81 (0.4%) were rated extreme by the healthcare service:
3 (0.02%) major; 702 (3.5%) moderate; 4,727 (23.9%) minor and 3,466 (17.5%) negligible. The remaining 10,833 (54.7%) clinical incidents did not receive a severity rating from the healthcare services.

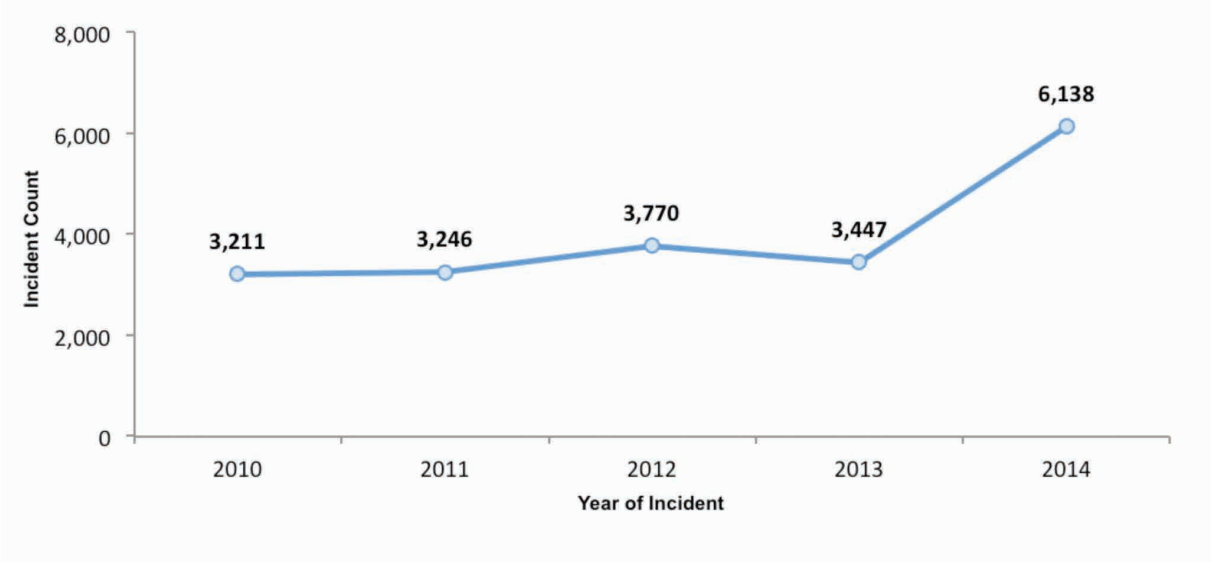


**Figure 9: Clinical incidents identified in Disability services, 2010-2014 inclusive**

### 4.7.2 Ten most common clinical incidents in Disability services nationally, 2010-2014 inclusive

The ten most common clinical incidents identified in Disability services 2010-2014 inclusive, accounted for the vast majority (93.4%) of all clinical care incidents in Disability during this time period (Table 7). The subgroup *"other"* (where the incident did not fall into one of the particularised categories) was particularly large (n=14,061, 71.0%). Further analysis of this data through sampling identified that they mainly relate to behavioural incidents and would fall under the WHO classification of exposure to behavioural hazards, now available on the NIMS. Extensive training and guides on how to use the NIMS is improving the quality and quantity of incident reporting. Choking episodes (n=579, 2.9%) are relatively specific to this patient population. Medication incidents, including missed medication, incorrect dosage and incorrect medication were relatively common, accounting for 13.9% (n=2,571) of the ten most common clinical incidents in Disability services during this five year period.

| Ten Most Common Clinical Incidents in Disability Services, 2010-2014 inclusive | Incident number (n) | Percentage (%) |
|---|---|---|
| Other | 14,061 | 71.0% |
| Missed Medication | 1,635 | 8.3% |
| Choking Episode | 579 | 2.9% |
| Incorrect Dosage | 576 | 2.9% |
| Signature of Healthcare Practitioner Omitted | 405 | 2.0% |
| Incorrect Medication | 360 | 1.8% |
| Sudden Collapse | 311 | 1.6% |
| Failure/Faulty Medical Device/Equipment | 208 | 1.0% |
| Incorrect Time | 207 | 1.0% |
| Incorrect Directions / Labelling | 165 | 0.8% |
| Ten Most Common Incidents | 18,507 | 93.4% |
| Overall Total | 19,812 | 100.0% |

**Table 7: Ten most common clinical incidents identified in Disability services nationally, categorised by the *please specify* field 2010-2014 inclusive**

### 4.7.3 Most common clinical incidents in Disability services nationally, tracked, 2010-2014 inclusive

The most common clinical incidents identified in Disability services, excluding the subgroup *"other"*, were tracked over this five year period, to help identify trends, and were analysed using the *"please specify"* field (Figure 10). All incidents increased, with a fivefold increase in incidents related to incorrect medication, a threefold increase in incidents related to choking episodes and missed medication and more than a doubling of incidents related to incorrect dosage and an increase in incidents related to omission of a signature of a healthcare practitioner.

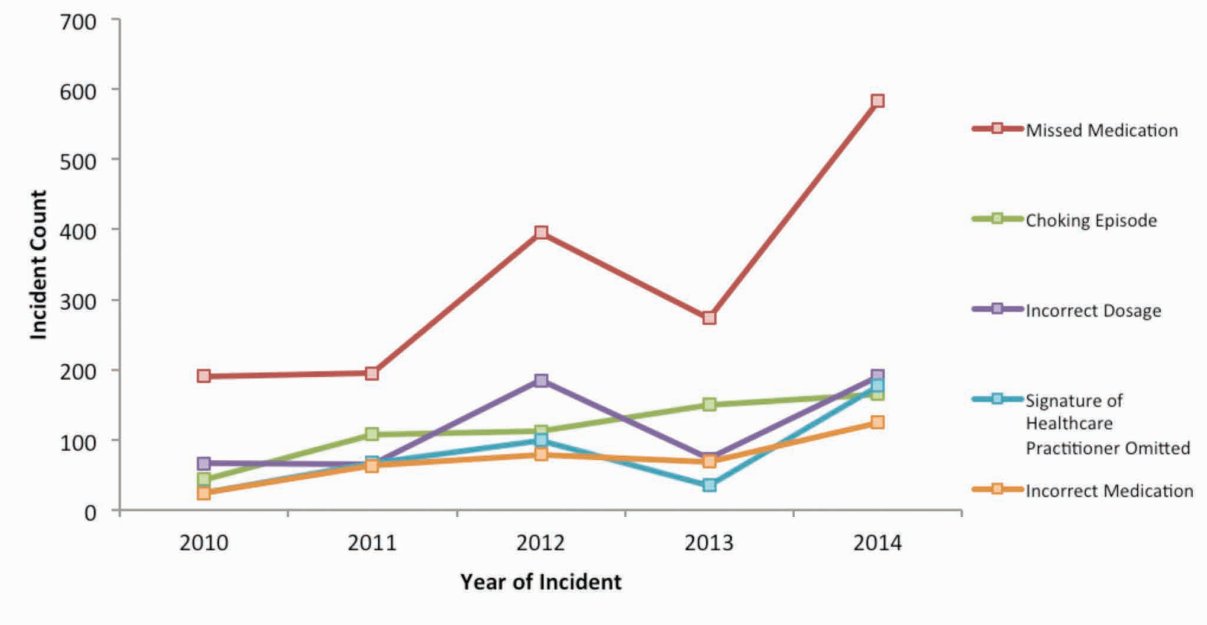


**Figure 10: Most common clinical incidents in Disability services nationally, tracked, categorised by the *please specify* field, 2010-2014 inclusive, excluding *"other"***

### 4.7.4 Suggestions

#### i) Implementation of strategies to reduce medication incidents

Similar to the recommendations outlined earlier, multiple strategies to increase medication reconciliation, would be useful, including, specific multi-phasic, multi-disciplinary training and education programmes regarding medication incidents; a clinical pharmacy service in all hospitals; introduction of a national drug kardex; introduction of an Electronic Health Care Record with Clinical Decision Support and Computerised Physician Order Entry nationally and empowerment of the patient/carer regarding knowledge of his/her medications.

#### ii) Risk assessment and management of choking episodes

Ensure multi-phasic, multi-disciplinary training and education regarding emergency treatment of choking episodes is implemented with regular drills and skills on site e.g. Heimlich manoeuvre. This training may form part of continuous professional development in the future.

On-going, proactive education and awareness that "choking episodes" are a significant, potential risk in this patient population is important. A high index of suspicion and a low threshold for referral for assessment of swallowing difficulties, if suspected, is crucial. This may include referral to speech and language therapy services for assessment, barium swallow or video fluoroscopy studies to ensure the airway is safe. Interventions may range from simple avoidance of certain thin consistencies and addition of a thickening agent, to different medication formulations, nasogastric feeding or Percutaneous Enteric Gastrostomy (PEG) tube feeding. These interventions may help avoid aspiration pneumonia and life-threatening choking episodes.

#### iii) Increased involvement of the patient, carer and/or family

Increased involvement of the patient, carer and/or family as an important member(s) of the multi-disciplinary care team, particularly at times of patient transition or when multiple teams are involved in care, would be helpful.

#### iv) Improved quality of clinical incident reporting

Significant education and training has been provided and continues to be provided regarding clinical incident reporting and categorisation by the clinical risk team of the SCA to relevant staff in healthcare services nationally.

## 4.8 Older persons

### 4.8.1 Clinical incidents in Older Persons nationally, 2010-2014 inclusive

Older Persons was the fifth most common service in which clinical incidents were identified during this 5 year period. There has been a significant increase in the number of incidents, (n=849) identified in the service of Older Persons, 2010-2014, which represents an increase of 72.1% (Figure 11). This may be related to increased reporting of clinical incidents in Older Persons, changes in clinical care or a combination of both. Overall, an increase in clinical incident reporting, over a range of severity of injury, is viewed as a positive finding, consistent with increased awareness of patient safety.

Regarding severity rating of the total clinical incidents identified in the Older Persons service (n=7,992), the healthcare services rated 135 (1.7%) as extreme; 6 major (0.1%); 1,161 (14.5%) moderate; 802 (10.0%) minor; 1,392 (17.4%) negligible and the remaining 4,496 (56.3%) did not receive a severity rating from the healthcare services.

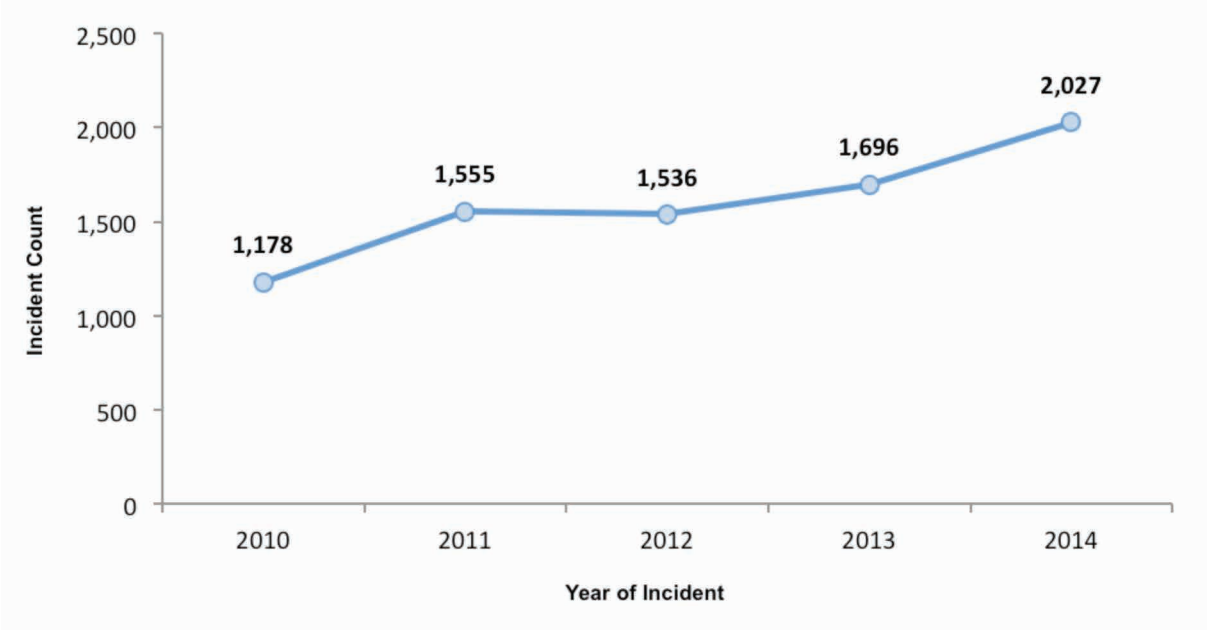


**Figure 11: Clinical incidents identified in Older Persons, 2010-2014 inclusive**

### 4.8.2 Ten most common clinical incidents in Older Persons, tracked, 2010-2014 inclusive

The ten most common clinical incidents identified in Older Persons 2010-2014 inclusive were analysed using the *"please specify"* field. The subgroup *"other"* was the most common. Further review of this subgroup data through sampling identified it mainly related to behavioural incidents and would fall under the WHO classification of exposure to behavioural hazards, now available on the NIMS. Extensive training and guides on how to use the NIMS is improving the quality and quantity of incident reporting. "Other" was followed by serious soft tissue damage (n=352, 4.4%). Incidents pertaining to medication were relatively common, including missed medication, incorrect dosage and incorrect medication, which, combined, accounted for 9.5% (n=687) of the top ten most common incidents in Older Persons during this five year period. Failure or faulty medical device or equipment (n=240, 3.0%), delay or failure to treat leading to an adverse outcome (n=232, 2.9%) and choking episodes (n=190, 2.4%) were identified within the ten most common clinical incidents (Table 8).

| Most Common Clinical Incidents in Older Persons, 2010-2014 inclusive | Incident number (n) | Percentage (%) |
|---|---|---|
| Other | 5,297 | 66.3% |
| Serious Soft Tissue Damage | 352 | 4.4% |
| Missed Medication | 284 | 3.6% |
| Failure/Faulty Medical Device/Equipment | 240 | 3.0% |
| Delay / Failure to Treat - Adverse Outcome | 232 | 2.9% |
| Incorrect Dosage | 221 | 2.8% |
| Choking Episode | 190 | 2.4% |
| Incorrect Medication | 182 | 2.3% |
| Unexpected Deterioration | 82 | 1.0% |
| Restraints/cot-side/bed-rails | 60 | 0.8% |
| Incorrect Directions / Labelling | 60 | 0.8% |
| Ten Most Common Incidents | 7,200 | 90.1% |
| Overall Total | 7,992 | 100.0% |

**Table 8: Most common clinical incidents identified in Older Persons, categorised by the *please specify* field 2010-2014 inclusive**

[Note: In excess of 10 clinical incidents are provided because some had equal numbers]

### 4.8.3 Most common clinical incidents in Older Persons, tracked, 2010-2014 inclusive

The most common clinical incidents in Older Persons identified using the *'please specify'* field were tracked over this 5 year period. All have increased. Delay or failure to treat leading to an adverse outcome increased by more than seven fold, failure or faulty medical equipment increased by twofold, while serious soft tissue injury, missed medication and incorrect dose all increased over this time period too, but to a lesser extent (Figure 12).

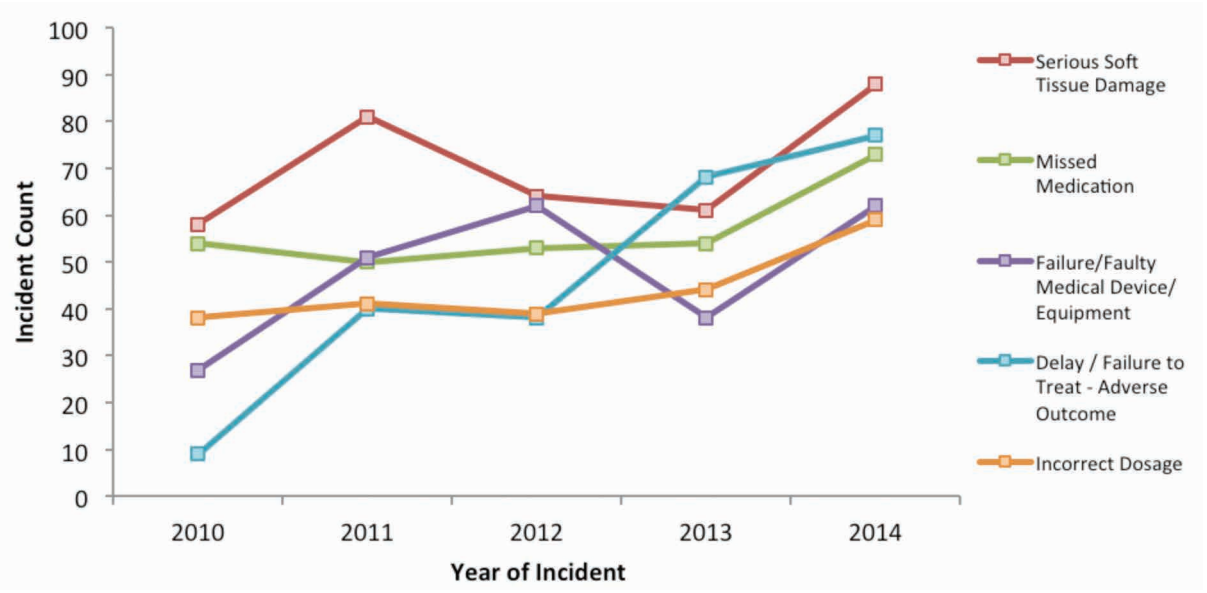


**Figure 12: Most common clinical incidents in Older Persons, categorised by the *please specify* field, 2010-2014 inclusive**

### 4.8.4 Suggestions

#### i. A strategy bundle to reduce medication incidents especially in patients with polypharmacy

Polypharmacy leads to a risk of medication incidents. Older Persons is a patient subgroup which is particularly vulnerable to polypharmacy due to co-existence of multiple morbidities. A multifaceted approach is required including

- multi-disciplinary, multi-phasic specific training and education programme
- a clinical pharmacy service in all hospitals
- introduction of a national drug kardex
- introduction of the Electronic Healthcare Record nationally with Clinical Decision Support and Computerised Physician Order Entry and portals for GP, community services and patients
- empowerment of the patient and family/carer to actively become more involved regarding *" know my medications"* programme and the multi-disciplinary team overall
- additional attention to medication reconciliation at times of patient transition including from hospital to home and vice versa

#### ii) Additional attention to care of skin and soft tissue in older people

- Older people often have thinner, more frail skin and less soft tissue than young people. Skin and soft tissue requires special attention to prevent pressure sores, which, in older people, may lead to complications due to their more vulnerable immune system e.g. septicaemia or osteomyelitis. Resourcing of special mattresses, beds and staffing (e.g. tissue viability nurses) may be required. Acquisition of stage 3 or 4 pressure ulcers after admission to a healthcare and social care service has been identified as a serious reportable event (SRE) by the HSE and internationally a *"never event"*. In a special report on SREs published by the HSE[6], November 2015, 20 (19%) of the 103 care management events, reported over a 19 month period, related to grade 3 or 4 pressure ulcers.

#### iii) Failed or faulty medical devices and equipment should be replaced or fixed respectively

Failed or faulty medical devices or equipment should be replaced or fixed respectively. Replacement of medical devices or equipment deemed "out of date" by the manufacturer has significant resource implications nationally. Reduction in the cost of replacement of medical devices and equipment may be attained by hiring of same through a central procurement process. Older persons may have extra medical devices or equipment due to their age, to assist mobility, lifting or hearing. Checks of equipment and medical devices should continue to be performed prior to use and regularly, consistent with manufacturer guidance.

#### iv) Prevention of delays and failing to treat in an older person

Delay or failure to treat leading to an adverse outcome is a significant incident identified in Older Persons. Due to the physiology of Older Persons and their sometimes blunted immune response, they do not always display the same clinical signs that younger adults display e.g. Older Persons do not always develop a fever with pneumonia or septicaemia. Therefore, a high level of clinical suspicion is required. They often have less reserve than a younger adult, so timely diagnosis and treatment is important where possible.

#### v) Multi-phasic, multidisciplinary team training in early identification, management and prevention of swallowing difficulties, both acute and chronic

Multi-disciplinary teams are trained in the emergency management of choking. Multi-phasic, multi-disciplinary team training and education regarding early identification, early referral, management and prevention of swallowing difficulties are important. A high index of suspicion and low threshold for referral for investigations and specialist opinion, if swallowing issues are a concern, are indicated.

# 5.0 CLAIMS CREATED

## 5.1 Background

National data was analysed regarding clinical claims created and their associated costs during the five year period 2010-2014 inclusive, to identify high risk areas to guide the development of service-specific risk management suggestions that may help improve patient safety and the patient experience in our healthcare service, nationally.

The Clinical Indemnity Scheme (CIS), which commenced on July 1st 2002 is still considered, from an actuarial viewpoint, an *"immature"* indemnity scheme. The CIS has included the indemnification of consultants since February 1st 2004 but only in respect of clinical incidents occurring on or after that date. Based on the inclusion of consultants in the CIS with effect from February 2004 and the known lag period between the date an incident occurs and the date a claim is created, a sharp increase in number of claims was expected 2010-2014 inclusive.

## 5.2 Claims

### 5.2.1 Claims created nationally, 2010-2014 inclusive

Clinical claims were reviewed pertaining to the period 2010-2014 inclusive. As expected, based on the *"immaturity"* of the Clinical Indemnity Scheme, a significant increase in clinical claims created was identified over this five year period (n= 157, which equates to a 35.1% increase). Additionally, an increase in general claims was documented (n=32, which equates to 36.4%), during this same time period (Figure 13). The delegation of the HSE under the General Indemnity Scheme (GIS) occurred in 2010 and had an impact on claims volume.

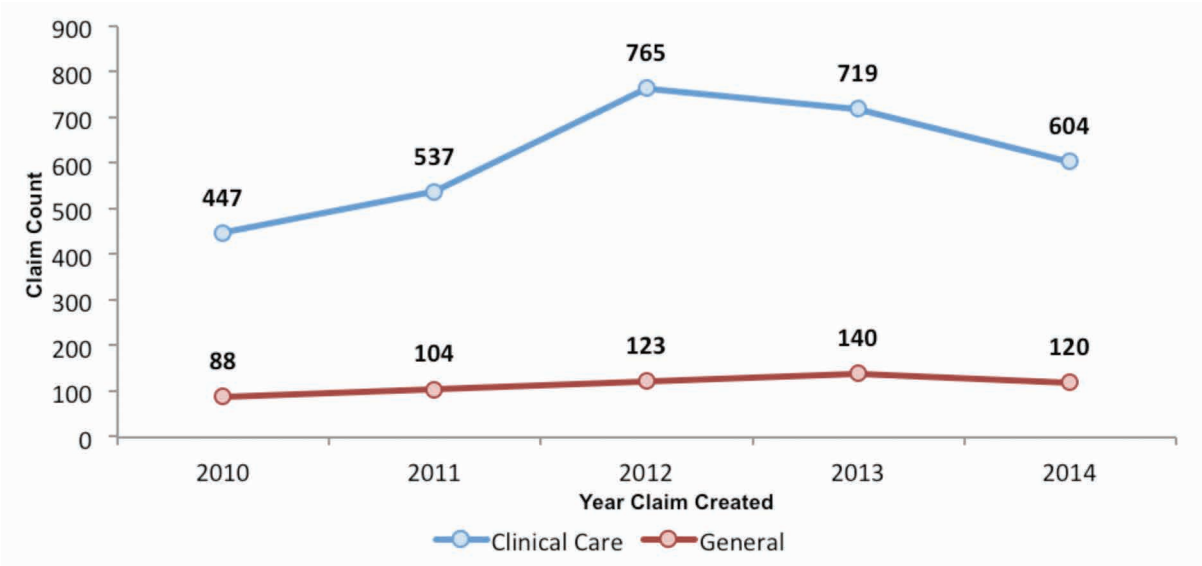


**Figure 13: Comparison of the number of clinical and general claims created nationally, 2010-2014 inclusive**

The peak in clinical claims in 2012 is largely explained by mass actions, including DePuy hip replacement (n=225) and symphysiotomies (n=11). The peak in 2013 is mainly accounted for by a combination of symphysiotomies (n=104), hysterectomies (n=100) related to the Lourdes Redress Scheme and DePuy hip replacements (n=49). By 2014, the figures for mass action claims had reduced significantly: [DePuy hip replacement (n=30) and symphysiotomies (n=20)] due to i) DePuy indemnifying the SCA in respect of Orthopaedic hip implant claims and ii) the impact of the Surgical Symphysiotomy ex-gratia payment scheme.

The claim rate was reviewed based on population data from the Central Statistics Office[1]. The clinical claim rate increased from 10 to 13 per 100,000 population between 2010 and 2014 respectively (Figure 14). However, regard must be had to mass action claims, as outlined in the previous paragraph, which grossly inflated the clinical claim rate. The general claim rate increased from 2 to 3 per 100,000 population over the same five year period.

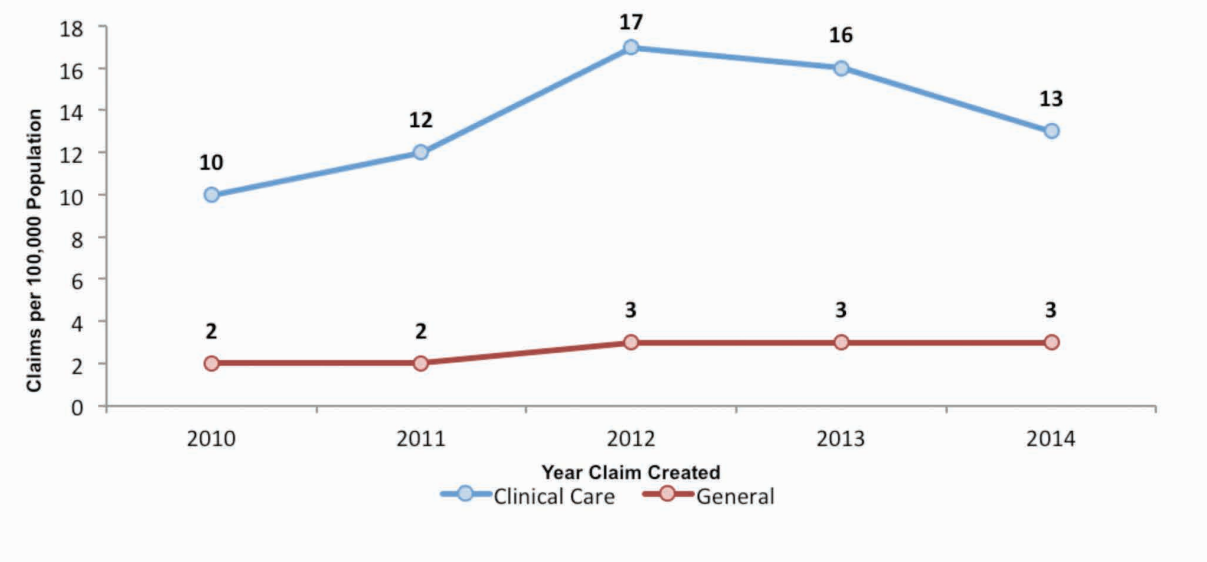


**Figure 14: Clinical and general claim create rate per 100,000 population, 2010-2014 inclusive**

## 5.2.2 Most common services

The most common services in which clinical claims were created nationally, 2010-2014 inclusive, were Surgery (n=1,100), Medicine (n=730), Maternity (n=713), Gynaecology (n=229) and *Other* (n=101). These will be analysed in further detail below.

## 5.2.3 International comparison

The national increase in clinical claims created in the Republic of Ireland was compared with data from the National Health Service Litigation Authority (NHS LA), (recently renamed the NHS Resolution). The latter demonstrated a sustained high level of new clinical negligence claims in 2014/15 in England. Overall, clinical negligence claims reported in England increased from 8,655 in 2010/11 to 11,497 in 2014/2015: an increase of 2,842 claims which equates to 32.8%.[7]

## 5.2.4 Ten most common clinical claims created nationally, 2010-2014 inclusive

The ten most common clinical claims, categorised by the *"please specify"* field, accounted for 70.2% (n=2,157) of all clinical claims created nationally during this five year period (Table 9). The most common clinical claim created nationally 2010-2014 inclusive was *"other"* where the claim did not fall into one of the particularised categories. Claims related to "diagnosis" including the categories

delayed diagnosis and failure to diagnose were relatively frequent, and combined accounted for 19.0% (n=410) of the ten most common clinical claims nationally. Claims related to failure or faulty medical device or equipment were common and largely were accounted for by the DePuy hip replacement mass action. Similarly, claims pertaining to unnecessary surgery or procedure and wrong procedure or operation were largely accounted for by the mass actions for symphysiotomies and hysterectomies (The Lourdes Redress Scheme). Claims pertaining to unexpected complications in the categories of during or following a procedure were relatively frequent (the combined figure accounting for 10.1% of the ten most common clinical claims). Claims pertaining to "delays" including delay or failure to treat leading to an adverse outcome featured in the ten most common clinical claims nationally for this time period. Hospital related deaths reported to the Coroner represent a small but relevant proportion of clinical claims in some specialities reviewed namely, Emergency Medicine, Cardiology, Gastroenterology and Respiratory Medicine. Specialists in these areas should be cognisant that although accounting for a relatively small number of claims, this patient cohort may involve on occasions, attendances before the Coroner's Court and clinical claims.

| Ten Most Common Clinical Claims Created nationally, 2010-2014 inclusive | Claim number (n) | Percentage (%) |
|---|---|---|
| Other | 795 | 25.9% |
| Failure/Faulty Medical Device/Equipment | 310 | 10.1% |
| Failure to Diagnose | 227 | 7.4% |
| Delayed Diagnosis | 183 | 6.0% |
| Unexpected Complications Following Operation/Procedure | 157 | 5.1% |
| Delay/Failure to Treat – Adverse Outcome | 145 | 4.7% |
| Unnecessary Surgery/Procedure | 131 | 4.3% |
| Wrong Operation/Procedure | 105 | 3.4% |
| Unexpected Complications During Operation/Procedure | 61 | 2.0% |
| Unintentional Punch/ Laceration to Organ | 43 | 1.4% |
| Ten Most Common Claims | 2,157 | 70.2% |
| Overall Total | 3,072 | 100.0% |

**Table 9: Ten most common clinical claims created nationally, categorised by the *please specify* field, 2010-2014 inclusive**

## 5.3 Cost

### 5.3.1 Cost of clinical claims finalised, 2010-2014 inclusive

The total cost of clinical claims finalised 2010-2014 inclusive was €288,796,591 of which awards/settlements accounted for €177,479,000, legal fees for the plaintiff €65,473,645, legal fees for the SCA €40,810,885 and *"others"*, which includes expert fees accounted for €5,033,061. Total legal fees expressed as a percentage of awards/settlements were 59.9% for this five year period. Total legal fees expressed as a percentage of awards/settlement was 62.1% in 2010 and reduced to 51.0 % in 2014 (Table 10). The average cost per clinical claim finalised inclusive of compensation and all costs (legal fees to the plaintiff, legal fees to the SCA, expert costs etc.) reduced from €152,329 in 2010 to €141,813 in 2014.

| Clinical Claims Finalised 2010-2014 | | | | | | |
|---|---|---|---|---|---|---|
| | 2010 | 2011 | 2012 | 2013 | 2014 | Total |
| Awards/Settlements | €30,299,383 | €33,366,641 | €34,435,812 | €34,356,197 | €45,020,967 | €177,479,000 |
| Legal Fees - SCA | €7,569,000 | €6,984,369 | €8,527,771 | €8,930,170 | €8,799,574 | €40,810,885 |
| Legal Fees -Plaintiff | €11,234,838 | €12,358,575 | €12,851,127 | €14,845,662 | €14,183,443 | €65,473,645 |
| Other | €860,623 | €843,273 | €953,272 | €1,175,018 | €1,200,876 | €5,033,061 |
| Total | €49,963,845 | €53,552,858 | €56,767,982 | €59,307,047 | €69,204,860 | €288,796,591 |
| Number of Claims | 328 | 314 | 340 | 333 | 488 | 1803 |

**Table 10: Cost of total clinical claims finalised nationally, 2010-2014 inclusive**

### 5.3.2 International comparison of cost

In the UK, the NHS Litigation Authority Report and Accounts 2014/15[7], identified that the top specialities accounting for the highest number of clinical negligence claims received in 2014/15 by speciality were Orthopaedic Surgery (14%), Emergency Medicine (A&E) (12%), General Surgery (11%), Obstetrics (10%), Gynaecology (6%), General Medicine (5%), Radiology (3%), Urology (3%), Gastroenterology (2%), Paediatrics (2%) and *Other* (32%). *Other* included 54 different speciality areas, each with a relatively small volume and value of claims which were aggregated to assist reporting.[7]

Regarding the value of clinical negligence claims received by the NHS Litigation Authority[7] in 2014/15 by speciality, Obstetrics was in first place (41%), followed by *Other* (20%) in second, Emergency Medicine (A&E) (8%) in third, Orthopaedic Surgery and Paediatrics in joint fourth (7% each), Neurosurgery and General Surgery in joint fifth (4% each), General Medicine in sixth (3%) and Radiology, Gynaecology and Ambulance in joint seventh place (2% each).

Interestingly, the NHS in England has experienced an increase in the costs associated with clinical negligence claims in recent years too. The NHS LA report and accounts 2014/15 identified the following potential drivers of the costs of claims:

i. an increase in the number of patients being treated by the NHS
ii. an increase in the number of patients claiming compensation as a proportion of reported incidents
iii. an increase in the number of patients who claim but do not recover compensation
iv. an increase in the number of lower value claims
v. disproportionate claimant legal costs for lower value claims
vi. excessive claims for legal costs from some claimant firms
vii. rising lump sums and annual costs, usually for care, over and above inflation, for high value claims[7]

## 5.4 Most common services

The most common services in which clinical claims were created nationally 2010-2014 inclusive were analysed in detail from a clinical viewpoint and included Surgery, Medicine, Maternity, Gynaecology and *Other.*

### 5.4.1 Clinical claims created in Surgery

#### 5.4.1.1 Clinical claims created in Surgery nationally, 2010-2014 inclusive

Consistent with a relatively *"immature"* Clinical Indemnity Scheme, from an actuarial viewpoint, (commenced July 1st 2002), the number of clinical claims created 2010-2014 inclusive increased. The peak in 2012 (n=414) was largely explained by the DePuy hip implant mass action (n=225), related to a faulty product (Figure 15). Overall an increase in number of claims created in Surgery was identified over this 5 year period (n=85, 75.2%). Orthopaedic and General Surgery were significant contributors to surgical claims, 2010-2014 inclusive.

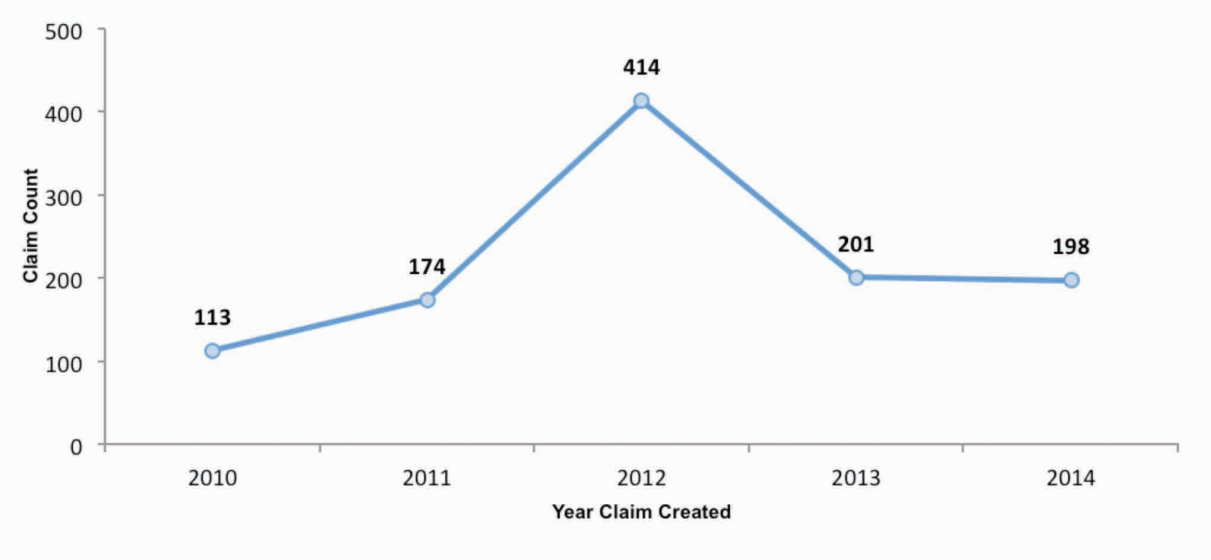


**Figure 15: Clinical claims created in Surgery nationally, 2010-2014 inclusive**

The ten most common clinical claims created in Surgery 2010-2014 inclusive were analysed using the *"please specify"* field on the NIMS (Table 11) and these accounted for 85.0% (n=935) of the total clinical claims (n=1,100) created in Surgery during this five year period. These included the subgroup *"other",* (n=295, 26.8%) where the clinical claim did not fall into one of the offered categories on the system, followed by failure or faulty medical device or equipment (n=292, 26.5%). The latter is largely accounted for by the DePuy hip replacement, mass action. Clinical claims related to "procedures" were relatively common including unexpected complication *"following"* and *"during"* a procedure or operation and failure or difficulty performing a procedure, which, when combined, accounted for 18.0% (n=168) of the ten most common clinical claims created in Surgery nationally. Clinical claims related to *"diagnosis",* including delayed diagnosis and failure to diagnose, were prominent and when combined accounted for 9.1% (n=85) of the ten most common clinical claims created in Surgery during this five year period. Clinical claims related to *"delays"* were relatively common and were in the ten most common clinical claims created in Surgery during this time period.

| Ten Most Common Clinical Claims Created in Surgery, 2010-2014 inclusive | Claim number (n) | Percentage (%) |
|---|---|---|
| Other | 295 | 26.8% |
| Failure/Faulty Medical Device/Equipment | 292 | 26.5% |
| Unexpected Complications Following Operation / Procedure | 119 | 10.8% |
| Delay / Failure to Treat - Adverse Outcome | 54 | 4.9% |
| Delayed Diagnosis | 50 | 4.5% |
| Failure to Diagnose | 35 | 3.2% |
| Unexpected Complications During Operation / Procedure | 33 | 3.0% |
| Unintentional Punch / Laceration to Organ | 22 | 2.0% |
| Missing / Retained Swab / Device / Needle | 19 | 1.7% |
| Failure / Difficulty Performing Procedure | 16 | 1.5% |
| Ten Most Common Claims | 935 | 85.0% |
| Overall Total | 1,100 | 100.0% |

**Table 11: Ten most common clinical claims created in Surgery nationally, categorised by the *please specify* field, 2010-2014 inclusive**

The most common clinical claims created in Surgery were tracked over five years, excluding *"other"* and mass actions (DePuy hip replacement), to help identify trends, using the *"please specify"* field on the NIMS (Figure 16). Delay or failure to treat leading to an adverse outcome and unexpected complications following an operation/procedure have increased; while delayed diagnosis and failure to diagnose have remained relatively stable and unexpected complications during an operation/procedure have decreased during this five year period. Numbers in some subgroups are relatively small.

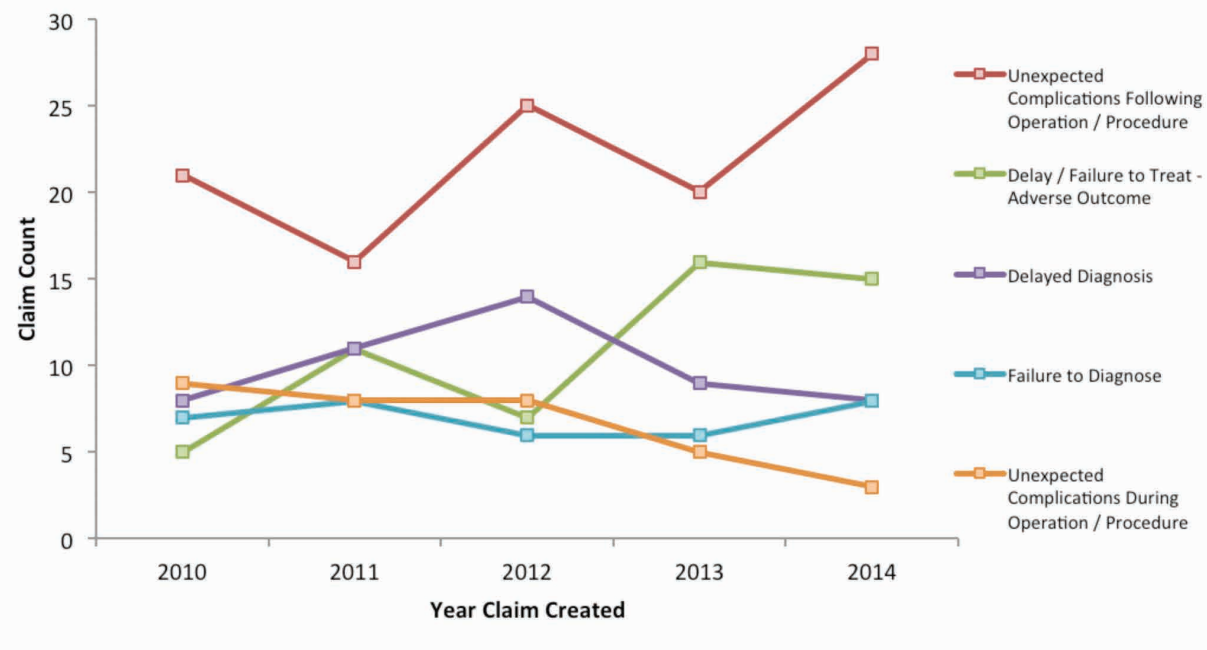


**Figure 16: Most common clinical claims created in Surgery nationally, tracked, categorised by the *please specify* field, 2010-2014 inclusive, excluding "other" and mass actions**

### 5.4.1.2 Cost of clinical claims finalised in Surgery nationally, 2010-2014 inclusive

The total cost of clinical claims finalised in Surgery 2010-2014 inclusive was €58,779,088, of which awards/settlements accounted for €31,227,533, legal fees for the plaintiff €16,222,547, legal fees for the SCA €10,158,971 and *"other"*, which includes expert fees, accounted for €1,170,038. Total legal fees expressed as a percentage of awards/settlements was 84.5% for this five year period. Total legal fees expressed as a percentage of awards/settlements in 2010 was 86.9% and reduced to 68.6% in 2014 (Table 12). It is worth noting that non-catastrophic injury clinical negligence claims invariably involve disproportionately high legal costs. The average cost per clinical claim, including all costs (legal fees for the plaintiff, legal fees for the SCA, expert costs etc.) reduced from €125,620 in 2010 to €77,039 in 2014.

| Clinical Claims Finalised in the Service of Surgery 2010-2014 | | | | | | |
|---|---|---|---|---|---|---|
| | 2010 | 2011 | 2012 | 2013 | 2014 | Total |
| Awards/Settlements | €6,123,376 | €5,419,518 | €6,130,163 | €6,256,709 | €7,297,767 | €31,227,533 |
| Legal Fees - SCA | €2,247,035 | €1,869,451 | €2,062,421 | €2,233,191 | €1,746,873 | €10,158,971 |
| Legal Fees -Plaintiff | €3,076,629 | €3,198,763 | €3,055,526 | €3,632,426 | €3,259,203 | €16,222,547 |
| Other | €235,629 | €179,640 | €204,097 | €297,162 | €253,509 | €1,170,038 |
| Total | €11,682,669 | €10,667,372 | €11,452,207 | €12,419,488 | €12,557,353 | €58,779,088 |
| Number of Claims | 93 | 92 | 95 | 106 | 163 | 549 |

**Table 12: Cost of clinical claims finalised in Surgery nationally, 2010-2014 inclusive**

### 5.4.1.3 International comparison

Orthopaedic and General Surgery accounted for a significant proportion of clinical claims in Surgery and were reviewed from an international perspective.

#### i) International comparison regarding Orthopaedic Surgery

Internationally, large scale clinical claims' data bases are rare. However, the National Health Service Litigation Authority (NHS LA) deals with claims brought against all public health trusts in England. A review of successful litigation cases pertaining to adult Orthopaedic claims between 2000 and 2006 (published 2010) was performed to establish trends in litigation and highlight specific areas of concern, so that care could be improved[8]. There were 4,847,841 elective and trauma-related Orthopaedic procedures performed in England in this time period and 2,312 successful legal cases taken against NHS Trusts of which 1,473 had sufficient detail to enter the review. While the frequency of successful litigation was relatively low, compared with the number of cases performed, it was financially costly to the NHS. The authors concluded that more than the equivalent of $321,695,072 USD was paid in adult Orthopaedic surgery-related settlements between 2000 and 2006. Infection (n=123) was the most common reason for successful litigation: both the presence of infection and the sequelae. In the remaining cases, two common themes were evident: issues with the consent process and the mismanagement of Orthopaedic conditions, particularly fracture, cauda equina syndrome and compartment syndrome. This review identified that education and vigilance remain important components of Orthopaedic training as many of the cases of successful litigation had a preventable cause.[8]

A separate review of NHS Litigation Authority payments in cases of medical negligence in Orthopaedic surgery (2004-2006) identified that of the 97 concluded cases studied, none proceeded to a court hearing[9]. Overall, 55% were abandoned by the claimants' solicitors while the remaining 45% were

settled out of court for sums ranging from £4,500 (sterling) to £2.7 million (sterling), with a median settlement being £45,000 (sterling). The authors identified that the cases settled out of court were usually the result of delay in treatment or diagnosis or because of substandard surgical technique.[9]

Defensive medicine includes medical practices that exonerate physicians from liability without benefits to patients. A national survey among Orthopaedic surgeons and Trauma surgeons in Austria, published in 2015[10], identified that the prevalence of defensive medicine was found to be 97.7%. The authors revealed that the average Orthopaedic surgeon requested 19.6 investigations per month for defensive reasons, which represented 28% of all diagnostic examinations. Participants were confronted with 1.4 liability claims per month. During the treatment of high risk patients, 81% of doctors requested additional procedures for defensive reasons. Expenditure of time for defensive practice amounted to 17% and 18% respectively in Orthopaedic and Trauma Surgery[10].

A national survey regarding the prevalence and costs of defensive medicine among Orthopaedic Trauma surgeons in the USA was performed for the first time in 2010, using the American Academy of Orthopaedic Surgeons Registry (n=1,214)[11]. Cost analysis was performed using Centres for Medicare and Medicaid data. For Orthopaedic Traumatologists, on average, 22% of all ordered tests were for defensive reasons (radiology 19%, computed tomographic scanning 23%, magnetic resonance imaging 27%, ultrasound 42%, referrals 29%, laboratory tests 23% and biopsies 16%). Defensive hospital admissions averaged 9% each month. Defensive medicine costs per respondent were calculated to be approximately $7,800 USD monthly or $94,000 USD per annum, which is 20% of each physician's spending. According to the 2010 American Academy of Orthopaedic Surgeons census, at that time, 2,724 Orthopaedic Trauma surgeons were in practice in the USA, therefore, the national cost of defensive medicine for Orthopaedic Trauma surgery was estimated to be $256.3 million USD annually in 2011. This is a significant health care cost with marginal benefit to patients. The authors concluded that policies aimed at managing liability risk may be useful in containing such practices.[11]

### ii) International comparison regarding General Surgery

In 2010, trends in litigation following laparoscopic cholecystectomy, the removal of the gall bladder by keyhole surgery, in England were compared with the USA and analysed.[12] Data was reviewed from the NHS Litigation Authority on clinical negligence claims pertaining to laparoscopic cholecystectomy between 1995 and 2009. Four hundred and eighteen claims were made of which 303 were settled. Sixty five percent (n=198) were found to be in the claimants' favour for a total cost of £20.4 million sterling. Operator error was the most likely cause of a claim and the only cause associated with a successful claim (p=0.023). Delay in recognition of complications was the second most common reason for initiation of a claim. Bile duct injury was the most frequent injury resulting in litigation and the most likely injury associated with a successful claim (p<0.001). The average payment made for a successful claim was £102,827 sterling. While findings from the USA were similar, the payments made were 4 fold higher. Strategies to improve surgical skills, prevent complications and earlier identification of complications, particularly bile duct injury, were identified by the authors as opportunities to help reduce patient morbidity and the litigation burden at that time point.[12]

Medical liability in General Surgery in Portugal was analysed by reviewing the Medico Legal Council reports of the National Institute of Legal Medicine and Forensic Sciences of Portugal related to General Surgery during 2001-2010.[13] Alleged cases of medical liability in General Surgery represented 11.2% of the total cases analysed by the Medico Legal Council. The majority of complaints were due to patients' deaths (75.4%), with laparoscopic cholecystectomy surgeries representing 55.2 % of cases. In more than half of the cases (n=55.2%), no *causal nexus* (i.e. causation) was found between the medical practice and the alleged harm.[13] Since then, laparoscopic surgical skills and experience have improved worldwide.

## 5.4.2 Clinical claims created in Medicine

### 5.4.2.1 Clinical claims created in Medicine nationally, 2010-2014 inclusive

The Clinical Indemnity Scheme is considered an *"immature"* indemnity scheme, in actuarial terms, and, as expected, the number of clinical claims created in Medicine increased 2010-2014 inclusive. This increase of 31 equates to a rise of 25.0% (Figure 17). A significant proportion of claims created in Medicine were made up of claims in the specialities of Emergency Medicine and General Medicine. The NIMS categorises Emergency Medicine under Medicine.

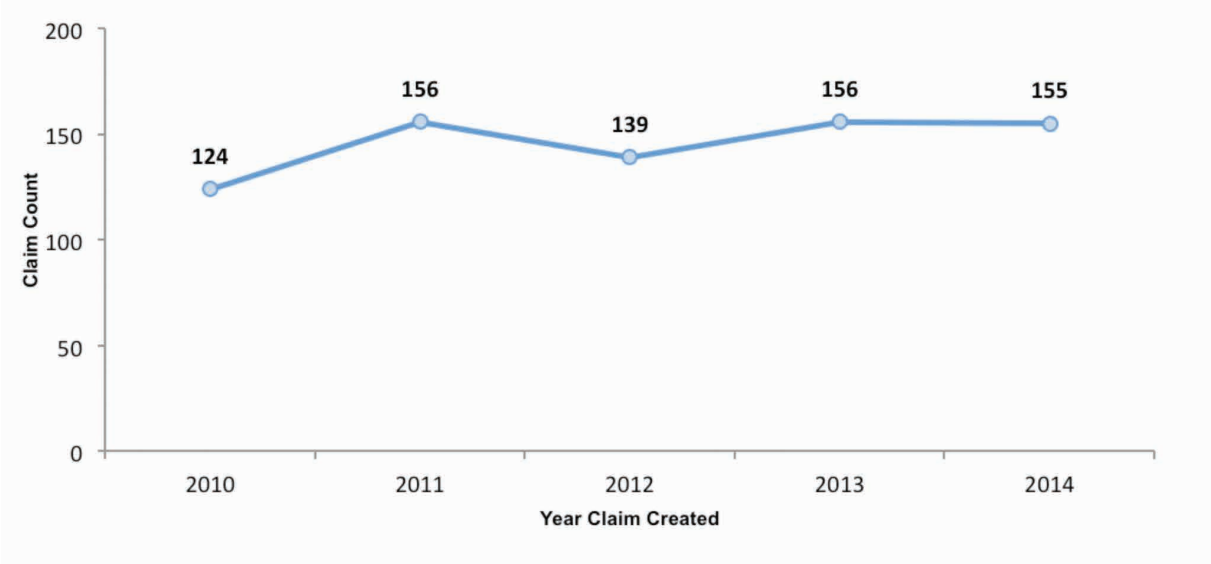


**Figure 17: Clinical claims created in Medicine nationally, 2010-2014 inclusive**

The ten most common clinical claims created in Medicine were examined using the *"please specify"* field (Table 13) and accounted for 83.0% (n=606) of total clinical claims created in Medicine during this time period. The subgroup *"other"* (n=234, 32.1%) was the most common clinical claim. Clinical claims related to *"diagnosis"* including failure to diagnose (n=150) and delayed diagnosis (n=95), when combined, accounted for 40.4% of the ten most common clinical claims created in Medicine during this time period. Clinical claims related to *"delays"* including delay or failure to treat leading to an adverse outcome and delayed diagnosis, featured prominently among the ten most common clinical claims created in Medicine. Clinical claims related to *"procedures"* including failure or difficulty performing a procedure, unexpected complications following a procedure/operation and incorrect procedure, when combined accounted for 4.1% (n=25) of the ten most common clinical claims created in Medicine. Claims pertaining to hospital-related deaths reported to the Coroner, while low in number, were relevant because practitioners should be aware that these may involve giving evidence to a coronial court and may lead to clinical claims.

| Ten Most Common Clinical Claims Created in Medicine nationally, 2010-2014 inclusive | Claim number (n) | Percentage (%) |
|---|---|---|
| Other | 234 | 32.1% |
| Failure to Diagnose | 150 | 20.5% |
| Delayed Diagnosis | 95 | 13.0% |
| Delay / Failure to Treat - Adverse Outcome | 63 | 8.6% |
| Injury Arising from Donation | 11 | 1.5% |
| Incorrect result applied to patient | 11 | 1.5% |
| Failure / Difficulty Performing Procedure | 11 | 1.5% |
| Hospital-related Death Rep. To Coroner | 9 | 1.2% |
| Unexpected Deterioration | 8 | 1.1% |
| Unexpected Complications Following Operation / Procedure | 7 | 1.0% |
| Incorrect Procedure | 7 | 1.0% |
| Ten Most Common Claims | 606 | 83.0% |
| Overall Total | 730 | 100.0% |

**Table 13: Ten most common clinical claims created in Medicine nationally, categorised by the *please specify* field, 2010-2014 inclusive**

The most common clinical claims created in Medicine, excluding the subgroup *"other"*, were tracked over a five year period, 2010-2014, to help identify trends, using the *"please specify"* field (Figure 18). Clinical claims related to delayed diagnosis reduced, while claims pertaining to delay or failure to treat leading to an adverse outcome have increased slightly and those related to failure to diagnose have remained relatively stable over this time period. The remaining categories accounted for less than five claims each, annually, including incorrect result applied to a patient, injury arising from donation and failure or difficulty performing a procedure (Figure 18).

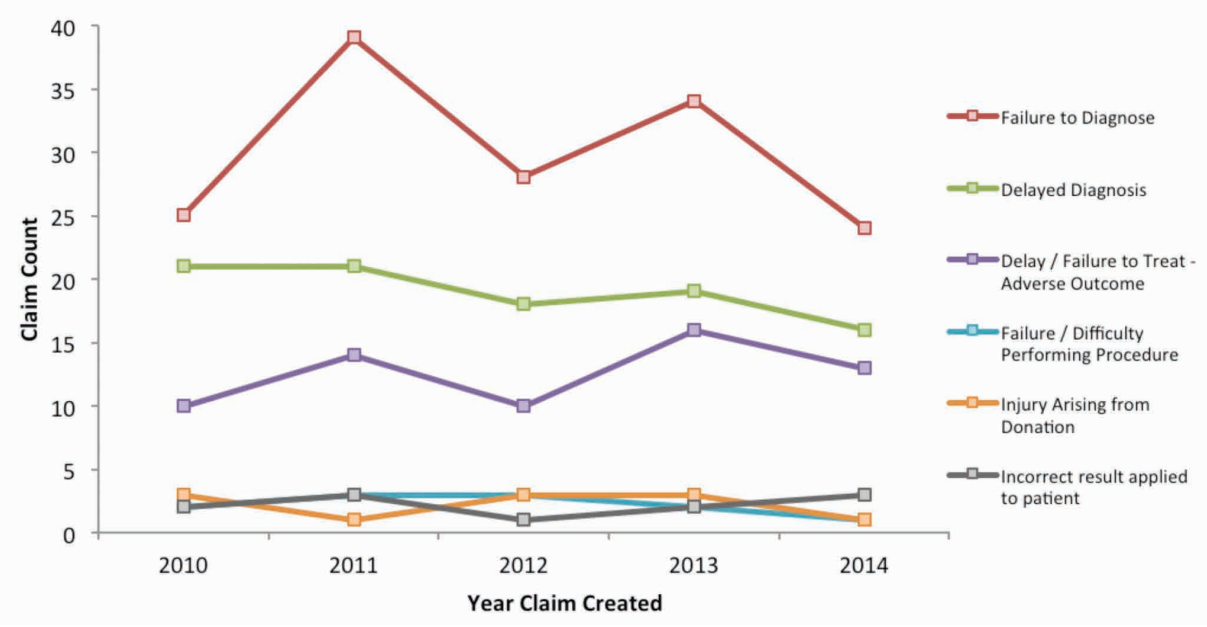


**Figure 18: Most common clinical claims created in Medicine nationally, tracked, categorised by the *please specify* field, 2010-2014 inclusive, excluding *"other"***

### 5.4.2.2 Cost of clinical claims finalised in Medicine nationally, 2010-2014 inclusive

The total cost of clinical claims finalised in Medicine, 2010-2014 inclusive was €80,689,304, of which awards/settlements accounted for €47,309,693, legal fees for the plaintiff €20,303,800, legal fees for the SCA €11,577,292 and *"others"* including expert fees accounted for €1,498,519 (Table 14). Total legal fees expressed as a percentage of awards/settlements during this five year period was 67.4%. Total legal fees expressed as a percentage of awards/settlements in 2010 were 83.6% and reduced to 51.7% in 2014. The average cost per clinical claim in 2010 was €102,519 and increased to €203,654 in 2014. This increase was explained by one outlier, a case involving catastrophic injury, in 2014, which was related to Emergency Medicine, a subset of Medicine on the NIMS.

| Clinical Claims Finalised in the Service of Medicine 2010-2014 | | | | | | |
|---|---|---|---|---|---|---|
| | 2010 | 2011 | 2012 | 2013 | 2014 | Total |
| Awards/Settlements | €6,858,257 | €9,462,797 | €7,918,980 | €7,377,511 | €15,692,147 | €47,309,693 |
| Legal Fees - SCA | €2,271,219 | €1,791,040 | €2,302,799 | €2,325,388 | €2,886,847 | €11,577,292 |
| Legal Fees -Plaintiff | €3,463,918 | €3,443,356 | €3,950,005 | €4,217,704 | €5,228,818 | €20,303,800 |
| Other | €221,510 | €231,989 | €305,735 | €312,221 | €427,063 | €1,498,519 |
| Total | €12,814,905 | €14,929,182 | €14,477,519 | €14,232,824 | €24,234,875 | €80,689,304 |
| Number of Claims | 125 | 111 | 119 | 89 | 119 | 563 |

**Table 14: Cost of clinical claims finalised in Medicine nationally, 2010-2014 inclusive**

### 5.4.2.3 International comparison

#### i) International comparison regarding Emergency Medicine

A review of the NHS Litigation Authority's annual report 2014/15 identified that Emergency Medicine, (referred to as Accident & Emergency), accounted for 12% of the clinical negligence claims received in 2014/15. Emergency Medicine was the third most common speciality after *"Others"*, (which was made up of 54 aggregated specialities) in first place and Orthopaedic surgery in second.[7]

In comparison, Irish data demonstrated that Emergency Medicine and General Medicine were the common specialities in which clinical claims were created in Medicine. The international literature was reviewed from these perspectives.

An epidemiological study of closed Emergency Department malpractice claims in a national data base of physician malpractice insurers in the USA, covering a 23 year study period (1985-2007), was performed at Johns Hopkins Hospital, Baltimore.[14] Data were received from the Physician Insurers Association of America (PIAA), an association whose participating malpractice insurance carriers collectively insure over 60% of practising physicians in the United States. Results identified that the largest sources of error included, errors in diagnosis (37%) followed by improper performance of a procedure (17%). Interestingly, in 18% of claims, no error could be identified by the insurer. The authors concluded that acute myocardial infarction (5%), fractures (6%) and appendicitis (2%) were the health conditions associated with the highest number of claims. Over two thirds of claims (70%) closed without payment to the claimant.[14]

#### ii) International comparison regarding General Medicine

In the NHS Litigation Authority report 2014/15[7], General Medicine accounted for 5% of the medico legal claims received in 2014/15 when categorised by speciality and was the seventh most common speciality for the number of medico-legal claims received in that year after *Others*, Orthopaedic

Accident and Emergency, General Surgery, Obstetrics and Gynaecology. General Medicine accounted for 3% of the value of clinical negligence claims received in 2014/15 when categorised by speciality. There was a paucity of data in the literature regarding malpractice claims in General Medicine, which incorporates aspects of multiple specialities. An analysis of different sub-specialities is presented later in this report.

## 5.4.3 Clinical claims created in Maternity services

### 5.4.3.1 Clinical claims created in Maternity services nationally, 2010-2014 inclusive

A detailed analysis of clinical claims created and costs in Maternity services has recently been published by the SCA: *Clinical incidents and claims report in Maternity and Gynaecology services: a five year review, 2010-2014.*[3] Of note, some differences in data exist between the recent report (Oct 2015) and this publication because the data were re-run for this report on a different date and during the time period between both data extractions, some claims were re-categorised, as part of an ongoing quality improvement process.

An increase in clinical claims created in Maternity services, 2010-2014 inclusive, was identified (n=18, which equates to an increase of 15.0%) (Figure 19). This increase was expected based on the time lag between consultants being covered by the CIS, with effect from 1 February 2004, and the later creation of claims in respect of clinical incidents which occurred on or post February 1st 2004. It is not unusual in catastrophic injury cases in maternity services, to have a time delay of approximately 6 years between the date the incident occurred and the date the claim is created. The peak in clinical claims seen in 2013 was explained by the mass action for symphysiotomies.

A symphysiotomy is an operative procedure in which the symphysis pubis is divided in a contracted pelvis to allow vaginal delivery of an infant. Symphysiotomies were generally performed between the 1920s and 1984. Caesarean sections have replaced this procedure as a safer way to deliver a baby with less morbidity for the mother. On 26th November 2013, Judge Yvonne Murphy was appointed by the then Minister for Health, Dr James Reilly to conduct an independent review of issues relating to symphysiotomy, which was published March 2014.[15] The government subsequently agreed a redress scheme, known as "the Surgical Symphysiotomy Payment Scheme" with three levels of compensation available depending on the severity of the injury: €50,000, €100,000 or €150,000. Compensation was awarded on an ex-gratia basis without admission of liability on the part of the State.

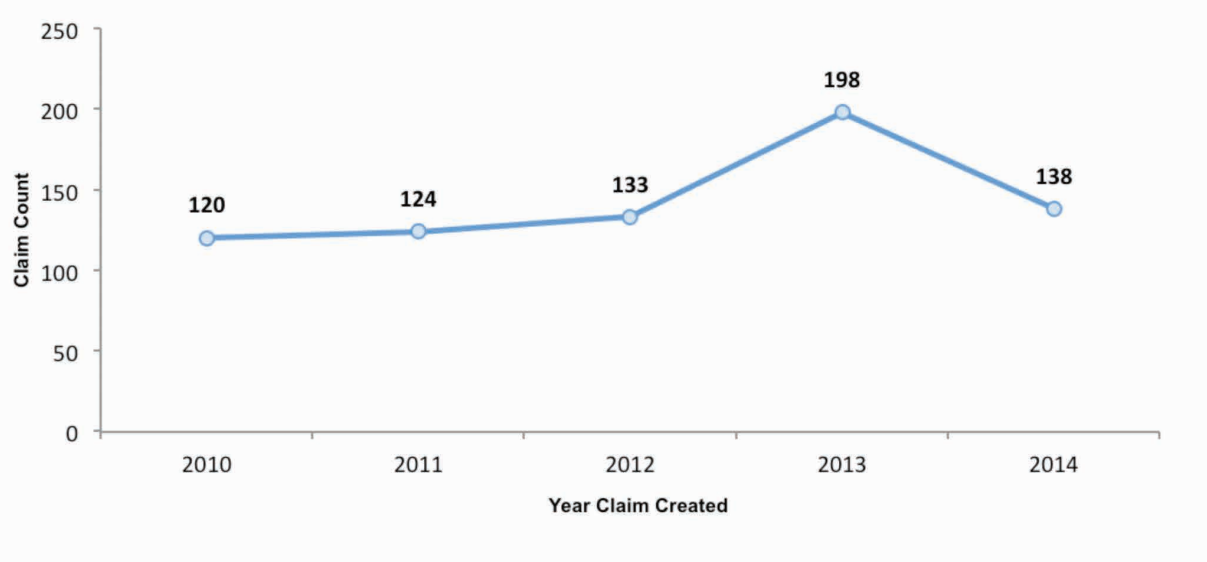


**Figure 19: Clinical claims created in Maternity services nationally, 2010-2014 inclusive**

The ten most common clinical claims created in Maternity services 2010-2014 inclusive, accounted for 61.0% (n=435) of the total clinical claims created in Maternity services (n=713) for this time period. This data was analysed using the *please specify* field (Table 15). Unnecessary surgery or procedure was most common (n=121, 17.0%) which was explained by the mass action for symphysiotomies. This was followed by the subgroup *"other"*, (n=99, 13.9%). When analysed in further detail, the subgroup *"other"* included alleged jejunal puncture at caesarean section, alleged ante-partum haemorrhage, alleged intrauterine death after clinician review and cardiotocogram (CTG) in hospital the previous day, alleged lack of supervision for a short period during change of shift of midwife with delivery of a baby unsupervised, alleged negligence and a solicitor's request for a chart, though no adverse event was identified on chart review. Claims related to 3rd and 4th degree perineal tears including breakdown of the perineum (n=42, 5.9%), stillbirth (n=38, 5.3%) and shoulder dystocia (n=35, 4.9%) were relatively common during this 5 year period (Table 15).

| Ten Most Common Clinical Claims Created in Maternity Services, 2010-2014 inclusive | Claim number (n) | Percentage (%) |
|---|---|---|
| Unnecessary Surgery / Procedure | 121 | 17.0% |
| Other | 99 | 13.9% |
| Perineal Tear (3rd & 4th Degree) (incl. breakdown of perineum) | 42 | 5.9% |
| Stillbirth | 38 | 5.3% |
| Shoulder Dystocia | 35 | 4.9% |
| Unexpected Neonatal Death | 25 | 3.5% |
| Cerebral Irritability / Neo-natal Seizure | 22 | 3.1% |
| Birth Injury (incl. Instrument Injury) | 20 | 2.8% |
| Post-partum Haemorrhage | 17 | 2.4% |
| Apgar <5@1, 7@5, cord BE <12, pH<7.2 | 16 | 2.2% |
| Ten Most Common Claims | 435 | 61.0% |
| **Overall Total** | **713** | **100.0%** |

**Table 15: Ten most common clinical claims created in Maternity services nationally, categorised by the *please specify* field, 2010-2014 inclusive**

The most common clinical claims, excluding the subgroup *"other"* and mass actions, were tracked over five years to help identify trends, using the *"please specify"* field (Figure 20). Overall, numbers are relatively small. There was a reduction in the number of clinical claims related to cerebral irritability/ neonatal seizure, with no claims created in this category in 2014. A reduction in claims pertaining to shoulder dystocia was documented over this 5 year period. Claims related to perineal tears (3rd and 4th degree including breakdown of the perineum) and stillbirth have remained relatively stable while claims related to unexpected neonatal death have increased during this time period.

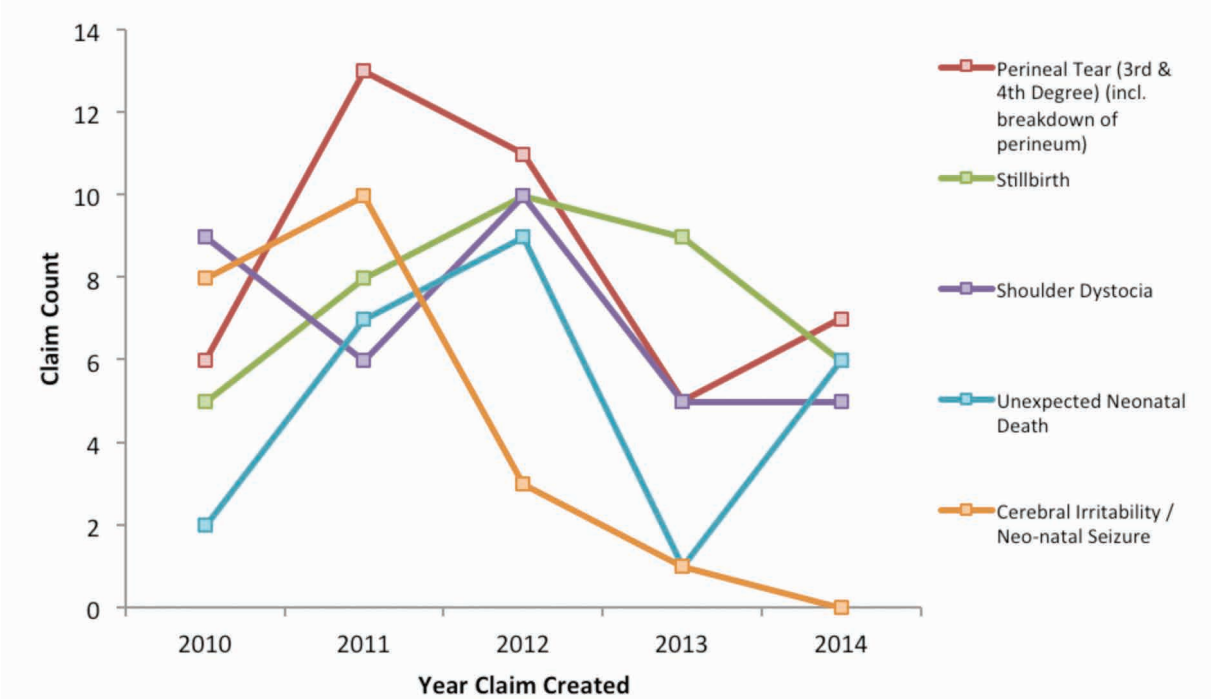


**Figure 20: Most common clinical claims created in Maternity services nationally, tracked, categorised by the *please specify* field, 2010-2014, excluding *"other"* and mass actions**

### 5.4.3.2 Cost of clinical claims finalised in Maternity services nationally, 2010-2014 inclusive

The total cost of clinical claims finalised in Maternity services, 2010-2014 inclusive was €124,204,745, of which awards/settlements accounted for €84,906,464, legal fees for the plaintiff €22,784,480, legal fees for the SCA €14,619,122 and *"others"* including expert fees accounted for €1,894,679 (Table 16). Total legal fees expressed as a percentage of awards/settlements over this five year period was 44.1%. Total legal fees expressed as a percentage of awards/settlements in 2010 were 39.4% and increased slightly to 40.7% in 2014. The average cost per clinical claim, inclusive of compensation and all costs (legal costs to the plaintiff, legal costs to the SCA, expert costs etc.), was €370,236 in 2010 and €400,493 in 2014. The increase in the average cost per clinical claim is due to the fact that in the period 2010-2014 certain catastrophic injury claims, which were initially settled on a Periodic Payment Order (PPO) basis, reverted to lump sums, thus pushing up the average cost per claim.

| Clinical Claims Finalised in Maternity Services 2010-2014 | | | | | | |
|---|---|---|---|---|---|---|
| | 2010 | 2011 | 2012 | 2013 | 2014 | Total |
| Awards/Settlements | €16,226,651 | €17,301,578 | €18,952,182 | €12,795,212 | €19,630,841 | €84,906,464 |
| Legal Fees - SCA | €2,399,535 | €2,591,664 | €3,421,066 | €2,774,940 | €3,431,917 | €14,619,122 |
| Legal Fees -Plaintiff | €3,987,478 | €4,926,855 | €4,895,258 | €4,424,313 | €4,550,576 | €22,784,480 |
| Other | €340,975 | €367,073 | €378,936 | €386,548 | €421,148 | €1,894,679 |
| Total | €22,954,640 | €25,187,169 | €27,647,442 | €20,381,013 | €28,034,481 | €124,204,745 |
| Number of Claims | 62 | 57 | 68 | 82 | 70 | 339 |

**Table 16: Cost of clinical claims finalised in Maternity Services nationally, 2010-2014 inclusive**

### 5.4.3.3 International comparison

The NHS Litigation Authority identified that the value of clinical negligence claims for Obstetrics was 41% of the total value of clinical claims received in 2014/15.[7] In its publication, *Ten years of Maternity Claims 2000-2010* (published 2012),[16] the NHS Litigation Authority outlined the causes and costs of finalised claims for that period. The total sum paid out in respect of 5,087 Maternity claims between 1st April 2000 and 31st March 2010 was £3,117,649,888 (£~3.1 billion sterling), from a cohort of approximately 5.5 million births. These included cerebral palsy (n=542 claims, with a total value of £1,263,581,324); cardiotocograph (CTG) interpretation (n=300, with a total value of £466,393,771); antenatal care (n=391, with a total value of £144,811,665); 3rd and 4th degree tears (n=200, £18,847,299 out of £31,202,836 for all perineal trauma); shoulder dystocia (n=250, with a total value of £103,520,832) and postpartum haemorrhage (n=111, with a total value of £3,024,833).[16]

A recent Spanish study reviewed 885 Obstetric and Gynaecology claims between 1986 and 2010.[17] It identified that labour, delivery and complications accounted for 33.1% of the claims of which 12.8% related specifically to caesarean section. Of the closed files reviewed, 37.7% were solved by an out of court procedure. Both the proportion of claims relating to Obstetrics and the average payment increased over the study period. The authors concluded that incidents such as retained foreign objects, tubal ligation, ultrasound diagnosis or neurologically impaired new-borns, deserve special attention regarding medico-legal issues.[17]

Similarly, a smaller French study, published in 2013, identified that the rate of litigation pertaining to Obstetrics at a university hospital tripled in a decade (study period 1997-2010).[18] The average rate of malpractice litigations was 2.4 per physician.

A retrospective analysis from Cornell Medical College (USA) reviewed the characteristics of paid malpractice claims settled in and out of court in the USA, using claims data from the National Practitioner Data Bank from 2005-2009.[19] It identified that claims with the following criteria were more likely to be tried in court than others, these included cases which involved Obstetric or Surgical error; adverse events to a foetus; where physicians had a prior malpractice report(s) which was paid by a state malpractice programme and cases in which the physicians were under 50 years of age. Interestingly, the mean payment amount ($592,283 USD versus $317,447 USD $p<0.01$); the per cent of payments over $1 million USD (41.9% versus 15.4%, $p<0.01$) and the time to decision (6.5 years versus 4.9 years, $p<0.01$) were significantly higher in claims involving a court's decision.[19]

A recent Danish study reviewed all Obstetric claims between 1995 and 2009 (n=1440), and identified that larger labour units (3,000-3,999 deliveries/year) had a lower approval rate for submitted claims (34.2%) compared with very large units (defined by authors as >4,000 deliveries/year, 38.6%), intermediate (1,000-2,999 deliveries/year, 41.7%) and small units (<1,000 deliveries/year, 50.0%) ($p<0.05$).[20] The majority of compensation claims were approved with reference to the *"specialist rule"*: assuming that if an experienced specialist had conducted the treatment differently, the injury could have been avoided. The authors concluded that a better availability of *in house Obstetricians* as well as auxiliary specialists may partially explain the findings.

Severe and fatal Obstetric injury claims in relation to labour unit volume were recently analysed in a nationwide panel study of labour units in Denmark.[21] It identified that high volume labour units appear to be associated with fewer approved and fewer fatal injury claims compared with units with less volume. The findings, the authors feel, support the concept of consolidation of units in Denmark. A suggested option was to tailor Obstetric patient safety initiatives according to the delivery volume of individual labour units.

A Yale-New Haven Hospital comprehensive obstetric safety programme, which began in 2003, consisted of measures to standardise care, improve teamwork and communication and optimize oversight and quality review: this demonstrated improvements in adverse outcomes.

An analysis of a comparison of the Yale–New Haven Hospital Comprehensive Obstetric Safety Programme with the Connecticut insurance market demonstrated that the former reduced liability claims and payments in the five years after the programme was commenced, while the latter experienced a stable number of claims and markedly increased cost per claim during the same time period.[22]

## 5.4.4 Clinical claims created in Gynaecology services

### 5.4.4.1 Clinical claims created in Gynaecology services nationally, 2010-2014 inclusive

Gynaecology was the fourth most common service in which clinical claims were created nationally 2010-2014 inclusive. A detailed review of clinical claims in Gynaecology services over this time period was recently published by the SCA.[3]

As outlined previously, due to the fact that consultants were covered by the CIS with effect from 1st February 2004, (i.e. in respect of clinical incidents on or after that date), it was expected that the number of clinical claims created in Gynaecology services would increase, 2010-2014 inclusive.

Absolute numbers were relatively small: an increase of 7 claims was identified, which equates to a rise of 26.9% (Figure 21). The peak in 2013 is largely explained by the mass action, the Lourdes Redress Scheme part II which arose from the findings and recommendations in the report of the Lourdes Hospital Inquiry, January 2006. The object of the scheme was to provide compensation for women who underwent unnecessary hysterectomy and who were excluded on age grounds (40+ years) from benefiting under the original scheme. The SCA operated part II of the Scheme on behalf of the Department of Health and the HSE.

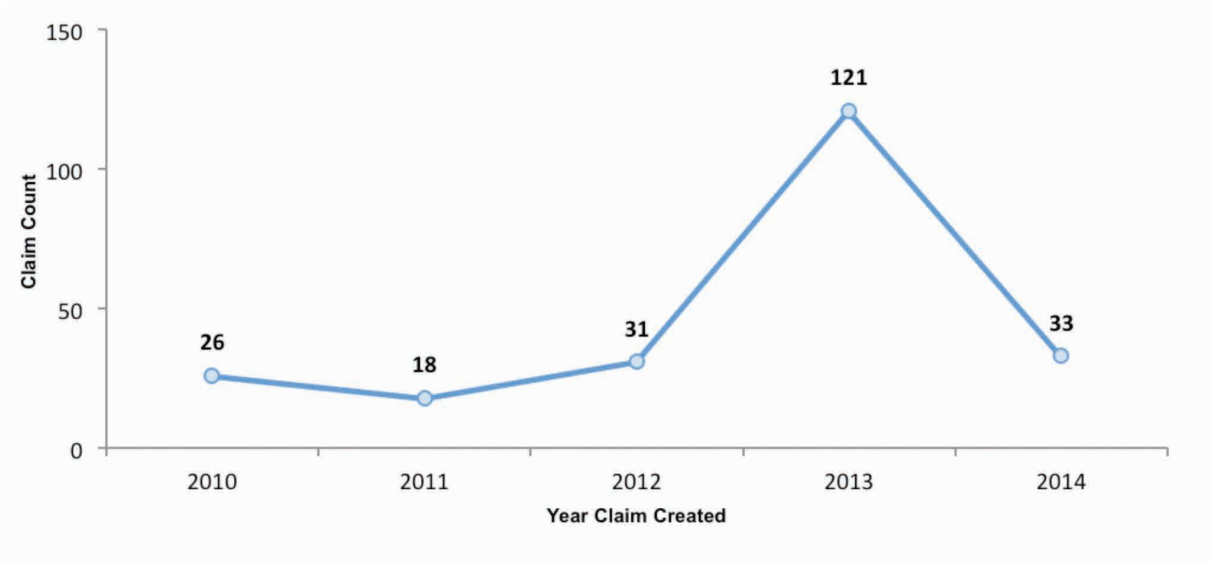


**Figure 21: Clinical claims created in Gynaecology nationally, 2010-2014 inclusive**

The ten most common clinical claims created in Gynaecology based on the *please specify* field, in the years 2010-2014 accounted for 85.6% (n=196) of all clinical claims created in Gynaecology nationally (n=229) for that time period (Table 17). Wrong operation or procedure was the most common clinical claim created (n=100, 43.7%) and pertained to hysterectomies as outlined above. The *"other"* group

was analysed in detail, manually, and included cases of failed tubal ligation, retained tissue following hysterectomy, post-operative complications of hysterectomy, complications of intra-uterine devices, delay in follow up of abnormal cytology, presentation for recurrent bleeding ultimately resulting in malignancy and solicitors' letters received without specific details. The third most common claim created in Gynaecology over this five year period was unexpected complication(s) following an operation/procedure (n=15, 6.6%), the fourth was unintentional laceration to an organ (n=12, 5.2%), while delayed diagnosis (n=9, 3.9%) was the fifth (Table 17).

| Ten Most Common Clinical Claims Created in Gynaecology, 2010-2014 inclusive | Claim number (n) | Percentage (%) |
|---|---|---|
| Wrong Operation / Procedure | 100 | 43.7% |
| Other | 30 | 13.1% |
| Unexpected Complications Following Operation / Procedure | 15 | 6.6% |
| Unintentional Punch / Laceration to Organ | 12 | 5.2% |
| Delayed Diagnosis | 9 | 3.9% |
| Unexpected Complications During Operation / Procedure | 8 | 3.5% |
| Missing / Retained Swab / Device / Needle | 8 | 3.5% |
| Delay / Failure to Treat - Adverse Outcome | 6 | 2.6% |
| Unnecessary Surgery / Procedure | 4 | 1.7% |
| Failure to Diagnose | 4 | 1.7% |
| Ten Most Common Claims | 196 | 85.6% |
| **Overall Total** | **229** | **100.0%** |

**Table 17: Ten most common clinical claims created in Gynaecology nationally, categorised by the *please specify* field, 2010-2014 inclusive**

The most common clinical claims created in Gynaecology (excluding the subgroup *"other"* and mass actions), 2010-2014 inclusive were reviewed, using the *"please specify"* field, and tracked over time (Figure 22). Overall, numbers were small and no single category of clinical claim occurred every year 2010-2014 inclusive. Unexpected complications *during* a procedure or operation increased while complications *following* a procedure or operation remained stable over this time period.

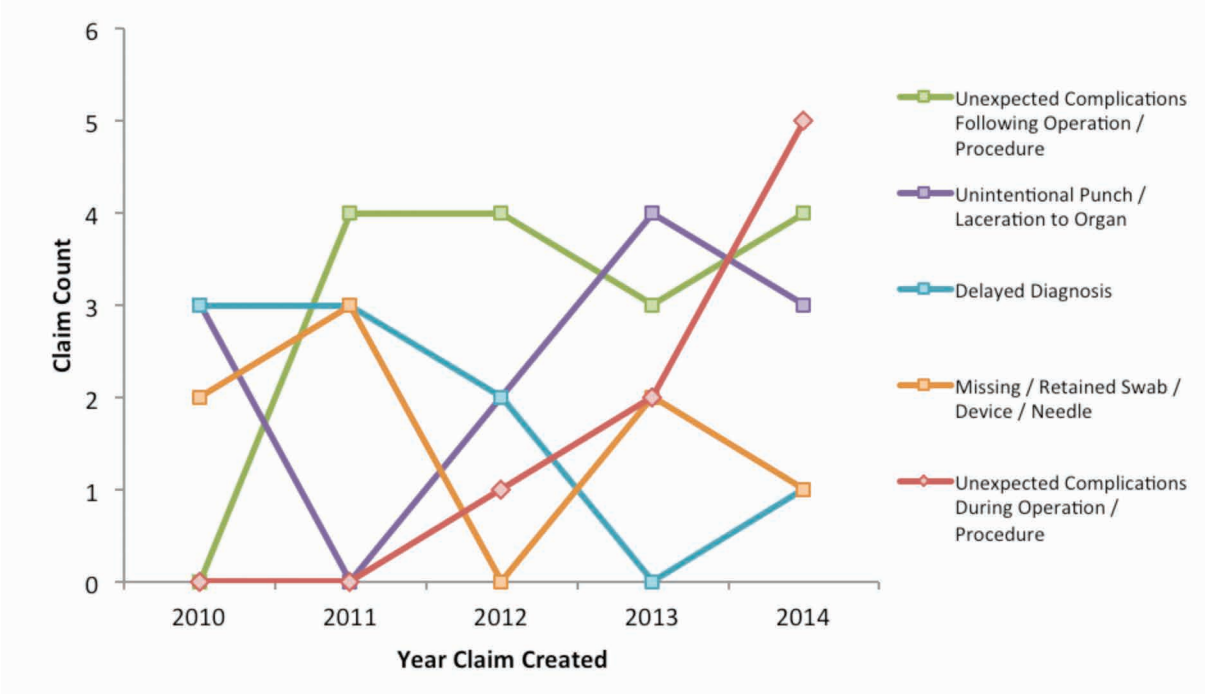


**Figure 22: Most common clinical claims created in Gynaecology nationally, categorised by the *please specify* field, tracked, 2010-2014 inclusive, excluding *"other"* and mass actions**

### 5.4.4.2 Cost of clinical claims finalised in Gynaecology nationally, 2010-2014 inclusive

The total cost of clinical claims finalised in Gynaecology services over this five year period was reviewed because clinical claim numbers and costs were relatively small. The total cost was €8,141,252 inclusive of compensation and all costs for 187 clinical finalised claims during this five year period (Table 18). The average cost per clinical claim inclusive of compensation and all costs (legal fees for the plaintiff, legal fees for the SCA, expert costs etc.) was €43,536, 2010-2014 inclusive.

| Clinical Claims Finalised in the Service of Gynaecology 2010-2014 | Total |
|---|---|
| Total cost of claims | €8,141,252 |
| Total number of clinical claims | 187 |
| Average cost per claim finalised | €43,536 |

**Table 18: Cost of clinical claims finalised in Gynaecology services nationally, 2010-2014 inclusive**

### 5.4.4.3 International comparison

The NHS Litigation Authority's annual report 2014/15 identified that Gynaecology accounted for 6% of clinical negligence claims received in that year and was the sixth most common speciality after *"Others"* (an aggregate of 54 different speciality areas, each with a relatively small volume and value of claims), Orthopaedic surgery, Accident and Emergency, General Surgery and Obstetrics. The value of Gynaecology claims as per the NHS litigation authority was 2% of the total value of clinical negligence claims received in 2014/15.[7]

Laparoscopy has become a valuable tool for the Gynaecologist in diagnosis and treatment of a wide variety of Gynaecological disorders. While its quicker recovery time is an advantage, potential life threatening complications include entry-related problems and injuries to viscera e.g. bowel, bladder or vasculature. A recent Cochrane database review in 2015 of 46 randomised controlled trials identified that no one laparoscopic entry technique is superior to the other for Gynaecology and non-Gynaecology surgery and quality of evidence in the studies was relatively poor.[23]

### 5.4.5 Clinical claims created in *Other* services

One hundred and one clinical claims were categorised into *"Other"* services where the claims did not fit into any of the offered categories.

#### 5.4.5.1 Cost of clinical claims finalised in *Other* services nationally, 2010-2014 inclusive

During this five year period, 42 claims were finalised in this service. Detailed manual analysis of the ten most costly claims in this group identified they were related to significant complications post procedure/operation (n=4); delayed diagnosis leading to complications (n=3), and failure to diagnose (n=2), (one of which resulted ultimately in cerebrovascular accident and death after discontinuation of warfarin). The total costs of these 42 claims including compensation and all costs (legal costs to the plaintiff, legal costs to the SCA, expert costs etc.) was €4,276,369.

## 5.5 Discussion regarding clinical claims created nationally and internationally

### 5.5.1 National Claims

Overall, the number of clinical claims created in Ireland, 2010-2014 inclusive is increasing. High risk services for clinical claims included Surgery, Medicine, Maternity and Gynaecology. The cost of claims finalised 2010-2014 was highest, not surprisingly, in Maternity services, followed by Medicine, Surgery and Gynaecology services. Total legal fees, expressed as a percentage of awards/settlements, was 62.1% in 2010 and reduced to 51.0% in 2014. The average cost per clinical claim including compensation and all costs (legal fees for the plaintiff, legal fees for the SCA, expert costs etc.) reduced from €152,329 in 2010 to €141,813 in 2014.

### 5.5.2 International claims

A significant publication in 2014 by Mello et al[24] reviewed national trends in the USA in medical liability claims and costs which showed a sharp reduction in the rate of paid claims and flat or declining levels in compensation payments and liability insurance costs over the proceeding 7 to 10 years. The authors discuss that state legislatures have enacted tort reforms such as caps on amount of damages paid, in an effort to reduce both volume and costs of claims (malpractice litigation). Attempts to introduce similar traditional reform measures at a federal level, the authors explain, have so far failed. The authors discuss non-traditional reforms which may be potentially important, including communication and resolution programmes, pre suit notification (similar to pre action protocols), laws that defend the apology regarding Open Disclosure, safe harbour legislation (where physicians who follow accepted guidelines are protected) and administrative compensation systems. Internationally, it is believed that several factors are required to combine, to change the current medical liability environment over the coming decade.

Liability claims and costs before and after implementation of a medical error disclosure program were analysed by Kachalia et al in 2010.[25] The University of Michigan Health System has, since 2001, offered full Open Disclosure and compensation to patients for medical errors. This retrospective before and

after analysis identified that the study could not establish causality. However, the average monthly rate of claims decreased from 7.03 to 4.52 per 100,000 patient encounters (rate ratio (RR) 0.64, [95% CI 0.44-0.95]). The average monthly rate of lawsuits decreased from 2.13 to 0.75 per 100,000 patient encounters (RR, 0.35 [CI 0.22 to 0.58]). Median time from claim reporting to resolution decreased from 1.36 to 0.95 years. Average monthly cost rates decreased for total liability (RR, 0.41 [CI, 0.26 to 0.66]), patient compensation (RR, 0.41 [CI,0.26 to 0.67]) and non-compensation related legal costs (RR, 0.39 [CI, 0.22 to 0.67])[25].

The State Claims Agency, together with the HSE, has co-led the national programme on Open Disclosure for many years. Training has occurred for healthcare staff working in all acute hospitals nationally. In 2015 in excess of 3,000 staff were trained in Open Disclosure at hospital and community healthcare organisations nationwide. Training sessions included briefing sessions, workshops of 4 hours duration and *train the trainer* 2 day courses. In Ireland, the legislation to protect the apology is awaited and is contained within the Civil Liability (Amendment) Bill 2017.

# 6.0 SPECIALITIES

## 6.1 Background

A number of specialities were analysed in detail from a clinical incident, claims and cost viewpoint including Emergency Medicine, Mental Health, Radiology, Cardiology, Gastroenterology, Respiratory, Neurology and Infectious Diseases. This gives stakeholders including specialists and multi-disciplinary care teams a holistic overview of their specific area from a national perspective. An increase in clinical incident numbers reported across the spectrum of severity of injury by a healthcare service is considered, nationally and internationally, to reflect a strong patient safety culture.

Prior to 2011, data was lacking internationally on the proportion of physicians who face malpractice claims in a year, the size of these claims and the cumulative career malpractice risk according to speciality. In a sentinel paper from Harvard, which gathered 40,916 physicians and 233,738 physician years covered, it was identified that for each year of the study, 7.4% of all physicians had a malpractice claim, with 1.6% having a claim leading to a payment.[26] Seventy eight per cent of all claims did not result in payments to plaintiffs.

## 6.2 Emergency Medicine

### 6.2.1 Clinical incidents in Emergency Medicine nationally, 2010-2014 inclusive

The data for Emergency Medicine including clinical incidents, claims and costs are a subset of the data for Medicine. Between 2010 and 2014, the number of clinical incidents identified in Emergency Medicine increased by 974, (from 1,906 in 2010 to 2,880 in 2014), which represented a 51.1 % increase (Figure 23). This increase may reflect a change in pattern of clinical incident reporting in Emergency Medicine (consistent with increased training and education regarding importance of clinical incident reporting), it may reflect a change in clinical care, or a combination of both.

Regarding severity rating, of the total number (10,835) of clinical incidents in Emergency Medicine during this five year period, 290 (2.7%) were rated extreme; 12 (0.1%) rated major; 3,766 (34.8%) rated moderate; 1,204 (11.1%) rated minor and 1,111 (10.3%) rated negligible. The remaining 4,452 (41.1%) clinical incidents did not receive a severity rating from the healthcare services.

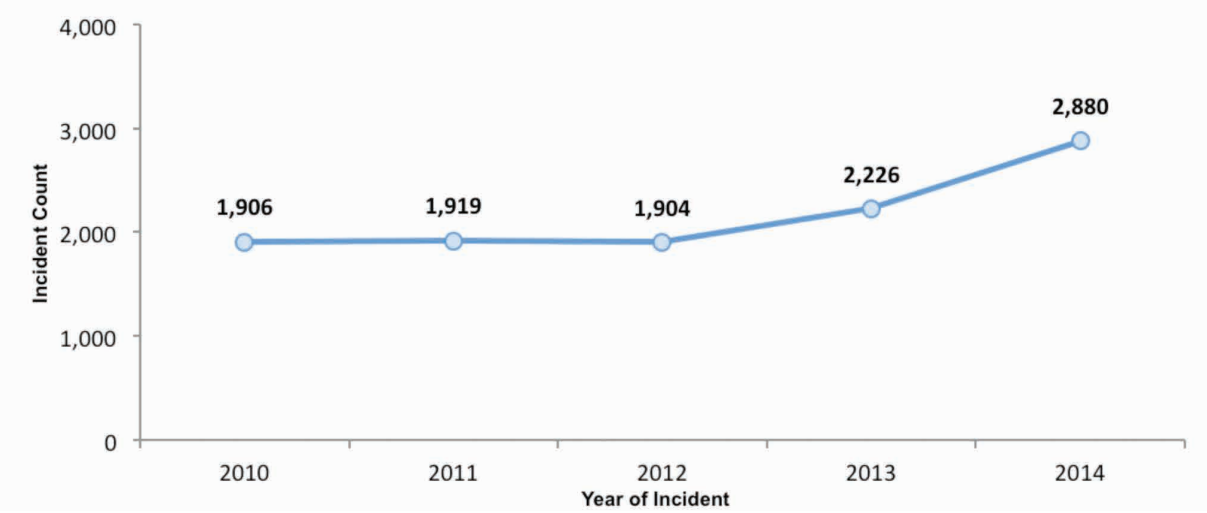


**Figure 23: Clinical incidents identified in Emergency Medicine nationally, 2010-2014 inclusive**

The ten most common clinical incidents nationally in Emergency Medicine, reported to the SCA 2010-2014 inclusive, were identified and analysed, using the *"please specify"* field (Table 19). The subgroup *"other"*, which is the category used when the incident does not fall into any of the particularised categories was the most common. Incidents related to *"delay"* were prominent including delay or failure to treat leading to an adverse outcome and incidents related to delayed diagnosis, which, when combined, accounted for 32.4 % (n=2,792) of the ten most common clinical incidents in Emergency Medicine nationally. Incidents pertaining to inappropriate admission or transfer (n=995, 9.2%) and serious soft tissue damage (n=832, 7.7%) were relatively common. Incidents pertaining to *"diagnosis"*, including delayed diagnosis and failure to diagnose, featured in the ten most common clinical incidents in Emergency Medicine nationally over this time period.

| Ten Most Common Clinical Incidents in Emergency Medicine, 2010-2014 inclusive | Incident number (n) | Percentage (%) |
|---|---|---|
| Other | 2,646 | 24.4% |
| Delay / Failure to Treat - Adverse Outcome | 2,343 | 21.6% |
| Inappropriate Admission/transfer | 995 | 9.2% |
| Serious Soft Tissue Damage | 832 | 7.7% |
| Delayed Diagnosis | 449 | 4.1% |
| Mislabelled Sample | 389 | 3.6% |
| Failure/Faulty Medical Device/Equipment | 387 | 3.6% |
| Self-discharge / Discharge Against Advice | 240 | 2.2% |
| Failure to Diagnose | 223 | 2.1% |
| Incorrect data | 126 | 1.2% |
| Ten Most Common Incidents | 8,630 | 79.7% |
| **Overall Total** | **10,835** | **100.0%** |

**Table 19: Ten most common clinical incidents identified in Emergency Medicine nationally, categorised by the *please specify* field, 2010-2014 inclusive**

The most common clinical incidents in Emergency Medicine, 2010 and 2014 inclusive, were tracked, excluding the subgroup *"other"*, using the *"please specify"* field in the NIMS to help identify trends. Increases were identified in incidents pertaining to inappropriate admission or transfer (almost 7 fold), serious soft tissue damage (3 fold), failure or faulty medical device /equipment (more than doubled) and delayed diagnosis. In contrast, delay or failure to treat leading to an adverse outcome and mislabelled sample remained relatively stable, 2010-2014 inclusive (Figure 24).

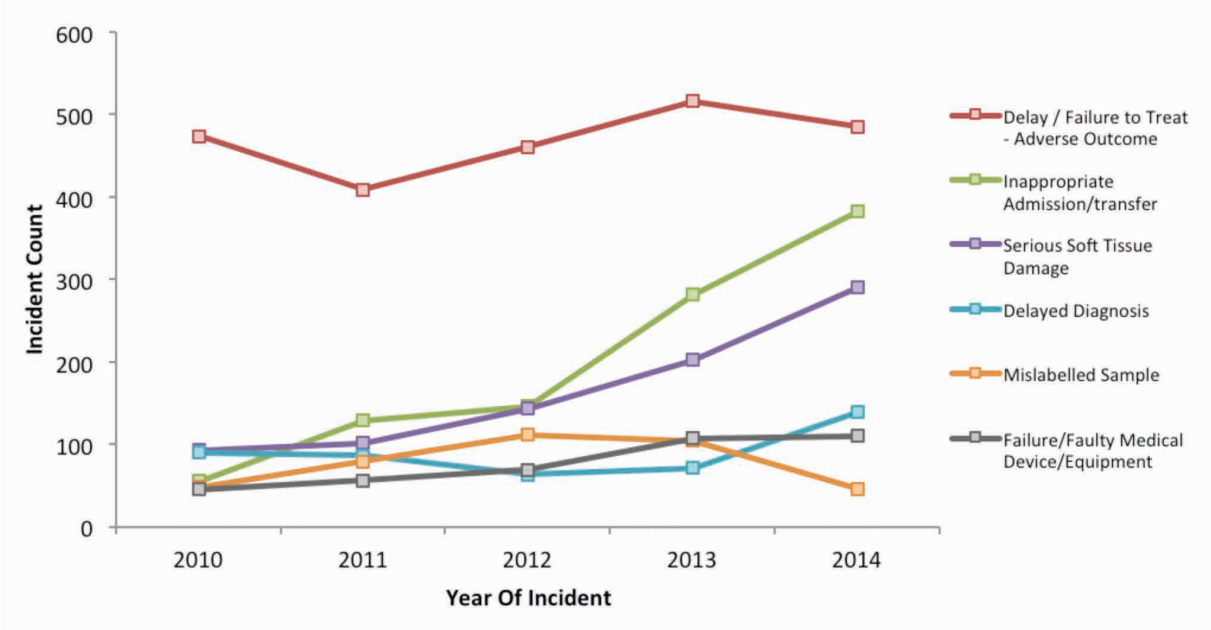


**Figure 24: Most common clinical incidents in Emergency Medicine nationally, tracked, categorised by the *please specify* field, 2010-2014 inclusive, excluding "other"**

### 6.2.2 Clinical claims created in Emergency Medicine, 2010-2014 inclusive

Overall, the number of clinical claims created in Emergency Medicine, 2010-2014 has increased by 63.2% (n= 24) (Figure 25).

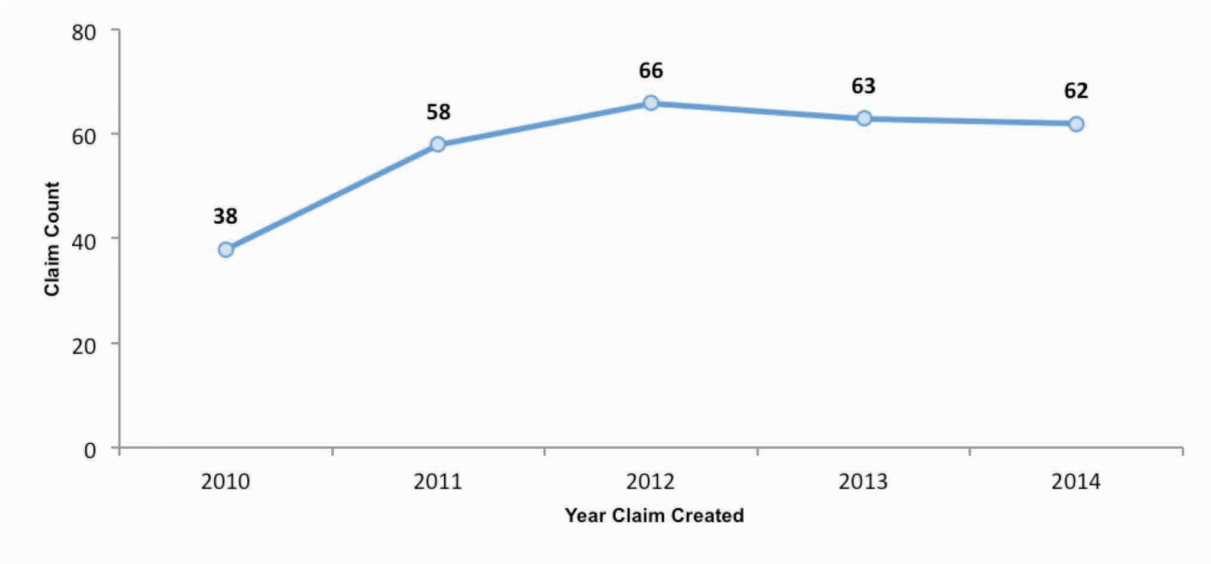


**Figure 25: Clinical claims created in Emergency Medicine nationally, 2010-2014 inclusive**

The most common clinical claims created in Emergency Medicine, 2010-2014 inclusive were identified and analysed, using the *"please specify"* field (Table 20). Some of these clinical claims were consistent with clinical incidents reported to the SCA during this time period. Clinical claims related to *"diagnosis"* featured prominently including, failure to diagnose (n=90) and delayed diagnosis (n=44), which combined accounted for 51.1% (n=134) of the ten most common clinical claims created in Emergency Medicine during this time period. Clinical claims related to *"delays"* were common, with

delay or failure to treat leading to an adverse outcome (n=31, 10.8%) and delayed diagnosis (n=44, 15.3%), both featuring in the ten most common clinical claims created in Emergency Medicine during this five year period. Clinical claims related to *"procedures"* including failure or difficulty performing a procedure (n=4, 1.4%) and unexpected complications during a procedure or operation (n=2, 0.7%) were less common and combined accounted for 2.3% (n=6) of the ten most common clinical claims created in Emergency Medicine, 2010-2014 inclusive. Hospital-related deaths reported to the Coroner were a small (n=3, 1.1%) but important percentage of clinical claims created in Emergency Medicine and clinicians should be aware that this patient population may occasionally involve giving evidence to the Coroner's Court and may lead to clinical claims.

| Ten Most Common Clinical Claims Created in Emergency Medicine, 2010-2014 inclusive | Claim number (n) | Percentage (%) |
|---|---|---|
| Failure to Diagnose | 90 | 31.4% |
| Other | 66 | 23.0% |
| Delayed Diagnosis | 44 | 15.3% |
| Delay / Failure to Treat - Adverse Outcome | 31 | 10.8% |
| Unexpected Deterioration | 4 | 1.4% |
| Foreign Body Left in situ | 4 | 1.4% |
| Failure / Difficulty Performing Procedure | 4 | 1.4% |
| Hospital-related Death Rep. To Coroner | 3 | 1.1% |
| Unplanned re-attend to A&E Within One Week | 2 | 0.7% |
| Unexpected Patient Fatality | 2 | 0.7% |
| Unexpected Complications During Operation / Procedure | 2 | 0.7% |
| Serious Soft Tissue Damage | 2 | 0.7% |
| Readmission Within 72 Hours of Discharge | 2 | 0.7% |
| Infiltration Injury / Leakage | 2 | 0.7% |
| Incorrect data | 2 | 0.7% |
| Adverse / Allergic Reaction to Known Allergen | 2 | 0.7% |
| Most common claims | 262 | 91.3% |
| **Overall Total** | **287** | **100.0%** |

**Table 20: Ten most common clinical claims created in Emergency Medicine nationally, categorised by the *please specify* field, 2010-2014 inclusive**

[Note: More than ten causes are listed here because some categories had equal numbers of claims]

The most common clinical claims created in Emergency Medicine were tracked over this five year period, excluding the subgroup *"other"*, to help identify trends, using the *please specify* field (Figure 26). An increase was identified in failure to diagnose and in delay or failure to treat leading to an adverse outcome (though numbers are small), reflecting common clinical incidents which were reported to the SCA during the same time period. Clinical claims created relating to delayed diagnosis remained relatively stable during this same time period. Claims pertaining to foreign body left *in situ* and unexpected deterioration were created in three out of the five years tracked though numbers were very low.

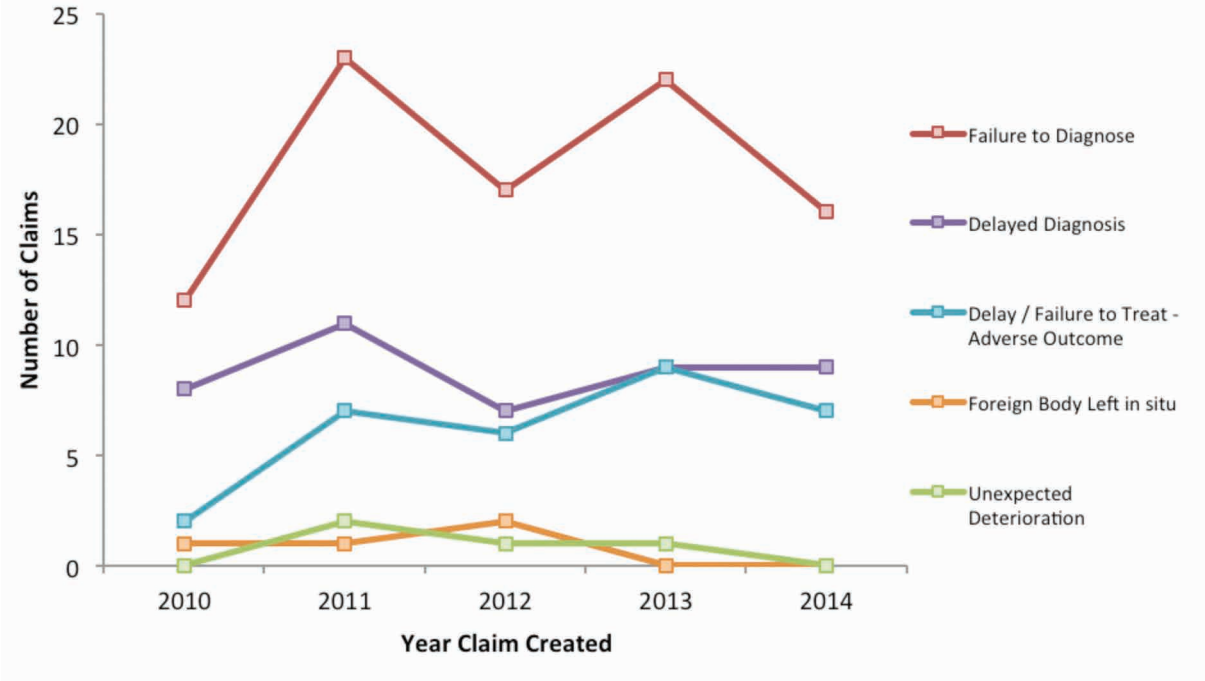


**Figure 26: Most common clinical claims created in Emergency Medicine nationally, tracked, categorised by the *please specify* field, 2010-2014 inclusive, excluding *"other"***

### 6.2.3 Cost of clinical claims finalised in Emergency Medicine nationally, 2010-2014 inclusive

The total cost of clinical claims in Emergency Medicine over the 5 year period 2010-2014 inclusive was €39,794,873 of which awards/settlements accounted for €23,766,447, legal fees for the plaintiff €9,896,047, legal fees for the SCA €5,405,714 and *others* including expert fees €726,665 (Table 21). Total legal fees as a percentage of damages during this five year period was 64.4%. The average cost per clinical claim including compensation and all costs (including legal fees to the plaintiff, legal fees to the SCA, expert costs etc.) was €95,498 in 2010 and increased to €283,209 in 2014. This increase was explained by one outlier (previously highlighted), a case involving a catastrophic injury, and a multi-million payment.

| Clinical Claims Finalised in the Sub-Service of Emergency Medicine 2010-2014 | | | | | | |
|---|---|---|---|---|---|---|
| | 2010 | 2011 | 2012 | 2013 | 2014 | Total |
| Awards/Settlements | €3,343,050 | €2,732,776 | €3,839,983 | €2,939,100 | €10,911,538 | €23,766,447 |
| Legal Fees - SCA | €1,238,451 | €816,561 | €1,152,385 | €853,933 | €1,344,384 | €5,405,714 |
| Legal Fees -Plaintiff | €1,791,023 | €1,684,811 | €2,031,263 | €1,574,342 | €2,814,608 | €9,896,047 |
| Other | €121,363 | €111,409 | €150,636 | €120,512 | €222,744 | €726,665 |
| Total | €6,493,888 | €5,345,557 | €7,174,267 | €5,487,888 | €15,293,274 | €39,794,873 |
| Number of Claims | 68 | 60 | 60 | 41 | 54 | 283 |

**Table 21: Cost of clinical claims finalised in Emergency Medicine nationally, 2010-2014 inclusive**

### 6.2.4 International comparison

In the NHS Litigation Authority[7] annual report 2014/15, Emergency Medicine (listed as *Accident and Emergency*) accounted for 12% of the clinical negligence claims received in 2014 and was ranked third most common after *"other"* (which included 54 different specialities, aggregated) and Orthopaedic Surgery. The value of clinical negligence claims received in 2014/15 by NHS LA for Emergency Medicine was 8% of the total value of all clinical negligence claims.

A large epidemiological study of closed Emergency Department malpractice claims in the USA identified 11,529 claims representing over $664 million USD in total liability over the 23 year study period.[14] The authors demonstrated that Emergency Medicine doctors were the primary defendants in 19% of claims and common errors included errors in diagnosis (37%), and improper performance of procedure (17%). No error could be identified by the insurer in 18% of claims. Over two thirds of claims (70%) closed without payment to the plaintiff, and 29% were paid through settlement. The minority of claims, 7%, were resolved by verdict, with the majority of these (85%) resolved in favour of the clinician. The authors identified that over time the average indemnity payments and expenses of litigation, adjusted for inflation, more than doubled, while both the total number of claims and number of paid claims decreased. The authors concluded that efforts to mitigate risk in the Emergency Department should include the diverse clinical specialities who work in this complex environment, with attention to those health conditions and potential errors with the highest risk[14].

A review of older medical literature is useful to identify if lessons are being learned from history. Twenty years ago in the UK, over 100 negligence claims (n=105) against Emergency Departments were reviewed.[27] These identified that over 50% (n=54) involved the missed diagnosis of a fracture, because of failure to perform a radiograph or to interpret radiographs correctly. The second most common cause of claims was missed or delayed diagnosis (excluding a fracture), due to incomplete clinical examination, or failure to perform a radiograph or interpret radiographs correctly. In the majority of claims (78%), senior house officers (SHOs; i.e. junior doctors) were allegedly responsible for the mistake. The authors concluded that SHOs in Emergency Medicine departments required careful training and supervision with ready access to senior medical advice, both clinical and radiological. The authors identified that most errors leading to claims, in retrospect, appeared to have been simple failures of patient history taking, physician examination, interpretation of radiographs and communication. Half of the claims were found to be indefensible[27]. Another smaller study, of the same vintage, from the UK, concurred that the majority of successful claims concerned missed fractures and that early radiograph reporting would likely reduce the risk of litigation[28]. It is of concern that commonality exists between the findings of these studies 20 years ago (1996, 1997) and the more recent study, over a decade later, by Brown et al (2010).[14]

A study in 2004 which analysed Emergency Medicine-related malpractice finalised claims in the Netherlands, identified similar trends: the majority of claims involved minor surgical conditions including fractures, joint dislocations, wounds, and tendon injuries with junior doctors (SHOs) involved in 76% of claims and consultant supervision documented in only 15% of healthcare records. The authors concluded that more junior doctor (SHO) supervision was required and specific training programmes for Emergency Medicine physicians were needed[29].

Interestingly, the SCA's much smaller analysis of finalised claims in Emergency Medicine in 2014 in Ireland concludes with somewhat similar findings and suggestions over 10 years later.

## 6.3 Mental Health

### 6.3.1 Clinical incidents in Mental Health Services nationally, 2010–2014 inclusive

An increase in the number of clinical incidents (n=594) in Mental Health services was identified, 2010-2014 inclusive, which represents a 44.5% increase. This may be due to a change in pattern of clinical incident reporting in Mental Health services (possibly as a consequence of increased training and education on this topic), increased clinical incidents or a combination of both (Figure 27). An increase in clinical incident reporting by health care services is considered good and reflective of a strong patient safety culture.

Regarding severity rating of clinical incidents in Mental Health, of the total number (n=7,382) of clinical incidents over this five year period 175 (2.4%) were rated extreme; 8 (0.1%) rated major; 931 (12.6%) rated moderate; 1,164 (15.8%) rated minor and 1,613 (21.9%) rated negligible. The remaining 3,491 (47.3%) clinical incidents did not receive a severity rating by the healthcare services.

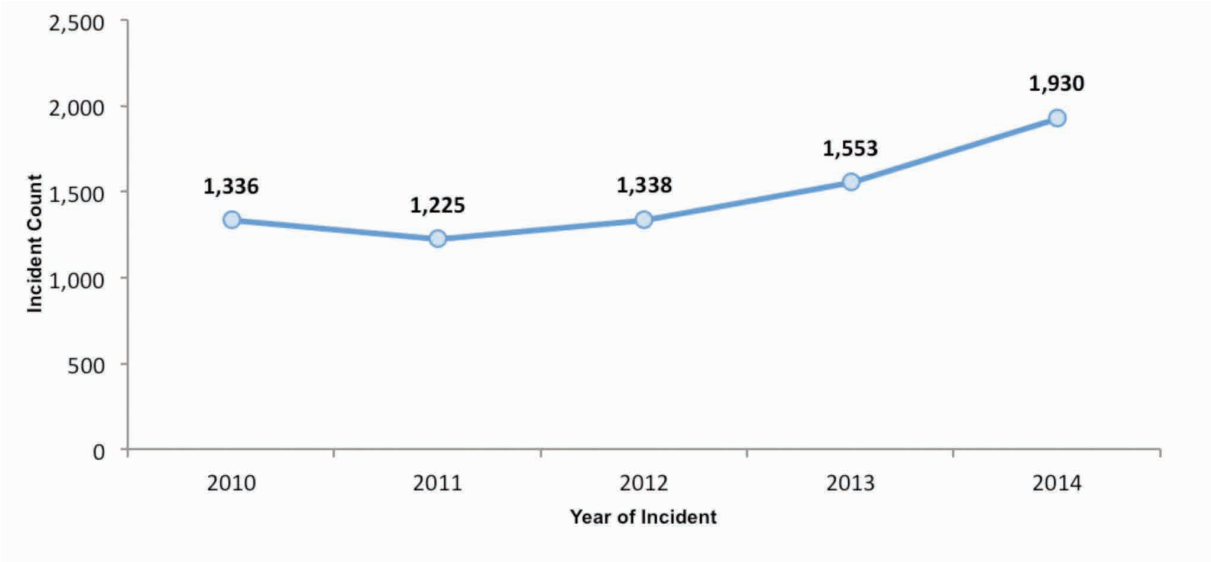


**Figure 27: Clinical incidents identified in Mental Health services nationally, 2010-2014 inclusive**

The most common clinical incidents identified in Mental Health services nationally, 2010- 2014 inclusive, excluding the subgroup *"other"*, were analysed using the *"please specify"* field in the NIMS (Table 22). The subgroup *"other"* (n=4,477, 60.6%) was the most common incident. Incidents related to choking episodes (n=326, 4.4%) and sudden collapse (n=311, 4.2%) featured in the ten most common list. Incidents related to medication were prominent and included incorrect medication, incorrect dosage, inappropriate self-medication and missed medication, which, when combined, accounted for 15.0% (n=974) of the ten most common incidents identified in Mental Health services during this five year period.

| Ten Most Common Clinical Incidents in Mental Health Services, 2010-2014 inclusive | Incident number (n) | Percentage (%) |
|---|---|---|
| Other | 4477 | 60.6% |
| Choking Episode | 326 | 4.4% |
| Sudden Collapse | 311 | 4.2% |
| Incorrect Medication | 291 | 3.9% |
| Incorrect Dosage | 260 | 3.5% |
| Inappropriate Self-medication | 256 | 3.5% |
| Delay / Failure to Treat - Adverse Outcome | 198 | 2.7% |
| Missed Medication | 167 | 2.3% |
| Clinical Records Missing / Misplaced | 105 | 1.4% |
| Unexpected Deterioration | 103 | 1.4% |
| Ten Most Common Incidents | 6,494 | 88.0% |
| **Overall Total** | **7,382** | **100.0%** |

**Table 22: Ten most common clinical incidents identified in Mental Health services nationally, categorised by the *please specify* field 2010-2014 inclusive**

The most common clinical incidents in Mental Health services, excluding the subgroup *"other"*, were tracked over five years using the *"please specify"* field, to help identify trends (Figure 28). Increases in incidents related to incorrect dosage (threefold increase), incorrect medication, inappropriate self-medication and choking episodes were documented. In contrast, a decrease in incidents pertaining to sudden collapse was identified.

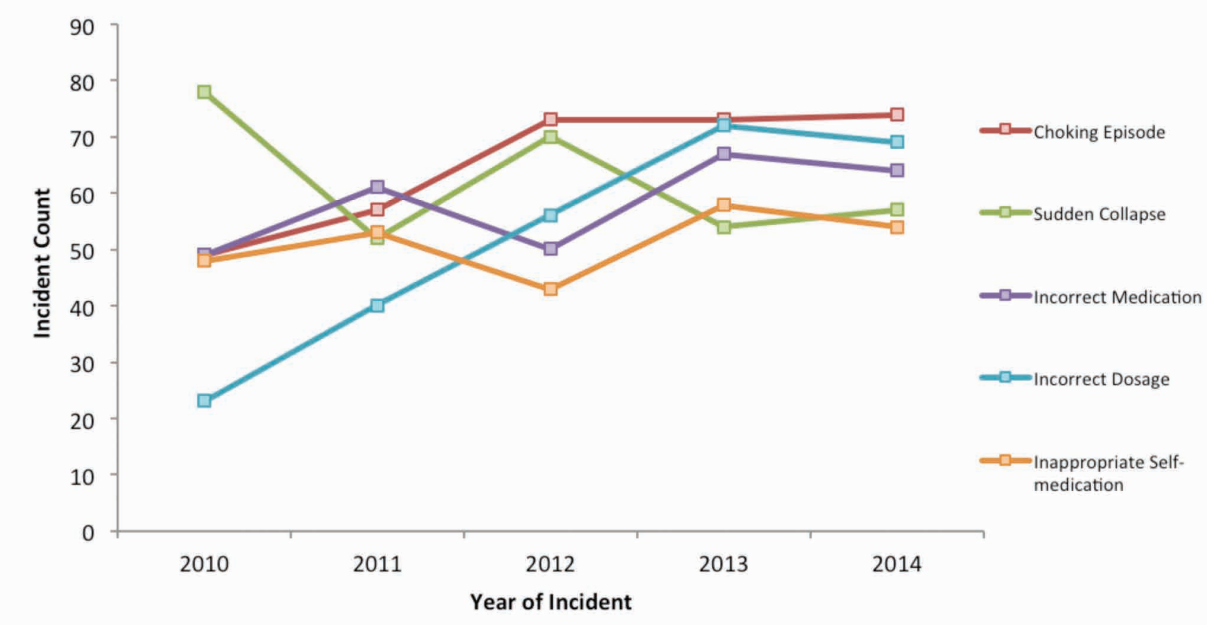


**Figure 28: Most common clinical incidents in Mental Health services nationally, tracked, categorised by the *please specify* field, 2010-2014 inclusive, excluding "other"**

### 6.3.2 Clinical claims created in Mental Health Services, 2010-2014 inclusive

Overall the number of clinical claims created in Mental Health services during this five year period was low and reduced from six in 2010 to two in 2014 (Figure 29).

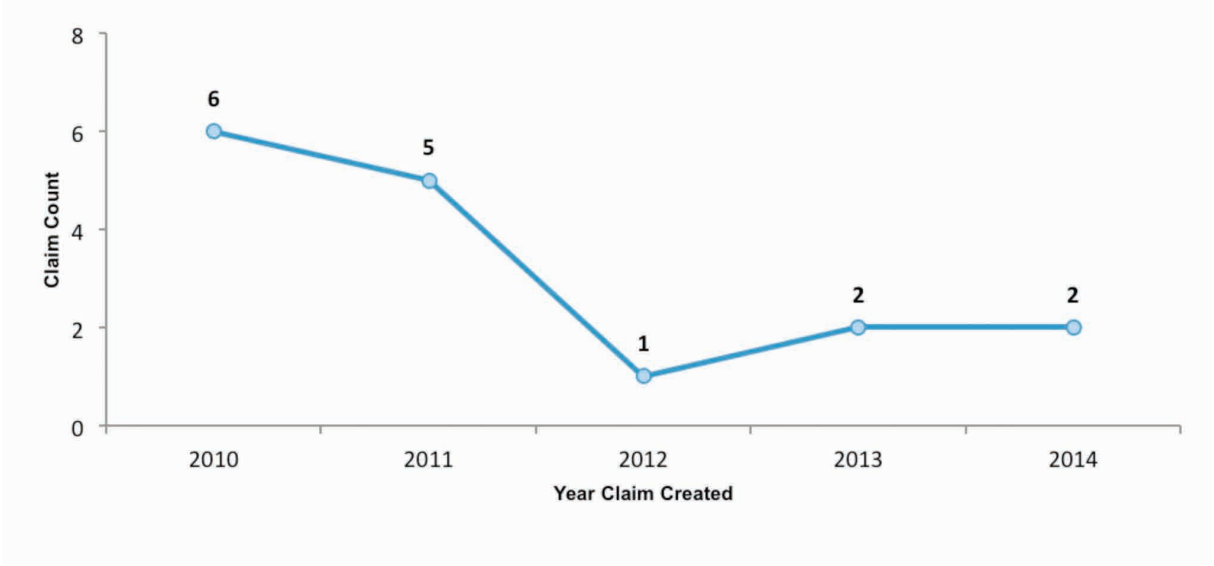


**Figure 29: Clinical claims created in Mental Health services nationally, 2010-2014 inclusive**

The most common clinical claims created in Mental Health services, 2010-2014 were identified using the *"please specify" field* and fell into seven categories (Table 23). These included the subgroup *"other";* medication errors (including incorrect medication plus incorrect dosage); delay or failure to treat leading to an adverse outcome; adverse or allergic reaction to a known allergen; incorrect result applied to a patient and hospital related death reported to the Coroner. Overall numbers of clinical claims created in Mental Health services were small. No significant trend was identified in the most common claims in Mental Health services between 2010-2014, due to these small numbers.

| Clinical Claims Created in Mental Health Services, 2010-2014 inclusive | Total Claims (n) | Percentage (%) |
|---|---|---|
| Other | 7 | 43.8% |
| Incorrect Medication | 2 | 12.5% |
| Delay / Failure to Treat - Adverse Outcome | 2 | 12.5% |
| Adverse / Allergic Reaction to Known Allergen | 2 | 12.5% |
| Incorrect result applied to patient | 1 | 6.3% |
| Incorrect Dosage | 1 | 6.3% |
| Hospital-related Death Rep. To Coroner | 1 | 6.3% |
| Total | 16 | 100.0% |

**Table 23: Most common clinical claims created in Mental Health services, categorised by the *please specify* field, 2010-2014 inclusive**

### 6.3.3 Cost of clinical claims finalised in Mental Health services nationally, 2010-2014 inclusive

Due to the relatively low number of clinical claims and cost in Mental Health services, the total cost of clinical claims for the five year period was reviewed. The total cost of clinical claims finalised, including compensation and all costs (legal fees to the plaintiff, legal fees to the SCA, expert costs etc.) was €1,363,364 for this five year period. The average cost per clinical claim was €59,277 (Table 24).

| Cost of Clinical Claims Finalised in Mental Health Services 2010-2014 | Total |
|---|---|
| Total cost of claims | €1,363,364 |
| Total number of clinical claims | 23 |
| Average cost per claim finalised | €59,277 |

**Table 24: Clinical Claims finalised in Mental Health Services nationally, 2010-2014 inclusive**

### 6.3.4 International comparison

Internationally, Psychiatry is considered a low risk speciality for being sued. A large USA study of malpractice risk, according to physician speciality, identified that the probability of facing a claim in the USA annually was 2.6% in Psychiatry compared with 19.1% in Neurosurgery[26]. This figure was based on malpractice data from 1991 through 2005 including 233,738 physician years of coverage. Psychiatry was the speciality ranked lowest in a list of physician specialities facing a malpractice claim annually. Additionally, the authors identified that Psychiatry was the speciality which had the lowest number of claims with payment to a plaintiff [26].

Similarly in a smaller European study (n=94 claims over 23 years), the risk of lawsuit and awards for compensation was very low in Psychiatry. The majority of claims studied related to diagnosis (63.83%), including assessment of suicide risk. Most claims related to hospital (62.8%) and emergency (52.5%) care.[30]

## 6.4 Radiology

### 6.4.1 Clinical incidents in Radiology nationally, 2010-2014 inclusive

There has been a significant increase in the number of clinical incidents reported by healthcare services to the SCA in Radiology, 2010-2014 inclusive (an increase of 398, which represents an increase of 71.3%). Much of this increase has occurred since 2013 (Figure 30). This may be related to increased clinical incident reporting in Radiology (as a result of increased training and education regarding clinical incident reporting), a change in clinical practice in Radiology nationally or a combination of both.

Regarding severity rating of clinical incidents in Radiology, of the total number (n=3,388) of clinical incidents over this five year period 71 (2.1%) were rated extreme; 2 (0.1%) rated major; 908 (26.8%) rated moderate; 431 (12.7%) rated minor and 440 (13.0%) rated negligible. The remaining 1,536 (45.3%) clinical incidents did not receive a severity rating by the healthcare services.

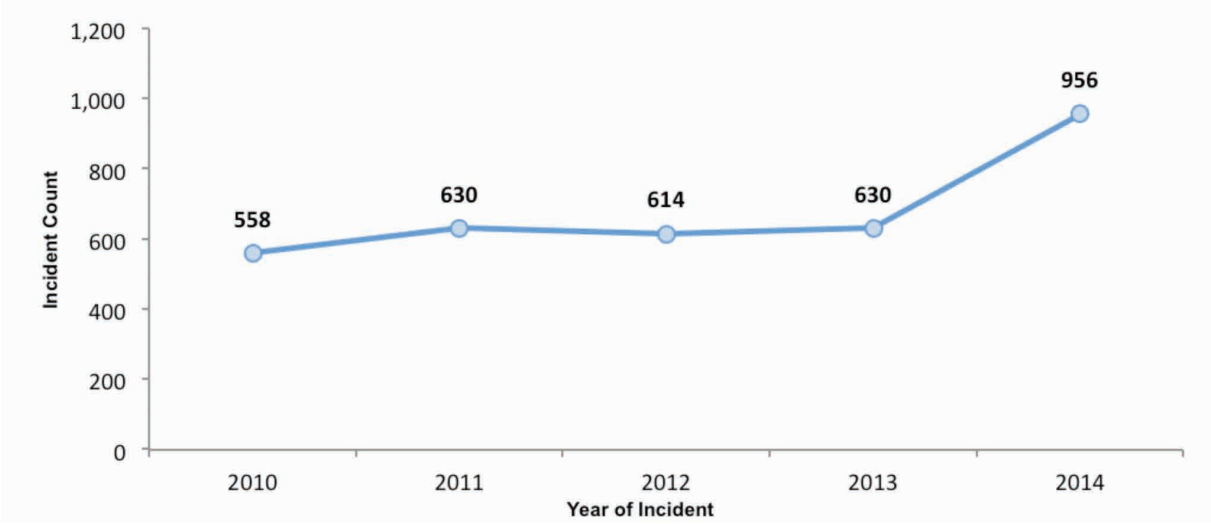


**Figure 30: Clinical incidents identified in Radiology nationally, 2010-2014 inclusive**

The ten most common clinical incidents identified in Radiology, 2010-2014 inclusive were analysed using the *"please specify"* field of the NIMS (Table 25). Radiology is different to other specialities due to the nature of the work involved. Infiltration or leakage of contrast media may cause injury to the patient and/or lead to poor quality images. Infiltration injury or leakage is relatively specific to Radiology and was the second most common clinical incident identified (n=346) during the studied time period. Incidents related to *"delays"* were prominent, including incidents related to delay or failure to treat leading to an adverse outcome (n=220) and delayed diagnosis (n=191) which, when combined, accounted for 17.2% (n=411) of the ten most common clinical incidents in Radiology reported by healthcare services to the SCA during this five year period. Delayed diagnosis is particularly important, especially if related to malignancy. Relatively specific to Radiology are clinical incidents related to cannula injury because cannulas are required when administering contrast media. Despite precautions, clinical incidents pertaining to radiation exposure accounted for 3% of all clinical incidents in Radiology during this time period.

| Ten Most Common Clinical Incidents in Radiology, 2010-2014 inclusive | Incident number (n) | Percentage (%) |
|---|---|---|
| Other | 849 | 25.1% |
| Infiltration Injury / Leakage | 346 | 10.2% |
| Delay / Failure to Treat - Adverse Outcome | 220 | 6.5% |
| Delayed Diagnosis | 191 | 5.6% |
| Failure/Faulty Medical Device/Equipment | 177 | 5.2% |
| Incorrect data | 154 | 4.6% |
| Incorrect anatomy | 136 | 4.0% |
| Wrong Medical Records Applied to Patient | 115 | 3.4% |
| Cannula Injury | 105 | 3.1% |
| Any other radiation exposure incident to patient | 102 | 3.0% |
| Ten Most Common Incidents | 2,395 | 70.7% |
| Overall Total | 3,388 | 100.0% |

**Table 25: Ten most common clinical incidents identified in Radiology nationally, categorised by the *please specify* field, 2010-2014 inclusive**

The most common clinical incidents, excluding the subgroup *"other"*, were tracked 2010-2014 inclusive, to help identify trends (using the *"please specify"* field" in the NIMS). The five most common incidents increased over this time period (Figure 31). Incidents related to delay or failure to treat leading to an adverse outcome and incidents related to infiltration injury or leakage more than doubled. A smaller increase was documented in clinical incidents pertaining to failure or faulty medical equipment or device, delayed diagnosis and incorrect data over this five year period (Figure 31). This increase in incidents pertaining to medical devices or equipment may partially be explained by an increase in complexity and diversity of procedures being performed in Radiology in recent years. Interventional radiologists have been performing intricate procedures that previously were performed by specialist surgeons e.g. neurosurgeons or cardiothoracic surgeons. The increased availability and use of CT and MRI over the last few years may explain some of these increases.

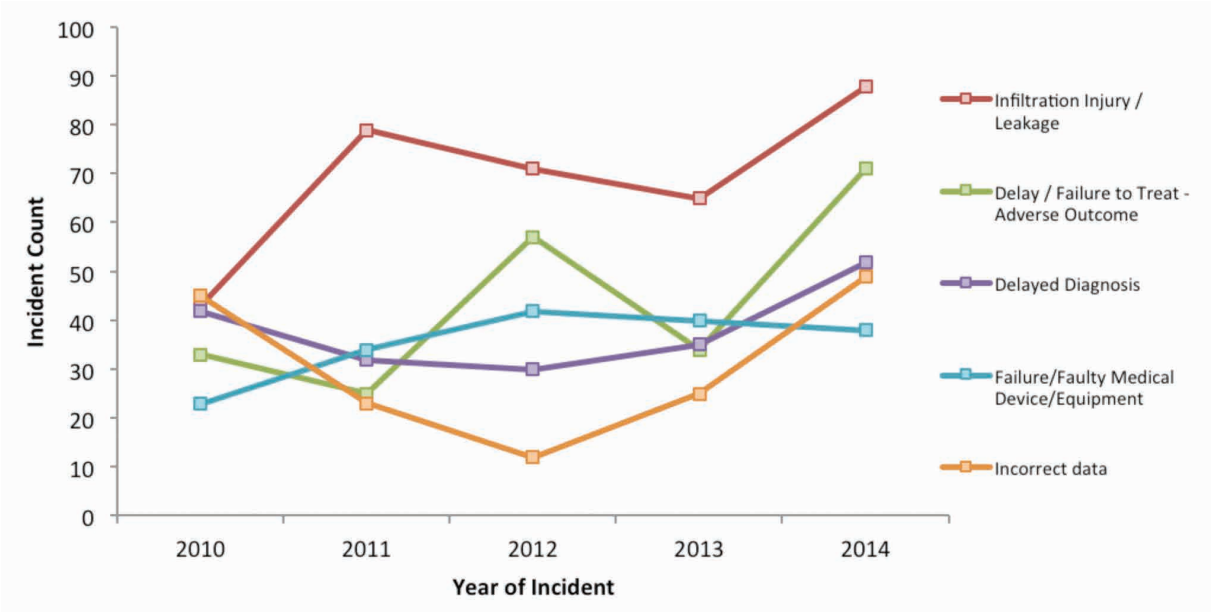


**Figure 31: Most common clinical incidents in Radiology nationally, tracked, categorised by the *please specify* field, 2010-2014 inclusive, excluding *"other"***

## 6.4.2 Clinical claims created in Radiology nationally, 2010-2014 inclusive

Overall, the total number of clinical claims created in Radiology has reduced from 14 in 2010 to 11 in 2014 (which equates to a 21.4% reduction, although numbers are relatively small). An increase has been identified since 2012 (Figure 32).

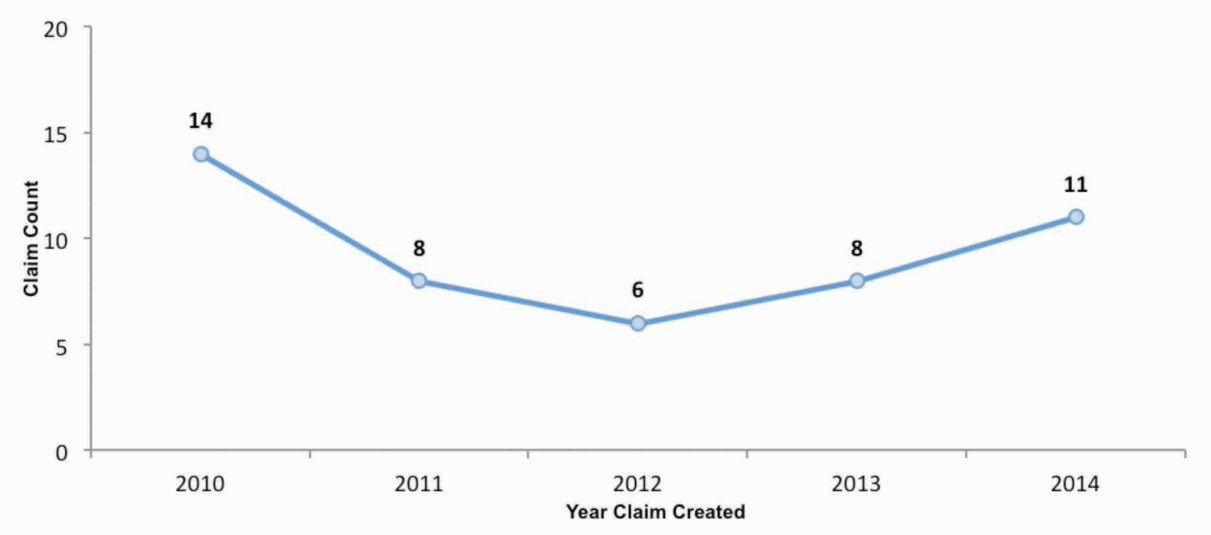


**Figure 32: Clinical claims created in Radiology nationally, 2010-2014 inclusive**

All clinical claims created in Radiology, 2010-2014 were analysed using the *"please specify"* field in the NIMS (Table 26). A significant proportion of clinical claims pertained to *"diagnosis"* including failure to diagnose (n=18) and delayed diagnosis (n=12) which, when combined, accounted for 63.8% (n=30) of all clinical claims created in Radiology during this time period. Additionally, clinical claims related to *"procedures"* featured including unexpected complications both *following* and *during* a procedure/operation and failure or difficulty performing a procedure, which combined, accounted for 8.5% (n=4) of total clinical claims created in Radiology, 2010-2014 inclusive. Interestingly, incorrect result applied to a patient (n=4, 8.5%) was relatively prominent among these clinical claims.

| Clinical Claims Created in Radiology nationally, 2010-2014 inclusive | Claim number (n) | Percentage (%) |
|---|---|---|
| Failure to Diagnose | 18 | 38.3% |
| Delayed Diagnosis | 12 | 25.5% |
| Other | 7 | 14.9% |
| Incorrect result applied to patient | 4 | 8.5% |
| Unexpected Complications Following Operation / Procedure | 2 | 4.3% |
| Unexpected Complications During Operation / Procedure | 1 | 2.1% |
| Injury to left foot and alleges failure to recognise a fracture and to inform of the risks of undergoing a nerve block | 1 | 2.1% |
| Failure / Difficulty Performing Procedure | 1 | 2.1% |
| All radiology records requested from 1 healthcare service | 1 | 2.1% |
| Overall Total claims | 47 | 100.0% |

**Table 26: Clinical claims created in Radiology nationally, categorised by the please specify field, 2010-2014 inclusive**

## 6.4.3 Cost of clinical claims finalised in Radiology nationally, 2010-2014 inclusive

The total cost of clinical claims finalised in Radiology nationally for this five year period amounted to €1,608,553 for 36 clinical claims. The average cost per claim in Radiology inclusive of compensation and all costs (legal fees to the plaintiff, legal fees to the SCA, expert costs etc.) was €44,682 (Table 27).

| Cost of Clinical Claims Finalised in Radiology 2010-2014 inclusive | Total |
|---|---|
| Total cost of claims | €1,608,553 |
| Total number of clinical claims | 36 |
| Average cost per claim finalised | €44,682 |

**Table 27: Cost of clinical claims finalised in Radiology nationally, 2010-2014 inclusive**

### 6.4.4 International comparison

A study published in February 2016 analysed the frequency, liability costs and clinical context of Radiology malpractice claims in the USA.[31] The Comparative Benchmarking System data base, a repository of more than 30,000 medical malpractice cases in the USA, was queried for finalised claims over a five year period (2008-2012). Radiology was the eighth most likely responsible service to be implicated in a medical malpractice claim with a median total paid loss (indemnity payment plus defence cost plus administrative expense) per closed claim of $30,091 USD. Radiology claims were most commonly associated with high and medium severity injuries, the outpatient setting and diagnosis-related allegations. A high proportion of claims pertained to cancer diagnosis. A total of 62.3% of Radiology claims were closed without indemnity payments, and approximately one third (37.7%) resulted in payments to plaintiffs, with a median indemnity payment of $175,000 USD.[31]

Simultaneously in Europe, a national survey of defensive medicine among Radiologists, practising in public hospitals in Austria, was performed and published in 2015. A high prevalence of defensive medicine was identified, with expenditure of time for defensive practice amounting to 9.2 hours per month in Radiology.[10]

An earlier sentinel paper in the New England Journal of Medicine reviewed the proportion of physicians who faced malpractice claims in a year according to speciality. Across all specialities, while 7.4% of physicians, annually, had a claim made against them, only 1.6% made an indemnity payment. Physicians practising in diagnostic Radiology fell into this bracket and ranked 18th overall regarding physician speciality, compared with neurosurgeons, thoracic cardio-vascular and general surgeons who were placed first, second and third respectively.[26]

## 6.5 Cardiology

### 6.5.1 Clinical incidents in Cardiology nationally, 2010-2014 inclusive

Data pertaining to Cardiology, including clinical incidents, claims and costs are a subset of data pertaining to Medicine. There has been an increase of 140 clinical incidents identified in Cardiology nationally, 2010-2014 inclusive, representing a 26.6% increase. Increased clinical incident reporting across the spectrum of severity of injury is considered nationally and internationally to be a positive finding, indicative of a strong patient safety culture. The increase identified may be related to a change in pattern of clinical incident reporting, increased clinical incidents in Cardiology services, or a combination of both (Figure 33).

Regarding severity rating of clinical incidents in Cardiology, of the total number (n=2,848) of clinical incidents over this five year period, 50 (1.8%) were rated extreme; 2 (0.1%) rated major; 444 (15.6%) rated moderate; 688 (24.2%) rated minor and 452 (15.9%) rated negligible. The remaining 1,212 (42.6%) clinical incidents did not receive a severity rating by the healthcare services.

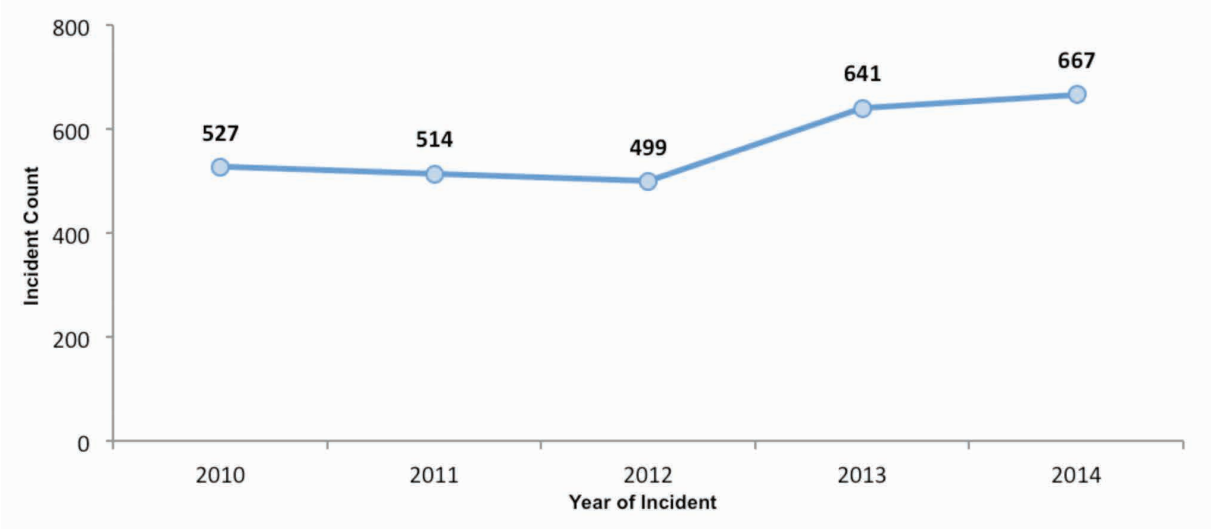


**Figure 33: Clinical incidents identified in Cardiology nationally, 2010-2014 inclusive**

The ten most common clinical incidents in Cardiology, nationally, 2010-2014 inclusive were analysed using the *"please specify"* field on the NIMS (Table 28). They accounted for almost 70% (69.6%) of the total clinical incidents pertaining to Cardiology, during this time period. The subgroup *"other"* was the most common (n=690, 24.2%), followed by failure or faulty medical device or equipment (n=348, 12.2%). *"Medication incidents"* featured prominently including incorrect dosage, missed medication and incorrect medication, which combined accounted for 16.7% (n=331) of the ten most common clinical incidents which were reported to the SCA by healthcare services in Cardiology, during this time period. Additionally, clinical incidents related to *"healthcare records"* were relatively common including missing or misplaced clinical records and incomplete records which, when combined, accounted for 12.2% (n=241) of the ten most common incidents in Cardiology nationally during this five year period.

| Ten Most Common Clinical Incidents in Cardiology 2010-2014 inclusive | Incident number (n) | Percentage (%) |
|---|---|---|
| Other | 690 | 24.2% |
| Failure/Faulty Medical Device/Equipment | 348 | 12.2% |
| Delay / Failure to Treat - Adverse Outcome | 178 | 6.3% |
| Incorrect Dosage | 145 | 5.1% |
| Clinical Records Missing / Misplaced | 130 | 4.6% |
| Incomplete Records | 111 | 3.9% |
| Serious Soft Tissue Damage | 110 | 3.9% |
| Missed Medication | 110 | 3.9% |
| Cannula Injury | 84 | 2.9% |
| Incorrect Medication | 76 | 2.7% |
| Ten Most Common Incidents | 1,982 | 69.6% |
| **Overall Total** | **2,848** | **100.0%** |

**Table 28: Ten most common clinical incidents identified in Cardiology nationally, categorised by the *please specify* field, 2010-2014 inclusive**

The most common clinical incidents which occurred in Cardiology, excluding the subgroup *"other"*, were tracked 2010-2014 inclusive, using the *"please specify"* field, to help identify trends (Figure 34). Both delay or failure to treat leading to an adverse outcome and failure or faulty medical device or equipment doubled, while incorrect dosage and missing or misplaced clinical records reduced, over this five year period. Incomplete records had a significant spike in 2013, which, on review, was identified to be related to one hospital. Incident numbers returned to baseline in this category in 2014.

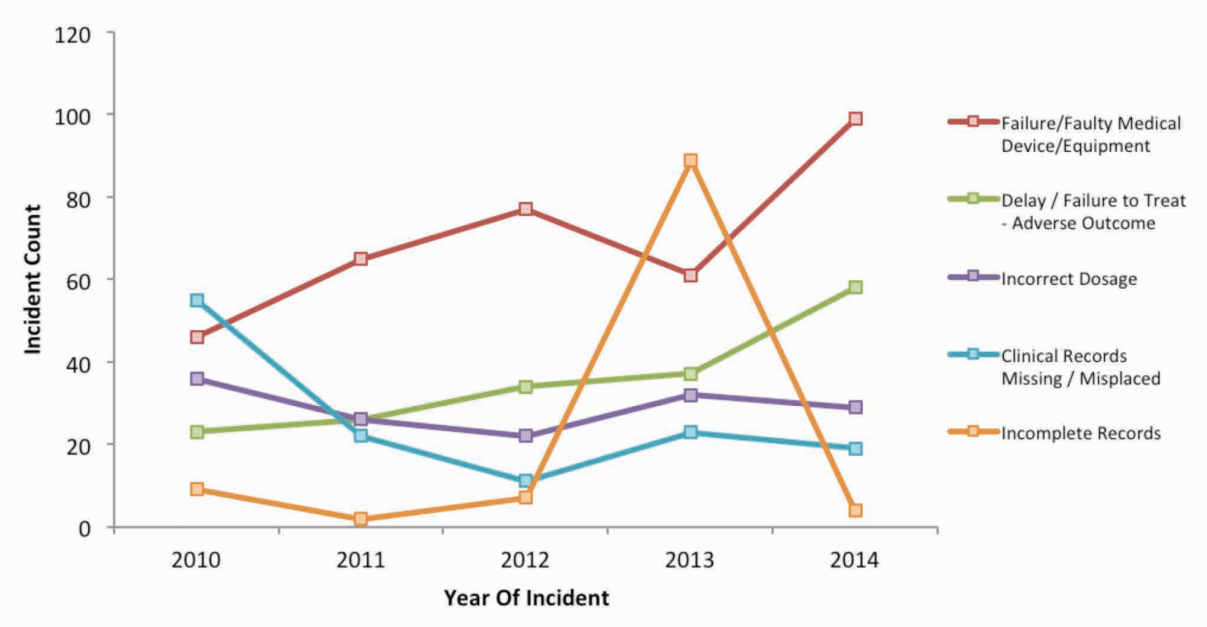


**Figure 34: Most common clinical incidents in Cardiology nationally, categorised by the *please specify* field, tracked, 2010-2014 inclusive, excluding *"other"***

### 6.5.2 Clinical claims created in Cardiology nationally, 2010-2014 inclusive

Overall, the number of clinical claims created in Cardiology, between 2010 (n=5) and 2014 (n=6) was relatively low and stable despite an increase in interventional procedures in Cardiology in recent years (Figure 35).

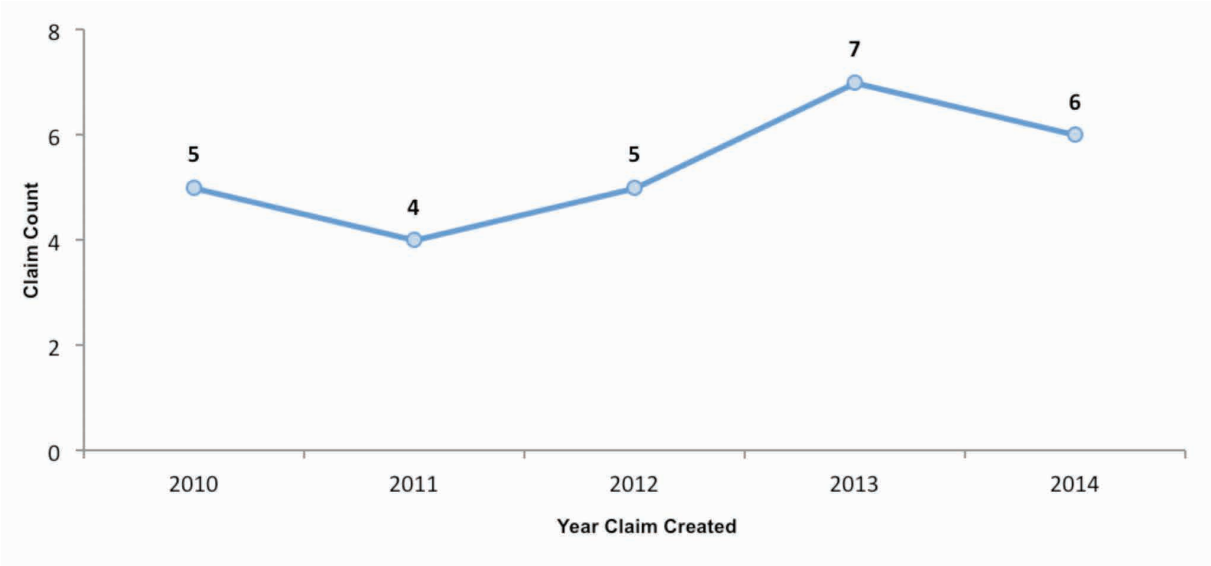


**Figure 35: Clinical claims created in Cardiology nationally, 2010-2014 inclusive**

The most common clinical claims created in Cardiology, nationally, 2010-2014, inclusive, underwent a detailed, manual, clinical analysis (Table 29). The subgroup *"other"* was most common (n=6, 22.2%) and included alleged misreading of an Electrocardiogram (ECG), alleged wrong dose of medication and alleged failure to treat. Clinical claims related to *"diagnosis"* were relatively frequent (n=6, 22.2%) including, failure to diagnose, delayed diagnosis, diagnoses related to myocardial infarction and diagnosis of a hole in the heart. Clinical claims created in Cardiology related to *"procedures"* including unexpected complication following and during a procedure or operation, incorrect procedure and failure or difficulty performing a procedure, when combined were not insignificant (n=4, 14.8%) during this five year period, though numbers are relatively small. Two clinical claims pertained to hospital-related death reported to the Coroner during this five year period.

| Clinical Claims Created in Cardiology, 2010-2014 inclusive | Claim number (n) | Percentage (%) |
|---|---|---|
| Other | 6 | 22.2% |
| Sudden Collapse | 2 | 7.4% |
| Hospital-related Death Rep. To Coroner | 2 | 7.4% |
| Failure to Diagnose | 2 | 7.4% |
| Failure/Faulty Medical Device/Equipment | 2 | 7.4% |
| ECG reading and diagnosis of myocardial infarction | 2 | 7.4% |
| Unexpected Complications Following Operation / Procedure | 1 | 3.7% |
| Unexpected Complications During Operation / Procedure | 1 | 3.7% |
| Transfer to Another Hospital / HDU | 1 | 3.7% |
| Serious Soft Tissue Damage | 1 | 3.7% |
| Incorrect Procedure | 1 | 3.7% |
| Incorrect Medication | 1 | 3.7% |
| Incorrect Dosage | 1 | 3.7% |
| Failure to diagnose hole in heart | 1 | 3.7% |
| Failure / Difficulty Performing Procedure | 1 | 3.7% |
| Delay / Failure to Treat - Adverse Outcome | 1 | 3.7% |
| Delayed Diagnosis | 1 | 3.7% |
| Total | 27 | 100.0% |

**Table 29: Clinical claims created in Cardiology nationally, categorised by the *please specify* field, 2010-2014 inclusive**

### 6.5.3 Cost of clinical claims finalised in Cardiology nationally, 2010-2014 inclusive

Due to the relatively small cost and number of claims, the total cost for the five year period was reviewed (Table 30). The total cost of clinical claims finalised in Cardiology nationally, 2010-2014 inclusive was €4,457,101 for 23 claims. The average cost per clinical claim inclusive of compensation and all costs (legal fees to the plaintiff, legal fees to the SCA, expert costs etc.) was €193,787.

| Cost of Clinical Claims Finalised in Cardiology 2010-2014 inclusive | Total |
|---|---|
| Total cost of claims | €4,457,101 |
| Total number of clinical claims | 23 |
| Average cost per claim finalised | €193,787 |

**Table 30: Cost of clinical claims finalised in Cardiology nationally, 2010-2014 inclusive**

### 6.5.4 International comparison

A large cohort of finalised claims in Cardiology (n=4,248) was analysed from the Physician Insurers Association of America, accounting for 1.8% of all finalised claims between 1985 and 2007 (published 2010).[32] Eighteen percent resulted in indemnity payments with an average indemnity payment of $248,291 USD. The authors identified that the most common allegation among finalised claims in Cardiology was diagnostic error and the most prevalent diagnosis was coronary atherosclerosis. Claims involving cardiac catheterisation and coronary angioplasty represented 12% and 7% of the cardiovascular finalised claims respectively. The authors concluded that aortic aneurysms and dissections, although relatively infrequent as outpatient clinic events, represent a substantial claims risk because of the high percentage of paid claims (30%) and the very high average indemnity payment ($417,298 USD).[32]

Subsequently, an American study, published in 2014, identified that rates of malpractice claims were higher among US Cardiologists (8.6%) than physicians overall (7.4%).[33] An indemnity payment in this study was made in 13.6% of cases. More than half of the claims involved patient death (n=304, 57.4%); were related to inpatient care (n=379, 71.5%); and/or involved a primary cardiovascular condition (n=416, 78.4%). Acute coronary syndrome was the most frequent condition (n=234, 44.2%). Interestingly, a substantial number of claims were non cardiovascular in nature (n=66, 12.5%) and included falls or mechanical injuries sustained while under a Cardiologist's care and included failure to diagnose cancer.[33]

Litigation specifically related to cardiac catheterisation was studied, reviewing finalised claims between 1985 and 2009, using the Physician Insurers Association of America (PIAA) registry (n=1,361 coronary angiography claims) and the Lexis Nexis Academic database (n=116).[34] The most common alleged error was improper performance. The alleged error with the highest payment was *"error in diagnosis"* ($270,916 USD). *"Not performing when indicated, procedure"* had the highest ratio of paid to finalised claims (41%). In regard to severity of injury, death was the most common outcome (44%). As expected, the highest ratio of paid to total finalised claims (43%) was for grave injuries. Of the 116 Lexis Nexis cases, litigation against physicians occurred in 90.5% of cases with judgements in favour of the patient in 29.5%. When death was the outcome (31% cases), doctors were highly likely to be sued (97%) and the judgement was more likely to be in the plaintiff's favour (44%). The authors explained that it is important that Cardiologists recognise these patterns of litigation as these may impact and improve processes of care.[34]

## 6.6 Gastroenterology

### 6.6.1 Clinical incidents in Gastroenterology nationally, 2010- 2014 inclusive

Data pertaining to Gastroenterology, including clinical incidents, claims and costs are a subset of data pertaining to Medicine. Overall there has been an increase of 149 in clinical incidents identified in Gastroenterology nationally, 2010-2014 inclusive, which represents a 54.4% increase (Figure 36). This number may reflect a change in pattern of clinical incident reporting, a change in clinical care in Gastroenterology or a combination of both. Generally an increase in clinical incident reporting across the spectrum of severity of injury is believed to be consistent with a strong patient safety culture.

Regarding severity rating of clinical incidents in Gastroenterology, of the total number (n=1,580) of clinical incidents over this five year period, 21 (1.3%) were rated extreme; 1 (0.1%) rated major; 142 (9.0%) rated moderate; 383 (24.2%) rated minor and 233 (14.7%) were rated negligible. The remaining 800 (50.6%) clinical incidents did not receive a severity rating by the healthcare services.

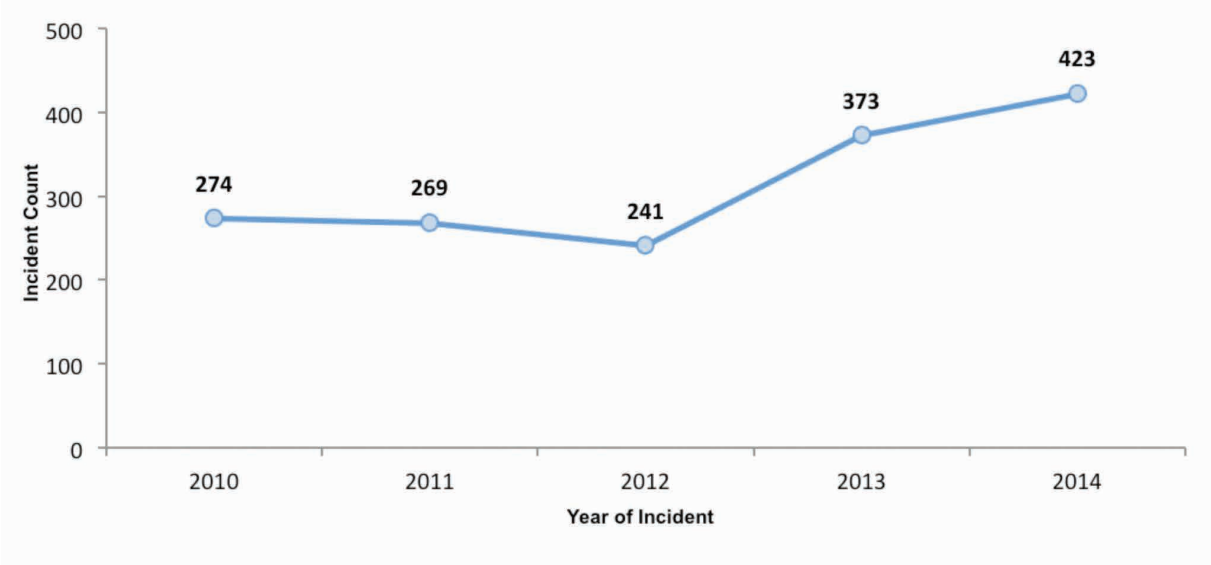


**Figure 36: Clinical incidents identified in Gastroenterology nationally, 2010-2014 inclusive**

The ten most common clinical incidents in Gastroenterology reported to the SCA (categorised using the *"please specify"* field), between 2010-2014 underwent a review (Table 31). Second to the subgroup *"other"* which was most common (n=365, 23.1%), were incidents pertaining to delay or failure to treat leading to an adverse outcome (n=133, 8.4%). Incidents related to *"records"* were prominent including incomplete records, missing or misplaced clinical records and wrong medical records applied to the patient, which when combined accounted for 23.0% (n=235) of the ten most common clinical incidents in Gastroenterology during this five year period. Additionally, *"incidents related to medication"* were relatively common including incorrect dosage, missed medication and incorrect medication which accounted for 16.6 % (n=169) of the ten most common clinical incidents identified in Gastroenterology nationally, during this five year period.

| Ten Most Common Clinical Incidents in Gastroenterology, 2010-2014 inclusive | Incident number (n) | Percentage (%) |
|---|---|---|
| Other | 365 | 23.1% |
| Delay / Failure to Treat - Adverse Outcome | 133 | 8.4% |
| Incomplete Records | 120 | 7.6% |
| Failure/Faulty Medical Device/Equipment | 82 | 5.2% |
| Clinical Records Missing / Misplaced | 73 | 4.6% |
| Incorrect Dosage | 66 | 4.2% |
| Missed Medication | 64 | 4.1% |
| Wrong Medical Records Applied to Patient | 42 | 2.7% |
| Incorrect Medication | 39 | 2.5% |
| Self-discharge / Discharge Against Advice | 37 | 2.3% |
| Ten Most Common Incidents | 1,021 | 64.6% |
| **Overall Total** | **1,580** | **100.0%** |

**Table 31: Ten most common clinical incidents identified in Gastroenterology nationally, categorised by the *please specify* field, 2010-2014 inclusive**

The most common clinical incidents identified in Gastroenterology nationally, excluding the subgroup *"other"*, were tracked over this five year period, to help identify trends (using the *"please specify"* field in NIMS) (Figure 37). Incidents related to delay or failure to treat leading to an adverse outcome have increased significantly (more than 15 fold) and incidents related to missing or misplaced clinical records more than doubled. No incidents related to incomplete records were identified in 2012. A spike occurred in 2013 (n=90) which subsequently reduced in 2014 to less than one third of the figure in 2013 (n=27). This spike pertained to one hospital. Incidents related to both incorrect dosage and failure or faulty medical device or equipment have reduced over this five year period.

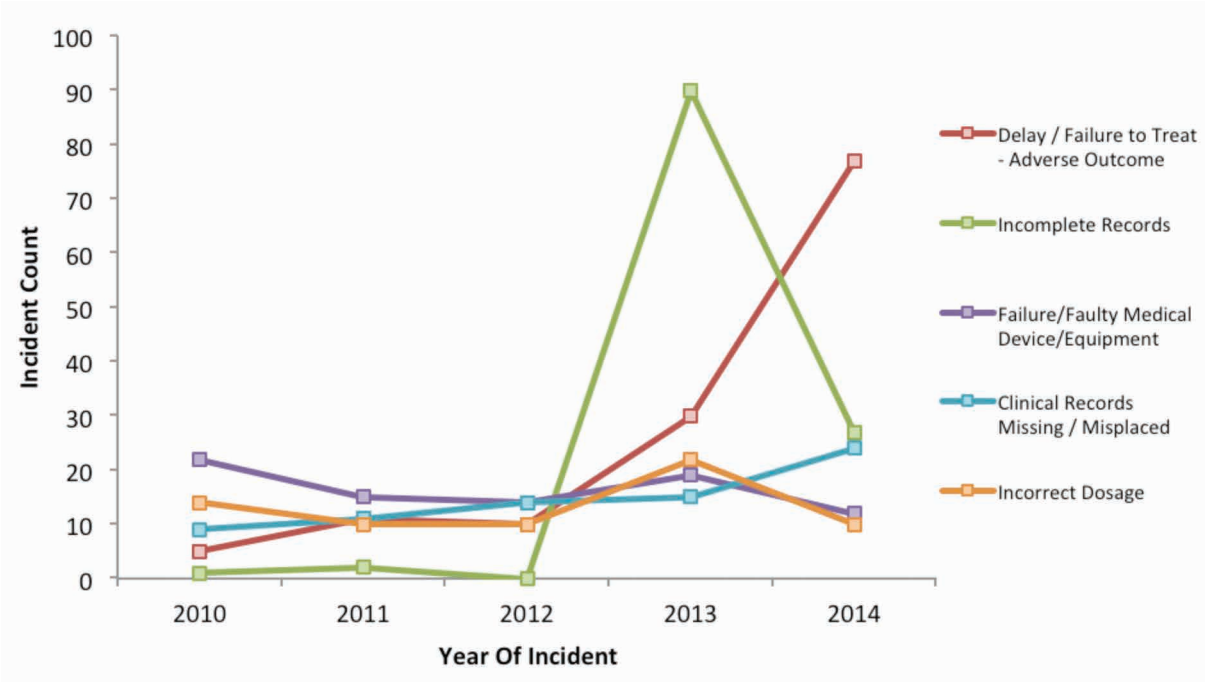


**Figure 37: Most common clinical incidents in Gastroenterology nationally, tracked, categorised by the *please specify* field, 2010-2014 inclusive, excluding *"other"***

## 6.6.2 Clinical claims created in Gastroenterology nationally, 2010-2014 inclusive

Overall, the number of clinical claims created in Gastroenterology remains relatively low (<6 annually) despite this being a speciality with multiple procedures (Figure 38).

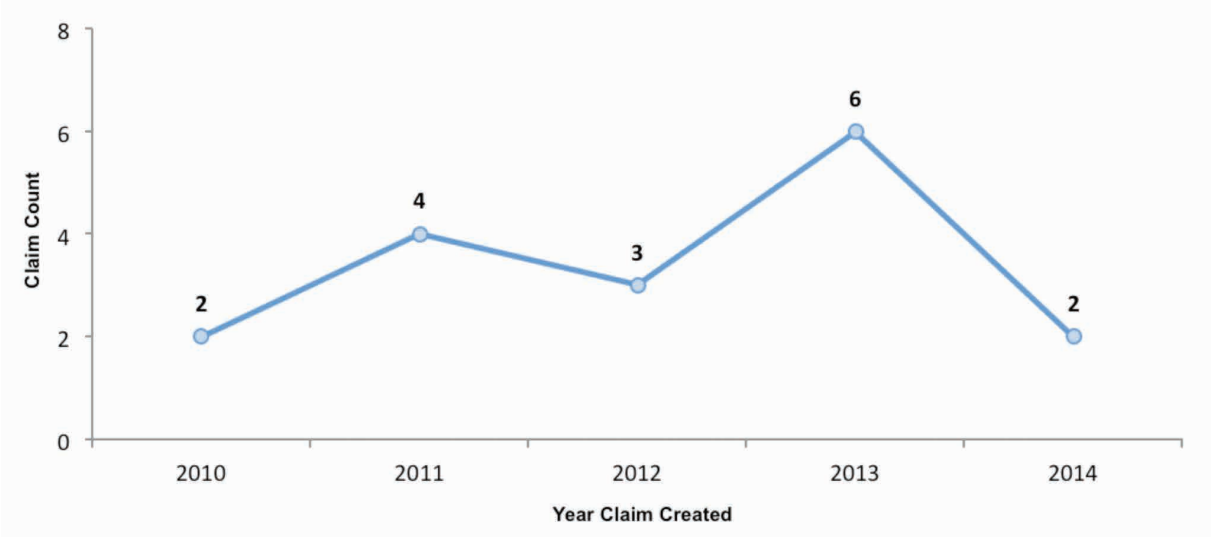


**Figure 38: Clinical claims created in Gastroenterology nationally, 2010-2014 inclusive**

Clinical claims created in Gastroenterology 2010-2014 inclusive were analysed using the p*lease specify* field in the NIMS. The subgroup *"other"* was most common (n=9, 52.9%), (Table 32).

Further detailed, clinical analysis identified that the subgroup *"other"* included alleged lost biopsy samples, alleged complications during or following a procedure including organ puncture and alleged dental damage. Clinical claims pertaining to *"delays",* including delays in treatment, leading to an adverse outcome and delays in diagnosis were documented. Clinical claims related to a procedure/ operation (n=2) and hospital-related death reported to the Coroner (n=1) were documented, but numbers were low.

| Clinical Claims created in Gastroenterology, 2010-2014 inclusive | Total Claims (n) | Percentage (%) |
|---|---|---|
| Other | 9 | 52.9% |
| Unexpected Complications During Operation / Procedure | 2 | 11.8% |
| Lost / Missing Test Results or Sample | 1 | 5.9% |
| Intubation complications including aspiration / Dental Damage | 1 | 5.9% |
| Incorrect result applied to patient | 1 | 5.9% |
| Hospital-related Death Rep. To Coroner | 1 | 5.9% |
| Delay / Failure to Treat - Adverse Outcome | 1 | 5.9% |
| Delayed Diagnosis | 1 | 5.9% |
| Total | 17 | 100.0% |

**Table 32: Clinical claims created in Gastroenterology nationally, 2010-2014 inclusive**

### 6.6.3 Cost of clinical claims finalised in Gastroenterology nationally, 2010-2014 inclusive

Due to the relatively small cost and number of clinical claims, the total cost for the five year period was reviewed. The total cost of clinical claims finalised in Gastroenterology, nationally, 2010-2014 inclusive, was €3,373,553. The average cost per clinical claim, inclusive of compensation and all costs (legal costs to the plaintiff, legal costs to the SCA, expert costs etc.) was €240,968 (Table 33).

| Cost of Clinical Claims Finalised in Gastroenterology nationally, 2010-2014 inclusive | Total |
|---|---|
| Total cost of claims | €3,373,553 |
| Total number of clinical claims | 14 |
| Average cost per claim finalised | €240,968 |

**Table 33: Cost of clinical claims finalised in Gastroenterology nationally, 2010-2014 inclusive**

### 6.6.4 International comparison

Malpractice claims within Gastroenterology were studied in the USA using the Physician Insurers' Association of America (PIAA) data over a 20 year period.[35] This identified that 66% of physicians involved in claims had previous claims experience. The most common reasons for claims were *errors in diagnosis* (28%) and *improper performance of a procedure* (25%). Seventy two percent of reported closed claims were settled out of court. Of 12,367 total claims in 2005 only 233 (1.8%) were within

Gastroenterology. The authors identified that Gastroenterology ranked below other procedurally-based sub-specialities in the number of claims per physician. The authors concluded that physicians with claims against them are likely to have further claims against them and should consider evaluating their practices.[35]

In a more recent USA study of malpractice risk by physician speciality (233,738 physician years)[26], Gastroenterology physicians ranked 6th amongst physicians in respect of facing a malpractice claim, annually, with neurosurgeons in first place, followed by cardiothoracic surgeons in second. However, Gastroenterology physicians ranked lower than all physicians for claims with a payment made to a plaintiff. Therefore the majority of claims created in Gastroenterology did not result in payment.[26]

In the NHS Litigation Authority annual report 2014/2015, Gastroenterology accounted for 2% of the clinical negligence claims received in 2014/2015 by the NHS in England.[7] The value of the claims created in Gastroenterology did not rank among the top 10 specialities and because this amount was relatively small, the NHS Litigation Authority aggregated it with other specialities from a value viewpoint.

## 6.7 Respiratory Medicine

### 6.7.1 Clinical incidents in Respiratory Medicine nationally, 2010-2014 inclusive

Data pertaining to Respiratory Medicine including clinical incidents, claims and costs are a subset of data pertaining to Medicine. In this speciality, the total number of clinical incidents decreased by 56, between 2010 and 2014, which represents a decrease of 22.3%. This may be related to improved clinical care in Respiratory Medicine, changes in patterns of clinical incident reporting or a combination of both (Figure 39).

Regarding severity rating of clinical incidents in Respiratory, of the total number (n=1,004) of clinical incidents over this five year period, 17 (1.7%) were rated extreme; 1 (0.1%) rated major; 140 (13.9%) rated moderate; 271 (27.0%) rated minor and 175 (17.4%) rated negligible. The remaining 400 (39.8%) clinical incidents did not receive a severity rating by the healthcare services.

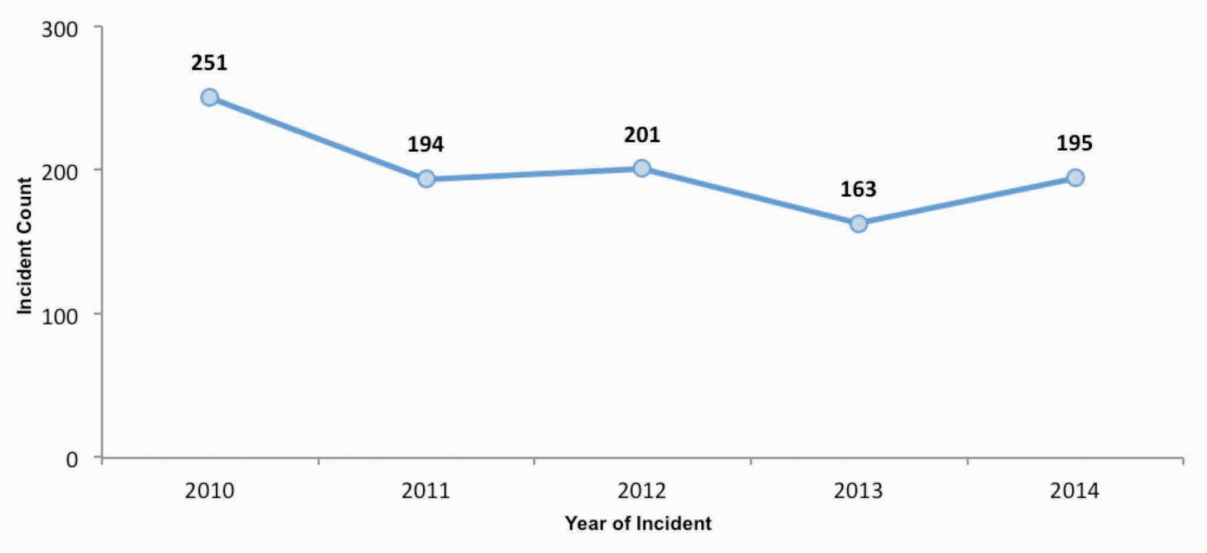


**Figure 39: Clinical incidents identified in Respiratory Medicine nationally, 2010-2014 inclusive**

Clinical incidents in Respiratory Medicine, 2010-2014 inclusive, were identified using the *"please specify"* field on the NIMS and studied (Table 34). After the subgroup *"other"*, clinical incidents related to serious soft tissue damage were most common (n=64, 6.4%), followed by failure or faulty medical device or equipment (n=43, 4.3%). Medication incidents were common including incorrect dosage, missed medication and incorrect medication, which when combined, accounted for 14.3% (n=94) of the ten most common clinical incidents identified in Respiratory Medicine during this time period.

| Ten Most Common Clinical Incidents in Respiratory Medicine, 2010-2014 inclusive | Incident number (n) | Percentage (%) |
|---|---|---|
| Other | 326 | 32.5% |
| Serious Soft Tissue Damage | 64 | 6.4% |
| Failure/Faulty Medical Device/Equipment | 43 | 4.3% |
| Incorrect Dosage | 40 | 4.0% |
| Cannula Injury | 34 | 3.4% |
| Missed Medication | 31 | 3.1% |
| Hospital-related Death Rep. To Coroner | 31 | 3.1% |
| Self-discharge / Discharge Against Advice | 26 | 2.6% |
| Incorrect Medication | 23 | 2.3% |
| Incorrect Frequency | 20 | 2.0% |
| Delay / Failure to Treat - Adverse Outcome | 20 | 2.0% |
| **Ten Most Common Incidents** | **658** | **65.5%** |
| **Overall Total** | **1,004** | **100.0%** |

**Table 34: Ten most common clinical incidents identified in Respiratory Medicine nationally, categorised by the *please specify* field, 2010-2014 inclusive**

[Note: More than ten incidents are listed because some categories contain equal numbers]

Clinical incidents in Respiratory Medicine, excluding the subgroup *"other"*, were tracked over this five year period using the *please specify* field (Figure 40). There was a reduction in incorrect dosage, missed medication, hospital-related deaths reported to the Coroner and failure or faulty medical device or equipment. In contrast, incidents related to cannula injury and serious soft tissue injury have remained essentially stable though a dip in the latter was documented in 2011 (Figure 40). Overall numbers are small.

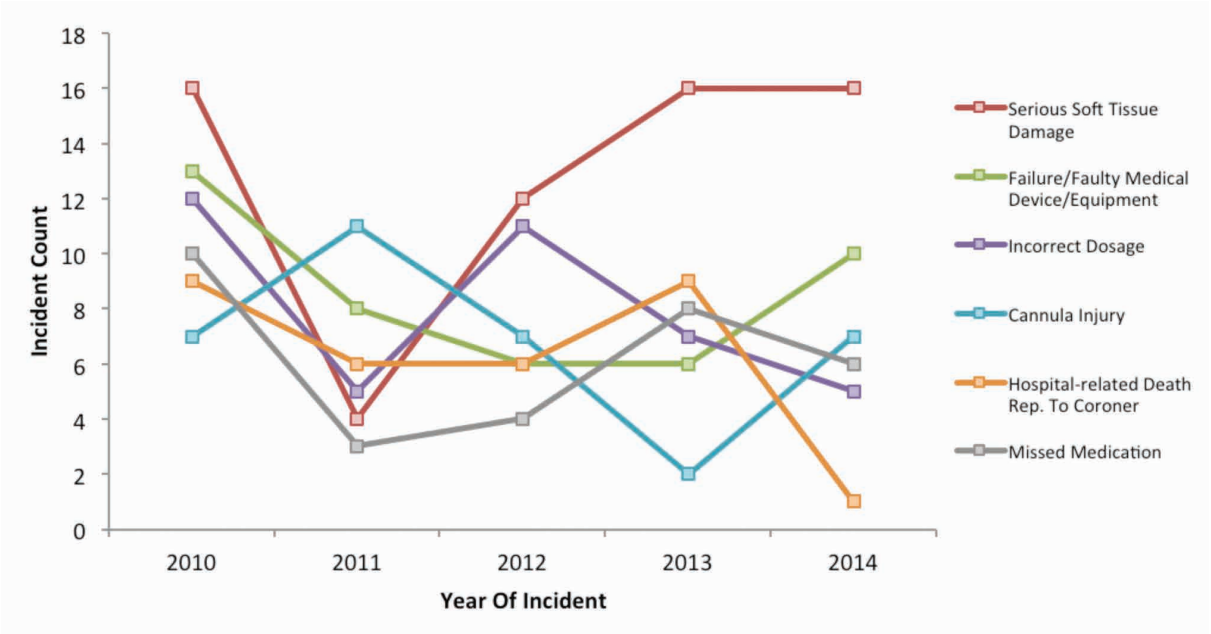


**Figure 40: Most common clinical incidents in Respiratory Medicine nationally, tracked, categorised by the *please specify* field, 2010-2014 inclusive, excluding *"other"***

## 6.7.2 Clinical claims created in Respiratory Medicine nationally, 2010-2014 inclusive

Overall, the number of clinical claims created in Respiratory Medicine remains small with a five year high in 2010 of five, reducing in 2014 to one (Figure 41).

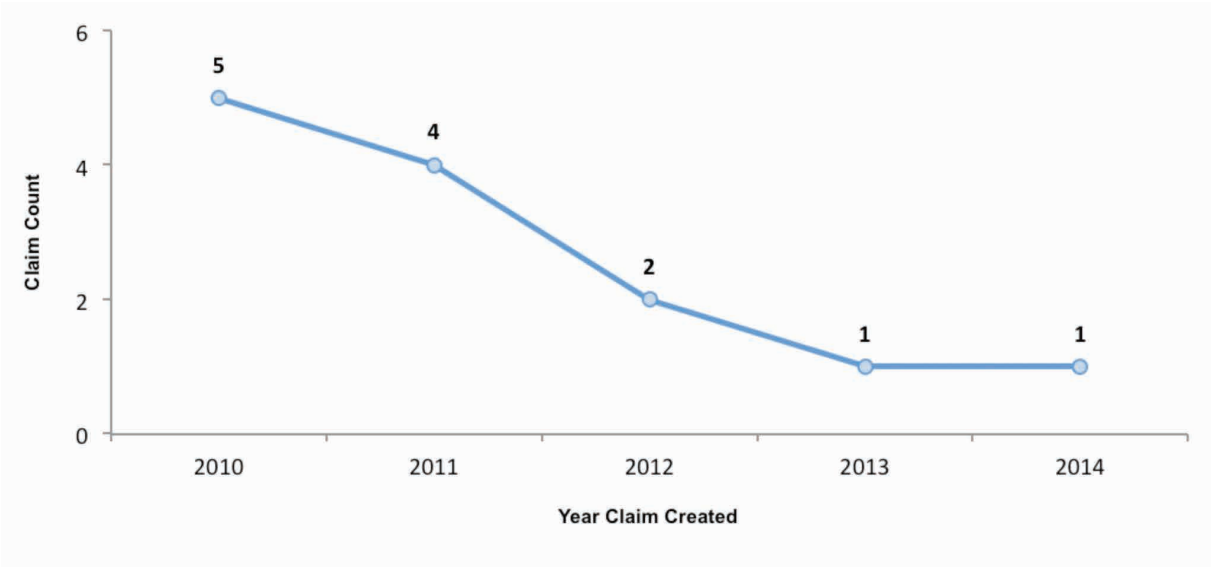


**Figure 41: Clinical claims created in Respiratory Medicine nationally, 2010-2014 inclusive**

Review of the most common clinical claims created in Respiratory Medicine, nationally, 2010-2014, inclusive, was performed using the *"please specify"* field (Table 35). It revealed that the subgroup *"other"* was the most common (n=6, 46.2%). Further detailed, clinical analysis of this subgroup identified that it included alleged complications related to Respiratory procedures and alleged extravasation of dye. The second most common claim created was failure to treat leading to an adverse outcome (n=3, 23.1%), followed by claims related to *"diagnosis"*, including failure to diagnose and delayed diagnosis. Hospital-related death reported to the coroner accounted for one clinical claim.

| Clinical Claims Created in Respiratory Medicine, 2010-2014 inclusive | Total Claims (n) | Percentage (%) |
|---|---|---|
| Other | 6 | 46.2% |
| Delay / Failure to Treat - Adverse Outcome | 3 | 23.1% |
| IV Infiltrates Causing Local Inflammation | 1 | 7.7% |
| Hospital-related Death Rep. To Coroner | 1 | 7.7% |
| Failure to Diagnose | 1 | 7.7% |
| Delayed Diagnosis | 1 | 7.7% |
| Total | 13 | 100.0% |

**Table 35: Clinical claims created in Respiratory Medicine nationally, categorised by the *please specify* field, 2010-2014 inclusive**

### 6.7.3 Cost of clinical claims finalised in Respiratory Medicine nationally, 2010-2014 inclusive

Due to the relatively small numbers and cost of clinical claims, the total cost for the five year period was reviewed. The total cost of clinical claims finalised in Respiratory Medicine, 2010-2014 inclusive, was €5,283,822. The median cost per claim* including compensation and all costs (legal cost for the plaintiff, legal costs for the SCA, expert costs etc.) was €36,671 (Table 36).

| Cost of clinical claims finalised in Respiratory Medicine nationally, 2010-2014 inclusive | Total |
|---|---|
| Total cost of claims | €5,283,822 |
| Total number of clinical claims | 6 |
| Median cost per claim finalised | €36,671 |

**Table 36: Cost of clinical claims finalised in Respiratory Medicine nationally, 2010-2014 inclusive**

* The median cost per claim was used here instead of the average cost per claim because there was significant variation with one outlier.

### 6.7.4 International comparison

The paucity of data in the international literature pertaining to clinical claims in Respiratory Medicine reflects the Irish experience, as outlined above. A study by Luce[36] published in 2008 identified that claims against Respiratory physicians, most commonly alleged injuries caused by errors in diagnosis, improper performance of procedures, failure to supervise or monitor care, medication errors and failure to recognise complications of treatment.

A large sentinel USA study (involving 40,916 physicians and 233,738 doctor years) ranked Respiratory Medicine ninth based on the number of physicians facing a malpractice claim annually, with neurosurgery in first place.[26]

## 6.8 Neurology

### 6.8.1 Clinical incidents in Neurology nationally, 2010-2014 inclusive

Data pertaining to Neurology, including incidents, claims and costs, is a subset of data pertaining to Medicine. There has been a significant increase in the number (n=40) of clinical incidents identified in Neurology between 2010 and 2014, representing a 36.0% increase (Figure 42). An increase in clinical incident reporting is considered to reflect an improved patient safety culture. The increase identified may be related to changes in patterns of clinical incident reporting, changes in clinical care in Neurology or a combination of both.

Regarding severity rating of clinical incidents in Neurology, of the total number (n=549) of clinical incidents over this five year period, 12 (2.2%) were rated extreme; 1 (0.2%) rated major; 36 (6.6%) rated moderate; 61 (11.1%) rated minor and 78 (14.2%) rated negligible. The remaining 361 (65.8%) clinical incidents did not receive a severity rating by the healthcare services.

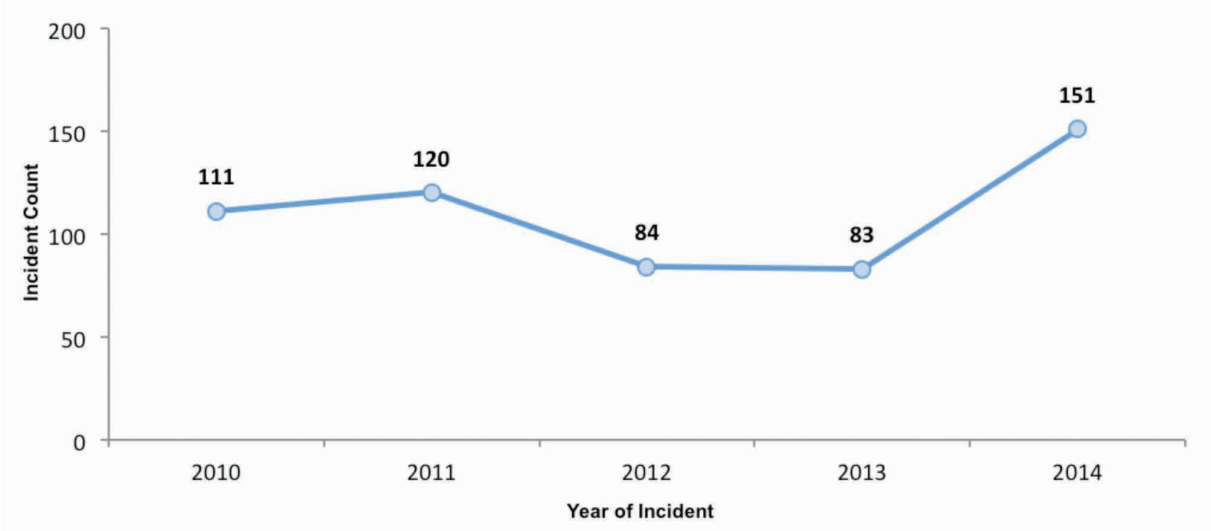


**Figure 42: Clinical incidents identified in Neurology nationally, 2010-2014 inclusive**

The ten most common clinical incidents identified in Neurology 2010-2014, inclusive, were reviewed using the *"please specify"* field (Table 37). It was identified that the subgroup "other" (n=142, 25.9%) was most common followed by clinical incidents related to failure or faulty medical device or equipment (n=36, 6.6%). *"Medication incidents"* including incorrect dosage, missed medication and incorrect medication were prominent, and when combined, accounted for 21.2% (n=79) of the 10 most common clinical incidents in Neurology. Incidents related to *"records"* were relatively common, including missing or misplaced clinical records and wrong medical records applied to a patient: when combined, they accounted for 11.5% (n=43) of the 10 most common clinical incidents in Neurology.

Twelve (2.2%) incidents pertaining to hospital-related deaths were reported to the Coroner during this time period. It is noteworthy that Neurology, Respiratory Medicine, and Infectious Diseases are three specialities where death reported to the coroner was listed in the ten most common clinical incidents while hospital death reported to the Coroner appeared as one of the ten most common clinical claims in Emergency Medicine, Cardiology, Gastroenterology and Respiratory Medicine. Specialists in these areas should be cognisant that while this is a relatively small number in their patient cohort, it is relevant and may involve, on occasion, attendances by practitioners before the Coroner's court.

| Ten Most Common Clinical Incidents in Neurology, 2010-2014 inclusive | Incident number (n) | Percentage (%) |
|---|---|---|
| Other | 142 | 25.9% |
| Failure/Faulty Medical Device/Equipment | 36 | 6.6% |
| Incorrect Dosage | 35 | 6.4% |
| Clinical Records Missing / Misplaced | 31 | 5.6% |
| Delay / Failure to Treat - Adverse Outcome | 30 | 5.5% |
| Missed Medication | 29 | 5.3% |
| Serious Soft Tissue Damage | 17 | 3.1% |
| Incorrect Medication | 15 | 2.7% |
| Incorrect Rate | 14 | 2.6% |
| Wrong Medical Records Applied to Patient | 12 | 2.2% |
| Hospital-related Death Rep. To Coroner | 12 | 2.2% |
| **Ten Most Common Incidents** | **373** | **67.9%** |
| **Overall Total** | **549** | **100.0%** |

**Table 37: Ten most common clinical incidents identified in Neurology nationally, categorised by the *please specify* field, 2010-2014 inclusive**

(Note: more than ten clinical incidents are listed because some had equal numbers)

The most common clinical incidents in Neurology, excluding the subgroup *"other"*, were tracked over this five year period, to help identify trends (using the *please specify* field), (Figure 43). Overall, numbers are small. An increase was identified in clinical incidents related to missing or misplaced clinical records (six fold increase), delay or failure to treat leading to an adverse outcome (threefold increase), missed medication and failure or faulty medical device or equipment, while a decrease was documented in clinical incidents pertaining to incorrect dosage. Numbers overall are small.

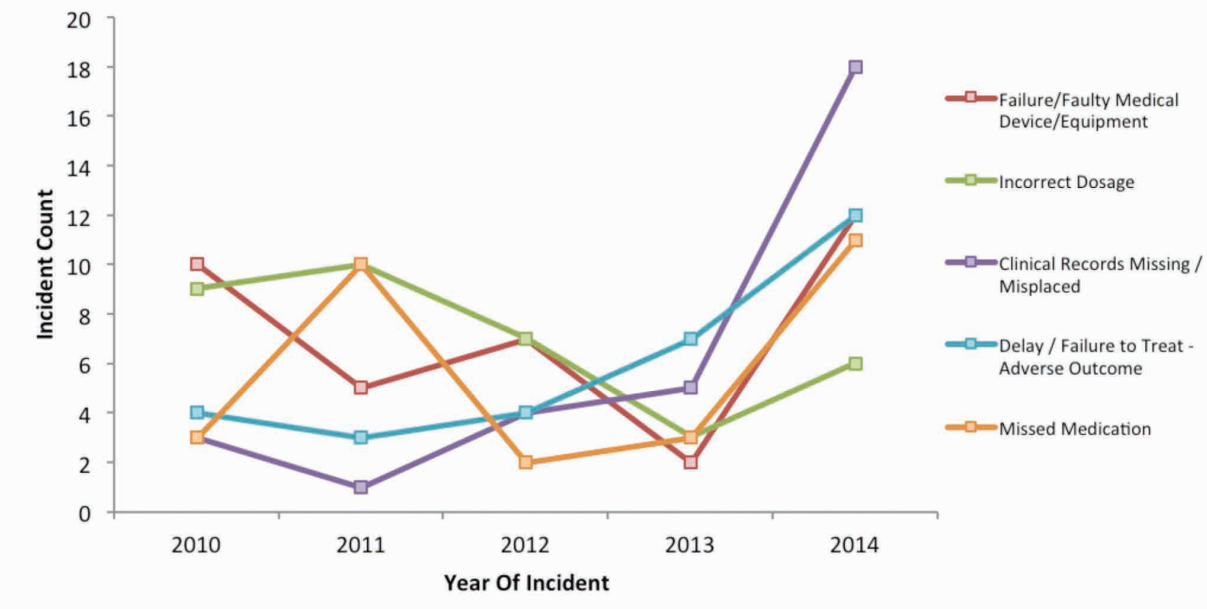


**Figure 43: Most common clinical incidents in Neurology nationally, tracked, categorised by the *please specify* field, 2010-2014 inclusive, excluding *"other"***

## 6.8.2 Clinical claims created in Neurology nationally, 2010-2014 inclusive

Overall, the number of clinical claims created in Neurology has remained low 2010-2014, inclusive (Figure 44). While there were no clinical claims created in Neurology in 2010, this number peaked at nine in 2012 and dropped to six in 2014.

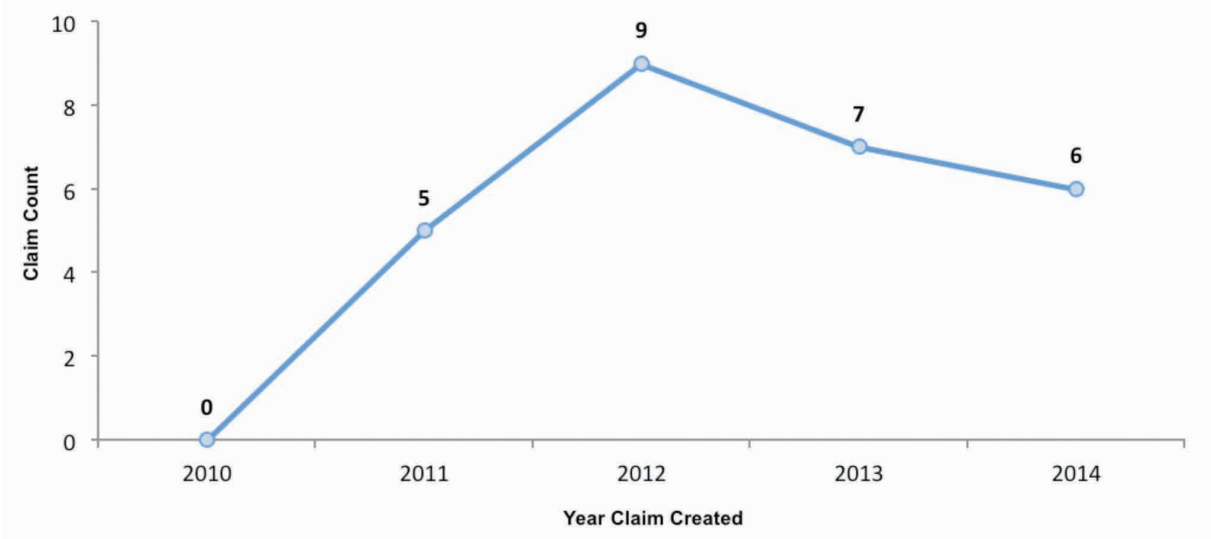


**Figure 44: Clinical claims created in Neurology nationally, 2010-2014 inclusive**

Clinical claims created in Neurology nationally, 2010-2014 inclusive were reviewed and included the subgroup *"other"* (n=7, 25.9%) (Table 38). Detailed, clinical analysis of this subgroup identified that it included claims pertaining to alleged misdiagnosis of subdural haemorrhage, alleged nerve and muscle damage related to a procedure, alleged pressure ulcer development leading to infection and alleged seizure. Clinical claims related to *"diagnosis"* were prominent, including failure to diagnose, delayed diagnosis and misdiagnosis which, when combined, accounted for 44.4% (n=12) of all clinical claims created during this five year period.

| Clinical Claims Created in Neurology, 2010-2014 inclusive | Total Claims (n) | Percentage (%) |
|---|---|---|
| Other | 7 | 25.9% |
| Failure to Diagnose | 6 | 22.2% |
| Delayed Diagnosis | 5 | 18.5% |
| Incorrect result applied to patient | 2 | 7.4% |
| Delay / Failure to Treat - Adverse Outcome | 2 | 7.4% |
| Unexpected Deterioration | 1 | 3.7% |
| Serious Soft Tissue Damage | 1 | 3.7% |
| Misdiagnosis with MND (Motor Neurone Disease) | 1 | 3.7% |
| Lumbar puncture procedure | 1 | 3.7% |
| Adverse Drug Interaction | 1 | 3.7% |
| Total | 27 | 100.0% |

**Table 38: Clinical claims created in Neurology nationally, categorised by the *please specify* field, 2010-2014 inclusive**

### 6.8.3 Cost of clinical claims finalised in Neurology nationally, 2010-2014 inclusive

Due to the relatively small number and cost of clinical claims, the total cost for the five year period was reviewed. The total cost of clinical claims finalised in Neurology nationally, 2010-2014 inclusive, was €4,616,898. The average cost per claim finalised in Neurology, including all costs (legal costs to the plaintiff, legal costs to the SCA, expert costs etc.) was €355,146 (Table 39).

| Cost of clinical claims finalised in Neurology nationally, 2010-2014 inclusive | Total |
|---|---|
| Total cost of claims | €4,616,898 |
| Total number of clinical claims | 13 |
| Average cost per claim finalised | €355,146 |

**Table 39: Cost of clinical claims finalised in Neurology nationally, 2010-2014 inclusive**

### 6.8.4 International comparison

In the NHS LA annual report 2014/15, Neurology ranked outside the ten most common specialities for the number of clinical negligence claims received. Overall, Neurology had a small volume and value of claims in the NHS in England.[7]

Johnston, a qualified doctor and lawyer in the USA, published an overview of neurological malpractice trends in 2010. He identified that recurring clinical claims involved headache, stroke, and epilepsy.[37]

The first systematic study of negligence claims for the treatment of neurological disorders in the UK (n=559) was published in 2007 and reviewed claims from the NHS LA database over a 10 year period.[38] While the speciality most frequently cited was Neurosurgery (n=241), this was followed by Neurology (n=172). The most common pathologies were intervertebral disc disease (27%); central nervous system tumours (21%); central nervous system infection (11%); and subarachnoid haemorrhage (9%). The most frequent misadventure was diagnostic error (44%). The authors identified that in 47% of cases, major permanent injury (e.g. hemiplegia or blindness) resulted from misadventure, with patient death occurring in 17% of cases. The total cost for all closed Neurological negligence claims accounted for 2% of total expenditure on claims for this time period (1995-2005). The authors concluded that the prominence of diagnostic error highlighted the need for early assessment by neurologists and prompt use of neuroimaging during the acute phase.

A more recent, large, Harvard analysis of malpractice risk by physician speciality in the USA (233,738 physician-years of coverage), identified that neurologists ranked thirteenth for physicians facing a malpractice claim annually.[26]

## 6.9 Infectious Diseases

### 6.9.1 Clinical Incidents in Infectious Diseases nationally, 2010-2014 inclusive

Data pertaining to Infectious Diseases, including clinical incidents, claims and costs, is a subset of data pertaining to Medicine. Overall there has been a significant decrease in Infectious Diseases related clinical incidents reported to the SCA by healthcare services between 2010-2014 inclusive. This decrease of 42, represented a 49.4% drop and may be related to improved clinical care in Infectious Diseases, changes in the pattern of clinical incident reporting or a combination of both (Figure 45).

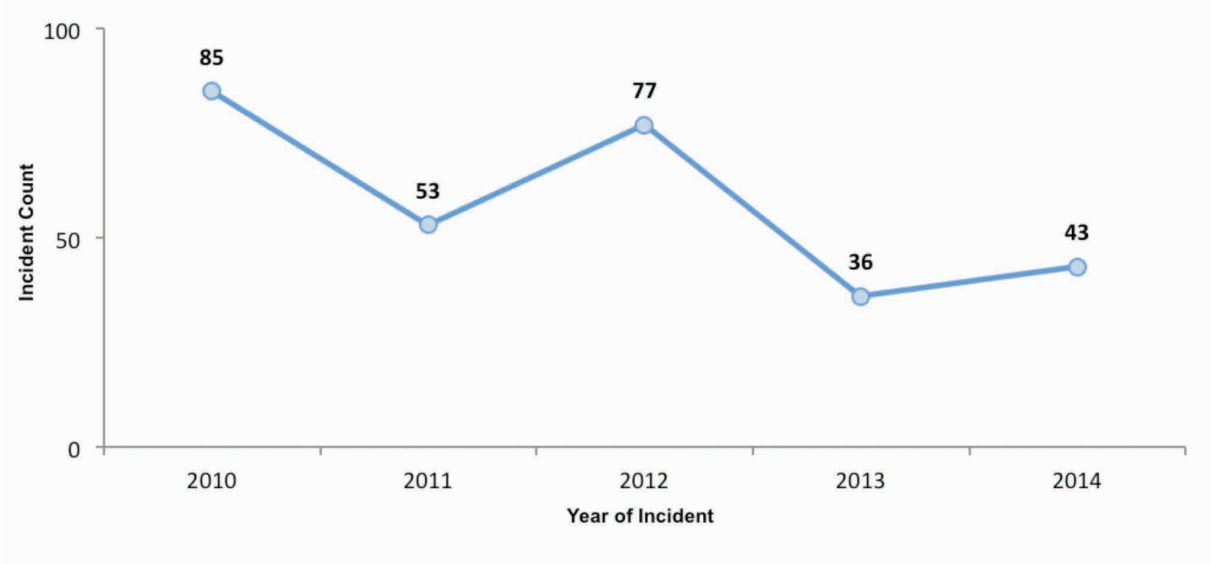


**Figure 45: Clinical incidents identified in Infectious Diseases nationally, 2010-2014 inclusive**

The ten most common clinical incidents related to Infectious Diseases, 2010-2014 inclusive were analysed using the *"please specify"* field (Table 40). The most common was the subgroup *"other"* (n=86, 29.3%), followed by serious soft tissue damage (n=39, 13.3%). Medication incidents were relatively common and included incorrect dosage, missed medication, and incorrect medication, which, when combined, accounted for 17.9% (n=40) of the ten most common incidents related to Infectious Diseases.

Hospital-related deaths reported to the Coroner (n=9) accounted for 4.0% of the ten most common clinical incidents identified 2010-2014 inclusive, related to Infectious Diseases. Though relatively small in number, this important patient population may potentially lead to attendances by practitioners before the Coroner's court for physicians.

| Ten Most Common Clinical Incidents in Infectious Diseases, 2010-2014 inclusive | Incident number (n) | Percentage (%) |
|---|---|---|
| Other | 86 | 29.3% |
| Serious Soft Tissue Damage | 39 | 13.3% |
| Incorrect Dosage | 18 | 6.1% |
| Delay / Failure to Treat - Adverse Outcome | 18 | 6.1% |
| Missed Medication | 14 | 4.8% |
| Hospital-related Death Rep. To Coroner | 9 | 3.1% |
| Incorrect Medication | 8 | 2.7% |
| Incorrect result applied to patient | 7 | 2.4% |
| Inappropriate Admission/transfer | 6 | 2.0% |
| Failure/Faulty Medical Device/Equipment | 6 | 2.0% |
| Delayed Diagnosis | 6 | 2.0% |
| Cannula Injury | 6 | 2.0% |
| Ten Most Common Incidents | 223 | 75.9% |
| **Overall Total** | **294** | **100.0%** |

**Table 40: Ten most common clinical incidents identified in the specialty of Infectious Diseases, categorised by the *please specify* field, 2010-2014 inclusive**

(Note: In excess of ten incidents are listed because some have equal numbers)

These clinical incidents, excluding the subgroup *"other"*, were tracked over five years using the *"please specify"* field, to identify trends (Figure 46). Numbers are low in all groups. There was a reduction in incidents related to incorrect dose, serious soft tissue damage and delay or failure to treat leading to an adverse event. A spike in incidents related to missed medication was documented in 2012 (n=10 in 2012 from n=1 in 2011) but has since essentially resolved, while incidents pertaining to hospital-related deaths reported to the Coroner were identified in four out of the five years reviewed.

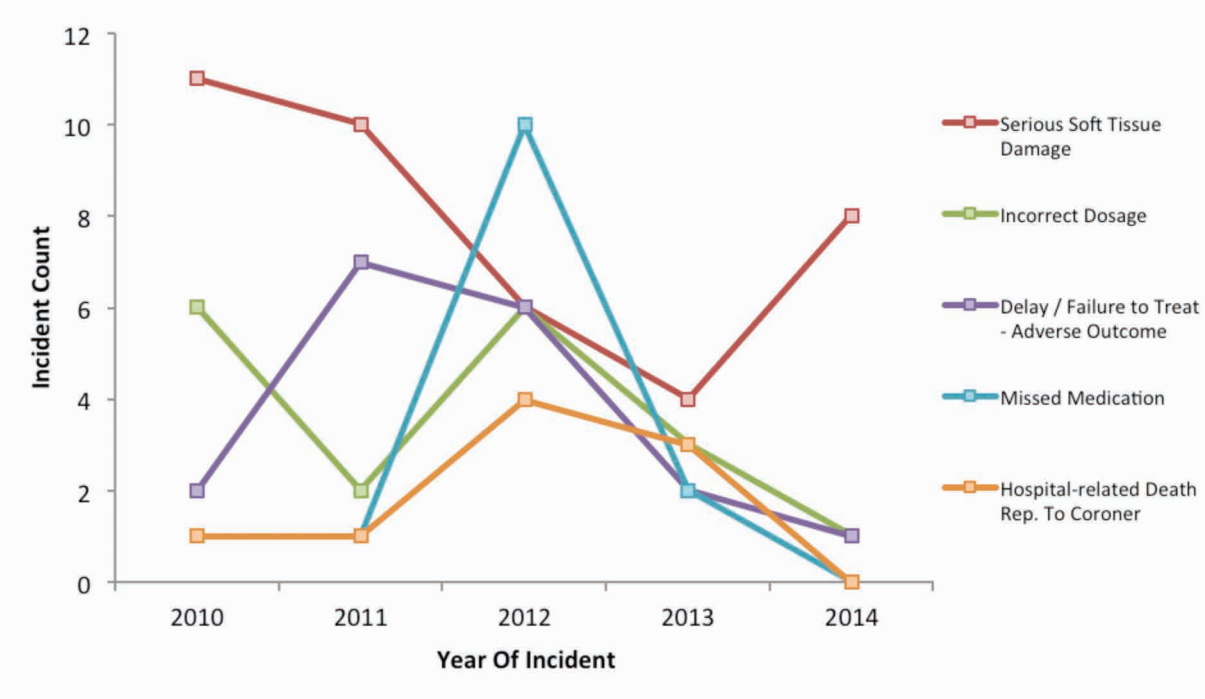


**Figure 46: Most common clinical Incidents in Infectious Diseases nationally, categorised by the *please specify* field, tracked, 2010-2014 inclusive, excluding *"other"***

### 6.9.2 Clinical claims created in Infectious Diseases nationally, 2010-2014 inclusive

The number of clinical claims in the speciality of Infectious Diseases has remained low over this five year period, increasing from one in 2010 and 2011 to two in 2013 and in 2014. Detailed, clinical review of the subgroup *"other"* identified that it included an alleged allergic reaction to topical treatment resulting in an alleged burn being sustained, an alleged Measles, Mumps and Rubella vaccine issue and an alleged failure to diagnose an infectious disease. Other clinical claims identified included alleged incorrect result of an infectious disease given to a patient due to alleged mislabelling of a blood sample and alleged delay or failure to treat (Table 41).

| Clinical Claims Created in Infectious Diseases nationally, 2010-2014 inclusive | Total Claims (n) | Percentage (%) |
|---|---|---|
| Other | 3 | 50.0% |
| Incorrect result applied to patient | 2 | 33.3% |
| Delay / Failure to Treat - Adverse Outcome | 1 | 16.7% |
| Total | 6 | 100.0% |

**Table 41: Clinical claims created in Infectious Diseases nationally, categorised by the *please specify* field, 2010-2014 inclusive**

### 6.9.3 Cost of clinical claims in Infectious Diseases nationally, 2010-2014 inclusive

Due to the relatively small number and cost of clinical claims in Infectious Diseases, the total cost for the five year period was reviewed. The total cost of clinical claims finalised in the sub-speciality of Infectious Diseases, 2010-2014 inclusive, was €2,076,592. The average cost per clinical claim including compensation and all costs (legal fees for the plaintiff, legal fees for the SCA, expert costs etc.) in Infectious Diseases nationally during this time period was €207,659 (Table 42).

| Cost of clinical claims finalised in Infectious Diseases nationally, 2010-2014 inclusive | Total |
|---|---|
| Total cost of claims | €2,076,592 |
| Total number of clinical claims | 10 |
| Average cost per claim finalised | €207,659 |

**Table 42: Cost of clinical claims finalised in Infectious Diseases nationally, 2010-2014 inclusive**

### 6.9.4 International comparison

When 233,738 physician years in USA were analysed in a large study for malpractice risk by physician speciality[26], the specialty of Infectious Diseases was not listed in the top 20. There is a paucity of data in the literature regarding studies of closed claims pertaining to the speciality of Infectious Diseases which is a relatively new speciality in Medicine in comparison to others e.g. Cardiology. Infectious Diseases is classified as a "low risk" speciality, by the Medical Protection Society, partly because it does not involve a specific procedure.

# 7.0 FINALISED CLINICAL CLAIMS

## 7.1 Background

Finalised clinical claims were analysed across different areas of Medicine in order to identify key causes of claims and contributing factors so that risk management suggestions to prevent occurrence and/or recurrence of clinical incidents may be provided. The period of time examined varied from one to ten years depending on the number of finalised claims involved. Finalised claims were analysed in Emergency Medicine, Paediatrics, Mental Health, Slips, Trips and Falls and retained foreign bodies in Gynaecology services. A finalised claim is a claim in which all matters associated with the claim have been agreed e.g. costs. Some associated payments and reimbursements may still be outstanding on finalised claims.

## 7.2 Emergency Medicine

### 7.2.1 An analysis of clinical claims finalised in a one year period in Emergency Medicine

#### Aim

To review all finalised clinical claims, nationally, pertaining to Emergency Medicine during 2014 and identify learning opportunities.

#### Methods

A retrospective one year review of all clinical claims finalised nationally in Emergency Medicine in 2014, pertaining to adults, was conducted by a clinical risk adviser. A report was generated using the NIMS and a search performed under the term 'Emergency Medicine'.

#### Results

Fifty five finalised claims were identified using the NIMS. Upon review, 23 (41.8%) were excluded: 10 were statute barred, 6 were withdrawn by the claimant, 3 pertained to Paediatric Emergency Medicine and 4 were did not specifically relate to this specialty and were re-classified on the NIMS. The remaining 32 underwent detailed, clinical analysis. Nineteen of these (59.4%) related to male patients. Two claims (6.3%) pertained to fatalities.

#### Fatal Claims

The two (6.3%) fatalities were male. One pertained to a 63 year old male who presented to the Emergency Department (ED) with urinary retention against a background of balanitis, diagnosed by the GP, for which Flucloxacillin had been prescribed. Examination in the ED revealed a tight phimosis. Relevant risk factors in his past medical history included hypertension, a quadruple coronary artery bypass and a previous cerebrovascular accident. Once the phimosis was opened, the patient passed urine and a decision was made to discharge him home. A single dose of intravenous amoxicillin and clavulanic acid (Augmentin) was administered prior to discharge and he developed an anaphylactic reaction. Treatment included intravenous steroids but not adrenaline. The patient deteriorated and subsequently sustained cardiac arrest. Despite appropriate treatment of the cardiac arrest, the patient died. He had no previous known drug allergies. Post mortem findings identified complete

occlusion at the origin of 1 coronary artery graft and 80% occlusion of the middle coronary artery bypass graft.

The second fatality related to a 46 year old male who presented to the ED with acute onset of severe abdominal pain and a known past medical history of peptic ulcer disease and chronic alcohol abuse. A diagnosis of acute gastritis was made. Treatment included the commencement of a proton pump inhibitor (PPI) and discharge to the GP, who was to arrange an oesophago-gastro duodenoscopy (OGD). Within 24 hours, the patient returned to the ED by ambulance, following a cardiac arrest at home. Despite resuscitation, the patient died. A post-mortem recorded cause of death as perforated duodenal ulcers.

## Non-Fatal Claims

Regarding the non-fatal claims (n=30), multiple specialities were involved, of which Orthopaedics (n=16) was the most common, followed by Surgery (n=5) and Cardiology (n=3), (Figure 47). One claim was identified in each of the following specialities: Infectious Diseases, Gastroenterology, Urology, Neurology, Gynaecology and Dentistry.

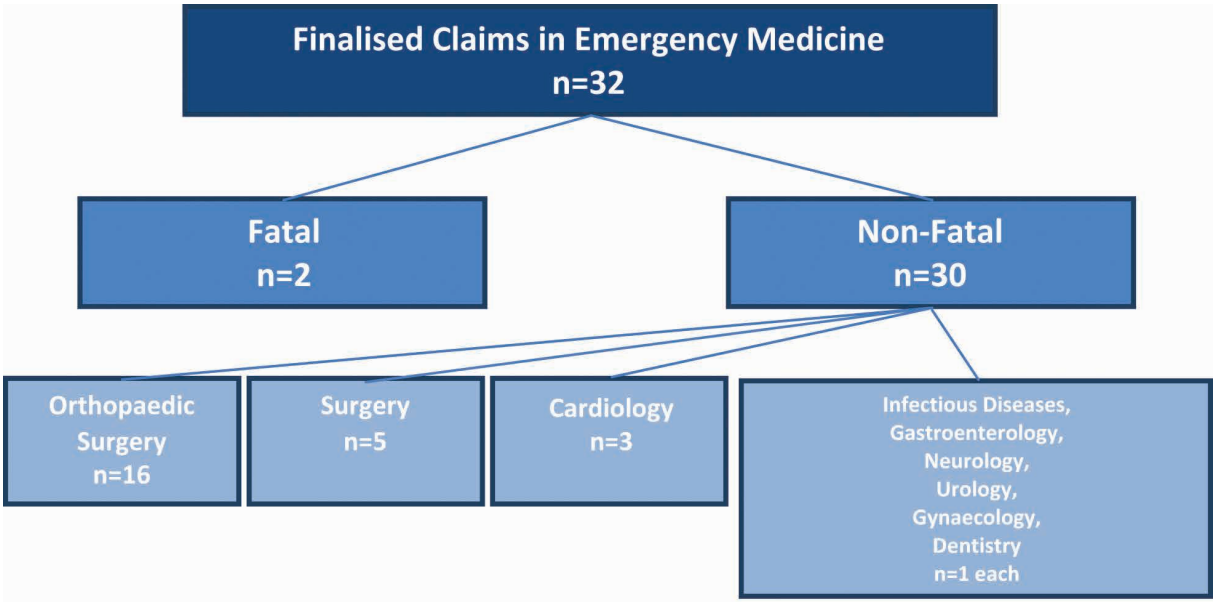


**Figure 47: Reviewed clinical claims finalised in Emergency Medicine in 2014**

## Orthopaedic Surgery

Regarding Orthopaedic Surgery (n=16), delayed diagnosis of a fracture (n=9), was the most common claim. This was followed by unexpected complication after treatment (n=3), which included infection (n=2) and nerve damage (n=1). The remaining Orthopaedic claims involved septic arthritis (n=1), cauda equina (n=1), treatment of a finger injury (n=1) and failure to x ray the correct limb (n=1). Some of these are discussed in more detail below.

One claim in Orthopaedic Surgery pertained to a 42 year old male who was referred by his GP to the ED with a diagnosis of possible septic arthritis. The patient had a history of hip pain, reduced range of movement and fever. A raised white cell count and neutrophil count was documented in the ED as being within the *'normal range'*. The patient was discharged with a diagnosis of muscular pain for which analgesia was prescribed. Due to the delay in diagnosis and treatment of septic arthritis, the patient subsequently required a total hip replacement, which expert opinion agreed was secondary to the aforementioned delay.

A delayed diagnosis of cauda equina resulted in permanent incontinence and long term back pain in a 28 year old female who presented to the ED with a history of trauma and dysuria. After medical review, a diagnosis of cystitis was made for which she was prescribed antibiotics and discharged. Urinalysis in the ED was normal. No neurological examination was performed. She subsequently presented to her GP on multiple occasions with on-going symptoms. MRI of the spine, 3 months later, identified cord compression and the patient proceeded to lumbar discectomy. The expert opinion stated that the patient's history and symptoms, on presentation to the ED, were suggestive of cauda equina syndrome and that the 48 hour *'window of opportunity'* was lost by discharging her, resulting in permanent symptoms.

Permanent loss of 10% of function of a 27 year old female's finger following a fall, resulted in a claim. The patient attended the ED following a fall and an injury to a finger on her right hand. Radiographs demonstrated a fracture dislocation. The fracture underwent manipulation and reduction. The patient was subsequently discharged with GP follow up. Two weeks later she attended her GP who referred her to the hand clinic where she was advised that surgery was required. Expert opinion was critical of the fact that no repeat radiograph was performed following the reduction of the fracture when she first presented to the ED. Expert opinion identified that the delay in diagnosis of suboptimal reduction post manipulation, resulted in on-going symptoms, the need for additional surgery and permanent, partial loss of function of the patient's finger on her dominant hand.

A delayed diagnosis and treatment of a grossly displaced fracture of the left distal femur shaft resulted in a claim by a 74 year old female who had her right lower limb and knee x-rayed instead of her left.

## Surgery

Regarding the five clinical claims pertaining to Surgery, three related to delayed diagnosis of appendicitis. One of these resulted in an emergency laparotomy for acute peritonitis secondary to a perforated and gangrenous appendix. The 29 year old female patient had presented two days earlier with abdominal pain, vomiting and diarrhoea and a diagnosis of gastritis had been made. Expert opinion criticised the lack of escalation to more senior staff and stated that a senior surgical team member would have managed the patient for appendicitis or appendix mass. The remaining two claims in Surgery pertained to complication following treatment.

## Cardiology

Clinical claims in Cardiology (n=3) pertained to a delayed diagnosis of a non-ST elevation myocardial infarction (non-STEMI) in a 49 year old female patient, a retro-peritoneal clot post angiogram in a 27 year old male and a suboptimal cardiopulmonary resuscitation where defibrillation was repeatedly impeded due to excessive chest hair in a 62 year old male. Regarding the non-STEMI, this involved inaccurate documentation of a troponin result which resulted in a six week delay in diagnosis of the patient's coronary artery stenosis. An angioplasty was subsequently required. The claim relating to suboptimal cardiopulmonary resuscitation involved a previously healthy male who collapsed at work with associated loss of consciousness. Elevated blood pressure was identified by the GP prior to referral to the ED, where the patient sustained a cardiac arrest. Multiple attempts at defibrillation were made before a shock was delivered successfully. Similar difficulties were encountered the following day in the ICU, using a different defibrillator, when the patient sustained another cardiac arrest. It was identified that the patient's chest hair was causing transthoracic impedance which prevented an effective shock being delivered. Hypoxic brain damage was sustained.

## Infectious Diseases

The single claim pertaining to the speciality of Infectious Diseases resulted from a high risk 39 year old female patient who presented with varicella infection to the ED, with known immunosuppression, secondary to a prior organ transplant. Delay in commencement of treatment for disseminated varicella zoster infection resulted in the patient sustaining acute renal failure and a cerebrovascular accident.

## Gastroenterology

The claim related to Gastroenterology pertained to a 34 year old male who presented to the ED post endoscopy with abdominal pain. A diagnosis of bowel perforation was considered due to mild tenderness in the lower abdomen and free air under the diaphragm on radiograph. He was discharged home from the ED because of resolution of symptoms. The patient subsequently re-presented with peritonitis and required an emergency laparotomy.

## Urology and Gynaecology

Two clinical claims relating to Urology and Gynaecology involved a delay in diagnosis of torsions. A 23 year old male required an orchidectomy following a delayed diagnosis of testicular torsion while a 29 year old female required a right salpingo-oophorectomy following a delayed diagnosis of ovarian torsion.

## Neurology

Regarding the clinical claim in Neurology, this involved a 46 year old female who presented with a sudden onset of severe headache. After a medical review, a diagnosis of migraine was made and intravenous prochlorperazine (a dopamine receptor antagonist, used as an antiemetic) was administered. She re-presented 24 hours later following a collapse. A brain CT scan demonstrated an acute subarachnoid haemorrhage. The patient survived but sustained long term brain injury.

## Dentistry

The clinical claim in dentistry pertained to a delay in implanting four broken teeth in an 18 year old female who presented to the ED.

## Processes

Analyses of the processes involved in the clinical claims in Emergency Medicine were performed (Table 43). Delay in diagnosis was the most common, (n=22, 68.8%), followed by delay in treatment (n=4, 12.5%) and unexpected complication of treatment (n=6, 18.8%). Poor quality documentation was identified as a key criticism in many of the finalised claims discussed.

| Process | Number (n) |
|---|---|
| Diagnosis | |
| - Delay in diagnosis | 22 |
| Treatment | |
| -Delay in treatment | 4 |
| -Unexpected complication of treatment | 6 |
| Total | 32 |

**Table 43: Processes identified in reviewed, finalised, clinical claims in Emergency Medicine, in 2014**

The above correlates with findings of a study undertaken in the USA[14] using data maintained by the Physician Insurers' Association of America (PIAA), a company which insures over 60% of practicing physicians. This study identified that errors in diagnosis (37%) and treatment incidents (17%) were common causes of claims in the ED. The NHS Litigation Authority Report 2014/15 identified that 12% of clinical negligence claims received in the NHS England 2014/2015, originated in the Emergency Department.[7]

## Cost

These 32 clinical claims were settled out of court. The total cost of the above finalised claims was €12,641,125 of which €9,263,013 pertained to awards/settlements, €2,177,830 to legal fees for the plaintiff, €1,041,181 to legal fees for the SCA and €159,101 for *"other"* which includes expert costs. Total legal fees expressed as a percentage of awards/settlements was 34.8% (Table 44). The average cost per clinical claim finalised in Emergency Medicine in 2014 inclusive of compensation and all costs (legal fees for the plaintiff, legal fees for the SCA, expert fees etc.) was €395,035.

| Number of Claims | Awards/ Settlements | Legal Fees – SCA | Legal Fees –Plaintiff | Other | Total |
|---|---|---|---|---|---|
| 32 | €9,263,013 | €1,041,181 | €2,177,830 | €159,101 | €12,641,125 |

**Table 44: Cost of reviewed, finalised, clinical claims in Emergency Medicine in 2014**

## Discussion

Working in the ED presents specific challenges. These include the clinical working environment, regular overcrowding and shortage of space within which to examine patients and a mix of both medical and surgical emergencies. The findings of this analysis are consistent with a previous older study of finalised claims in Emergency Medicine which identified that most errors, which led to claims, appeared, in retrospect, to have been simple errors in history taking, physical examination, communication and interpretation of radiographs.[27] The authors advised that non consultant hospital doctors (NCHDs) employed in the Emergency Department need careful training and supervision with access to senior medical advice.

## Suggestions and learning opportunities

### i. Specific Emergency Medicine education and training Induction programme

Implementation of a Specific Education and Training Induction Programme for all NCHDs due to work in Emergency Departments, focusing on the diagnosis and management of medical and surgical emergencies in addition to the common clinical and radiological presentations of fractures, is

recommended. This blended learning (on-line and face to face) may be completed partially prior to starting in post (e-learning) with the remainder during the first few weeks in post as "training in multi-disciplinary teams".

#### ii. Supervision and escalation to more senior colleagues

NCHDs should seek a senior colleague's advice for guidance if they feel they are operating outside their area of expertise. Direct clinical supervision of doctors in training in the ED in key practical skills and patient management steps has been shown to be important in providing quality patient care.[39]

#### iii. Recognition of the high risk patient and appropriate timely management

Recognition, prioritisation and appropriate management of the high risk patient in the Emergency Department is essential to achieve a positive care outcome.

#### iv. Documentation

Training regarding documentation in the healthcare record, as outlined by the HSE standards and recommended practices, is important.[40] Multidisciplinary audit, regarding compliance with these standards, is suggested to ensure continuous improvement in documentation. Poor quality documentation was identified in many of the above finalised claims and highlighted as an issue in multiple national healthcare reports over the last decade.[41,42,43]

#### v. Implementation of a laboratory alert policy

Implementation of a laboratory alert policy in all hospitals to ensure that all critical laboratory results are conveyed by phone to the requesting doctor and/or relevant ward is recommended.

## 7.3 Mental Health

### 7.3.1 An analysis of claims finalised in Mental Health services

#### Aim

To review finalised claims pertaining to Mental Health services, in 2014, and to identify opportunities for learning.

#### Methods

A retrospective 1 year review of claims in Mental Health services pertaining to clinical issues, finalised in 2014 was conducted. The claims were obtained from the NIMS based on the service of "Mental Health", followed by manual, clinical review by clinical risk advisers.

#### Results

Eleven finalised claims relating to clinical issues in Mental Health services were initially identified on the NIMS. Six of these were excluded, of which two claims had been discontinued, two had been statute barred and two did not relate to clinical issues and were re-classified on the NIMS. The remaining five claims underwent detailed clinical analysis, all of which involved fatalities.

There were two attempted suicides in approved Mental Health centres, leading, ultimately, to death in intensive care units. A third death occurred in a residential Mental Health setting. The remaining 2 deaths occurred within 24 hours of attendance at an Emergency Department (ED). Three of the patients were male, aged 21, 26 and 42 years while the two females were 36 and 41 years. Due to the small number of claims, some details of the cases have been altered to prevent recognition.

## Attempted suicides (leading ultimately to death) and death by misadventure in Mental Health services

A 41 year old female was admitted voluntarily to an acute Mental Health centre with a known history of depression, deliberate self-harm and several suicide attempts. A hospital, plastic, laundry bag found under the patient's pillow was confiscated. Subsequently, the patient was found by staff lying in bed with a plastic, hospital, refuse bag over her head and a cord, (possibly from a hooded tracksuit), tied tightly around her neck. She was cyanosed, unresponsive and pulseless. Despite resuscitation and transfer to an intensive care unit, the patient died four days later. The autopsy report stated the cause of death was hypoxic ischaemic encephalopathy due to, or as a consequence of, asphyxiation.

A 42 year old male, was brought by ambulance to the Emergency Department after a suicide attempt: he had been rescued from a river. He had a past history of suicidal ideation and adjustment disorder. The patient was admitted to an acute Mental Health unit. He requested to have a shower. He was found hanging, ten minutes later, from the shower frame with a ligature (shoelace) tied around his neck. Despite resuscitation and transfer to an intensive care unit, he died sixteen days later. It was identified that the medical entry *"high suicide risk"* had been altered in the health care record. This had a direct effect on the level of observation prescribed for and received by the patient. Cause of death was identified as anoxic brain injury due to, or as a consequence of, hanging (self-inflicted).

The third case involved a 26 year old male with a known history of schizophrenia, depression, alcohol abuse, illicit drug use, previous admissions to Mental Health services and noncompliance with medications. He had been out on a day pass and returned to the community residential setting having consumed alcohol. Assessment by nursing staff identified his speech was coherent and he had a steady gait. Clozapine (antipsychotic medication) was administered, as prescribed. In the early morning, on hearing a noise consistent with vomiting, the nursing staff went to the patient's room where he was found unresponsive. Despite resuscitation, he died. Cause of death at inquest was identified as aspiration of gastric contents secondary to combined effects of clozapine and ethanol. The death was recorded as death by misadventure.

## Two patients presented at an Emergency Department 24 hours prior to death

A 21 year old male was brought to the Emergency Department (ED) having attempted suicide by hanging from a goal post. He had a history of depression and a previous medication overdose. After clinical review by the Psychiatry Registrar on call, transfer to an acute Mental Health unit for voluntary admission was organised. The patient was left unattended in the waiting room of the acute Mental Health unit and subsequently left and went home. That evening, he was found hanging with a ligature tied around his neck, from a beam in his bedroom. Despite being resuscitated, he died in the intensive care unit 48 hours later.

The second case involved a 36 year old female who presented to the ED with acute alcohol intoxication and a past history of depression, alcohol abuse and drug overdoses. She was assessed in the ED. The patient refused admission to the Psychiatry ward for detoxification as was recommended by the Psychiatry team. A miscommunication occurred between the Psychiatry and Medical teams regarding admission and the patient was discharged with a planned review the following day by the community Psychiatry team. The following day, the patient was found dead at home. Cause of death was identified as central nervous system (CNS) depression due to fatal alcohol intoxication causing respiratory and cardiac arrest.

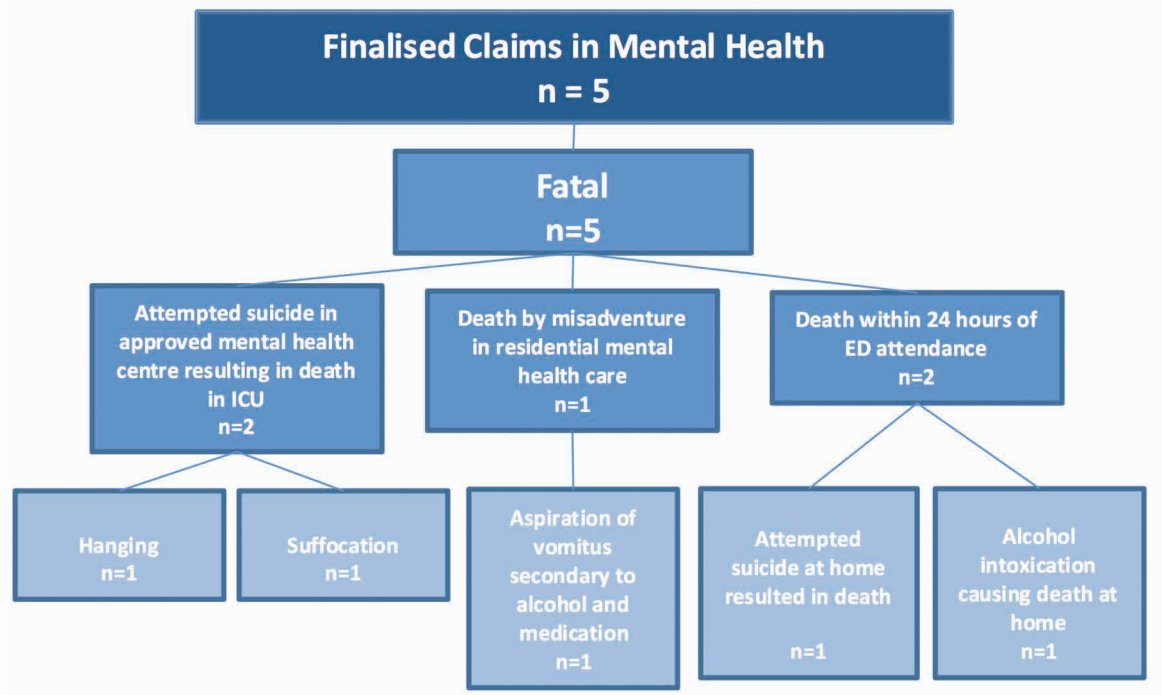


**Figure 48: Reviewed claims finalised in Mental Health Services in 2014**

## Reporting obligations in Ireland

It is a statutory requirement to report to the Mental Health Commission all *"sudden unexplained deaths of any patient availing of a Mental Health service or recently discharged and not in receipt of a Mental Health service within seven days of the date of occurrence* (of the death).[44,45] It is a policy requirement to report these deaths to the HSE[46] and a statutory requirement to report all adverse incidents to the State Claims Agency.[47]

## Suggestions and learning opportunities

### 1. Avoidance of access to "lethal means"

Ligatures were common to three of the deaths in these claims: shoe laces and a cord, likely from a hooded jacket. A hospital, plastic, refuse bag was used to induce asphyxiation and a shower frame used as a ligature point. There is a duty of care to keep lethal means away from patients identified as high suicide risk. The Mental Health Commission Judgement Support Framework (2015)[48] provides guidance as to the legislative requirement for approved centres. Powell et al [49] highlight that, in practice, it is difficult to predict which suicidal in-patients will proceed to suicide.

### 2. Clear protocol for observing patients at high risk of suicide

Patients identified as high risk of suicide should be kept under observation while awaiting hospital admission.

### 3. Implementation of effective communication and clinical handover

Good communication at time of admission, during transfer to different wards or services and discharge to the community is critical in a patient's journey through the healthcare system. Implementation of the National Clinical Effectiveness Committee (NCEC) published guideline *Communication (Clinical Handover) in Acute and Children's Hospital Services*[50] is recommended. This incorporates the ISBAR3 communication tool: Identification, Situation, Background, Assessment, Recommendation, Read-Back and Risk.

### 4. Documentation

Guidance regarding documentation in healthcare records is available from the HSE[40] and from professional regulatory bodies in Ireland e.g. the Medical Council[51] and the Nursing and Midwifery Board of Ireland.[52] Adherence is important in the provision of high quality and safe care to patients.

### Cost

The total cost of the reviewed five claims including awards/settlements was €1,478,746. The average cost per claim inclusive of compensation and all costs (legal fees for the plaintiff, legal fees for the SCA, expert fees etc.) was €295,749.

## 7.4 Paediatrics

### 7.4.1 An analysis of clinical claims finalised in one year in Paediatrics

### Aim

To review all finalised clinical claims pertaining to Paediatrics in 2014, and identify opportunities for learning.

### Methods

A retrospective one year review of all finalised, clinical claims pertaining to Paediatrics was conducted. The NIMS had no specific category for Paediatrics until 2015, so a search was performed using the age band 0-17 years on NIMS. All claims underwent manual, clinical review.

### Results

Forty eight claims relating to Paediatrics were identified by the NIMS. On review 32 were excluded of which twenty one related to *"birth specific injury"*, a category within "Maternity services". A detailed report on Maternity Services was published by the SCA in October 2015. The other eleven were excluded due to quality data issues and were reclassified on the NIMS. The remaining sixteen claims underwent detailed review. Regarding location, fifteen (93.8%) pertained to acute hospitals and one (6.3%) to the community. Of the fifteen relating to acute hospitals, two occurred in tertiary paediatric centres. In relation to gender, ten (62.5%) involved males. Analysis of the age profile identified that nine (56.3%) involved children under the age of 5 years. Two finalised claims (12.5%) were the result of fatalities (Figure 49)

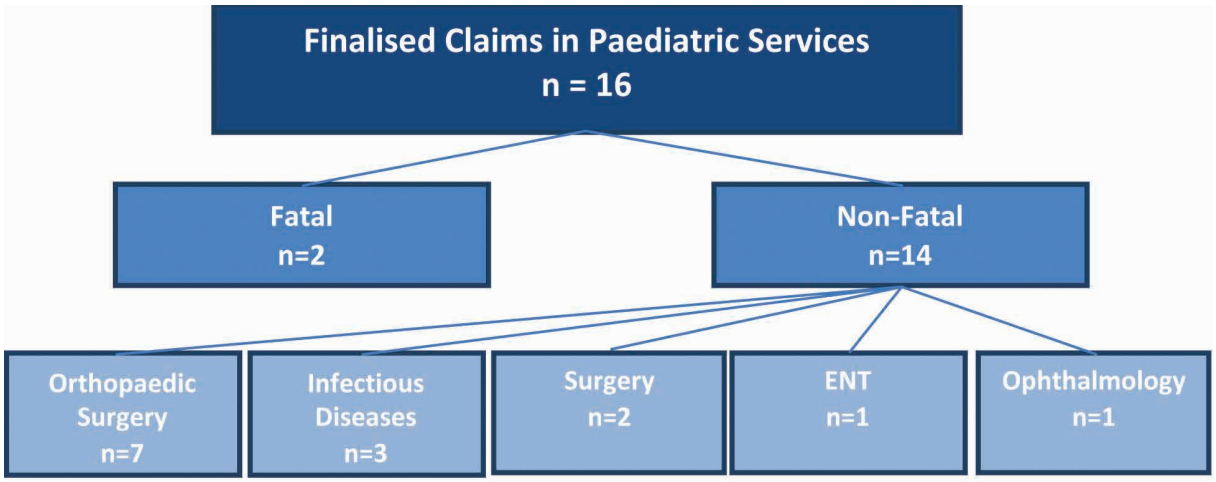


**Figure 49: Reviewed clinical claims finalised in Paediatrics in 2014**

## Fatal claims in Paediatrics

Of the two fatal claims, one related to a five month old boy with bacterial meningitis. The child presented with fever to the Emergency Department (ED). A diagnosis of viral infection was made and analgesia was prescribed and the infant was discharged home with advice to return if symptoms persisted. Clinical deterioration ensued. After re-presentation, pneumococcal meningitis was diagnosed on lumbar puncture (gram positive diplococci). Despite appropriate intravenous treatment, the infant subsequently died eight hours post admission in the high dependency unit.

The second fatal claim related to a dislodged endotracheal tube in an 18 month old, ex premature infant (26 weeks gestation) who presented to the ED with respiratory symptoms. A diagnosis of bronchiolitis was made with suspected concomitant bacterial infection. The child underwent treatment with intravenous antibiotics, was intubated, ventilated, and transferred to the adult intensive care unit (ICU) while awaiting transport to a paediatric ICU. Attempts were made to transfer the infant but he was too unstable. The endotracheal tube became blocked and dislodged. The infant suffered a cardiac arrest and despite resuscitation, care was withdrawn two weeks later due to severe hypoxia and confirmed brain death.

## Paediatric non-fatal finalised claims

Regarding the non-fatal finalised claims (n=14), these pertained to five specialities: Orthopaedic Surgery (n=7), Infectious Diseases (n=3), Surgery (n=2), and one claim each in the specialities of Otolaryngology/Ear, Nose and Throat (ENT) and Ophthalmology (Figure 49).

## Orthopaedic Surgery

Orthopaedic Surgery was the most common speciality involved in the non-fatal claims (n=7). The mean age of the children involved was 9.4 years, ranging from 8 months to 16 years of age. Five cases pertained to boys. Two claims were related to fractures involving the ulna: 1 was additionally associated with a displaced fracture of the radius while the other additionally involved dislocation of the radial head. In the former, while diagnosed correctly, treatment was incorrect resulting in the need for a second surgical procedure and prolonged recovery. In the latter, the radial head dislocation was not identified resulting in delayed surgical intervention and length of recovery. Both fractures were related to trauma resulting from falls: from a trampoline and a bouncy castle respectively.

A further Orthopaedic claim pertained to missed slipped upper femoral epiphyses (SUFE) in a 13 year old female referred to the ED by her GP with hip pain. The formal radiograph report, received after the patient was discharged, raised the suspicion of SUFE. No contact was made with the patient. One month later, the patient re-presented after a minor fall and the diagnosis of SUFE was confirmed on radiograph. The delay in diagnosis resulted in chronic pain, poor surgical outcome, restricted joint movement and the likely need for further surgery later in life.

A systems error resulted in a delayed diagnosis of developmental dysplasia of the hip in an infant with a known family history of same. Despite parental requests, the hip radiograph, although ordered, was not performed in the hospital until the infant was 9 months old, by which time surgical repair was required.

A fall from *"monkey bars"* resulted in avulsion of a patella tendon in a 13 year old boy. The radiology report 5 days later identified a calcific density in the ligamentum patella. The patient was not contacted regarding this report. Two months later the patient presented to his GP, was referred to the fracture clinic where the avulsion was diagnosed and surgically treated.

## Infectious Diseases

The category with the most significant clinical outcome, though not the most common, was Infectious Diseases. The fatal claim, discussed above, resulted in death due to pneumococcal meningitis. One non-fatal claim involved missed septic arthritis, secondary to *Haemophilus influenza b* septicaemia which resulted in several corrective surgeries for leg length discrepancy. Two further cases were finalised without any payment (after legal review): one pertained to Bacillus-Calmette-Guerin (BCG) vaccination that required surgical drainage (a known complication) while the other pertained to a child who received 2 antibiotics which had not been prescribed for him, but resulted in no obvious harm to the patient.

## Surgery

There were two finalised claims related to Surgery. One pertained to an upper labial frenulum release but the procedure performed was lingual frenulum release. The other claim related to a chemical burn on the foot of a 17 year old male, sustained during a procedure to remove an ingrown toe nail. The expert report concluded that the burn was secondary to the chemical solution (phenol/alcohol) used. Treatment involved intravenous antibiotics and a review by the Plastic Surgery team.

## Otolaryngology / Ear Nose and Throat (ENT)

The case related to Otolaryngology/ENT, pertained to a delay in diagnosis of profound deafness, resulting in the need for bilateral cochlear implants. Parental and GP concerns regarding hearing were raised when the female infant was 6 weeks of age. The infant underwent multiple audiology assessments, two Auditory Brainstem Response (ABR) tests under general anaesthesia and insertion of grommets. The extent of the hearing loss was identified at fourteen months of age and cochlear implants were surgically inserted.

## Ophthalmology

This claim pertained to a traumatic eye injury sustained in a 16 year old boy playing hurling, while wearing his helmet. He presented to the ED with pain. Although adequately treated from a head injury view point, no test of visual acuity was performed and no ophthalmology consult was obtained. A computed tomography (CT) scan was suggestive of early infection close to the eye and the adjacent sinus. No antibiotics were prescribed. A few days later, the child re-presented with acute loss of vision and significant intra-orbital swelling, which required surgical decompression. Sight was not recovered. The expert concluded that the loss of sight may have been related to infection, trauma or both.

## Cost

The total cost of reviewed, clinical claims, finalised in Paediatrics in 2014 was €3,181,559. The average cost per claim including all costs (compensation, legal fees to the plaintiff, legal fees to the SCA, expert opinion etc.) was €198,847.

## Discussion

Finalised claims were analysed to identify key clinical incidents and help guide future practice. Many of the finalised, clinical claims involved young children less than 5 years of age and the majority pertained to males. This concurs with a much larger study from the USA[53] of finalised claims in Paediatrics (n=2,283) which identified that 59% were boys and 47% of children were young (less than 2 years of age). The most common conditions from which the children died in Selbst et al's analysis were infection-related: meningitis and pneumonia, not dissimilar to the findings of the SCA's much smaller study.

## Suggestions and learning opportunities:

### i. Specific Training and Education Induction Programme

Completion of a specific blended learning (online and face to face) training and education induction programme in Paediatrics is suggested. Part of this may be completed on line prior to commencement in post and the remainder during the first few weeks of being in post. Sick children present with very different symptoms and signs to those of adults. Focused training in Paediatric medical and surgical emergencies, common fractures and orthopaedic conditions specific to Paediatrics is important (e.g. Slipped Upper Femoral Epiphysis (SUFE) or Perthe's disease). This training would be in addition to current training in Advanced Paediatric Life Support.

### ii. Seek specialist advice or a senior colleague's advice

Early referral to a subspecialist in Paediatrics is important if a child presents to the ED with a specific problem. If this is not available, junior doctors should seek a senior colleague's advice for guidance if they feel they are operating outside their area of expertise.

### iii. Clear, accurate, timed, documentation

Clear documentation in the healthcare record and adherence to HSE standards is recommended.[40] Poor documentation has been a recurring theme in reports on healthcare in Ireland over the last few years.[41,42,43]

### iv. Screening for developmental dysplasia of the hip

Access to ultrasound screening for developmental dysplasia of the hip (DDH) is required nationally. Ultrasound screening has been shown to be important in preventing morbidity and late diagnosis.[54]

### v. Immunisation

Ensuring a good uptake of vaccinations in Paediatrics is critical to the successful prevention of certain infectious diseases. Introduction of vaccines to prevent meningitis and septisaemia in infants and children has been successful.[55]

### vi. Paediatric Early Warning System

Implementation nationally of the Paediatric Early Warning System is important in the detection of the deteriorating child. This was published by the National Clinical Effectiveness Committee in November 2015[56] and indorsed by the Minister for Health.

### vii. HSE Universal New-born Hearing Screening Programme

The HSE Universal New-born Hearing Screening Programme[57] was introduced, nationally, in 2012 to help ensure early identification and management of permanent childhood hearing impairment. This programme requires adequate resourcing to ensure appropriate staff are in place to review and follow up these babies in a timely manner, when identified by the screening programme.

### viii. Implementation of the HSE National Policy and Procedure for Safe Site Surgery (2013)

Implementation of the HSE national policy and procedure for safe site surgery[58] is important to help ensure safe practice and reduce common and avoidable risks associated with surgical error.

## 7.5 Slips, Trips and Falls

### 7.5.1 An analysis of claims finalised in one year relating to Slips, Trips and Falls

#### Aim

To review claims, finalised, in 2014, pertaining to Slips, Trips and Falls of a clinical nature and identify learning opportunities.

#### Methods

A list of claims pertaining to Slips, Trips and Falls was obtained from the NIMS. These are classified as *"patient-related claims"* on the NIMS: some of which are "state of the premises related "(e.g. fall on a wet floor), while others pertain to clinical care. This latter group underwent detailed, clinical review using a standard template.

#### Results

Forty two finalised claims were initially identified by the NIMS of which 21 (50%) had a clinical factor and these were selected for further detailed analysis. Date of incident ranged from 2001 through to 2012. The majority related to females (n=14, 66.7%), with a mean age of 57.3 years (range 19-77 years). Twenty (95.2%) of the 21 claims occurred while the patient was moving without supervision.

Regarding the type of injury, the most common injury sustained was a fracture (n=10, 47.6%), followed by soft tissue injury (n=6, 28.6%), head and facial injury (n=4, 19.0%) and mouth injury (n=1, 4.8%), (Figure 50). Five fractures involved *"hip, femur or pelvis"*. There was no fatality directly attributable to a fall.

Soft tissue injuries (n=6) involved bruising and/or laceration to the neck, shoulder and hip, deep laceration to the base of the thumb and bilateral quadriceps tendon rupture. Head and facial injuries (n=4) included temporo-mandibular joint dislocation, an eye injury resulting in blindness (pre-existing bilateral corneal transplants), laceration to the head requiring consultation from plastic/ reconstructive surgery and laceration to the bridge of the nose. The injury to the mouth involved laceration of a lip during a dental procedure.

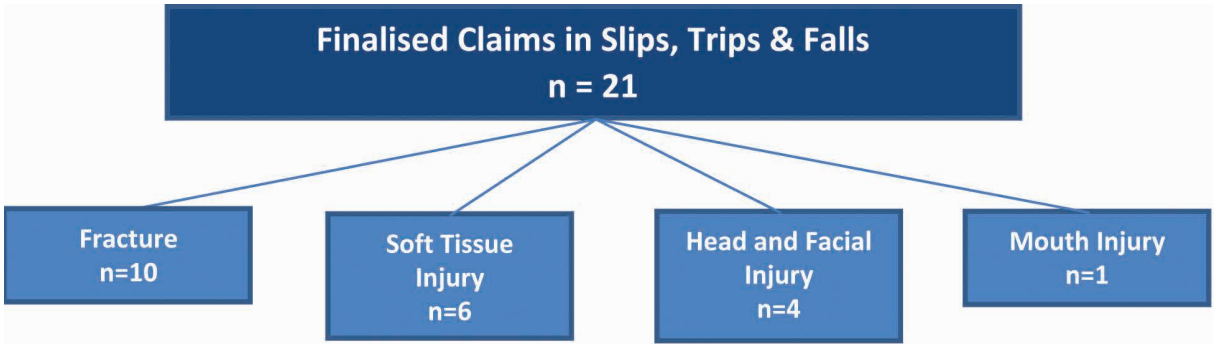


**Figure 50: Injuries sustained in reviewed claims finalised, nationally pertaining to Slips, Trips and Falls in 2014**

Patient factors may have contributed to these events, such as pre-existing patient morbidities (n=19, 90.5%) including dementia, arthritis, diabetes, cancer and sarcoidosis. Language and communication difficulties were identified in five (23.8%) of these finalised claims.

Regarding task and technology factors, availability and use of protocols was a concern in five (23.8%), while availability and accuracy of test results was a concern in 3 (14.3%). Delay or failure to recognise a complication was identified in six (28.6%). Defective equipment was identified in 1 case (4.8%).

The majority of claims were related to surgical sub-specialities (n=12, 57.1%) including Emergency Medicine (n=4, 19.0%) and Orthopaedics (n=3, 14.3%), while there was one claim (4.8%) each in General Surgery, Otolaryngology/ENT, Neurosurgery, Plastics/Reconstructive surgery and Urology. Medicine accounted for 9 (42.9%) claims including General Medicine (n=6, 28.6%), Older Persons (n=2, 9.5%) and Intellectual Disability (n=1, 4.8%). The range of sub specialities involved highlights the need for all to be aware of the importance of the risk of falls and institute preventative measures accordingly, (Figure 51).

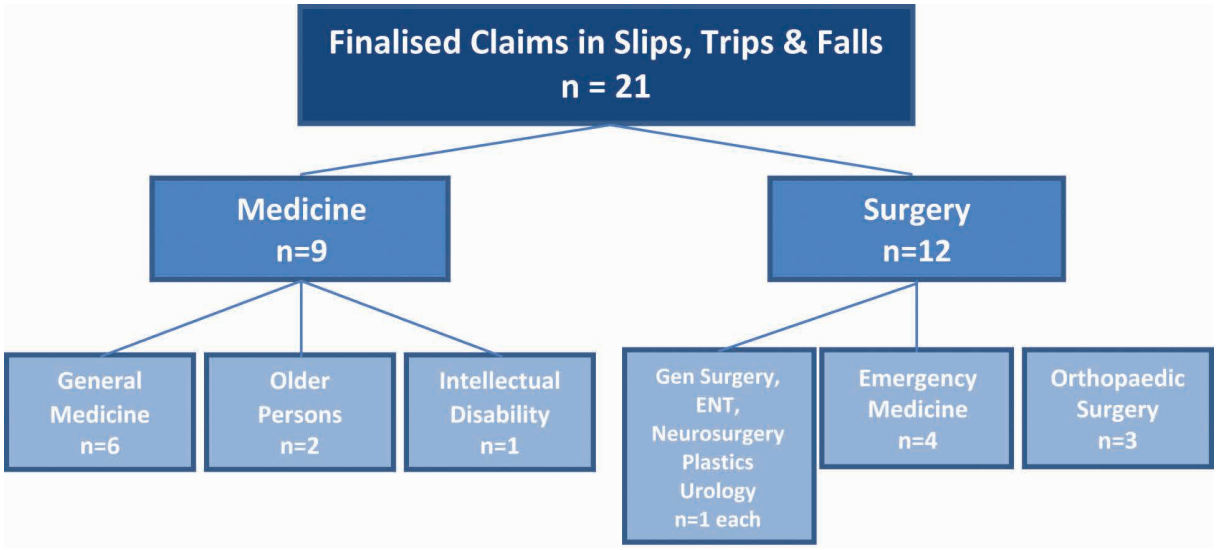


**Figure 51: Specialities involved in reviewed claims finalised, pertaining to Slips, Trips and Falls in 2014**

The majority (n=18, 85.7%) of these claims had been previously reported as an incident by the Healthcare service to the SCA. Open disclosure practice was evident in the majority (n=19, 90.5%).

## Cost

The cost of reviewed claims finalised in slips, trips and falls was €768,358 for 21 claims (Table 47). The average cost per claim inclusive of compensation and all costs (legal fees for plaintiff, legal fees for the SCA, expert fees etc.) was €36,588.

| Cost of clinical claims finalised in slips, trips and falls nationally, 2010-2014 inclusive | Total |
|---|---|
| Total cost of claims | €768,358 |
| Total number of clinical claims | 21 |
| Average cost per claim finalised | €36,588 |

**Table 45: Cost of reviewed claims finalised pertaining to Slips, Trips and Falls in 2014**

## Discussion

The vast majority of claims pertained to incidents where the patient was *"moving without supervision"*. This is not dissimilar to findings from a retrospective analysis of the NHS Litigation Authority database of clinical negligence claims resulting from falls in hospitals in England 1995-2006 (n=479 closed claims, which identified that the majority of claims resulted from *"falls whilst walking"*, *"from beds or trolleys "* or *"transferring from a chair"* (n=308, 64.2%).[59] This NHS study identified "hip/femoral/pelvic fracture" as the primary injury in 42.4% (n=203) of finalised claims while this primary injury accounted for 23.8% (n=5) in the SCA's small review.

The claims involved multiple specialities (with a predominance of Surgery over Medicine), highlighting the need, across all specialties, for clinical risk assessment for falls and bone health. Nearly half of the claims pertained to people who were > 65 years of age: a high risk group, though, of note, 1 patient was only 19 years who slipped and fell post-surgery while in the shower.

The SCA is co-leading with the HSE on AFFINITY: the implementation of the national strategy on falls prevention and enhanced bone health. AFFINITY involves the development of an integrated approach between the community and acute hospitals to prevent falls and fractures in Ireland's ageing population. On-going resources are required. The National Clinical Programme for Older People has outlined a model of care pathway[60] for older persons in Ireland. Internationally, the British Orthopaedic Association Blue Book Standards[61] are useful guides while the international programme "Capture the Fracture"[62] offers a best practice framework for benchmarking fracture liaison services.

## Learning opportunities and suggestions:

Primary and secondary prevention are key to preventing falls and the potential associated morbidity and mortality. Suggestions include the following:

### i. Primary and secondary prevention

The importance of performing clinical risk assessment for falls and bone health should be highlighted across all areas in both Medicine and Surgery. Falls are not confined to "older persons" alone. However, health and social care professionals should target older persons, especially those aged 65 years or more, for screening for risk of falls in acute hospitals and the community.

An individualised, multi factorial falls and bone health risk assessment should be performed on all "high risk" patients admitted to hospital. Interventions should be identified, appropriate to the risk factors. This "high risk" group should include older persons and patients at risk (primary prevention) in addition to patients admitted to hospital with a fall (secondary prevention).

### ii. Adoption of international guidance

Currently, in the absence of Irish guidelines / standards, health care services should consider adopting the UK quality improvement Fall Safe Care Bundle[63]; the recommendations of the National Institute for Health and Care Excellence (UK) guidance on falls in older people[64] and the more recent NICE Quality Standard (NICE Quality Standard)[65] which addresses the need for assessment after a fall and interventions to prevent further falls (secondary prevention).

### iii. Continued resourcing of the AFFINITY Programme

It is suggested that the HSE should continue to resource the national AFFINITY programme: which it co-leads with the SCA "Preventing falls and fractures in Ireland's Ageing Population"[66] and continue to resource the Irish Hip Fracture Database (IHFD).

## 7.6 Gynaecology

### 7.6.1 Retained foreign bodies in Gynaecology services - a national review of 10 years of finalised claims, 2004-2014.

#### Aim

To review all finalised claims pertaining to retained foreign bodies in Gynaecology services between 2004 and 2014.

#### Methods

A retrospective review was performed of all finalised claims pertaining to retained foreign bodies in Gynaecology services, in public hospitals in Ireland over a 10 year period. A list was obtained using the NIMS and a search carried out using the terms 'Gynaecology services' and 'foreign body left in situ'.

#### Results

Fifteen claims pertaining to retained foreign bodies in Gynaecology were identified over the 10 year period of which one was statute barred. The file contained insufficient information and was excluded from the review. Of the remaining 14 claims, 4 related to incidents in 2002, 3 in 2006, 2 each in 2004 and 2007 and 1 in 2001, 2005 and 2009.

Regarding the identity of the foreign body, 8 (57.1%) were swabs or gauze; 3 (21.4%) were intrauterine contraceptive devices (IUCDs, Mirena coils), and there was 1 (7.1%) of each of the following: the tip of a catheter, part of a drain and a needle. A consultant Obstetrician and Gynaecologist was present in 6 (42.9%) of the cases, in addition to a non-consultant hospital doctor.

A review of the associated surgeries revealed that: 4 (28.6%) were related to Evacuation of Retained Products of Conception (ERPC), 3 (21.4%) were related to IUCD insertion or removal, 2 (14.3%) were related to hysterectomy (1 with associated bilateral oophorectomy), 2 (14.3%) related to colposcopy and biopsy or large loop excision of the transformation zone and 1 (7.1%) was related to each of the following; myomectomy, Tension free Vaginal Tape (TVT) urethral sling procedure and fallopian tubal ligation (Figure 53).

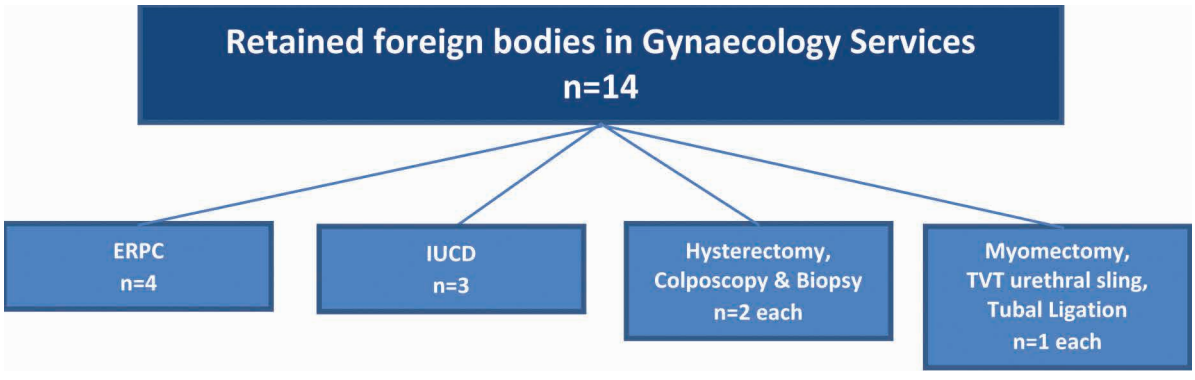


**Figure 52: Surgeries and procedures associated with retained foreign bodies in Gynaecology services nationally: analysis of finalised claims 2004-2014 inclusive**

All patients received the antibiotic combination recommended, at that time point, of metronidazole and co-amoxiclav. The mean number of antibiotic courses received was 1.25. Patients with retained swabs (n=8, 57.1%), presented with a combination of symptoms including: offensive discharge, pain, vaginal bleeding and pain on micturition, with most patients experiencing multiple symptoms. Two

patients with unintended, retained IUCDs had no symptoms, while the third presented with hirsuitism, raised hormone levels on testing, weight gain and depression. A retained drain caused pain for 18 months. A retained needle was asymptomatic until it presented with a tender lump at the site of the previous surgical scar and a retained tip of a catheter, which fell off during an ERPC, caused no symptoms.

The mean duration a retained swab was unintentionally left *in situ* was 15 days, after removal of outliers (one of which was 11 weeks and the other 5 years and 11 months). Out of the 3 cases where a high vaginal swab result was documented, 1 was culture positive, with anaerobes. Identification of the retained swab (n=8) was made by a GP in 3 (37.5%) cases, by a hospital doctor in 3 (37.5%), and by a patient in 2 (25%).

The other foreign bodies were retained for longer durations. Retention of an IUCD varied from 10 days in one case, 11 months in the second and 13 months in the third. The retained needle, which had been adhered to a suture, broke off while superficial tissue layers were being sutured, following a myomectomy. Due to significant blood loss in the patient at the time of surgery and the knowledge that the foreign body was superficial, it was not removed at the time. Subsequently, it was removed under local anaesthetic.

Similarly, retention of a tip of a catheter at an ERPC was identified at the time of removal of the catheter, at the end of the procedure. This catheter tip was removed three days later at hysteroscopy. A segment of a drain, which was inserted post hysterectomy and bilateral oophorectomy, broke off and was left in situ for 18 months prior to its identification and surgical removal.

Medium and long term associations, identified by both patient and consultant physician, included psychiatric and psychological diagnosis (n=5, 35.7%); recurrent urinary tract infection and bladder surgery (n=1, 7.1%); chronic pain (n=1, 7.1%) and bilateral uterine tubal occlusion on hystersalpingogram (n=1, 7.1%).

## Discussion

Retained foreign bodies are items unintentionally left inside patients after surgery or a procedure. These are most commonly swabs, needles, and surgical instruments. The Joint Commission[67] has, for a number of years, considered a retained foreign body a reportable, sentinel event. The Centers for Medicare and Medicaid Services (a Federal agency within the US Department of Health and Human Services responsible for the administration of several key federal healthcare programmes) consider a retained foreign body a hospital-acquired condition and a "never event"[68] for which additional reimbursement to manage this complication is not provided. Similarly, the NHS has listed a retained foreign body as a "never event" [69] and the HSE listed it as a Serious Reportable Event.[46]

## Counting

Counting of sponges, needles and surgical instruments is critical, though not fully reliable. Due to the fact that counting swabs, sharps, and instruments is a major factor in the prevention of retained foreign bodies, guidelines for the performance of counting swabs/sponges and sharps were published by the American College of Surgeons in 2005[70], (updated in 2016)[71] in addition to the Association of Perioperative Registered Nurses.[72] They recommended counts, before the procedure to establish a baseline, before closure of a cavity within a cavity, before wound closure begins, at skin closure or at the end of the procedure, and at the time of permanent relief of either the scrub nurse or circulator. Despite the practice of counting swabs, errors still occur. Previous studies have suggested that in 62% to 88% of cases in which foreign body retention occurs, the sponge count is erroneously reported as correct.[73,74]

## Radiology

Most institutions rely on radiologic screening to help resolve counting discrepancies. Cima et al's[73] study at the Mayo Clinic in Minnesota, which performed routine high-resolution radiographs on all patients who underwent operations, identified 34 retained foreign bodies and an incidence rate of 1 in 5,500 surgeries. The 34 occurrences included 23 swabs, 3 needles, 7 miscellaneous items (including clips, stents and drill bits), and 1 instrument. Two swabs were found in the vaginal vault after obstetric procedures.

System approaches to reduce retained foreign bodies have been advocated. Goldberg et al.[75] recently outlined the Association of Perioperative Registered Nurses (AORN's) recommended practices for prevention of retained surgical items and exemplified appropriate strategies for this multi-disciplinary approach. Multidisciplinary, quality-improvement, programmes have demonstrated reduction in the incidence of retained foreign bodies (from 1 every 16 days to 1 every 69 days), and the rate of retained foreign bodies (decreased from 0.52 to 0.11 per 1,000 surgeries).[76]

Other patient safety initiatives, nationally and internationally, include implementation of the WHO Surgical Safety Checklist[77], the HSE Safety Pause[78] and the Communication (Clinical Handover)[50] in Acute and Children's Hospital Services Guideline which incorporates the ISBAR tool (identify, situation, background, assessment and recommendations).

## Cost

The total cost of finalised claims (n=14), pertaining to Gynaecology, analysed above, was €322,043.

Many of the national and international recommendations outlined below have been implemented across the Gynaecology services nationally:

i) Ensuring a counting policy is implemented, audited and reviewed (including double counting, use of white boards and documentation).

ii) Clear documentation of swab and instrument count in the notes after a Gynaecological procedure.

iii) Implementation of the process of swab count reconciliation by performing a vaginal exam or radiograph when the count cannot be reconciled (depending on the procedure performed).

iv) Use of radiopaque and tailed swabs for vaginal packing: (detection tails can be clipped onto the drapes outside the vagina).

v) Implementation of the Communication (Clinical Handover)[50] in Acute and Children's Hospital Services

vi) Implementation of a quality improvement programme which ensures each retained foreign body case or near miss is investigated thoroughly. Ensure that "lessons learned" are disseminated to front line workers and all relevant staff.

vii) Implementation of a multi-phased, multidisciplinary training and education programme to all staff in the operating room and gynaecology outpatient clinic.

viii) Audit of retained foreign bodies with dissemination of data, and all updates on policies or guidelines (national or international) to all relevant stakeholders.

ix) Increasing staff numbers in Gynaecology services (medical and nursing) to levels consistent with international guidelines.

## Conclusion

The retention of foreign bodies in Gynaecology Services continues to be an opportunity for improvement. Continued emphasis on education, training, and implementation of recommendations and audit of practices is a priority.

# 8.0 CONCLUSION

## Background

The Clinical Indemnity Scheme (CIS) was established on July 1st 2002 and consultants first became indemnified by the scheme with effect from February 1st 2004 but only in respect of clinical incidents occurring on or after that date. Therefore, the CIS is considered to be an *immature* indemnity scheme in actuarial terms and is not expected to plateau, in terms of volume and cost, of clinical claims, until 2020.

## Incidents

An increase in clinical incident reporting by healthcare services across the range of severity of injury is considered to be a positive finding, indicative of a strong patient safety culture. Clinical incidents increased by 6,521 (16.2%), 2010-2014 inclusive. The clinical incident rate increased from 883 in 2010 to 1,014 in 2014 per 100,000 population.

The most common clinical incident nationally was *"other"*, where the incident did not fall into one of the particularised categories. This category is reducing over time with the wider range of categories and pick list options offered by the NIMS, (which has replaced STARSWeb) and training and education on incident reporting. This was followed by incidents pertaining to delay or failure to treat leading to an adverse outcome (n=9,681, 4.7%). Medication incidents featured prominently and included incorrect dose, missed medication and incorrect medication on admission, transfer or discharge, which combined accounted for 14.7% (n=17,830) of the ten most common clinical incidents. Incidents pertaining to failure or faulty medical device or equipment, serious soft tissue damage and clinical records missing or misplaced were common. Incidents related to Maternity services including post-partum haemorrhage and perineal tears (3rd and 4th degree including breakdown of the perineum) ranked in the ten most common incidents identified nationally and reported to the SCA, 2010-2014 inclusive.

Medicine, Maternity, Surgery, Disability and Older Persons were the most common services, in decreasing order, in which clinical incidents were identified and reported to the SCA. Each service was analysed in detail and the ten most common clinical incidents in each service was identified. Suggestions to prevent the occurrence and/or recurrence of common clinical incidents were highlighted.

Suggestions were provided to help these clinical incidents. Improvement in quality and standardisation of clinical incident reporting nationally is required. Most clinical incidents are related to systems' issues rather than due to an individual's practice and resolving the former has resource implications. Strategies suggested to help prevent medication incidents included implementation of a clinical pharmacy service in all hospitals; multi-phasic multi-disciplinary specific training and education in medication incidents; medication reconciliation at times of patient transfer; introduction of a national drug kardex and empowerment of the patient and/ or carer to *"know your medications"*.

Suggestions regarding prevention of delays and failure to treat leading to adverse outcomes were offered including introduction of the Electronic Healthcare Record nationally; reduction in waiting lists for procedures and investigations and implementation of the NCEC Clinical Handover (Communication) and Early Warning Systems guidelines nationally. Consideration may be given to a seven day week for elective diagnostic services and direct access to GPs for certain investigations and procedures.

Repair or replacement of medical devices or equipment which are faulty or failing respectively is required either through purchase or hiring of same. Particular attention should be given to skin and soft tissue care, especially in vulnerable patient groups (those with mobility issues, older persons and children). Introduction of the Electronic Healthcare Record will help prevent incidents of missing or misplaced clinical records.

## Claims

As outlined above, the CIS is still considered *"immature"* in actuarial terms and the volume and cost of claims is expected to grow as the scheme matures, eventually plateauing in approximately 2020. The number of clinical claims created, 2010-2014 inclusive, increased nationally, as expected, based on the *"immaturity"* of the CIS (n=157, which equates to a 35.1% increase). The clinical claim rate increased from 10 to 13 per 100,000 population during this time period. This was largely explained by mass actions including those relating to DePuy hip replacement, symphysiotomies, and the Lourdes Redress Scheme for hysterectomies.

The ten most common clinical claims created nationally 2010-2014, inclusive, were identified and included *"other"* where the claims did not fall into one of the particularised categories. Claims related to *"diagnosis"* including delayed diagnosis or failure to diagnose were relatively frequent, and combined accounted for 19.0% of the ten most common clinical claims. Claims related to failure or faulty medical device or equipment were common and largely were accounted for by the DePuy hip replacement mass action. Similarly, unnecessary surgery or procedure and wrong procedure or operation were largely accounted for by the mass actions for symphysiotomies and hysterectomies (The Lourdes Redress Scheme). Claims pertaining to unexpected complications "following" or "during" a procedure were relatively frequent (The combined figure accounting for 10.1% of the ten most common clinical claims). Claims pertaining to *"delays"* including delay or failure to treat leading to an adverse outcome featured in the ten most common claims nationally for this time period.

High risk services identified for clinical claims included Surgery, Medicine, Maternity services, Gynaecology and *Other* (where the claims did not fall into any of the offered categories) services. These were analysed and the ten most common clinical claims created in each service reviewed. National data were compared with international peer reviewed, data from published studies of closed claims in the same services for "lessons learned".

Hospital related deaths reported to the Coroner represent a small but relevant proportion of clinical claims in some specialities reviewed namely, Emergency Medicine, Cardiology, Gastroenterology and Respiratory Medicine. Specialists in these areas should be cognisant that while a relatively small number of claims, this patient cohort may involve on occasions, attendances before the Coroner's Court and clinical claims.

## Cost

Overall, the total number of clinical claims finalised annually 2010-2014, inclusive, increased and, therefore, cost increased. The total cost of clinical claims finalised during this 5 year period was €288,796,591 of which awards/settlements accounted for €177,479,000, legal fees for the plaintiff were €65,473,645, legal fees for the SCA were €40,810,885 and *"others"*, which includes expert fees accounted for €5,033,061. Total legal fees expressed as a percentage of awards/settlements were 59.9% for this five year period. Total legal fees expressed as a percentage of awards/settlements was 62.1% in 2010 and reduced to 51.0 % in 2014. The average cost per clinical claim finalised, inclusive of compensation and all costs (legal fees for the plaintiff, legal fees for the SCA, expert costs etc.) reduced from €152,329 in 2010 to €141,813 in 2014.

## Specialities

Specialities were analysed from a clinical incident, claims and cost viewpoint including Emergency Medicine, Mental Health, Radiology, Cardiology, Respiratory, Gastroenterology, Neurology and Infectious Diseases.

## Finalised claims

Finalised claims were reviewed in multiple specialities, learning points identified and suggestions made including in Emergency Medicine, Paediatrics, Mental Health, Gynaecology services pertaining to retained foreign bodies and Slips, Trips and Falls.

# 9.0 PATIENT SAFETY

## 9.1 International Patient Safety

The landscape of patient safety has changed over the last two decades. The Institute of Medicine's (USA), first quality report *"To Err is Human: building a safer health system"*[79], identified preventable lapses in patient safety resulting in 44-98,000 Americans deaths each year, the eighth leading cause of death at that time and a cost of $29 billion annually. The majority of these problems were systems related and not the fault of individual providers. Subsequently, the Joint Commission, the major accrediting body in the USA, established its first annual National Patient Safety Goals (NPSG)[80] and the National Quality Forum listed 28 serious reportable events (never events)[81] that should not happen.

Following this, a change in approach occurred: a payment system was used as a driver for patient safety with Centres for Medicare and Medicade Services (CMS) announcing they would not reimburse for certain conditions, including wrong side/site surgery or hospital acquired infection. The Institute of Healthcare Improvement (IHI) published its global trigger tool which allowed services to track their own adverse events.

Based on modern studies published between 2008 and 2011, John James published an updated estimate of premature deaths associated with preventable harm. This figure was estimated at between 200,000-400,000 per year.[82]

Internationally, publications have documented that voluntary incident reporting alone leads to under-reporting. A paper by the United States Department of Health identified that hospital staff did not report 86% of events to voluntary incident reporting systems.[83]

Simultaneously, in the U.K., the patient safety movement was underway. The National Reporting and Learning System (NRLS), a central database of patient safety incident reports, was founded in 2003 and, since then, over four million incident reports have been submitted. The NRLS provided and published feedback to NHS organisations including comparative reporting rates, regularity and speed of reporting, the top ten incident types reported and incidents reported by degree of harm. The NRLS has recently become a part of the NHS Improvement National Patient Safety Team and reports are now published on the NHS Improvement Website.

## 9.2 National Patient Safety

The report of the Commission on Patient Safety and Quality Assurance, Building a Culture of Patient Safety[84], published in July 2008 had 134 recommendations. These concerned the provision of a high quality health service delivered in an effective way in a safe environment. These were grouped as follows: involvement of patients, carers and service-users; leadership and accountability in the system; organisational and professional regulatory framework; quality improvement and learning systems and implementation. Since then multiple progressive steps have taken place nationally. Regarding reporting of incidents nationally to the SCA, the NIMS was rolled out in mid-2015. In October 2015 the State Claims Agency published a *"Clinical Incidents and claims report in Maternity and Gynaecology services- a five year review, 2010-2014"*[3] which analysed national data on incidents, claims and costs contextualised with international data. In January 2016 the then Minister for Health, Minister Varadkar, launched Ireland's first *National Maternity Strategy – Creating a better future*

*together-National Maternity Strategy 2016-2016*[85] which is a roadmap for the improvement of services over the next ten years. In March 2016, the first Irish Maternity Indicator System (IMIS) National Report[86] was published by the HSE. This report was the first annual national account of activity and outcomes of maternity care in Ireland. It demonstrated measurement, analysis and comparison of Maternity activities and clinical outcomes nationally in 2014. The same month, the HSE first published the Maternity Patient Safety Statements[87] for the country's 19 maternity hospitals and units which are updated monthly. Reporting in an honest and open way helps build trust and improves clinical performance and the culture of safety. Other HSE initiatives include Open Disclosure, a national programme run in partnership with the SCA; implementation of Early Warning Scores; the Productive Operating Theatre Programme and the funding of the Diploma in Leadership and Quality in Healthcare, run in conjunction with the Royal College of Physicians in Ireland (RCPI).

The National Patient Safety Office (NPSO) located within the Department of Health was launched in December 2016. It focuses on leading key patient safety policy initiatives. An increased number of national clinical guidelines have been published by the National Clinical Effectiveness Committee, endorsed by the Minister for Health. Collaboration of all stakeholders nationally and internationally together with more real time data analysis should further improve patient safety.

# 10.0 FUTURE INITIATIVES

Future initiatives consist of further analysis and interrogation of national data both real time and from finalised claims. Increased identification of high risk areas in clinical medicine and targeting these for focused education and training is important. More health outcomes research through analysis of finalised claims and collaborative research in specific high risk areas of concern to help provide risk management suggestions to reduce clinical incidents and promote patient safety, is important.

Measurement of the impact of implementation of risk management interventions is crucial. Further collaboration intra-institutionally, inter-institutionally, nationally and internationally is critical to success. Collaboration must be with all stakeholders, including frontline staff, senior executive hospital and hospital group teams, HSE national directorate, Department of Health, patients, Universities and post graduate training bodies both at a national and international level. Ensuring that the patient, his/her safety and experience remain central to the SCA's work is vital. The pillars of clinical risk, including data analysis, education (under, post graduate and continuous professional development) and research, together with collaborative action between all stakeholders, should reduce clinical incidents and promote patient safety in the Irish healthcare system.

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