

The Procurement of Human Stem Cells for Blood Banking

The procurement of human stem cells from umbilical cord blood for cord blood banking purposes is both a topical and sometimes controversial issue. The Agency, over the last number of weeks, has received a number of queries from Clinical Indemnity Scheme (CIS) enterprises concerning the implication of CIS cover for nurses/practitioners involved in the procurement of umbilical cord blood for storage.

We have decided, thus, by means of this editorial, to set out the relevant legislation governing the procurement of umbilical cord blood for storage, together with the scope of CIS cover as it applies in the particular circumstances.

The procurement of umbilical cord blood for storage, with the intention of future human application, can only take place in a hospital/healthcare enterprise if that hospital/healthcare enterprise is either:

- a. An authorised Tissue Establishment
- b. Has a procurement contract with a Tissue Establishment that satisfies the legislative requirements.

The relevant legislation concerning the procurement of umbilical cord blood is contained in *S.I. 158 of 2006* known as *European Communities (Quality and Safety of Human Tissues and Cells) Regulations 2006*. In Ireland, the Irish Medicines Board (IMB) is the competent authority for the implementation of this legislation.

In relation to CIS cover, a doctor/midwife/nurse will be covered by the CIS, in respect of the procurement of umbilical stem cells, **ONLY** in those circumstances where:

- a. The hospital/enterprise had applied for and received an authorisation from the IMB,

OR

- b. The procurement has been requested by a treating clinician and thereafter organised by the **Irish Blood Transfusion Service (IBTS)**, an enterprise specified in the schedule attached to the NTMA delegation order and an authorised Tissue Establishment for this purpose,

AND

Where such an employee, in accordance with the relevant legislation, had received appropriate training, and was carrying out the described professional medical services with the express knowledge and consent of the hospital's/enterprise's management.

CIS cover applies, routinely, where a specimen of umbilical cord blood is taken for diagnostic, treatment or palliative purposes of the mother and/or infant e.g. Rhesus status, blood gases, etc.

It should be noted that **NON-DIRECTED** procurement of umbilical stem cells does not come within the provision of

professional medical service as defined in the National Treasury Management Agency (Delegation of Functions) (Amendment) Order 2007. Thus, a doctor/midwife/nurse who procures umbilical cord blood on foot of a contract with a third party (i.e. not for and on behalf of the enterprise) is **NOT** covered by the CIS for such procurement.

Hopefully, our readers, and those with a special interest in this topic, will find the foregoing helpful in terms of defining, with particularity, the scope of CIS cover as it applies in the particular circumstances. 

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Nurse / Midwife Prescribing in Practice

Introduction

A significant development for the Irish Health Service has been the introduction of the first Nurse/Midwife Prescribers. They were registered with An Bord Altranais on the 26th of January 2008.

Changes in Legislation

The Medicinal Products Prescription and Control of Supply (Amendment) Regulations 2007 and the Misuse of Drugs (Amendment) Regulations were signed into law on 1st of May 2007. This legislation sets out the requirements for prescribing by Nurses and Midwives, they are;

- The Nurse/Midwife must be employed by a health service provider
- The medicinal product must be one that is given in the usual course of service provided in the health setting in which the Nurse/Midwife is employed
- The prescription is issued in the usual course of the provision of that health service.

The An Bord Altranais registration number must be written on all prescriptions written by a Registered Nurse/Midwife Prescriber (RNP).

Support and education in the clinical area is provided by a Medical Consultant practicing in the same clinical area that the Nurse/Midwife will prescribe.

Organisational structures and support are provided by Director of Nursing/Midwifery, Pharmacy, Drugs and therapeutics committee Prescribing Site co-ordinators and Clinical Governance.

My role as an RNP

As a Clinical Midwife Manager working in the Delivery Unit of the National Maternity Hospital, I viewed the opportunity to become a Nurse/Midwife

Prescriber as a valuable extension to my role. The addition of prescriptive authority to my midwifery and nursing skills improves care.

Working as a member of a multi-disciplinary team, the ideal is that the care required by the patient is provided by the right member of the team, at the right time and in the right environment.

I can prescribe for patients in my care with whom I have a therapeutic relationship. This enables me to decide what is appropriate for their optimal care. In many clinical areas, including the Labour ward, getting the timing of interventions right has a significant impact on how a patient perceives the care they receive.

For a labouring woman having to wait for analgesia to be prescribed can be stressful for both her and her partner. This can have a negative impact on her birth experience. In this situation the timely prescription of analgesia will not only alleviate the pain but also reduce anxiety. Nurse/Midwife prescribing is a new experience for all but has been very well received by the women we care for. Nurse/Midwife prescribing in my experience is not a separate role but rather an enhancement of my clinical position as a midwife manager responsible for provision of care to women in labour.

In the hospital environment, many routine treatments (e.g. prophylactic antibiotic therapy for Group B streptococcus prevention) may be delayed as medical staff are busy dealing with emergency situations which are given priority. This can have a negative impact on the quality of service provided. As a Nurse/Midwife Prescriber, the ability to prescribe treatments such as this provides both quality and continuity of

care for the woman and allows for a more efficient use of human resources within the organization.

Continued Professional Development

Having obtained academic qualification and assessment as competent by a clinical mentor, the RNP must demonstrate continued clinical competence as required by both the organisation in which they practice and those required by An Bord Altranais. Audit of prescribing activity is also the responsibility of each prescriber and the results of this Audit are reported in accordance with conditions set out in the collaborative practice agreement.

The Prescribing Experience

The introduction of prescriptive authority to Nurses and Midwives in the Irish healthcare setting could potentially be perceived as having negative aspects, this however has not been my experience. Support from all healthcare professionals has been great, it has been welcomed as an opportunity for sharing care and continues development of holistic, patient centered care.

Nurse/Midwife prescribing has provided a basis to develop relationships between all disciplines involved in healthcare. Mutual professional respect and communication is essential to the development of this role. Prescription writing is only one aspect of my professional role and defined by my scope of practice. To date, it has been a very positive experience, I would hope and expect that many nurses and midwives will extend their role and find it to be the same positive and rewarding experience.

*Martina Murphy BNS, RGN, RM, RNP.
National Maternity Hospital, Holles St.,
Dublin 2.*

Consent - Frequently Asked Questions

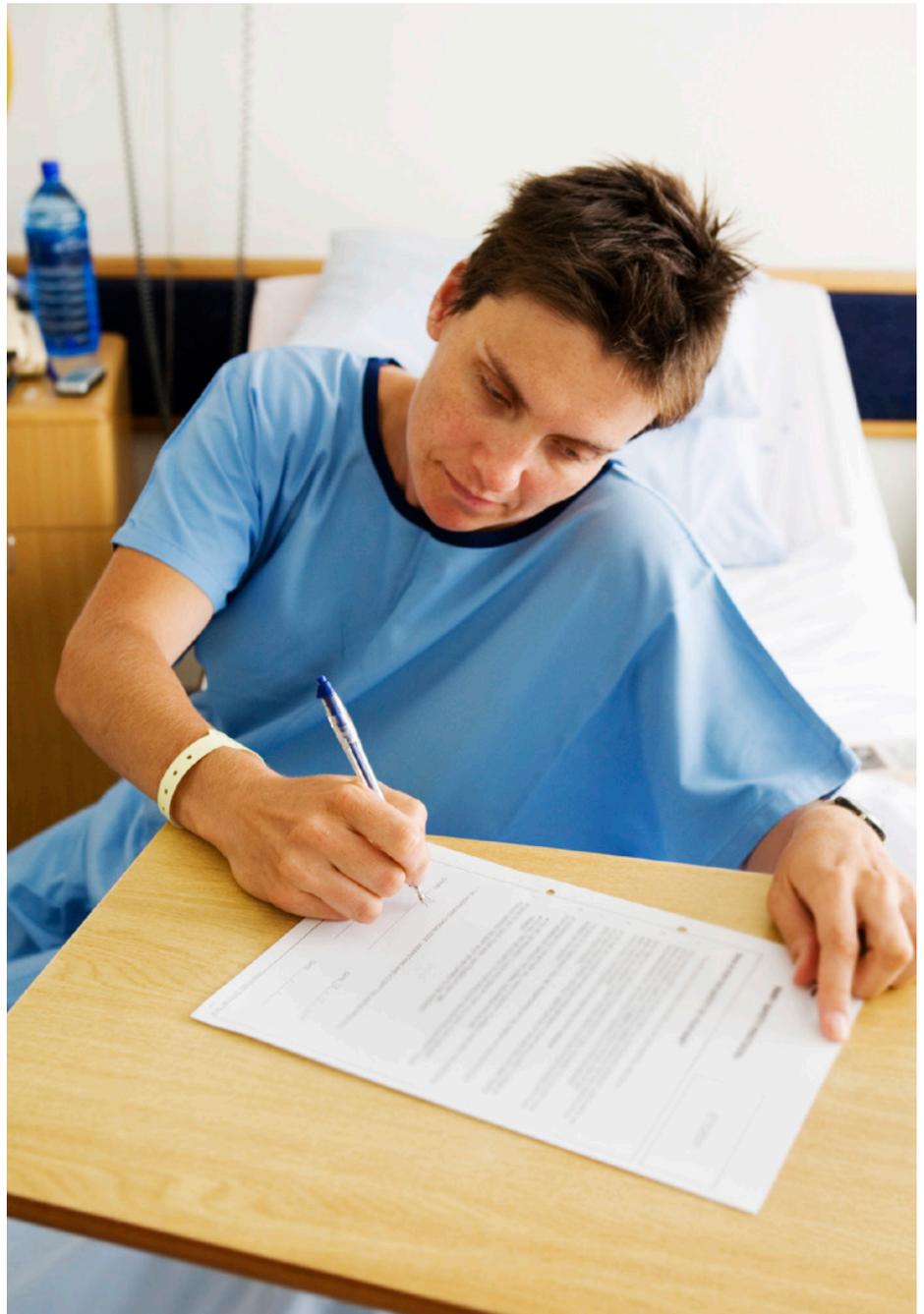
Much has been written about the issue of Consent. There are many and varied written protocols, guidelines and policies all relating to Consent

And, there is good reason why this would be the case. The process of informed consent is very important to both the treating clinician and of course the patient. There is little doubt that consent can be a complex issue. There have also been seminal cases heard in the courts in the last ten years that have underpinned the importance of informed consent.

With so much already written about consent, what more can we offer on the subject where there exists tomes of documentation already. We thought therefore that it might be of interest to look at some of the more commonly asked questions that have arisen from healthcare professionals on informed consent.

What knowledge/expertise does a medical co-signee need for a patient's consent to be valid?

This depends on the experience of the doctor. Obviously the more experienced the better but the most important thing is that the medical co-signee has knowledge of the treatment/procedure and can; (a) explain the treatment/procedure, and (b) answer the patient's questions about the treatment/procedure. For example, an SHO can obtain a valid consent if they have experience and knowledge of the treatment/



procedure. It is unwise for any doctor to obtain consent where they have insufficient knowledge about the treatment/procedure involved.

The IDEAL situation is that the clinician with the responsibility for the patient's treatment/procedure, obtains the consent and discusses the issues with the patient. It is not optimal practice to delegate the consent process.

When is the most appropriate time to obtain consent?

The best time for the consent process to start is as soon as the treatment plan or procedure is being considered. The process should begin at the clinic/OPD and continue to the day before or of admission where it can be re-visited and the patient given an opportunity to ask any questions he/she may have. It is

good practice to obtain consent at the pre-operative consultation.

If 2/3 weeks pass, is the consent still valid?

YES, so long as the circumstances or nothing else for the patient and the procedure have changed in the interval. In other words nothing has changed but the passage of time.

Is there a definitive period of time in which a consent remains valid?

There is no definite period but up to 3 months has been mooted. It is always best to leave it to a clinician to decide if it is best to revisit the consent. The most important aspect is that the treatment/procedure has been discussed with the patient who has been warned of any material risks.

How important is the content and layout of the consent form?

This will vary according to the type of procedure involved. The purpose of the consent form is to evidence the discussion of the proposed treatment or procedure with the patient. The patient should also be informed of the risks associated with either course.



By the time the patient is signing the consent form, the discussions above should already have been recorded in

the medical notes. The consent form alone is not sufficient evidence that a patient has provided a properly informed consent.

The consent form is the final piece of the consent process.

What level of risk disclosure is required?

This has already been well documented and common law has already legislated in a number of well-known cases. The case of *Geoghegan-v-Harris (2000)* set out the 'reasonable patient approach', which was recently re-stated by the Supreme Court in *Fitzpatrick-v-White (2007)*. The court went on to explain that the reasonable patient test is one whereby the patient has a right to know and the practitioner a duty to advise of all possible risks associated with the proposed form of treatment.

How can consent be obtained in an emergency?

In a life-threatening emergency, a clinician may administer the necessary medical treatment without the patient's consent. If however, there is any way to discuss and inform the patient along the way then the opportunity should be taken, that is, if he/she are conscious.

Will the process be different for semi-urgent cases?

The process will be the same as the process for elective treatment, that is, in brief;

- (a) discussion with the patient
- (b) note the records, and
- (c) obtain written consent.



What is the consent process for purely elective surgery?

This type of process places a much greater burden upon the doctors who will need to discuss the proposed procedure in detail with the patient and advise all material risks. Again, all discussions and conversations should be duly recorded in the medical records.

It is important to spend time on consent.

Consent over the telephone - is this valid?

Consent should not be obtained over the telephone unless it is an emergency and a life-threatening situation!

If in doubt about any matters on consent it may be necessary to seek legal advice from the hospital's legal advisers.

If it is an emergency, please avail of the Clinical Indemnity Scheme's Emergency Medico-legal helpline at (01) 6640909. 📞

*Philip Fagan, FCII
Clinical Claims Manager*

Safety Briefing : Vincristine

Vincristine is a well-known drug administered intravenously in the treatment of cancer. It is a vinca alkaloid, derived from the Madagascar periwinkle and has been in use since it was originally approved by the FDA in July 1963. It is commonly used as part of chemotherapy regimens to treat lymphomas and leukaemias.

Since 1968 inadvertent spinal administration of Vincristine has been reported in a variety of international settings 56 times. The accidental injection of Vincristine into the spinal canal (intrathecal administration) has a mortality rate of almost 100%. Inadvertent intrathecal administration has resulted in patients developing ascending paralysis due to encephalopathy, spinal nerve demyelination and intractable pain leading almost always to a slow and painful death. Various measures have been adopted over the years to try and prevent this error but it re-occurs again and again. The WHO highlighted a recent case in Hong Kong (July 2007) where a 21 year old died after being administered Vincristine accidentally via a spinal route in error. The USA has reported a death from intrathecal Vincristine since then.¹² Similar events have been reported in many countries, which highlights the worldwide nature of this problem^{1-10, 12}. **There have also been reports of fatalities with other vinca alkaloids given intrathecally in error¹².**

Previous guidance in relation to intravenous administration of Vincristine via syringe has been superseded, as fatal incidents have been reported due to the inadvertent administration of

Vincristine by the intrathecal route, even where large volume syringes have been used as a safety measure^{1,13}. The World Health Organisation (WHO) has published new guidance in relation to administration of Vincristine via intravenous minibag infusion to avoid accidental death¹.

WHO Vincristine Safety Recommendations

The WHO World Alliance for Patient Safety has consulted expert opinion widely and recommended:

- 1 The labelling of Vincristine should include a clear warning label that reads: **'FOR INTRAVENOUS USE ONLY - FATAL IF GIVEN BY OTHER ROUTES'**.
- 2 Syringes should not be used for Vincristine administration.
- 3 **Vincristine should where possible be prepared by dilution in small volume intravenous bags (the 'minibag' technique), rather than in a syringe, to protect against accidental administration via a spinal route.**
- 4 **Guidance from USA (ISMP¹², Joint Commission⁹), UK (NPSA¹³), France¹⁴ and WHO¹ advise ALL vinca alkaloid preparations should be administered via minibag.**

For adults, prepare vincristine in an intravenous bag in 50mL of sodium chloride 0.9% and administer it as a short intravenous bolus over 5-10 minutes. Smaller volumes (dilution in 20-50 mL)⁸ are suggested for children.

Preparation of Vincristine in a minibag prompts doctors and nurses to question any error as patient positioning makes it difficult to attach a bag to a spinal

needle, and fluid bags are only rarely delivered via a spinal route. In addition, knowing that the cerebrospinal fluid is only 150ml gives an instinctive understanding that it is dangerous to deliver large volumes of fluid via a spinal route¹.

Vincristine is a vesicant drug i.e. it can cause damage if it leaks from the vein into the surrounding tissue (known as extravasation) which may lead to a lot of pain and severe necrosis at the site. While administering Vincristine via minibag IV infusion has been criticised as potentially increasing the risk of extravasation injury, reported incidence is similar and infrequent for both syringe and minibag¹¹. There have been no reports of extravasation from Vincristine minibags to date from Irish hospitals, or in England and Wales¹³.

Hospitals in Ireland should review their practice of Vincristine and other vinca alkaloid formulation and administration, in the light of WHO and international guidance. The Safety & Quality Council of Australia, the Joint Commission (USA), the Institute of Safe Medication Practices (USA), FDA (USA), and the National Patient Safety Agency (UK) all support the use of a minibag to administer Vincristine⁷⁻¹⁰, and other vinca alkaloids^{1,13,14}.

Irish Medical Safety Network (IMSN)

Vincristine References

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Case Report - Consent

Please note that the following case report is based on a real case.

Royal Victoria Eye and Ear Hospital...

The State Claims Agency successfully represented the Eye and Ear Hospital in the Supreme Court case of Paul Fitzpatrick - v - Aida White as nominee of the Royal Victoria Eye and Ear Hospital. Mr Justice Kearns delivered Judgment on the 15th of November 2007.

The Plaintiff decided for cosmetic reasons to explore the possibility of correcting a squint of his left eye. He was assessed and deemed suitable for surgery. On the day of the operation, the Plaintiff met with the Registrar 30 minutes before surgery. The Plaintiff was in his gown but had not been sedated as part of his premeds.

The Plaintiff's case was that he was left with double vision, headaches and was not warned of any complications. Had he been warned of the risks, he said that he would have "walked straight out of the hospital". The Registrar's evidence was that he would have advised of the common and rare complications, including the risk of double vision.

High Court Judgment, delivered in 2005, found that the Plaintiff had not established on the balance of probability that the surgeon had failed to warn him of the risk of double vision. The Court also found that the Plaintiff's prime concern was the cosmetic effect and his attitude towards surgery would not have altered had he been warned.

Since 2000, Irish courts have adopted the "reasonable patient test" in assessing



what risks should be disclosed to the patient pre-operatively. This case provided the Supreme Court with the first opportunity in many years to revisit the issue of informed consent. The Court endorsed the application of the reasonable patient test and applied it to elective treatment.

The obligation to warn:

The requirement of a medical practitioner to give a warning of any material risk which is a known complication of an operative procedure properly carried out.

Content of the warning:

If there is a significant/material risk which would affect the judgement of a reasonable patient, then it is the responsibility of a doctor to inform the patient of that risk.

Time of warning:

On appeal, the Plaintiff accepted that a comprehensive warning had been

given. The issue remaining was whether a warning delivered so shortly before the operation was sufficient to discharge the duty of care or whether it was invalid because the Plaintiff could neither assimilate it nor act upon it.

In the context of elective surgery, a warning given only a short time before an operation is undesirable. In this case, however, there was no evidence that the patient could not understand the warning. The Court stated that in other cases where a warning is given late in the day, particularly where the surgery is elective, the outcome might well be different.

The Court also accepted that, given that his motivation was an improved cosmetic effect, the Plaintiff would have undergone the surgery irrespective of the nature of the warning. 

Helene Engelstoft
Clinical Claims Manager

In October 2006, the inaugural meeting of the Paediatric Forum was organised and facilitated by the Clinical Indemnity Scheme in Treasury Buildings in Dublin

The objective was to have a forum where those healthcare professionals who had an interest in Paediatric and/or risk could network, share ideas, debate pertinent issues, promote and showcase quality initiatives and areas of good practice. The invitation originally extended to those healthcare professionals who worked within the acute care settings, namely the 11 District Units, 5 Regional Departments and the 3 National Paediatric Hospitals. The initial agenda dealt specifically with the issue of consent in Paediatrics as, given the ever-changing societal factors in Ireland, this area has become a major concern to those working within the Paediatric arena. Ruth Maher, Our Lady's Hospital for Sick Children, Crumlin and Susan Moriarty, Clinical Indemnity Scheme delivered presentations. Ruth kindly shared the progress to date on a collaborative approach to consent guidelines between the Council for Children's Hospitals Care and the three national Paediatric hospitals. Susan Moriarty gave a detailed overview of frequently asked questions with regard to consent in Paediatrics. Delegates also received a breakdown of the types of incidents reported nationally on to STARSWeb and a detailed analysis of the

top five incidents with regard to Paediatrics.

Delegates were advised that the success of this forum would be down to active participation and engagement. The delegates were asked to indicate how frequently they want this meeting held and what topics would they like to see addressed at future events. Based on the feedback from the group, it was agreed to hold this event twice a year, and the agenda to reflect those topics indicated on the feedback forms. After discussing in detail the possible options of locations, it was decided that while theoretically arranging meetings outside Dublin is equitable, the general consensus was that, practically, it was easier for most delegates to travel to Dublin.

For the next meeting scheduled in March 2007, following discussions with key personnel within the Primary, Community & Continuity Care setting (PCCC), an invitation was extended to those working within the childcare sector in the community. The second meeting dealt with Children First Guidelines & Child Protection issues, a presentation given by Denise Kirwan, Comyn Kelleher Tobin Solicitors. Eileen Relihan, St. James's Hospital and Ciara Kirke, Adelaide Meath & National Children's Hospital, gave presentations dealing with various aspects of medication safety.

Due to the increasing number of attendees, the 3rd and 4th events were hosted in Farmleigh House, Phoenix Park. In November 2007, Rosemary Smyth, Mental Health Commission

gave a presentation dealing with the changes to the Mental Health Act 2001, specifically addressing Child and Adolescent Mental Health. Philip Fagan, Clinical Indemnity Scheme and Emily Eagan, Barrister at Law addressed the issue of medical records. Mary Tumelty, Children's University Hospital Temple Street addressed the risks associated with the transport of an ill child.

The 4th and most recent meeting of the Paediatric Forum was held in May 2008, where Carole Boylan, Children's University Hospital Temple Street, had the opportunity to showcase S.P.A.C.E., a pilot program for parents and carers who are concerned about their children who self harm. Maria Brenner, University College Dublin gave a presentation on Paediatric Restraint, the Irish Perspective. Joan Broderick, Children's University Hospital, shared the experience of the Emergency Departments' development of a specific paediatric triage model. The final presentation from Deirdre Hyland, Mental Health Commission, highlighted the progress of the commission to date and the need for further collaboration between MHC and Acute Paediatric Services.

The next meeting is due to be held in Q1 of 2009, with the agenda, date and venue to be confirmed.

If you are interested in attending or showcasing a quality initiative at this event, please contact Anne Marie Oglesby, Clinical Risk Advisor at amoglesby@ntma.ie.

*Anne Marie Oglesby
Clinical Claims Advisor*

NOTICE BOARD

State Claims Agency CIS Conference

Patient Safety - "Windows of Opportunity"

Croke Park, Dublin

DEFERRAL NOTICE - NOVEMBER 19TH 2008

In recognition of the current constraints on staff recruitment within the HSE, and embargo on travel for HSE personnel, the decision has been made at this time, with considerable regret, to defer the CIS conference planned for November 2008 to 2009.

Congratulations

Congratulations to the HSE, DOHC and the National Council on Ageing and Older People on the recent publication of their strategy 'Prevent Falls and Fractures in Ireland's Ageing Population'.

See <http://www.hse.ie/eng/> for details.

E-mail changes

Please note the change of e-mail address for the Clinical Risk Advisors and the Clinical Claims Managers.

Inserting ntma.ie instead of cisweb.ie
e.g. aduffy@ntma.ie

The cisweb.ie address will still operate but for a limited time period only

Obstetric Forum December

Contact Dr. Karen Robinson

ALTERNATIVE PLAN TO Quality and Safety Exhibition Day

In conjunction with European Health and Safety Week 2008

NATIONAL REPORT OF HEALTH & SAFETY EVENTS

You are invited to include events that you are organising for European Health and Safety week in a National Report. This National Report will be compiled and written by the Quality and Safety Working Group of the HSE Achievement Awards and will be available to staff and public on the HSE website.

The purpose of this National Report is:

- To share the excellent regional initiatives carried out during European Health and Safety week
- To communicate your organisation's work
- To enhance your organisation's profile
- To share successes and learn from others

We are hoping that participation in this project will be rewarded in the scoring system for the 2009 HSE Achievement Awards.

At this time you are invited to submit a STATEMENT OF INTEREST outlining the events/projects you are planning for the week of October 20th - 24th 2008.

Deadline for receipt of Statement of Interest via email or post is **October 19th 2008**.

Once you submit a statement of interest you will be contacted by a member of the Quality and Safety working group during the week of October 27th, 2008 to answer a number of questions around the event to help inform the national report. These questions will focus on

the following:

- number of participants in attendance
- number of organisers involved
- barriers to success of the event
- challenges
- keys to success
- what you would do differently in the future
- lessons learned for organisers and participants
- Management involvement in organisation of event

You will then be requested before November 15th 2008 to submit any evidence that the event has taken place such as attendance sheets, fact sheets, patient/staff evaluation forms or posters advertising the event.

IMPORTANT: By submitting a Statement of Interest you are agreeing to:

1. Nominate a contact/lead person for this project
2. Allow the name/contact details of your lead person be included in the National Report
3. Share your knowledge with others through your nominated lead person (permission from facility management must be agreed prior to participation)
4. Collect evidence of the activities undertaken in your facility, e.g. photos, attendance sheets, fact sheets, patient/staff evaluation forms etc.
5. Send that evidence to the address below by November 15th, 2008.
6. Participate (lead person) in a 10-15min telephone conversation with a member of our working group during the week of October 27th, 2008

STATEMENT OF INTEREST FORM: BLOCK CAPITALS PLEASE!

The following events/projects are being planned in our facility for European Health and Safety Week:

Lead Name	Title	Lead Phone
Lead Email		Facility
Signature of Management		(CEO, GM, DON etc.)

- For general information regarding National Report contact mariet.kehoe@hse.ie (phone 087-2632781)
- For submission of STATEMENT OF INTEREST contact denise.mccarthy@hse.ie or by post: Quality & Risk Dept, Room 76, Eye, Ear and Throat Hospital, Western Road, Cork .

Clinical Indemnity Scheme,
The State Claims Agency,
Treasury Building, Lower Grand Canal Street, Dublin 2.