New Minister for Health - Reforms to Come

As was widely predicted, Dr James Reilly TD has been appointed Minister for Health in the new coalition Government. Dr Reilly, who was first elected to the Dáil in 2007, has held the position of Fine Gael health spokesperson for a number of years. In July 2010, he was appointed the deputy leader of Fine Gael.

Dr Reilly promises to be a reforming Minister for Health as evidenced in his speech to the Fine Gael conference in Killarney on 19th March 2010 entitled “FairCare: Fixing the Irish Health Service”. In that wide-ranging speech, Dr Reilly promised to place the patient “at the centre of everything, making the patient number one”.

At the core of Dr Reilly’s FairCare reforms is the notion that “Money Follows the Patient”. He explained this concept as follows: “No longer will hospitals receive a budget for a year, so that when money runs out, operations cease, regardless of how efficiently or in-efficiently the money’s been used. The only people who suffer under this system are the patients”.

Dr Reilly envisages that each hospital will be paid per patient seen, per procedure performed, per surgery carried out. The emphasis will be that the health service will treat everyone equally, that everyone will be insured.

There is little doubt about the reforming principles of FairCare right across the health, public health and social care spectrum. These include the following:

- Health insurance companies, supported by State payments into a Risk Equalisation Fund, will be obliged to provide a comprehensive range of services and treatments, by way of an insurance package, to every resident at the same price, irrespective of age and health status.
- Hospitals will be governed by local hospital trusts and become more responsive to the needs of their local communities.
- New primary care centres will be established to serve local communities.
- The State will retain responsibility in respect of the provision and procurement of long-term ‘care services’, including the delivery of long-term care for older people, disability and mental health services and children and family services.
- A more streamlined Department of Health will have key responsibility for policy development and implementation, legislation and public health promotion in addition to a key role in the monitoring and evaluating of the performance of health and social services.
- A new Patient Safety Authority, which will subsume HIQA, will be established.
- The Health Insurance Authority will be integrated into the Financial Regulator and will be reconfigured to enable it to scrutinise, regulate and supervise the private health insurance market.

It is also suggested that the Minister will introduce and pilot a no fault compensation scheme for children who have suffered catastrophic birth injuries. The concept of a no fault compensation scheme for children who have suffered catastrophic birth injuries has been around for some time now. The No Fault Working Group, which considered this topic for a number of years, has not yet reported. There is little doubt that this is a complex area and one which will merit a great deal of detailed consideration. It is this Agency’s experience that families caring for a catastrophically birth injured infant receive inadequate care packages, generally, from the State and this is recognised by the courts when awarding large special damages in relation to the cost of future care, aids and appliances etc.

The new Minister faces some considerable challenges as he seeks to push through the major health reforms as set out in the FairCare document. This is particularly so, having regard to the sheer size of the Government’s fiscal challenge and the foudroyant banking crisis. The Minister is to be commended, however, for the wide-ranging reforms and he has the best wishes of all as he seeks to introduce necessary reforms to transform the delivery of our health services.

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Prescribing and Administration of Known Allergens

All enterprises indemnified by the Clinical Indemnity Scheme (CIS) are required to notify clinical incidents and near misses to the agency using the STARSWeb system. During the period January 1, 2004 - December 31, 2010, a total of 35,510 events relating to medication safety were reported. 751 of these were categorised as “adverse/allergic reaction to a known allergen”. Prescribing and/or administration of Augmentin® or Tazocin® in known penicillin allergy accounted for 149 of these events.

124 claims relating to medication safety were intimated during this period, of which 33 arose as a result of prescribing/administration of a known allergen, i.e. over one quarter of all medication-related claims. This led to fatalities in 4 patients, 2 of which were accounted for by administration of Augmentin® or Tazocin® to a known allergen. This led to fatalities in 4 patients, 2 of which were accounted for by administration of Augmentin® or Tazocin® to a known allergen. A further number of patients experienced significant morbidity leading to admission to Intensive Care Units and increased length of stay in hospital.

**Medication involved in Fatal Anaphylaxis**

An analysis of fatal anaphylactic reactions to medication over a 10 year period in the United Kingdom found anaesthetic agents, principally neuromuscular blockers, responsible for the largest number of deaths, followed by cephalosporins, penicillins and contrast media (Table 1). This study includes reactions to known and previously unknown allergens.

### How to reduce the risk

1. **Ensure patients understand their allergies**
   Patients must be aware of the medication(s) to avoid and the nature of their reaction and carry this information with them, e.g. in a Medic-Alert bracelet or similar. Referral to an allergy clinic may be helpful, particularly where there is doubt as to which medication a patient is allergic to.

2. **Check allergy status immediately before prescribing, dispensing or administering medication: Every drug, every patient, every time**
   Failure to consider allergies when prescribing, dispensing or administering medication is the crucial contributory factor to this error type. A shift in practice is needed to ensure allergy status is considered at the essential point, i.e. immediately before prescribing, dispensing or administering any medication. A known allergen was prescribed and/or administered, despite the allergy being documented on the front of the Prescription and Administration Record in 63 of 66 reported incidents/near misses in an Irish teaching hospital.

3. **Check reliable references for cross-allergies**
   Referring to reliable drug references, e.g. British National Formulary or Summaries of Product Characteristics (product information) on [www.imb.ie](http://www.imb.ie) or [www.medicines.ie](http://www.medicines.ie), is necessary.

4. **Document/Record allergies to medication**
   Lack of availability/accessibility of reliable information regarding patient’s allergy history at the point of prescribing, dispensing or administering medication can result in this error type. This may be due to the patient’s record/documentation being inaccessible, incorrect or incomplete, or when the patient is not able to communicate or their knowledge is incorrect (e.g. state allergy to the wrong medication) or incomplete (e.g. unsure of nature of the reaction or to which medication).

The Drug Prescription and Administration Record and all prescription forms should include a section to document allergies/intolerances to medication. The allergy section should always be completed, with the allergy or NKDA (No Known Drug Allergies) before prescribing and/or administering any medication.

### Drug Class Number Agents involved and numbers of fatalities

<table>
<thead>
<tr>
<th>Drug Class</th>
<th>Number</th>
<th>Agents involved and numbers of fatalities</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anaesthetic</td>
<td>35</td>
<td>19 suxamethonium, 7 vecuronium, 7 “at induction”, 6 atracurium</td>
</tr>
<tr>
<td>Antibiotic</td>
<td>27</td>
<td>12 cephalosporin, 10 aminopenicillin, 2 amphotericin, 1 benzylpenicillin, 1 cipfloxacin, 1 vancomycin</td>
</tr>
<tr>
<td>Other drugs</td>
<td>15</td>
<td>6 NSAIDs, 5 gelatins, 3 ACE inhibitors, 2 protamine, 2 vitamin K, 2 acetazolamide, 1 etoposide, 1 pethidine, 1 dexamethase, 1 streptokinase, 1 local anaesthetic</td>
</tr>
<tr>
<td>Contrast Media</td>
<td>11</td>
<td>9 iodinated, 1 technetium, 1 fluorescein</td>
</tr>
</tbody>
</table>

Table 1. Deaths caused by drug-related anaphylaxis in the UK between 1992 & 2001
Allergy wristbands are used in some hospitals as an extra warning that a patient has an allergy. They should act as a trigger to confirm the allergy status with the patient or to review the allergy history on the patient’s chart. The efficacy of this strategy varies and care must be taken if implementing this to ensure that it has maximum impact and avoids the problems identified in many areas, e.g. failure to consider wristband warning when prescribing and administering known allergens, confusion with other wristband alerts, failure to apply wristbands, lack of clarity regarding responsibilities to apply wristbands.

5. Maximise the impact of computerised systems

Computerised prescribing systems can eliminate the risk of this error type, if they are configured to:

a. Require the entry of allergies or NKDA (No Known Drug Allergies) before the first medication is prescribed.
b. Cross-reference allergens with alerts to prescribers if an allergen is prescribed.
c. Ensure that alerts cannot be overridden or, that they can be overridden only if the allergy status is updated (e.g. if documented allergy status was incorrect).

However, if systems are not configured in this way, healthcare professionals may rely on them to prevent the errors with known allergens and an error may therefore not be intercepted by the computerised system.

6. Treatment of anaphylaxis

Rapid diagnosis and evidence-based treatment of allergies and anaphylaxis can minimise the impact on the patient. Anaphylaxis to medication can be rapidly fatal. Analysis of fatal anaphylactic reactions included 21 patients who suffered reactions to drugs. They found anaphylaxis occurred a median of 5 minutes following contact with the drug (range 1-120 minutes), with immediate deaths in 10 and delayed deaths in 11. Shock without respiratory compromise occurred in 12 of the 21 drug-related anaphylactic deaths. Pulmonary oedema was present at post-mortem in 18 of 21 deaths, but in many cases of fatal anaphylaxis, no specific findings are present at post-mortem.

- Ensure that treatment guidelines are accessible, clear and that healthcare professionals are trained in their use.
- Ensure that facilities for the treatment of anaphylaxis (including availability of oxygen, adrenaline for intramuscular injection, chlorphenamine, hydrocortisone and intravenous fluids) are available in all areas that medication is administered.

Is it a “True” Allergy?

Occasionally, a patient may believe that they have an allergy or intolerance, but the history is inconsistent with this. Healthcare professionals may be faced with a dilemma, as using the medication may risk a serious or fatal adverse reaction or anaphylaxis, while avoiding the medication unnecessarily may lead to the use of more expensive and less effective drugs. In this circumstance, healthcare professionals must ensure that medication is not prescribed, dispensed or administered unless the following process is followed:

a. The allergy or intolerance has been ruled out (this may include allergy testing where available).
b. A discussion has taken place with the patient detailing the risks and benefits of proposed treatments and alternatives.
c. The patient expressly agrees to receiving treatment with the proposed medication.
d. The discussion with the patient and risk/benefit consideration is documented in the Healthcare Record.
e. All documentation of the allergy is amended to indicate the patient’s true status.
f. The patient (and/or parents, carers) and healthcare professionals providing care to them (e.g. GP, nursing home, hospitals) are informed of the updated information.

Further Information

The Irish Medication Safety Network is preparing “Best Practice Guidelines for Reducing Preventable Harm to Patients with Known Drug Allergies in Irish Hospitals”, which will be available shortly on their website, www.imsn.ie

References

2. Personal communication, 2010

Ciara Kirke, Medication Safety Co-ordinator Adelaide & Meath Hospital Dublin, incorp. the National Children’s Hospital, Tim Delaney, Programme Lead, Medication Safety, Quality & Clinical Care Directorate, HSE, and Dr. Ailis Quinlan, Head of the Clinical Indemnity Scheme

Medication Events reported to the State Claims Agency (Jan - Dec 2010)

- Incorrect Dosage: 42%
- Missed Medication: 18%
- Incorrect directions/labelling: 11%
- Incorrect Medication: 15%
- Medication on admission/discharge/transfer incorrect or not reconciled: 10%
- Other Categories: 4%

n=6882
Heartbeat Symposium – 22 November 2010

On 22nd November 2010 a symposium, jointly organised by the Clinical Indemnity Scheme and the HSE, was held at Farmleigh House, Phoenix Park, Dublin. The aim was to bring together the people and the hospitals interested in improving heart attack care in Ireland through the use of Heartbeat.

The Heartbeat Programme is an Irish campaign to reduce deaths from heart attack by assuring best practice in the care of heart attack patients using the American Institute for Healthcare Improvement (IHI) methodology to achieve sustainable improvement. Heartbeat began in 2006 with 5 hospitals and expanded to 15 hospitals by late 2010. There were 75 delegates from 25 acute hospitals and 6 other institutions. Attendees included consultants and nurses from Cardiology & Emergency Medicine, Ambulance personnel and others involved in improving the care of cardiac patients.

Speakers included Dr David Vaughan, Clinical Director for Resource Utilisation HSE, who gave an outline of the history and methodology of the IHI and encouraged delegates to think about managing quality. The second speaker, Dr Siobhan Jennings, Consultant in Public Health Medicine, described the rationale and components of the Heartbeat programme, detailing the 8 evidence based areas of care along with the results over the 4 years since initiation.

The guest speaker, Dr Noeleen Devaney, Improvement Advisor and IHI Fellow from Northern Ireland outlined the improvement tools especially the use of the plan, do, study, act (PDSA) cycle emphasising the need to select the team and undertake small tests of change. She highlighted the need to openly share findings and results within a team fostering an improvement culture rather than a judgmental culture. There was time allocated for each of the 9 tables to work as a group selecting a problem area, establishing measures and to plan a test for change. In the afternoon there were six short presentations from the ‘coal face’ stressing the importance of communit-i-cations within hospital (Letter-kenny) and the place of information (Cork) in achieving high quality AMI care, the evolution of improvement in reperfusion from 2002 to current availability of Heartbeat as an aid (Wexford), the challenge of the shift towards primary angio-plasty (Connolly), early recognition of symptoms by patient and professionals (Mater) and a novel development testing the transmission of ECG from ambulance to Cardiology (Galway). Dr Jennings, in place of Prof K Daly, Clinical Lead for ACS Programme who was unable to attend, spoke about the Acute Coronary Syndrome programme within the Quality and Clinical Care Directorate. She gave an outline of what is envisaged for the ACS programme, the work to date, the approach to planning and the role of Heartbeat within the Programme.

Feedback from the day was positive with 95% of people who filled in evaluation forms (54%) stating that their expectations were met on the day and that they felt the event would either influence or change their practice.

In summary, this symposium focusing on improving heart attack care using Heartbeat, achieved effective networking across disciplines and regions of the country and fostered solution generation as well as acting as a training event.

Acknowledgements
Organisers and facilitators
Brendan Cavanagh, Dr Siobhan Jennings, Anne Marie Oglesby, Kate O’Donovan, Anne Sinnott, Kathleen Twomey, Brendan Cavanagh, Dr David Vaughan.

AMI Heartbeat committee

Chairs and Speakers:
Anne Carrigy, Dr Davida de la Harpe, Dr Noeleen Devaney, Dr Siobhan Jennings, Ken Maleady, Mary Morrissey, Anne Mc Shane, Anne Marie Oglesby, Paudie O’Riordan, Kate O’Donovan, Anne Sinnott, Kathleen Twomey, Brendan Cavanagh, Dr David Vaughan.

The results from the most recent Heartbeat bulletin combining the first 3 years data and the 4th year data (Oct 09 to Sept 10) show the following:

- Data on 1093 patients with STEMI collated from 13 hospitals (beginning with data from 5 hospitals in 2006)
- Average age was 62 years
- 75% male and 45% over 65 years of age
- 57% of admission out of hours (out of hours taken as outside Mon-Fri 9am-5pm)
- Aspirin on admission is achieved for 90% of patients in most hospitals
- Beta blocker on admission is achieved for 90% of patients in less than half of the hospitals
- Timely reperfusion therapy has varied over the first four years. Importantly some hospitals have achieved steady improvement over time while others have varied in this. This remains the biggest challenge.
- Aspirin and lipid lowering drugs on discharge is achieved for 90% of patients in most hospitals
- Beta blockers, inhibitors/ARBs and smoking cessation counselling (for smokers) is achieved for 90% of patients in less than half of the hospitals though this has improved considerably in the last year
- In-hospital mortality improved in the first 3 years but dropped in year 4: Year 1 - 12.4%; Year 2 - 7.3%; Year 3 - 5.4% and Year 4 - 8.25%

Note additional 4 hospitals joined the programme in year 4.
Research indicates that warning signs precede virtually every critical inpatient event

Numerous international studies found that between 30 per cent and 84 per cent of patients who suffer cardiopulmonary arrest show signs of deterioration in the 24 hours before the arrest. Other studies have also shown that up to 50% of patients admitted to ICU received sub-optimal care prior to ICU referral and that the referral is often delayed unnecessarily. If these signs are identified and managed appropriately, these deaths may be preventable.

The National ALERT™ Steering Group Committee invited delegates to attend a conference on November 4th 2010 to address the early recognition and treatment of the deteriorating patient. Members of the national steering group include Valerie Clarke - St James’s Hospital, Margaret Gleeson - Nenagh Hospital, Marie Horgan - St Luke’s Hospital Kilkenny, Dr John Kellett - Nenagh Hospital, and Anne Marie Oglesby - State Claims Agency.

The event was hosted and sponsored by the State Claims Agency and was held in Farmleigh House in Phoenix Park. The Deteriorating Patient Day aimed to introduce participants to the latest theories regarding patient safety with specific focus on the Deteriorating Patient. The programme specifically introduced the concepts of current Acute Medical Programme, situational awareness with regard to the recognition of the deteriorating patient; ALERT and Early Warning Scores, the establishment of Rapid Response Teams and formalised communication tools.

The conference was a combination of both didactic and interactive learning processes. The event was open to Senior Healthcare Managers, Clinical Leads, Consultants, Clinical Risk Managers, and Senior Healthcare Professionals from all disciplines. The faculty included Dr. Garry Courtney, Dr. John Kellett, Valerie Clarke, Gerry Allen, Anne Marie Oglesby, Margaret Gleeson, Marie Horgan and Eileen Relihan. Anne Marie Oglesby welcomed delegates and opened the day. Dr Garry Courtney gave an overview of the National Acute Medicine Programme which created the backdrop to developing such a study day. Dr John Kellett discussed the early recognition and treatment of the deteriorating patient. This was followed by a presentation by Valerie Clarke, Alert Coordinator for St James Hospital who discussed the concept Early Warning Scores and the need for ALERT training (Acute Life-threatening Events Recognition and Treatment). Gerry Allen discussed the establishment of a rapid response team/medical emergency team in South Infirmary - Victoria University Hospital in Cork and the effects such a team had on the outcome for patients’ survival following in-hospital cardiac arrest. Following lunch, which included a guided tour of Farmleigh House, there were 2 short presentations introducing some excellent hospital initiatives - Eileen Relihan Medication Safety Officer from St James Hospital introduced the Tabard System and Margaret Gleeson introduced an “Intensitiy of Care” tool developed in Nenagh Hospital. These were then followed with a presentation by Anne Marie Oglesby who discussed the need for structured communication in healthcare settings such as the SBAR Communication Tool. Delegates were then given the opportunity to use the various tools discussed and highlighted throughout the day via vignettes/scenarios requiring delegates to calculate early warning scores and to communicate their concerns regarding a patient’s condition utilising the SBAR format.

69 delegates representing 24 acute hospitals and 2 other institutions attended the day, with delegates being asked to complete an evaluation of the day. The response rate was 66.66% (n=46) of which 97.82% found the training to be either extremely or very relevant to their practice and 91.30% of the respondents felt that the training event would either influence or change their practice.

The day created lots of opportunity for discussion and networking, with many delegates expressing their intention of introducing these various initiatives to their respective organisations with the ultimate view of improving patient safety. All speakers have kindly given their permission to have their presentations available on-line and can be accessed via www.stateclaims.ie/ ClinicalIndemnityScheme/presentations.html.

References are available upon request.

Anne Marie Oglesby, Clinical Risk Advisor, Clinical Indemnity Scheme
On 20th May 2010, Mr Justice Quirke gave judgement in favour of the defendants in the case of Denis O’Leary v. Health Service Executive and Khalid M. Ali Chiad Al-Safi [2008/3328P].

Background
In early 2002, at Mercy University Hospital, Mr O’Leary was diagnosed with and treated for genitourinary tuberculosis. By August 2002, he was found to have no useful function in his left kidney. He was managed conservatively until early 2006 when his condition deteriorated.

A consultant urologist advised him to undergo augmentation cystoplasty. He explained that if Mr O’Leary did not undergo the surgery there was a real threat to his right kidney, with a consequent risk of his needing dialysis or a kidney transplant.

The consultant moved to another hospital before he could perform the surgery. Mr Al-Safi, locum consultant urologist arranged to review Mr O’Leary in his clinic on 12th April 2006. He discussed with him the risks and benefits of augmentation cystoplasty. In May 2006, Mr O’Leary underwent uneventful surgery. However, he was unhappy with his residual symptoms and sued.

The Claim
The claim was heard over 21 days at the High Court in Dublin. One of the key elements of Mr O’Leary’s claim was that the augmentation cystoplasty was performed without his informed consent because Mr Al-Safi failed to disclose to him all of the known facts, risks and alternatives associated with the surgery.

The Outcome
Mr O’Leary was unsuccessful in proving any element of his claim. For the purpose of this article our report is confined to the allegation concerning the absence of informed consent.

Mr O’Leary’s surgical experts gave evidence of the risks they said ought to have been discussed with him, which included the following:

Surgery may not relieve frequency, urgency and pain; may not provide an efficient emptying reservoir; was likely to require Mr. O’Leary to perform self-catheterisation for life; could result in bowel dysfunction, recurrent infections, stone formation, mucus production and blood electrolyte abnormalities.

Mr O’Leary gave evidence that his original consultant urologist told him he needed...
surgery to reduce the risk of kidney failure and the requirement for dialysis; that he would need to self-catheterise for a short time after surgery. He said he had asked if there was any alternative to surgery and was advised there was not.

He alleged that Mr Al-Safi pressurised him to undergo the surgery. In particular, that Mr Al-Safi told him the surgery would be of benefit to him; would avoid or reduce the risk of kidney failure; that it was a routine operation which would be 100% successful and following the surgery he would be perfect; would urinate every 5-6 hours and he would be able to sleep normally. Mr O’Leary gave evidence that had Mr Al-Safi told him of a risk of cancer he would not have undergone the surgery.

Mr Al-Safi gave evidence that he went through the risks and benefits of surgery with Mr O’Leary both in his clinic on 12th April; 2006 and in the ward on the eve of surgery. Following the review on 12th April 2006, Mr Al-Safi recorded the following entry in the chart and also communicated the same information by letter to Mr O’Leary’s GP.

Aug cyst explained fully to him: need for I.S.C.; noct wetness; bowel obst and re-exploration, need for post-op medications to control symptoms.

Mr Al-Safi gave evidence that, in addition to his written record above, he discussed with Mr O’Leary the nature and extent of the surgery; the significance of his having a small bladder and non-functioning left kidney; the consequent risk to his right kidney; the need for an increase in the capacity of the bladder; that the need for self-catheterisation might be permanent and life-long and that Mr O’Leary might need re-exploration surgery if there was a bowel obstruction or complication resulting from the surgery. He said that he also discussed the risk of nocturnal wetness, infection, stones and a very small but real risk of cancer, for which he would need annual review.

Having heard all the witnesses of fact and expert witnesses, Mr Justice Quirke found in favour of the defendants. In particular, he made the following finding:

I did not find [Mr O’Leary] to be a reliable or credible witness. I am not satisfied that he has established, on the evidence and on the balance of probabilities that Mr Al-Safi failed to advise him of all the known facts and risks associated with augmentation ileocystoplasty. I found Mr Al-Safi to be a conscientious witness and I believe that his account of the warnings which he gave to [Mr O’Leary] in respect of the risks associated with augmentation cystoplasty is probably an accurate and correct account.

Observations
As can be seen from this summary, it is not essential to record in the medical records every element of each communication with a patient during the process of obtaining a patient’s informed consent. However, our experience is that potential clinical witnesses in a medical malpractice claim are often relieved to find they have recorded detailed notes in the chart or in contemporaneous correspondence with GPs or others.

What must be remembered is that it is the nature of litigation for conflicts to arise between witnesses of fact in their recollection of events. In every case, the trial judge listens carefully to each witness and makes a determination as to the reliability and credibility of that witness and the weight to be attached to their evidence.

Siobhán Coleman, Solicitor
Clinical Claims Manager

(This decision is under appeal.)
Upcoming Event
The Clinical Indemnity Scheme (CIS) at the State Claims Agency invite you to attend

Systems Analysis Training
June 16th 2011
Farmleigh House, Phoenix Park, Dublin

Open to clinical leads, risk managers and healthcare managers.

There is no charge to attend this course however places are limited with booking essential.

Contact: joreilly@ntma.ie or 01 6448463 no later than Friday June 3rd 2011.

A Quality Initiative to share?
Have you a quality initiative that you would like to share, if so contact the Editor aduffy@ntma.ie
- Approximately 700 words
- Making a difference to delivery of care
- Project/study/initiative does not necessarily have to be complete

CIS Website Additions
The 2010 Statistics will be available to view and download in the near future at
www.stateclaims.ie

Comments and Submissions
can be forwarded to info@stateclaims.ie

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