CLINICAL RISK INSIGHTS

Welcome to the second issue of Clinical Risk Insights brought to you by the Clinical Risk Unit of the State Claims Agency (SCA). In this issue you will find articles on orthopaedic implant incidents, cauda equina syndrome, getting service user identification right and a closed claim case study in which communication came under the spotlight.

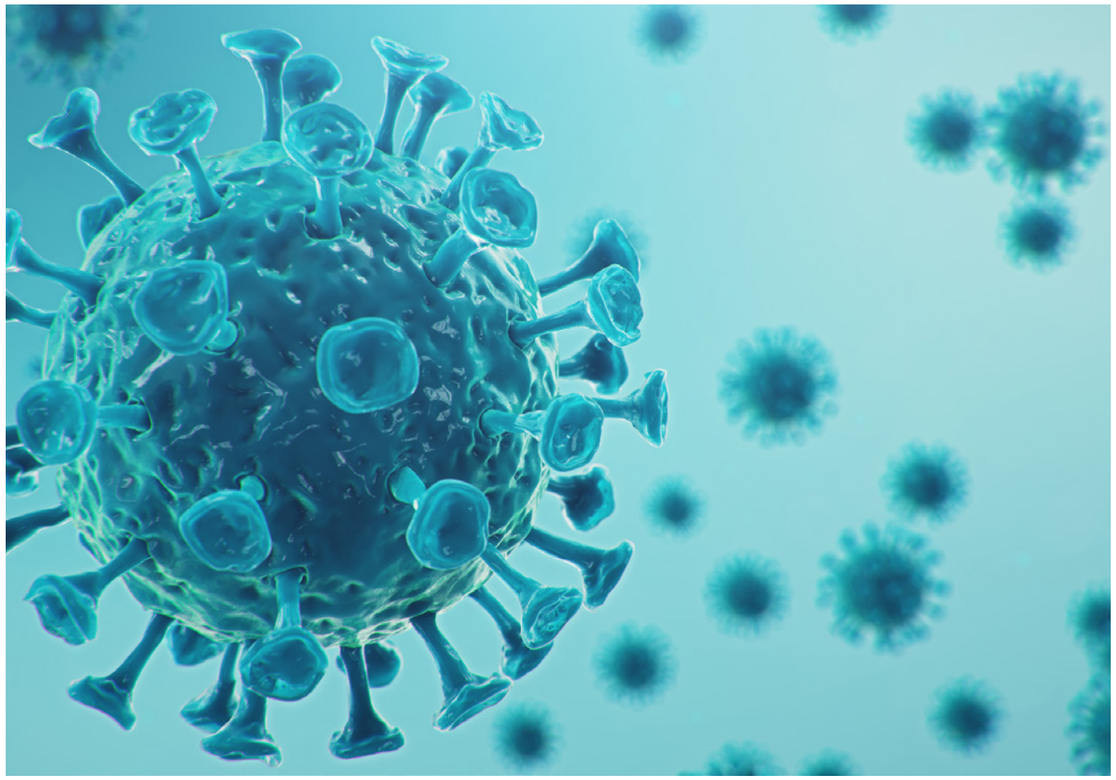
Editorial

When this issue of Clinical Risk Insights was being planned in the early weeks of 2020, COVID-19 was a distant threat. Since then the threat has been realised and the world of health and social care has been challenged like never before. We are now in the midst of a pandemic that has already extracted an enormous toll in terms of mortality, morbidity and human suffering.

Throughout the COVID-19 pandemic, health and social care workers have been on the frontline, at greater risk of infection, dealing with the emotional and psychological impact of the delivery of care in a crisis situation. As highlighted by the WHO, healthcare workers encounter increased risk of healthcare associated infections, violence, accidents, stigma, illness and death. Furthermore, working in stressful environments exacerbates risks to the physical and mental health and safety of healthcare workers making them more prone to errors which might lead to patient harm.

The interrelationship between health and social care worker safety and patient safety was recently given prominence through the theme for World Patient Safety Day 2020 'Health Worker Safety: A Priority for Patient Safety'. The SCA supported this year's campaign by reminding health and social care services that health and social care worker safety and patient safety go hand in hand and highlighting what can be done to enhance worker safety. With this in mind, it is important that you all continue to be aware of and care for your own wellbeing, and that of your colleagues, so that you can continue to effectively care for others.

It has been heartening to see the many innovative ways in which health and social care personnel have responded to the crisis.



New models of care and care pathways have been developed and different ways of working and providing care, such as telehealth and remote consultation, have come to the fore. It is to be hoped that innovation, where effective and when it contributes to better and safer care, can be sustained.

The pandemic will have far-reaching consequences for health and social care delivery into the future. As the number of new COVID-19 cases ebbs and flows, the challenge of providing non-COVID-19 care in a world constrained by COVID-19 has emerged. All this brings additional risk, and it is as important now as ever to be guided by the principles of patient safety.

Reporting of incidents and adverse events by health and social care enterprises to NIMS, as well as being a statutory requirement, allows for rapid learning at local and national level. In the early stages of the pandemic, the SCA, in consultation with the HSE, updated NIMS to allow for the reporting of incidents related to COVID-19. It also supported, and continues to support, incident reporting in new locations such as testing centres and assessment hubs.

The SCA's risk units analyse COVID-19 incidents on a weekly basis and feed back real-time learning to the HSE in order to assist with risk mitigation. This analysis has also informed a number of patient safety and risk advisory notifications issued by the SCA in relation to COVID-19. The SCA's COVID-19 Indemnity Advices and Risk Advices, available at **www.stateclaims.ie**, provide an overview of indemnity and risk advice in relation to the COVID-19 pandemic.

Although COVID-19 has dominated our thinking in recent months, risk unrelated to COVID-19 remains. In addition, many of the factors underpinning clinical risk are common to COVID-19 and non-COVID-19 care. Although the articles presented in this newsletter, do not focus specifically on COVID-19, the learning to be derived from them is just as relevant now as ever.

Dr Cathal O'Keeffe
Head of Clinical Risk, SCA

Wrong side / wrong size orthopaedic implants

In this article, Mark McCullagh, Clinical Risk Adviser, highlights the risk of implanting the wrong side or size prosthesis during orthopaedic surgery, and discusses international experience and risk mitigation.

The implantation of an incorrect side or size prosthesis during orthopaedic surgery is an avoidable surgical error, which can cause significant patient harm, entail revision surgery and may result in litigation. In addition to the effects on the patient and the clinical staff involved, implantation of the incorrect prosthesis during orthopaedic surgery can cause severe reputational damage to the healthcare institution.

Orthopaedic implants are designed to function in either a left or right limb and are manufactured in various sizes. The SCA is managing a number of claims against Irish hospitals in which the wrong side component or wrong size component was inserted in the course of a total hip arthroplasty (THA) or total knee arthroplasty (TKA) joint replacement procedure. This type of incident is potentially a Category 1C Serious Reportable Event (SRE) as defined by the HSE, i.e. wrong surgical procedure performed on a patient by a healthcare service provider.[1]

International experience

A review of 550 claims relating to consent and non-technical errors (i.e. patient safety failures) in orthopaedic operating theatres in England and Wales found that 24 claims with a total cost of £2.9 million (€3.4 million) related to implantation of an incorrect prosthesis.[2]

Case reports documenting wrong side orthopaedic implants have also been published. A UK report involved the insertion of a left femoral component into a right knee during TKA in a 72-year-old woman.[3] This patient required revision surgery. In another case from Saudi Arabia, a right femoral component was inserted into the left knee during TKA in a 72-year-old woman.[4] In this case, the left knee was described as 'functioning well' and no further surgery was undertaken.

The UK's Healthcare Safety Investigation Branch (HSIB) published a report in 2018 into the implantation of a wrong prosthesis during THA in a 62-year old-man.[5] In this case, which required the implantation of four components, the second two components were from a different manufacturer to the first two. The error was identified when details were entered into the National Joint Registry. Further surgery was judged unnecessary and the patient remains under regular review.

Substandard communication

It has been reported that the majority of cases of wrong-site surgery in orthopaedics involved communication breakdown.[6] It is likely that wrong side / wrong size orthopaedic implant incidents involve miscommunication within or between hospital multi-disciplinary teams.

A number of solutions to reduce the risk have been proposed:

+ The introduction of an 'implant time out' to ensure the surgeon and theatre staff confirm the appropriateness of the prosthesis prior to implantation[2]
+ The implementation of a scanning system to identify wrong prostheses prior to surgical implantation[5]

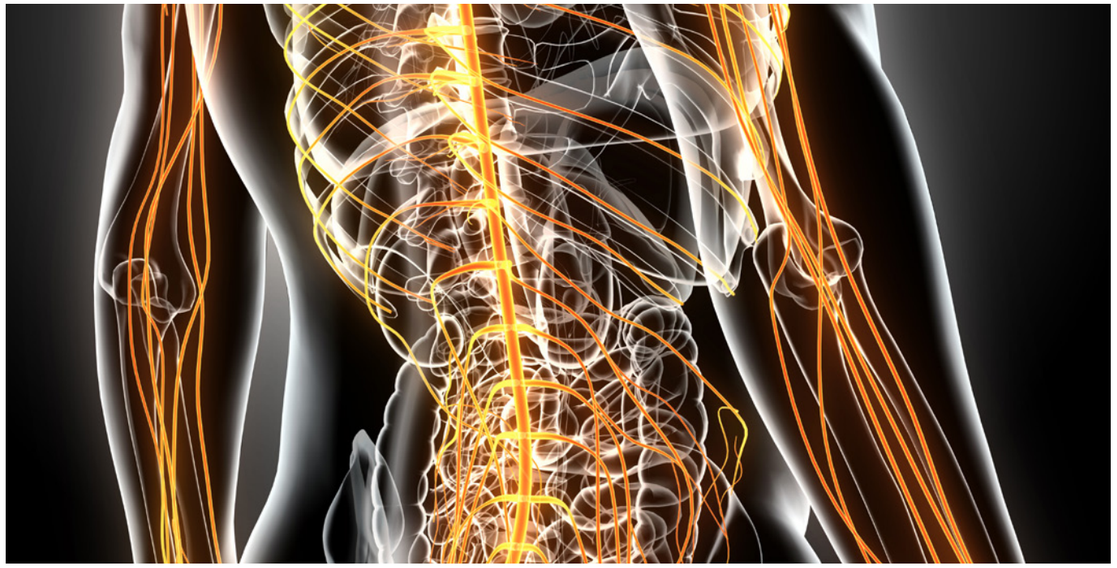
Conclusion

Wrong side / wrong size orthopaedic implant incidents are avoidable errors which have the potential to cause harm to patients and require further surgery, and may result in litigation. International evidence and SCA experience suggest that these incidents are not as uncommon as might be expected. Risk mitigation strategies include a greater focus on communication around selection of prosthetic components and adoption of electronic patient safety solutions.

References available on request.

Cauda equina syndrome

In this article, Mr Keith Synnott, Consultant Orthopaedic and Spine Surgeon at the Mater Hospital, describes the importance of early MRI scanning when the condition is suspected, to allow for early treatment and reduced risk of significant disability.



Cauda equina syndrome (CES) can have devastating consequences for patients and can be associated with significant litigation costs. Between 2008 and 2018, the SCA finalised 41 claims relating to CES, resulting in paid damages of in excess of €20 million.

What is Cauda equina syndrome?

The cauda equina are a collection of nerves that originate in the spinal cord and pass through the spinal canal in the lower back. These nerves supply the lower limbs and, in particular, the bowel and bladder. CES is a clinical syndrome with signs and symptoms of dysfunction of the nerves of the cauda equina.

The typical 'red flag' symptoms of CES are bilateral sciatica, perianal sensory disturbance and bowel or bladder dysfunction (Table 1). Patients presenting with these symptoms require prompt diagnosis and intervention. CES is most commonly caused by a disc herniation but can also be caused by compression as a result of degenerative disc and joint disease, tumours, infections or bone fragments in fractures. CES can be acute or chronic. Acute CES presents with a sudden onset of symptoms. If the compression is not relieved promptly permanent and severe disability can result.

Symptoms of cauda equina syndrome

- **Severe low back pain**
- **Motor weakness, sensory loss, or pain in one or both legs**
- **Saddle anesthesia**
- **Recent onset of bladder dysfunction**
- **Recent onset of bowel incontinence**
- **Sensory abnormalities in the bladder or rectum**
- **Recent onset of sexual dysfunction**
- **A loss of reflexes in the extremities**

Table 1. 'Red flag' symptoms for CES[1]

Diagnosis

The gold standard for definitive diagnosis is Magnetic Resonance Imaging (MRI) in conjunction with clinical evaluation i.e. a thorough history and examination. Neither imaging nor clinical evaluation alone are sufficient to reach a diagnosis.[2] On occasions where an MRI is contraindicated, diagnosis may be made with computed tomography (CT) scanning with, or without, myelography.

> **Where there is any clinical suspicion of CES an urgent MRI scan should be performed.**

There is evidence that clinical evaluation alone is neither sensitive nor specific enough to make or out rule a diagnosis of CES.[3,4] Presentations with just back pain may be associated with bowel or bladder issues. Where there is any clinical suspicion of CES an urgent MRI scan should be performed. The sole reliance on clinical judgment, even that of a senior consultant, is not recommended.

Cases of CES can present to any GP or ED nationally but treatment is provided in a limited number of centres, necessitating transfer and consequent delay. MRI scanning should be available as close as possible to where a patient with suspected CES will present.

The scan can be read by a remote surgical team facilitating expedited treatment, leading to improved outcomes. It should be acknowledged that there will be negative scans confirming that CES is not the diagnosis, and these should be accepted as providing reassurance that cases are not being missed.

Costs

Missed or delayed diagnosis of CES can by catastrophic for the patient, resulting in avoidable paralysis, incontinence, sexual dysfunction and chronic pain. There are also substantial medico-legal consequences of missed CES. As the disabilities are significant, the sums involved in settling cases where negligence is found are substantial (Table 2). These personal and financial costs far outweigh the costs of negative scans.

CES related data*	Total
Number of incidents reported	**42**
Number of claims received	**71**
Number of claims finalised	**41**
Total paid amount on finalised claims	**€20,901,261**

Table 2. SCA incident and claims data for CES (1/01/2008 – 31/12/2018)
**Data correct as of 30/11/2019*

Conclusion

Having a standardised set of criteria to define and diagnose CES and having comprehensive access to MRI scanning will facilitate more rapid diagnoses and treatment of the condition. This, in turn, will improve outcomes and reduce the potential for significant disability and long-term impacts.

References available on request.

Getting service user identification right

In this article, Cliodhna Grady and Natasha Coen, Clinical Risk Advisers, examine why service user identification errors can occur and how health and social care professionals can avoid them.

While conducting analysis of incidents recorded on NIMS, the SCA's Clinical Risk Unit has noted a number of incidents relating to service user identification.

Incorrect service user identification can result in medication errors, transfusion errors, diagnostic errors and procedures being carried out on the wrong person or wrong site.

For example, in one incident reported on NIMS, the incorrect date of birth was present on all documentation and ID wristbands. This meant cross-matched blood for the patient could not be used because of the incorrect documentation.

It is the primary responsibility of every health and social care professional to check the identity of service users and match the correct person with the correct care, before care is administered.

Risk factors

A number of factors which may increase the risk of service user identification errors have been identified:

+ Two service users with similar names or illnesses
+ In an outpatient setting, where ID wrist bands may not be used as an information source
+ A service user who is non-communicative, unresponsive or confused
+ Two records existing for the same service user, e.g. two records with different order of a double-barrel surname
+ Inadequate procedures and policies for the correct identification of service users

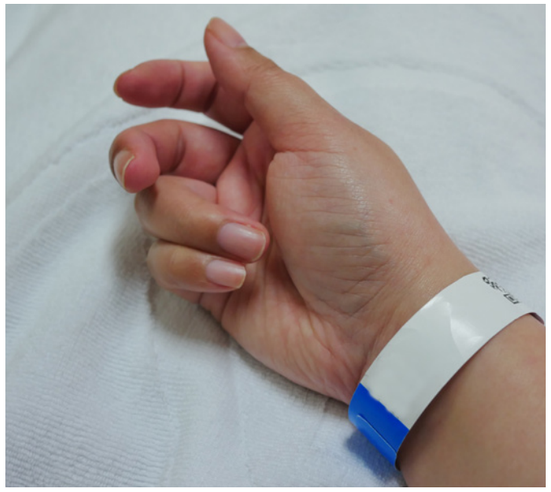
What can you do to minimise the risk?

A standardised approach to service user identification practices across the organisation will help to reduce the frequency of these incidents.

Consideration should be given to implementing the following measures to reduce the risk of error:[1,2]

+ ID wristbands should include these four core identifiers: last name, first name, date of birth, hospital / MRN number
+ On admission, use at least two identifiers to verify a service user's identity
+ At each encounter ensure the details are correct and up to date
+ Ask the service user to identify themselves before receiving any medication and prior to any diagnostic or therapeutic intervention
+ Even if the service user is familiar to the health and social care professional, check their details to ensure the right person receives the right care
+ Ensure wristbands are legible and replace those that are difficult to read
+ Encourage the service user to play an active role in the identification process - empower the service user to speak up when they identify an error relating to their identification, procedure or care plan
+ Where service users cannot communicate, e.g. intra-operatively, in the ICU, alternative patient identification methods should be employed

References available on request.



Closed Claim Case Study – Communication under the spotlight

In this closed claim case study, Katie Toher, Solicitor and Clinical Claims Manager, discusses how communication between the treating clinician and nursing staff, in relation to a patient's previous medical history, was a key element in the case.

The plaintiff was admitted to an Irish hospital for the removal of a left-sided pacemaker and the implantation of a new right-sided pacemaker. The left-sided pacemaker had initially been inserted eleven years previously after an episode of collapse. Following the removal of the old pacemaker, and pending the implantation of the new pacemaker, the plaintiff was transferred back to the ward.

Details of case

The plaintiff sued the hospital after he suffered a syncopal episode lasting six seconds during a visit to the bathroom, striking his head. This fall occurred when he was awaiting the implantation of the new pacemaker. He was left with a scar on his forehead and sought compensation for his injury.

The basis for the plaintiff's claim was two-fold. First, he alleged that, following the removal of his old pacemaker and leads, there was a failure to provide a temporary pacing wire pending implantation of the new pacemaker. Second, he alleged that the nursing care plan, which allowed him to walk around the ward while on telemetry, was negligent.

Outcome of case

The plaintiff was not successful in relation to the first aspect of his claim. The Court held that there was no negligence on the part of either the cardiologist or the surgeon in making the decision not to insert a temporary wire in this case. However, in relation to the second aspect of his claim, the Court found that there was negligence on the part of the cardiologist for failure to instruct the nursing staff that, having regard to his premorbid history of syncope and falls, the plaintiff should have been confined to bed and accompanied on visits to the bathroom.

Both the nursing and cardiology experts for the hospital gave evidence that being confined to bed with a necessity to be accompanied into the bathroom was wholly unrealistic for a patient who was fully mobile, scored zero on two falls risk assessments and who was on telemetry monitoring. The Court rejected this and accepted the plaintiff's expert evidence that he should only have been allowed to walk strictly under supervision and that, having regard to his medical history, this should have been communicated clearly to the nursing staff. This aspect of the decision highlights the importance of documenting a patient's

relevant history in the chart and communicating this information, with the relevant instructions, clearly to the nursing staff.

When it came to the question of legal costs, the Court determined that the plaintiff was not entitled to the entirety of his costs because he was unsuccessful on the 'temporary wire' aspect of his claim. The Court held that it was appropriate to adopt a more nuanced approach to the issue of costs in this case, rather than applying the usual "costs follow the event" rule. As well as the clinical aspects, this judgment highlights the risk for plaintiffs when pleading allegations that may not stand up to scrutiny in Court.

Learning outcome

Good communication between health and social care professionals and patients, and between and within healthcare teams, is an essential element of effective and safe healthcare. In this case substandard communication resulted in the patient sustaining an injury and ultimately led to clinical litigation. This case is a reminder that good documentation and clear oral instructions are integral to quality healthcare, as well as serving to protect staff from the risk of future litigation.

Clinical Risk Insights
Noticeboard

INDEMNITY ADVICES: COVID-19

A description of the scope of cover of the State indemnity schemes having regard to the many scenarios anticipated in response to the COVID-19 pandemic is available here:

https://stateclaims.ie/uploads/publications/State-Claims-Agency-Risk-Advisory-Notice-COVID-19-April-2020.pdf

RISK ADVISORY NOTICE: COVID-19

A description of the SCA's risk management advice for the health and social care sector in response to the COVID-19 pandemic is available here:

https://stateclaims.ie/uploads/publications/State-Claims-Agency-Risk-Advisory-Notice-COVID-19-April-2020.pdf

OTHER RISK MANAGEMENT ADVICES

Patient Safety Notifications and Risk Advisory Notices have been issued by the SCA. The COVID-19 Telehealth Risk Advisory Notice is available here:

https://stateclaimsagency.newsweaver.com/1b942n532a/1sybd8jsopv

SCA NATIONAL QUALITY, CLINICAL RISK & PATIENT SAFETY CONFERENCE 2020

2020 - Conference
The SCA National Quality, Clinical Risk & Patient Safety Conference 2020 has been cancelled.

2021 - Save the Dates!
We will be running the conference virtually in 2021 as three webinars scheduled for:

- 25 March 2021, 11am -12pm
- 29 April 2021, 11am -12pm
- 27 May 2021, 11am - 12pm

Across these conference webinars, we will examine, together with national and international speakers, the theme 'Implementing and sustaining change in health and social care,' including the legacy of COVID-19 on the delivery of care. Full details will be confirmed in due course.

Please contact the Clinical Risk Unit with any queries via stateclaims@ntma.ie