Identifying Emerging Medical Indemnity Risk in Victoria
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1.1 What is the role of VMIA?

VMIA is the insurer for the State of Victoria. In this capacity VMIA is interested in identifying and monitoring emerging areas of risk. One area of interest is the public healthcare sector where emerging risk relating to clinical practice may lead to foreseeable medical indemnity claims.

VMIA works in partnership with public health services and other agencies to highlight areas of potential risk and develop strategies to minimise the occurrence and impact of harm to patients, health services, and the Victorian government. Accordingly, VMIA plays an active role across the Victorian public health sector in areas relating to:

- Risk identification and mitigation
- Incident notification and analysis
- Premium setting
- Claims processing and resolution

Areas of emerging risk are anticipated to have a significant influence on each of these areas and will therefore become an area of ongoing monitoring by VMIA.

The purpose of this paper is to highlight potential areas of emerging risk to develop strategies with Victorian hospitals to minimise the likelihood and impact of these risks upon consumers of public health services.

1.2 What are emerging medical indemnity risks?

To obtain compensation against a claim of medical indemnity, a consumer must successfully prove:

- That actual harm or injury has occurred as a result of medical intervention
- That the doctor owed a duty of care at the time of intervention
- That there was a breach of duty of care (negligence)
- That the breach caused the harm.

Many areas of potential risk are already known and or actively anticipated, however, despite careful monitoring, new risks are also likely to emerge.

Emerging risks can be defined as a potential but as yet unproven “changes in the likelihood of an unexpected or unwanted outcome occurring” (Burdon, 2008). In insurance terms, these risks may be potentially significant, but are not yet fully understood. Accordingly, emerging risks require proactive identification and ongoing monitoring to estimate their impact upon future claims, capital reserves and premium settings across the Victorian public healthcare system.
1.3 How are emerging risks related to claims?

The presence of clinical risk increases the likelihood of an adverse event. Adverse events leading to patient harm increase the likelihood of a medical indemnity claim. While a number of factors may lessen the chances of a patient pursuing a medical indemnity claim, the most fundamental strategy to reduce claims is to manage the occurrence of risk.

Foreseeable risks are those that can be reasonably anticipated based upon known patient characteristics, treatment complications and/or past experience. Emerging risks are less readily identifiable and require proactive consideration by health services.

1.4 How are areas of emerging risk identified?

Emerging risks associated with changes in clinical practice are by their very nature, difficult to identify. Areas of emerging risk that may lead to foreseeable claims of medical indemnity typically involve:

**Changes in clinical practice** associated with:

- Failure to comply with quality systems implemented to minimise patient harm
- Departures from evidence-based clinical practice
- The adoption of new approaches to standard practice
- The introduction of new practices or technology

**And/or changes in claimant behaviour** associated with:

- Public perceptions of safety or quality in care, increasing the desire to seek legal redress for unexpected outcomes arising from medical interventions
- Public awareness legal outcomes favouring compensation for specific types of claims.

Risks associated with the introduction of new technologies or clinical practices are usually assessed and monitored by health services (such as via training, supervision, and patient monitoring). Notwithstanding, any changes in clinical practice may also be subject to the re-emergence of known risk factors that can lead to medical indemnity claims, including but not necessarily limited to:
1. **Interpersonal behaviours** that discount or ignore a patient's experience.

2. **Failure or delays in appropriate diagnosis.**

3. **Provision of inadequate information** to actively involve patients in decisions about their treatment options and/or consequences (informed consent).

4. **Provision of inappropriate clinical training**, support and/or supervision to staff.

5. **Failure to identify and/or manage preventable complications** of procedures or other clinical interventions.

6. **Poor communication** to patients about treatment outcomes and subsequent care planning.

7. **Inadequate monitoring or follow-up** of patient progress to detect changes in outcome and plan appropriate interventions.

8. **Poor documentation** of clinical decision-making and patient outcomes.

To identify changes in clinical practice that might result in the re-emergence of risk factors for medical indemnity claims, a number of different sources of information must be examined, including:

- Current claims data
- Medical indemnity providers
- Medical defence lawyers
- The Office of the Health Services Commissioner
- Specialist clinical audit and advisory councils
- The Department of Health
- Emerging peer-reviewed literature
- Media publications
- Information published by organisations involved in claims litigation.

These sources have been investigated to highlight a number of areas that may be susceptible to an increase in indemnity claims over the next five years.
1.5 Which areas will be a focus of attention?

The following areas are presented to promote conversations with health services about the likelihood of potential risks associated with variations in, or departures from, standard clinical practice, and strategies that might be employed to minimise the impact of any potential harm to patients, clinicians and public hospitals across Victoria.

1.5.1 Hospital-Acquired Infection

Nosocomial infections are a significant public health problem in hospitals despite a range of infection control interventions. These infections cause delays in patient recovery from infections such as pneumonia, bloodstream infections, urinary tract infections and surgical site infections. At worst, hospital-acquired infections may contribute to patient mortality.

While it has been argued that a number of hospital bacteria are endemic in Australian hospitals and not preventable, it is generally acknowledged that certain strategies should be employed by hospitals to prevent both the development of antibiotic resistance and the spread of resistant organisms. Such measures include active hospital infection surveillance and control programs that attend to a range of issues such as timely hand-washing, aseptic techniques and adequate sterilisation/disinfection protocols. Other measures involve clinical interventions that consider prudent antimicrobial use, shorter hospital stays and minimal use (and early removal of) invasive devices.

Hospital-acquired infections are potential sources of medical indemnity claims where there is evidence of breakdowns in local infection control procedures. Several claims have already been made on this basis in the USA and UK. In addition, claims have also been raised from incidents where health services have failed to diagnose and treat hospital-acquired infections in a timely fashion. Accordingly, the number of claims associated with hospital-acquired infection is anticipated to increase.

1.5.2 Patient Suicide in Mental Health

Mental health sits within the top 10 high risk areas of medical indemnity claims managed by VMIA (VMIA, 2011). Media reports have drawn particular attention to issues of patient harm while receiving treatment by public mental health services. For example, The Age newspaper in Melbourne reported:

“[t] has in recent months exposed a series of alleged clinical failings regarding the deaths of 36 psychiatric inpatients in recent years. It has also exposed several attempts by health services to conceal information about inpatient deaths and sexual assaults from police and families” (The Age, 2012).

Investigations in Victoria and other jurisdictions have identified ‘patient absconding’ as a particular area of concern, with the potential to lead to harm of psychiatric patients while undergoing active treatment by mental health services.

Patient absconding (going absent without leave) from psychiatric wards is the first area of concern and one of the most common incidents reported by hospitals. In addition to loss of ongoing treatment, other negative outcomes of absconding have included violence to others, patient self-neglect, self-harm and suicide.
Up to 70% of psychiatric patient suicides have been reported to occur while patients have absconded from inpatient units. A number of claims have been brought against hospitals following episodes of absconding and/or suicide. These claims are expected to continue. It is also considered that claims relating to absconding and harm may increase, particularly if negative media reports foster inaccurate public perceptions about the frequency of absconding, and/or erode public confidence about the safety of patients in mental health facilities.

1.5.3 Tele-Health

Tele-Health can most conveniently be described as “healthcare delivered from a distance”. In its broadest definition, Tele-Health encompasses a broad range of services, including provision of health information and administrative support (Uniquest, 2011). Other specific uses include video consulting, Tele-monitoring (remote monitoring is the transmission of medical data for disease and injury management and prevention, such as the monitoring of patients undergoing dialysis, or support and care to patients with chronic conditions living at home), and Tele-education (the transmission of medical information, for the training of health professionals or consumers). Despite the existence of guidelines and standards for the use of Tele-Health, several medico-legal risks have been identified. These become more prevalent with untrained service providers, including physicians and staff, with no formal accreditation requirements for Tele-Health proficiency in existence.

Informed consent may be misunderstood if specific information is not provided to patients about the nature, benefits and risks associated with tele-consultation, and how information arising from the consultation may be disseminated. Patient confidentiality and privacy can be inadvertently compromised during the course of video consulting (“electronic eavesdropping”). Diagnostic errors may occur where there is overreliance on electronically transmitted data (such as for visual information or clinical observations made by non-specialist clinicians). Other issues regarding appropriate credentialing and visiting rights must also be clarified for doctors providing tele-consultation to specific health services. Clarification of responsibility for follow-up treatment and documentation of clinical consultation processes, must also be carefully considered.

1.5.4 Perineal Tears

Perineal trauma, specifically spontaneous tears, occurs in up to 43% of vaginal births. Anal sphincter ruptures (also known as fourth degree lacerations) occur in up to 2% of vaginal births. Such trauma may result in ongoing pain, emotional discomfort and distress and, in anal sphincter ruptures, faecal incontinence. Women giving birth for the first time (primiparas) are more likely to experience serious lacerations.

It has been suggested by some that the increasing rate of perineal trauma, particularly spontaneous first-and second-degree lacerations, has corresponded with a decrease in episiotomy rates. A range of other factors has also been suggested to contribute to an observed increase the risk of laceration, including the more widespread use of the “hands-poised” approach to delivery.

If rates of perineal trauma continue to rise, it is likely that this will lead to an increase in medical indemnity claims. In addition, delays in timely and appropriate recognition, classification and repair of perineal tears have also been reported to influence the likelihood of subsequent medical indemnity claims.
1.5.5 Mesh Surgery

Vaginal mesh surgeries using non-absorbable meshes have become popular in recent years to treat pelvic organ prolapse and stress urinary incontinence. The mesh devices act like a hammock or sling to support pelvic organs. In Australia, vaginal mesh was granted Therapeutic Goods Administration (TGA) approval in August 2008.

A number of complications are known to be associated with mesh surgery including mesh shrinkage, tissue erosion, infection, and malposition, in addition to a range of functional impairments depending upon the surgical site involved.

In 2008, the US Food and Drug Administration published an alert regarding trans-vaginal placement of surgical mesh, after receiving more than 1,000 reports of complications (FDA, 2008). Similarly, the National Institute for Clinical Excellence (NICE, 2008). While improvements in mesh technology and surgical application have appeared in more recent years, others have suggested that these procedures should be considered experimental.

An increase in the number of claims associated with vaginal mesh surgery, has already been observed across Australia. Assuming a doctor uses the mesh for a purpose approved by the TGA, it appears most likely that problems with informed consent will influence the likelihood of subsequent medical indemnity claims. Accordingly, particular emphasis should be placed upon counselling patients on all aspects of the procedure, including all benefits and risks, especially where a new device is used without sufficient published safety or adverse outcome data.

1.5.6 Robotic Surgery

Robotic surgery is a surgical tool that facilitates complex laparoscopic surgical procedures. It is not capable of independent movement, but responds to the surgeon’s commands via an advanced remote-control system, using hand and foot controls. Sitting at a separate console, the surgeon manipulates the robot’s camera and instrumentation, and thus perform precise laparoscopic surgery.

The most commonly performed robotic surgery procedure worldwide is robotic-assisted laparoscopic radical prostatectomy (robotic prostatectomy). Other procedures that have been performed using robotic-assisted surgery include anterior resection for rectal cancer, hysterectomy, partial nephrectomy, radical cystectomy for bladder cancer, and selected head and neck cancers. Although robotic surgery has been reported to reduce morbidity and hospital stay when compared to conventional open surgery, its superiority over conventional surgery remains unproven.

A number of potential medico-legal issues have been associated with robotic surgery including, surgeon inexperience resulting in patient injury, and lack of information provided to patients to enable sufficiently informed consent. Other issues may foreseeably relate to the duration of patient immobilisation and the level of active patient monitoring that is required to ensure that preventable harm is avoided (eg tissue necrosis).
1.5.7 Fly-In-Fly-Out Surgery

Fly-In-Fly-Out (FIFO) medicine mainly relates to surgical services provided to rural or remote areas, where a specialist surgeon and perhaps anaesthetist and other theatre staff arrive, deliver the service and leave, with shared aftercare provided by a more general surgeon, resident general practitioner or other appropriate team member. The Royal Australasian College of Surgeons (RACS) has indicated that this is the least preferred method of providing regional surgical services (RACS, 2005).

A range of procedures are typically performed under FIFO arrangements, including colonoscopies and gastroscopies, cataract extraction, cystoscopies, minor gynaecological procedures, and minor general surgery (such as removal of lesions).

While it can be argued that FIFO provides access to health services that remote residents would not otherwise have, there are potential medical indemnity risks. In particular, aftercare following the departure of the treating specialist may be a source of claims, particularly if complications arise with which the GP or other local doctor is not familiar and access to specialist advice or follow-up interventions is unavailable or delayed.

1.5.8 Management of Overweight/Obese Patients

Recent Australian data has indicated that around two in every three males and half of all females are either overweight or obese (Australian Bureau of Statistics, 2011). Other studies indicate that these figures may be higher. Overweight and obesity are associated with an increased risk of a number of co-morbidities, including cardiovascular problems, deep venous thrombosis, Type 2 diabetes, some cancers, knee and hip problems, and sleep apnoea. The practical management of overweight/obese patients presents an increasing challenge for hospital staff in relation to the technical complexity of medical and surgical interventions, the course and duration of patient recovery, the availability of appropriate hospital equipment and the maintenance of safe working practices.

Data from the USA has reported an increasing number of claims based on failures by doctors to monitor, treat or educate patients regarding the risks of their obesity. Medical specialties most frequently involved included obstetrics/gynaecology, gastroenterology, internal medicine, geriatric medicine and pathology.

In obstetrics, complications arising in obese women can include gestational diabetes and hypertension, and difficult deliveries involving macromomic (weighing more than 4.5kg or 10lb) infants. In the USA, some obstetrician/gynaecologists now refuse to treat women weighing more than 91kg because of medical indemnity risk. For overweight/obese patients undergoing surgery, risks of complications such as renal failure, wound complications and prolonged hospital or intensive care stay and even death are increased, especially in more severely obese patients. This risk is heightened by the presence of co-morbidities.

It has been suggested that additional attention be paid to a number of areas in relation to management of overweight/obese patients to reduce the risk of complications and subsequent indemnity claims. Areas for additional consideration have included (but are not limited to) explanations about risks and complications relating to patient weight, recommended delays in treatment (pending appropriate weight loss), pre-operative anaesthesia, technical challenges of particular procedures (including patient manipulation or handling), the availability of appropriate equipment, the availability of staffing and equipment to manage intra-operative or post-operative complications, and the need to consult with other specialists to advise on potential issues, complications and/or management strategies.
1.5.9 The Deteriorating Patient

A range of measures has been developed to deal with the deteriorating patient. These include protocols for measurement and documentation of observations and escalation of care, use of formal handover protocols and mechanisms for providing a rapid response when clinical deterioration occurs. Issues associated with management of the deteriorating patient have been previously described in recent VMIA publications (VMIA, 2011). Despite these measures, it is recognised that suboptimal care of deteriorating hospitalised patients still occurs, resulting in higher rates of adverse events and mortality than may reasonably be anticipated.

Major issues relating to medical indemnity relate to failure or delays in patient diagnosis and compromising timely and appropriate intervention. It has been suggested that a greater focus be placed on earlier components of the deteriorating patient pathway, including measurement and documentation of vital signs and appropriate escalation of patient care. Other factors impacting on the capacity to respond to patient deterioration, include poor communication between health professionals (for example when patients are moved between departments or hospitals), failure to address language and cultural barriers preventing communication of symptoms by the patient, lack of accountability where a patient is under the care of more than one treating team, and levels of staff experience in managing patients with particular conditions. In addition, failure to clarify advanced care planning arrangements with patients may also lead to inappropriate interventions and increase the subsequent risk of potential medical indemnity claims.

1.5.10 Patient Falls in Hospital

Accidental falls are the most commonly reported patient safety incident in hospital settings. In Australian hospitals, patient falls comprise 38% of documented adverse events. Between 30% and 40% of falls result in injury, such as soft tissue injury (e.g. bruises, lacerations), cranial trauma and fractures. It is estimated that 1–3% of falls in hospital lead to fractures (Oliver D, Killick S, Even T, Willmott M, 2008). In addition to the physical trauma, patients who fall may also experience fear of falling and anxiety, which in turn can often cause loss of self-confidence in mobility tasks and decline in function. Other outcomes resulting from falls have been reported to include increased length of in-hospital stay, functional decline, increased mortality and litigation claims. Despite the overall frequency of falls, clinical negligence claims have historically represented a very low proportion of the total number of claims in countries such as Australia.

Notwithstanding, claims resulting from falls-related injuries have been brought against hospitals in other overseas jurisdictions for some time, and have also been a focus of more recent legal attention in Australia. Medical indemnity claims have arisen where there is evidence of breakdowns in falls risk management protocols, (including provision of appropriate equipment, environmental modifications and supervision or timely attendance by hospital staff). Claims may also arise where health services fail to diagnose and treat falls related injuries in a timely fashion. Accordingly, the number of claims associated with falls causing injury to patients will be an area of ongoing monitoring.
1.5.11 Electronic Health Records Management

E-Health refers to the use of electronic or computerised systems within health services for the purposes of medical record documentation or medication prescription. Some perceive that the use of electronic medical records (E-Health) will assist in reducing future medical indemnity risk by improving service provider communication, and access to relevant clinical information. There is also evidence that modern health information technology can improve documentation (both legibility and completeness), enhance follow-up of abnormal tests, provide clinicians with relevant guidelines at the time of ordering treatment and minimise medication errors.

The electronic transmission and storage of patient data has raised a number of medico-legal concerns. These include protection of patient privacy and confidentiality, concerns about the capacity to access relevant information by service providers and issues relating to the timeliness and accuracy of documentation. Additional concerns have been raised about the potential for errors to occur if health care personnel are unfamiliar with new electronic documentation (and/or treatment ordering) systems in hospitals including delays and/or errors in administering appropriate treatments to specific patients.

1.5.12 Public Perceptions of Hospital Performance

Public perceptions and expectations about access to services and the outcomes of service delivery are changing. Attitudes towards the provision of public health services are influenced by frustrations obtaining care, critical media coverage about the alleged quality of care at individual health services and increased awareness of medical indemnity lawsuits – causing more people to believe they have claims worth pursuing. This is reflected in the increasing number and cost of claims for “nervous shock” identified by VMIA.

There is growing awareness that mistakes do occur in medical practice and that these mistakes may have serious consequences. This awareness is fed via media publications, reports by government agencies and peak bodies and by information freely available on the internet, including websites maintained by solicitors working in the area of medical indemnity.

Given the numerous sources of information bringing medical error to public notice and highlighting consumer rights, the public is now much more aware of the fallibility of medical diagnosis and treatment and the possibility of bringing legal actions against hospitals and health professionals.
1.6 How will VMIA assist in managing areas of emerging risk?

VMIA will contribute to the future identification and proactive management of emerging medical indemnity risks through the following strategies:

1. **Monitoring key indicators** relating to incident notifications, rate of claims and claims costs in areas of potential risk to public health services.

2. **Identifying emerging evidence** from trends in litigation, published information and conversations with bodies involved in minimising the impact of adverse events.

3. **Establishing priority areas** for organisational attention through VMIA’s Strategic and Emerging Risk Committee.

4. **Supporting strategic projects** to manage risks in designated priority areas.

5. **Broadening engagement with health services** to discuss the likelihood of emerging risks and local responses to minimise their potential impact.
References

The Age, State's failings over deaths, 18 February 2012.


