

## **The State Claims Agency Clinical Indemnity Scheme Incident Notification Requirements.**

### **Preface**

The Clinical Indemnity Scheme (CIS) was established in July 2002, within the State Claims Agency (SCA), (S.I. No. 63 of 2003, *National Treasury Management Agency (Delegation of Functions) Order 2003*) to rationalise the existing medical indemnity arrangements by transferring to the State, via health boards (now the HSE), hospitals and other health agencies, responsibility for managing clinical negligence claims and associated risks. Under the scheme, which is managed by the State Claims Agency (SCA), the State assumes full responsibility for the indemnification and management of all clinical negligence claims against enterprises and practitioners covered by the scheme.

The State Claims Agency has a mandate to:

- Provide clinical indemnity on the basis of “enterprise liability” (i.e. the enterprise assumes liability for all its employees’ alleged clinical negligence).
- Manage claims made against the enterprises in a timely and cost-effective manner.
- Assist the enterprises to reduce the numbers of clinical claims through risk management initiatives.
- Drive and support safe patient care,
- Guide and support clinical risk management in all the enterprises.

Section 8(4)(a) and (b) set out the powers of the State Claims Agency in relation to the deployment of measures to be taken to prevent the occurrence, or to reduce the incidence of acts, omissions or other matters occasioning or that may occasion delegated claims against such an Authority, including measures to identify sources of risk that may occasion such claims.

Thus, it is open to the State Claims Agency, inter alia, to provide the following:

- (a) The provision of information, instruction and training for the purposes of enabling the enterprise to ascertain whether any such risk exists and if it does, of increasing the awareness of its existence and encouraging the adoption by that enterprise of appropriate measures to counter any such risk
- (b) The assessment of any risk, including a determination of whether it could give rise to a serious hazard;
- (c) The evaluation of the adequacy of the measures adopted by such an Authority to counter any such risk; and
- (d) The provision to such an Authority of safety audits, inspections and reviews.

Whilst Section 11(2), by virtue of its wording, calls for the State authority to engage in a predictive assessment as to when and what adverse incident might give rise to a claim, it is the practical and recommended practice that Authorities notify **all** adverse incidents, using the STARSWeb system. This achieves two distinct goals as follows:

- (a) The STARSWeb database will properly reflect the national picture as to the rate and type of adverse incidents (to include clusters of similar incidents) which, in turn, will inform appropriate risk management responses/programmes; and
- (b) Will ensure the contemporaneous investigation of adverse incidents likely to give rise to claims, thereby ensuring the best possible defence of claims.

The above notification process is no different to that which has operated, historically, between hospitals, practitioners and their medical malpractice insurers/indemnifiers.

The enterprises covered by the Clinical Indemnity Scheme are listed in S.I. No. 63 of 2003 *National Treasury Management Agency (Delegation of*

*Functions) Order 2003 (Appendix 1) and National Treasury Management Agency (Delegation of Functions)(Amendment) Order 2007*

The enterprises vary widely in size and service delivery, ranging from former health board regions (where cover is provided to hospitals, community care services, community hospitals etc.) to small organizations providing services for clients with intellectual or physical impairment.

### **The CIS Team**

The team, at the State Claims Agency, is headed by Ciarán Breen, Director. Dr. Ailis Quinlan, Head of the Clinical Indemnity Scheme (CIS), has responsibility for the clinical risk management function. The Clinical Claims Managers have legal or insurance qualifications and the Clinical Risk Advisers have nursing, para-medical or medical backgrounds.

### **Claims Management at the SCA**

The Clinical Claims Managers at the State Claims Agency are responsible for the formulation of claims' management strategies in relation to the entire range of clinical negligence claims brought against enterprises and practitioners covered by the CIS. Following their thorough examination of medical records and detailed consultation with practitioners, the clinical claims managers' decisions are informed, inter alia, by relevant case law, expert peer review and solicitors' and Counsels' advices.

In addition, the clinical claims managers manage hospital inquests on behalf of participating hospitals and practitioners ensuring legal representation for hospitals/practitioners at such inquests. The claims management team also operate an emergency medico-legal helpline.

### **Risk Management at the SCA**

In addition to the management of clinical claims, the Agency also has responsibility for advising and assisting enterprises concerning the adoption of effective clinical risk management policies.

Clinical risk management is based on three principles, i.e. Risk identification, risk analysis and risk control. International research and experience suggests that this approach will be successful only in the context of a "just and fair" culture. This requires a review of the entire process that caused the occurrence of an adverse event, rather than focusing on the individual healthcare worker involved in the actual event.

The team of Clinical Risk Advisers at the Clinical Indemnity Scheme has responsibility for providing clinical risk management advice and support to healthcare enterprises. They provide advice and assistance to all clinical enterprises covered by the CIS and work with risk management and other relevant personnel at enterprise level, to support patient safety. This includes encouraging the early notification of incidents and "near-misses" and identifying local and national trends in relation to incidents and claims.

### **Interface between Clinical Risk Management and Claims Management**

An integrated approach to Clinical Risk Management and Claims Management has been adopted at the SCA, as suggested by international best practice.

Clinical Claims Managers and Clinical Risk Advisers operate as a team. Each has responsibility for defined enterprises, in order to develop and strengthen a close working relationship between the CIS and all enterprises covered by the scheme.

Clinical Risk Advisers (CRA) notify their Claims colleagues of serious adverse events that may give rise to litigation while also ensuring that an appropriate risk management exercise is carried out at enterprise level. Likewise, if a Claims Manager, during investigation of a claim, forms the view that an issue would benefit from a clinical risk review at enterprise level, s/he will refer it to the relevant CRA who, in turn, will liaise with the relevant enterprise/clinical manager.

### **CIS Requests for Further detail**

The CRAs review all of the incidents reported on STARSWeb. When it appears that a serious incident has been notified, the CIS Clinical Risk Advisers will contact the lead person with responsibility for Risk management within the Enterprise and request further details to ensure the correct context has been applied to the incident. Further details relating to the event will be sought, specifically related to injury sustained, outcome of diagnostics performed that establish the level of harm, risk grading of the **impact** of the incident, description of event.

This is necessary in order to establish:

- Whether the incident is as serious as it appears,
- To ensure that appropriate risk management strategies have been put in place to mitigate recurrence.

This information will also enable the relevant Clinical Claims manager at the SCA to form an opinion regarding whether to open a pre-claims file. Where the Clinical Claims Manager opens a pre-claim, this facilitates best claims management practice by ensuring that contemporaneous statements are taken from staff who may well move to different enterprises, if not other jurisdictions, in the aftermath of an adverse event.

### **Clinical Incident Reporting System-STARSWeb**

A key feature of the CIS is electronic incident reporting to a national database. The CIS has established and maintains a national database for adverse clinical incidents and “near-misses”. A confidential, highly secure web-based IT system (known as STARSWeb) links hospitals and other healthcare enterprises to the CIS core database.

National rollout of the STARSWeb system commenced in November 2003. The majority of enterprises covered by the scheme are now live on the system. Whilst the system incorporates a co-existing Claims Management functionality, the clinical incident reporting feature is designed to support

sharing of learning gleaned from an analysis of “near misses” and serious adverse clinical events, at local and national levels.

Based on this data, the CIS, in conjunction with the enterprises, is able to identify and analyse developing trends and patterns. Data can be manipulated to provide a wide range of report options. Any enterprise may use the system to benchmark itself against the national picture or as an aid for quality improvement initiatives within the enterprise.

The system is subject to ongoing revision and review.

### **Training and education**

The learning gleaned from the ongoing review of serious adverse events, together with models of best practice, is disseminated through seminars, workshops and the CIS website.

### **Website**

The CIS website includes information regarding “Frequently Asked Questions”, reports on STARSWeb data, quarterly newsletters and links with relevant organizations. This may be accessed by following the link to the Clinical Indemnity Scheme from the State Claims Agency website at <http://www.stateclaims.ie/ClinicalIndemnityScheme/introduction.html>

## **Role of the Enterprises covered by the Clinical Indemnity Scheme**

### **Clinical Risk management**

Each enterprise is required to develop and promote a culture that supports clinical risk management.

All enterprises covered by the CIS have a statutory duty to;

- Report all adverse incidents to the SCA.
- Furnish relevant information when requested to do so.
- Preserve relevant evidence.
- Permit and facilitate SCA investigation to include furnishing when requested to do so by the SCA, complete and properly ordered medical records.

### **Reporting of Clinical Adverse Events**

All adverse **clinical** events must be reported, as a matter of course, to the CIS, via the STARSWeb system, by those enterprises that are “live” on the system, and by paper notification for all other enterprises awaiting access to the live system.

### **STARSWeb Incident and Claims Reporting Guidelines**

The SCA has issued guidelines to each of the enterprises, concerning the notification of adverse clinical incidents Appendix 1 for STARSWeb Incident and Claims Reporting Guidelines re-issued in August 2008.

It is imperative that all enterprises now live on STARSWeb adhere to the revised 2008 STARSWeb Incident and Claims Reporting Guidelines.

*Please note that in the event that we continue to receive paper incident forms, letters of request for records or unsolicited medical records from Enterprises that are live on STARSWeb, we will have no option but to shred or return this documentation to you.*

*Please note that in the event that we receive correspondence from you without a STARSWeb reference number endorsed thereon, we will have no option but to return this documentation to you.*

### **Complaints**

When a complaint regarding an adverse event relating to clinical care is submitted to an enterprise, it is essential that each enterprise has a system in place to identify whether such adverse clinical events have been reported to the CIS via STARSWeb, and if not, to take action to report same, as soon as is practicably possible.

### **STARSWeb Training**

STARSWeb training is currently provided by the SCA on an on-going basis. 2 levels of course are offered – in-putter training and reporting training. In-putter training for beginners is for personnel starting to use the system. Reporting training is for personnel who have gained experience with the system and who are looking to create reports on the data already logged onto the system for their area.

### **Pick list Changes/Requests for enhancement:**

Pick list changes or requests for enhancement on the STARSWeb system may be requested using a Request for Enhancement Form, which can be obtained from the CIS. All requests will be considered and reviewed by the CIS CRA team and feedback given to the requester regarding the decisions reached.

### **STARSWeb User Support:**

Support for users of STARSWeb is provided by:

Maeve Wright: (01) 664 0906

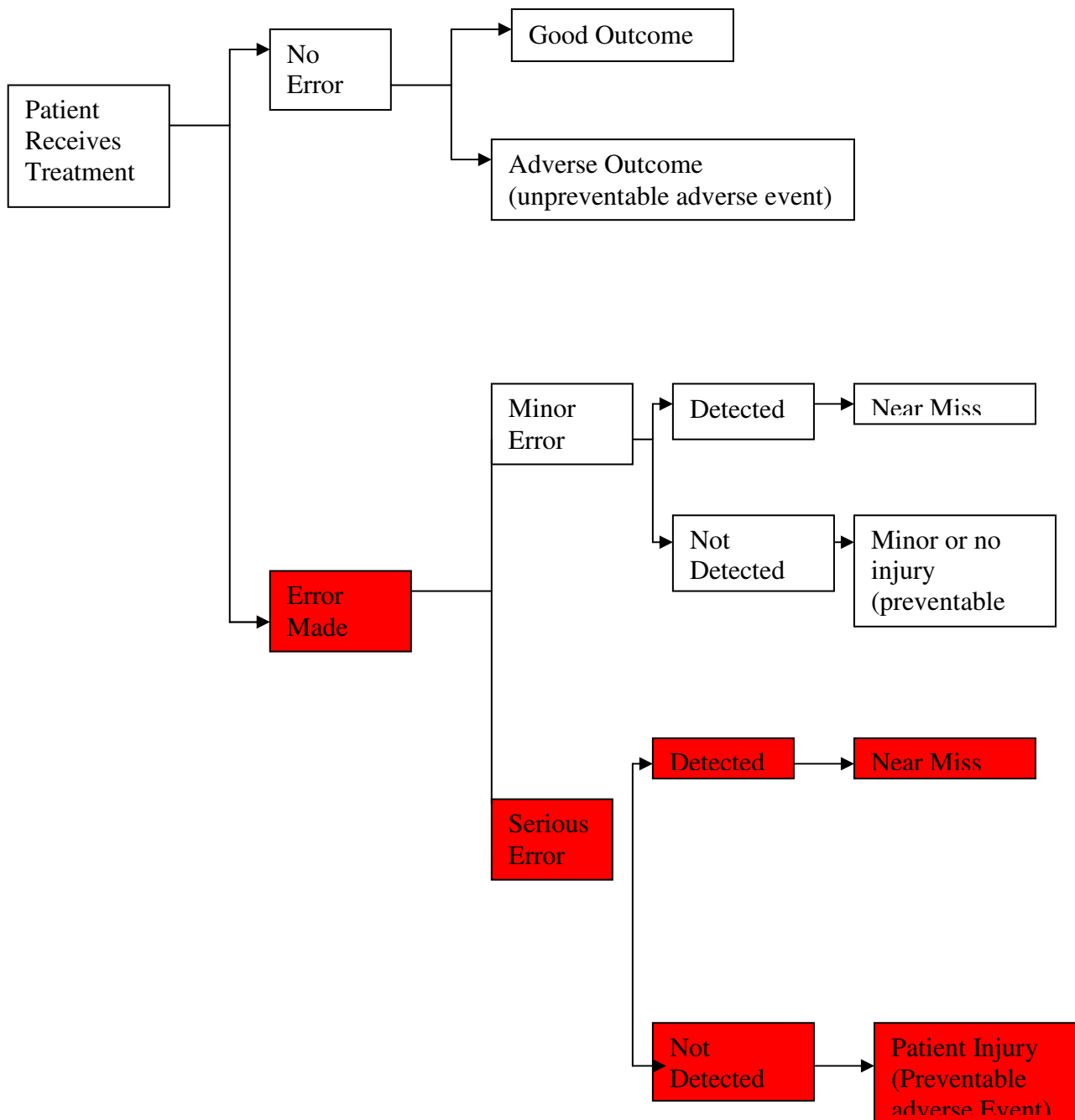
Rebecca Hamill: (01) 664 0926

## **Rapid Notification of Serious Adverse Clinical Event.**

Rapid notification of all serious adverse clinical events is essential to enable the SCA to identify:

- Potential litigation
- Quality improvement opportunities at enterprise level

A verbal or email notification should be made to the relevant CIS Clinical Risk Adviser within 48 hours of occurrence of such an event. The adverse event should of course also be notified routinely via STARSWeb. A list of adverse clinical events requiring this action is listed in Appendix 2 for the guidance of all enterprises. On receipt of these notifications, the CIS Clinical Risk Adviser will generally request more detailed information from the reporting enterprise. This information will include, but is not limited to, the outcome of any relevant diagnostics that establish the level of harm, further treatment delivered, date of Coroner's Inquest etc.



**Figure 1:** Framework for identifying errors. (Adapted from Doing What Counts for Patient Safety: Federal Actions to Reduce Medical Errors and Their Impact, 2000)

## **Reviews of Serious Adverse Clinical Events**

When a review of a serious adverse clinical event has been carried out by an enterprise, a copy of the report should be attached to the incident on STARSWeb and an email sent to the relevant CIS Clinical Risk Adviser as a matter of course.

## Appendix 1:

### STARSWeb Incident and Claims Reporting Guidelines (Updated – August 2008)

1. Enter details of the notifiable clinical incident on STARSWeb and obtain the STARSWeb reference number.
2. Where correspondence e.g. complaint letter, solicitor's letter is received by an Enterprise and the related clinical incident has not previously been recorded on STARSWeb, the relevant clinical incident should be recorded on STARSWeb by the Enterprise on receipt of that correspondence.
3. To protect the anonymity of the patient/client/resident please ensure that the name of the patient/client/resident is not inadvertently used in the "Further Details of Event" field or in any document/note attached as an "Attachment", or in any other free text field on STARSWeb.
4. When corresponding with the SCA, always quote the STARSWeb reference number.
5. Do not send any documentation, (other than original solicitor's letter of claim) to the SCA, whether records request, complaint letter, medical records etc, unless specifically requested by the SCA.
6. Solicitors' letters / letters of claim / legal proceedings should always be forwarded to SCA with the STARSWeb reference number endorsed thereon.
7. Specifically, in relation to records requests, always update the relevant field on STARSWeb where the records request relates to a specific incident already on STARSWeb.

Where the records request relates to a matter / incident not on STARSWeb, and which, in the opinion of the Enterprise, is related to a notifiable clinical incident, the incident should be recorded on STARSWeb and the records request field updated.

Ciarán Breen  
Director, State Claims Agency

## **Appendix 2:**

### **List of Serious Adverse Clinical Events for Rapid Notification to the CIS**

- Surgery performed on the wrong body part
- Surgery performed on the wrong patient
- Wrong surgical procedure performed on a patient
- Unintended retention of a foreign object in a patient after surgery or other procedure, including retained vaginal swabs and tampons.
- Unexpected Intra-operative or immediately postoperative death.
- Unplanned return to operating suite.

### **Product or Device Events**

- Patient death or serious adverse outcome associated with the use of contaminated drugs, devices, or biologics provided by the health care facility
- Patient death or serious adverse outcome associated with the use or function of a device in patient care in which the device is used or functions other than as intended
- Patient death or serious adverse outcome associated with intravascular air embolism that occurs while being cared for in a health care facility

### **Patient Protection Events**

- Patient suicide, or attempted suicide, resulting in serious adverse outcome while being cared for in a health care facility
- Patient death or serious adverse outcome associated with patient absconding.
- Infant discharged to the wrong person

### **Care Management Events**

- Patient death or serious adverse outcome associated with high alert drugs as determined by Drugs & Therapeutic Committees, pharmacy etc.

- Patient death or serious adverse outcome associated with a medication error (e.g., errors involving the wrong drug, wrong dose, wrong patient, wrong time, wrong rate, wrong preparation, or wrong route of administration)
- Patient death or serious adverse outcome associated with a haemolytic reaction due to the administration of ABO/HLA-incompatible blood or blood products
- Maternal death.
- Serious adverse outcome associated with labour or delivery.
- Death or serious adverse outcome associated with delayed diagnosis.
- Death or serious disability (kernicterus) associated with failure to identify and treat hyperbilirubinaemia in neonates
- Hospital Related death reportable to the Coroner
- Patient death or serious adverse outcome due to spinal manipulative therapy

### **Environmental Events**

- Any incident in which a line designated for oxygen or other gas to be delivered to a patient contains the wrong gas or is contaminated by toxic substances
- Patient death or serious adverse outcome associated with a burn incurred from any source while being cared for in a health care facility
- Patient death or serious adverse outcome associated with a fall while being cared for in a health care facility
- Patient death or serious adverse outcome associated with the use of restraints or bedrails while being cared for in a health care facility

(Adapted from The National Quality Forum's List of the 28 "Never Events")

## Appendix 3:

### Glossary of Terms:

In order to ensure that definitions are in line with internationally agreed definitions, the World Healthcare Organisation Final Technical Report for The Conceptual Framework for the International Classification for Patient Safety v.11 has been adopted where possible.

- **Safety:** the reduction of risk of unnecessary **harm** to an acceptable minimum.
- **Hazard:** a **circumstance, agent** or action with the potential to cause harm.
- **Event:** something that happens to or involves a **patient**.
- **Patient Safety:** the reduction of risk of unnecessary **harm** associated with **healthcare** to an acceptable minimum.
- **Healthcare-associated harm:** **harm** arising from or associated with plans or actions taken during the provision of healthcare, rather than an underlying **disease** or **injury**.
- **Patient safety incident:** an **event** or **circumstance** which could have resulted, or did result, in unnecessary **harm** to a **patient**.
- **Risk:** the probability that an **incident** will occur.
- **Harmful incident (adverse event):** an **incident** which resulted in **harm** to a patient.
- **Harm:** impairment of structure or function of the body and/or any deleterious effect arising there from. Harm includes **disease, injury, suffering, disability** and death.
- **Contributing Factor:** a **circumstance, action** or influence which is thought to have played a part in the origin or development of an **incident** or to increase the **risk** of an **incident**.
- **Incident type:** a descriptive term for a category made up of incidents of a common nature, grouped because of shared, agreed features.
- **Adverse reaction:** unexpected harm resulting from a justified action where the correct process was followed for the context in which the event occurred.
- **Side effect:** a known effect, other than that primarily intended, related to the pharmacological properties of a medication.
- **Preventable:** accepted by the community as avoidable in the particular set of circumstances.
- **Detection:** an action or **circumstance** that results in the discovery of an **incident**.
- **Mitigating factor:** an action or **circumstance** which prevents or moderates the progression of an **incident** towards harming a **patient**.

- **Patient outcome:** the impact upon a patient which is wholly or partially attributable to an **incident**.
- **Degree of harm:** the severity and duration of harm, and any treatment implications, that results from an **incident**.
- **Ameliorating action:** an action taken or **circumstances** altered to make better or compensate any **harm** after an **incident**.
- **Actions taken to reduce risk:** actions taken to reduce, manage or control any future harm, or probability of **harm**, associated with an **incident**.
- **Accountable:** being held responsible
- **System failure:** a fault, breakdown or dysfunction within an organization's operational methods, processes or infrastructure.
- **System improvement:** the result or outcome of the culture, processes, and structures that are directed toward the prevention of **system failure** and the improvement of **safety** and **quality**.
- **Root cause analysis:** a systematic iterative process whereby the factors which contribute to an **incident** are identified by reconstructing the sequence of events and repeatedly asking why? Until the underlying root causes have been elucidated.
- **STARSWeb:** A web-based IT system for the purposes of notification of incidents that links enterprises to the CIS central database that is held in the SCA