



Gníomhaireacht Bainistíochta an Chisteáin Náisiúnta
National Treasury Management Agency

An Gníomhaireacht Stáit um Éilimh
State Claims Agency

CLINICAL INCIDENTS AND CLAIMS REPORT IN MATERNITY AND GYNAECOLOGY SERVICES

A FIVE YEAR REVIEW: 2010-2014

October 2015

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ii. Abbreviations

CHO:	Community Healthcare Organisation
CIS:	Clinical indemnity scheme
CTG:	Cardiotocography
ERPC:	Evacuation of Retained Products of Conception
HCR:	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 Incidents Management System
NNTP:	National Neonatal Transport Programme
NPSA:	National Patient Safety Agency
SCA:	State Claims Agency
SCBU:	Special Care Baby Unit
SRE:	Serious Reportable Event

iii. Definitions

Claim: 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/oral request.

Close Date: Official date that the claim was closed on the National Incident Management System, with all financials relating to the claim being settled.

Incident: An unplanned or uncontrolled instance of an occurrence, which causes [or has the potential to cause] injury, ill-health, and/or damage.

Legacy data refers to incidents whereby the specific category was not available prior to the upgrade of NIMS.

National Incident Management System (NIMS): Incidents [which include claims] are reported using the “National Incident Management System” [previously known as STARSWeb]. This is hosted by the State Claims Agency [SCA] for the HSE, other Healthcare enterprises and State Authorities. An incident can be a harmful incident [adverse event], no harm incident, near miss, dangerous occurrence [reportable circumstance] or complaint.

Outstanding estimated liability refers to the State Claims Agency’s best current estimate of the ultimate cost of resolving a claim, minus any payments already made. It includes all foreseeable costs such as settlement amounts, claimant legal costs and defence costs [such as fees payable to legal counsel, engineers, consultants etc]. Outstanding estimated liability may be revised on a regular basis in light of any new information received.

Severity Rating: These severity ratings are derived from the outcome of the injury at the time of the incident as listed in the table below.

Outcome at 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

Note: Monetary values and percentages in this report may be rounded.

1. FOREWORD

The Clinical Risk team is an integral part of the State Claims Agency (SCA) which has the responsibility for managing the Clinical Indemnity Scheme (CIS). The CIS indemnifies all doctors, nurses and allied health care professionals in delegated health care and other enterprises. The SCA is the name used by the National Treasury Management Agency (NTMA) when carrying out its claims and associated risk management functions.

The over-arching aim of this first dedicated *Clinical Incidents and Claims Report in Maternity and Gynaecology Services: a 5 year review 2010-2014*, is to help improve patient safety, quality of care and patient experience by outlining detailed clinical information over a 5 year period, to reduce the risk of occurrence of clinical incidents and harm and assist in promoting patient safety.

This dedicated national report of both clinical incidents and claims in Maternity and Gynaecology services tracks national data over a 5 year period; analyses the most common causes of clinical incidents and claims, compares and contrasts the 19 Maternity services nationally, in an anonymised manner, reviews the total expenditure incurred over time; provides a 10 year in-depth review of retained foreign bodies from analysis of closed medico-legal claims and outlines the results of a national survey of acute hospitals regarding the modes and patterns of incident reporting to the SCA.

Internationally, it is accepted, and the SCA concurs, that if a hospital has a high incidence of reporting patient safety incidents, this generally reflects a strong patient safety culture.

The quality of the data in this report reflects the quality of the data reported to the National Incident Management System (NIMS, formerly known as STARSWeb) by Maternity and Gynaecology services nationally.

This report aims to improve and make safer the patient journey by elucidating the facts clearly, highlighting variation in clinical incident reporting nationally, demonstrating detailed, national data pertaining to clinical incidents and clinical claims in Maternity and Gynaecology services, encouraging further review of opportunities for improvement, contextualising the national data by comparing and contrasting it with international data, and where appropriate, by stimulating further discussion and making risk management recommendations.

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2. EXECUTIVE SUMMARY

Aims

The aims of this first, dedicated, *Clinical Incidents and Claims Report in Maternity and Gynaecology Services: a 5 year review 2010-2014*, are:

1. To help improve patient safety, quality of care and patient experience by outlining detailed clinical information over a 5 year period, assist in the reduction of the risk of occurrence of clinical incidents and harm and help promote patient safety.
2. To present the available national data, adjusted for activity (e.g. birth rate), tracked over a 5 year period, and contextualise it by comparing and contrasting with international data, from medical and scientific journals and international reports, where appropriate.
3. To help stimulate further, focused discussion among all stakeholders involved in Maternity and Gynaecology services and assist in promoting further cohesive, national action regarding clinical risk reduction, improved patient safety and patient experience.
4. To help highlight potential target areas for postgraduate and undergraduate medical, midwifery and nursing education, in addition to education of all other health and social care professionals.
5. To encourage increased reporting of clinical incidents of all severities (including those resulting in harm and no harm), so that further trends and patterns in incident reporting may be identified earlier, risk recommendations may be provided more swiftly, and further clinical incidents and harm may be prevented.
6. To improve the quality of incident reporting by highlighting its importance.

What information does this report analyse?

This report:

- is a dedicated Maternity and Gynaecology services report providing detailed, national data on both clinical incidents and claims.
- tracks and analyses national, clinical incident and claims data pertaining to Maternity and Gynaecology services, over a 5 year period, 2010-2014, using a run chart format, to help identify patterns and trends.
- provides an in-depth analysis of the most common clinical incidents and most common and most costly clinical claims, pertaining to Maternity and Gynaecology services, adjusted for activity (e.g. birth rate), where available.
- contextualises national clinical incident and claims data pertaining to Maternity and Gynaecology services with international data, from peer reviewed medical scientific journals and national reports, where relevant. Published clinical national and international guidance on topics is referenced where appropriate.

- facilitates the anonymous comparing and contrasting of Maternity and Gynaecology services with other Maternity and Gynaecology services nationally, regarding incidents reported and claims created over a 3 year period, 2012–2014 inclusive.
- analyses the total transactional expenditure for Maternity and Gynaecology services nationally over a 5 year period and discusses in detail its core components and amounts involved in euro millions.
- performs a detailed review of a focused topic over a 10 year period: *“Retained foreign bodies in Maternity and Gynaecology services: a 10 year review of closed medico-legal claims”*, to identify lessons that may be learned and disseminate them to relevant stakeholders, in particular, front line workers.
- outlines and reviews results of the first *“National Survey of Modes and Patterns of Incident Reporting in Acute Hospitals in Ireland”* undertaken in the first half of 2015.

General

What we know:

Internationally, it is accepted, and the SCA concurs, that if a hospital has a high incidence of reporting patient safety incidents, then this generally reflects a strong **patient safety culture**.

It is a **statutory obligation** for healthcare services covered by the CIS to report adverse events to the SCA.

Increased reporting of clinical incidents, [involving harm and those involving no harm] should lead to **earlier identification of patterns and trends in clinical incidents**, to earlier risk management recommendations and hopefully earlier prevention of clinical incidents and harm, thereby improving patient safety.

This report has analysed data that was reported to NIMS by the Maternity and Gynaecology services and cannot comment on clinical incidents reported to separate reporting systems, which were not reported to NIMS.

Findings: What new information does this report provide?

Variation

Variation exists nationally regarding the modes and patterns of incident reporting, including the percentage of incidents reported to the SCA, the backlog of incidents that exists from a volume and time delay perspective, what incidents are reported and who makes the decisions to report these incidents.

Lack of uniformity

Lack of uniformity exists across services in relation to severity of injury ratings [impact scoring system], particularly in relation to incidents rated as *extreme*. This represents an opportunity for improvement. Internationally, this is a recognised area for improvement.

Quality of the data reported

The quality of the data in this report reflects the quality of the data reported on STARSweb, which was then migrated to NIMS. In certain instances, this quality is **suboptimal**.

Mis-categorisation

Mis-categorisation exists at times where clinical incidents are rated *extreme* but resulted in “no harm” to the patient.

Lack of consistency

Lack of consistency exists across Maternity services nationally regarding reporting of certain clinical incidents.

Comparisons are inaccurate

Overall, variation and lack of standardisation in incident reporting makes comparisons between Maternity and Gynaecology services inaccurate.

Under-reporting

Under-reporting of incidents exists nationally: 59% of new patient claims received in the first 6 months of 2015 had no previous patient safety incident reported to the SCA. Increased clinical incident reporting is encouraged. Internationally, under-reporting has been documented as an opportunity for improvement.

Maternity services

General

The 75 incidents rated as *extreme*, out of a total of 9,787 incidents, which occurred in Maternity services in 2014, underwent a detailed, manual and clinical analysis. Not all were true “*extreme incidents*”: some incidents pertained to “no injury” to the patient, while others pertained to death in infants, who, due to their extreme prematurity were incompatible with life, despite maximal medical intervention. Therefore the true number of extreme incidents which occurred in Maternity services in 2014 is less than 75.

Most common incidents in Maternity services which occurred 2010-2014 inclusive, reported to NIMS, in decreasing frequency

Maternity incidents were tracked over a 5 year period and compared to international figures where appropriate. Our national figures are not dissimilar to international figures, where available.

- **Other** is the most common incident category that occurred between 2010 and 2014. *Other* is the category used, when none of the known categories applied to the incident. Due to the fact that it is a free text category, it is difficult to extract information from it. This category should reduce further over time with the use of NIMS.
- **Post-partum haemorrhage**
Post-partum haemorrhage (PPH) has increased as an incident which occurred between 2010 and 2014. This is consistent with some international findings. National figures fall within the international range of published figures.

- **Perineal tear (3rd and 4th degree including breakdown of the perineum)**
Perineal tears have reduced since 2012 and are now closer to 2010 figures. Internationally, the published incidence varies. National figures lie within the published international range.
- **Apgars <5 at 1 minute, 7 at 5 minutes, cord base excess <12 and pH <7.2**
Occurrence of this incident has reduced significantly, almost halving, between 2010 and 2014.
- **Unexpected transfers to the special care baby unit (SCBU) or neonatal intensive care unit (NICU)**
Occurrence of this incident has increased between 2010 and 2014, which may reflect recent advancements in treatments and interventions in the rapidly advancing speciality of Neonatology. This pertains particularly to the survival of infants with extreme prematurity and very low birth weight.
- **Unplanned re-attendance**
Occurrence of this incident has increased between 2011 and 2014 and represents a significant workload for the Maternity services. Different models of out of hours primary medical care services and different Maternity service structures make this incident difficult to compare with international figures.
- **Shoulder dystocia**
Occurrence of this incident has reduced between 2012 and 2014. National figures fall below those reported in international studies.
- **Complications leading to transfer to the operating theatre post second stage of labour**
Occurrence of this incident has mildly reduced between 2010 and 2014. The majority pertained to manual removal of a retained placenta. National figures for the latter fall below the internationally published figures for developed countries.

Maternity Services Claims

Some claims in Maternity services are low in number but high in monetary value e.g. hypoxic ischaemic encephalopathy.

The **6 most common claims** created in Maternity services, 2010-2014 inclusive, excluding mass actions, included the categories of “other”, perineal tear; shoulder dystocia, stillbirth, unexpected neonatal death and cerebral irritability/neonatal seizure.

The **top 6 claims by monetary cost** created in Maternity services, 2010-2014 inclusive, included “other”, hypoxic ischaemic encephalopathy, cerebral irritability, apgars <5 at 1, 7 @ 5, cord BE <12, pH < 7.2, birth injury (including instrumental injury) and shoulder dystocia. Cost, for the purposes of this report, is defined as the total transactional expenditure plus the outstanding estimated liability.

Variation was identified when the 19 Maternity services nationally were compared and contrasted, in an anonymised manner, for incident rate per 1,000 live births, between 2012 and 2014.

Variation, but in a different pattern, was identified when the 19 Maternity services nationally were compared, anonymised, from a “claim created” perspective per 1,000 live births, between 2012 and 2014. Numbers are small and caution is recommended when reviewing. Continued surveillance of data is critical.

Gynaecology services

- There were 11 Gynaecology services incidents reported as *extreme* in severity in the year 2014, out of a total of 1,403 incidents reported.
- **Delayed/cancelled surgery**
This incident has increased 10 fold between 2010 and 2014. This warrants further analysis by services and continued surveillance.

The most common incidents which occurred in Gynaecology services, adjusted for activity, were in decreasing order:

- **Other**
Other is the most common incident that occurred in Gynaecology services [see earlier] and refers to a category used when none of the known categories applied to the incident, prior to the upgrade to NIMS,. This category is expected to reduce with increased use of NIMS. Information from individual incident reports was reviewed.
- **Unplanned re-attendance**
This increased as an incident which occurred between 2010 and 2014. This may reflect changing patterns of attendance at secondary rather than primary care services, [due to changes in out of hours services in the latter], increased awareness of reporting, change in clinical care, or a combination of some or all of the above.
- **Healthcare records missing/misplaced, incomplete records and incorrect data**
Overall the combined figure for these incidents which occurred reduced from 2010 to 2014. An electronic healthcare record may resolve some of these difficulties.
- **Patient falls without supervision**
Occurrence of this incident has decreased from 2011 to 2014. This may be related to work performed through the National Falls and Bone Health Project, AFFINITY [Activating Falls and Fracture Prevention In Ireland Together] programme, which is a joint programme between the SCA and the HSE.
- **Failure/faulty medical device/equipment**
Occurrence of this incident has increased between 2010 and 2014, though a significant proportion of this increase pertained to a temporary issue with a clinical information system at one Maternity service.
- **Delayed/cancelled surgery- as above**
- **Unexpected complications following an operation/surgical procedure**
There has been a relatively small increase in the occurrence of this incident from 2010 to 2014.
- **Unintentional punch/laceration of an organ**
Occurrence of this incident has reduced between 2010 and 2014 and is a recognised complication of surgery in Gynaecology.

The 6 most common and 6 most costly claims created in Gynaecology services, excluding mass actions, were plotted over time. Overall numbers were relatively small.

Variation was identified when the 19 co-located Gynaecology and Maternity services nationally were compared, in an anonymised manner, from an "incident count" and claim created perspective over a 3 year period: 2012-2014 inclusive. Three services had no claims in Gynaecology created over this time.

Total transactional expenditure in Maternity and Gynaecology services

Total transactional expenditure reflects payments made in a given year. These payments include professional fees, awards and expenses.

Total transactional expenditure in Maternity services

- Total transactional expenditure on Maternity services related claims in 2014 [of which 98% were clinical] was €58 million.
- Total transactional expenditure paid on clinical claims in Maternity services was 54% of all clinical care related claims in the year 2014 [€106 million].
- Total transactional expenditure on Maternity services related claims has increased 80% from €32 million in the year 2010 to €58 million in 2014.
- Total transactional expenditure on clinical care related claims has increased 44% from €74 million in the year 2010 to €106 million in 2014.

Total transactional expenditure on cerebral palsy claims

- Total transactional expenditure paid on cerebral palsy claims in 2014 was €47million, which is 82% of the total expenditure on clinical claims in Maternity services in 2014 and 45% of the total expenditure in respect of all clinical care claims [€106 million].
- Total transactional expenditure paid on cerebral palsy increased 77% from €26.7 million in 2010 to €47 million in 2014.
- This increase is explained by the fact that during the relevant time period, some Periodic Payment Orders (PPOs) converted to “catastrophic injury lump sum payments”, some “returnable PPO” claims were revisited before the courts and in other cases families specifically requested lump sum settlements.

Total transactional expenditure paid on Gynaecology services related claims

- Total transactional expenditure on clinical claims in Gynecology services was €4.2 million in 2014, which accounted for 4% of the total transactional expenditure on clinical claims in 2014. Expenditure on claims in Gynaecology has increased almost 3 fold in 5 years from €1.4 million in 2010.

Retained foreign bodies in Maternity and Gynaecology services: a 10 year review of closed claims

There were 30 closed claims for retained foreign bodies in Maternity services and 14 in Gynaecology services between 2004 and 2014.

National and international recommendations to prevent the occurrence of retained foreign bodies include; implementation of clinical handover, implementation of specific counting protocols, use of radiopaque and tailed swabs, swab count reconciliation, clear documentation of swab, needle and instrument count, review of all cases of retained foreign body with dissemination of feedback regarding causal and contributing factors to front line staff, and audit and tracking of implementation of policies, protocols, guidelines and learning from claims. Ongoing education at undergraduate and postgraduate level regarding retained foreign bodies is recommended together with regular, multi-phased education and training of front line staff within hospitals. Some or all of these recommendations have been implemented in the Maternity and Gynaecology services nationally. Continued vigilance is required.

Results of the national survey regarding the modes and patterns of incident reporting in acute hospitals in Ireland in 2015

The majority (n=49, 96%) of acute hospitals, nationally, in the first quarter of 2015 reported to NIMS, one (2%) did not. This has since been rectified.

Six (12%) acute hospitals **dual report** i.e. they report to 2 incident reporting systems, which is inefficient.

Five (10%) acute hospitals send all their incidents to an **offsite, central location** from where the incidents are then entered on an incident reporting system.

Administrators log the data pertaining to incidents in the majority (n=40, 80%) of acute hospitals nationally.

A **quality, safety and risk manager** decides what incidents are reported on NIMS in the majority (n=33, 66%) of acute hospitals, nationally.

The majority of acute hospitals (n=34, 68%) use **“a list”** to identify which incidents should be reported to NIMS. All incidents should be reported.

Nine (18%) acute hospitals, **report to the SCA, only 50% or less than 50% of the incidents** notified to them. The majority (n=38, 76%) of acute hospitals responded that they report between 75-100% of incidents to the SCA.

In the majority (n=34, 68%) of acute hospitals, one month is the **“delay time”** before an incident, notified to an acute hospital, is reported to the SCA. Of these 34, 16 (32%) acute hospitals notify the SCA within 1 week, 13 (26%) within 2 weeks and 5 (10%) within 4 weeks.

A **backlog** of incidents to be notified to the SCA exists in just over half of acute hospitals (n=26, 52%) nationally. The volume of the backlog is less than 100 incidents in 12 hospitals but greater than 500 in 6 hospitals.

While the majority (n=45, 90%) of acute hospitals responded that it is a **statutory obligation** to report adverse events to the SCA, 5 (10%) did not.

Variation exists nationally across the acute hospitals regarding different modes and patterns of reporting incidents to SCA.

Future: How will the SCA’s clinical risk team make improvements?

- Further **encourage clinical incident reporting of all severities**: including harm and no harm, through education and training provided by the clinical risk team.
- Further encourage and support **more uniformity** across services regarding reporting of **severity ratings**, through education and training provided by the clinical risk team.
- Encourage all healthcare services to **send copies of investigation reports** pertaining to extreme and major incidents and serious reportable events (SREs) to the clinical risk team so that lessons learned and risk management recommendations can be disseminated in an anonymised fashion, nationally, to front line workers and all stakeholders to help prevent occurrence of further clinical incidents and improve patient safety.

- Earlier identification of **patterns and trends in clinical incidents** of minor, negligible and near miss severity with development of risk management recommendations to help prevent clinical incidents causing harm and help improve patient safety.
- Further **improve communication** between the clinical risk team and all stakeholders through increased face to face meetings; providing detailed information on clinical incidents and claims through further publication of reports; offering risk management recommendations and feedback from lessons learned through investigation reports received; further facilitating real time communication regarding trends and patterns in clinical incidents; communicating comparisons of national clinical incidents and claims data with international figures, providing further education and training sessions; providing further support and advice by phone, e-mail, website and hospital site visits, and providing detailed information on specific topics at invited talks at both an institutional and national level.
- Adopt a **more proactive approach** in high risk areas e.g. Maternity services; further review of international practices and lessons learned that have led to reduction in clinical incidents, and further analysis of specific factors that influence court decisions regarding liability.
- Further detailed review of **focused topics** by analysis of clinical negligence settled claims for common causal and contributing factors. Disseminate lessons learned to all stakeholders, present results at national and international scientific medical meetings and publish in peer reviewed scientific journals, where appropriate.
- Ongoing **education and training sessions** on Open Disclosure, incident reporting, systems analysis investigation and documentation
- **Post graduate medical education:** Write and deliver a post graduate medical clinical risk and medico-legal course at the Royal College of Physicians of Ireland [RCPI], September 2015 [completed] and April 2016.
- **Continued collaboration** with the HSE, in two national programmes, **Open Disclosure** and **AFFINITY**.

3. INTRODUCTION

This dedicated Maternity and Gynaecology services report provides national data on both clinical incidents and claims, over a 5 year period [2010-2014]. It provides a detailed analysis of the most common clinical incidents and claims and the most costly clinical claims, for these services. It compares data to published international figures and compares and contrasts the 19 Maternity services nationally in an anonymised manner from both an incident and claims perspective. Additionally, it reviews total expenditure paid, in detail for both services.

A 10 year review of closed medico-legal claims pertaining to retained foreign bodies in Maternity and Gynaecology services was performed and the results and recommendations are outlined.

Results of a “*National survey of modes and patterns of incident reporting in acute hospitals In Ireland 2015*” are discussed.

The over-arching aim of this dedicated Clinical Incidents and Claims Report in Maternity and Gynaecology Services, is to help improve patient safety, quality of care and the patient experience by outlining detailed clinical information over a 5 year period to assist in the reduction of occurrence of clinical incidents and harm and promote patient safety.

Throughout this report, we have been mindful of the journey taken by mothers, their babies and women who were unwell.

Reviewing both incidents and claims permits assessment as to whether clinical incidents which occurred in the past are continuing to recur, are reducing or increasing in frequency, or appear to have resolved. This report focuses on specific, target areas within Maternity services, a high risk speciality, where opportunities for improvement remain nationally. A number of significant reports^{2,3,4,5} pertaining to Maternity services in Ireland have been published recently.

From 1st February 2004, the Clinical Indemnity Scheme [CIS] inception cover for consultant doctors. Internationally, the CIS may be considered “immature” in terms of its development as a clinical negligence scheme, by virtue of its early years post development. Knowing that claims often take a number of years to evolve, it is timely that a 5 year review has now been undertaken.

This report:

- Analyses national clinical incident data in Maternity services for the year 2014 and compares it to national data for the years 2010-2013.
- Contextualises national clinical incident data in Maternity services by comparing and contrasting it with international data from peer-reviewed medical scientific publications and national reports, where relevant.
- Reviews national clinical claims data in Maternity services for the year 2014 and compares it to national data from the years 2010-2013.
- Compares and contrasts the 19 Maternity services nationally from a clinical incident and claims perspective, over a 3 year period, 2012-2014, in an anonymised fashion.
- Analyses Gynaecology services in a similar detailed manner to Maternity services, as outlined above.

- Reviews a focused topic: *“Retained Foreign Bodies in Maternity and Gynaecology Services: a 10 year review of closed medico-legal claims.”*
- Outlines the results of the first *“National Survey of modes and patterns of Incident Reporting in Acute Hospitals in Ireland”*, undertaken in the first half of 2015.
- Outlines the future aims of the clinical risk team at the SCA.

National Incident Management System (NIMS) and STARSWeb

The SCA upgraded STARSWeb to NIMS in June 2014. NIMS is an end to end risk management tool that enables all healthcare and state authorities delegated to the SCA, to manage clinical and non-clinical incidents. Currently, NIMS is being implemented nationwide to the acute hospitals and community healthcare organisations [CHOs]. As part of the upgrade to NIMS, a new taxonomy consistent with the World Health Organisation [WHO]⁶ was introduced to facilitate more consistent reporting. Additionally, certain fields have become mandatory e.g. date of birth.

Throughout this report, the term *“legacy data/not known”* and the category *“other”* will be encountered. Legacy data refers to incidents whereby the specific category was not available prior to the upgrade to NIMS. *“Other”* refers to a category used, when none of the known categories applied to the incident. Due to the fact that it is a *“free text”* category, it is therefore difficult to extract information from it. It is envisaged that once all healthcare and social care enterprises are reporting patient safety incidents directly onto NIMS, both *“legacy data”* and the category of *“other”* should reduce significantly. In the interim, the data contained in this report reflects data collected on the STARSWeb system which was then migrated over to NIMS. Over time, it is expected that superior quality data pertaining to severity of injury and injury types will be available.

Tables and figures [graphs] for the most common and most costly incident and claim types in Maternity and Gynaecology services are compiled using a category of *“please specify”* on NIMS. This field is a free text field and has some limitations regarding accuracy but provides the reader with the best available data at this point in time [run date of 11st June 2015]. The use of NIMS by healthcare enterprises should improve the quality of data reported to the SCA. All tables and figures [graphs] from NIMS are as at 11th June 2014.

The incidents and claims in this report refer to incidents which *“occurred”* and claims which were *“created”* during the time frames quoted. For the purposes of this report an *“incident which occurred”* is defined as an incident which occurred and was notified to SCA. Clearly, incidents could have occurred which were not notified to the SCA or may be notified in the future.

4. MATERNITY SERVICES

Clinical incidents, claims and total expenditure

4.1 INCIDENTS IN MATERNITY SERVICES IN 2014

4.1.1 Background

In 2014, a total of 9,787 incidents occurred in Maternity services which were notified to NIMS, of which 9,397 (96%) were clinical. The severity of an incident is based on the actual outcome or injury at the time of occurrence of the incident. The NIMS classification of severity is based on the HSE Risk Assessment Tool ⁷, which includes 5 categories: extreme, major, moderate, minor and negligible. One difference is that NIMS separates the extreme category into two: death and permanent incapacity, which incorporates psychosocial injury.

4.1.2 Severity rating of incidents in Maternity services in 2014

Regarding severity rating of the incidents which occurred and were notified to NIMS, the largest subset was severity rating “not known” or “legacy data” of injury, which contained 6,832 (70%) incidents. Legacy data refers to incidents whereby the specific category was not provided or utilised in STARSWeb prior to the upgrade to NIMS. Severity of injury was not a mandatory field on the STARSWeb system resulting in the majority of cases not being categorised by those inputting data. It is not always possible to know the severity of the injury at the time of occurrence of the incident and this may only become apparent over time. However, where possible, reporting the severity of the injury is useful.

Seventy five incidents (0.77% of total maternity incidents) were reported as extreme, 10 (0.1%) as major, 1,240 (13%) as moderate and 1,630 (17%) as either minor or negligible (Figure 1).

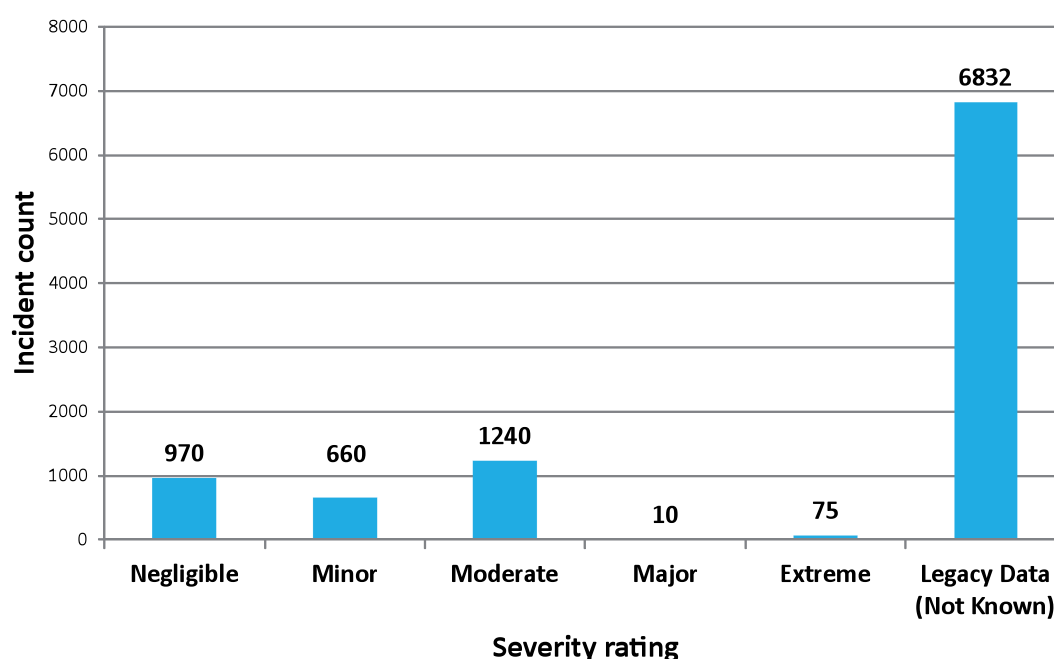


Figure 1: Severity rating of incidents in Maternity services which occurred in 2014

4.1.2.1 Incidents rated extreme and major severity

A breakdown of the 75 incidents in Maternity services rated *extreme* and the 10 rated *major* based on “type of injury” category on NIMS is provided in Table 1 below.

Severity Rating	Type of Injury	No. of Incidents
Extreme		
	Cut/Laceration/Graze/Scratch	1
	Death	6
	Haemorrhage	2
	Deterioration	5
	Neonatal death	7
	Stillbirth	17
	No Injury	2
	Other	10
	Legacy Data [Not Known]	21
	None	4
Extreme Total		75
Major		
	Legacy Data [Not Known]	10
Total Extreme & Major Incidents		85

Table 1: Incidents in Maternity services, which occurred in 2014, categorised by severity rating and type of injury.

4.1.2.2 Incidents rated extreme

Further reports were run to elucidate more detailed information pertaining to these incidents rated *extreme* in severity. This required manual, detailed, clinical analysis of the actual text submitted by the services, in respect of each individual incident to identify the following detail.

Of the 75 incidents rated *extreme*, 1 was reported by the Maternity service in duplicate using different NIMS numbers and was therefore eliminated. Review of the remaining 74 *extreme* and 10 *major* incidents, identified that they were reported by 13 of the 19 Maternity services nationally, with the exception of 2 *extreme* incidents, where the location was unclear but was subsequently identified by the clinical risk team [Figure 2].

The 74 *extreme* incidents were divided on manual, clinical review into 3 categories: maternal (n= 21, 28%), baby (n=48, 65%), and other (n=5, 7%), [Figure 2]. All were categorised as clinical.

Maternal

Regarding the clinical incidents rated as *extreme*, related to mothers, 4 incidents related to deaths: of which 3 occurred in hospital and 1 in the community after delivery, details of which were clarified by the clinical risk team because the final outcome was unknown at the time of incident being reported. There were 17 other *extreme* incidents reported, including: vaginal bleed, post-partum haemorrhage, uterine rupture, third degree tear with blood loss and emergency caesarean section [Figure 2].

Baby

Regarding the clinical incidents rated as *extreme*, relating to babies; 38 related to deaths in-utero or post-delivery, of which 9 were less than 24 weeks gestation, and/or had a birth weight of less than 500 grams. One baby had a congenital anomaly in this group. Twenty three deaths were of greater than or equal to 24 weeks gestation [perinatal deaths], of which 5 had congenital anomalies including spina bifida, trisomy 18, absent corpus callosum, atrial septal defect and multi-cystic kidneys. Some babies had multiple anomalies. Six of the baby deaths which occurred and were notified to NIMS had no information included regarding the gestational age or the birth weight [Figure 2].

Regarding the non-fatal *extreme* clinical incidents pertaining to the baby (n=10, 13.5%), this group included: babies transferred to a tertiary centre for neonatal hypothermia treatment, transfer to the neonatal intensive care unit (NICU), incorrect dose of medication, undiagnosed breech and lack of monitoring by cardiotocography (CTG).

Other

Regarding the “*other group*”, 3 incidents were related to healthcare records which were partially or wholly unavailable, 1 incident pertained to communication and 1 incident to unlabelled specimens.

Six of these clinical incidents [Table 1] rated as extreme, had “no injury/none” reported and are therefore mis-categorised as “*extreme*”.

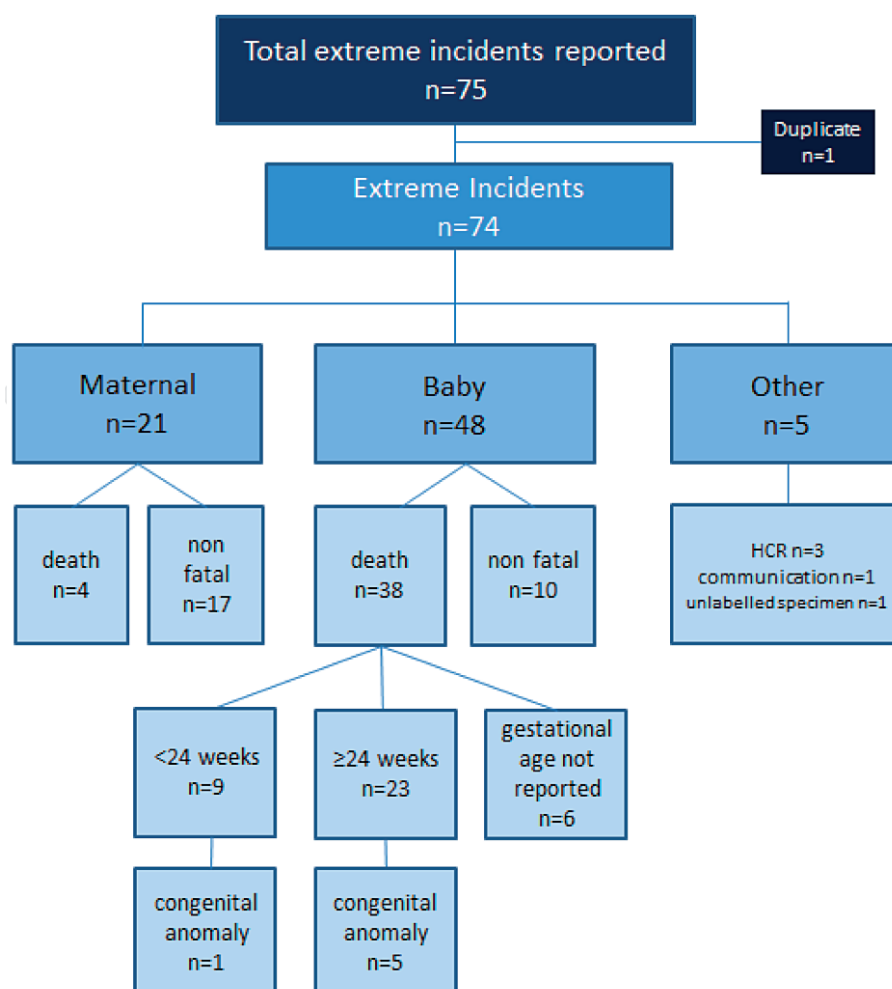


Figure 2: Clinical incidents rated extreme in severity which occurred in 2014 in Maternity services.

Note: Although some infants are born less than 24 weeks gestation with a heartbeat, and therefore are “born alive”, sadly, due to their extreme prematurity, they are not generally capable of survival outside the womb, despite maximal medical intervention. The gestational age at which a baby is capable of survival is reducing over time as medical therapies and interventions advance.

4.1.2.3 Clinical incidents rated major

A review of the 10 clinical incidents in Maternity services, with a severity rating of *major* under the “type of injury” field in NIMS, revealed type of injury “not known” (Table 1). Detailed, manual analysis of individual incident text identified the following: 3 incidents related to the mother [a third degree tear, a post-partum haemorrhage and an early self-discharge], 2 incidents related to the baby [reported as an “intrauterine death” and a cord prolapse with satisfactory baby outcome], 2 incidents pertained to equipment [a ventilator and availability of TED stockings], 2 related to outpatient appointments [the timing and an investigation result] and 1 incident was a duplicate entry reported to NIMS (Figure 3).

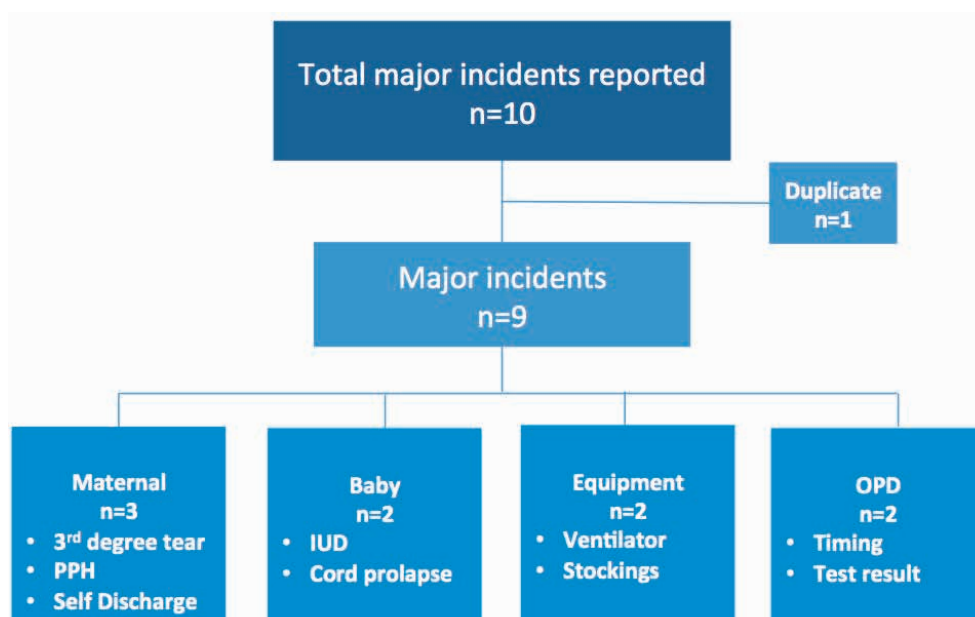


Figure 3: Clinical incidents rated major in severity which occurred in 2014 in Maternity Services

4.1.2.4 Perinatal and Maternal Mortality

The Perinatal Statistics’ Report⁸ provides detail regarding perinatal mortality in Ireland which has fallen from 8.1 per 1,000 live and still births in the year 2004, to 6.3 per 1,000 in the year 2013. This represents a 22.2% decrease over the decade.

The Confidential Enquiry into Maternal Deaths (CEMD), a programme investigating Maternal Death in the UK and Ireland, has, since June 2012, been carried out by the MBRRACE-UK (Mothers and Babies Reducing Risk through Audits and Confidential Enquiries) collaboration, commissioned by the Health Care Quality Improvement Partnership, HQIP.

The report, *Saving Lives, Improving Mother’s Care*⁹, published in December 2014, [Lessons learned to inform future Maternity care from the UK and Ireland, Confidential Enquiries into Maternal Death and Morbidity 2009-2011], identified that the mortality rate per 100,000 maternities by triennium, 2009-2011 is 10.63. The rate of maternal deaths in the UK has decreased from 11.39 in 100,000 women giving birth between the years 2006-2008. This is largely due to a decrease in direct maternal deaths, but not indirect deaths i.e. death from chronic medical conditions such as heart disease, neurological or mental health conditions.

4.1.3 Incident occurrence by month of year

The peak incident rate per 1,000 live births in Maternity services which occurred in 2014, does not coincide with the changeover of non consultant hospital doctors (NCHDs) in the months January and July. This finding is consistent with analyses of previous years' data [Figure 4].

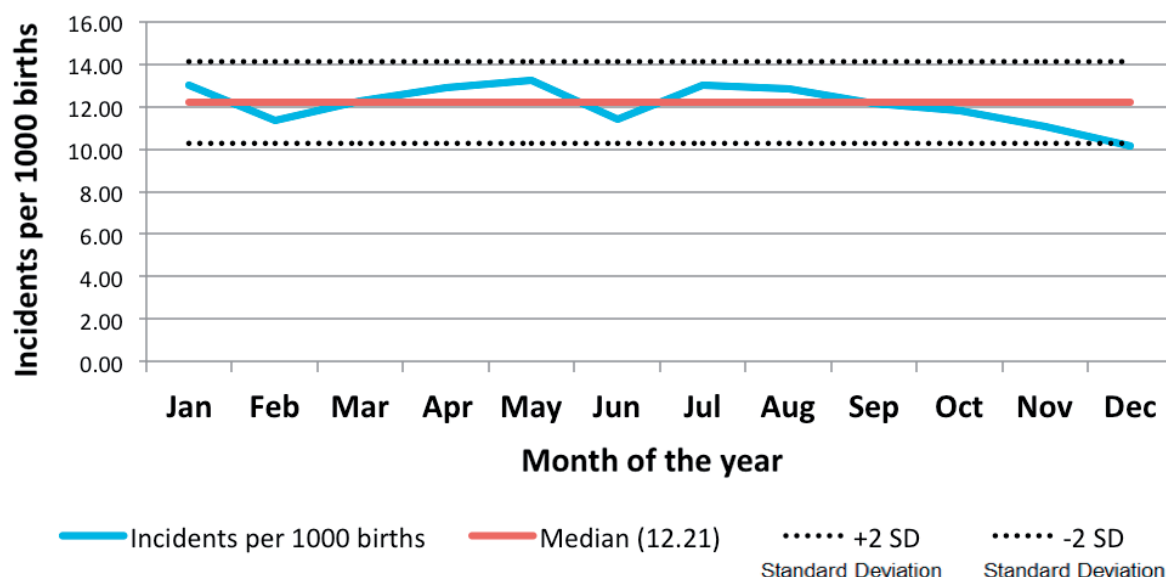


Figure 4: Incident rate per 1,000 live births which occurred in 2014 by month of year

4.2 INCIDENTS IN MATERNITY SERVICES 2010-2014

4.2.1 Severity rating of incidents in Maternity services which occurred, 2010-2014 inclusive

A review of the severity rating of incidents which occurred during the years 2010-2014 inclusive, identified that "not known/legacy data" dominated annually [Table 2]. The number of incidents reported in the extreme category peaked at 196 in the year 2010 and was mainly related to healthcare records from one Maternity service (n=119). Subsequently, this reduced to 67 in 2011 and then increased to 75 in 2014. Changes in patterns of reporting, improved quality of reporting and changes in clinical practice may all have contributed to this increase.

	Extreme	Major	Moderate	Minor	Negligible	Legacy Data/Unknown	Total
2010	196	3	1243	512	449	7665	10068
2011	67	2	965	734	487	7220	9475
2012	27	2	915	785	387	7674	9790
2013	56	0	1386	889	484	7423	10238
2014	75	10	1240	660	970	6846	9801

Table 2: Severity rating of incidents in Maternity services that occurred, 2010-2014 inclusive

4.2.2 TEN MOST COMMON INCIDENTS IN MATERNITY SERVICES WHICH OCCURRED, 2010-2014 INCLUSIVE

The ten most commonly occurring incidents in Maternity services in the years 2010-2014 inclusive, categorised by “incident type/please specify” on NIMS, together with numerical values were identified [Table 3]. As outlined earlier in this report, the category of “please specify” utilises free text and, therefore, has some limitations regarding accuracy, but is the best category currently available to provide clinical detail.

The “other” category, which is the most common, relates to incidents which occurred in Maternity services outside the offered “incident type” categories [see earlier explanation]. Further analysis of this category for 2014, revealed that the severity rating was very poorly populated for this category, as previously discussed. This emphasises the importance of the severity of injury being reported. Over time, it is anticipated that the “other” category should decrease when all services report incidents on NIMS.

Ten most common Maternity incidents, 2010-2014 inclusive	Total incident count
Other	9,469
Post-partum haemorrhage	4,322
Perineal tear [3rd & 4th Degree] [incl. breakdown of perineum]	3,695
Apgar <5@1, 7@5, cord BE <12, pH<7.2	3,544
Unexpected transfer to SCBU/NICU	3,233
Shoulder dystocia	1,927
Unplanned re-attendance	1,919
Complications -> transfer to operating theatre post 2nd stage	1,392
Legacy data/not known	1,092
Clinical records missing/misplaced	930
Total	31,523

Table 3: Ten most common incidents in Maternity services which occurred 2010-2014 inclusive

4.2.3 Most common incidents in Maternity services, tracked over 5 years, 2010-2014 inclusive

The top 7 most commonly reported incidents which occurred in Maternity services and were notified to NIMS were analysed in further detail. They were tracked over a 5 year time period, 2010-2014, to assess trends and patterns [Figure 5]. This data excludes mass actions. This analysis demonstrated that the “other” group remained the most common clinical incident which occurred in Maternity services over this time period and while it reduced from 2010 to 2011, it has been relatively stable since. Further analysis identified that in 2014, there were 1,647 incidents categorised as “other” some of which included incidents pertaining to caesarean section, haemorrhage, pain, delayed procedure, consent, prescriptions, emergencies and monitoring of the baby. Regarding total incident count reported between 2010 and 2015: post-partum haemorrhage (PPH) and unplanned re-attendance have increased in number, while perineal tear (3rd and 4th degree), unexpected transfer to the SCBU or NICU have remained relatively stable. The group with low apgars and low pH have decreased in number.

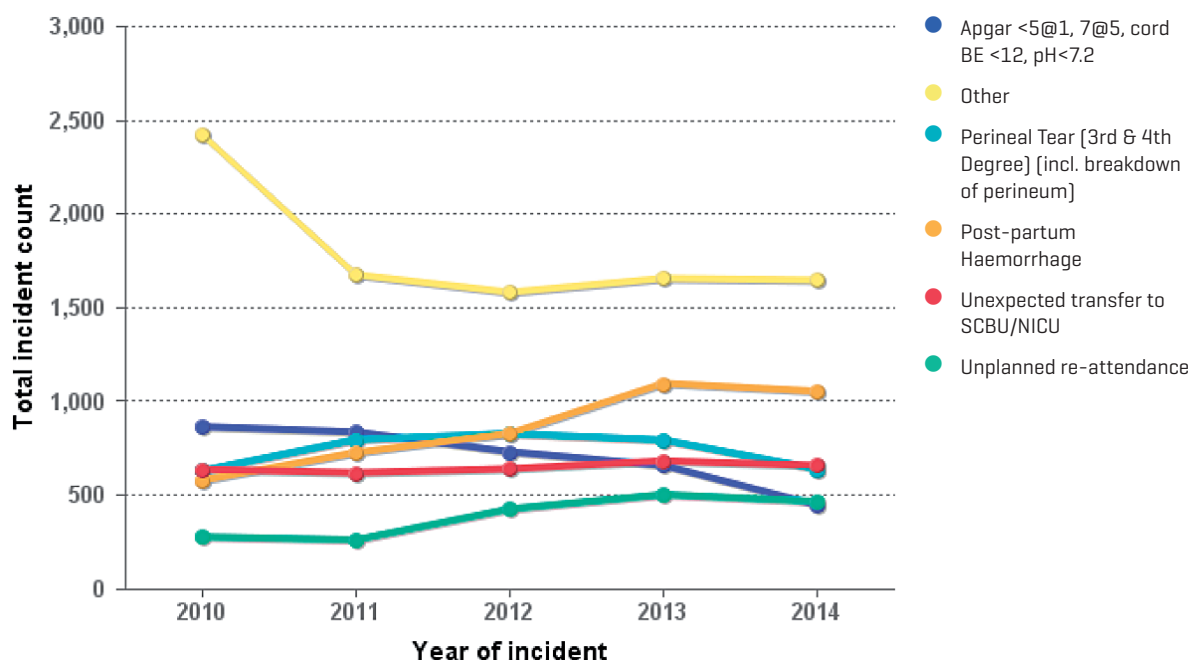


Figure 5: Six most common incidents tracked over 5 years, 2010-2014 inclusive, in Maternity services, excluding mass actions

4.2.4 Detailed analysis of the most common incidents in Maternity services 2010-2014 inclusive

The total incident count was divided by the total number of births in the 19 Maternity services in the years 2010 to 2014. The latter figures were obtained from the Health Service Executive^{10, 11, 12} rather than the Perinatal Statistics Reports,⁸ because the latter includes home births and births in private hospitals.

4.2.4.1 Post-partum haemorrhage

Post-partum haemorrhage, reported to NIMS per 1,000 live births, which occurred between the years 2010-2014 inclusive, has steadily increased with a peak in the year 2013 of 16/1,000 births (Figure 6). Globally, the incidence of post-partum haemorrhage is increasing in high resource settings, the reasons for which are unclear^{13,14}. Weeks et al¹⁵ suggested that an understanding of the differences in post-partum haemorrhage after “normal” and “complicated births” could explain temporal changes in its incidence. This group suggests that slowly rising post-partum bleeds in well-resourced settings may be explained by rising rates of birth intervention and risk factors. Risk factors include obesity, previous post-partum haemorrhage, multiple pregnancy, anaemia, macrosomia, age over 40 years, induction of labour, prolonged labour, placental abruption, caesarean delivery, and Asian ethnicity¹⁶. Primary post-partum haemorrhage is the most common form of major obstetric haemorrhage and is defined as the loss of 500mls or more of blood from the genital tract within 24 hours of the birth of a baby¹⁷. Post-partum haemorrhage is estimated to affect 1-15% of vaginal births, depending on the definition used, the method of assessing blood loss, the setting and the population studies¹⁵. Mortality from post-partum haemorrhage is decreasing worldwide¹⁵.

Guidance

National: A clinical practice guideline on the Prevention and Management of Primary Post-partum Haemorrhage [at the time of birth] was published by the Royal College of Physicians of Ireland¹⁸ and the Directorate of Strategy and Clinical Programmes Health Service Executive in October 2012.

International: The Society of Obstetricians and Gynaecologists of Canada¹⁹ and the Royal College of Obstetricians and Gynaecologists UK¹⁵ published a guideline pertaining to PPH in 2000 and 2009 respectively while the National Institute for Health and Care Excellence [NICE] published guidance in 2007 and updated it in 2014²⁰.

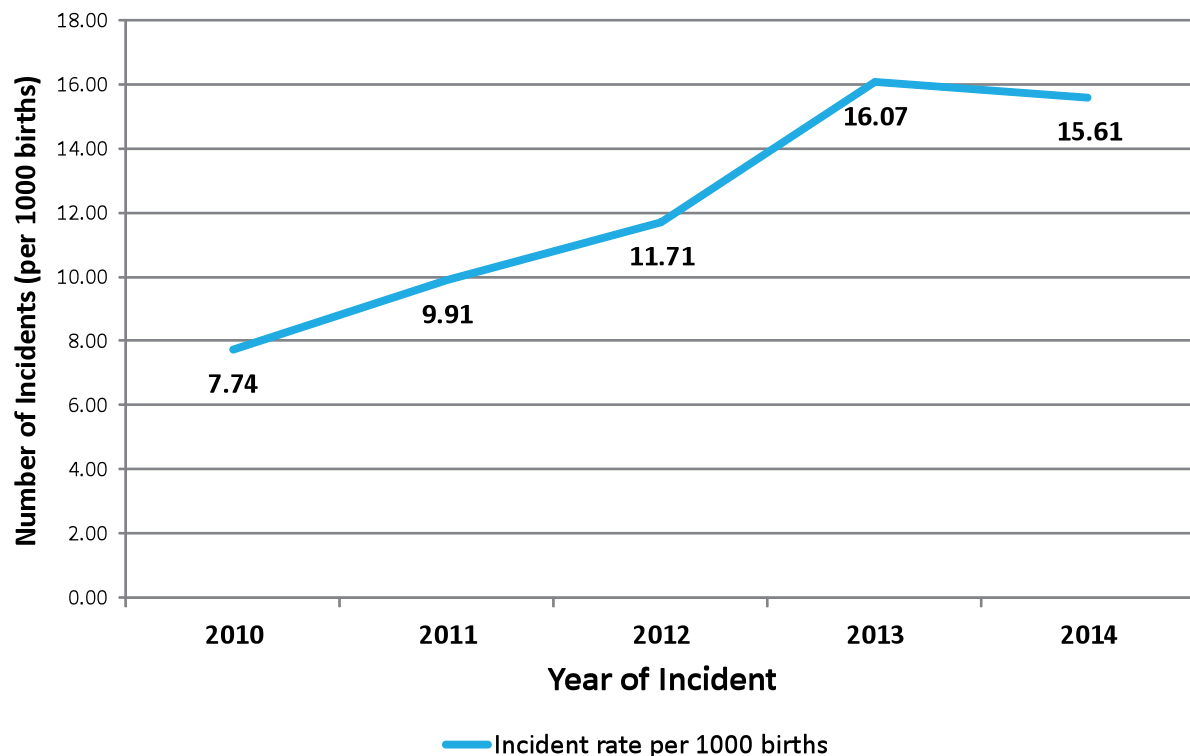


Figure 6: Post-Partum Haemorrhage per 1,000 births which occurred 2010-2014 inclusive

4.2.4.2 Perineal Tear (3rd, and 4th degree including breakdown of the perineum)

Perineal tear (3rd and 4th degree including breakdown of the perineum) reported per 1,000 births in the years 2010-2014 inclusive, appears to have peaked in 2012 and decreased since then with 9.44 per 1,000 births reported in 2014 [Figure 7]. The incidence of perineal trauma varies markedly between studies with occurrence tending to be higher in hospital compared with community settings²¹. It may be associated with significant morbidity including faecal incontinence, chronic perineal pain and dyspareunia²².

Clinical diagnosis of obstetric anal sphincter injury [OASIS] comprising a third or fourth degree tear, occurs in approximately 3% of women after delivery of their first baby, and 0.8% of women who have previously delivered at least one baby²³. However, results from a systematic review from 2008, indicate that the incidence may be as high as 11%²⁴. A large prospective observational UK study published in 2013, identified that OASIS occurred in 6.6% [86/1,302] of nulliparae and 2.7% [33/1,452] of multiparae overall, and occurred mainly in hospitals²⁵. Known risk factors are instrumental delivery [forceps associated with a higher risk than ventouse], longer duration of second stage of labour, large birth weight, and occipito posterior position²⁵.

Guidance

International: NICE [2014]²⁰, the RCOG UK [2015]²⁶ and the National Patient Safety Agency [NPSA]²⁷ have guidance in place for assessment and repair of perineal trauma.

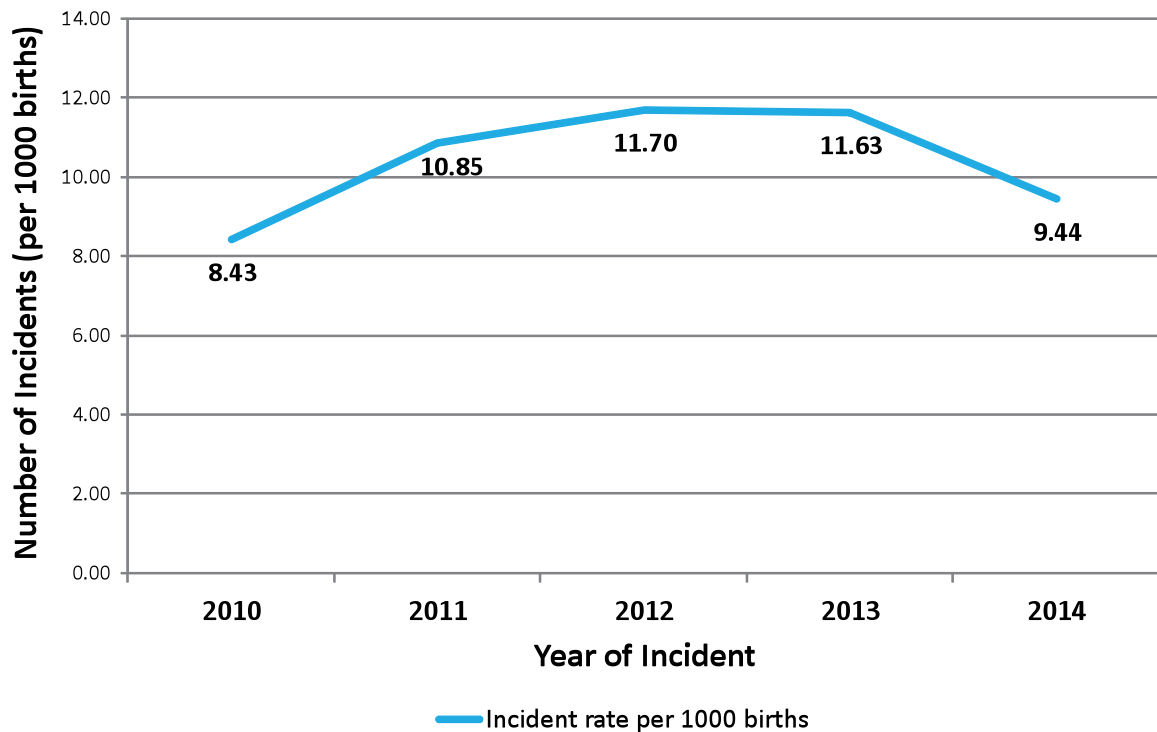


Figure 7: Perineal Tear (3rd & 4th degree including breakdown of the perineum) per 1,000 births, which occurred, 2010-2014 inclusive

4.2.4.3 Apgar score < 5 at 1 minute, 7 at 5 minutes, cord base excess <12 and pH <7.2

The number of incidents reported, with apgar score < 5 at 1 minute, 7 at 5 minutes, cord base excess <12 and pH <7.2 which occurred in the years 2010 to 2014 per 1,000 births, has almost halved [from 862 in 2010, to 444 in 2014][Figure 8]. This was not associated with an increase in hypoxic ischaemic encephalopathy [HIE] or cerebral irritability incidents, both of which have significantly smaller numbers. This suggests the decrease noted may not be related to re-categorisation but rather may be related to improved clinical care, patterns of reporting or a combination of both [see later].

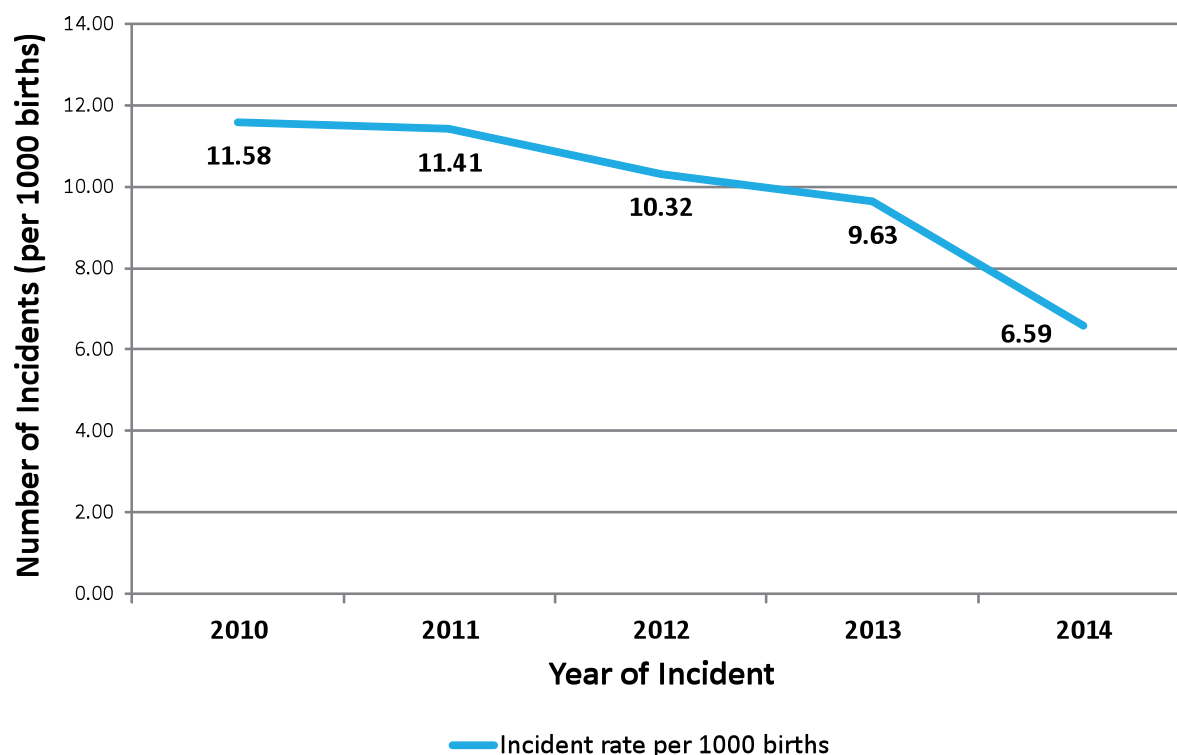


Figure 8: Apgar score <5@1, 7@5, cord BE<12, pH<7.2 per 1,000 births which occurred, 2010-2014 inclusive

4.2.4.4 Unexpected transfers to the Special Care Baby Unit (SCBU) or Neonatal Intensive Care Unit (NICU)

Neonatology is a rapidly evolving speciality. Premature birth is a significant cause of infant and child morbidity and mortality.

Unexpected transfers to the SCBU or NICU reported per 1,000 births have increased slightly between the years 2010 to 2014 (Figure 9). This increase is not surprising considering recent, rapid advancements made in neonatal medical interventions and treatments e.g. neonatal therapeutic hypothermia. Despite technological advances and efforts of child health experts over recent years, the extremely premature infants [less than 28 weeks gestation] and extremely low birth weight infants [<1,000g] remain high risk for death and disability, with 30-50% mortality and in survivors, at least 20-50% risk of morbidity²⁸.

Further analysis of the year 2014 (n=655 incidents) identified that a significant proportion were related to prematurity, caesarean sections [planned or emergency] respiratory distress, low birth weight in addition to requirement for antibiotics, macrosomia and low blood sugar.

The establishment of the National Neonatal Transport Programme (NNTP) on a 24/7 basis over the last few years is a significant step forward. NNTP provides a high quality standardised retrieval service for the stabilisation and transportation of premature and sick neonates to regional, neonatal and surgical intensive care units, in, from and to Ireland.

The increased rate of admission to SCBU/NICU likely reflects national and international practice of improved survival in infants with extreme prematurity and very low birth weight. Additionally, increased awareness of reporting may be a factor.

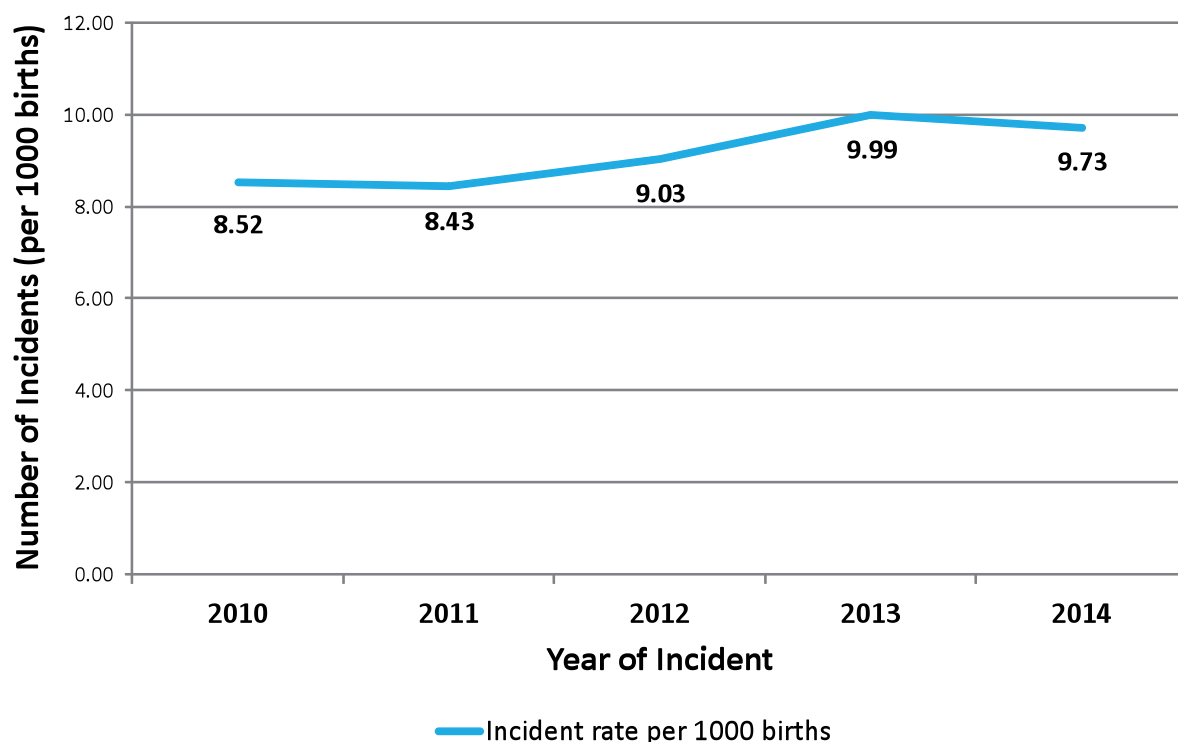


Figure 9: Unexpected transfers to the SCBU/NICU per 1,000 births which occurred, 2010-2014 inclusive

4.2.4.5 Unplanned re-attendance

Unplanned re-attendance has increased from 3.68 to 6.87 per thousand live births, between the years 2010 and 2014 (Figure 10). Detailed review identified incidents pre and post-delivery: the latter pertaining to both mother and baby. Infection (wound and urinary), pain, bleeding, poor feeding, Evacuation of Retained Products of Conception (ERPC), phototherapy for jaundice and weight loss were included in the incidents reported in 2014 (n= 463). Despite further analyses, no obvious causes were identified to explain the increase since 2010 (n= 274).

Direct clinical presentations to secondary care, that could have been managed in primary care have been the subject of much study. Previously, an Irish study documented that attendance at a maternity hospital emergency room accounted for a considerable workload (350 attendances in 1 month). It identified a low level of use of primary care services (38% were referred by a General Practitioner), that a significant proportion (39%) belonged to socio-economic group 6 and that the majority (59%) attended outside normal hours²⁹. Internationally some maternity services are structured differently to those in Ireland (e.g. free standing midwifery units) and different models of afterhours primary medical care services exist, which make comparison difficult.

Overall the increase may reflect heightened awareness to re-attend for clinical advice should mothers and/or carers have any concerns, change in the out of hours primary care services, altered patterns of reporting, changes in clinical practice or a combination of some or all of the above.

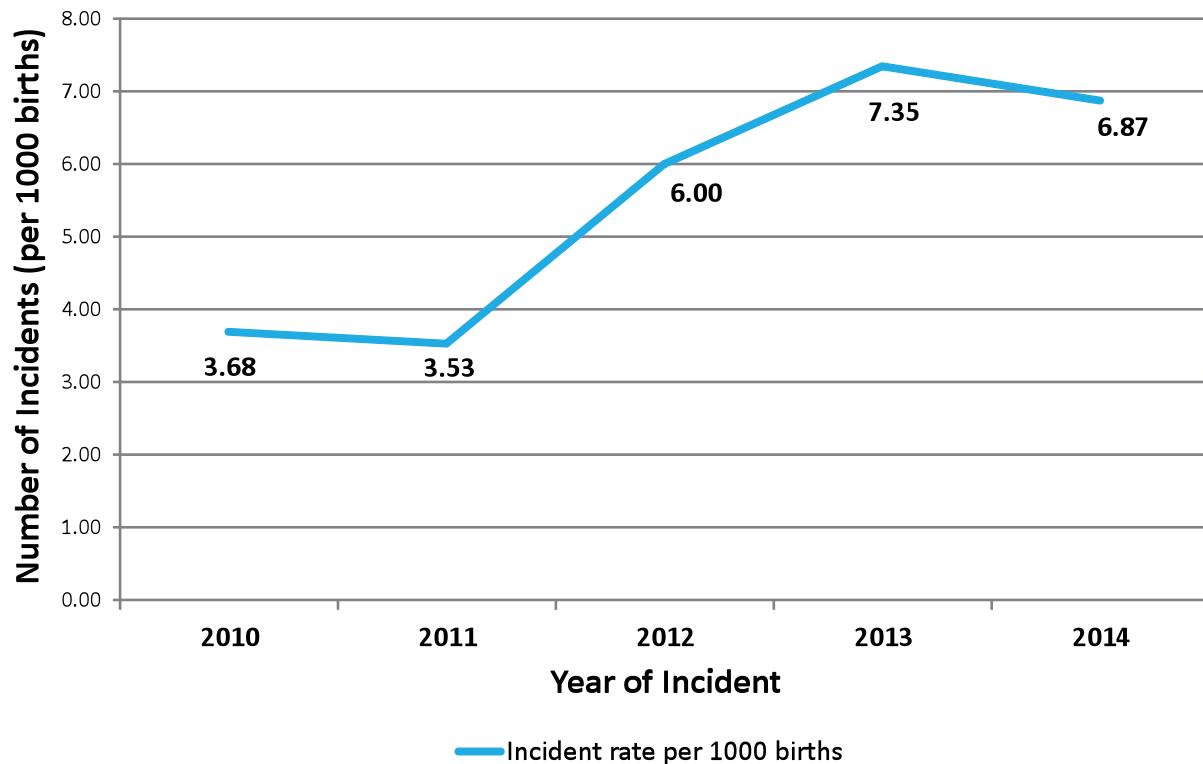


Figure 10: Unplanned re-attendances to Maternity services per 1,000 live births which occurred, 2010-2014 inclusive

4.2.4.6 Shoulder dystocia

While definitions may vary, shoulder dystocia is generally defined [as Resnick³⁰ did in the 1980s] as a “vaginal cephalic delivery that requires additional obstetric manoeuvres to deliver the fetus after the head has delivered and gentle traction has failed”^{30,31}. Variation exists in the reported incidence of shoulder dystocia³² but studies involving the largest number of vaginal deliveries [34,800 to 267, 228] report incidences of between 0.58% and 0.70%^{33, 34, 35, 36, 37, 38}. Figures for Ireland fall below this range, with 4.99 incidents of shoulder dystocia per 1,000 live births notified in 2014 [n=336] [Figure 11].

Risk factors include macrosomia [greater than 4.5 kg], diabetes mellitus, maternal body mass index >30kg/m², previous shoulder dystocia, induction of labour and prolonged [first or second stage] labour³¹. However, 48% of births complicated by shoulder dystocia occur with infants whose birth weight is less than 4,000g³⁴.

Maternal morbidity is increased with shoulder dystocia, particularly by the incidence of post-partum haemorrhage [11%] and 3rd and 4th degree perineal tears [3.8%]. The incidence of both is unchanged despite the number and type of manoeuvres used to effect delivery^{39, 40}. Brachial plexus injury is one of the most significant complications to the baby of shoulder dystocia, complicating 2.3% to 16% of such deliveries^{40, 41, 42,43}. The majority of cases of brachial plexus injury resolve with less than 10% resulting in permanent neurological dysfunction⁴¹.

Guidance

International: Shoulder dystocia is included in the Practical Obstetric Multi-Professional Training [PROMPT]⁴⁴ which some maternity services use to train staff. Published guidance is available from RCOG, UK [2012]³¹.

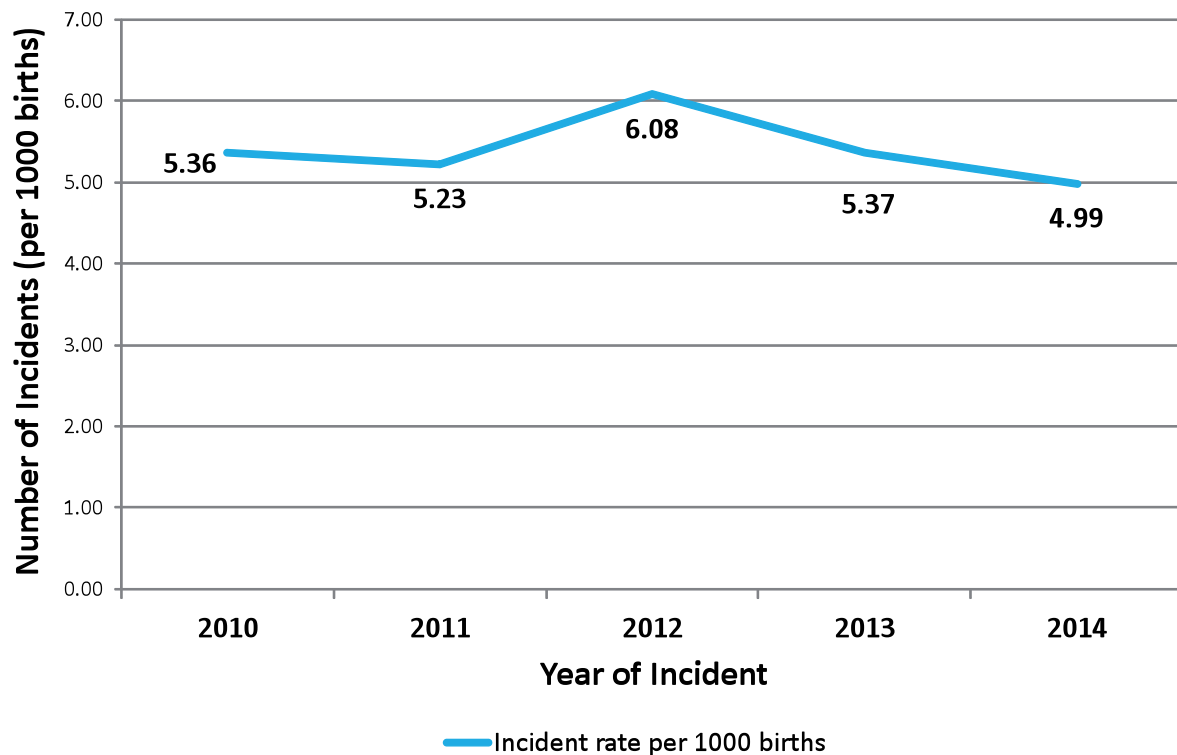


Figure 11: Shoulder dystocia per 1,000 live births which occurred, 2010-2014 inclusive

4.2.4.7 Complications leading to transfer to the operating theatre post second stage of labour

Complications leading to transfer to the operating theatre post second stage of labour per 1,000 births increased in the year 2011 but have reduced in the year 2014 to just below the 2010 figure [$n=246$ in 2014 and $n=281$ in 2010] (Figure 12). Closer analysis of these complications revealed that of the 246 incidents reported in the year 2014, 203 [82.5%] were for manual removal of the placenta, which is indicated for *retained placenta*, while some others were mis-categorised. The incidence and importance of retained placenta varies greatly around the world. In less developed countries, it affects ~0.1% of deliveries but has a 10% case fatality rate. In more developed countries, it is more common [~3% vaginal deliveries] but very rarely associated with mortality⁴⁵.

Part of this difference is accounted for by the difference in definitions used. Retained placenta may be defined as “lack of expulsion of the placenta within 30 minutes of delivery of the infant^{46, 47}. This is a reasonable definition in the third trimester when the third stage of labour is actively managed [i.e. administration of a uterotonic agent before delivery of the placenta and controlled cord traction], because 98% of placentas are expelled by 30 minutes in this setting⁴⁵. However, in the second trimester and/or with physiological management of the third stage [i.e. delivery of the placenta without the use of uterotonic agents or cord traction], it takes about 60 minutes before 98% of placentas are expelled. These findings suggest that the definition, or the timing of intervention, should

take into account the gestational age at delivery and how the third stage of labour is managed. In part for these reasons, the World Health Organization [WHO] concluded that the length of time before making a diagnosis of retained placenta should be “left to the judgement of the clinician”⁴⁸. A retained placenta increases the risk of a post-partum haemorrhage by five fold¹⁶.

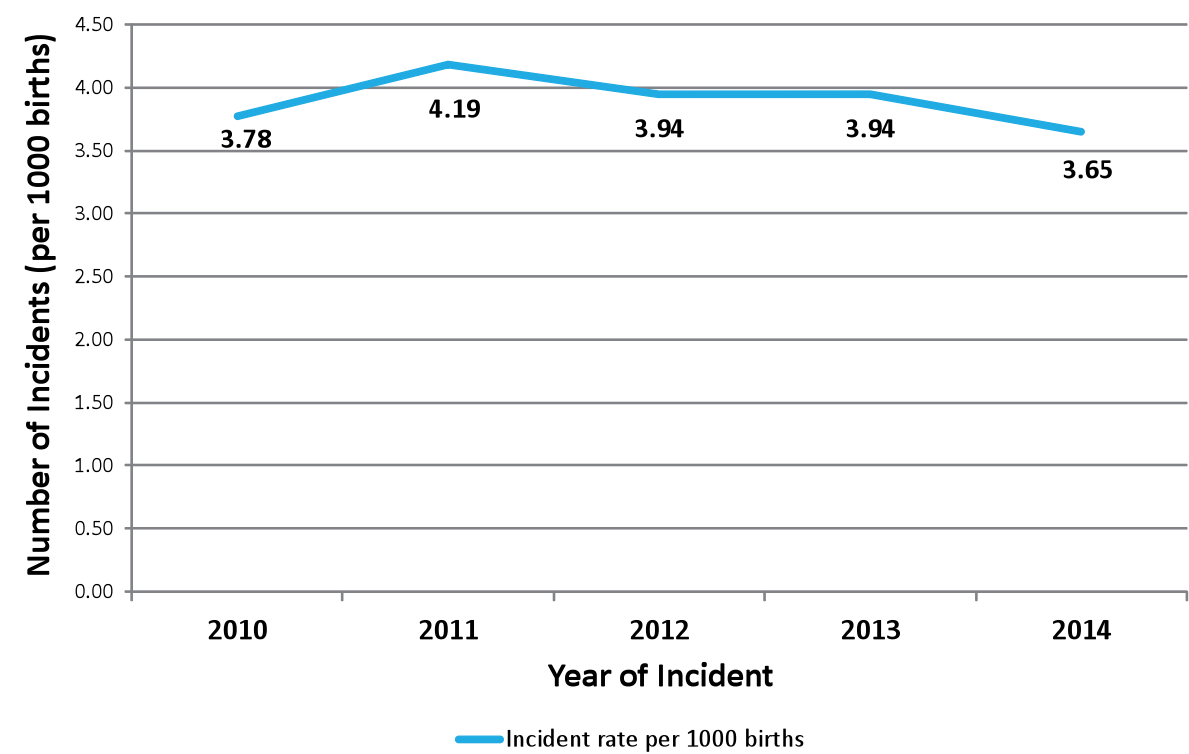


Figure 12: Complications leading to transfer to the operating theatre post second stage of labour per 1,000 births which occurred, 2010-2014 inclusive

4.3 CLAIMS CREATED IN MATERNITY SERVICES IN 2014

4.3.1 Claims created in Maternity services by severity rating in 2014

Claims in Maternity services offer opportunities for learning. In 2014, a total of 140 claims in maternity services were created, of which 137 [98%] were clinical. Based on severity rating, in 96 claims [68.6% of total maternity services claims], severity was “*not known/legacy data*”, 11 [7.8%] were rated *extreme*, 3 [2%] *major*, 26 [19%] *moderate*, and 2 [1.4%] each were rated *minor* and *negligible* [Figure 13].

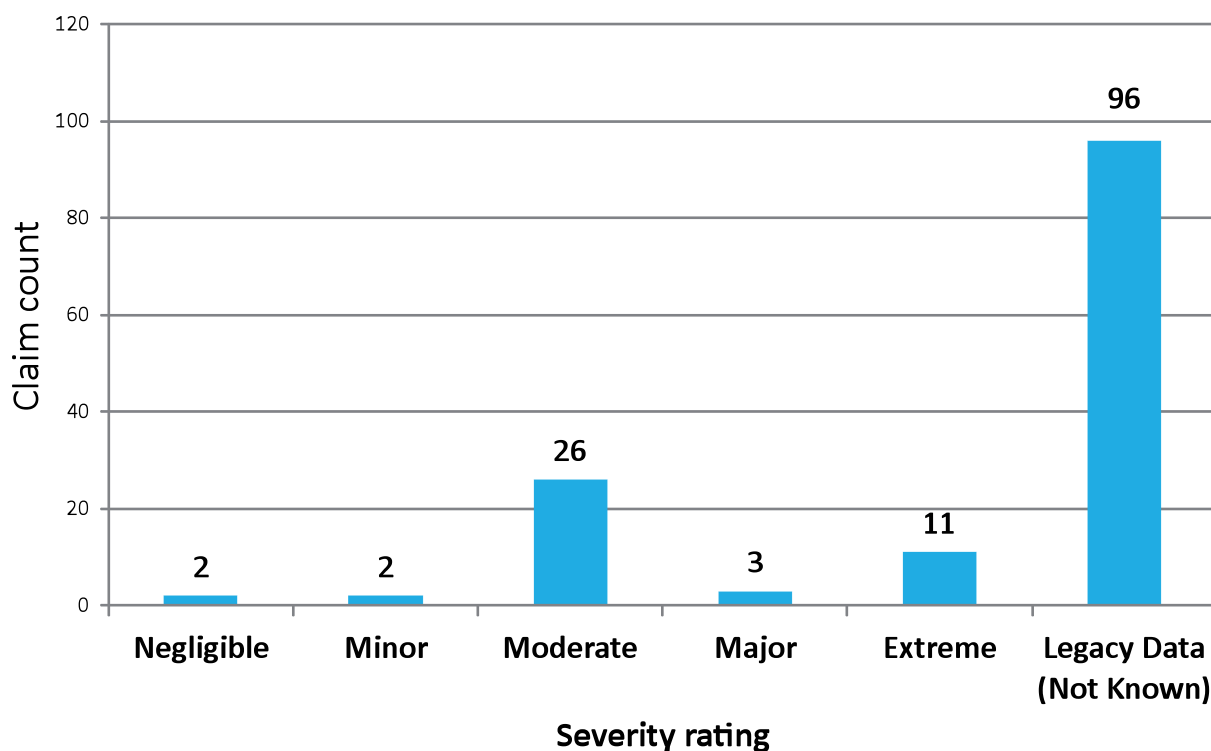


Figure 13: Claims created in Maternity services created in 2014 by severity rating

4.4 CLAIMS CREATED IN MATERNITY SERVICES, 2010-2014 INCLUSIVE

4.4.1 Ten most common claims created in Maternity services, 2010 to 2014 inclusive

The 10 most common claims in Maternity services created between 2010 to 2014, categorised by claim type, including mass actions were analysed and are outlined below [Table 4].

Ten most common claims created in Maternity services, including mass actions, 2010-2014	Total Claim Count
Unnecessary surgery/procedure*	121
Other	112
Perineal tear [3rd & 4th degree] [incl. breakdown of perineum]	43
Shoulder dystocia	38
Stillbirth	38
Unexpected neonatal death	25
Cerebral irritability/neo-natal seizure	22
Birth Injury [incl. Instrument Injury]	20
Post-partum haemorrhage	17
Apgar <5@1, 7@5, cord BE <12, pH<7.2	16

Table 4: Ten most common claims created in Maternity services, 2010-2014 inclusive

* Mass action

The most common claims for this time period was wrong surgery/procedure which is explained by the mass action for symphysiotomies.

4.4.2 Most common claims created in Maternity services, tracked over 5 years, 2010-2014 inclusive

When categorised by claim type, excluding mass actions, the top six most common maternity claims, between the years 2010 to 2014, were reviewed over time for trends and patterns. These included, in decreasing order, "other", perineal tear [3rd and 4th degree, including breakdown of perineum], shoulder dystocia, stillbirth, unexpected neonatal death, shoulder dystocia and cerebral irritability/neonatal seizure [Figure 14].

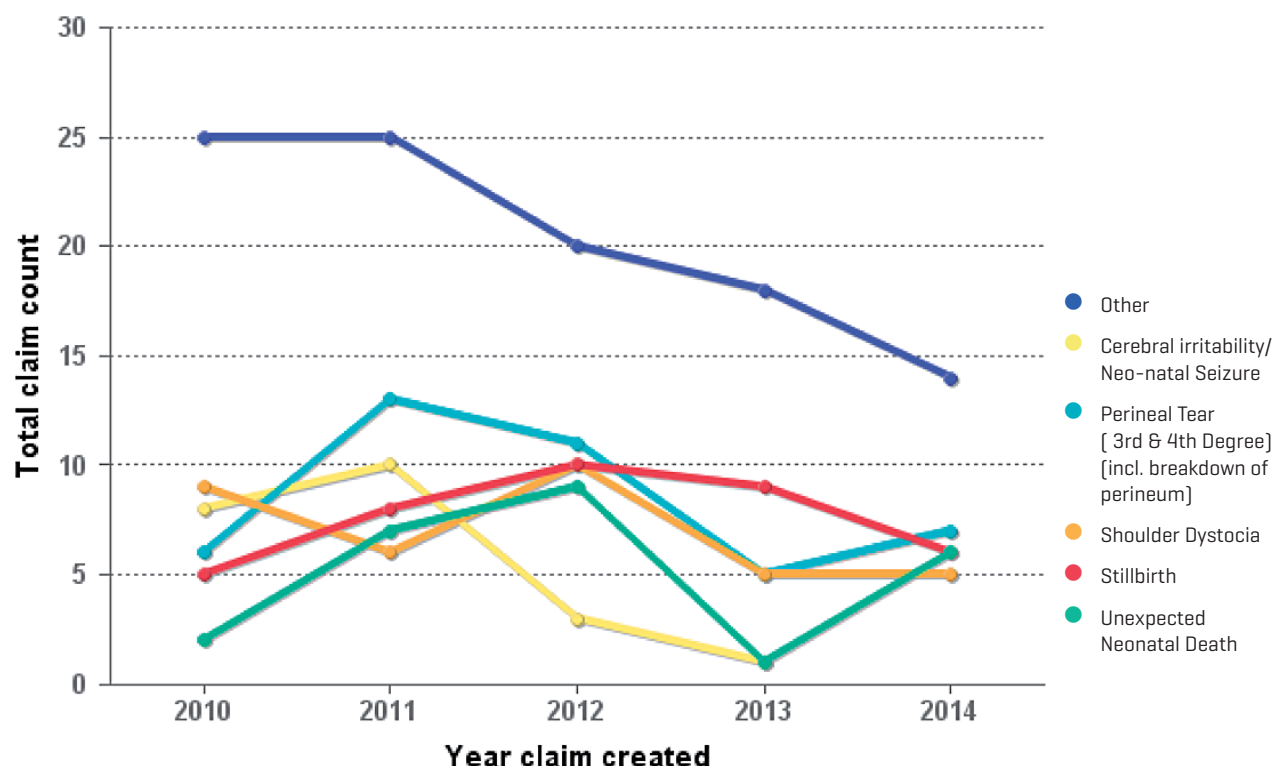


Figure 14: Six most common claims created in Maternity services tracked over 5 years 2010-2014 inclusive, categorised by claim type, excluding mass actions

The subgroup “other” has steadily reduced since 2011 which may be related to better quality of reporting or that more claims over the last 4 years fall into known categories of claim type. This “other” group included: jejunal puncture at caesarean section, ante-partum haemorrhage, intrauterine death after review and CTG in hospital the previous day, lack of supervision for a short period during change of shift of staff with delivery of baby unsupervised, alleged negligence and a solicitor’s request for a chart despite no adverse event being identified on chart review.

There has been a reduction in the absolute number of claims for perineal tear (3rd and 4th degree) and shoulder dystocia from 2012 to 2014 but numbers are small in these 2 groups and particularly small in the remaining 3 subgroups. Overall, the total number of claims in maternity services have increased from 122 in 2010, to 140 in 2014.

4.4.3 Top clinical claims created in Maternity services by cost

In contrast to the list of *most common* clinical claims, the *top clinical claims created by cost* in Maternity services, 2010-2014, was analysed [Table 5]. Cost for the purposes of this report is defined as total expenditure paid plus the outstanding estimated liability. In some categories, while the number of claims in Maternity services is small, the overall expenditure is high, particularly in catastrophic injury cases.

Top claims created in Maternity services categorised by cost 2010-2014

Other
HIE (Hypoxic Ischaemic Encephalopathy)
Cerebral Irritability/Neo-natal Seizure
Apgar <5@1, 7@5, cord BE <12, pH<7.2
Birth Injury (incl. Instrument Injury)
Shoulder Dystocia
Failed Instrumental Delivery Leading CS
Unnecessary Surgery/Procedure
Unexpected transfer to SCBU/NICU
Unexpected Complications Following Operation/Procedure

Table 5: Top 10 claims created by cost in Maternity services, 2010-2014 inclusive

The tables listed, as outlined previously, are drawn up using a category of “please specify” which utilises free text and, therefore, has some limitations regarding accuracy but is the best category currently available to provide detail.

4.4.4 Top 6 claim types created in Maternity services by cost, tracked over 5 years, 2010-2014 inclusive

The top 6 claim types, categorised by cost in Maternity services, tracked over 5 years between 2010 and 2014, excluding mass actions, were studied [Figure 15]. These included the subgroup “other”, shoulder dystocia, birth injury, including instrumental delivery, cerebral irritability/neonatal seizure and hypoxic ischaemic encephalopathy (HIE) all of which have decreased from the 2010 figure, though numbers are small.

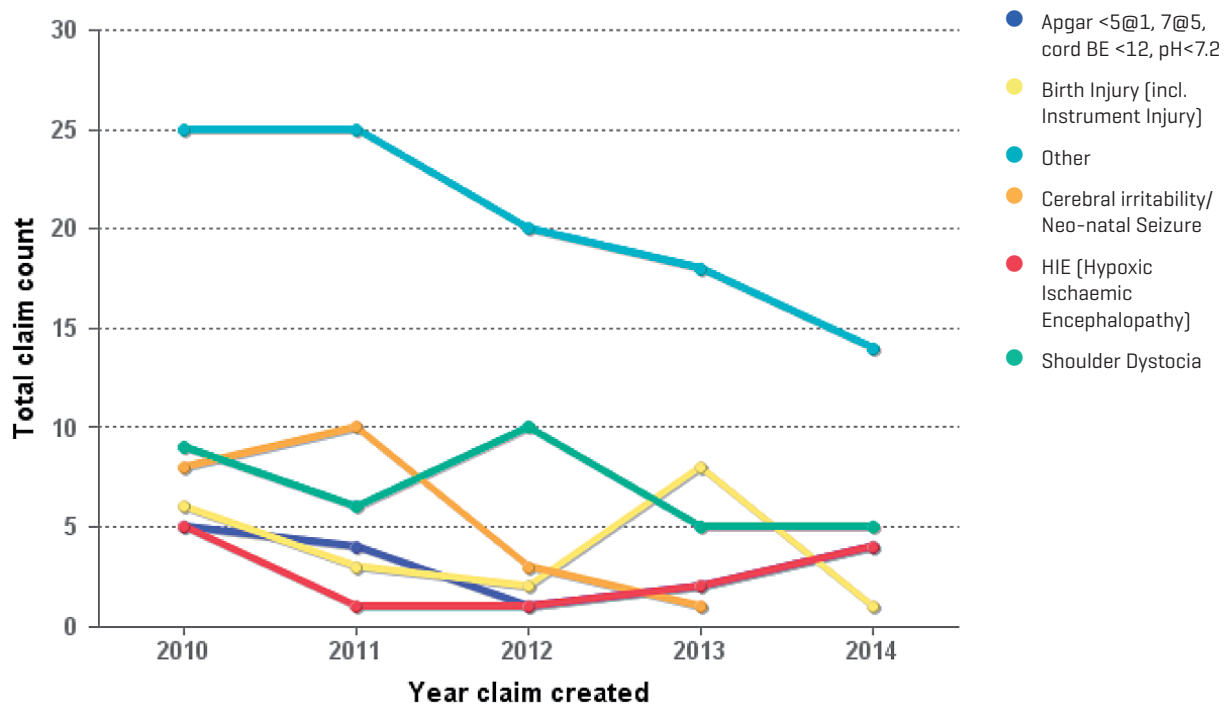


Figure 15: Top 6 claims created by cost in Maternity services, tracked over 5 years, 2010-2014, excludes mass actions

While the subgroup “other”, cerebral irritability/neonatal seizure and shoulder dystocia are common to both lists i.e. most common claims and most costly claims, the claims for birth injury, hypoxic ischaemic encephalopathy and low apgars are of very high value though small in number.

4.5 COMPARISON OF THE 19 MATERNITY SERVICES NATIONALLY, ANONYMISED, INCIDENTS AND CLAIMS IN 2014

4.5.1 Background

A high rate of incident reporting in a service is nationally and internationally accepted as being reflective of a culture of strong patient safety, risk awareness and high quality in patient care. The SCA concurs with this. High reporting, particularly of moderate, minor, negligible and near miss incidents demonstrates a diligence and awareness of the importance of incident reporting. It is through the identification of patterns and trends that the clinical risk team can make clinical risk management recommendations which may prevent clinical incidents of extreme and major severity occurring and causing harm, thereby enhancing patient safety. Early identification of one *extreme* or *major* rated incident or a pattern/in “*incidents with no injury incurred*” may help prevent further incidents and ultimately enhance patient safety and the patient experience.

Clinical services, nationally and internationally, compare themselves to similar sized services in an attempt to benchmark their work. Reducing variation in care and aiming for standardisation of care which is equal or superior to best international practice, is a desired outcome.

This report provides data pertaining to the 19 Maternity services regarding incidents and claims in the year 2014 and for the years 2012 to 2014, compared in an anonymous fashion. Each of the 19 Maternity services will have their own identity revealed to them. They will be blinded to the identity of the other 18 Maternity services. The services have been grouped according to activity (i.e. birth rate) so that each service can benchmark itself against a service of similar activity for incident and claim rate and the median nationally for both. The identity of HSE Maternity services will be revealed only to the National Directorate of the HSE. For other stakeholders, which are not Maternity services, they will be able to review the data in an anonymised fashion only at the present time. Future developments may include the requirement to provide linked data to key stakeholders including post graduate training bodies.

4.5.2 Clinical incident rate per 1,000 live births in the 19 Maternity services, anonymised, in 2014

A comparison was made with the 19 public Maternity services nationally, based on total Maternity services incidents [clinical and non-clinical], adjusted per 1,000 live births in 2014. The number of births in each Maternity service was obtained from the HSE^{10, 11, 12}. The hospitals are grouped, for ease of comparison, according to their activity (i.e. birth rate), and anonymised.

The median clinical incident rate in the 19 Maternity services nationally in 2014 was 117.22 incidents per 1,000 births [Figure 16].

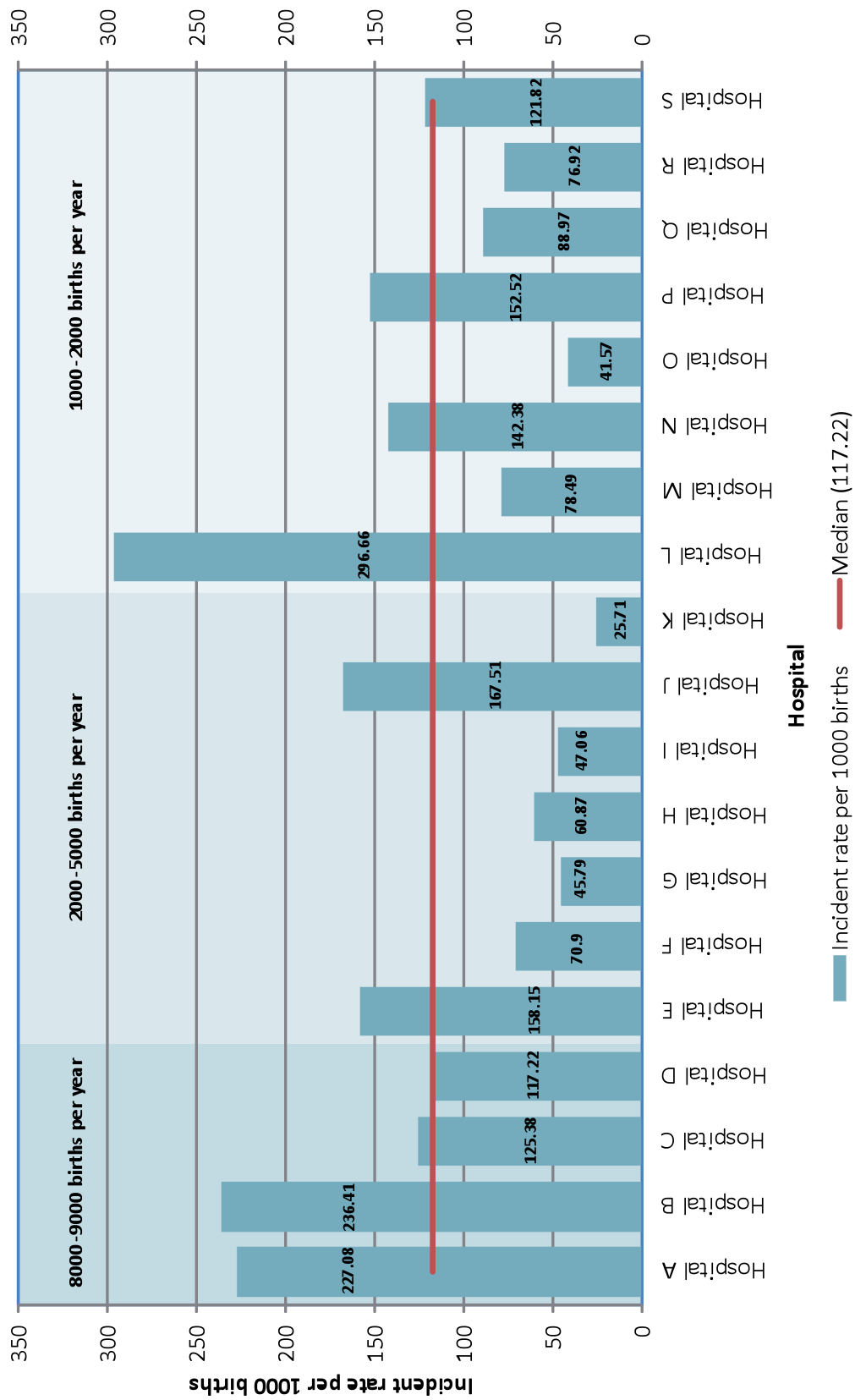


Figure 16: Incident rate in Maternity services per 1,000 births for each of the 19 Maternity services, anonymised, which occurred in 2014

4.5.2.1 Clinical incidents in Maternity services with 8,000-9,000 births/year in 2014

Regarding clinical incidents in the 4 stand alone Maternity services, with birth numbers of between 8,000 to >9,000 per year, significant variation in incident reporting was identified. Two services reported approximately half the number of incidents as the other two [Figure 16].

Further detailed analysis of individual incident reports identified that there was a difference in reporting patterns between the 4 Maternity services e.g. a difference exists between the services as to how they report infants with Apgar scores of < 5 at 1 minute, 7 at 5 minutes, base excess of 12 and pH of < 7.2. Three services recorded low numbers of newborn infants who fulfilled all 4 criteria. In contrast, the fourth service appeared to include newborn infants that fulfilled any 1 of the above criteria and had incidents with infants born acidotic, with cord pH <7.2 but with good apgars of 9 at 1 and 10 at 5 minutes.

Some maternity services reported deaths of babies of less than 24 weeks gestation or of weight less than 500g whereas other maternity services did not. This may be explained by the fact that, human viability, defined medically as the gestational age at which the chance of survival is 50%, is currently approximately 24 weeks in developed countries²⁸. Standardisation of reporting is required to facilitate accurate comparisons.

4.5.2.2 Clinical incidents in Maternity services with 2,000-5,000 births/year in 2014

Regarding co-located Maternity services having between 2,000 and 5,000 births per year, variation was again identified within this group. On more detailed analysis, certain services reported more PPH than others. This may be due to a varied awareness of the need to report PPH, varied definitions of PPH, that PPH occurs more frequently in some services, or a combination of some or all of the above [Figure 16]. Consistency in the use of definitions is important.

4.5.2.3 Clinical incidents in Maternity Services with 1,000-2,000 births/year, in 2014

Regarding Maternity services having 1,000 to 2,000 births per year, variation was again identified, which, on detailed analysis, was mainly related to reporting in the category “other” and, to a lesser extent, PPH.

4.5.3 Incident rate per 1,000 live births in 19 Maternity services, anonymised, 2012-2014 inclusive

A detailed review of the incident rate per 1,000 live births in the 19 Maternity services for each year between 2012 and 2014 was collated and plotted [Figure 17]. This provides a graphical picture over a 3 year period of different patterns and trends in incident rate reporting across Maternity services, nationally. The different patterns of reporting of clinical incidents discussed earlier between the 4 stand alone Maternity services has remained relatively consistent over the last 3 years. Thirteen of the 19 Maternity services have demonstrated increased clinical incident reporting from 2012 to 2014.

4.5.4 Claims rate per 1,000 live births in 19 Maternity services, anonymised, in 2014

The claim rate per 1,000 live births for each of the 19 public Maternity services for the year 2014 was compared [Figure 18]. The median claim rate was 1.76 per 1,000 live births nationally. Ten of the 19 services, including the 4 stand alone maternity services, fall below or on this median, despite having quite different incident reporting rates, as outlined earlier.

Some variation exists in claim rate identified in the services having 2,000-5,000 births per year which may be expected secondary to the range of births per year. While variation is noted in the services having 1,000-2,000 births/year, caution should be exercised in interpreting numbers which are relatively small, as they are for all groups nationally [Figure 18]. Continued, detailed surveillance of data is essential.

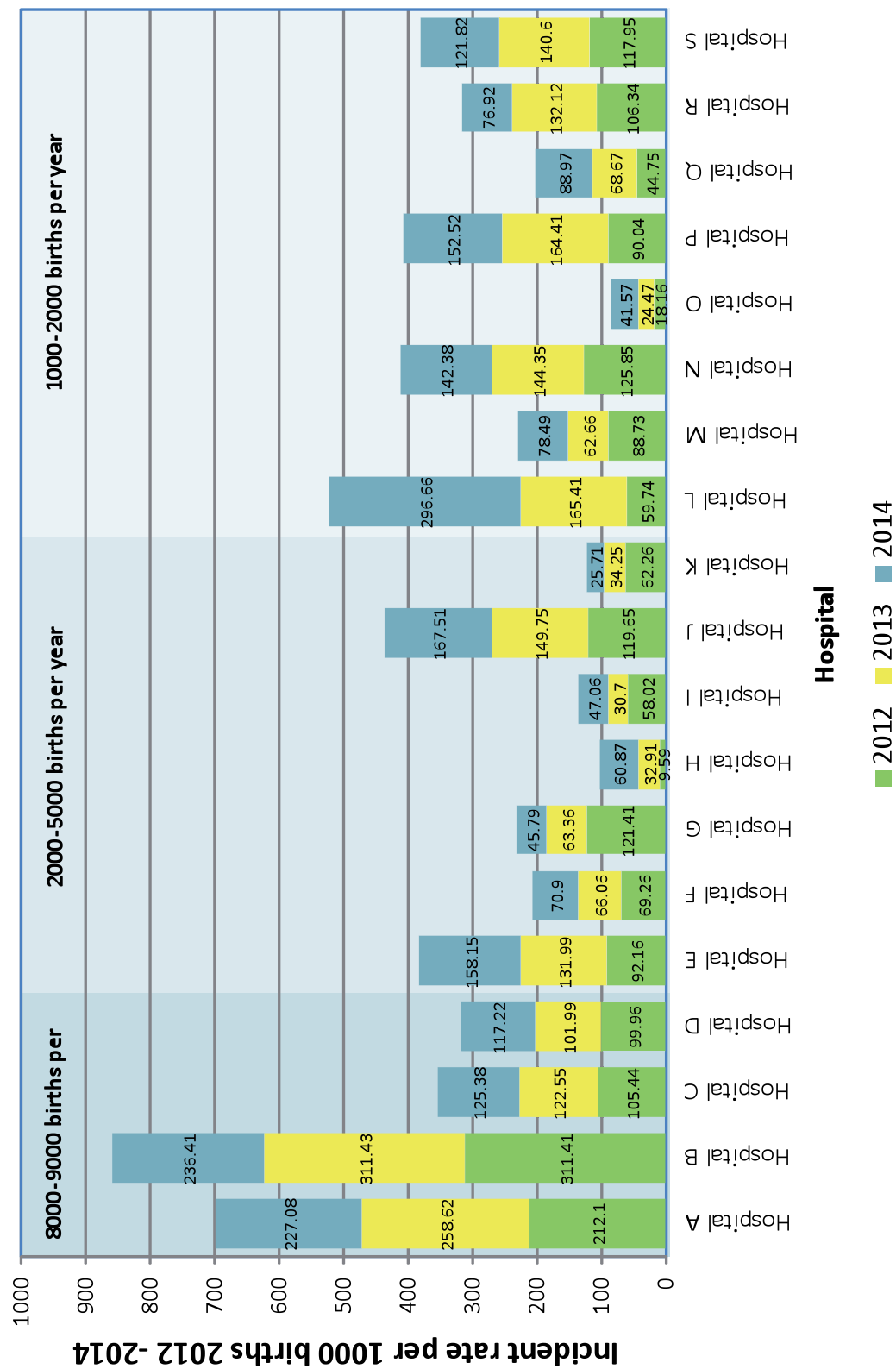


Figure 17: Incident rate per 1,000 births for each of the 19 Maternity services, anonymised which occurred 2012 to 2014

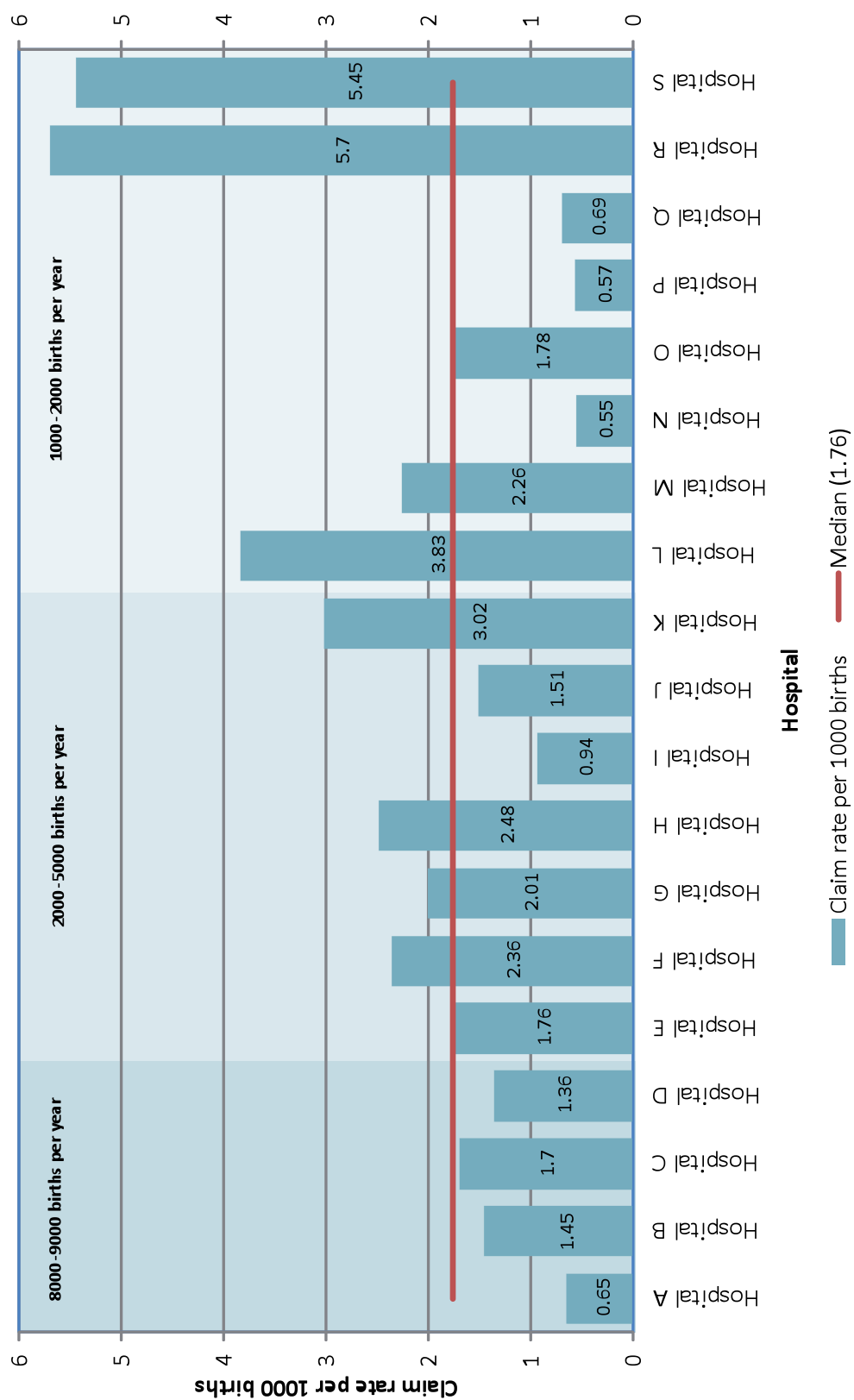


Figure 18: Claim rate per 1,000 live births for each of the 19 Maternity services, anonymised, created in 2014

4.5.5 Clinical claim rate per 1,000 live births in 19 Maternity services, anonymised, 2012-2014 inclusive

The claim rate for each Maternity service over a 3 year period was analysed and plotted (Figure 19). This provides baseline data for patterns and trends to be followed over time. Numbers are small and caution should be exercised in their review.

4.6 TOTAL TRANSACTIONAL EXPENDITURE ON CLAIMS IN MATERNITY SERVICES

Total transactional expenditure reflects payments made in a given year. These payments include professional fees, awards and expenses.

4.6.1 Total transactional expenditure on claims in Maternity services in 2014

- Total transactional expenditure paid on Maternity services related claims was €58 million in the year 2014 of which 98% were clinical (Table 6).
- Total transactional expenditure paid on clinical claims in Maternity services was 54% (€57.3m) of all clinical care related claims in the year 2014 (€106 million).

4.6.2 Total transactional expenditure on claims in Maternity services, 2010-2014 inclusive

- Total transactional expenditure on clinical care related claims has increased 44% from €74 million in 2010, to €106 million in the year 2014 (Table 6).
- Total transactional expenditure on clinical claims in Maternity related claims has increased 80% from €32 million in the year 2010 to €58 million in the year 2014.

4.6.3 Total transactional expenditure on cerebral palsy claims: 2014 and 2010-2014

- Total transactional expenditure paid on cerebral palsy claims was 82% (€47 million) of the total expenditure on clinical claims in Maternity services in 2014 (Table 6).
- Total transactional expenditure on cerebral palsy claims has increased 77% from €27 million in the year 2010 to €47 million in 2014.

This increase is substantially explained by the fact that during this time period, some claims which settled on a Periodic Payment Order (PPO) basis have converted to “lump sum” payments. Additionally, the cumulative effects of more PPOs, over time, has led to an increase in payments at intervals of 2 years. These are referred to as “returnable PPO claims”. Other catastrophic birth injury claims have been settled, at the request of parents and legal guardians, *ab initio*, on a lump sum settlement basis.

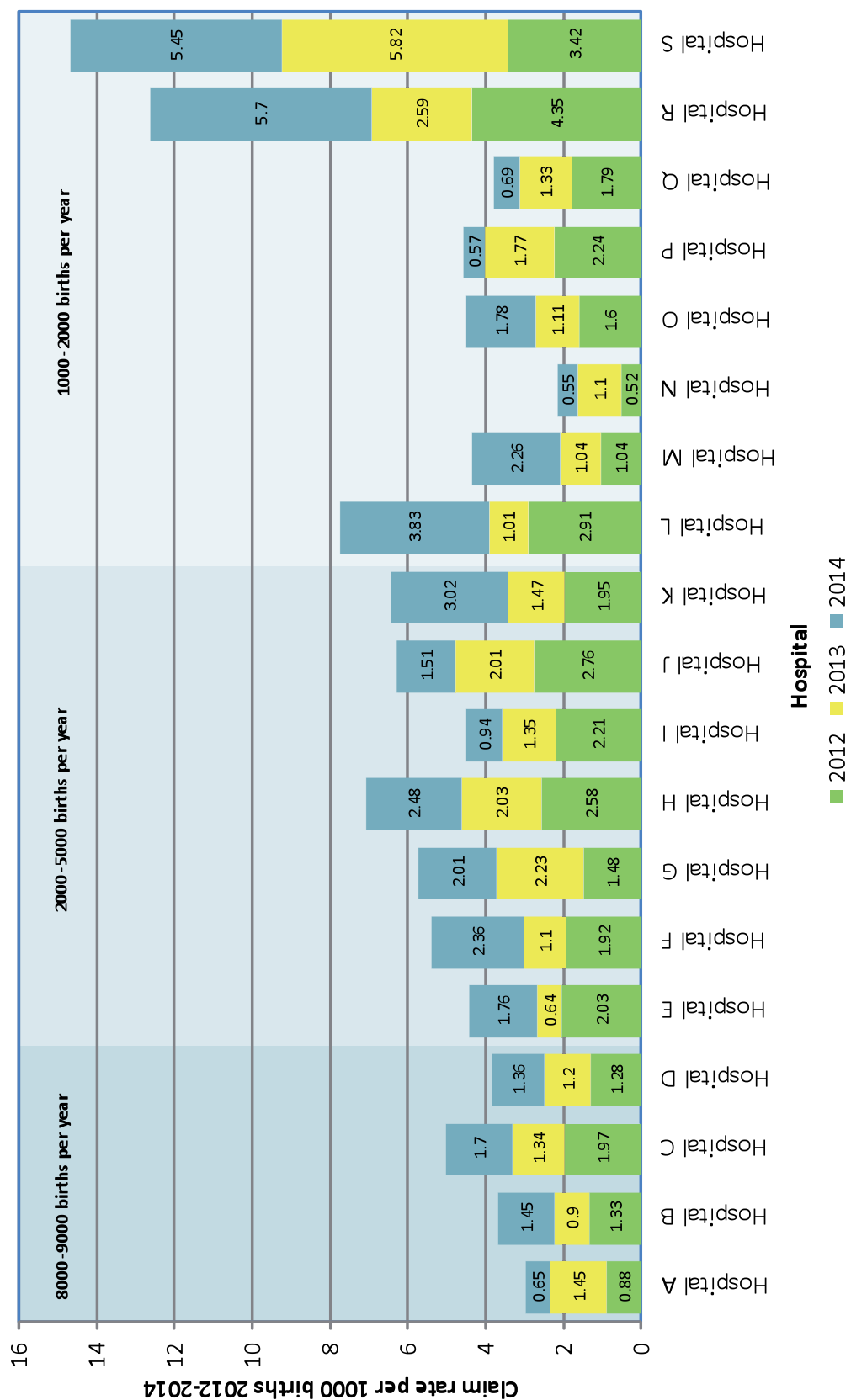


Figure 19: Claim rate per 1,000 live births for the 19 Maternity services, anonymised, created 2012-2014 inclusive.

Total Transactional Expenditure 2010-2014			
	Clinical Care	Maternity Services	Cerebral Palsy
2010	€74,001,771	€32,465,259	€26,736,843
2011	€87,850,611	€43,941,633	€28,683,495
2012	€77,501,523	€36,417,698	€26,618,838
2013	€116,104,083	€61,899,366	€46,935,986
2014	€106,182,012	€58,440,206	€47,199,603

Table 6: Total transactional expenditure paid on clinical care, Maternity services & cerebral palsy related claims, 2010-2014 inclusive

4.6.4 Breakdown of total transactional expenditure on claims in Maternity services, 2010-2014 inclusive

Damages and legal costs have both increased significantly between 2010 and 2014, though more so the latter which has more than doubled [Table 7]. This has culminated in a significant increase in overall total transactional expenditure for Maternity services. Despite more than a two fold increase, between 2010 and 2014, expert costs remain relatively low in comparison [Table 7]. Figure 20 provides a graphical picture of the breakdown of total transactional expenditure between 2005 and 2010.

Maternity Services				
Year of Transaction	Damages (€m)	Legal Costs (€m)	Expert Costs (€m)	Overall Transactional Expenditure (€m)
2010	24	7.86	0.61	32.5
2011	29.57	13.67	0.69	43.9
2012	22.32	13.03	1.07	36.4
2013	44.62	16.07	1.21	61.9
2014	40.47	16.53	1.44	58.4

Table 7: Breakdown of total transactional expenditure (in € millions) in Maternity related claims, 2010-2014 inclusive

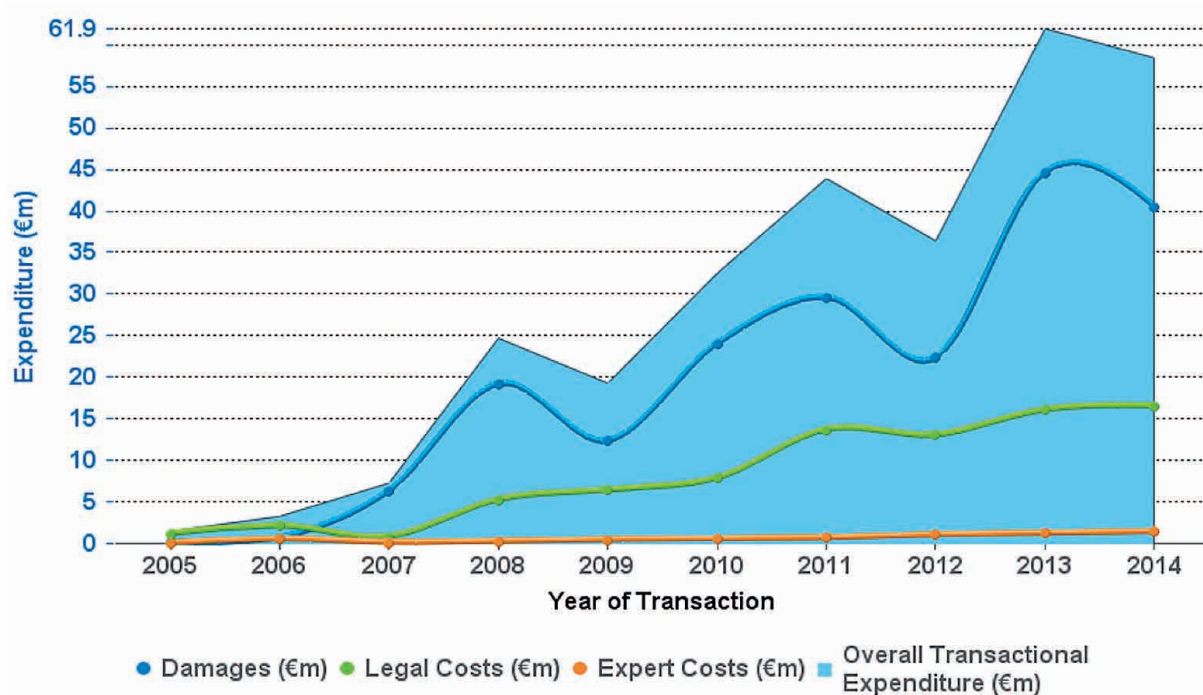


Figure 20: Total transactional expenditure (in € millions) in Maternity services, 2005–2014 inclusive

4.6.5 Total expenditure on claims in Maternity services in the United Kingdom 2000–2010 inclusive

In its publication, *Ten years of Maternity Claims 2000–2010*⁴⁹, [published 2012] the National Health Service Litigation Authority [NHSLA] outlined the causes and costs of closed 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 £3,117,000,000 (£3.1 billion), 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]; CTG interpretation [n=30 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 million for all perineal trauma]; shoulder dystocia [n=250 with a total value of £103 million] and PPH [n=111, with a total value of £3 million].

5. GYNAECOLOGY SERVICES

Clinical incidents, claims and total expenditure

5.1 INCIDENTS IN GYNAECOLOGY SERVICES THAT OCCURRED IN 2014

A total of 1,403 Gynaecology incidents occurred and were notified to the SCA in the year 2014, of which 1,279 [91%] were clinical. This total number of incidents includes incidents which occurred nationally both in the 19 co-located Gynaecology and Maternity services and in the non co-located Gynaecology services.

5.1.1 Severity rating of incidents in Gynaecology services that occurred in 2014

Regarding severity rating of Gynaecology incidents, 931 [66%] were rated as *not known/legacy data*; 11[0.8%] extreme, 1 major [0.07%], 144 [10.2%] moderate and the remainder minor or negligible [Figure 21]. The 11 clinical incidents rated *extreme* included cardiac arrest, asystole with recovery, equipment failure, miscarriage misdiagnosis, *Clostridium difficile*, delayed diagnosis, missing test results, incorrect documentation of procedure, and healthcare records mislaid or incomplete. The remainder had insufficient details reported.

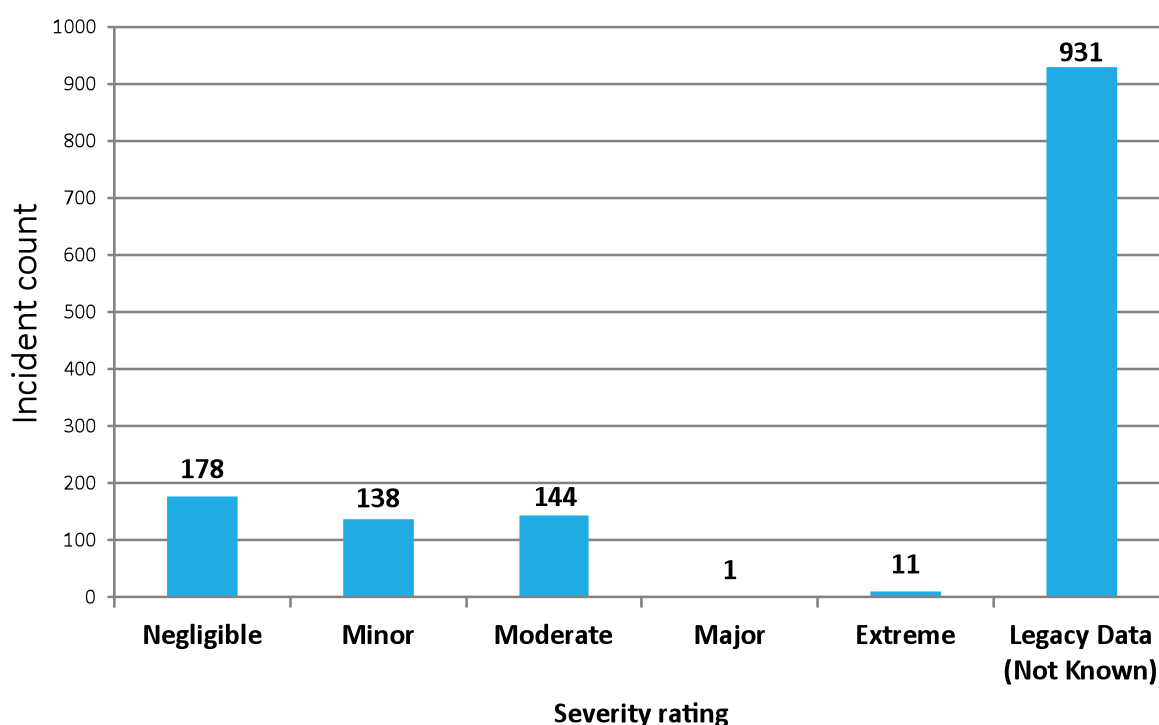


Figure 21: Severity rating of incidents which occurred in Gynaecology services in 2014

5.2 INCIDENTS IN GYNAECOLOGY SERVICES THAT OCCURRED, 2010-2014 INCLUSIVE

There has been an increase in the number of incidents which occurred in Gynaecology services, notified to the SCA, between 2010-2014 (n=1,000 in 2010, increased to n=1403 in 2014), [Table 8]. This increase of ~40% may reflect increased awareness of reporting with a stronger culture of patient safety, a change in clinical practice or a combination of both.

Overall there has been a decrease in the number of incidents which occurred, rated as *extreme* in Gynaecology services, which reached a peak of 62 in 2010 [Table 8]. Detailed, manual review of each individual incident identified that the majority of the *extreme* rated incidents in 2010 were related to healthcare records from one co-located Gynaecology and Maternity service (n=47). This was the same service that had rated a large number of health care record incidents as *extreme* in Maternity services, the same year. Numbers of extreme incidents have significantly reduced since then.

	Extreme	Major	Moderate	Minor	Negligible	Legacy Data	Total
2010	62	1	113	115	103	606	1000
2011	23	0	183	120	113	588	1027
2012	5	1	177	84	103	648	1018
2013	2	0	142	90	103	801	1138
2014	11	1	144	138	178	931	1403

Table 8: Severity rating of incidents in Gynaecology services which occurred, 2010-2014 inclusive

5.2.2 Ten most common incidents in Gynaecology services which occurred, 2010-2014 inclusive

The ten most common incidents which occurred in Gynaecology services between 2010-2014, inclusive was analysed [Table 9]. The subgroup "other" was the most common incident and, as previously discussed, pertains to incidents which did not fit into any of the known or offered incident categories. The second most common incident was unplanned re-attendance, followed by healthcare records missing/misplaced, patients falls, failure/faulty equipment or device, delayed or cancelled surgery, incorrect data records and unexpected complications following operation.

Ten most common incidents in Gynaecology services which occurred, 2010-2014 inclusive	Total Count
Other	1,296
Unplanned re-attendance	371
Health care records missing/misplaced	310
Patient fall moving w/o supervision	230
Failure/faulty medical device/equipment	213
Delayed/cancelled surgery	200
Incorrect data	181
Legacy data	152
Incomplete records	147
Unexpected complications following operation/procedure	137

Table 9: Ten most common incidents in Gynaecology services which occurred, 2010-2014 inclusive

5.2.3 Most common incidents in Gynaecology services, tracked over time, 2010-2014 inclusive

Further detailed analysis was performed by tracking the top 6 most common incidents over a 5 year period to assess if patterns or trends were evident or emerging [Figure 22].

This revealed that the subgroup “other” is increasing since 2011 and reached a peak in 2014. Detailed manual review of information from individual reports identified that almost one third of these “other” incidents came from one Gynaecology service. Incidents included delay in patient procedure due to “emergency surgery”, cancelled surgery/procedure, pain, bleeding, incorrect information, equipment and consent incidents.

Unplanned re-attendance and delayed/cancelled surgery reports are increasing over time. A definite increase in failure/faulty medical equipment/device is noted since 2013. Between 2010 and 2014, the subgroup, clinical records missing/misplaced and patient falls without supervision, appear to have decreased [Figure 22].

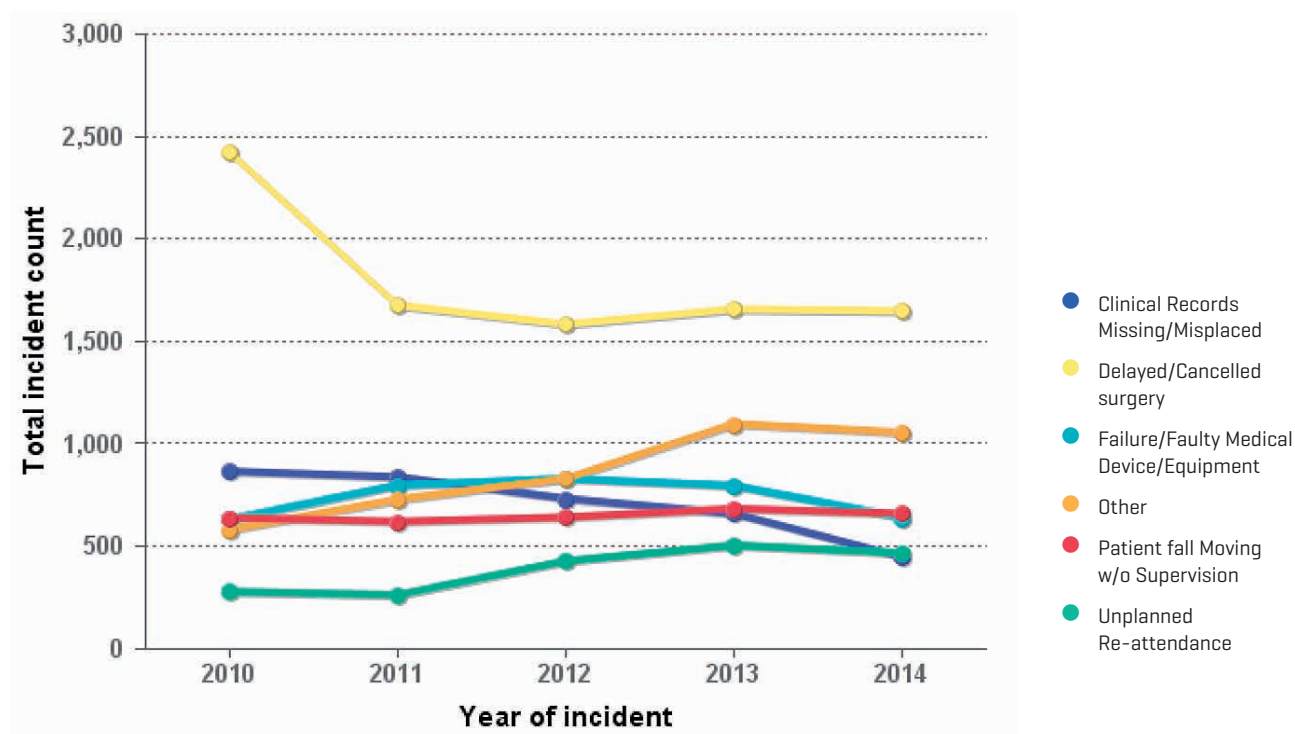


Figure 22: Six most commonly-occurring incidents in Gynaecology services which occurred, 2010 to 2014 inclusive

5.2.4 Detailed analysis of the most common incidents in Gynaecology services, 2010-2014 inclusive

The data was adjusted for activity levels by dividing the number of incidents reported by the total number of discharges, in the category of “diseases and disorders of the female reproductive system” reported annually by the Healthcare Pricing Office^{50, 51}. Discharge figures for 2014 are not yet available so the figure for 2013 was used as the closest estimate available at this time. Each incident was subsequently reviewed separately in more detail for further analysis.

5.2.4.1 Unplanned re-attendance

The number of incidents reported has significantly increased between 2010 and 2014. There were 117 incidents reported in the year 2014 in this category and they related to incidents such as pain, bleeding, Evacuation of Retained Products of Conception (ERPC), hysterectomy, mastitis and endometritis [Figure 23]. This increase, from 37 reported in 2010, may reflect changing patterns of attendance at secondary care rather than primary care locations, increased awareness of reporting, change in clinical care or a combination of some or all of the above.

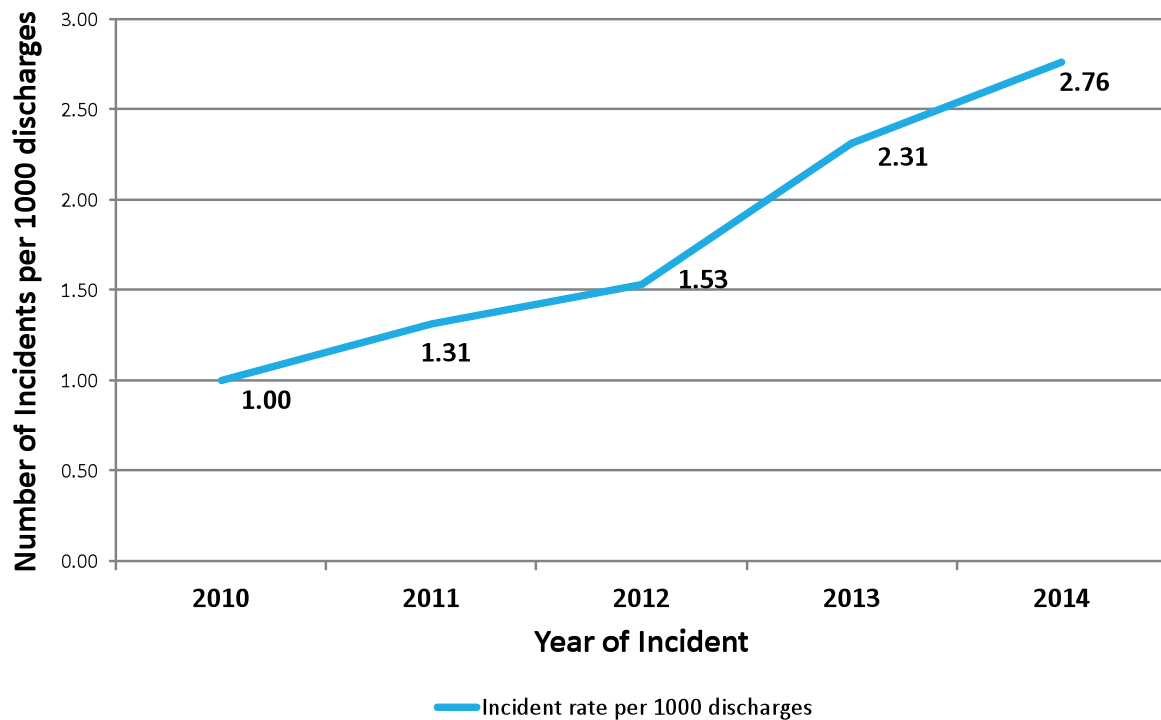


Figure 23: Unplanned re-attendance per 1,000 discharges for disorders and diseases of the female reproductive system, 2010–2014 inclusive

5.2.4.2 Healthcare records missing/misplaced, incomplete records and incorrect data

Healthcare records missing or misplaced was a common incident which occurred in Gynaecology services, notified to the SCA, in the years 2010 to 2014 [Figure 24]. Additionally, incidents pertaining to incomplete records and incorrect data were in the top 10 most commonly reported. The graph below combines all three categories to track the effect over time. The combined incidents have reduced from 3.46 per 1,000 discharges in 2010 to 2.95 per 1,000 discharges in 2014. Introduction of an Electronic Healthcare Record (EHR) should help resolve some of these issues. A recent, comparative cohort design study, undertaken in an Australian tertiary Maternity service, identified that an EHR demonstrated significant improvements to the collection of best practice variables, was more available to relevant clinical staff with the appropriate log in and information was more easily retrieved than from paper hand held records⁵².

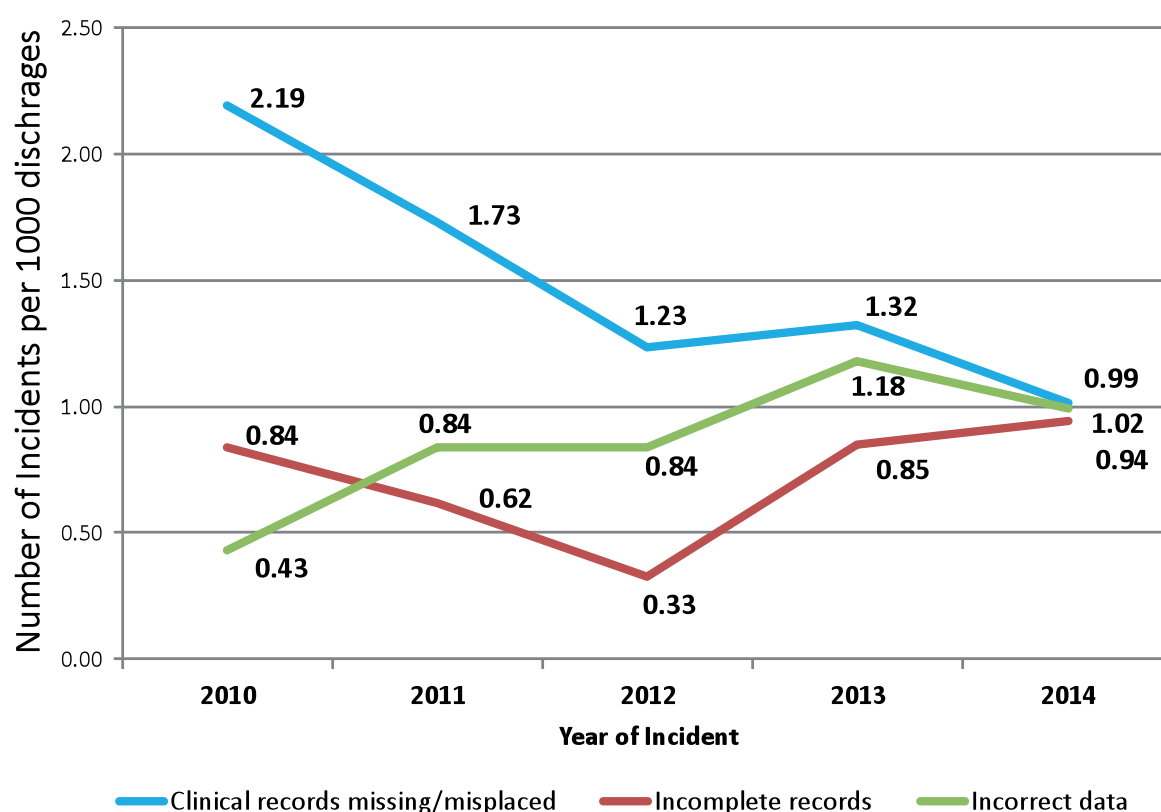


Figure 24: Incomplete records/incorrect data/clinical records missing/misplaced per 1,000 discharges for diseases and disorders of the female reproductive system, which occurred, 2010–2014 inclusive

5.2.4.3 Patient falls without supervision

While patient falls remain a problem nationally and internationally, a gradual decline in reported falls in Ireland has been documented from the year 2011 to 2014: [rate reduced from 1.27 in 2010 to 0.90/1000 discharges in 2014; n=54 in 2011 to n=38 in 2014] (Figure 25). This may be related to work performed through the National Falls and Bone Health Project, AFFINITY (Activating Falls and Fracture Prevention in Ireland Together) programme which is a collaborative programme between the SCA and the HSE. Slips, trips and falls in Ireland contribute to 1/3 of the incidents reported to the SCA. The HSE submitted a Partner Commitment to the European Innovation Partnership on Active and Healthy Ageing action group in 2012. The latter aims to increase the average healthy life years in the European Union by 2 years by the year 2020 with significant reduction in morbidity and savings in cost. Clinical guidelines exist pertaining to “Falls risk assessment and management of patient falls”. In some services internationally, such as the King Edwards Hospital, Western Australia, all Gynaecology inpatients and day cases [in addition to maternity inpatients] are assessed for risk of falls⁵³.

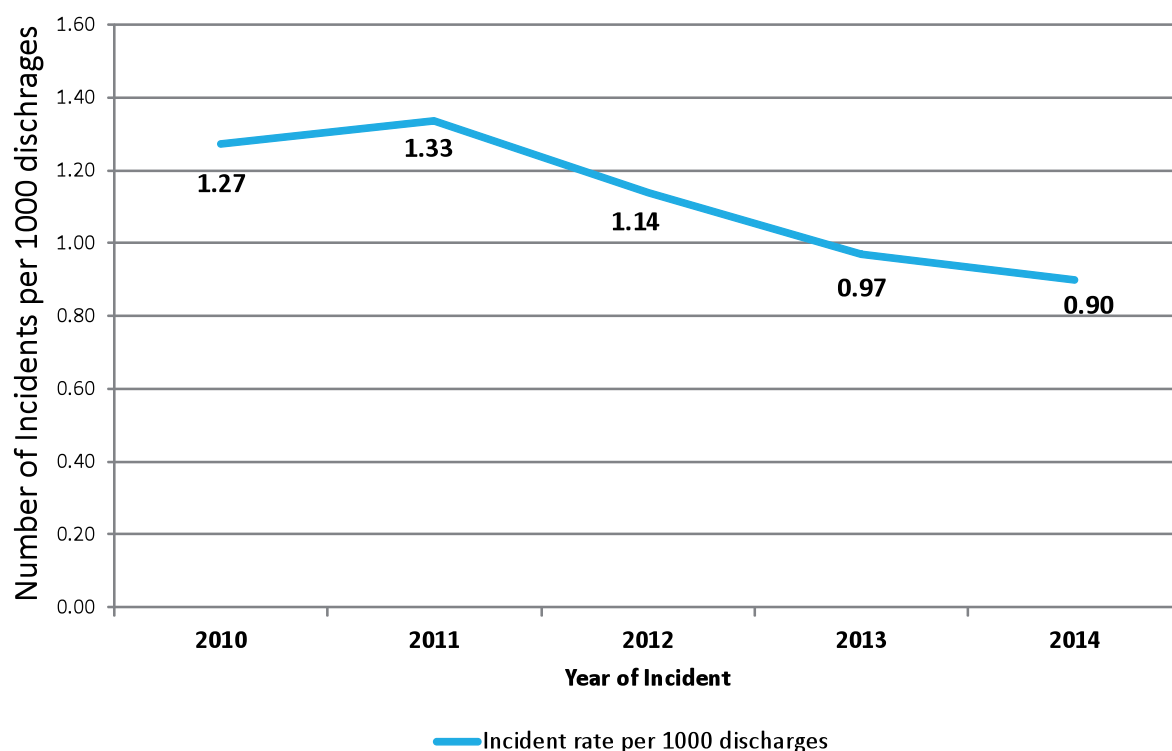


Figure 25: Patient falls/moving without supervision per 1,000 discharges for diseases and disorders of the female reproductive system, 2010–2014 inclusive

5.2.4.4 Failure/faulty medical device/equipment

This category covers a broad range of devices and equipment. A detailed analysis highlighted an increase from 25 incidents which occurred in 2013 to 82 in 2014, of which a significant proportion (n=31) pertained to 1 service, where there was a temporary issue with a clinical information system which captures and archives still images and video [Figure 26]. Other incidents which occurred, related to ablation therapy, laparoscopic camera malfunction, temperature regulation equipment, stirrups, mattress and trolley problems.

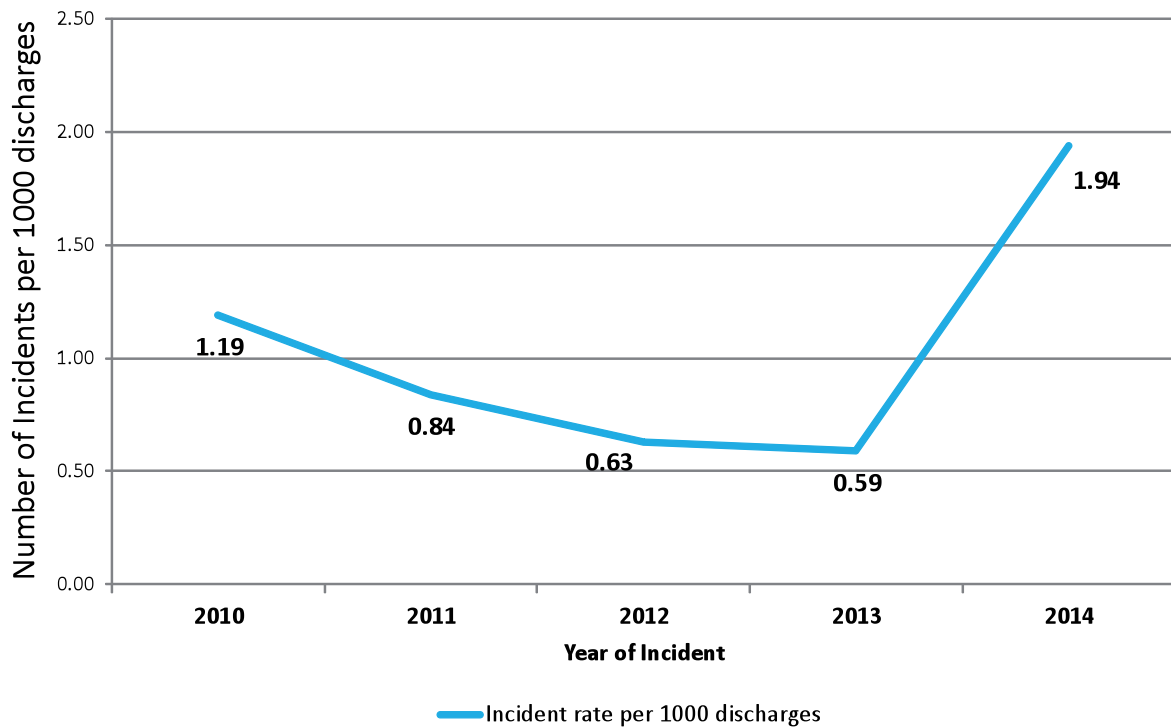


Figure 26: Failure or faulty medical device/equipment per 1,000 discharges for diseases and disorders of the female reproductive system, which occurred, 2010–2014 inclusive

5.2.4.5 Delayed or cancelled surgery

Detailed analysis demonstrated that delayed/cancelled surgery figures, adjusted for activity, increased more than 10 fold between the years 2010 [n=10] to 2014 [n=101]. The reasons reported by Maternity services for cancellations included “emergency cases” and “over-run in theatre”. This increase may be related to access to inpatient beds. It may reflect that the work in Maternity services is sometimes more of an emergency nature, while in Gynaecology it is generally, though not always, more elective. This area may be worth further analysis by Maternity services to assess if the delayed surgeries were related to benign or malignant Gynaecological conditions [Figure 27].

Internationally, cancelled surgeries are an issue. In the UK, the number of cancelled elective surgeries, as reported by NHS England, has increased between 2013/2014 to 2015: it represents 1.1% of all elective activity for the first quarter (1 January - 31 March) of 2015 compared with 0.9% for the same period 2013/14⁵⁴.

A recent Australian study revealed that “day of surgery cancellations” were 7.2% with the top 4 reasons accounting for 65% of all cancellations including patient medically unfit, operation not necessary, postponement due to patient condition, and patient late or no show⁵⁵. Patient rather than hospital related reasons accounted for more cancellations in a recent U.S. study, where they concluded that a cancellation rate of less than 2% is achievable⁵⁶. Seim et al.⁵⁷ identified a lack of meaningful explanation for the “day of surgery cancellation” in up to 36% of cases at a US teaching hospital, highlighting the need for quality data to guide cancellation reduction strategies.

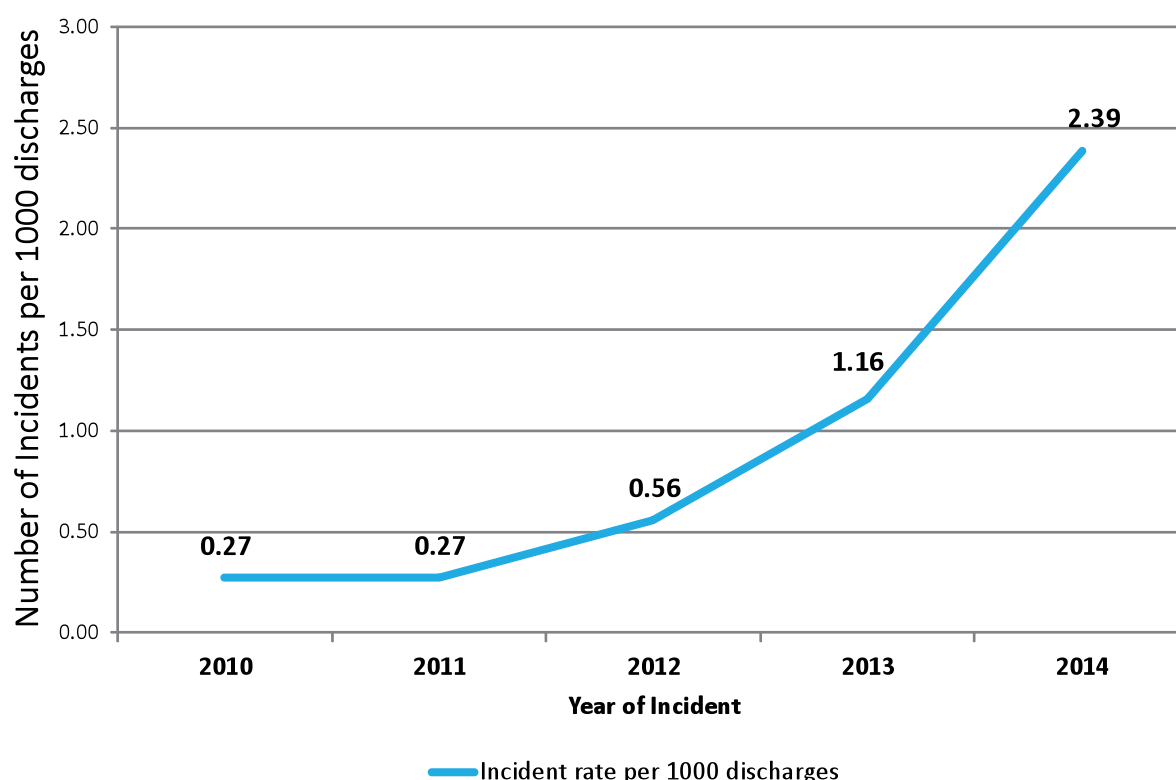


Figure 27: Delayed/cancelled surgery per 1,000 discharges for diseases and disorders of the female reproductive system, which occurred, 2010–2014 inclusive.

5.2.4.6 Unexpected complications following an operation/surgical procedure

This was the next most common incident which occurred in Gynaecology services and notified to the SCA. While unexpected complications following an operation/surgical procedure appeared to have a once-off spike in the year 2013 (n=44), this had reverted almost to 2010 figures in the year 2014 (n=21, rate of 0.5/1,000 discharges) [Figure 28]. Detailed analysis identified that pain, bleeding and urinary retention were among the common complications.

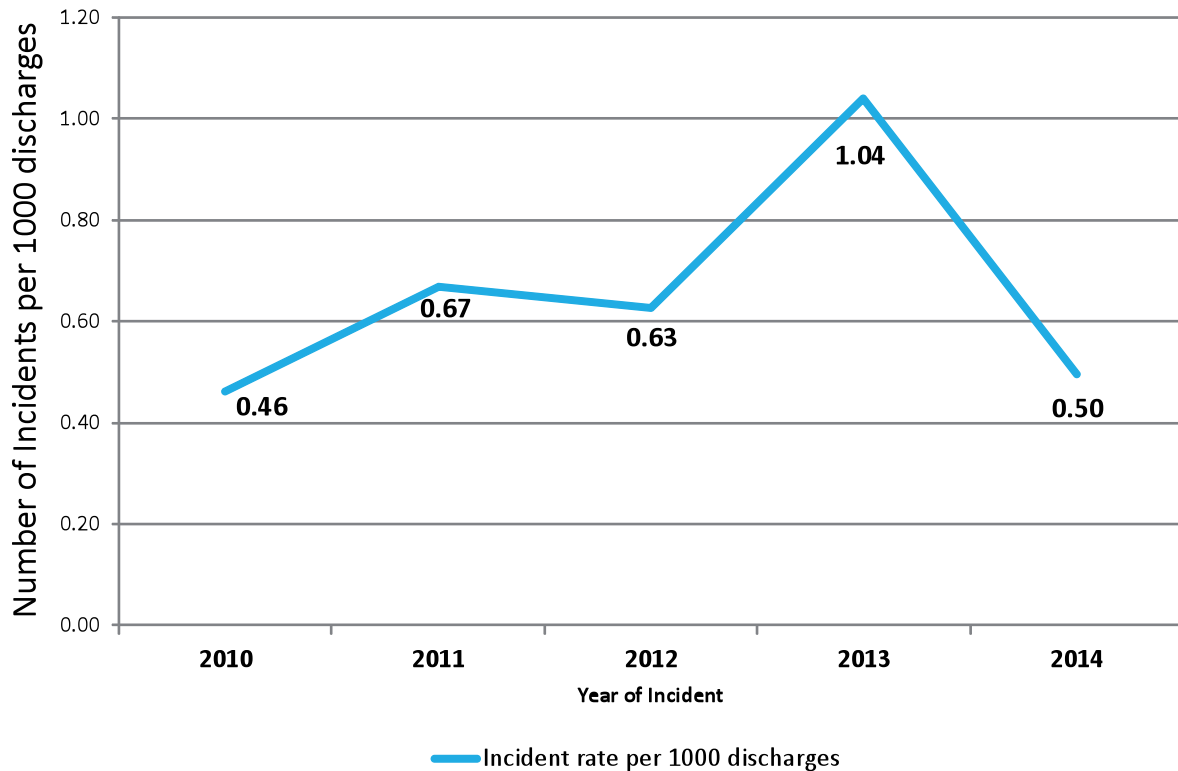


Figure 28: Unexpected complications following operation/surgical procedure per 1,000 discharges for diseases and disorders of the female reproductive system, which occurred, 2010–2014 inclusive

5.2.4.7 Unintentional punch/laceration of an organ

The subsequent most common incident which occurred in Gynaecology services was unintentional punch/laceration of an organ [Figure 29]. There has been a slight reduction overall in the “unintentional laceration of an organ” rate between 2010 [0.76/1,000 discharges in 2010 to 0.59/1,000 in 2014: n=28 in 2010 to n=25 in 2014]. The 25 incidents reported in the year 2014 included laceration to the uterus, bladder, stomach and bowel.

Extensive gynaecological surgery often entails meticulous dissection near the bladder, rectum, ureters, and great vessels of the pelvis. The risk of complications depends upon the extent of, and approach to, surgery in addition to patient characteristics. Understandably, the more common complications from this surgery relate to injuries to these viscera and occur during extensive resections for the treatment of cancer or when anatomy is distorted due to infection or endometriosis. Due to the range of surgeries and pathology involved, no overall international incidence is applicable.

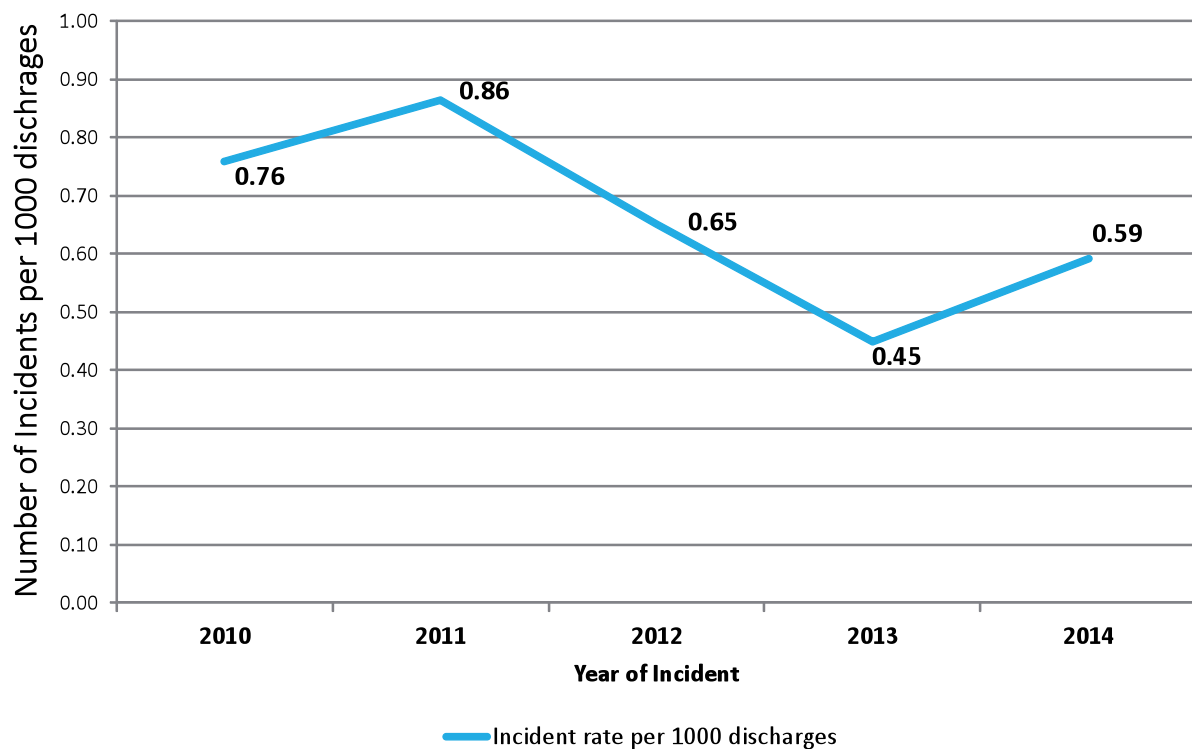


Figure 29: Unintentional punch/laceration to an organ per 1,000 discharges for diseases and disorders of the female reproductive system, which occurred, 2010–2014 inclusive

5.3 CLAIMS CREATED IN GYNAECOLOGY SERVICES IN 2014

In 2014, 33 Gynaecology related claims were created, all of which were clinical.

5.3.1 Claims created in Gynaecology services by severity rating in 2014

Regarding severity rating of the clinical claims created in Gynaecology, this was *not known/legacy data* in 22 [67%], major in 1 [3%], and moderate in 10 [30%] [Figure 30].

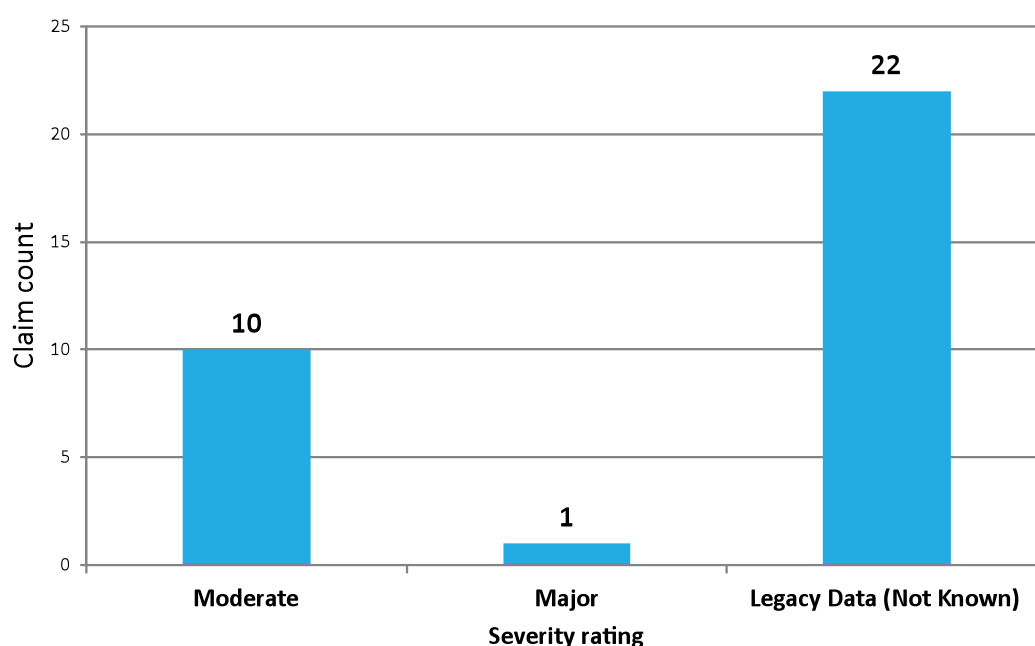


Figure 30: Clinical claims in Gynaecology services created in 2014 by severity rating

5.3.2 Claims in Gynaecology services created, 2010–2014 inclusive

5.3.2.1 Ten most common claims created in Gynaecology services, 2010–2014 inclusive

The 10 most common Gynaecology claims created in the years 2010 to 2014 inclusive, are outlined in Table 10. Wrong operation/surgical procedure is the most common (n=100). This is explained by the mass action, the Lourdes Hospital Redress Scheme. This scheme 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 bilateral oophorectomy. The government approved this non-statutory scheme and the establishment of an independent redress board to determine applications and direct *ex gratia* payments to be made by the Minister for Health in accordance with this scheme.

The “other” group was analysed in detail manually and identified some cases of failed tubal ligation, retained tissue following hysterectomy, post-operative complications of hysterectomy, complications of an intra-uterine device [IUD], delay in follow up for abnormal cytology, presentation for recurrent bleeding ultimately resulting in malignancy and solicitors’ letters without any details [Table 10].

Other common claims created include complications following or during an operation, laceration of an organ or a retained foreign body.

Ten most common claims in Gynaecology services, created 2010-2014 inclusive	Total Claim Count
Wrong operation/procedure*	100
Other	31
Unexpected complications following operation/procedure	16
Unintentional punch/laceration to organ	12
Unexpected complications during operation/procedure	10
Delayed diagnosis	9
Missing/retained swab/device/needle	8
Delay/failure to treat - adverse outcome	6
Failure to diagnose	5
Unnecessary surgery/procedure	4

Table 10: Ten most common claims in Gynaecology services 2010-2014 inclusive

5.3.2.2 Most common claims created in Gynaecology services, plotted over 5 years, 2010-2014 inclusive

The 6 most common claims created in Gynaecology, plotted over 5 years, 2010-2014, categorised by claim type and excluding mass actions were reviewed and analysed [Figure 31]. Overall, numbers are low.

5.3.2.3 Top claims by cost in Gynaecology services, 2010-2014 inclusive

In contrast, the top 10 claims created in Gynaecology services in the years 2010-2014 inclusive, based on cost are outlined below [Table 11]. Cost is defined as total transactional expenditure plus outstanding estimated liability. This list is not very dissimilar to that of the “most common claims in Gynaecology”. Clinical claims in Gynaecology differ in value from some of those in Maternity services, where the value of the latter may reach millions of euro per claim, e.g. catastrophic injury claims.

Top ten claims in Gynaecology services based on cost, 2010-2014 inclusive
Other
Unexpected Complications During Operation/Procedure
Delayed Diagnosis
Unintentional Punch/Laceration to Organ
Unexpected Complications Following Operation/Procedure
Delay/Failure to Treat
Failure to Diagnose
Wrong Operation/Procedure
Missing/Retained Swab/Device/Needle
Transfer to Another Hospital/HDU

Table 11: Top 10 claims in Gynaecology services based on cost, 2010-2014 inclusive

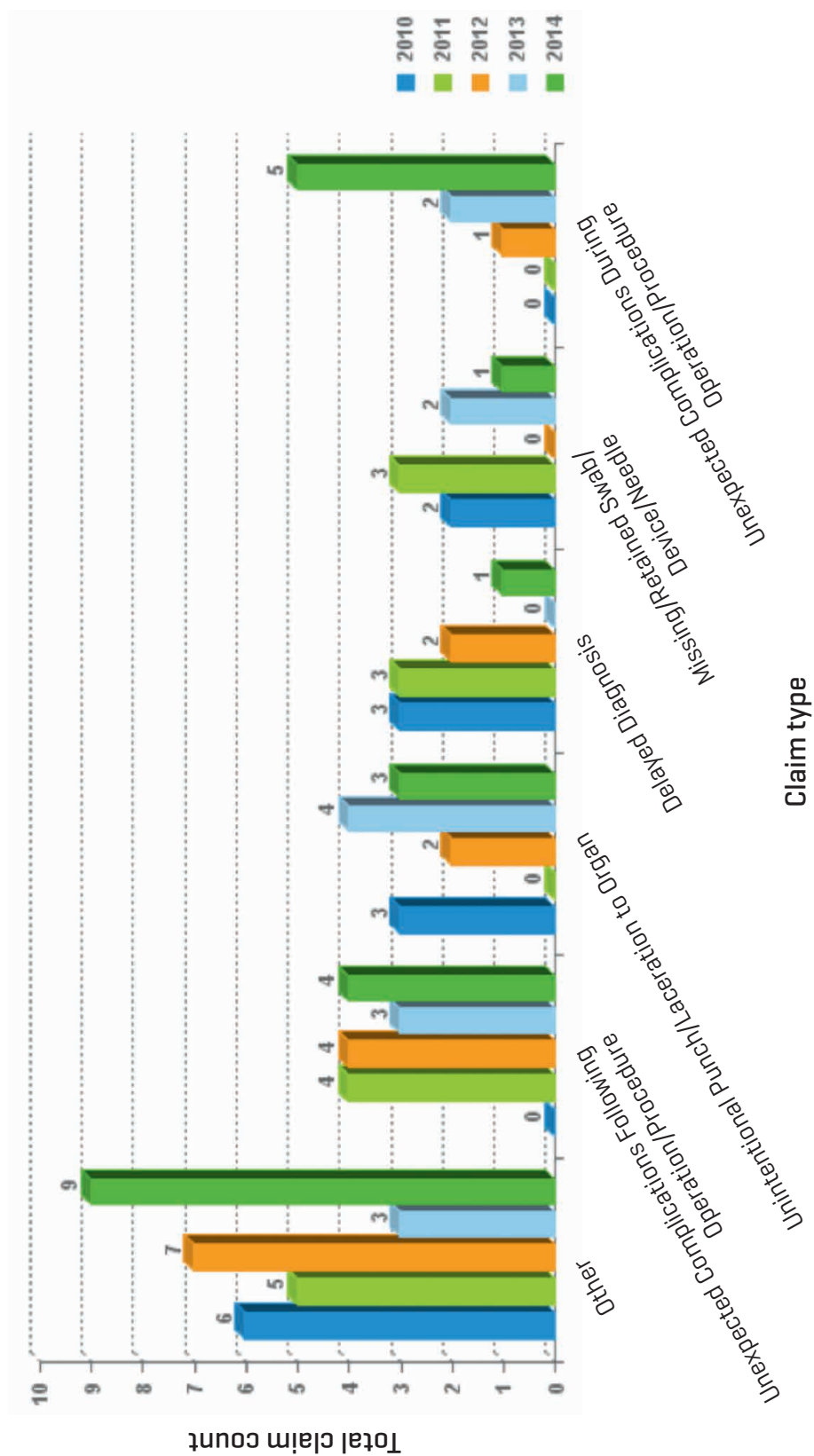


Figure 31: Six most common claims created in Gynaecology services, plotted over 5 years, 2010-2014 inclusive, categorised by claim type, excluding mass actions

5.4 COMPARISON OF THE 19 CO-LOCATED GYNAECOLOGY AND MATERNITY SERVICES ANONYMISED

5.4.1 Background

Gynaecology services co-located with Maternity services at the 19 locations nationally were analysed from an incident and claims perspective.

Clinical services, nationally and internationally, compare themselves to similar sized services in an attempt to benchmark their work. The aim is to reduce variation in care and achieve standardisation of care which is equal or superior to best international standards.

For the first time, this report is providing data pertaining to the 19 co-located Gynaecology and Maternity services regarding incidents and claims for 2014 and between 2012-2014 compared in an anonymous fashion. Each individual co-located Gynaecology service will have the identity of their service revealed to them but they will be blinded to the identity of the other 18 services. The activity of each individual Gynaecology service was not available, so incidents and claims are *not adjusted for activity*, as was done for Maternity services. Numbers are significantly smaller for Gynaecology services, particularly claims.

5.4.2 Number of incidents which occurred in Gynaecology for each of the 19 co-located Gynaecology and Maternity services, anonymised, in 2014

The actual “incident count” is reported here, rather than the “rate” because activity data was not available for each service in Gynaecology for 2014 [Figure 32]. Cognisant that some services have a higher Gynaecology activity than others, variation is noted with hospital A reporting a higher number of incidents than others, similar to its reporting pattern in Maternity services [Figure 16]. A high level of reporting, as outlined previously, is generally accepted to reflect a strong culture of patient safety, particularly where claims are low [Figure 34]. A detailed review of these incidents [453 from hospital A], revealed a large proportion of “other” (n=90), delayed or cancelled surgery (n=88), unplanned re-attendance (n=53), PPH (n=34), transfer to another hospital (n=39) and urinary retention (n=15).

5.4.3 Number of incidents which occurred in Gynaecology for each of the 19 co-located Gynaecology and Maternity Services, anonymised, 2012-2014 inclusive

The number of incidents which occurred in the 19 co-located Gynaecology services, plotted over 3 years [2012-2014], was analysed, varied patterns of reporting by different hospitals emerge [Figure 33].

5.4.4 Number of claims in Gynaecology for each of the 19 co-located Gynaecology and Maternity services, anonymised, 2012-2014 inclusive

Overall, the number of claims in Gynaecology is relatively low and some Gynaecology services (hospitals J, K and N) had no claims created over the time period 2012-2014 [Figure 34].

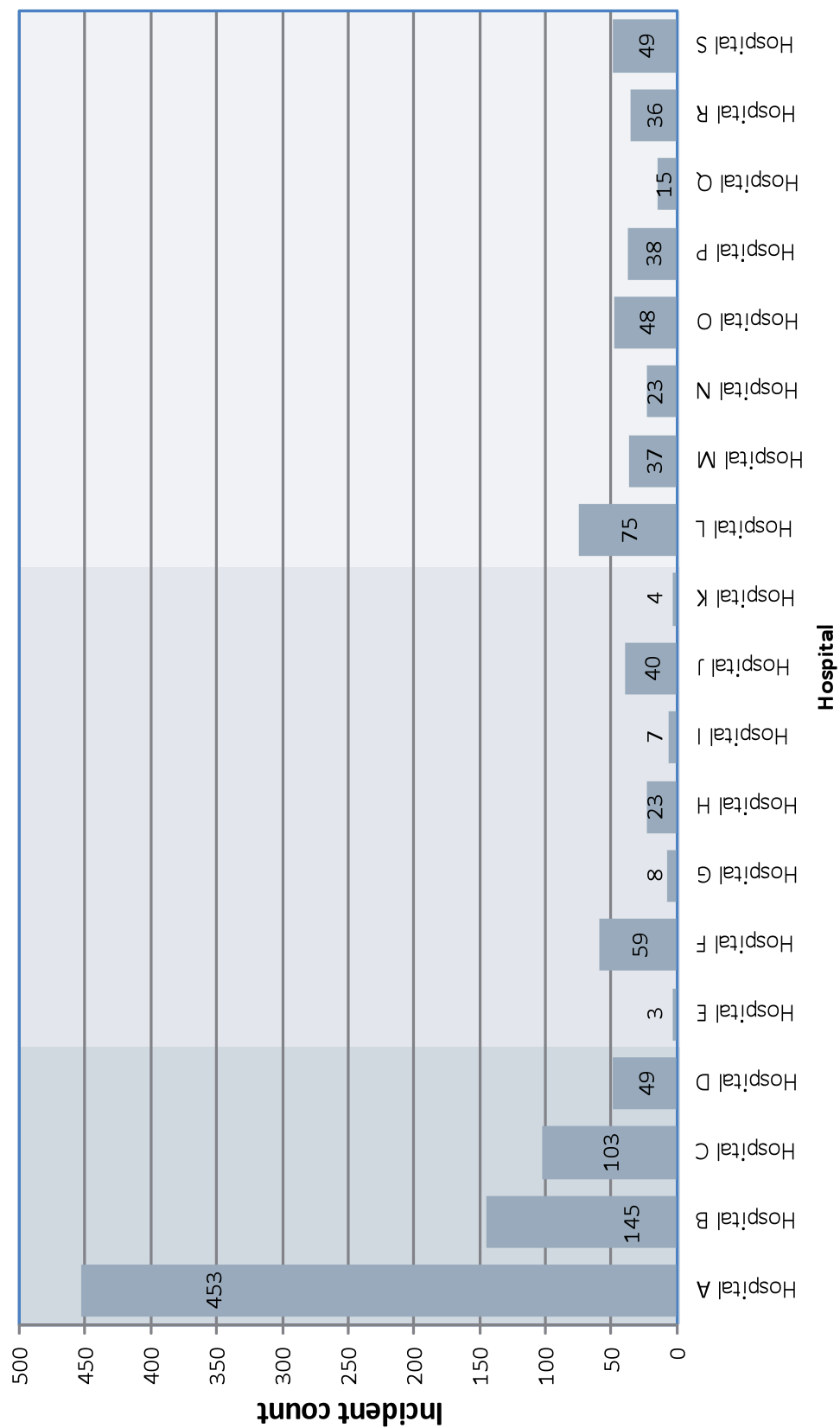


Figure 32: Number of incidents which occurred in Gynaecology services, for each of the 19 co-located Gynaecology and Maternity services, anonymised, in 2014

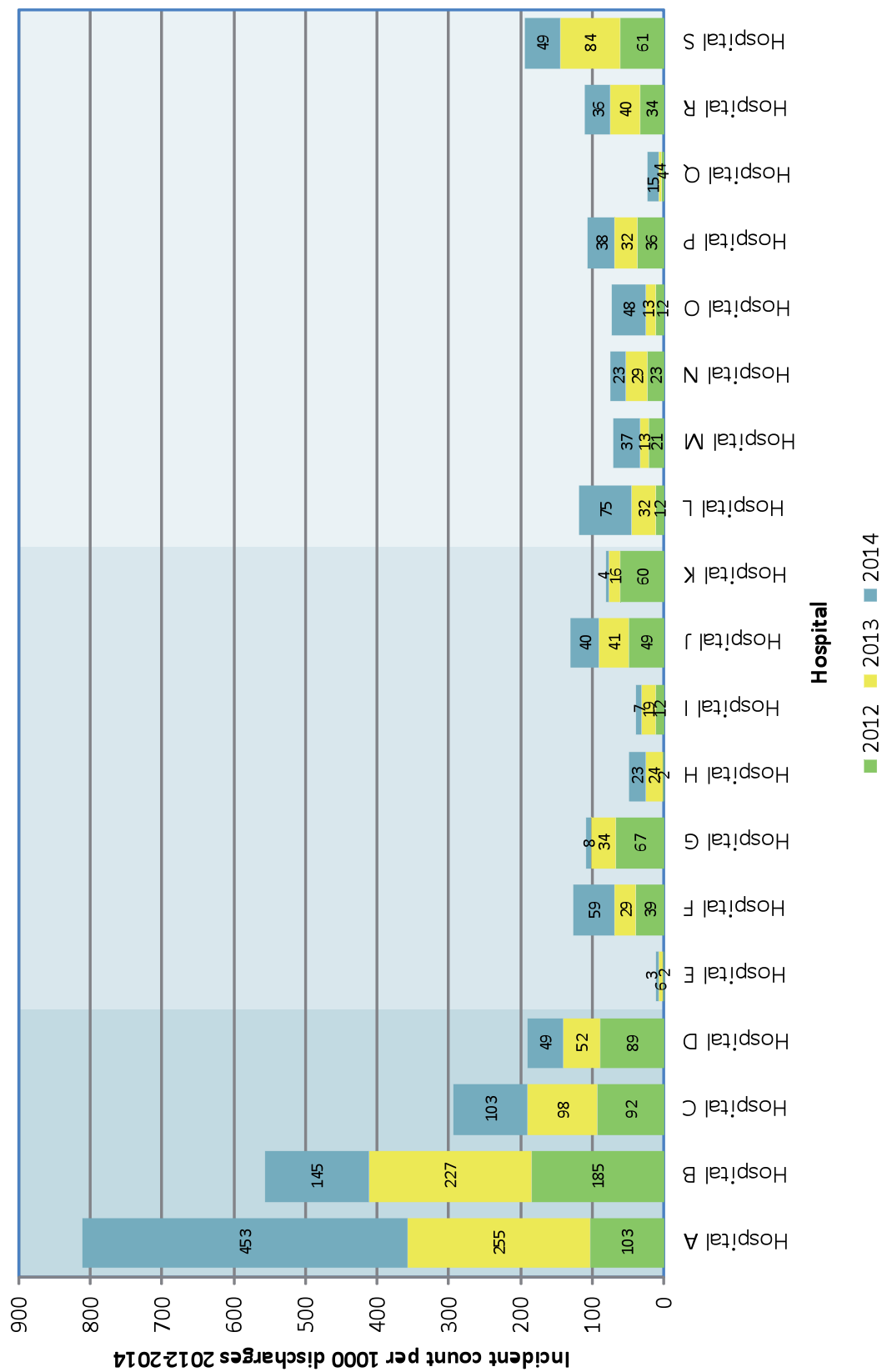


Figure 33: Number of incidents in Gynaecology services for each of the 19 co-located Gynaecology and Maternity services, anonymised, which occurred 2012–2014 inclusive

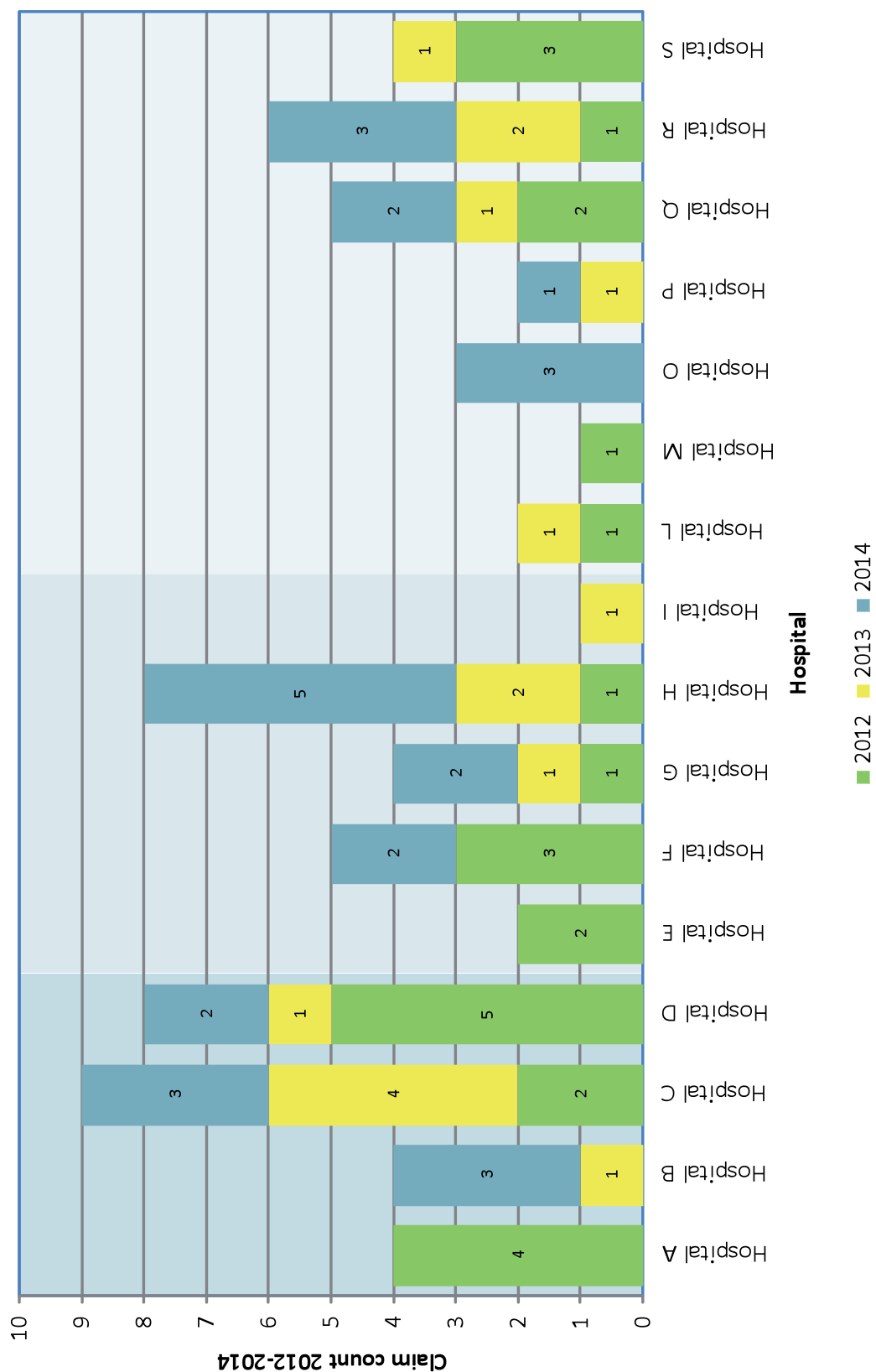


Figure 34: Number of claims created in Gynaecology for the co-located Gynaecology and Maternity services, anonymised, created, 2012-2014 inclusive

5.4.5 Total Expenditure on claims in Gynaecology services

5.4.5.1 Total expenditure on claims created in Gynaecology services and total clinical care, 2010-2014 inclusive

Total expenditure on claims created in Gynaecology in 2014 amounted to €4.2 million which accounts for -4% of the total expenditure for total clinical claims in 2014. Expenditure on claims in Gynaecology services has increased almost 3 fold in 5 years from €1.4 million in 2010 [Table 12].

	Total Transactional Expenditure 2010-2014	
	Clinical Care	Gynaecology
2010	€74,001,771	€1,425,887
2011	€87,850,611	€1,597,067
2012	€77,501,523	€1,866,563
2013	€116,104,083	€2,826,166
2014	€106,182,012	€4,196,680

Table 12: Total expenditure on claims created in Gynaecology services and total clinical care, 2010-2014 inclusive

5.4.5.2 Breakdown in total expenditure on claims created in Gynaecology services, 2010-2014 inclusive

Total expenditure has significantly increased in Gynaecology related claims due to legal fees [a more than 2 fold increase] and damages [a more than 4 fold increase] between 2010 and 2014 [Table 13]. Expert's costs have trebled in the same time period [Table 13]. A breakdown of the damages, legal fees and expert costs between 2005 and 2014 is provided graphically in Figure 35.

Gynaecology				
Year of Transaction	Damages (€m)	Legal Costs (€m)	Expert Costs (€m)	Overall Transactional Expenditure (€m)
2010	0.42	0.97	0.04	1.4
2011	0.65	0.91	0.03	1.6
2012	1.11	0.71	0.05	1.9
2013	1.52	1.22	0.08	2.8
2014	1.9	2.18	0.12	4.2

Table 13: Total transactional expenditure paid on claims created in Gynaecology services, 2010-2014 inclusive

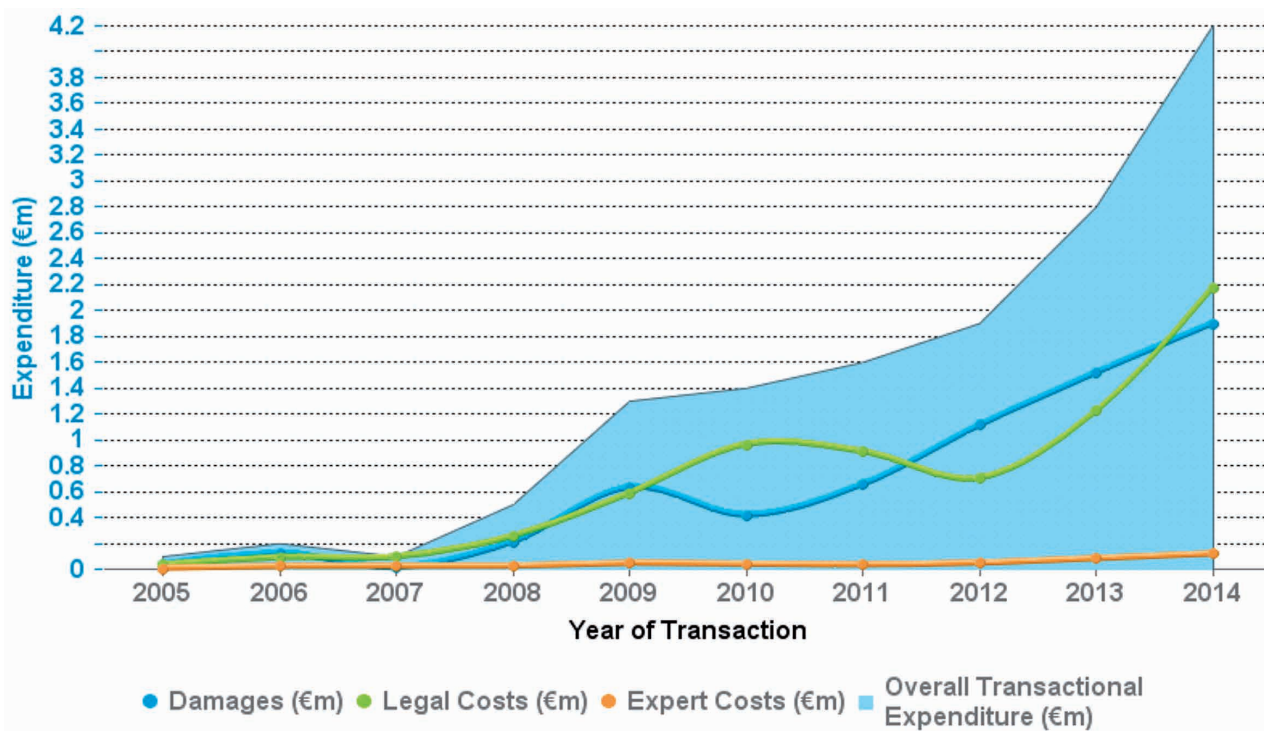


Figure 35: Total transactional expenditure (in € millions) in Gynaecology services, 2005-2014 inclusive

6. FOCUSED TOPIC: RETAINED FOREIGN BODIES IN MATERNITY AND GYNAECOLOGY SERVICES – A 10 YEAR REVIEW OF CLOSED CLAIMS

A 10 year national review of closed medico-legal claims pertaining to retained foreign bodies in Maternity and Gynaecology Services was performed.

6.1 Background

In the *res ipsa loquitur* legal doctrine [the Latin phrase “the thing speaks for itself”], the elements of duty of care, breach and causation are inferred from an injury that does not ordinarily occur without negligence. Retained foreign bodies are indefensible at law: medical negligence is admitted and the amount paid in respect of the claim is generally proportional to the morbidity incurred. A retrospective 10 year file review [legal file and health care record], of all closed claims pertaining to foreign bodies under the specialities of Maternity and Gynaecology Services, using NIMS, was performed. This period of time was chosen to ensure adequate numbers were obtained for this analysis.

6.2 Retained foreign bodies in Maternity Services – a national review of 10 years of medico-legal closed claims

Aim: To review all medico-legal closed claims pertaining to retained foreign bodies in Maternity services, in public hospitals nationally over a 10 year period, [2004-2014] and identify opportunities for learning.

Methods: A retrospective review was performed of the SCA’s claims files and health care records of all closed claims files in Maternity services in the 19 public hospitals nationally between the years 2004 to 2014. A list was obtained using the NIMS and a search was carried out using the terms “*Maternity services*” and “*foreign body*”. The files were reviewed by one Consultant Physician.

Results: Thirty closed claims for retained foreign bodies in Maternity services were identified after files review. Regarding the nature of the foreign body, 28 [93.3%] pertained to retained swabs, 1 [3.3%] to a retained epidural catheter tip and 1 [3.3%] to a retained instrument.

Regarding location and surgical procedure involved, 5 [16.7%] foreign bodies were left *in situ* in the operating theatre, of which 4 were post caesarean section and 1 was post repair of a third degree tear incurred during delivery [Figure 36]. Twenty five [83.3%] foreign bodies were left *in situ* in the delivery ward, of which 17 [56.7%] were associated with instrumental delivery, seven [23.3%] with non-instrumental delivery and 1 [3.3%] with an epidural catheter tip. Regarding the 17 associated with instrumental delivery, twelve [40%] were left *in situ* following vacuum deliveries, 2 [6.7%] following forceps deliveries and 3 [10%] following the use of both vacuum and forceps.

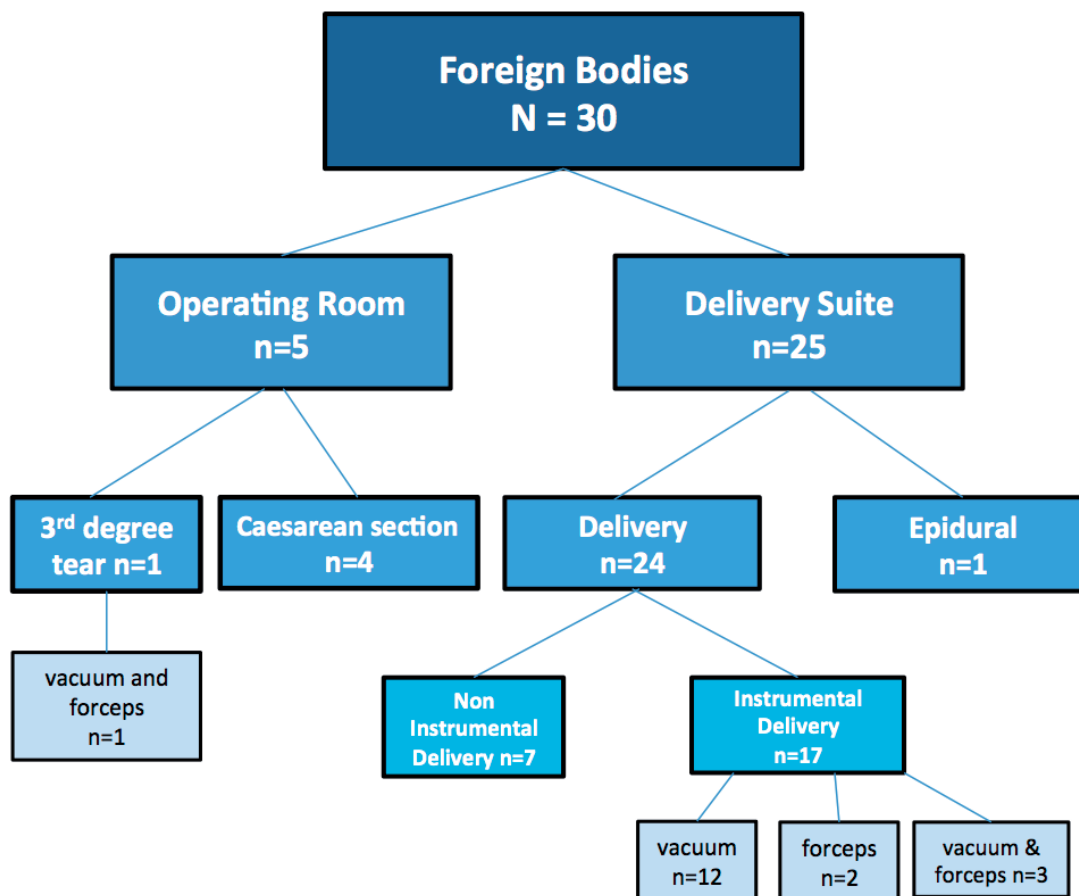


Figure 36: Retained foreign bodies in Maternity services claims: location and associated procedure

Seventeen [56.7%] occurred following episiotomy repair, 6 [20%] following repair of tear incurred during delivery and 2 [6.7%] post repair of both a tear and an episiotomy [Table 11]. Primigravida women were most commonly affected [n=20, 66.7%] in this review.

All patients with retained swabs [n=28, 93.3%] were symptomatic with combinations of pain, foul smelling discharge, difficulty walking and sitting and general malaise. Regarding confirmed infection on testing, insufficient information was available on all cases regarding high vaginal swab, which was culture positive in 4 cases, of which 2 cultured *Group B Streptococcus* and 2 anaerobes.

Eleven days was the mean duration that the foreign body was left *in situ* prior to identification [range < 1 day to 35 days]. A mean of 1.8 visits to health care professionals occurred in order for retention of a foreign body to be identified [range 0-4 visits]. Regarding who identified the foreign body, this was most commonly by a hospital doctor in 13 [43.3%] cases, by the patient during self-examination in 8 [26.7%] cases, by a General Practitioner in 7 [23.3%] and a public health nurse in 2 [6.7%] cases.

Regarding treatment, 3 [10%] patients were admitted from home for intravenous antibiotic treatment. Metronidazole and co-amoxiclavulanic acid was the most common antibiotic combination therapy prescribed [n=27, 90%]. One patient with a penicillin allergy was treated with erythromycin, another received flucloxacillin instead of co-amoxiclavulanic acid and one with intravenous gentamycin in theatre.

Regarding workload, in one case, the doctor suturing the episiotomy was called away to an emergency situation on two occasions during the procedure.

In one case, it was thought that an instrument was retained. This instrument was identified on a radiograph following a caesarean section performed because of *Group B Streptococcal* infection. On initial reading of the radiograph, the surgeon's impression was that the instrument was most likely in the patient's clothes or bed. These were searched in addition to the x-ray table. No instrument was identified and repeat x-radiograph confirmed the position of the instrument. The patient was symptomatic despite treatment with intravenous antibiotics. Laparotomy was performed but did not identify any foreign body. The instrument was subsequently identified on repeat check of the x-ray table, under the mattress.

Regarding outcomes, dehiscence of episiotomy and delayed healing with secondary intention was identified in 1 [3.3%] case, while pelvic inflammatory disease was identified in 2 [6.7%] cases. Two [6.7%] patients required an exploratory laparotomy, of which 1 additionally required abscess drainage.

Fourteen [46.7%] women were diagnosed with psychiatric conditions, which included post-natal depression [requiring pharmacotherapy, psychotherapy, or both] and mild adjustment disorder. Psycho sexual complications [n=7, 23.3%], poor bonding with the baby [n=5, 16.7%] and loss of earnings, [n=1, 3.3%] were identified as being associations with a retained foreign body.

Closed Claims pertaining to Retained Foreign Bodies in Maternity Services 2004-2014		
Episiotomy	n	
Vacuum	10	
Non instrumental	4	
Forceps	1	
Vacuum & forceps	2	
		17
Tear		
Non instrumental	3	
Vacuum	2	
Vacuum & forceps [3rd degree repair Operating Room]	1	
		6
Episiotomy & Tear		
Forceps	1	
Vacuum & forceps	1	
		2
Other		
Caesarean Section	4	
Epidural catheter tip	1	
		5
Total		30

Table 14: Closed claims pertaining to retained foreign bodies in Maternity Services, 2004-2014 inclusive

Discussion

The Joint Commission, USA, states that a retained sponge left in a patient unintentionally after a vaginal delivery is a reviewable sentinel event and is reportable as a breach in quality and patient safety⁵⁸. The NHS lists “retained foreign object post procedure including interventions related to birth” as a *never event*; an incident considered unacceptable and eminently preventable⁵⁹.

Gawande et al’s⁶⁰ landmark controlled study of malpractice claims and incident reports involving retention of surgical instruments and swabs, filed between January 1st 1995 and 2001 by the Controlled Risk Insurance Company [CRICO], identified 61 retained foreign bodies, of which 22% were left in the vagina. Risk factors identified, included performance of an emergency procedure, unexpected change in the procedure, failure to count swabs and instruments, a procedure involving more than 1 surgical team and patients with significantly high body mass index [BMI].

Despite education and training, the Minnesota Department of Public Health reported in 2009 that obstetric cases comprised 25% of the total retained foreign bodies identified between the years 2004 and 2008. Internationally, retained foreign bodies continue to remain a concern: 186 retained swabs were identified in closed maternity claims by the NHS litigation authority [NHS LA] between 2000 and 2010⁴⁹ at a cost of £3,021,910.

Internationally, guidance has been published to help prevent recurrence: The National Institute of Health and Clinical Excellence [NICE] guidance *Intrapartum care*²⁰ includes recommendations on the basic principles for perineal repair which include needle and swab counts pre and post procedure. The National Patient Safety Agency produced a rapid response report in May 2010 requiring the NHS organisations to have set processes in place when using swabs during vaginal delivery or perineal repair⁶¹.

Recommendations

Many of the following national and international recommendations have already been implemented by Maternity services nationally.

- Implementation of a specific **counting protocol** for sharps and swabs pre and post vaginal delivery, similar in standard to that of an operating theatre (double counting by two individuals, one of which is a registered nurse, and whiteboards).
- **Clear documentation** of swab and instrument count in the notes after vaginal delivery.
- Implementation of the process of **swab count reconciliation** by performing a vaginal exam or radiograph when the count cannot be reconciled.
- Use of only **radiopaque and tailed swabs** for vaginal packing: (detection tails can be clipped onto the drapes outside the vagina).
- Implementation of the **Communication [Clinical Handover] in Maternity Services National Clinical Guideline**⁶² at vaginal delivery and repair of episiotomy and/or tear.
- Implementing a **quality improvement** programme which ensures each retained foreign body case or near miss is investigated thoroughly, consistent with HSE Safety Incident Management policy⁶³ and lessons learned disseminated to front line workers.
- Multi-phased, multidisciplinary **training and education programme** to all staff involved in the labour ward.

- Implementation of the **Irish Maternity Early Warning System (IMEWS)**, National Clinical Guideline⁶⁴ which contains the communication tool ISBAR [identify, situation, background, assessment and recommendation], in any patient with clinical deterioration possibly related to sepsis from a retained foreign body.
- **Audit** of retained foreign bodies with dissemination of data, and information pertaining to updates on policies or guidelines [national or international]. Audit of above practices.
- **Increase staff numbers** in Maternity services [medical, nursing and midwifery] to levels consistent with international guidelines.

Conclusion

Symptoms of perineal pain and foul smelling lochia in a woman post-delivery should trigger concern for foreign body retention. Examination to rule out a foreign body should be performed prior to any treatment. Many of the above recommendations have already been implemented over the last few years across the Maternity services nationally, which should lead to a reduction or, hopefully, elimination of retained foreign bodies and improve patient safety. Continued vigilance in this area is required.

6.3 Retained foreign bodies in Gynaecology services - a national review of 10 years of medico-legal, closed claims

Aim: To review all retained foreign body, medico-legal claims, closed in the speciality of Gynaecology, nationally in public hospitals over a 10 year period (2004 to 2014) and identify opportunities for learning.

Methods: A retrospective review was performed of all closed claims files and health care records pertaining to retained foreign bodies in Gynaecology services, in public hospitals in Ireland over a 10 year period. This list was obtained using the NIMS. Files were reviewed by one consultant physician.

Results: Fifteen claims of 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 cases of foreign bodies, 4 were left *in situ* 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 [IUDs, 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. The consultant obstetrician/gynaecologist was present in 6 (42.9%) of the cases, in addition to the 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.

All patients received the antibiotic combination of metronidazole and co-moxiclavulanic acid. The mean number of antibiotic courses received was 1.25.

Patients with retained swabs (n=8, 57.1%), presented with a combination of the following 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 hirsutism, raised hormone levels on testing, weight gain and depression. The retained drain caused pain for 18 months, the retained needle was asymptomatic until it presented with a tender lump at the site of the previous surgical scar and the tip of the catheter used in 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. Regarding who identified the 8 retained swabs, this was identified by the general practitioner in 3 [37.5%] cases by the hospital doctor in 3 [37.5%], and by the patient in 2 [25%]. The mean number of visits by patients to health care professionals, to identify the retained swab, was 1.5 [outlier of 5 years excluded].

Regarding the other foreign bodies retained, duration of unintentional retention of an IUCD was longer than that of a swab, and varied from 10 days in one case, 11 months in the second to 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 and the knowledge that the foreign body was superficial, it was not removed at the time. It was subsequently removed under local anaesthetic. Similarly, retention of the tip of the catheter at ERPC was identified at the time of removal of the catheter, at the end of the procedure. This catheter tip was removed 3 three days later at hysteroscopy. A segment of a drain, inserted post hysterectomy and bilateral oophorectomy, was left in situ for 18 eighteen months prior to its 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 hysterosalpingogram (n=1, 7.1%).

Discussion

Retained foreign bodies are items unintentionally left inside patients after surgery. These are most commonly swabs, needles, and surgical instruments. The Joint Commission has, for a number of years, considered a retained foreign body a reportable, sentinel event, and the Centers for Medicare and Medicaid Services [insurance schemes] considers it a hospital-acquired condition and a “never event” for which additional reimbursement to manage this complication will not be provided⁶⁵. The HSE listed retained foreign body as a Serious Reportable Event [SRE] in 2015⁶⁶.

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, the American College of Surgeons⁶⁷, in conjunction with the Association of Perioperative Registered Nurses [AORN], issued guidelines for the performance of counting of all swabs/sponges and sharps⁶⁸. Counts are recommended: 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^{69,60}.

Radiology

Most institutions rely on radiologic screening to help resolve counting discrepancies. Cima et al.'s⁶⁹ 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 objects have been advocated. Goldberg et al.⁷⁰ 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]⁷¹.

Other patient safety initiatives, nationally and internationally, include implementation of the Surgical Safety Checklist (WHO),⁷² HSE safety pause⁷³ and use of communication tools such as ISBAR (identify, situation, background, assessment and recommendations).

Recommendations

Similar to retained foreign bodies in Maternity services, many of the national and international recommendations outlined below have been implemented across the Gynaecology services nationally:

- Ensuring a **counting policy is implemented**, audited and reviewed (including double counting, use of white boards and documentation).
- **Clear documentation** of swab and instrument count in the notes after gynaecological procedure.
- Implementation of the process of **swab count reconciliation** by performing a vaginal exam or radiograph when the count cannot be reconciled.
- Use of **radiopaque and tailed swabs** for vaginal packing: (detection tails can be clipped onto the drapes outside the vagina).
- Implementation of the **Communication [Clinical Handover] in Maternity Services National Clinical Guideline, 2014**⁶².
- Implementing a **quality improvement** programme which ensures each retained foreign body case or near miss is investigated thoroughly. This is consistent with HSE policy⁶³. Ensure that lessons learned are disseminated to front line workers.
- Multi-phased, multidisciplinary **training and education programme** to all staff involved in the labour ward and operating room.
- **Audit** of retained foreign bodies with dissemination of data, and any updates on policies or guidelines (national or international). Audit of above practices.
- **Increasing staff numbers** in Gynaecology services (medical and nursing) to levels consistent with international guidelines.
- **Implementation of HSE safety pause**⁷³ and education regarding the importance of situational awareness.

Conclusion

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

7. National Survey of the Modes and Patterns of Incident Reporting in Acute Hospitals in Ireland: 2015

7.1 Patient Safety International

The landscape of patient safety is changing. The Institute of Medicine's [USA], first quality report *"To Err is Human: building a safer health system"*⁷⁴ [published 1999], identified preventable lapses in patient safety resulting in 44–88,000 Americans who die each year, the eighth leading cause of death and a cost of \$29 billion annually. The majority of these problems are systemic and not the fault of individual providers. In 2002, the Joint Commission, the major accrediting body [USA], identified 6 National Patient Safety Goals [NPSG] and the National Quality Forum listed 28 serious reportable events [*never events*] that should not happen.

Subsequently, a change in approach occurred: a payment system was used as a driver for patient safety with centres for Medicare and Medicaid Services [CMS] stating 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, revealing that 30% of admitted patients experience adverse events. Based on modern studies published between 2008 and 2011 and applying the global trigger tool to the whole population of the U.S.A., John James published an updated estimate of premature deaths associated with preventable harm. This figure was estimated at between 200,000–400,000 per year⁷⁵. Internationally, publications have documented that incident reporting is low. A recent paper from the United States Department of Health identified that hospital staff did not report 86% of events to incident reporting systems⁷⁶.

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 provides feedback to NHS organisations including the comparative reporting rates, regularity and speed of reporting, the top 10 incident types reported and the incidents reported by degree of harm.

7.1.1 Patient Safety National

The report of the Commission on Patient Safety and Quality Assurance, *Building a Culture of Patient Safety*⁷⁷ [the "Madden report"], published 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. Regarding reporting of incidents, NIMS has had over 1 million incidents reported since its inception in 2005 [then STARSWeb].

7.2 Results of the national survey of the modes and patterns of incident reporting by acute hospitals

"If you do not measure it – you cannot improve it".

No baseline data existed regarding the modes and patterns of incident reporting by acute hospitals in Ireland. Baseline data is critical so that the effect of changes implemented, can be measured.

A national survey of the modes and patterns of incident reporting by acute hospitals was performed by the Clinical Risk team at the SCA, in the first half of 2015. The list of acute hospitals obtained from the HSE, Acute Hospital Division January 2015 [appendix 1]. All sites (n=50, 100%) responded, though not all sites answered every question.

Results from the responses obtained:

Q 1 Do you report incidents to STARSWeb/NIMS?

Forty nine (98%) hospitals responded that they report incidents on STARSWeb/NIMS, 1 (2%) answered it did not.

Q 2 Do you report to both STARSWeb/NIMS and another system?

Seventeen (34%) answered that they **dual report** to both STARSWeb/NIMS and another incident reporting system: of which 11 (22%) listed the local in-house database, 5 (10%) listed Q Pulse and 1 (2%) listed the Respond system.

Q 3 Do you send all your incidents to a central site for entering on a reporting system?

Five (10%) responded that all their incident reports are sent centrally to a location off site, Kilcreene Orthopaedic Hospital, Kilkenny, from where they are then notified to STARSWeb/NIMS; 1 (2%) responded that they are sent centrally to the Saolta group [*"which is configured according to Saolta directorates rather than hospitals"*] and 1 answered that in the past it had sent all reports to a HSE location offsite in Clonminch, Tullamore.

Q 4 Who logs/enters on the computer the incidents in your hospital?

In 40 (80%) hospitals, an **administrator** enters the data on the computer, while in 7 (14%) hospitals a clinical risk manager performs this task and in 3 (6%) all staff have access, because there is incident reporting at point of occurrence [Figure 37].

Who logs/enters on the computer the incidents/adverse events in your hospital? (n=50)

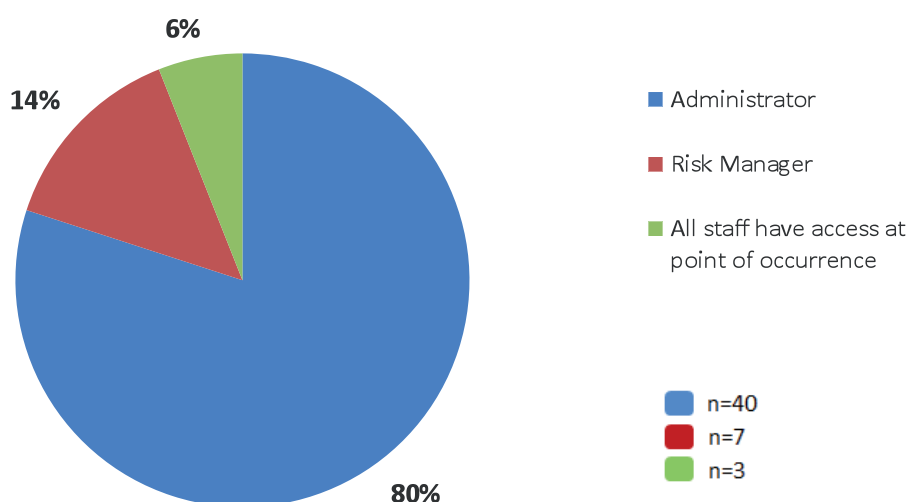


Figure 37: Who logs/enters on the computer the incidents/adverse events in your hospital?

Q 5 Who decides what incidents are reported to STARSWeb/NIMS?

Regarding who decides which incidents notified to acute hospitals are subsequently reported to STARSWeb/NIMS, varied responses were obtained. In 33 [66%] hospitals a quality, safety and risk manager was involved in the decision +/- another staff member; in 11 [22%] hospitals, all incidents are logged; in 3 [6%] hospitals administrative staff decide; in 2 [4%] hospitals senior management decide, and in 1 [2%] hospital the Director of Nursing makes the decision.

Q 6 Do you have a list to identify which incidents are reported to STARSWeb/NIMS?

Thirty four [68%] acute hospitals have a "list" to identify which incidents should be reported to NIMS while, 15 [30%] do not and 1 [2%] does not report to STARSWeb/NIMS [Figure 37].

Do you have a list to identify which incidents/adverse events are reported on STARSWeb/NIMS? (n=50)

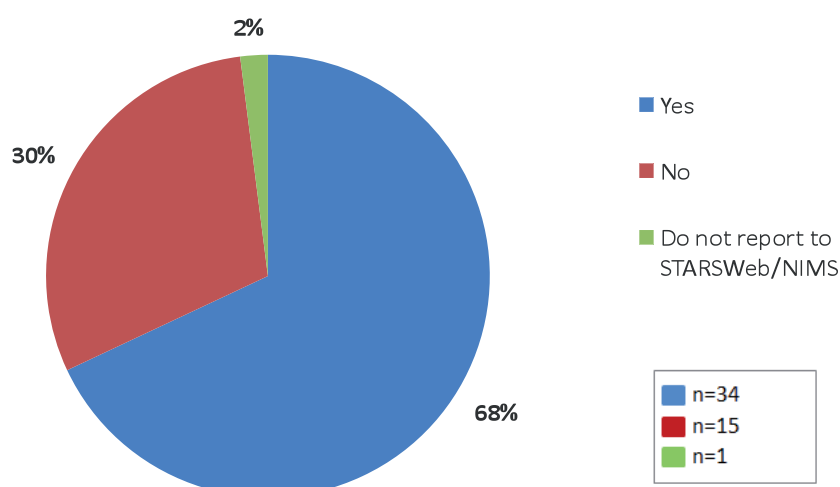


Figure 38: Do you have a list to identify which incidents/adverse events are reported on STARSWeb/NIMS?

Q 7 Approximately what percentage of incidents are reported to STARSWeb/NIMS?

The majority (n=38, 76%) of hospitals responded that they report between 75-100% of incidents to STARSWeb/NIMS:

- 9 (18%) hospitals report 50% or less of incidents, of which 4 (8%) report between 10-30% of incidents and 2 (4%) report less than 10% of incidents.
- 1 (2%) hospital reports between 50-75% of incidents
- 1 (2%) hospital confirmed that it does not report to NIMS and 1 (2%) hospital did not answer the question.

Approximately what percentage of incidents/adverse events are reported to STARSWeb/NIMS? (n=49)

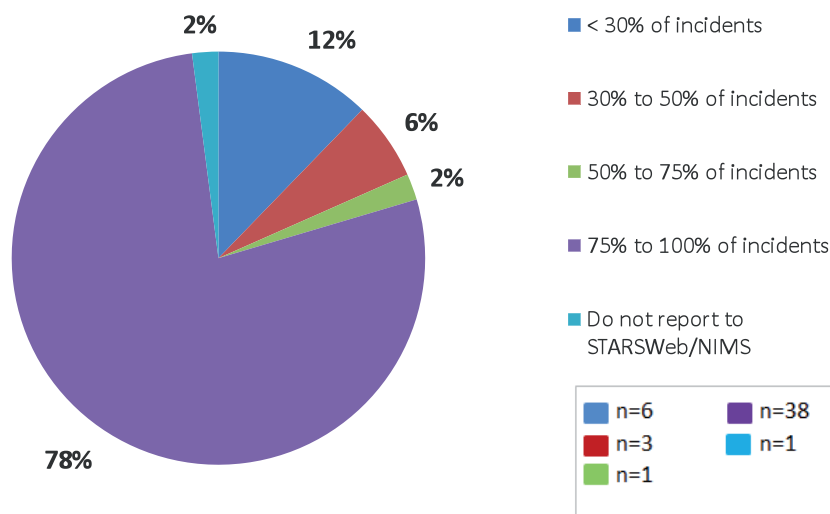


Figure 39: Approximately what percentage of incidents/adverse events are reported to STARSWeb/NIMS?

Q 8 What is the average time frame between the incident occurring and reporting the information to STARSWeb/NIMS?

This was quantified as follows;

- 1 month in 34 (68%) hospitals: of which 16 (32%) were within 1 week, 13 (26%) within 2 weeks and 5 (10%) within 4 weeks
- 1-3 months in 8 (16%)
- 6 months in 1 (2%)
- and in the remaining 7 (14%) hospitals; 2 (4%) responded "do not know", 2 (4%) responded "it varies", 2 (4%) did not answer the question and 1 (2%) did not report to STARSWeb/NIMS.
- One respondent answered that Maternity incidents are given priority and reported within 24-48 hours while incidents without an adverse outcome may take months to report. Shortage of staff was cited as an issue.

Q 9 Is there a statutory obligation to report to STARSWeb/NIMS?

Forty five [90%] acute hospitals answered correctly that it is a statutory obligation to report adverse events to NIMS, while 5 [10%] answered it is not.

Q 10 If the incident is reported on another reporting system, does that fulfil the hospital's statutory obligation to report to STARSWeb/NIMS?

Thirty eight [76%] hospitals were aware that reporting incidents on a reporting system separate to NIMS did not fulfil the statutory obligation, while 6 [12%] said it did and 6 [12%] did not answer the question.

Q 11 Do you have a backlog of incidents to report to STARSWeb/NIMS?

Twenty six [52%] hospitals answered "yes", while 24 [48%] answered "no".

Q 12 How big is this backlog?

Regarding the size of the backlog of incidents to be reported, by the 26 hospitals with a backlog: 12 hospitals answered less than 100 incidents; 8 answered between 100-500; 3 hospitals answered between 500-1,000 incidents and 3 hospitals answered greater than 1,000 incidents.

7.2.1 Conclusions and discussion from the national survey

While the majority (n=49, 98%) of acute hospitals nationally in the first quarter of 2015 reported incidents to STARSWeb/NIMS, not all did. This has since been rectified. There are a number of acute hospitals "dual reporting" i.e. reporting incidents on two incident reporting systems e.g. *Respond* or *Q pulse*. This is inefficient. The *Incident Information Management System* (IIMS), was a reporting system utilised in the Midlands, until recently and run by the HSE. This has now been discontinued and a number of years of data was transferred in June 2015 to the NIMS system. It is unclear exactly how many of these ~12,000 patient related incidents were previously reported to SCA. Using one system that fulfils the statutory obligation to report to SCA [i.e. NIMS] is logical, eliminates duplication of effort and ensures that national data is available so that trends and patterns in clinical incidents may be recognised early and interventions made to enhance patient safety.

There is a move away from use of a central location offsite to send all incident reports. Hospitals should report directly to NIMS. A "list of clinical incidents that should be reported" may be confusing, because there is a legal obligation to report all adverse events, independent of a list. Regarding any serious incident, concerns or queries, the clinical risk team is available and can be contacted by phone or email. Some services contact the team immediately after an *extreme* or *major* clinical incident has occurred, to inform the team and obtain advice, which is helpful for both parties.

Reporting incidents in a timely fashion facilitates the earlier identification of patterns and trends which allow risk management recommendations to be made earlier to prevent incidents recurring and harm to patients. Regarding quality of data, concise, detailed information, including severity of injury, where possible, in "telegram style" is most efficient. The clinical risk team provides education and training regarding incident reporting. This national survey provides a snap shot of patterns and modes of incident reporting in a changing environment where it is generally recognised that the more incidents a service reports, the stronger its patient safety culture.

7.3 The percentage of new patient claims received by the SCA, without a previous patient safety incident received

The percentage of new patient claims received without a previous patient safety incident reflects a degree of under-reporting in the past. Clearly, not all claims can be predicted at the time of the incident, because there may be no evidence of injury, or knowledge that an actual adverse event has occurred e.g. development of a fistula over time. There is a paucity of data in the literature regarding what an “expected/acceptable percentage” might be. While some new patient claims may not be pursued subsequently by the plaintiff, it is clear that on review of other clinical claims, a definite adverse event occurred at the time of the incident.

The percentage of new patient claims received without a previous patient safety incident reported to the SCA is calculated weekly, monthly and quarterly by the clinical risk team. For the first 6 months of 2015, this figure averaged 59%. A national report reviewing this data for 2014 revealed services that were good at reporting incidents and those that were less good at reporting incidents, which subsequently became claims. Unreported incidents cannot be addressed, therefore trends and patterns are missed and opportunities for intervention and improvement lost. Promoting a fair, just culture, encouraging incident reporting, learning from reported incidents and dissemination of this learning, together with risk management recommendations, should help promote patient safety.

7.4 Incident reporting across hospitals nationally

As expected, when analysed, some variation existed in the number of incidents reported by different hospitals of similar bed capacity across the country. Different specialities within a hospital report differently: while some specialities report a high number of incidents, other specialities report a low number of incidents when compared to the same specialities in other hospitals of similar activity and bed capacity. This may reflect different patterns and modes of reporting, different patient safety cultures within a hospital, differences in clinical practice, or a combination of some or all of the above.

Promoting a culture of increased incident reporting [pertaining to harm and no harm], is important so that lessons can be learned and communicated to front line staff in the hope of preventing further incidents and harm. Through triangulation of the above data, a knowledge base has been built up about current and past modes and patterns of reporting in different geographical areas and different hospitals across the country. Education and training regarding incident reporting in hospitals continues to be available through the clinical risk team at the SCA.

8. CONCLUSION

8.1 What the report outlines

This is a **dedicated Maternity and Gynaecology services report**, providing detailed national data on both clinical incidents and claims.

It **tracks and analyses** national clinical incident and claims data pertaining to Maternity and Gynaecology services **over a 5 year period**, 2010-2014, using a run chart format to help identify patterns and trends.

It provides an **in-depth analysis of the most common clinical incidents** and most common and most costly clinical claims, pertaining to Maternity and Gynaecology, services adjusted for activity [e.g. birth rate].

It **contextualises** national clinical incident and claims data pertaining to Maternity and Gynaecology services with **international data**, from peer reviewed medical scientific journals and national reports, where relevant. Published clinical national and international guidance on topics is referenced where appropriate.

It facilitates the **anonymous comparison and contrasting** of Maternity and Gynaecology services with other **Maternity and Gynaecology services nationally**, regarding clinical incidents reported and claims created over a 3 year period, 2012-2014.

It analyses the **total expenditure for Maternity and Gynaecology services** nationally over a 5 year period and discusses, in detail, its core components and amounts involved in euro millions.

It performs a **detailed review of a focused topic over a 10 year period**: *“Retained foreign bodies in Maternity and Gynaecology services: a 10 year review of closed medico-legal claims”*, to identify lessons that may be learned and disseminated to relevant stakeholders, front line workers in particular.

It outlines and reviews results of the first *“National Survey of Modes and Patterns of Incident Reporting in Acute Hospitals in Ireland, 2015”* undertaken and provides data on the percentage of new patient claims received which do not have a previous clinical incident report sent to the SCA, January to June, 2015

8.2 What new information does this report provide?

Under-reporting of clinical incidents exists nationally: 59% of new patient claims received in the first 6 months of 2015 had no previous patient safety incident reported to the SCA. Further clinical incident reporting is encouraged. Internationally this has been documented as an opportunity for improvement.

Quality of the data reported: the quality of the data in this report, reflects the quality of the data reported to NIMS [formerly known as STARSWeb]. In certain instances, this quality is **suboptimal**.

Variation exists nationally regarding the modes and patterns of incident reporting: including the percentage of incidents reported to the SCA, the backlog that exists from a volume and time delay perspective, what incidents are reported and who makes the decision to report which incidents.

Lack of uniformity exists across services in relation to the categorisation of **severity of injury [impact scoring system]**, pertaining to clinical incidents in Maternity services. This is an area which requires improvement.

The overall **variation and lack of standardisation** in incident reporting makes comparisons between Maternity and Gynaecology services inaccurate.

Maternity and Gynaecology incidents and claims were tracked over time and compared to international figures where appropriate and available. Our figures are not dissimilar to international figures where available.

Retained foreign bodies in Maternity and Gynaecology services: a 10 year review of closed claims: implementation of clinical handover, implementation of specific counting protocols, use of radiopaque and tailed swabs, swab count reconciliation, clear documentation of swab, needle and instrument count; review of all cases of retained foreign body with dissemination of feedback regarding causal and contributing factors to front line staff; audit and tracking of implementation of policies, protocols, guidelines and learning from claims are all relevant and important national and international recommendations to prevent the occurrence of retained foreign bodies. Education at undergraduate and postgraduate level regarding this serious reportable event is recommended together with regular, multi-phased education and training of front line staff within hospitals. Some or all of these recommendations have been implemented in the Maternity and Gynaecology services nationally.

Variation exists nationally across the acute hospitals regarding **different modes and patterns of reporting incidents to SCA**.

9. FUTURE

How will the SCA's clinical risk team make improvements?

- Further **encourage clinical incident reporting of all severities: including harm and no harm**, through education and training provided by the clinical risk team.
- Further **encourage and support more uniformity** across services regarding reporting of **severity of injury**, through education and training provided by the clinical risk team.
- Encourage all healthcare services to **send copies of investigation reports** pertaining to extreme and major incidents and SRES, to the clinical risk team so **that lessons learned** and risk management recommendations can be **disseminated** in an anonymised fashion nationally to front line workers and all stakeholders to help prevent occurrence of further clinical incidents and improve patient safety.
- Earlier identification of **patterns and trends in clinical incidents** of minor, negligible and near miss severity with development of risk management recommendations to help prevent clinical incidents causing harm and help improve patient safety.
- Further **improve communication** between the clinical risk team and all stakeholders through increased face to face meetings; by providing detailed information on clinical incidents and claims through publication of reports; offering risk management recommendations and feedback from lessons learned through investigation reports received; facilitating real time communication regarding trends and patterns in clinical incidents; communicating comparisons of national clinical incident and claims data with international figures in a contextualised manner; providing further education and training sessions and further support and advice by phone, email, website and hospital site visits and providing detailed information on dedicated topics at invited lectures at national conferences.
- Adopt a **more proactive approach** in high risk areas e.g. Maternity services; further review of international practices and lessons learned that have led to reduction in clinical incidents; further analysis of specific factors that influence court decisions regarding liability.
- Further detailed review of **focused topics** by analysis of clinical negligence settled claims for common causal and contributing factors. Disseminate lessons learned to all stakeholders, present results at national and international scientific medical meetings and publish in peer reviewed scientific journals, where appropriate.
- Ongoing **education and training sessions** on Open Disclosure, incident reporting, and documentation.
- **Post graduate medical education:** Write and deliver a Postgraduate Medical Clinical Risk course at the Royal College of Physicians of Ireland [RCPI] September 2015 [completed] and March 2016.
- **Continued collaboration** with the HSE, in two national programmes, **Open Disclosure** and **AFFINITY**.
- **Feedback is invited on this report** and all services provided [or not provided] by the clinical risk team so that changes may be made, where appropriate and possible, and further support be provided to stakeholders by the clinical risk team.

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11. APPENDIX

List of acute hospitals obtained from the Health Service Executive, Acute Hospitals Division

1. AMNCH Tallaght Hospital – Paediatric
2. AMNCH Tallaght Hospital – Adult
3. Cavan General Hospital
4. Monaghan Hospital
5. Louth County Hospital Dundalk
6. UHL Croom Hospital
7. ULH Group Nenagh Hospital
8. Ennis Hospital
9. University Hospital Limerick
10. Cork University Hospital
11. Kerry General Hospital
12. Connolly Hospital
13. Midland Regional Hospital Tullamore
14. Bantry General Hospital
15. St Vincent’s University Hospital
16. St Luke’s Radiation Oncology Network Dublin
17. St. Columcille’s Hospital
18. University Maternity Hospital Limerick
19. Sligo Regional Hospital
20. South Tipperary General Hospital
21. Kilcreene Orthopaedic Hospital
22. MRHP
23. St. Luke’s General Hospital
24. Wexford General Hospital
25. Our Lady of Lourdes

26. CUMH
27. University Hospital Waterford
28. Naas General Hospital
29. National Maternity Hospital
30. Beaumont Hospital
31. Mercy University Hospital, Cork
32. Saolta PHB
33. RVEEH
34. Letterkenny General Hospital
35. Our Lady's Hospital, Navan
36. South Infirmary-Victoria University Hospital
37. Cappagh National Orthopaedic Hospital
38. Galway University Hospital
39. Mallow General Hospital
40. Mullingar
41. Mayo General Hospital
42. Roscommon Hospital
43. Rotunda Hospital
44. St. Michael's Hospital
45. St. John's Hospital, Limerick
46. Coombe Women & Infants University Hospital
47. Mater Hospital
48. Temple Street Children's University Hospital
49. St James's Hospital
50. OLCHC

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