# CLINICAL RISK INSIGHTS

**Welcome to the latest issue of Clinical Risk Insights, brought to you by the Clinical Risk Unit of the State Claims Agency. In this issue, you will find articles on surgical injury of the spinal accessory nerve, safe management of peripheral intravenous cannulae, a clinical claim case study on postpartum haemorrhage and some updates on NIMS, the National Incident Management System.**

## Editorial

**In recent months, we have once again seen enormous challenges for the delivery of health and social care. We have experienced a third wave of COVID-19 in Ireland - the most deadly - driven by a highly transmissible strain of the virus.**

**Furthermore, the HSE is now facing the additional challenges posed by the cyber-attack on its IT systems last month. In response, we have seen once again health and social care professionals dig deep to find the resilience to face these challenges.**


### Challenging landscape

The State Claims Agency (SCA) recognises the enormous impact of the recent IT cyber-attack on the provision of health and social care services and clinical care within the HSE and the related risks. We realise that in many situations, health and social care personnel have been providing care in challenging situations, relying on paper-based systems, hand-written results, without access to patients' and service users' healthcare records and previous test results, and with limited access to diagnostic tests. The SCA's advice in relation to indemnity, incident reporting and risk management in the context of the cyber-attack situation can be viewed **here**.

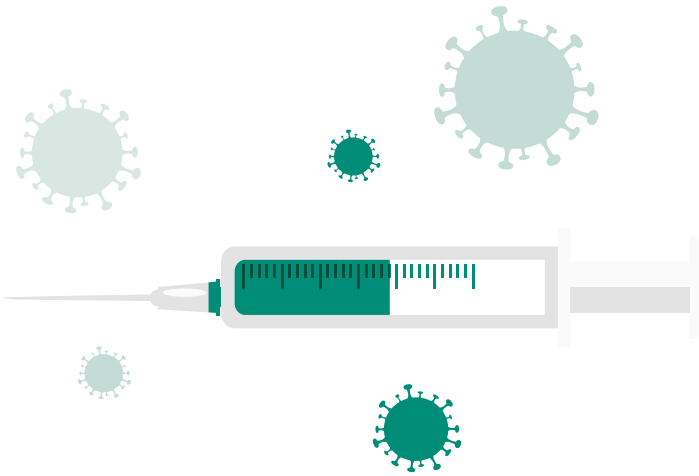
Health and social care personnel also faced huge challenges earlier this year when the third wave of COVID-19 reached our shores. However, this wave coincided with the commencement of the COVID-19 vaccination campaign, possibly the biggest public health initiative ever undertaken in Ireland. The benefits of the vaccines were initially apparent in the dramatic reduction in the number of health and social care workers being infected, as well as in the number of outbreaks in hospitals and residential care settings. The more recent significant reduction in the number of COVID-19 deaths is hugely positive.

### Minimising litigation risk and incident reporting

Since the COVID-19 vaccines are covered by State indemnity, any clinically significant vaccine incidents must be reported on NIMS, the National Incident Management System. We continue to monitor reported COVID-19 incidents, including COVID-19 vaccine incidents, and to share relevant learning with the HSE and frontline staff. We have liaised with the HSE and Health Products Regulatory Authority (HPRA) to provide guidance on the appropriate reporting of vaccine incidents to all three bodies.

## Opportunities to sustain change in health and social care delivery

COVID-19 has both forced and accelerated change in the way health and social care is delivered. Opportunity may lie in the enormous difficulties presented by COVID-19. Irish health and social care services have responded with remarkable agility to the COVID-19 crisis. New ways of working have been developed and implemented. We are exploring some of these new developments, such as telemedicine and integrated care, in our **2021 webinar series** and asking have changes come about that have the potential, in the post-COVID-19 world, to provide safer and higher quality care for services users. We hope that many of you will be able to join the final two webinars in the series, which have been postponed until autumn due to the cyber-attack.



I hope you enjoy and find the cases, issues and updates presented in this edition of Clinical Risk Insights to be of benefit.

**Dr Cathal O'Keeffe**
**Head of Clinical Risk**

# Surgical injury of the spinal accessory nerve

**In this article, Professor Patrick Broe, retired Consultant Surgeon and Clinical Director at the RCSI Hospital Group, highlights the causes of surgical injury to the spinal accessory nerve, which is frequently not recognised, and discusses the risks with performing surgical cervical lymph node biopsy.**

Damage to the spinal accessory nerve has life-long implications for the patient and can be associated with significant litigation costs.

The State Claims Agency received five claims in the last six years relating to spinal accessory nerve injury, two of which were finalised resulting in paid damages of €261,308.

| Spinal accessory nerve injury related data* | Total |
|---|---|
| Number of claims received | 5 |
| Number of claims finalised | 2 |
| **Total paid amount on finalised claims** | **€261,308** |

*Table 1. NIMS (National Incident Management System) data for spinal accessory nerve injury claims *Data correct as of 25/2/21*

## Clinical vignette

A 17-year-old female was referred to a surgical clinic by her GP with a four-month history of persistent cervical lymphadenopathy in the posterior neck, with no other symptoms. An excision biopsy of one of the nodes was advised and performed two weeks later under general anaesthetic. Histology showed a benign, "reactive" node and the reporting pathologist raised the possibility of Toxoplasmosis. Only then did it emerge that the family owned a cat.

Eighteen months later the patient was referred by her GP to a neurologist with a four-month history of weakness in her left arm and discomfort in her left shoulder. The neurologist made a diagnosis of left spinal accessory nerve injury, due to the previous lymph node biopsy. Nerve conduction studies confirmed complete motor conduction block at the level of the surgical scar in her neck.

Repair of the nerve was performed by a plastic surgeon, using a supraclavicular nerve graft. Nerve conduction studies, one year later, showed minimal partial re-innervation and no further return of muscle function could be expected.

## Surgical injury of the spinal accessory nerve

The commonest cause of injury to the spinal accessory nerve is iatrogenic, occurring as it does during surgical excision biopsy of cervical lymph nodes in the posterior triangle of the neck. A 3-8% incidence rate following cervical node biopsy is recorded. The nerve is extremely vulnerable because it is covered only by the skin and subcutaneous fascia in the posterior triangle of the neck. The vast majority of surgeons are unaware that they have injured or transected the nerve during the procedure. Numerous case reports and small series question the diagnostic value of cervical node biopsy because the pathology report is almost always benign/reactive.

Recognition of the injury within six months of the node biopsy operation allows for timely re-exploration of the wound and either primary repair of the nerve or interposition nerve grafting. The trapezius muscle then has a good chance of recovery. Patients identified later, with a significant muscular deficit, are unlikely to benefit from repair.

## Management of cervical lymphadenopathy

Cervical lymphadenopathy is common in children and young adults. In most patients, it is benign and self-limiting and, in most instances, the pathology is benign/reactive.

**Causes of cervical lymphadenopathy are shown in Table 2.**

| Causes of cervical lymphadenopathy | |
|---|---|
| **Infection**<br>+ bacterial<br>+ viral<br>+ fungal<br><br>Chronic scalp conditions (e.g. eczema) | **Characteristically anterior triangle lymphadenopathy**<br>+ Bacterial infections<br><br>**Characteristically posterior triangle lymphadenopathy**<br>+ Rubella<br>+ Toxoplasmosis<br>+ Atopic eczema |

*Table 2.*

Following an appropriate history and physical examination, and provided there are no alarming features (large node size, hard consistency, associated skin induration) a three to four-week period of observation is appropriate, followed by a review. Serology tests for EBV, CMV and Toxoplasmosis are worthwhile if there's a history of immunocompromise, or if there's a cat in the household.

In the knowledge that the vast majority of cases are benign and self-limiting, there is no indication to proceed to biopsy early in the clinical course. There may be increasing anxiety in the patient, or their parents, with the persistence of the lymphadenopathy, particularly if there has been a previous history of lymphoma or other cancers in the family. To allay anxiety, and in some other instances, fine needle aspiration (FNA) of the node can be performed, and where the node(s) are larger, core biopsy could be considered. Open biopsy under local or general anaesthetic should be a last resort in cases where the FNA or core biopsy results are inconclusive.

If open lymph node biopsy is necessary, the procedure, even though considered minor and routine, should be performed by an experienced surgeon who is aware of the potential for injury to surrounding structures, such as the spinal accessory nerve in the case of posterior triangle node biopsy. If a trainee or more junior surgeon performs the procedure, it must be under supervision of a senior, experienced colleague. Damage to the spinal accessory nerve has life-long implications for the patient, which is a high price to pay to confirm what is, in most cases, a benign process.

> **Damage to the spinal accessory nerve has life-long implications for the patient**

*References available on request.*

# Peripheral Intravenous Cannula – Reducing the risks

## In this article, Cliodhna Grady, Clinical Risk Advisor, describes the complications associated with peripheral intravenous cannula (PIVC) management and how health and social care professionals can avoid them.*

The complications associated with PIVC management can have a significant effect on service users' health and quality of life, and increase the cost of healthcare through the need for prolonged hospital stays and treatment. For example, mismanagement of PIVCs can result in blood stream infections, which may require prolonged courses of intravenous antibiotics. This in turn can drive anti-microbial resistance.

PIVC-related adverse incidents recorded on NIMS, the National Incident Management System, include infiltration, extravasation, phlebitis, haematoma formation, and failure to remove a cannula prior to discharge.

To reduce the risk of adverse effects to service users, health and social care professionals need appropriate education and training in PIVC management to ensure they undertake this role competently.

### Risks associated with PIVC

Possible complications of PIVC management are:

+ **Infection** - Bacteria may enter through the insertion site, resulting in local infection or blood stream infection
+ **Extravasation** (infiltration of the injected fluid into the surrounding tissue) - particularly during administration of contrast media and iron infusions, which can cause significant skin staining
+ **Phlebitis** (vein irritation, more common in older service users) - due to the presence of the catheter, irritation from fluids injected or infection
+ **Haemorrhage/haematoma formation** at puncture site - increased risk in service users on anticoagulant medication

### What can you do to minimise the risk?

+ Implement infection prevention and control (IPC) best practices for the care and management of PIVCs, if not already in place
+ Consistently apply aseptic technique for all aspects of PIVC care to minimise PIVC-related infections
+ Assess once every shift to see if the PIVC is still required; it should generally be removed if it has not been used in the previous 24 hours
+ Assess the IV site using a visual phlebitis score to assess for signs of tenderness, swelling, inflammation or thrombosis on every shift
+ Clean and flush the cannula at every access; if pressure is felt during flushing, force should not be applied; PIVC should be removed and only re-sited if still required
+ Remove PIVC if any signs of tenderness, inflammation or phlebitis and only re-site if still required
+ Implement and document care bundles, which minimise PIVC-related incidents:
  - Complete insertion care bundle, including insertion date and time, site and size of cannula, number of attempts
  - Review PIVC maintenance bundle once every shift
  - Document date, time and reason for IV cannula removal; once removed check cannula integrity to ensure the device is complete
+ Include the presence of PIVC / IV lines into the shift handover process
+ Incorporate the PIVC care record into the discharge process / checklist to ensure all IV lines / cannulae have been removed prior to discharge and documented in the patient healthcare record
+ Establish an ongoing system of audit to ensure compliance with best practice in relation to PIVC management

*References available on request.*

**This advice presented in this article was developed in consultation with the HSE's Antimicrobial Resistance and Infection Control team.*

# Closed Claim Case Study – Postpartum Haemorrhage

**In this closed claim case study, Emmajane O'Halloran, Solicitor and Clinical Claims Manager, outlines the details of a case relating to postpartum haemorrhage with a second degree perineal tear in a regional hospital.**

A plaintiff sued a regional hospital alleging that the hospital failed to take sufficient steps to stop a significant postpartum haemorrhage on time. The haemorrhage occurred following the birth of the plaintiff's baby.

## Details of case

Various initial steps were taken to stem the bleeding including suturing and vaginal packing but those steps were unsuccessful. The plaintiff was moved to theatre and was estimated to have lost approximately 1.5 litres of blood. The repair was a difficult procedure which lasted almost two hours and the operative findings were a large perineal haematoma, second-degree perineal tear, well-contracted uterus and a right paravaginal tear.

The plaintiff's claim was that, as a result of events, she had suffered an unnecessarily traumatic experience, had required an extensive blood transfusion and was left extremely traumatised and suffering a significant ongoing psychological injury.

The plaintiff's expert was not critical of the steps taken by the defendants once the bleeding and tear were identified, but was critical of the speed at which those steps were undertaken. The plaintiff's expert gave evidence that the plaintiff should have been moved to the operating theatre 36 minutes earlier than had occurred and, if the plaintiff had been moved earlier, the blood loss would have been less and the trauma was likely to have been less as well.

## Outcome of the case

The Court accepted that the plaintiff was a completely genuine witness who gave her evidence truthfully and there was no doubt that her life had been significantly damaged by the events. The Court also accepted that the plaintiff met the criteria for post-traumatic stress disorder and her distress continued.

In addressing liability and applying the test set out in *Dunne v The National Maternity Hospital & Another [1989]* IR 91, the Court accepted the evidence of the defendants' expert that the treatment provided to the plaintiff was acceptable and could not conclude that the defendants were in any way negligent.

The Court held that the hospital had followed approved practice at the time and the plaintiff had not demonstrated that the practice had inherent defects, which ought to have been obvious to any person giving the matter due consideration.

The Judge believed that if the plaintiff had been taken to theatre sooner she would have suffered less blood loss and probably less psychiatric trauma, however, the Judge indicated that this was speculative given the finding that the hospital was not negligent. The plaintiff had therefore failed in her claim which was accordingly dismissed.

**This case is currently under appeal**

# Managing the risk of postpartum haemorrhage events

## In this article, Cliodhna Grady, Clinical Risk Advisor, sets out risk management advice on the management of postpartum haemorrhage.

Obstetric haemorrhage remains one of the major causes of maternal mortality in both developed and developing countries. Primary postpartum haemorrhage (PPH) is the most common form of major obstetric haemorrhage. The definition of a primary PPH is the loss of 500mls or more of blood from the genital tract within 24 hours of the birth of a baby. **Uterine atony** accounts for 70% of PPH; other causes include **trauma** to the genital tract, **retained products** (placental tissue, membranes or clots) and **coagulopathies**.

| Risk factors for PPH | |
|---|---|
| **Antenatal risk factors** | **Intrapartum risk factors** |
| + Previous retained products of conception / PPH<br>+ Hb <8.5g/dl<br>+ BMI > 35<br>+ Grand multiparity<br>+ Antepartum haemorrhage<br>+ Overdistention of the uterus (multiple pregnancy, polyhydramnios, macrosomia)<br>+ Existing uterine abnormalities<br>+ Low lying placenta<br>+ Maternal age > 35 | + Induction of labour<br>+ Prolonged first, second or third stage<br>+ Oxytocin use<br>+ Precipitate labour<br>+ Operative delivery<br>+ Caesarean section |

All maternity units should have a **multi-disciplinary protocol** for the management of PPH, with **regular skill drills** to practice and enhance a coordinated response to this obstetric emergency.

*References available on request*

## 1. Be aware of risk factors

All health professionals involved in the care of women in labour should be aware of the risk factors for PPH (see table). **If risk factors for PPH** are identified, these should be highlighted in the woman's healthcare record and be included at **clinical handovers**. A **care plan** covering the third stage of labour should be discussed with the woman and **documented** in the healthcare record. That said, most cases of PPH have no identifiable risk factors, therefore **vigilance and early recognition** of haemorrhage is required in all settings.

## 2. Be vigilant for early signs of haemorrhage

It is important to be aware of the physiological increase in circulating blood volume during pregnancy meaning that the signs of hypovolemic shock may be less sensitive in pregnancy. **Continuous monitoring** of the woman's **clinical condition, observations, uterine tone and vaginal blood loss** in the immediate postpartum period is essential.

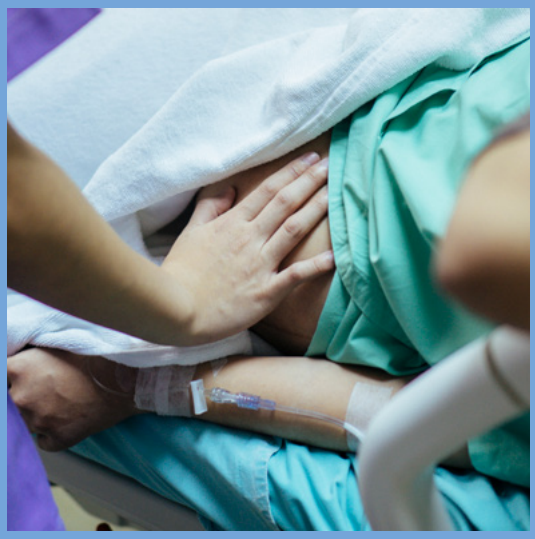
## 3. Focus on timely management

When PPH occurs, timely management is crucial, in addition to **effective communication** and **teamwork**. Visual estimation often underestimates blood loss and other methods of measuring of blood loss should be employed. Therapeutic interventions should be directed towards the causative factor, endeavouring to identify the **source of bleeding** and arrest it.

## 4. Communicate clearly and effectively

Communication with the woman and her birth partner is essential. **Clear information** of what is happening should be provided from the outset of the PPH event. **Debriefing** the woman (and her birth partner) is important, allowing time to discuss the events surrounding the haemorrhage, and should be offered to the woman and her birthing partner following a PPH.

### The Major Obstetrics Haemorrhage Project



**According to the National Women and Infants Health Programme (NWIHP), for every woman who dies of pregnancy-related causes, twenty or thirty others experience morbidity, potentially causing permanent damage to their normal functioning. NWIHP notes that major obstetric haemorrhage (MOH) and, specifically, the incidence of postpartum haemorrhage is increasing in Irish maternity units and there is a need to reduce this increasing trend. NWIHP further notes that a MOH audit in 2011-2013 showed good practices being followed in Irish maternity units, however, standardising these practices and sharing learning would be beneficial.**

**In this context, a joint venture between NWIHP and the National Perinatal Epidemiology Centre – the Major Obstetrics Haemorrhage Project - has commenced. The aim of this initiative is to lower the incidence of MOH in maternity units by developing a standardised approach to measurement, audit, policies and procedures and training modules.**

*References available on request*

# NIMS & NIRF updates

## National Incident Report Form

To improve data quality and enhance incident reporting, the "Clinical Care" section of the National Incident Report Form (NIRF) – 01 Person will be redesigned in the coming months.

The **clinical procedures** and **birth specific procedures** sections of the NIRF 01 will be updated, in line with feedback from health and social care services.

The changes will:

+ Make NIRF 01 more user-friendly, with additional options available and more intuitive pathways for reporting
+ Improve data quality with higher-level options to choose from
+ Allow for additional information to be gathered for each incident

**SECTION H WHAT TYPE OF HAZARD DID THIS INCIDENT RELATE TO?** (Tick one option from Steps 1, 2, 3 & 4)

| Step 1. | Step 2. | Step 3. | Step 4. |
|---|---|---|---|
| ☐ Birth Specific Procedures | ☐ Caesarean Section (Elective)<br>☐ Caesarean Section (Emergency)<br>☐ Instrumental Delivery (Forceps)<br>☐ Instrumental Delivery (Vacuum)<br>☐ Instrumental Delivery (Multiple Instruments)<br>☐ Non Instrumental Delivery | ☐ Communication / Consent<br>☐ Diagnosis / Assessment<br>☐ Documentation / Records<br>☐ Equipment<br>☐ Care / Management<br>☐ Procedure / Treatment<br>☐ Intervention<br>☐ Screening / Prevention<br>☐ Specimens / Results<br>☐ Tests / Investigations<br>☐ Unknown<br>☐ Other | ☐ Adverse Effect<br>☐ Failure / Malfunction<br>☐ Foreign Body left in Situ<br>☐ Inappropriate for Task / Wrong device<br>☐ Incomplete / Inadequate<br>☐ Lack of Availability<br>☐ Not performed when indicated / Delay<br>☐ Pre Existing Medical Condition<br>☐ Shoulder Dystocia<br>☐ Unavailable / Mislabelled / Lost<br>☐ Wrong Body Part / Site / Side<br>☐ Wrong Patient<br>☐ Wrong Process / Treatment / Procedure<br>☐ Other _____ |
| ☐ Clinical Procedures | ☐ Invasive<br>☐ Non Invasive | | |

REDESIGN

*Figure 1: NIRF 01 to be redesigned.*

## What will change in NIRF 01?

The key changes are:

1) The incident classification **Birth Specific Procedures** will be changed to **Labour / Delivery**
2) The incident classification **Clinical Procedures** will be replaced with three new categories:
   a) **Diagnosis**
   b) **Care Management**
   c) **Surgical/Medical Procedures**

An example below shows how the changes will appear on the NIRF with the new category Surgical/Medical Procedures.

| | | | |
|---|---|---|---|
| ☐ Surgical/Medical Procedures | ***Stage of Procedure***<br>☐ Pre Procedure<br>☐ Intra Procedure<br>☐ Post Procedure | ***Care Process***<br>☐ Assessment/Monitoring<br>☐ Tests/Investigations<br>☐ Treatment/Intervention | ☐ Adverse event/patient safety incident<br>☐ Incomplete/inadequate:<br>☐ *Communication*<br>☐ *Consent*<br>☐ *Documentation*<br>☐ *Equipment*<br>☐ *Unknown/other*<br>☐ Lack of availability<br>☐ Not performed when indicated/Delayed<br>☐ Retained foreign object<br>☐ Wrong body part/site/side<br>☐ Wrong patient<br>☐ Wrong process/treatment/procedure |
| | ***Name of Initial Procedure***<br>_____<br>***Name of subsequent Procedure? (if required a return to theatre)***<br>_____ | | |

*Figure 2: Example of how the changes will appear on the NIRF with the new category Surgical/Medical Procedures.*

The updated NIRF 01 will allow for the name of a surgical/medical procedure to be captured; a second procedure can be captured if a service user required a return to theatre; and health and social care services can pinpoint at what stage of the procedure, and during what care process, an incident occurred.

The current NIRF 01 will remain in place until the new redesigned NIRF 01 is issued later in 2021.

## NIMS Upgrade

NIMS, the National Incident Management System, has also undergone some changes. NIMS has been upgraded to a new version of the platform since 10 May 2021.

### What are the main benefits of this change?

+ NIMS users benefit from an enhanced security model, entry workflows and template capabilities, including significant improvement in the look and feel of the NIMS application
+ The updated version of NIMS no longer requires Microsoft Silverlight, and is now accessible using most modern browsers including Google Chrome, Microsoft Edge and Firefox. Users should no longer access NIMS using Internet Explorer
+ NIMS still operates largely as before and users are not expected to have any difficulty using the new screens

This important upgrade enhances overall user experience of NIMS and helps to ensure that NIMS is ready for future developments and improvements to benefit users.


### Useful Resources

We have prepared brief training resources to help you get familiar with the new NIMS layout:

+ **Video Tutorial: Navigating the new NIMS platform**
+ **How to navigate the new NIMS platform**

For technical issues, please contact the NIMS Helpdesk: **NIMSHelpdesk@ntma.ie.**

# Clinical Risk Insights
## Noticeboard

### EVENT REPORT: QUALITY, CLINICAL RISK AND PATIENT SAFETY WEBINAR – 29 APRIL 2021

The first webinar in our series of Quality, Clinical Risk and Patient Safety Webinars took place on Thursday, 29 April 2021.

This series aims to educate and inspire those involved in advancing service user safety in health and social care.

**Event overview**
At our April webinar, we examined the theme 'Implementing and Sustaining Change in Health and Social Care – Systems and Services Focus', in the context of the COVID-19 pandemic, with speakers including:

+ **Dr John Harden,** Deputy Clinical Director for Scotland, Scottish Government and Consultant in Emergency Medicine, University Hospital Wishaw, NHS Lanarkshire
+ **Julie Bellew,** Deputy IT Delivery Director, Office of the Chief Information Officer, HSE
+ **Alexander Mason,** Business Analyst, Office of the Chief Information Officer, HSE

The webinar was attended by over 250 health and social care professionals – including HSE and Department of Health representatives, consultants, midwives, nurses and risk managers.

**Presentation slides and webinar recording**
The available presentation slides can be found on our **website** and the webinar recording is available on request from **QPSClinicalRisk@ntma.ie.**

### QUALITY, CLINICAL RISK AND PATIENT SAFETY WEBINARS - THURSDAY, 27 MAY AND THURSDAY, 17 JUNE 2021 – POSTPONEMENT AND NEW DATES

In light of the ongoing issues related to the recent IT cyber-attack on the HSE, due to which many HSE staff would be unable to attend the webinars, the State Claims Agency has postponed the Quality, Clinical Risk and Patient Safety webinars which were due to take place on Thursday, 27 May 2021 and Thursday, 17 June 2021.

**Save the new dates**
The new dates we have identified to run the final two webinars are:

- Thursday, 30 September 2021
- Thursday, 14 October 2021

Registration for these dates will open in due course. The updated programme is available **here.**

If you have any queries, please get in touch with **QPSClinicalRisk@ntma.ie.**

### NIMS QUERIES AND INFORMATION

+ For general queries, such as how to log an incident, contact the NIMS Helpdesk at **NIMSHelpdesk@ntma.ie** or **01 2384240.**
+ For HSE-related queries, such as system change requests, contact **NIMS@hse.ie.**