Clinical Indemnity Scheme
Newsletter

CIS Newsletter, July 2011

Clinical Negligence Litigation - Time for a New Approach!

The Working Group on Medical Negligence Litigation and Periodic Payments is currently engaged on its Module 2 deliberations, with the following terms of reference:

1. To examine the present system within the courts for the management of claims for damages arising out of alleged medical negligence and to identify any shortcomings within the system.
2. To make such recommendations to the President (of the High Court) as may be necessary in order to improve the system and eliminate shortcomings.

Underlying the Group's Module 2 terms of reference and its deliberations, there is an implied assertion that the current clinical negligence litigation system contains flaws and shortcomings. There is, of course, no surprise in this. Ask any clinical negligence practitioner, who represents the plaintiff or defendant, and he or she will state that the current system is overly adversarial, too lengthy and too costly. In addition, patients wait too long to be compensated because the existing system is somewhat dysfunctional.

The Working Group will produce its Module 2 report in due course and it is beyond the scope of this editorial to predict what it may conclude and recommend. Equally, it would be wrong to guess its conclusions and/or recommendations in this editorial. One can anticipate, however, that the Group will conclude that the current system for the management of claims for damages arising out of clinical negligence is past its *"sell-by"* date and requires to be substantially re-vamped.

Meanwhile, in advance of the Group's report and the recommendations therein, there is much that can be accomplished, on a voluntary basis, by the plaintiff and defendant parties, by way of introducing functional changes to the management of the current clinical negligence litigation system. To bring about this change, there is a requirement to approach clinical negligence litigation from a different perspective. That requirement brings with it a more trusting and less adversarial set of relationships between the parties to the litigation. The emphasis has to be on honest engagement of each other by the parties, the earlier sharing of experts' reports, the narrowing down of points of difference, in relation to liability and causation, with the singular aim of paying compensation to plaintiffs at considerably reduced delivery costs.

Thus, in advance of the Group's conclusions and recommendations, it is possible for the plaintiff and defendant parties/practitioners to restructure their relationships, to engage one another respectfully and bring about the appropriate behavioural changes thus making the system more functional and recognising that many plaintiffs, in clinical negligence actions, have been damaged/injured and require to be compensated appropriately. Similarly, it must be kept in mind that an adverse clinical negligence event traumatises hospitals and doctors whose primary aim is not to cause harm and/or injury but to bring healing to patients.

It is time to reform the current system and to bring about the necessary changes. The responsibility for this rests equally with defendants' and plaintiffs' practitioners and indemnifiers/insurers. The good news is that there appears to be sufficient goodwill between the parties to bring about the necessary changes.

Contents in this issue

Care Bundles in Irish Healthcare - Is there a role for bundles in a Maternity Setting?

We are all familiar with the term "bundle" in the commercial environment. Product bundling is a marketing strategy that involves offering several products for sale as one combined product. You must purchase the entire bundle or none at all. The idea is if you purchase several products together you get the best value for money. Similarly in healthcare "you get much improved outcomes if you combine a small number of elements, all scientifically robust into a bundle. A bundle acts as a cohesive unit to ensure all steps of care are reliably delivered and documented appropriately. This should result in reduced clinical variation and a reduction in patient morbidity." (IHI.org 2005) The Institute for Healthcare Improvement have developed some Perinatal Bundles:

The Elective Induction Bundle Composite and the Augmentation Bundle

These bundles each contain four elements three of which are in common. The elements in common are:

- **Normal Foetal Status:** ascertained by CTG prior to the commencement of syntocinon and continuous electronic monitoring while syntocinon is being administered.
- **Pelvic Examination:** This element included documentation of a complete pelvic assessment with cervical examination (dilatation, effacement, position and consistency), station of the presenting part and an assessment of the foetal position.
- **Hyperstimulation:** This element must be recognised and managed throughout the administration of syntocinon. The accepted definition for hyperstimulation is > 7 contractions in a 15 minute period, or > 4 contractions in a 10 minute period averaged over a 30 minute window.

The Elective Induction Bundle Composite includes the element of:

- Gestational Age 39 weeks or greater documented prior to Induction of Labour.

The Augmentation Bundle includes the element of:

- Estimated Foetal Size, documented prior to initiation of syntocinon e.g. by palpation or recent ultrasound examination.

Why Introduce these Perinatal Bundles?

- Syntocinon is the most commonly used drug in labour. It may be used to either induce or augment labour. The alleged misuse of syntocinon has been implicated as an associated factor in a number of cases of cerebral palsy (CIS, 2011). The birth of any compromised infant but particularly one who later develops cerebral palsy is devastating for the infant and family and traumatic for the staff involved.
- The increase in the induction rate over the past 10 years from 26% - 31.6% has seen a concurrent rise in the caesarean section rate from 17% - 25.8%. A number of these caesarean section births are performed due to a suspicion of foetal distress in which syntocinon is often a contributing factor. A reduction in the national caesarean section rate by 1% could save the exchequer 8 million euro according to Professor Michael Turner.

Background to the Project.

Audit:

In order to assess our present documentation and management when syntocinon is administered to either induce or augment labour, I compiled an audit of 20 charts, 10 in the induction of labour category and 10 following augmentation of labour with syntocinon. I reviewed the charts with reference to the elements of the perinatal bundle composites. The most notable finding in the complete audit was that hyperstimulation was demonstrated in 12 of the 20 cases. Hyperstimulation was responded to by decreasing or discontinuing the syntocinon and obtaining an obstetric review only in the cases where it was associated with changes in the CTG, which occurred in half the cases.

The audit was important in that it demonstrated that all components of the perinatal bundles are recorded to a greater or lesser extent, but **NOT** consistently and **NOT** for every patient. The sceptics among you may say a bundle is just a checklist with a fancy name. That is not so as a bundle consists of "have to do" interventions, while a checklist often has "nice to do" elements. IHI.org says a bundle is a means to ensure that the application of **all** interventions is consistent for **all** patients at all times thereby improving outcomes.

Questionnaire:

I compiled a questionnaire for midwifery staff to elicit their experience of the use of syntocinon in labour. The questionnaire demonstrated that syntocinon is frequently used to either induce or augment labour. There is awareness of the association between syntocinon, hyperstimulation and foetal distress, but not of the possible long-term effect as in the case of cerebral palsy.

What is the advantage of introducing these Perinatal Bundles?

- Improve patient safety and perinatal outcomes when syntocinon is use to either induce or augment labour.
- Raise the awareness of the potential danger of syntocinon as a drug when associated with hyperstimulation of the uterus.
- Promote consistency in monitoring contractions, recognition and management of hyperstimulation and documentation.

Conclusion:

As Meade said *"Never doubt that a small group of thoughtful committed people can change the world; indeed it's the only thing that ever has!"*

Susan Kelly, Clinical Risk Manager, Coombe Women and Infants University Hospital, Dublin.

Appendix 1

Perinatal Bundle - Elective Induction Bundle Composite
Data Collection Tool

Elements:
□ **Gestational Age 39 weeks or >.** Documented prior to initiation of syntocinon.
Team Definition_____
□ **Normal Fetal Status:**. Assessed and documented prior to initiation of syntocinon *and* during administration.
Team Definition__20 minute reassuring CTG prior to commencement of syntocinon, continuous CTG while on syntocinon_____
□ **Pelvic Examination:** This element includes documentation of a complete pelvic assessment with cervical examination (dilation, effacement, station of the presenting part, cervical position and consistency;+/- Bishop's Score), and an assessment of the fetal position.
Team Definition__As above_____
□**Hyperstimulation:** Recognition and management throughout the administration of syntocinon. >4 contractions in a 10 minute period averaged over a 30-minute period.
Team Definition: ___> 4 contractions in a 10-minute period or > 7 contractions in a 15-minute period_____

Instructions: Review 5 charts each week where syntocinon was used to electively induce labour.
N: Total number of individual components in place (5 charts X 4 elements= 20)
D: Total number of elective induction components possible in 5 charts reviewed (20).

Month _____Week _____

Chart	Gestational Age	Normal Fetal Status	Pelvic Examination	Hyperstimulation	Total
#1					
#2					
#3					
#4					
#5					

→ When a rate of 95% or greater compliance is reached for at least _____data points, move to the All or Nothing Measure (Elective Induction Bundle).
Coombe Women & Infants University Hospital amended from Institute for Healthcare Improvement.

Appendix 2

Perinatal Bundle - Augmentation Bundle
Data Collection Tool

Elements:
□ **Estimated Fetal Size (EFS):** Documented prior to initiation of syntocinon.
Team Definition__Estimated fetal size may be by ultrasound or on palpation_____
□ **Normal Fetal Status:**. Assessed and documented prior to initiation of syntocinom *and* during administration.
Team Definition__20 minute reassuring CTG prior to commencement of syntocinon continuous CTG while on syntocinon_____
□ **Pelvic Examination:** This element includes documentation of a complete pelvic assessment with cervical examination (dilation, effacement, station of the presenting part, cervical position and consistency;+/- Bishop's Score), and an assessment of the fetal position.
Team Definition__As above_____
□**Hyperstimulation:** Recognition and management throughout the administration of syntocinon. >4 contractions in a 10 minute period averaged over a 30-minute period.
Team Definition: ___> 4 contractions in a 10-minute period or > 7 contractions in a 15-minute period_____

Instructions: Review 5 charts each week where syntocinon was used to augment labour.
N: Total number of individual components in place (5 charts X 4 elements= 20)
D: Total number of augmentation components possible in 5 charts reviewed(20).

Month _____Week _____

Chart	EFS	Normal Fetal Status	Pelvic Examination	Hyperstimulation	Total
#1					
#2					
#3					
#4					
#5					

→ When a rate of 95% or greater compliance is reached for at least _____data points, move to the All or Nothing Measure (Augmentation Bundle).
Coombe Women & Infants University Hospital amended from Institute for Healthcare Improvement.

NoWDOC and the RCGP Quality Assurance Accreditation Award

Although the CIS has no remit for provision of indemnity for GPs, the agency is pleased to share the details of a quality initiative designed to provide safe and effective primary care.

NoWDOC is a GP Co-operative providing urgent out-of-hours GP care to patients in the North West. In January 2011 the Royal College of General Practitioners (RCGP) Northern Ireland presented NoWDOC with a Quality Assurance Accreditation Award. NoWDOC is the first GP Cooperative to achieve this quality accreditation and it was the first inter-national accreditation for the RCGP. Angela Tysall who was the HSE Service Manager for the NoWDOC Service during the accreditation process describes the experience.

Dr Diarmuid Hegarty, Medical Director, NoWDOC; Angela Tysall, HSE Service Manager for the NoWDOC Service; and Dr Martin Coyne (NoWDOC Chairperson at the time)

The NoWDOC journey to accreditation started in 2007 when we began working with CAWT* to set up a cross-border GP out-of-hours service for patients living in designated border areas in County Donegal. It became apparent to us that patients were accessing GP out-of-hours care on both sides of the border and that the service being accessed in Northern Ireland was quality assured with strict quality standards in place. We felt that in order to develop the NoWDOC service and other cross border services, we needed to demonstrate that the standards we work to are recognised as equivalent and accept-able to those in Northern Ireland.

We made contact with the RCGP and started working with them to adapt their accreditation programme for suitability to the Republic of Ireland setting.

The RCGP Quality Assurance Accreditation programme sets out 73 standards and these standards ensure that the GP out-of-hours service meets legal and professional requirements; ensures that risks to patients and staff are managed and minimised; and that the service meets the requirements of the clinical governance agenda.

The essential features of the programme are that it is professionally led and multi-disciplinary in nature with a focus on the activities of the entire out-of-hours team and the service delivered to patients. The accreditation process involves written submissions and an external peer review involving a detailed site visit, interviews with the co-op management, GPs, reception and clerical staff as well as conducting vehicle inspection and interviews with drivers.

Our multi-disciplinary team worked on developing and improving systems in the service for two years in preparation for the assessment by the RCGP. We experienced tangible quality improvements within the service while preparing for accreditation and it was a very positive experience for the staff and GPs involved. We were well supported during this time by the RCGP and the ethos was very definitely formative, educative and supportive.

Our RCGP site assessment took place on January 14th and on January 26th we were notified that we had achieved accreditation. The feedback from the assessment team was very positive and they made a special note of the additional care we have taken to ensure that patients with access issues, sensory problems and disabilities are well cared for. It is a source of tremendous pro-fessional satisfaction for everyone in NoWDOC to be able to demonstrate to others that we provide a high quality service. It is very important to us that patient care and the patient experience is central to how we organise and develop our service and that patients are involved in this process.

If you is interested in finding out more about the accreditation award and the NoWDOC experience, please contact **Dr Diarmuid Hegarty, NoWDOC Medical Director on (074) 917 8135.**

Note:

Co-operation and Working Together (CAWT) is a cross border health and social care partnership comprising the Health and Social Care Board and the Public Health Agency in Northern Ireland, the HSE in the border counties and the Southern and Western Health and Social Care Trusts in Northern Ireland.

Angela Tysall, Project Manager,
National Advocacy Unit, Quality and Patient Safety Directorate

Case Report: HSE fail to secure High Court Order...

HSE fail to secure High Court Order compelling medical treatment of four-year old

The Health Service Executive very recently made an application to the High Court seeking an Order directing medical treatment be given to a four year old boy suffering from leukaemia, against the wishes of the child's parents.

The boy's parents had refused to consent to a second round of treatment for their son, who also suffers from Down Syndrome. They told the Court that they wished to obtain opinions from paediatric oncologists abroad, before subjecting the child to further treatment here. They said the child was in remission, but that in the event that he had a relapse, they would give permission for further treatment.

The HSE argued that time was of the essence in the treatment of the child, and stated that he would have an 80% prospect of survival if the treatment was administered now. They described the proposed treatment as "life-saving". The HSE argued that they had a responsibility to vindicate the legal and constitutional rights of the child and had made the application to court in order to protect his interests.

View of the Court:

The application was heard by Mr Justice Nicholas Kearns, who held that it would be wrong for him to make an Order directing that the child undergo further "distressing" treatment, in circumstances where there was no imminent threat to his life and where the parents wished to seek a second opinion from specialists abroad. The Judge spoke with the parents of the child in private and stated that he was satisfied that they were completely responsible and had the best interests of their child at heart, and further that they understood the concerns expressed by the hospital and the risks involved in deferring further treatment. He adjourned the matter for a period of two weeks to allow the parents to make enquiries abroad.

When the matter came before the Court two weeks later, the Court was informed that the matter had been settled and a treatment regime for the boy had been agreed between the hospital and the child's parents. No Order of the Court was required.

Analysis:

This case can be compared with a November 2010 case where the HSE made an application for an Order allowing doctors to administer anti-retroviral prophylaxis to the newly born child of a HIV-positive mother. The HSE argued that administration of these drugs for a four week period from birth would significantly reduce the risk of HIV transmission to the child. The mother of the unborn child opposed the administration of the drugs on the basis they represented a serious risk to her child. Mr. Justice Bermingham held that the mother's opposition to the anti-retroviral drugs was "unjustified" and would put her unborn child at unnecessary risk. He held that it was necessary for the Court to override the wishes of the mother as it was in the best interests of the child to have the risk of HIV transmission reduced and granted an Order directing that the child should receive such medical treatment as doctors considered necessary to achieve this.

It is evident from these two cases that, when considering whether to grant an Order compelling medical treatment of a minor, against the wishes of the child's parents, the Court will take into account whether there is any imminent threat to the child as a result of not having the treatment. Further, the Court will look to the reasonableness of the parent's behaviour and their understanding of the risks involved and ultimately what is in the best interests of the child in question. These applications for treatment appear to be dealt with very much on a case by case basis, based on the individual facts of each case.

Zoe Richardson
Solicitor/Clinical Claims Manager

National Modified Early Warning Score and Education Programme (Compass)

The Health Service Executive (HSE) is committed to the provision of safe, high quality care for patients. Patient safety and quality are central to the delivery of healthcare. The HSE, among others, is a signatory to the 'Patient Safety First' declaration of commitment. There is an increasing body of evidence to show that patients who have become acutely unwell on general wards may have received suboptimal care and that action taken during these early stages can prevent deterioration progressing to cardiac arrest[1]. The National Early Warning Score and associated education programme for the early detection and management of deteriorating patients is about improving outcomes for patients by improving the safety record in our health services. The National Early Warning Score initiative, and associated education programme, is a work stream of the Acute Medicine Programme, in association with the Critical Care, Emergency Medicine, and Elective Surgery programmes, Quality and Patient Safety, Office of the Nursing and Midwifery Services Director, Clinical Indemnity Scheme, the Assistant National Director, Acute Hospital Services - Integrated Services Directorate, Irish Association of Directors of Nursing and Midwifery (IADNAM) and Therapy Professionals.

A national governance group, following consultation, has agreed a National Modified Early Warning Score (MEWS) system, and associated education programme for implementation in acute hospitals. There is now a nationally agreed practice for recognising and responding to clinical deterioration, available for implementation and use in the acute adult services. While other countries have recommended and sought to do this Ireland is the first to achieve it.

Recent evidence and international experience has identified that a systematic approach to identification and management of the deteriorating patient can improve patient outcomes, prevent death and reduce morbidity. Early warning scores have been developed to facilitate early detection of deterioration by categorising a patient's severity of illness and prompting nursing, and other healthcare professionals, to request a medical review at specific trigger points, utilising structured communication tools whilst following a definitive escalation plan. Essential components to ensure early recognition and treatment of the deteriorating patient include the following - staff education, accurate observations recording and score calculation, a definitive escalation policy, rapid response systems, effective clinical communication, education, clinical audit and evaluation.

Escalation Of Care

In line with requirements of the regulatory body, the Health Information and Quality Authority (HIQA) it is the responsibility of each acute hospital service to outline clearly their escalation protocol for deteriorating patients at present and in the future. The protocol should take into account the recommendations of the Acute Medicine and Critical Care Programmes. An escalation protocol sets out the organisational response required in dealing with different levels of abnormal physiological measurements and observations. This response may include appropriate modifications to nursing care, and therapies, increased monitoring, review by the primary medical practitioner or team or calling for emergency assistance from intensive care or other specialist teams. Primary responsibility for caring for the patient rests with the primary medical practitioner or team. In this context, the escalation protocol describes the additional supporting actions that must exist for the management of all patients. Although these actions should be tailored to the circumstances of the facility, it should include some form of emergency assistance where advanced life support can be provided to patients in a timely way. A protocol regarding escalation of care is an essential requirement for responding appropriately to clinical deterioration.

Rapid Response Systems

Where severe deterioration occurs it is important to ensure that the capacity exists to obtain appropriate emergency assistance or advice prior to the occurrence of an adverse event such as a cardiac arrest. Different models that have been used to provide this assistance include senior medical staff, Emergency Response Teams (ERT), and critical care outreach. The emergency assistance provided as part of a rapid response system is additional to the care provided by the attending medical practitioner or primary medical team.

Clinical Communication

Effective communication and team work among clinicians is an essential requirement for recognising and responding to clinical deterioration. Communication failures between teams contribute to delays in referrals and in delivering appropriate essential care, which contributes to increased morbidity and mortality[2]. A number of structured

communication protocols exist that can be used for handover and as part of ongoing patient management. The recommended communication tool for healthcare professionals, when communicating in relation to the deteriorating patient, is ISBAR – (I = Identify yourself, S= Situation - describe it, B= background to patient's condition, A= Assessment, R= Recommendation).

Education

Having an educated and suitability skilled and qualified workforce is essential to provide appropriate care to patients whose condition is deteriorating. Education should provide knowledge of observations and identification of clinical deterioration, as well as appropriate clinical management skills. Skills such as communication and effective team work are needed to provide appropriate care to a patient whose condition is deteriorating, and should also be part of staff development and empowerment. The education programme recommended by the HSE is the COMPASS© programme. This will be available to healthcare staff such as doctors, nurses and therapy professionals. The training needs to be coordinated by designated staff within, or supporting, the healthcare facility. In addition continuation of training in basic life support and professional development training in advanced life support programmes, appropriate to the clinical facility, is advised. Compass is an interdisciplinary education programme designed to enhance healthcare professionals understanding of patients who are clinically deteriorating and the significance of altered clinical observations. It also seeks to improve communication between healthcare professions, adopt a patient centred, quality driven approach, enhancing the timely management of patients. The education programme was developed in conjunction with the development and implementation of a Modified Early Warning Score (MEWS) and the implementation of a redesigned general (MEWS) observation chart for clinical practice areas. The programme has been modified to suit the Irish healthcare system with the kind permission of ACT Health, Australia.

Evaluation and Audit

Evaluation of new systems is important to establish their efficacy and determine what changes might be needed to optimise performance. Ongoing monitoring is necessary to track changes in outcomes over time and to check that these systems are operating as planned. Clinical audit is recommended to support the continuous quality improvement process in relation to implementation of the national MEWS system. The recommended minimum standard for audit includes: Utilization of the ISBAR communication tool, utilisation and accuracy of completion of the patient observation chart incorporating the MEWS, and utilization of the 'track and trigger' response mechanism - the MEWS Protocol. Systems should be evaluated to determine whether they are improving the recognition of and response to clinical deterioration. Evaluation may include collecting and reviewing data on calls for emergency assistance, adverse events such as cardiac arrests, unplanned admissions to intensive care and hospital deaths.

Spreading the Word

An essential part of the initiative is to spread awareness of the programme to all key stakeholders therefore a multi-disciplinary information day highlighting this initiative and the Compass programme was held June 22nd 2011 in Farmleigh House with 166 attendees representing 61 different Irish healthcare organisations including acute care sector, PCCC and various educational institutions. The aim of the day was to showcase the progress to date and ensure awareness of the National Modified Early Warning Score and associated education programme (Compass). Presentations from the day are available for review with the kind permission of all speakers on http://www.stateclaims.ie/ClinicalIndemnityScheme/presentations.html.

Further information on the National Early Warning Scores and Education Programme (Compass) is also available on the HSE Intranet site

http://www.hse.ie/go/nationalearlywarningscore/

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Eilish Croke, Lead National Early Warning Score Project;
Avilene Casey, Chair of Early Warning Score National Advisory Group

1. Smith GB et al. 'Hospital-wide Physiological Surveillance. A new approach to the identification and management of the sick patient' Resuscitation 2006; 71: 19–28.

2. National Confidential Enquiry into Patient Outcome and Death (2005) An acute problem. National Confidential Enquiry into Patient Outcome and Death. http://www.ncepod.org.uk/2005report. Accessed June 28th 2011.

NOTICE BOARD

Medico-legal Helpline

Monday - Friday
09.00 - 17.30 hr.

Tel: 01 - 664 09 09

Amended CIS notification form and amended STARS picklist

can be accessed via ***http://www.stateclaims.ie/ClinicalIndemnityScheme/IncidentNotificationRequirements.html***

Comments and Submissions

can be forwarded to
info@stateclaims.ie

The CIS newsletter is also available on our website @ www.stateclaims.ie in CIS Publications section

Recently Uploaded Presentations

www.stateclaims.ie/ClinicalIndemnityScheme/presentations.html

- National Modified Early Warning Score and Education Programme (Compass), Farmleigh House, Dublin
- The National Early Warning Score and Associated Education Programme, Eilish Croke.
- Acute Medicine Programme, Professor Shane O'Neill.
- Guiding Framework and Policy for the National Early Warning Score System to Recognise and Respond to Clinical Deterioration National EWS System Project and associated Education Programme.
- Implementation of the National Early Warning Score and associated Education Programme.
- MEWS and MET initiative. Local implementation experience: AMNCH Dr John Cullen.
- MEWS Bleep System in Connolly Hospital, Dolores Dempsey:Ryan, Nurse Practice Development Coordinator (Acting), Connolly Hospital.
- Nurses experience and attitudes toward an EWSS and MET. Gerry Allen, Advanced Nurse Practitioner in Cardiology, South Infirmary-Victoria University Hospital Cork.
- How to implement and continuously improve - Quality Improvement vs. Quality Assurance.
- Report of Audit Subcommittee, Maria Donnelly, AMNCH.
- COMPASS Programme Overview, Maria Horgan, St. Luke's Hospital, Kilkenny.

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