Introduction to CIS & Clinical Risk Management.

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Clinical Indemnity Scheme.
Presentation aims:

• Introduction to CIS

• Introduction to Clinical Risk Management

• Introduction to Adverse event reporting.
National Treasury Management Agency

↓

State Claims Agency

↓

Clinical Indemnity Scheme
State Claims Agency:
Established under National Treasury Management Agency (Amendment) Act 2000.
(Start date : 3 December 2001.)

Clinical Indemnity Scheme established : 1 July 2002
• Delegation Order made: 18 February 2003.
CIS...... Who are we?

- CIS was established in July 2002
- Established as a result of a rise in obstetric litigation.
- Private Indemnifiers would no longer provide indemnity.
- State took over the indemnity of all public and voluntary hospitals.
- Enterprise Liability
Relevance of C.I.S. to You

CIS will: - Offer Risk Management Advice and Support

And in the event of a claim:-

1. Represent the interests of healthcare professional
2. Investigate claim
3. Appoint and liaise with legal team
4. Appoint and liaise with experts
5. Pay the legal costs of the case
6. Pay a Court award or settlement, if applicable.
CIS Cover Inclusions

- Professional medical services
- Needle stick to *patients* during clinical care
- Good Samaritan acts within island of Ireland (N&S)
- Representation at Coroners’ Inquests
- Clinical care during transfer of patients
- Occupational Health vaccinations-HSE
CIS Cover Exclusions

- Private hospitals
- Good Samaritan acts outside the Island of Ireland
- Needlestick injury to Staff
- Disciplinary hearings
- Defamation
- Criminal cases

*NB: Supplementary insurance*
What is covered by CIS?

- CIS provides cover for personal injury claims brought by patients/clients/service users who allege medical malpractice arising from the provision of or failure to provide “Professional Medical Services”

For further details on the State Claims Agency and the Clinical Indemnity Scheme log onto www.stateclaims.ie
Clinical Indemnity Scheme:

• Clinical Claims Managers

• Clinical Risk Advisors
So why Clinical Risk Management????
What is Risk Management?

“The culture, process and structures that are directed towards realizing potential opportunities whilst managing adverse effects”

AS/NZS 4360:2004
Historically, this could summarise the Irish attitude to the whole arena of Clinical Risk Management........
Numerous studies have shown errors & adverse events are common and a major problem in all healthcare settings:

- California Medical Insurance Feasibility Study 1974 = 4.6% of all hospitalisations had a “potentially compensatable event”

- Harvard Medical Practice Study 1984 = 3.7% of all hospitalisations; 69.6% were preventable.

- Quality in Australian Healthcare Study 1992 = 13% of all hospitalisations; 51% were preventable.

- Utah & Colorado Medical Practice Study 1992 = 2.9% of all hospitalisations; Just over 50% were preventable.
International Evidence

Canada (2004) 7.5%

New York (1991) 3.7%

Colorado/Utah (1999) 3.3%

UK (2000) 11%

Denmark (2001) 9%

Australia (1994) 16%

New Zealand (2001) 13%
• The US Institute of Medicine (1999) estimates that *each year* between 44,000 and 98,000 people die as a result of preventable clinical error.

• This is greater than the total number of deaths due to car accidents, breast cancer and AIDS combined.
To put it into an Irish Context:

- Hipe Data – Day Cases = 246,531
  In Patients = 505,414
  Total = 751,945

- Harvard Study -
  4% Adverse Events; 70% of these were preventable

Expect 30,000 adverse events Per Annum from acute sector. 21,000 preventable.
Ireland

Human Cost

• 717 – 1600 Irish deaths attributable to preventable medical error (Circa, 2003)
Drivers for Risk Management

- Public expectation in the face of scandals and growing awareness
- Many services were not subject to independent regulation and inspection
- Variations in the standard of care and treatment
- Advances in medicine, technology and professional practice
- Need to comply with legislation e.g. Mental Health Act 2001, H&S 2005
- Corporate Governance
- Rising indemnity costs
## Escalating Indemnity Costs

### Medical Defence Premia for hospital consultants

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<td>33.1</td>
<td>30.4</td>
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</table>
What is patient safety?

“Reducing unintended harm or accidental injury associated with health care treatment rather than the disease process”

Brennan et al 1991
Valuing Patient Safety & Good Practices

- Good Consent Practice
- Evidence Based Practice
- Good Documentation
- Good Infection Control Practice
- Right Patient Right procedure
- Respecting Patient Confidentiality

Valuing Patient Safety
Clinical Risk Management:

Definitions:

• Risk management for health care entities can be defined as an organised effort to identify, assess, and reduce where appropriate, risks to patients, visitors, staff and organisational assets.
Core Risk Management Processes are:

- **Identifying risk:** Adverse events & near miss reporting
- **Analysing risk:** Measurement of impact on Enterprise
- **Controlling risk:** Guidelines, policies & strategies
Risk Management Framework

Set of Elements of an organisation’s management system concerned with managing risk

Structures must be in place for effective risk management to take place, at local, organisational, regional, national level
Overview

Risk Management Process:
- Communication and Consultation
- Establish the context
- Identification of Risk
- Analysis of Risk
- Evaluation of Risk
- Treatment of Risk
- Monitoring and reviewing
Risk Management Process Overview

Establish the context
Identify risks
Analyse risks
Evaluate risks
Treat Risks

Communicate and Consult

Monitor and Review

AS/NZS RM Standard 4360: 2004
Risk Identification
Historically: Medical errors detected by
• Mortality/Morbidity Committees
• Claims Data
• Retrospective Chart Review

Problems
• Costly
• Little insight into error reduction strategies.
• Important errors that do not result in injury may go undetected.
<table>
<thead>
<tr>
<th>Likelihood</th>
<th>Impact</th>
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<tbody>
<tr>
<td></td>
<td>Low/ none</td>
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<tr>
<td>Almost certain</td>
<td>5</td>
</tr>
<tr>
<td>Likely</td>
<td>4</td>
</tr>
<tr>
<td>Possible</td>
<td>3</td>
</tr>
<tr>
<td>Unlikely</td>
<td>2</td>
</tr>
<tr>
<td>Rare</td>
<td>1</td>
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</table>

Rare – Could only occur in exceptional circumstances
Unlikely – May occur in time. Very infrequent.
Possible – May occur occasionally.
Likely – Likely to occur imminently or in short term.
Almost Certain – Will occur or does regularly occur.
"First of all...do I hafta admit something nobody can prove?"
Why Incident Reporting?

All human activities carry a degree of risk and their success or failure depends on their management.

Incident Reporting
• Identifies potential risks or exposures
• Prevents subsequent recurrences
• Flags adverse events
• Develops a body of knowledge
• Provide record of events
• Allows ranking of risks
• Makes staff aware that there is a spectrum of outcome
• Makes organisations more safety conscious
• Facilitates Learning
Methods of Learning From Reporting

- It can generate alerts regarding significant new hazards
- Lessons learned by health-care organizations from investigating a serious event can be disseminated.
- Analysis of many reports by the receiving agency or others can reveal unrecognized trends and hazards requiring attention.
- Analysis of multiple reports can lead to insights into underlying systems failures and generate recommendations for “best practices” for all to follow.

WHO DRAFT GUIDELINES FOR ADVERSE EVENT REPORTING AND LEARNING SYSTEMS (2005)
Near Miss Reporting:

• In risk management terms a “near miss” is considered a free lesson, and as such staff need to be made aware of the importance of reporting all incidents and near misses.
Reasons for not reporting

• Fear of Blame
• High Workload
• Belief that incident did not warrant report

Solutions

• Simplified methods of Reporting
• Clear Definitions
• Education
• Feedback
• Reassurance to staff re purpose.

Vincent, Stanthorpe, J Eval Clin Practice 1999:5 (1) 13-21
Incident Reporting & STARS:

• Clinical incidents are reported to the CIS without patient identification details

• CIS Risk Advisors do not generally have access to the identities of patients or staff involved in a clinical incident

• Each participating enterprise has reporting access only to its own data.
• Through STARS, access is available to aggregate national data on clinical incidents and claims but not to data on EL and PL incidents and claims.

• Individual enterprises can use functions on STARS to record their own EL & PL incidents.
282,045 clinical incidents / “near misses” logged on system to end August 2009.

3,522 of these events have gone on to become claims
• These figures are based on incidents logged onto the STARSWEB database.
• This by no means captures a true picture of the total amount of incidents occurring at local level.
• Encouragement is needed at local level to ensure that staff realise the importance of incident reporting, including “near misses”
How will you know there’s a claim?

- Aware of the incident as it occurs and you have reported it
- Informed by your consultant
- Contacted by the Clinical Risk Manager / Claims Co-ordinator
- Contacted directly by the Clinical Indemnity Scheme
- Personally receive a letter of claim from the patient’s solicitor
What do you do?

• If a claim is made, do not be alarmed

• Notify your Claims Co-ordinator

• Review your involvement with reference to the medical records

• Prepare a statement/report for Clinical Indemnity Scheme (“Privileged – Prepared in Contemplation of Litigation at the request of CIS”)

• Stay in contact with the CIS and notify any changes in your contact details
Importance of Statements

• Provide first hand information of the incident complained of
• Clarify your involvement in the case
• Assist in interpreting the clinical records
• Used to brief relevant clinical expert(s)
• Shared with defence legal team
• Assist in assessing liability
• Based on the factual information of the statements and expert evidence, the Enterprise will swear a Verifying Affidavit (validate the fact) in respect of the Defence
Statement Format

• Name

• Address

• Qualifications and when obtained

• Employment status at the time

• Previous relevant experience

• Set out in chronological order your involvement in the patient’s treatment

• Any other comments (you feel are relevant)

• Signature and date
Claims Investigations

“Thank God! A panel of experts!”
Claims Investigations

- Medical records reviewed
- Statements sought
- Relevant expert opinion(s) commissioned
- Solicitors appointed to deal with the legal proceedings
- Additional statements or further explanations may be required
- Meeting/Conference call, as required
- Consultations with solicitors and/or counsel, as required
- Pre-trial consultation with full defence team – if case is proceeding to hearing
Clinical claims resolved
• to date 979-(total amount paid €38.4 million).
• 2008 to end August 312-(total amount paid €17.6 million).
Why Settle?

- No records/missing records (in part or full)
- Poor records
  - Absent/inadequate entries (sparse note taking)
  - Unclear clinical plan
  - Illegible handwriting or abbreviations
  - Inability to identify signatures
- Negligence
- Consideration of the probable judicial attitude to Plaintiff’s injuries
Learning from Claims?

Closed Claims Analysis

Issues

• Wrong site surgery
• Communication
• Team working
• Informed consent
• Documentation error
“Medicine used to be simple, ineffective and relatively safe, 
Now it is complex, effective and potentially dangerous”

- Cyril Chanter, Former Dean, Guy’s King’s & St. Thomas’s Medical and Dental School, Lancet 1999
Emergency Medico-Legal Helpline
Most Frequent Queries

• Consent
• Confidentiality
• Records
• Aftermath of adverse event
• Advice re communication with relatives of patients
Sharing the Learning

CIS Fora:
• Obstetrics
• Paediatrics
• HAI
• etc
Clinical Risk Management – Models of Error & Risk Assessments
(TCD Medical Students - Session 2)
Anne Marie Oglesby,
Clinical Risk Advisor,
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Clinical Indemnity Scheme.
“Rather than being the instigators of an accident, operators tend to be the inheritors of system defects...their part is usually that of adding the final garnish to a lethal brew whose ingredients have already been long in the cooking”

(Reason 1990)
“Errors and accidents are, by definition, unintentional. Nobody sets out to make an intentional mistake. Any product or system that depends on perfect human performance is fatally flawed”.
We all make mistakes!
Models of Error

- **The Person Model**: Focuses on the errors and violations of individuals. Remedial efforts directed at people at the “sharp end”.
- **The System Model**: Traces the causal factors back into the system as a whole. Remedial efforts directed at situations, defences and organisations.
Getting the right balance
James Reason’s Swiss Cheese Model

Some holes due to Active Failures

Some Holes Due to Latent Conditions

Hazards

Defences, Barriers and Safeguards

James Reason, 1990
Active Failures
(These are known as Care Delivery Problems)

The unsafe acts, errors, or violations performed by staff at the “sharp end” of the system or patient. (Reason, 2000). They include the following:

• Action slips or failures, such as picking up the wrong medication

• Cognitive failures, such as memory lapses and mistakes either through ignorance or misreading a situation

• Violations such as deliberate deviations from safe practices, policies, procedures or standards.
Examples of Care Delivery Problems

- Failure to monitor, observe or act.
- Incorrect (with hindsight) decision or action.
- Not seeking help when necessary.
- Failure to note faulty equipment.
- Not following an agreed protocol (without clinical justification).
- Incorrect protocol applied.
- Wrong treatment given.
Latent Conditions
(These are known as Contributory Factors)

created as a result of decisions taking at a higher level within the organisation, their damaging consequences may lay dormant for a while becoming evident when they combine with local triggering factors such as:

- Understaffing
- Inadequate equipment
- Inadequate supervision
• Latent conditions can be identified and remedied before the occurrence of an adverse event.

• This can lead to proactive risk management as opposed to reactive risk management.
Contributory Factors

Specific:

• Individual factors may include lack of knowledge or experience of particular staff.
• Task factors might include the non-availability of test results or protocols.
• Team factors might include poor communication between staff.
• Work environment might include high workload or inadequate staffing.
Consider:

• Does the lack of knowledge shown on this occasion imply that any member of staff require additional training?
• Does this particular problem with the protocol mean that the whole protocol needs to be revised?
• Does this specific instance of poor communication reflect more general problems within the unit?
• Is the high workload due to a temporary and unusual set of circumstances, or is it a more general problem affecting patient safety?
Understanding Adverse Event

Organisational and Corporate Culture

Contributory factors influencing Clinical Practice
- Work Environment Factors
- Team Factors
  - Individual staff factors
- Task Factors
  - Patient Factors

Care Delivery Problems
- Unsafe Acts
  - Errors
  - Violations

Defence Barriers

Incident

Latent Conditions

Error and Violation Producing Conditions

Active Failures

(Adapted from “The Human Factor” James Reason)
# Framework of contributory factor influencing clinical practice

(Thomas Vincent 1998)

<table>
<thead>
<tr>
<th>Factor Types</th>
<th>Contributory Influencing Factor</th>
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<tbody>
<tr>
<td>Patient factors</td>
<td>Condition e.g. complexity and seriousness</td>
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<tr>
<td></td>
<td>Language and communication</td>
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<td></td>
<td>Personality and social factors</td>
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<tr>
<td>Task factors</td>
<td>Task design and clarity of structure</td>
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<td></td>
<td>Availability and use of protocols</td>
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<tr>
<td></td>
<td>Availability and accuracy of test results</td>
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<tr>
<td></td>
<td>Decision-making aids</td>
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<tr>
<td>Individual (staff) factors</td>
<td>Knowledge and skills</td>
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<td>Competence</td>
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<td>Physical and mental health</td>
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<tr>
<td>Team factors</td>
<td>Verbal communication</td>
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<td></td>
<td>Written communication</td>
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<td></td>
<td>Supervision and seeking help</td>
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<td></td>
<td>Team structure (congruence, consistency, leadership etc.)</td>
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</tbody>
</table>
Framework of contributory factor influencing clinical practice (Cont’d)

<table>
<thead>
<tr>
<th>Factor Types</th>
<th>Contributory Influencing Factor</th>
</tr>
</thead>
</table>
| Work environmental factors            | Staffing levels and skills mix  
Workload and shift patterns  
Design, availability and maintenance of equipment  
Administrative and managerial support  
Environment  
Time delays                                                                 |
| Organisational and management factors | Financial resources and constraints  
Organisational structure  
Policy, standards and goals  
Safety culture and priorities                                                                 |
| Institutional factors                 | Economic and regulatory context  
National health service executive  
Links with external organisations                                                                 |
A Top Down & Bottom Up approach, and a “just & fair” culture should be encouraged.
Opportunities for Change:

• It is essential that the Risk Management System is supported from the top – without support and backing from management it will not succeed.

• A fundamental part of Risk Management is about changing behaviour towards safer care.

• This change comes about through learning; from the level of the individual healthcare provider to the level of management and all points in between.
Supporting Staff

- Imperative that staff are supported by their Enterprise in the incident management process.
- Finger pointing does not work
- The **most valuable** asset of any enterprise is its staff.
- It is essential to provide organisational learning by providing regular feedback to staff.
- All primary stakeholders should be involved in the planning and implementing of a **proactive** Risk Management System.
Summary of Prerequisites for Success:

- Representation from Executive on Risk Management Committee.
- “Just & Fair” Culture.
- Incident and Claims Review Committee.
- Clear indicators on what should be reported.
- On going education on how to report clinical incidents.
- Recognised Risk Rating Tool.
- Database Management.
- Feedback to staff.
- Re-evaluation of the efficacy of introduced corrective strategies.
Risk Assessment
Risk Assessment:

Definition:
Clinical Risk Assessment is a proactive process in which information is collected about an organisation or clinical service in order to identify what clinical risks may exist.
The process of risk assessment seeks to answer four simple questions:

1. What can go wrong?
2. How bad?
3. How often?
4. Is there a need for action?
Risk can be any of the following:

- Clinical
- Environmental
- Financial
- Economic
- Political
- Public perceptions & reputation
The benefits of risk assessment:

• Strives for the optimal balance of risk by focusing on the reduction or mitigation of risk while supporting innovation.

• Helps organisations comply with standards.

• Supports better decision making through a solid understanding of all risks and their likely impact.

• Highlights the weakness and vulnerability in procedures, practices & policy change.
When to do a risk assessment?

A risk assessment should be conducted at various stages of change, development or project:

- Early on- to help ensure basic design provides appropriately safe care
- During detailed design- to help ensure risks are considered throughout
- Modification- post implementation to help ensure that new risks are not unintentionally introduced.
It is important to differentiate between a ‘Hazard’ & ‘Risk’:

• **Hazard**: a situation with the potential to cause harm

• **Risk**: the combination of likelihood and consequence of hazards being realised
Who should do the risk assessment?

- Risk assessments should be conducted with staff for which the risks are relevant.
- Management teams will need to advise on strategic risks.
- Clinical teams will need to be involved when assessing an individual patient’s care or a procedural risk in their department.
- All parties involved including patients and the public can be involved.
**Roles:**

The risk assessor:

- Responsible for preparation, facilitating the assessment meeting and ensuring the recommendations are picked up.

- A structured approach should be followed, open discussion encouraged and discussions & recommendations summarised.
Multi-disciplinary team (MDT) clinical & non-clinical:

Contributions from participants during the assessment meeting will assist in identifying:

- Hazards
- Causes
- Consequences & controls
- Risk ranking
- Developing recommendations
The Recorder:

• An essential role to support the risk assessor and record the discussion and recommendations during the assessment meeting

• They need to be conversant with the process and understand the activities. They need an understanding of ‘language’ and common acronyms
There are 4 stages of Risk Assessment:

1. Planning the risk assessment
2. Map out the service to be assessed
3. Risk assessment meeting
4. Review & follow-up
Examples of the various tools used:

- Failure modes & effects analysis (FMEA)
- Healthcare failure modes & effects analysis (HFMEA)
- Hazard analysis & critical control points
- Hazard & operability
- Barrier analysis & development of risk controls
- Probabilistic risk assessment

(There are over 40 different tools currently in use)
• It is important to become familiar with local processes.
• Various risk assessment tools available.
• Generic tools
• Condition specific tools – e.g. falls, cardiac etc.
Event Imminent????

- Central Venous Catheter
- Epidural Catheter
- Gastrostomy Tube
- Arterial Catheter

(Cronin, G. Learning from critical incident reviews)
Excerpt from patient’s notes……..

• Pg.1:  05.21 - Admitted May 28th.

• Pg. 23 : 05.10- Peri-operative nursing note

• Pg. 21: 05.15- Anaesthetist’s obs. begin

• Pg. 35: Head Observation chart – dated May 26th.
Story of a Claim

16 Y.O. girl with Hx of In-growing toenail

• Presented to day ward with her mother.

• Patient herself consented for “Bilat. Wedge Resection of Great Toe”.

• Surgeon mis-read consent form and operated on both toes.

• Nurse in recovery room noted two toes bandaged.

• IV Cyclimorph administered for pain relief.

• Surgeon *then* asked patient to consent for bilat. Surgery and mother not informed of same.
Story of a Claim - contd.

Follow-up by CIS

• Confusion re two consent forms for same day
  (Surgeon eventually clarified position)

• Claim indefensible, settled for €20,000.
Claims Issues –
Records/Documentation

• Accuracy
• Retention
• Storage

(HSE, NHO Medical Records Retention Policy - May 2007.)
"There's been some sort of mistake. He came to clean the windows."
**Communication Failure in the Operating Theatre**

<table>
<thead>
<tr>
<th>Failure in 31% of 421 events</th>
<th>Result</th>
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<tr>
<td>• Info. Missing (36%)</td>
<td>• Team tension</td>
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<tr>
<td>• Poor timing (46%)</td>
<td>• Resource waste</td>
</tr>
<tr>
<td>• Issues not resolved (24%)</td>
<td>• Delay</td>
</tr>
<tr>
<td>• Key people absent (21%)</td>
<td>• Procedural deviation</td>
</tr>
</tbody>
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*Lingard et al. Communication failures in the operating room.*

*Qual Saf Health Care 2004; 13:330-4*
Retained swabs/Foreign Bodies

Review of 153,263 surgical procedures
• 1,059 count discrepancies
  • needles (62%)
  • Surgical instruments (22%)
  • Sponges (15%)

• Count Discrepancy increases with “Human Operator” factors.
  • >1 nursing team involved
  • Increasing duration of surgery
  • Emergency procedures
  • “Late time” procedures


29 Claims
Exercises

Aoccdrnig to a rscheearch at Cmabrigde Uinervtisy, it deosn't mttae in waht oredr the ltteers in a wrod are, the olny iprmoetnt tihng is taht the frist and lsat ltteer be at the rghit pclae. The rset can be a total mses and you can sitll raed it wouthit porbelm. Tihs is bcuseae the huamn mnid deos not raed ervey lteter by istlef,but the wrod as a wlohe.
Can you count the black dots??

Count the black dots! :o)
Which knob turns on the burner??

Hob A

Hob B
“Quality Management and Risk Management are inextricably linked. Where high quality care exists, risk is invariably low. Conversely, where quality is compromised the risk to the patient increases”
“To err is human. To cover up is unforgivable, and to fail to learn is inexcusable”

Sir Liam Donaldson

Perspectives in Health-The magazine of the Pan American Health Organisation Vol 10, No 1, 2005
An effective risk management system can bring you from this........
To this.........
Contact Details

Clinical Indemnity Scheme
(01) 6640900

Emergency Medico-Legal Helpline
(01) 6640909

Website: www.stateclaims.ie

Thank you!
Thank You....... Questions???