Clinical Indemnity Scheme
Newsletter

CIS Newsletter, April 2012

Controlling Legal Costs in Clinical Negligence Actions

There has been a good deal of recent, adverse criticism of the disproportionately high level of legal costs associated with the resolution of clinical negligence cases. Some media commentators and politicians alike have suggested that some kind of radical action, to curtail such costs, is required.

It is a fact, which has been stated in this editorial previously, that legal costs associated with the resolution of clinical negligence cases have remained stubbornly high, despite the prevailing deflationary influences elsewhere in the economy. Why is this so?

It is the case that lawyers for plaintiffs in clinical negligence actions have, over the years, successfully argued that clinical negligence cases are complex to investigate and advance to trial and, thus, are deserving of a "premium" rate over standard personal injury actions when it comes to setting the "professional fee". Over the past number of years, the Taxation of legal costs system largely confirmed this view, that clinical negligence actions were deserving of significantly enhanced professional fees, when compared to other "running down" actions.

More recently, however, the Taxation of legal costs system has begun to scrutinise, and adjust downwards, the level of professional fees charged in these cases on the basis of a "work done" principle rather than one of a "percentage of the award or settlement". This new approach comes by way of a welcome change. There has also been recent judicial comment that legal costs must be reduced so as to reflect the reality of the wider economic climate. Thus, it appears that the two institutions of State which ultimately set the acceptable level of legal costs are signalling the downwards adjustment of such costs.

For its part, the State Claims Agency (SCA) has implemented its own maximum efforts to curb legal costs. In 2011, the Agency, following a public tendering process, reduced and capped the level of professional fees its solicitor panel firms can earn. In the same year, the Agency negotiated legal costs savings, in respect of plaintiffs' lawyers Fee Bills, of €5.6 million.

It is also worth pointing out that despite an independent actuarial forecast that the Agency would require to spend €106 million on resolving clinical negligence cases in 2011, it actually spent €81 million i.e. a saving of €25 million on the actuarial forecast. An intrinsic part of this overall saving related to controlling and reducing the Agency's legal costs.

It is likely that the Working Group on Medical Negligence Litigation, which is due to issue its second report soon, will recommend the adoption of a pre-action protocol in respect of clinical negligence cases. The purpose of such a protocol will be to significantly reduce the number of medical negligence claims which ultimately proceed to litigation. If the protocol is introduced in the future, legal costs in respect of these cases should be contained at more acceptable levels. Whilst it is accepted that legal costs would be front-loaded, following the adoption of a pre-action protocol, it is to be hoped that there will be savings on costs in the longer term consequent upon cases being settled at a much earlier stage i.e. pre-litigation. There should also be significantly less reliance on counsel.

To conclude, thus, some of the necessary changes to control legal costs in clinical negligence cases are occurring. However, more needs to be achieved and it is hoped that the Legal Services Regulatory Bill, when enacted, will provide other welcome outcomes in terms of reducing legal costs.

Contents in this issue

E-learning programme in Blood Transfusion Practice

A seminal United States study by the Institute of Medicine (1998) estimated that up to 98,000 deaths occur annually due to errors by health workers[1]. In Ireland almost 30,000 incidents were reported under the Clinical Indemnity Scheme in 2010[2]. Many of these incidents were preventable and have been examined by national haemovigilance systems including Ireland[3].

The Official Journal of the European Union (2003, p.L33/33) states "Haemovigilance shall mean a set of organised procedures relating to serious adverse events or unexpected events or reactions in donors or recipients and the epidemiological follow-up of donors".[4] The National Haemovigilance Office (NHO) analyses reports of adverse events and reactions in recipients, and advises on ways to improve blood transfusion practice. NHO data consistently identifies transfusion of the incorrect component as the most frequent error, and root cause analysis attributes over 90% of errors to human failure and lack of knowledge by clinical practitioners[5].

According to the literature, Continuing Professional Education (CPE) programmes can reduce such errors [6, 7, 8]. Furthermore, the EU Directive 2002/98/EC requires hospitals involved in blood transfusion practice to provide evidence of staff training as part of an annual accreditation process[9]. Studies show however, that face-to-face training can be difficult as staff have competing work and personal demands, and varying skills and educational levels [10, 11, 12, 13, 14]. Furthermore, as highlighted in a study conducted by the NHO on near-miss events training is often fragmented and not prioritised, with little protected time [15].

E-learning programmes may address some of these problems and the Effective Use of Blood Group of the Scottish National Blood Transfusion Service (SNBTS) developed an e-learning programme aimed at practitioners involved in blood transfusion practice. The Irish Blood Transfusion Service has a licence for this programme, which is provided free of charge to Irish hospitals. Initially a pilot study was conducted at 5 hospitals, and following feedback from these sites implementation began on a national basis in 2008. Of the almost 80 hospitals engaged in blood transfusion practice, 74 use the programme. It is also mandatory for medical and nursing undergraduates at several universities. The programme consists of eight modules covering various aspects of blood transfusion such as, the administration of blood components, complications of blood transfusion, indications for Anti-D immunoglobulin, and laboratory aspects of blood transfusion practice. Each module consists of several units, and includes interactive scenarios and an assessment. Of the just over 9,000 registered users, more than half (n=5353, 58%) are nurses, 23 per cent (n=2064) medical staff, and the remaining 19 per cent consists of practitioners from various roles such as medical scientists, phlebotomy, porters and students.

A small (n=72) survey (adapted from Atack and Rankin, 2002)[16] conducted by the NHO in 2010 found overall learner' evaluation of the programme was positive[16]. The majority (84%) reported the programme is easy to navigate, and almost all (96%) found the content easy to understand. Although most (89%) felt e-learning was a convenient way to participate in CPE, only 10% accessed the programme off-site. The majority (90%) appreciated being able to access the course at a convenient time. Thirty-three per cent said they preferred face-to-face learning to e-learning, commenting they missed the social interaction, nevertheless nearly all (92%) said they would take another e-learning course. In addition, while self-reporting behaviours must be interpreted with caution, over 88% of respondents felt their knowledge of blood transfusion practice had improved, commenting the programme was "a good learning tool", "learner-centred", and "more interesting". Furthermore, almost all (97%) felt it was relevant to their practice. A study (n=678) in the United Kingdom reported similar findings. Respondents noted the pro-gramme 'made a notable difference to practice,' and they were more aware of the risks associated with blood transfusion and how to avoid them[17]. The majority (79%) indicated they complied with best practice even in an emergency. The authors were however, concerned that 'one in five patients may be at risk of an adverse event occurring because staff failed to follow the correct procedures' [17]. Therefore, while these studies demonstrate e-learning is an effective supplement for CPE further research is needed to measure if learners' knowledge is transferred and applied in practice and improves patient safety and the quality of care.

The Reference section for this article is on the next page.

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Clinical Inbox - An I.T. Solution for Radiology Report Communication

Diagnostic testing is an increasingly large proportion of the patient care pathway in modern healthcare. However this has not been matched by efforts to simplify or rationalise the diagnostic algorithms and more patients are getting more tests and this trend is set to continue. Further the explosion in diagnostics has outpaced the development of systems to allow efficient result verification which potentially exposes patients to risk through systems failure. It has been stated that: *"Communication of a diagnosis so that it may be beneficially utilized may be all together as important as the diagnosis itself."*

The vast range of pathologies and processes under study in any radiology practice greatly limits the ability to categorise such reports in a manner that facilitates computerised alerting systems. Our IT department (Mark Farrell and Jenny Costello) developed a software platform based on the existing hospital information system (HIS) and we looked to them to develop a paper light system that would provide a superior communication model for imaging result management.

CHANGING PRACTICE

STEP 1. Define Imaging Report Communication Responsibilities

There is a reciprocal duty of care in result report communication. Fundamentally those who order tests and initiate the diagnostic pathway have a basic duty to check the results and ensure appropriate clinical action. Equally those who perform the tests have a duty to produce results in a timely manner that aids communication to the referrer.

STEP 2. Agree Uniform Report Categorisation/Lexicon

We categorised results based on significance, promptness of action required and the likelihood the referrer was expecting the results.

I. **Critical Unexpected Findings**
II. **Urgent Unexpected Findings**
III. **Unexpected Findings**
IV. **Expected Findings**
V. **Normal**

STEP 3. Define Uniform Computer Coding Nomenclature and Defined Communication Pathways

Radiology QA meetings defined an agreed uniform nomenclature that was implemented with the help of our IT department.

CODE RED: Critical, expected or unexpected finding may require immediate action. Requires verbal communication with referring clinician and recording of the name of clinician and time and date of communication in the radiological report. Result will be flagged on Clinical Inbox.

CODE AMBER: Urgent, expected or unexpected finding may require an action sooner than routine but not necessarily immediately. Requires verbal communication with referring clinician and recording of the name of clinician and time and date of communication in the radiological report. Result will be flagged on Clinical Inbox.

CODE BLUE: Neither critical nor urgent but the radiologist wishes to assign a greater priority of the report to bring it to clinician attention. Result will be flagged on Clinical Inbox.

NO CODE: Neither critical, urgent nor unexpected. The radiologist feels the report may be communicated through the normal reporting pathway. No-Code reports may be normal or abnormal. The result will not be flagged on Clinical Inbox. The result will be checked and acted upon based on individual clinician practices.

STEP 4. Design an electronic platform for result safety nets - Clinical Inbox

An electronic platform filters critical, urgent and unexpected radiological reports using the coding nomenclature applied by the interpreting radiologist. This allows the referrer to review all clinically important radiological reports in a single specialised electronic folder.

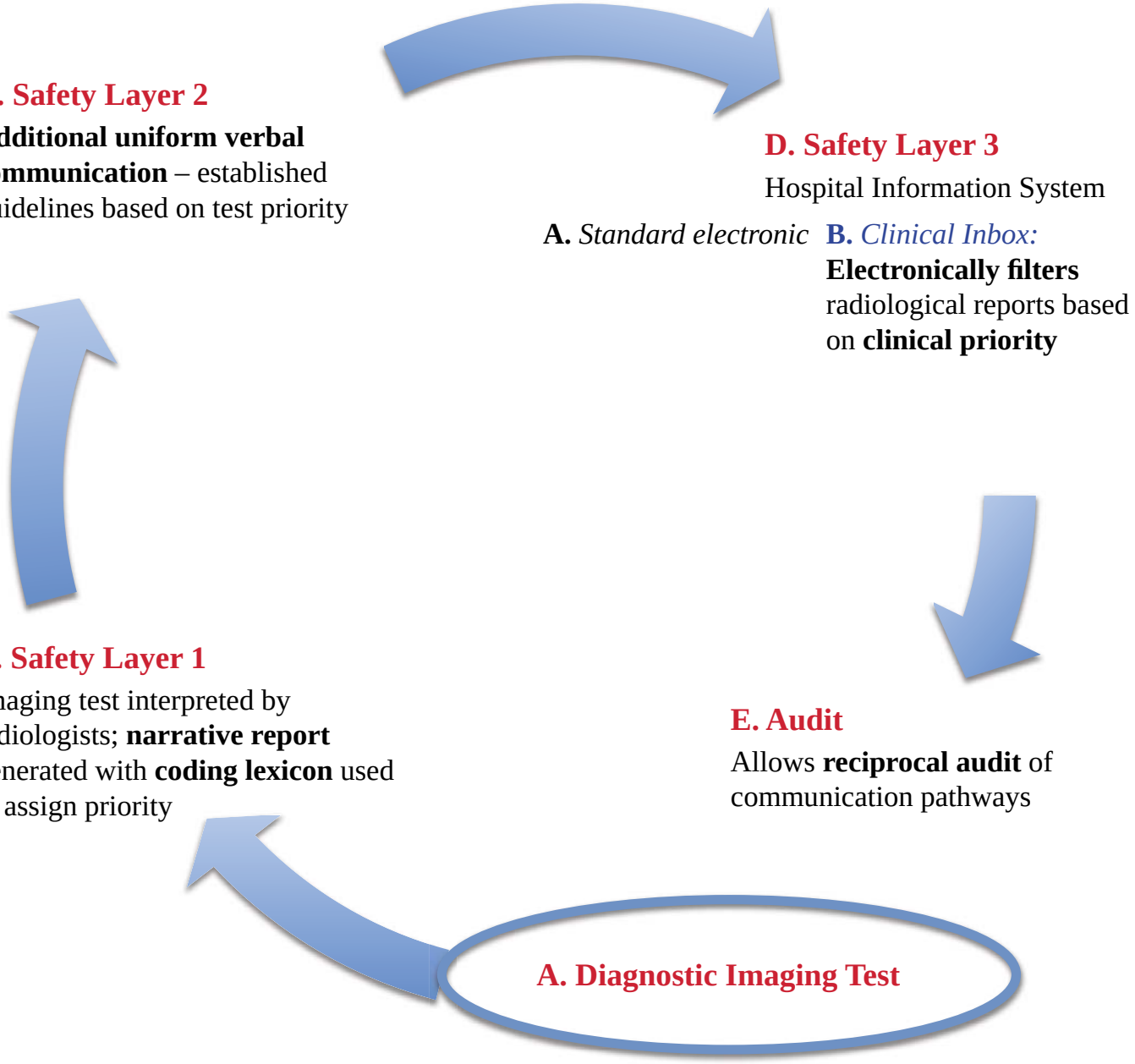
The current layered safety net method of communicating radiological reports is outlined overleaf.

Conclusion

With the help of our radiology and IT departments we have implemented a system for report communication. It is a layered system of safety nets.

1. We produce a report in a timely fashion through standard electronic and paper pathways.
2. We phone the referrer with significant findings.
3. We code unexpected or expected significant findings to reflect our concern for timely action and this deposits the report in a special priority folder on this hospital information system.

We anticipate this system is simply a first step and full uptake will require experience and change in result management



culture. It will be enhanced with moves towards the electronic patient record NIMIS/PACS and the inevitable incorporation of modern communication technology such as SMS and email. There will also likely be move towards more universal standards of practice nationally and internationally both for hospital and primary care settings.

I think it is clear that systems such as this will form the basis of QA and audit initiatives for diagnostics in the future, which will check that those ordering tests check all those results and act upon them whilst those producing the results communicate them in a timely and effective manner.

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Quality Assurance (QA) progress in key diagnostic areas

College makes significant progress in developing new approaches to supporting Quality Assurance in key diagnostic areas.

There are currently three National Quality Assurance (QA) Programmes in Histopathology, Radiology and GI Endoscopy led respectively by the Faculty of Pathology, RCPI, Faculty of Radiologists, RCSI and the Conjoint Board of the RCPI and RCSI. The programmes are managed by Royal College of Physicians of Ireland (RCPI) in collaboration with the National Cancer Control Programme (NCCP); National Cancer Screening Service (NCSS); the HSE Directorates of Quality and Patient Services, Integrated Services, Information and Communication Technology; the Department of Health and the Independent Hospital Authority of Ireland (IHAI).

The development of the QA Programmes arose from the recognition by the Faculty of Pathology, RCPI, Faculty of Radiologists, RCSI and the Conjoint Board RCPI/RCSI that there were few formal measures currently in place to reassure the public that error is kept to a minimum and to demonstrate that Histopathologists, Radiologists and GI Endoscopists operate to the highest international standards. Recently at the second *Patient Safety First* Conference held in February 2012 Dr Tony Holohan, Chief Medical Officer of the Department of Health commended the QA Programmes for their medical leadership and commented "that they represent and will represent a radical meaningful change in quality assurance for the Irish healthcare system".

Programme Aims and Objectives

The QA Programmes aim to establish national QA frameworks that ensure patient safety and enhancement of patient care with timely, accurate and complete diagnoses and reporting. The QA Programmes will also provide evidence-based assurance to the public of the quality of Irish diagnostic services.

The objectives of the programmes are to:

- Develop QA guidelines in respective disciplines
- Identify key quality measures which
  - Are important to patient safety and patient care
  - Are a true indicator of performance
  - Contribute to service improvement
  - Are measurable and worth the effort
  - Are actionable
  - Have intelligent targets
- Support implementation with the development of ICT systems for the collation, review and reporting of data nationally
- Develop National Quality Marks
- Support the development of a culture of Quality Assurance

The benefits of the National QA Programmes will be improved patient care and public confidence in the diagnostic services covered, less need for large scale look backs, the identification of good practice and identification of areas requiring development.

QA Guidelines

The three QA Programmes have adopted a systems-based approach to quality assurance and have developed and published guidelines for the implementation of each of the QA Programmes. These guidelines outline recommended QA activities and associated Key Quality Indicators and are available to read online:

- Histopathology- www.rcpi.ie/Faculties/Pages/FacultyofPathologyQualityAssurance.aspx.
- Radiology - www.radiology.ie/practice/faculty-policy-and-procedure-documents/
- GI Endoscopy - http://www.rcpi.ie/News/Pages/NationalQualityAssuranceProgrammeinGastro-IntestinalEndoscopylaunchedatRCPI.aspx

The QA Programmes have participation from both public and private histopathology laboratories, radiology departments and endoscopy units. The implementation of the guidelines is supported through the QA Programmes and reports for review by the respective laboratory, radiology department or endoscopy unit will be provided.

At a glance reporting

An essential component of these three programmes is the development of web-enabled health intelligence systems to store, analyse, provide access and report on key quality data locally and nationally. These systems will allow individual hospitals to access and analyse their own data and generate reports.

The National Quality Assurance Intelligence System - Histopathology (NQAIS Histopathology) has been evolved to support the National QA Programme in Histopathology. A central database has been created to store the data exported from all the laboratories. This NQAIS system was designed, developed and deployed through collaboration between the RCPI, Health Intelligence Unit HSE, HSE ICT and the system developers OpenApp. It is based on the Health Atlas Ireland platform

created by Health Intelligence Ireland. Similar NQAIS Radiology and NQAIS Endoscopy ICT systems are also being developed for those programmes.

The reports generated by NQAIS have been uniquely designed to draw the eye towards areas of potential concern so that individual hospitals can review their quality, in both a local and national context, at a glance. Every row in the report summarises the story for each parameter using easy to read colour coded graphics and important numeric values. Figure 1 illustrates an example of a section of a report for turnaround times of Histology samples. The "diamonds" outlined in blue represent the spread of turnaround times for the hospital (white indicates above quality mark, yellow on quality mark, red below quality mark) in the context of the national pattern (grey diamond). The median turnaround time over a selected time window is shown in the trend plot both for the hospital and nationally.

A detailed Information Governance Policy which sets out how all quality data pertaining to individual laboratories will be governed, processed, stored, accessed and reported has been developed for all programmes.

Progress to date

The National QA programme in Histopathology was launched in 2009 and the QA Guidelines have been implemented in 34 hospitals with histopathology laboratories in Ireland. These laboratories are now performing QA and clinical audit activities as per the guidelines and capturing this QA activity in their laboratory information systems. As part of the Programme QA data will be extracted from local Laboratory Information Systems, encrypted and submitted to the NQAIS central database on a regular basis. The ICT system to extract data from the Laboratory information systems is currently being rolled out and tested at all participating hospital sites. To date QA data has been successfully extracted and validated from seven laboratories and they are now live and generating QA reports from NQAIS.

The National QA programme in Radiology commenced in 2010 and has published Guidelines and over 70 public and private radiology departments are conducting a number of QA activities. The ICT requirements specification for QA data collection, analysis and reporting is nearing completion. Documentation is being prepared for a public procurement by the HSE of the ICT systems to support the QA Programme.

The National QA Programme in GI Endoscopy, commenced in 2011, has published Guidelines which are being implemented in 37 public hospitals. Invitations to participate in the programme have also been issued to 17 private units. The ICT requirements specification to support the QA programme is also under development.

If you have any queries on this or any other aspect of the programmes please do not hesitate to contact the Acting Programme Manager, Judy Gannon at judygannon@rcpi.ie or on 01 8639768.

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Total Turnaround Time Histology

(# labs)	Median	Snapshot	Trend	Upr qtr	Lwr qtr	# outliers	% day 3	% day 5	% day 7	% day 10
(6) Total TAT Histology	4.50			11.0	3.0	3	28.79	59.09	62.12	71.21
(6) Small biopsy TAT	10			12.0	7.5	-	6.67	20.0	26.67	53.33
(6) GI endoscopic biopsy TAT	13			15.0	11.0	3	-	-	6.67	20.0

Figure 1. Example of a section of a NQAIS Histopathology report.
Please note the figures and quality marks used in this diagram are mock and for the purposes of illustration only.

Case Report - Postoperative complications

Helene Engelstoft, Clinical Claims Manager, State Claims Agency

High Court Judgment of Ms Justice Irvine delivered on November 25th, 2011. Case of Paul Hegarty and Mercy Hospital Cork.

The plaintiff, a 34 year old man with a history of ulcerative colitis, developed a toxic megacolon with a risk of developing perforation and potentially fatal peritonitis. He required an emergency subtotal colectomy which was performed on February 12th 2007. A major part of the plaintiff's large bowel was removed and the rectal stump was closed off. An ilostomy was fashioned from the small bowel and the plaintiff was left with a stoma in the abdomen supporting a colostomy bag.

Six days after his operation, he became quite ill and on February 18th he had an exploration under general anaesthetic. He had developed a rare but well established complication, namely a leak from the rectal stump which caused a pelvic abscess and this infection in turn had caused the plaintiff's wound to breakdown. He underwent extensive surgery and approximately twelve further procedures to eradicate the infection.

A pelvic swab taken on February 27th was reported positive for MRSA on March 1st and the Plaintiff was isolated. The Plaintiff was already taking linezolid among a wide range of antibiotics, since the 26th February, to which MRSA is considered to be sensitive.

Seven to ten days prior to his discharge, the Plaintiff was made aware that he had a least one negative MRSA test result and that he required three negative results to no longer be a risk in respect of MRSA. As of the date of discharge on the 5th April 2007, he had had three negative MRSA test results which were communicated to him.

The Court was asked to consider two issues in respect of liability:

1) Was the defendant negligent in failing to properly appraise the plaintiff of the complications of the first surgical procedure?

The judge was satisfied that the plaintiff had been fully informed of the complications which arose from his initial surgery. She found that there was no effort on the part of the defendant to conceal the rare but well recognized complication.

It was accepted that the surgeon had met with the plaintiff post surgery on four occasions and had fully explained the findings in terms which he ought to have been readily able to understand.

Having regards to the intrusive nature of the ongoing procedures which followed, the judge could not accept that the Plaintiff was not informed of the nature of the complications.

2) Was the defendant negligent in adequately advising the plaintiff of the significance of the MRSA positive finding? Did the defendant post 1st March mislead the Plaintiff into believing that he continued to have MRSA infection until the date of his discharge from the hospital?

The judge accepted that the surgeon had a lengthy meeting with the Plaintiff during which we explained the significance of this result. At no stage was the Plaintiff given any information that MRSA had been responsible for any of the complications encountered following his subtotal colectomy.

Judge Irvine highlighted that the pleadings were premised upon the existence of some type of conspiracy on the part of the defendant to hide from the Plaintiff the true nature of the complications which were discovered in the course of the second operation. This argument was later not pursued.

Causation

If the Plaintiff came to the conclusion that any of the complications arising from his original surgery were caused by MRSA or that MRSA was a significant contributing factor to the resolution of those complications, those concerns were not caused by any positive act or omission on the part of the defendant.

Breach of Duty

There was no failure by the defendant to keep the Plaintiff fully informed regarding his medical condition, or to cause him to come to an erroneous view of his complications or the significance of his MRSA infection. Regardless of whatever drug regime he was administered he had to be treated in isolation and could not be reassured about his status until he had had three negative results.

Damages

Judge Irvine said that had she found in favour of the plaintiff she would still have had to dismiss the claim because he had not established that he sustained a compensatable injury. The plaintiff had suffered high levels of anxiety when he was diagnosed as being MRSA positive. Negligence is not complete until an alleged breach of duty goes on to cause damage to the extent recognized by law ie. a recognizable psychiatric injury.

The case was deemed to be an wholly unmeritorious, unjustified and unwarranted attack on the medical and nursing staff of the defendant hospital who at all times provided him with excellent care over a period when his life and health were at grave risk without which he might not have survived.

The plaintiff has appealed the judgement.

NOTICE BOARD

Launch of eTraining Module

The State Claims Agency has, this month, launched its eTraining modules for the STARSWeb system. The SCA is pleased to announce this significant development.

We have added eTraining to allow you to provide training to new users at their desk in a convenient and cost effective manner.

The modules have been designed and recorded to replicate the live training environment and have been recorded, produced and numbered 1 - 8, mirroring how they would be presented during an inputting training session.

This format gives full control of the training session to the potential new user in being able to rewind, pause and forward the session.

They are also a source of reference for existing users.

We are interested to get your feedback on the eTraining modules, and all comments are welcome.

Comments and Submissions

can be forwarded to
info@stateclaims.ie

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

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