The State Claims Agency (SCA) officially launched the new risk management, NIMS tool (rebranded from NAEMS - see p11), the successor to the former STARSWeb system, on 16th June 2014. The new system is currently being rolled out to certain State authorities and other chosen clinical sites. NIMS represents a considerable upgrade to the old system and will enable all sites to report incidents in accordance with their statutory reporting obligation to the SCA (Section 11 of the National Treasury Management Agency (Amendment) Act, 2000).

One of the considerable changes brought about by NIMS is the shift in nomenclature away from the standard insurance categorisations of employer’s liability/public liability/property damage and clinical. Instead, NIMS employs the categorisations of patient (clinical care), patient (other), staff, member of the public etc. This shift in nomenclature accords more with international categorisations and will enable the Agency, and healthcare enterprises, thus, to more accurately (a) classify incident data and (b) contrast such data with international comparator data.

NIMS is a true risk management system providing end-to-end incident reporting, incident investigation, outcome and recommendation tracking and powerful data analysis tools. Its superior reporting module will enable all participating sites to report on, interrogate and interpret their data so to drive better risk management standards in those sites. Rolling out a new system to State authorities and health enterprises represents a considerable challenge for the SCA and the participating sites. The new system will only be successfully rolled-out where the participating sites devote the IT, personnel, time and training resources to ensure it becomes a major management information tool at local and national levels. The roll-out of NIMS, therefore, provides the perfect opportunity for participating sites to receive a “State of the Art” incident reporting management and risk analysis system, thus enabling them to take appropriate decisions in the light of accurate and up-to-date incident investigation and claims’ information.

NIMS belongs to its participating sites and will be the sum of its many parts in terms of national trends etc. As a national system endorsed and supported by all the key stakeholders and the only one which fulfils the statutory obligation of participating sites to report their incidents and claims, it is imperative that the sites work generously with the Agency to truly embed the system across the State sector. This also calls for the abandonment of older, less intuitive and developed incident reporting systems be replaced by NIMS as the only national system for the reporting and management of incidents.

Ciarán Breen - Director of the State Claims Agency (SCA)
An evaluation of the guidance for the use of Oxytocin in maternity services in Ireland

An Evaluation of the Policies, Procedures, Protocols and/or Guidelines for the Use of Oxytocin to induce or augment/accelerate labour currently employed in maternity services in Ireland

BACKGROUND and CONTEXT

Nineteen public maternity services (hospitals/units) in Ireland are indemnified by the State Claims Agency (SCA). Clinical negligence claims for harm caused in these services account for 20-25% of claims and 60% of costs paid. Likewise in England, maternity claims as a group are the most expensive clinical negligence claims and the second highest by volume. In the United States, oxytocin is strongly associated with medical negligence claims, and review of such malpractice claims reveals that it is involved in more than 50% of the situations leading to birth trauma. Hence, it is no surprise that Oxytocin is listed as a high alert medication. Likewise, in Ireland a substantial number of claims suggest that Oxytocin (Trade Name: Syntocinon) is a causative/contributory factor.

There is currently no national guidance for the Use of Oxytocin to Induce or Augment/Accelerate Labour. This deficit, the associated risks and infant deaths implicating Oxytocin have been the subject of media scrutiny over the last eighteen months.

One of the greatest risks to patient safety and quality improvement is variation and variability in practice. Clinical guidelines provide a means by which variability in practice can be minimised and are a critical component to support the delivery of safe, high quality care.

The aim of this project was to ascertain the nature and extent of the specific, contemporary, evidence informed clinical guidance for the use of Oxytocin to induce and or augment/accelerate labour in each of the nineteen maternity services. There is both a need and merit this in light of the current development of a national clinical guideline by the Health Service Executive’s National Clinical Programme for Obstetrics and Gynaecology. The information gleaned has the potential to assist with determining the methodologies to be employed for both dissemination and implementation of the clinical practice guideline once approved.

METHODOLOGY

An explanatory letter and questionnaire was issued to all maternity services. The development of the questionnaire was informed by Standard 2 – Criterion 5: Use of Oxytocin from the NHS Litigation Authority’s (NHSLA) Maternity Clinical Risk Management Standards. This specifies the minimum requirements, in that a maternity service must have approved documentation for the use of Oxytocin in the first and second stages of labour.

KEY FINDINGS

The response rate from the maternity services was 94.7% (n=18), with 72.2% (n=13) submitting the guidance requested. Each service provided the number of Whole Time Equivalents (WTE) together with the number of individuals of both Consultant Obstetricians and Registered Midwives and the number of births in 2013 within their service as requested. The number of Consultants is 4.6/100,000 of the female population. This is well below the OECD average of 27.3/100,000.

There is specific and approved guidance available for the Use of Oxytocin to Induce or Augment/Accelerate Labour in 94.4% (n=17) services. One service (5.5%) has no guidance. The type of guidance reported includes: guidelines (13); local policies (6); protocols (5); procedures (3) and a checklist (1).

CONSENT

No service obtains explicit written consent from women prior to commencing Oxytocin. Three services (17.6%) explained that it is “explained in detail to the patient” (1) or that verbal consent is obtained (2). There is no reference to obtaining informed consent in the draft guideline under development. Clearly, this is an area that must be addressed.

ASSESSMENT

Guidance must include details regarding assessment prior to the commencement of Oxytocin. Such details regarding assessment of the woman prior to commencing Oxytocin are incorporated in 77.7% (14) services prior to induction, yet in only 66.7% (12) for augmentation/acceleration of labour. Furthermore, there was a lack of specificity and significant variations in the components of these assessments. There was no explicit reference to gestational age or estimation of foetal weight in the written responses, yet three of the guidelines do refer to gestation. On service uses the NICE (2008) Clinical Guideline which refers to assessing gestation. Arguably the implementation of a national guideline would address this significant lack of standardisation.

DOCUMENTATION

All respondents (18) indicated that this assessment is documented in a variety of areas in the woman’s maternity health-care record, with the labour records/section (9) and partogram (2) featuring most. Similarly, there is an explicit requirement to document an individual management/care plan in the woman’s healthcare record when commencing in 72.2%
RECOMMENDATIONS: IMPROVING CARE AND LEARNING LESSONS RELATING TO THE USE OF OXYTOCIN

1. Communication with the Clinical Lead, National Clinical Care Programme: Obstetrics and Gynaecology and presentation to the Clinical Advisory Group and Working Group with regard to developing a national strategy for the implementation, monitoring and auditing of a national clinical practice guideline for the use of Oxytocin for induction and acceleration/augmentation of labour through the Local Implementation Boards.

2. Review closed claims where Oxytocin has been a causal/contributory factor and benchmark against the minimum requirements of the NHSLA Maternity Standards. Learning to be incorporated into the development of the National Clinical Guideline.

3. Participate in the review of the Practice Standards for Midwives by the Nursing and Midwifery Board of Ireland with a view to influencing the incorporation of explicit guidance in respect of Oxytocin in the next edition.

4. Engage with key stakeholders to develop a national Information Leaflet for women.

5. Develop a specific national education programme in collaboration with key stakeholders.

6. Presentation of findings to Claims Managers and Clinical Risk Advisers in the SCA.

7. Presentation of findings to the maternity services.

8. Further research into the current guidance and practice in the use of Oxytocin.

CONCLUSION

The aim of the project was achievable by utilising the NHSLA’s minimum requirements to focus on key elements. The strength of this evaluation can be attributed to the significant response rate and also to the actual guidance submitted. A real opportunity now exists in endeavouring to influence the completion of the development and implementation of a national clinical guideline for the use of Oxytocin for induction and the augmentation/acceleration of labour as a matter of urgency. Standardisation is key to improving outcomes for women and their babies. They deserve only the best. Correspondingly, this could reduce the number of clinical negligence claims associated with the use of Oxytocin and ultimately the cost to the Irish taxpayer.

Mary Godfrey, Clinical Risk Adviser, SCA

References for this article are available upon request
Protection of Life During Pregnancy Act 2013

The Protection of life During Pregnancy Act 2013 (the Act) commenced on 1 January 2014. In September 2014 the Department of Health issued guidelines\(^1\) (the Guidelines) for medical practitioners to provide further guidance in relation to the operation of the Act in practice. In this article, we look at the operation of the Act, the statutory procedures to be followed when assessing patients under the Act and the relevant guidance.

**SUMMARY**

If a health professional is of the opinion that a pregnant woman might be at risk, he or she is expected to make urgent referral to an appropriate medical practitioner for further assessment under the Act. The Act provides for three instances in which a “medical procedure” in respect of a pregnant woman can be carried out, during the course of which or as a result of which, an unborn human life is ended (i.e. a termination of pregnancy). A medical procedure is defined as including the prescribing of any drug or medical treatment by a medical practitioner. Unborn human life is defined under the Act as “…such a life during the period of time commencing after implementation in the womb of the woman and ending on the complete emergence of the life from the body of the woman”. The three instances whereby a medical procedure will be lawful if certain criteria are met are:

1. Where there is a risk of loss of life as a result of a physical illness (Section 7 of the Act);
2. Where there is a risk of loss of life from physical illness in an emergency (Section 8 of the Act); and
3. Where there is a risk of loss of life from suicide (Section 9 of the Act).

Except in the case of emergencies under Section 8, medical procedures can only be carried out in an “appropriate institution”. Hospitals which are appropriate institutions are scheduled in the Act.

**SECTION 7 – RISK OF LOSS OF LIFE FROM PHYSICAL ILLNESS**

Under Section 7 it is lawful for a medical procedure to be carried out where there is a risk of loss of life to the pregnant woman from a physical illness. Physical illness is defined as including a physical injury but specifically does not include suicide. Under this section two medical practitioners (one being an obstetrician who practices at an appropriate institution and the other of a relevant speciality) must examine the patient and jointly certify that the test has been met:

(a) That there is a real and substantial risk of loss of the woman’s life from a physical illness; and

(b) In their reasonable opinion, (being an opinion formed in good faith which has regard to the need to preserve unborn human life as far as practicable), that risk can only be averted by carrying out the medical procedure.

In carrying out this assessment, the Act states that one of the medical practitioners should, where possible, consult with the patient’s general practitioner with her consent. If both doctors determine (the decision must be unanimous) that the test has been met, they shall complete the pro-forma Section 7 Certificate (a prescribed statutory form which must be completed in advance of carrying out the medical procedure)\(^2\). The completed Certificate will then be forwarded by the obstetrician to an appropriate institution to make the necessary arrangements for carrying out the medical procedure at that institution. For the procedure to be lawful, it must be carried out by an obstetrician at an appropriate institution. Appropriate follow up should be arranged by the doctor of a relevant speciality must be a doctor registered in the specialist division of the Medical Council whose speciality is relevant to the care and treatment of the physical illness from which the pregnant woman is suffering. In order for a woman to meet the criteria for a medical procedure under this section, both doctors must jointly certify that the following test has been met:

**SECTION 8 – RISK OF LOSS OF LIFE FROM PHYSICAL ILLNESS IN EMERGENCY**

Under Section 8 it is lawful for a medical procedure to be carried out where there is a risk of loss of life to the pregnant woman from a physical illness in an emergency. Medical practitioners are allowed to carry out medical procedures in an emergency, even if these procedures are not usually lawful or would normally not be carried out in the absence of an emergency. In carrying out this assessment, the Act states that one medical practitioner should, where possible, consult with the patient’s general practitioner with her consent. If one doctor determines (the decision must be unanimous) that the test has been met, they shall complete the pro-forma Section 8 Certificate (a prescribed statutory form which must be completed in advance of carrying out the medical procedure). The completed Certificate will then be forwarded by the medical practitioner to an appropriate institution to make the necessary arrangements for carrying out the medical procedure at that institution. For the procedure to be lawful, it must be carried out by a medical practitioner at an appropriate institution. Appropriate follow up should be arranged by the medical practitioner of a relevant speciality.
obstetrician who carried out the procedure.

SECTION 8 – RISK OF LOSS OF LIFE FROM PHYSICAL ILLNESS IN AN EMERGENCY

Under Section 8 it is lawful to carry out a medical procedure where there is a risk of loss of life to the pregnant woman due to physical illness in an emergency. Under Section 8 only one medical practitioner must examine and assess the pregnant woman and believe in good faith that:

a. There is an immediate risk of loss to the woman’s life from her physical illness; and
b. That the medical procedure is in his or her opinion, (being an opinion formed in good faith which has regard to the need to preserve unborn human life as far as practicable), immediately necessary in order to save the life of the woman.

The medical procedure must then be carried out by the same medical practitioner who made the assessment and determined that the test had been met. The Guidelines recommend that it is an obstetrician who carries out the medical procedure. If this is not possible, then it should be the most senior clinical practitioner on duty. In addition, a multidisciplinary approach should be considered. The medical procedure must be certified using the pro-forma Section 8 Certificate (a prescribed statutory form) before the medical procedure is carried out, or if not possible, within 72 hours of the carrying out of the procedure. Conscientious objection does not apply in the case of an emergency.

SECTION 9 – RISK OF LOSS OF LIFE FROM SUICIDE

Under this section it is lawful to carry out a medical procedure if three medical practitioners (an obstetrician and two psychiatrists), having each examined the woman have determined and certified that the following test has been met:

a. That there is a real and substantial risk of loss to the woman’s life by way of suicide; and
b. In their reasonable opinion (being an opinion formed in good faith having regard to the need to preserve unborn human life as far as practicable) that risk can only be averted by carrying out the medical procedure.

The Act provides strict requirements in relation to the practitioners involved in assessments under Section 9. The obstetrician and one of the psychiatrists must practice at an appropriate institution. The other psychiatrist must practice at an approved centre or by or on behalf of the HSE. In addition, one of the two psychiatrists must have provided mental health services to women in respect of pregnancy or postpartum care. If possible one of the medical practitioners should consult with the patient’s general practitioner, with her consent, for the purposes of obtaining additional information for their assessment. Any of the three practitioners can examine the patient first. If the first practitioner determines the test has been met, the patient is referred to the second practitioner, if the second practitioner deems the test has been met, the patient is referred to the third practitioner. If at any point one of the medical practitioners determines the test has not been met, non certification will apply. If all three of the practitioners are of the opinion that the test has been met, the pro-forma Section 9 Certificate (a prescribed statutory form) which must be completed in advance of carrying out the medical procedure is completed and forwarded to an appropriate institution and the obstetrician makes the necessary arrangements for carrying out the procedure. The procedure must then be carried out by an obstetrician at an appropriate institution and appropriate follow up should be arranged for the patient.

SECTION 10 – APPLICATION FOR REVIEW

Where a patient has not met the requirements for a medical procedure under the Act, the patient must be informed in writing of their right to a formal review of the decision. The patient is still entitled to seek a second opinion as per standard medical practice and the review procedure under the Act is
patient or someone acting on her behalf can make an application to the HSE to review the decision. The HSE will then establish a review committee within three days of receipt of the application. If the review is in relation to a Section 7 certification, the review committee will consist of an obstetrician who practices at an appropriate institution and a doctor of a relevant specialty. A Section 9 review committee consists of an obstetrician and psychiatrist who practice at an appropriate institution and a psychiatrist who practices at an approved centre or for and on behalf of the HSE. One of the psychiatrists must have provided mental health services to women in respect of pregnancy or post partum care. The review committee must complete the review within 7 days from its date of establishment. Each member of the committee must examine the woman, not just her medical records. They all must certify in good faith that there is a real and substantial risk of loss of the pregnant woman’s life from either a physical illness or suicide and that in their reasonable opinion, that risk can only be averted by carrying out the medical procedure. A pregnant woman or person acting on her behalf is entitled to be heard by the review committee. The committee can also require a medical practitioner to produce records and/or other documents and to attend in front of the committee to provide assistance to it; failure to do so is an offence.

If each member of the review committee determines the test has been met (the decision must be unanimous), the relevant pro-forma statutory certificate shall be completed and forwarded to an appropriate institution and arrangements shall be made for the carrying out of the procedure. If the committee determines the test has not been met, they shall advise the patient in writing. If the woman’s circumstance becomes an emergency while the review process is on-going, she can undergo a medical procedure if the requirements of Section 84 have been met.

OBLIGATION TO MAINTAIN RECORDS

All medical procedures carried out under the Act must be notified to the Minister for Health within 28 days of the procedure having been carried out. Notification must be made by the “person in charge” (the Guidelines recommend this be done by the CEO, Clinical Director or Master). There is a pro-forma statutory Notification Form4 which is to be used for notifying the Minister for Health which consists of Parts A, B & C. The Guidelines state that Part A (patient information) shall be retained on the patient’s records and Parts B & C shall be sent to the Minister for Health. The Minister for Health will prepare an annual report covering each notification that he had received over the course of the previous year.

GENERAL ISSUES FOR CONSIDERATION

- Informed consent is required for medical procedures under the Act. However, where there is an immediate risk of loss of life in the case of an emergency under Section 8 consent is not required.
- Conscientious objection applies to procedures under Sections 7 & 9 (not 8), however, there remains an obligation on the medical practitioner to transfer the patient to another practitioner.
- The Act & Guidelines do not place a gestational limit on the carrying out of medical procedures. Therefore, there is no specific stage in pregnancy below which the certifying doctors will not have to consider the possibility of preserving the life and dignity of the unborn where practicable without compromising the life of the mother.
- Clinicians responsible for the pregnant woman’s care will need to use their clinical judgment as to the most appropriate procedure to be carried out, i.e. a medical or surgical medical procedure or an early delivery by induction or Caesarean section. Following certification, if the pregnancy is approaching viability, a multi-disciplinary discussion should take place to ascertain the most appropriate clinical management.
- At all stages of the process patient confidentiality must be paramount for all health personnel involved.
- Health professionals will need to be mindful of child protection issues when dealing with minors.

Michaela Herron, Clinical Litigation Solicitor, SCA

REFERENCES

3 As above
4 As above
5 Section 8 of the Act sets out the requirements for a medical procedure where there is an immediate risk of loss of life to the pregnant woman in an emergency.
Case Study: Falls Case Defended

Recently the State Claims Agency successfully defended a falls case in a Dublin hospital.

The patient was an 85 year old gentleman who had a history of falls as well as a number of underlying conditions including a history of deep venous thrombosis, inconsistent blood pressure, imbalance, chronic renal failure, confusion/early dementia and a psychiatric history. The proceedings were taken on the plaintiff’s behalf by his daughter following a review by a consultant psychiatrist which confirmed the plaintiff’s inability to take proceedings on his own behalf. In the course of the hearing it transpired that the plaintiff was not aware of the existence of the proceedings.

ALLEGATIONS

The plaintiff alleged that due to the hospital’s negligence he had sustained a hip fracture while mobilising from his bed to the toilet. The plaintiff had non-operative management of his injury and was non-weight bearing for a period of six weeks post-accident. This period resulted in a degree of muscle atrophy with the alleged consequence that he never returned to his pre-injury baseline level of mobility. The central allegations were that:

- the hospital failed to have sufficient regard for the fact that the plaintiff fulfilled a number of risk factors associated with falling, and
- the hospital failed to provide suitably qualified medical staff to provide adequate treatment to, and supervision of, the plaintiff.

The plaintiff’s daughter criticised the level of supervision and the absence of a care assistant. That criticism was expanded upon further by the plaintiff’s nursing care expert. In her opinion the falls preventative measures implemented by the hospital were of a minimum standard. Her evidence was that the use of orange wrist bands, falls signage over the plaintiff’s bed and the provision of hip protectors were insufficient measures. She alleged that the following further preventative measures were also necessary:

- a review of the plaintiff’s medication;
- the use of a motion alarm;
- one-to-one supervision and/or moving the plaintiff’s bed to an area in the ward where he could be closely supervised.

Interestingly, it became apparent upon cross examination that the nursing expert had not questioned the location of the plaintiff’s bed and was unaware that it was immediately adjacent to the nurses’ station, which had a large window facing into the ward.

DEFENCE

The various criticisms raised on behalf of the plaintiff were dealt with by the hospital’s Director of Nursing, the plaintiff’s treating Consultant Geriatrician and by an independent expert Consultant Physician and Geriatrician instructed by the SCA.

The Director of Nursing gave evidence in relation to the proximity of the plaintiff’s bed to the nursing station and the toilet. She also gave evidence that a nursing ratio of three qualified nurses and one healthcare assistant for this 28 bedded ward was sufficient in her experience. She stated that in her experience one-to-one supervision often caused agitation in patients and that motion detectors were not suitable in the ward in question, as they often caused further distress to patients. She also explained that at the time of the accident (7:05am) the ward would have been active because the administration of medicines began at 6:00am. As the plaintiff was on a number of medications he would have been attended to by nurses during the period in question, however, she said that on occasion it is simply not possible to prevent falls such as this.

The plaintiff’s treating Consultant gave evidence in relation to his medical history and explained that the hospital did every thing possible to rule out medication being a contributing factor to his falls risk. However, given that the plaintiff was on a number of psychiatric drugs, withdrawal of such medication could only be done on an incremental basis in order to avoid adverse consequences. The treating Consultant’s evidence was also that the plaintiff presented as mildly confused with the exception of one episode of agitation. Accordingly, in her opinion, one-to-one supervision was not indicated in this case.

The evidence of both the hospital’s Nursing Director and the treating Consultant was supported by the evidence of our expert witness. In his opinion the hospital could not have done anything more to prevent this unfortunate fall. The expert listed the following measures which were adopted by the hospital:

- Conducting a “STRATIFY” Falls Risk Assessment;
- Implementing a Nursing Care Plan on the basis of that assessment (which included an orange wrist band to identify the plaintiff as a falls risk and placing falls alert signage over the plaintiff’s bed);
Provision of hip protectors;

Advising the plaintiff regularly not to mobilise without assistance or supervision;

Detailed instructions regarding use of a call bell (although the plaintiff’s cognitive impairment reduced the efficacy of this measure somewhat);

Use of a rollator zimmer frame as a mobility aid;

Regular ongoing work with physiotherapists;

In response to the criticisms of the plaintiff’s expert regarding the requirement for additional fall preventative measures, the hospital’s expert said that a number of medications had been discontinued in the correct manner in an attempt to reduce the plaintiff’s risk of falling. Regarding the alleged necessity for motion alarms he said that such alarms could be intrusive to patients in circumstances where they could be activated every time a patient moved. They could also be a considerable disturbance to other patients. He referred to an unsuccessful pilot study in an Irish hospital in the early 2000’s where the motion alarms were removed after one week. Accordingly his view was that evidence does not support the use of such alarms.

In response to the alleged requirement for one-to-one supervision the expert explained that up to 40% of older hospital patients are at higher risk of falling, and it is clearly unrealistic in an acute hospital setting (or indeed in a long-stay setting) to provide individual monitoring to all such patients. In any event, it would be almost impossible for the designated person to concentrate solely on one patient if other patients in view required assistance. He said that in some circumstances, even where a member of staff sees a patient falling, it is not always possible to stop this occurring. He recounted such an incident occurring before his own eyes.

The hospital’s expert witness also addressed the issue of bed rails and their unsuitability in this case. He said that whilst bed rails can be used as safety devices to reduce the risk of accidentally slipping or rolling from the bed, they are not designed to prevent someone from getting out of bed, particularly in the case of a confused patient such as the plaintiff. All evidence suggests that such patients are much more likely to climb over the rails or attempt a potentially dangerous exit at the foot of the bed, which can cause more serious accidents than would occur in their absence. Indeed, hundreds of asphyxia deaths have been reported from entrapment between rails and mattresses, most involving patients with cognitive impairment.

Finally, in response to the criticism that the hospital should have had the plaintiff’s shoes and his rollator zimmer frame available to him at his bed, our expert was of the view that whilst it can be difficult to get the level of care correct in cases like this, the provision of shoes and the rollator zimmer frame would have served as an invitation to the plaintiff to attempt to mobilise unassisted and therefore could not be recommended.

**JUDGEMENT**

In dismissing the case the Court found that the hospital had been fully aware of the plaintiff’s condition and took all necessary precautions to care for him. The Judge commended the hospital’s management of the case. She found that the individual care plan put in place for the plaintiff was most appropriate, that she had no criticism in relation to the staffing levels, that one-to-one supervision was not appropriate in this case and, in any event, may not have prevented the accident. She accepted the hospital expert’s evidence in this respect.

The Judge found that the only alternative in this case was to immobilise the patient which would have been very distressing for him, or to use cot sides, which in light of the hospital expert’s evidence, would probably have had a worse outcome from the plaintiff’s perspective. She also accepted that the alarm monitors suggested by the plaintiff’s expert were not a viable solution; rather they would have caused absolute chaos within the hospital as well as distress to patients. She noted that fortunately the plaintiff did not require surgery and she accepted that he was back to his baseline mobility level within six weeks.

Taking all of the above into consideration she found that no case had been established against the hospital.

Whilst the care in this case was exemplary there is no doubt that having excellent notes in the hospital chart was vital in terms of defending the case.

Michelle Rabbette, Solicitor/Clinical Claims Manager, SCA

**MAIN RISK MANAGEMENT POINTS**

- Falls risk assessment completed
- Care plan implemented and adhered to
- One-to-one supervision unwarranted
- Despite exemplary care, this fall was unpreventable
- Comprehensive notes in the chart were essential to successful defence.
Consent: the doctor’s perspective

Allegations are increasing, that doctors fail when obtaining consent, to ensure that the patient understood the information. Obtaining consent from a patient is well taught in the U.S.A. and central to the patient doctor relationship.

Firstly, they teach the simple consent acronym PARQ: “procedure” (what it entails), “alternatives” (including nothing), “risks” (of the procedure and the alternatives) and “questions” (invite the patient to ask questions). Doctors write “PARQ” in the medical notes to demonstrate they have considered all elements. The case of Birch v University College Hospital (UK) exemplifies the importance of above where the doctor was found negligent, because although he informed the patient of the risks of catheter angiography which led to her stroke, he did not discuss the comparative risk of magnetic resonance imaging.

Secondly, the “10 points to remember”:
- When do you need consent?
  - with any intervention conducted by a doctor on a service user
- What information should be given?
  - diagnosis, prognosis, purpose of intervention, potential complications including failure, alternatives or taking no action
- Where should consent be obtained?
  - in a private and appropriate location
- How should it be obtained?
  - using comprehensible communication, interpreter if required
- Time?
  - give plenty of time to discuss, never rush
- Timing?
  - in outpatients, weeks prior to the elective procedure and re discuss closer to event
- Leaflets?
  - helpful, but they never replace discussion with individual patients
- Validity of consent?
  - patients must be acting voluntarily, be mentally competent to make a decision and receive sufficient information in a comprehensible manner
- Age?
  - sixteen years is the age one can give consent to surgical, medical or dental treatment without requiring consent from parents.

Sokol, (barrister and medical ethicist), reminds doctors of an important point which lawyers actively consider in clinical negligence cases: that it is not enough just to impart information, doctors must do so in a manner that the patients will understand. He illustrates this with the case of Mrs Lybert who after a sterilisation procedure became pregnant. Although the consultant had documented in his notes “not 100%”, the judge concluded the warning was not sufficiently “clear and comprehensible”. He found that had an appropriate warning been given, contraception would have been used and pregnancy avoided.

To protect us as doctors, to take “reasonable and appropriate steps” to ensure the patient understands the information, we should invite questions (the “Q”), offer leaflets and encourage their reading, and/or consider recording the consultation and providing a copy to the patient.

Documentation is critical. A careful legible note while time consuming, is worthwhile. Writing out potential specific side effects is helpful even if the patient sustains one not listed, because it demonstrates the detail to which they were discussed. As a doctor, I think Sokol’s suggested statement is worthy of consideration: “procedure, alternatives and risks explained in clear terms. Questions invited but none asked. Patient appears to understand. Leaflet provided. Patient advised to read”. This aims to benefit both patients and doctors.

Dr. Dubhfeasa Slattery, MB BCh, MRCPI (Paeds), FRCPI, M Med Sci, PhD
Head of Clinical Risk, SCA

REFERENCES:
1 Sokol D. Let’s stop consenting patients.BMJ2014;348:g2192
2 Birch V University College Hospital NHS Foundation Trust (2008) EWHC 2237(QB)
3 HSE Consent Policy 2012
4 Sokol D. Defending the sophisticated consent attack. BMJ 2014;349:g6432
5 Lybert v Warrington Health Authority (1996) 7 Med LR 297

Dr Dubhfeasa Slattery, recently appointed Head of Clinical Risk, SCA.
The vision of the National Strategy is a “life free from falls and fractures in our ageing population”. AFFINITY (Activating Falls and Fracture Prevention in Ireland Together), the national implementation project, aims to prevent harmful falls amongst persons aged 65 years and older, enhance the management of falls and improve health and wellbeing through a focus on bone health. To do this effectively it will need to take account of human factors and in particular non-technical skills i.e. the cognitive and social skills that complement worker technical skills. The main categories of non-technical skills that are important for safer operations of relevance to AFFINITY are: situational awareness, decision making, communication, team working, leadership, managing stress and coping with fatigue. Using these categories we can see how human factors can enhance safety and efficient operations, by reducing the likelihood of error and consequently the risk of adverse outcomes.

1. To learn more about AFFINITY or get involved, please contact National Joint Co-ordinators:
   Irene O’Byrne-Maguire  T: 01 238 4184
   iobyrnemaguire@ntma.ie or
   Roisin Maguire  M: 087 2394583
   roisin.maguire@hse.ie


3. AFFINITY (Activating Falls and Fracture Prevention in Ireland Together) Peer Learning

AFFINITY Peer Learning sessions take please every 6-8 weeks, for an hour, from 11.30-12.30pm usually. The next one is provisionally scheduled for February 2015. They are delivered to your workstation/place using telco and remote session technology (PDF presentation emailed in advance as backup)

Peer Learnings sessions aim to build a Community of Practice (CoP) to share experiences and practical resources, hence helping realise the vision of a “life free from (harmful) falls and fractures in our ageing population”.

Learning outcomes include:

- The identification of critical elements needed to develop/enhance falls prevention and bone health programmes in different settings – primary care, community, residential care and hospitals.
- Gaining tangible insights into how different settings are building partnerships in existing ISAs/new Community Health Organisations (CHOs) to develop/enhance an integrated care pathway (ICP) for older persons.
- Learning practical approaches to help maintain momentum, problem solve challenges, and build for sustainability.
- Learning how early adopters (scalable unit partnerships) are integrating, implementing and innovating to deliver the vision and objectives of AFFINITY.

Format: 20 minutes presentation and the rest Q & A.

Contact Louise Holohan by email on lholohan@ntma.ie to register your interest in joining the AFFINITY Peer Learning Sessions.

Irene O’Byrne-Maguire, Clinical Risk Adviser, SCA
National Incident Management System (NIMS) Progress Update

RECAP
The State Claims Agency (SCA), in conjunction with the Department of Health, HSE, Voluntary Health Enterprises and other key stakeholders, has upgraded STARSWeb. In the previous issue of the newsletter we discussed the upcoming implementation of the National Incident Management System (NIMS), the establishment of a Governance Group to oversee this roll out and the development of a new National Incident Report Form. For the full article see the April 2014 edition of the SCA newsletter.

1. REBrANDING
The National Adverse Event Management System (NAEMS) has been rebranded! Originally the primary objective of the project was to build a risk management system for risk managers/subject matter experts to manage their harmful incidents also known as ‘adverse events’. Throughout the course of the project, the scope expanded and the system also catered for no harm incidents, near misses, dangerous occurrences and complaints in line with the World Health Organisations definition of an incident and the HSE Safety Incident Management Policy. Thus, it made sense to rename the system the National Incident Management System (NIMS).

2. NIMS IMPLEMENTATION
NIMS (formally NAEMS) successfully went live on the 16th June 2014 with the upgraded system now available to all in the State Claims Agency. NIMS has since been implemented in a large number of sites:

- Rotunda Hospital;
- All Prisons in the Irish Prison Service including HQ;
- All Brigades and Formations of the Defence Forces including HQ.

The system is currently being implemented in the Mater Misericordiae University Hospital and Midlands Regional Hospital, with a go-live date set for February 2015.

3. NIMS GOVERNANCE
Since the establishment of the NIMS Governance Group significant progress has been made in relation to identifying a suite of Quality Patient Safety Indicators in conjunction with Quality & Patient Safety. This has been included in the HSE Service Plan 2015. A steering group has also been established to develop and drive this National Implementation Plan with Cora McCaughan (Head of the HSE Serious Incident Management Team) nominated as Chair of the group. The objective of the NIMS Steering Group is to implement the system to all Healthcare Enterprises by Q3 2015 as per the HSE Service Plan 2015.

4. NATIONAL INCIDENT REPORT FORM (NIRF)
A National Incident Report Form (NIRF) was developed by the State Claims Agency in conjunction with all stakeholders including the HSE and voluntary hospitals. By using the NIRF you are assured of the accuracy of data and clarity of information being reported. There are four forms in total; Person, Property, Crash/Collision and Dangerous Occurrences (Reportable Circumstances)/Complaints. The NIRF shall be implemented simultaneously to the system.

5. UPCOMING ENHANCEMENTS
The State Claims Agency is continually working on new enhancements within NIMS. The enhanced complaints module is due for release in Q1 and is designed in accordance with the HSE Complaints Policy. This module will allow Complaints Officers to log complaints and the associated issues on NIMS in line with the HSE Pillars and manage these through to closure. Other upcoming enhancements include the recommendations module and the audit tool which are both due for release in 2015.

Katie Nugent, National Co-ordinator for the Implementation of NIMS

Driving and supporting safe patient care through effective claims and risk management
When ZERO is the only acceptable measure of success  

Establishment of HSE Risk Committee

"Adverse events result from the interaction of the patient, the patient’s disease, and a complicated, highly technical system of medical care provided not only by a diverse group of doctors, other care givers, and support personnel, but also by a medical-industrial system that supplies drugs and equipment. Reducing the risk of adverse events requires an examination of all these factors as well as of their relation with each other."  Leape, L.L. et al (1991)

It is against this reality and the fact that healthcare is a 24/7, complex, ever evolving service that seeks to meet the ever changing needs of our citizens that the H.S.E. has adopted an Integrated Risk Management policy to guide the management of risks associated with the services provided.

WHAT IS INTEGRATED RISK MANAGEMENT?

Integrated Risk Management can be defined as: “A continuous, proactive and systematic process to understand, manage and communicate risk from an organisation-wide perspective. It is about contributing to strategic decision making in the achievement of an organisation’s overall corporate objectives”. (H.S.E. Integrated Risk Management Policy 2013)

In support of this policy the HSE has established a Health Services Executive Risk Committee. The Committee is authorised by the HSE Directorate (governing body for the organisation) to:

- investigate any activity within its terms of reference;
- seek any information or explanations that it requires from any employee of the HSE or anybody totally or partially funded by the HSE. All employees and bodies funded are directed to co-operate with any request made by the Risk Committee;
- secure the attendance of persons with relevant experience and expertise if it considers this necessary; and,
- investigate any matter it deems relevant, brought to its attention by whomsoever, including, but not limited to, good faith reports in relation to quality, safety and risk.

The Committee focuses principally on non-financial matters, especially:

- Processes related to the identification, measurement, assessment and management of risk in the HSE;
- Promotion of a risk management culture throughout the health system.

The Committee exercises an advisory role in relation to its duties. It is not responsible for any executive functions and is not vested with any executive powers.

CONTEXT

Healthcare is provided 24 hours a day, 7 days a week. Dramatic advances in the diagnosis and treatment of disease have made care processes more complex. In addition, the aging population, resource limitations, a critical shortage of qualified healthcare personnel in a growing list of locations and specialties, together with challenges created by restructuring within the healthcare system, create strain on the system. This increases the likelihood of adverse events that sometimes lead to lethal consequences.

Fortunately, due to the efforts and vigilance of healthcare personnel, many of these possible events are prevented or mitigated.

HOW RISKY IS HEALTHCARE?

Most of the interactions with the healthcare system are error free and meet the needs of the service user and relevant standards. However, when we look at the evidence from other countries we are alerted to a worrying situation that researchers have documented preventable injuries and deaths in every setting where measurement was attempted. There is no reason to believe that the Irish healthcare system would be very different.

Countries such as the U.S.A., U.K. and Australia have published their findings that conveyed their recognition that their systems were not safe. The US Institute of Medicine Report To Err is Human (1999) estimated that between 44,000 and 98,000 of their citizens die each year as a result of medical errors. In the U.K., An Organization with a Memory (National Health Service, 2000), estimated that adverse events, in which harm is caused, occur in approximately 10% of patient admissions, or about 850,000 times a year. The Quality in Australian Health Care Study (Wilson et al, 1995) reported that 16.6% of admissions were associated with an adverse event, and, of these, 51% were considered highly preventable.

We do know that in Ireland in 2012 there were 67,000 adverse events reported to the State Claims Agency (SCA) of which 52,000 were related to “clinical”. The actual financial cost of such events is many tens of millions of euros per year, but to this financial cost must also be added the human pain and suffering that individuals and families and friends suffer together with the reputational damage inflicted as a result of such adverse events.

It is fully acknowledged that staff is the greatest resource
available to the system. It is important therefore, that the specific health and safety issues pertaining to staff and the workplaces, in which they work, are actively managed at a minimum as required by relevant legislation.

We are supportive of and look forward to the system wide implementation of the National Incident Management System (NIMS) which we as a committee will utilize, together with other sources of information, such as external and internal inspections and audits, protected disclosures and good faith reporting, to inform us on the performance of the system. The Committee also welcomes that a HRB/HSE collaboration is funding the Irish National Adverse Events Study which will establish an accurate figure for adverse events occurring in our hospitals and will be published next year.

The Health Service Executive, National Service Plan 2015, reinforces its commitment to Safety and Quality by the putting in place of a new Quality and Patient Safety Enablement Programme and a new Accountability Framework. It also sets out its suite of Performance Indicators for 2015.

As a Risk Committee we will advise the Director General and the Directorate as set out in our charter and are focused on ensuring that the Integrated Risk Management policy is embraced throughout the entire system. This will assist with creating a safety culture within which are implemented, coordinated and comprehensive strategies to eliminate preventable adverse events.

As a Committee we will advise and provide feedback on the corporate risk register and corresponding effectiveness of the systems established by management to identify, assess, manage, monitor and report on risks.

We look forward to reviewing the progress made in terms of agreed Key Performance Indicators and especially the full implementation of recommendations and lessons learned from all statutory, internal and external reviews and audits.

Tom Beegan, Chairman HSE Risk Committee

The Increasing (Claims) Cost of Social Protection

Since the 1st of August the Irish compensation landscape has been changed with the introduction of Recovery of Benefits and Assistance (RBA) Scheme. The scheme, introduced in Section 13 of the Social Welfare and Pensions Act of 2013, provides for the repayment of certain state benefits by insurers (including the State Claims Agency on behalf of state authorities) to the Department of Social Protection that previously had only been paid to a plaintiff as a result of an accident.

The Department of Social Protection expect to be refunded in the region of €25 million in benefits from insurers, including the State Claims Agency who manage personal injury and clinical negligence claims brought against certain state authorities, including government ministers and health enterprises.

**PREVIOUS REGIME**

Hitherto where a claimant suffered personal injury and received benefits from the Minister for Social Protection the payment of these benefits, in some instances, could reduce an insurer’s liability by being deducted from a loss of earnings claim. It also left the Minister for Social Protection with no recourse to recover these benefits paid notwithstanding the liability of the insurer or authority for the compensation claim which arose as a result of their insured’s neglect. Clearly, from the taxpayer’s perspective, it was not ideal and required legislative change. A road map for such change was available from the UK where not only were social welfare benefits but also hospital charges recovered directly from insurers and state authorities.
A NEW REGIME
The Recovery of Benefits and Assistance Scheme is administered by the Department of Social Protection. The legislation provides that insurers and state authorities are themselves liable to repay the Minister for Social Protection for the following benefits that have been paid to a plaintiff in a personal injury action:

1. Illness benefit
2. Partial capacity benefit
3. Injury benefit
4. Incapacity supplement
5. Disability pension
6. Disability allowance

It is important to specify that it is the compensator (primarily for State authorities this will be the State Claims Agency who will seek reimbursement of this outlay from the relevant state authority) who is liable and not the injured party. The compensator’s liability will run from the date on which the injured person first became entitled to the benefit as a result of the personal injury and ending on the earliest of the following:

1. The expiration of the period of 5 years from that date;
2. The date upon which a compensator makes a payment in full and final discharge of any claim made by, or in respect of the insured person as a result of the personal injury;
3. The date an agreement is made under which an early repayment is treated as having been made in final discharge of any such claim.

The legislation has set out a specific road map within which the compensator has to follow. In this regard state authorities should contact their relevant claims manager who are well versed in the technicalities of the legislation, should they require specific information on how to deal with such applications. Also any personal injury action against a state authority which falls outside the remit of the State Claims Agency would also be covered by the RBA scheme and assistance can be provided by the State Claims Agency to deal with such matters or provide guidance.

Essentially however the compensator is obliged to repay the Minister the benefits paid subject to the limits above.

In the event a compensator wishes to appeal the decision of the deciding officer benefits must be paid in full before an appeal will be allowed. Again there are specific time frames which can be clarified if required.

HOW DOES THIS INCREASE CLAIMS COSTS?
A simple example will illustrate the effect of the new regime. Take a member of the public sector who is unfortunate to be injured and is pursuing a personal injury action against a state authority. The employee will no doubt be paid in accordance with the relevant authority’s sick pay scheme however they may also make an application to social protection for some benefit such as injury benefit or illness benefit.

Upon receipt of their personal injury claim the claims manager will also submit an application to the Recoverable Benefits Section to establish the nature of the benefit paid and the amount of same. Should the injury be significant the claimant may find themselves out of work and eventually claiming social welfare benefit, for example, up to five years. Considering such welfare benefit accrues at a rate of €188 per week this can leave the compensator liable to repay the Minister for Social Protection the sum of approximately €48,880 before making any payment toward the claimant’s compensation (general damages and special damages), lost earnings or legal costs. This will inevitably lead to increased payments by the State Claims Agency to reimburse the Minister for Social Protection the relevant benefits and have a knock on effect on the state authority budget.

The common good would favour the liability for such benefits resting with the compensator whose insured’s negligent act caused the injury which resulted in the benefit being paid to the injured party and from the tax payer’s perspective the new scheme has to be lauded.

It will no doubt have an influence on the reserving policy of the State Claims Agency and consequentially on the budgets of state authorities. Whilst it may seem like robbing Peter to pay Paul (or when it comes to personal injury claims against the Department of Social Protection, robbing Joan to pay Joan) the overall effect should be to reduce the budget for the Department of Social Protection which has much to offer the taxpayer in these constrained times.

Ben Mannering, Solicitor/Claims Manager, SCA
Launch of CISM Work Positive Framework Pilot

Following the development of an innovative psychosocial risk assessment tool specific to critical incidents, the State Claims Agency (SCA) and Critical Incident Stress Management (CISM) Network Ireland are launching the pilot stage of the project. This project is known as the CISM Work Positive Framework.

A review by the SCA (2012) showed that a conservative estimated cost to the State from psychological injury claims will be in the region of €11 million. Furthermore, the Health and Safety Authority specify that all employers are legally required to assess the working environment for systems and practices which lead to hazards/risks, including stress, and where necessary, put in place preventive measures.

A number of organisations have signed up to participate in the pilot stage of the project including the National Ambulance Service, St. Vincent’s University Hospital, the Probation Service, Department of Transport, Road Safety Authority and the Irish Prison Service to name but a few.

Ms. Sharon Gallagher, a research and health psychologist, is the project co-ordinator for the pilot scheme.

Once validated, this risk assessment tool will become an accepted tool for risk management, supported by the HSA. The SCA, as Project Sponsor, have fully funded, managed and maintained oversight of the project to date.

The primary goal of the CISM Work Positive Framework is for organisations to adopt the risk reduction methodology through interventions, in order to reduce risk, foster wellbeing in the workplace and adhere to national policy and statutory obligations.

It will have particular use in high risk occupations, for example, healthcare services, emergency/rescue services, and security agencies. The SCA estimate that 70,000 employees in the State sector alone have the potential to be exposed to a critical incident. These organisations will require a psychosocial risk assessment for these high risk activities. The CISM Work Positive Framework allows an organisation to assess a large number of employees in a systematic and efficient manner with minimum impact on resources.

The multistage framework is primarily based on international best practice and involves four stages: (see table)

<table>
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<tr>
<th>Stage</th>
<th>What is Involved?</th>
<th>Who is involved?</th>
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<tbody>
<tr>
<td>1. Identify Hazard</td>
<td>Job content analysis Online tool: Measures work stress, general wellbeing and experience of Critical Incidents</td>
<td>Manager/H&amp;S Officer Employees of participating organisations</td>
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<tr>
<td>2. Assess Risk</td>
<td>Assess outcome indicators Review current support measures in place</td>
<td>Manager/H&amp;S Officer</td>
</tr>
<tr>
<td>3. Action Plan</td>
<td>Develop and implement intervention plans</td>
<td>Manager/H&amp;S Officer</td>
</tr>
<tr>
<td>4. Review</td>
<td>Monitor and review</td>
<td>Manager/H&amp;S Officer</td>
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On conclusion of the pilot, organisations will have a completed bespoke psychosocial risk assessment which shall be in compliance with legislation and future national policy. In addition, they will have developed an action plan which will identify appropriate solutions to manage critical incident stress within their organisation. Confidentiality is assured at all stages throughout the project.

For further information on the project please contact the SCA at cism@ntma.ie.

Brian Larkin, Enterprise Risk Manager, SCA
We have rebranded!

Following the recent updated National Treasury Management Agency (Amendment) Act 2014 our brand has changed. However in all other aspects our business continues as usual.

Clinical Risk Advisers from the State Claims Agency at the Graduation Ceremony in HIQA Offices, Smithfield having completed the Institute for Healthcare Improvement (IHI) Open School for Health Professions Online Programme, August 2014.

Left to right: Ms Mary Godfrey, Ms Bernie O'Byrne-Maguire, Ms Marie Kehoe O’Sullivan, Director, Safety and Quality Improvement, HIQA, Dr Karen Robinson, Ms Claire O’Regan and Dr Ailis Quinlan, Head of Clinical Indemnity Scheme, SCA (in absentia).

The SCA newsletter is also available on our website @ www.stateclaims.ie under ‘News’ section

E-cigarettes in the workplace

In 2004, smoking was formally banned in Irish workplaces with the introduction of the Public Health (Tobacco) Act 2002. While e-cigarettes are not subject to the smoking ban, organisations could revise their smoking-free workplace policies to include e-cigarettes as a form of tobacco. The policy should indicate that smoking in any form through the use of tobacco products (pipes, cigars and cigarettes) or "vaping" with e-cigarettes is prohibited. It is advised that all policies be updated accordingly for e-cigarettes and such updates are communicated appropriately to all employees. The HSE have introduced a ban on the use of e-cigarettes in all health service facilities and has made a commitment that all its campuses will be tobacco-free by 2015.

The Road Traffic Act 2014

Novice Drivers

August 2014 saw the most recent amendment to the Road Traffic Act and the introduction to Irish roads of the novice driver. Novice drivers are required to display N-plates on the vehicle for a period of 2 years (where the vehicle is a motorcycle, the rider must wear an N-tabard).

It is advised that organisations review their driving policies to include the requirement of novice drivers and the associated risk implications. It is the responsibility of the novice driver to ensure that he/she conforms to the requirements under the Road Traffic Act, including notification of any penalty points received. State indemnity will continue to apply to newly qualified novice drivers.

For more information on novice drivers please visit http://www.rsa.ie/RSA/Licensed-Drivers/Driving-licence/Novice-Plates-Introduction/

Comments and Submissions

can be forwarded to

stateclaims@ntma.ie

The State Claims Agency,
Treasury Building,
Grand Canal Street, Dublin 2.