

# The Medico-Legal Implications of Guidelines

Medico-Legal Session  
World Congress of Internal Medicine  
23 March 2010  
7.45-8.45am

# Outline

- Professor Carolyn Sappideen:
  - The “required standard of care”
  - Key court decisions and recent liability reforms
- Dr Hugh Aders
  - Role of experts v guidelines in medico-legal assessments
  - Impact of guidelines on Courts, Tribunals, and Insurers
- Dr Marie Bismark
  - Implications for clinical practice
  - Medico-legal future of guidelines

# Medical Negligence: 5 areas

1. **Compensation** claims: tort of negligence  
(replaced by no fault compensation in NZ)
2. **Consumer rights**: services must be rendered with reasonable care and skill
3. **Professional misconduct**
4. Statutory **duty to report** “flagrant departure” from professional practice standards
5. **Criminal** negligence: manslaughter

# Medical negligence - Standard of care

*“The standard of care to be observed by a person with some special skill or competence is that of the ordinary skilled person exercising and professing to have that special skill” (Rogers v Whitaker 1992)*

# Medical Negligence – Standard of Care

- Tailored to skill that practitioners hold themselves out as possessing. For example:
  - *Melchior v Syd Adv Hosp* (specialist foot and ankle surgery)
  - *Marko v Falk* (specialist upper GI endoscopist at 3° centre)
- Judged at time of alleged negligence and not in light of subsequent knowledge; serious risks of hindsight bias
- Reasonable standard not best practice
- No allowance for inexperienced (*Imbree*)
- Difficult where team treatment (*Wilsher*)

# Professional standard: common law

- Defendant is not negligent if he or she:
  - “acted in accordance with a practice accepted as proper by a responsible body of medical men skilled in that particular art. [He or she is not negligence] merely because there is a body of opinion who would take a contrary view” (*Bolam v Friern Hospital 1957*)
- “*In short, the law imposes the duty of care but the standard of care is a matter of medical judgment*” (*Sidaway 1985*)
- BUT peer opinion must “*withstand logical analysis*” and adequately assess risks and benefits (*Bolitho 1997*)

# Professional standard: Civil liability reform

- Civil Liability Act NSW allows for differing opinions and does not require universal acceptance of a practice  
*“A [professional is not liable] in negligence ... if ... the professional acted in a manner that [at the time] was widely accepted in Australia by peer professional opinion as competent professional practice.”*
- Similar provisions in Qld, SA, Tas, Vic, WA; no provisions in ACT and NT; no equivalent NZ
- Cannot be relied upon “if ...opinion is irrational (Vic, unreasonable)”

# Patient-centred standard: Informed consent

- Importantly, the professional standard does not determine negligence in duty to warn cases (*Rogers v Whitaker* 1992)
- Principle of autonomy - duty to warn of material risks:  
*“evidence of acceptable medical practice is a useful guide for the courts, (but) it is for the courts to adjudicate on what is the appropriate standard of care after giving weight to the paramount consideration that a person is entitled to make his own decisions about his life”*
- Unchanged by civil liability reforms - professional standard does not apply to duty to warn cases

# Professional standard: *Black v Lipovac* case

- In 1977, GP prescribed aminophylline suppository for a child with moderate asthma, resulted in brain damage
- Drug considered dangerous by substantial body of medical opinion; many GPs used only in hospital or extreme cases
- Court held Dr Black liable despite the view that:
  - “*some quite respectable medical authorities would have found nothing wrong with Dr Black's treatment. ...However, if a practice is flawed, it is the duty of the courts to say so.*”
- Today, the statutory test is whether peer opinion regards the practice as competent practice (not ACT, NT); Dr Black may have satisfied the statutory standard unless peer opinion was “irrational” (Vic “unreasonable”). Was it?

# Professional standard: role of guidelines

- In treatment and diagnosis cases, “reasonable standard” is determined by reference to professional practice
- Evidence of expert witnesses is tested and supported by medical evidence and literature
- Guidelines are influential but not conclusive:
  - Compliance with guidelines supports a finding of no negligence unless conduct was irrational/unreasonable (Vic)
  - Failure to comply with guidelines promotes settlement, but does not automatically establish negligence, must be justified

# Criminal Negligence: Manslaughter

- 1 conviction for med manslaughter in 1843 (Dr Valentine)
- 3 charges since 1990, Patel current
- Requires high degree of negligence:  
*“mere negligence will not do, there must be wicked negligence...negligence so great, that you must be of the opinion that the prisoner has a wicked mind....she was reckless and careless whether the creature died or not.”*  
(*R v Taktak* 1988 NSW)

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# Defence Organisation's Perspective

Some case examples

- Civil proceedings
- Complaints and Medical Boards

Have Guidelines improved standards of care?

- Anaesthetic hypoxic episodes

Summary

# Case 1

- 20 year old female presented to Accident and Emergency
- Diagnosed with “reactive polyarthrititis”; prescribed Indocid
- 2 weeks bed, malaise, vomiting,
- After Hours Locum Service GP: “viral illness”
- 1 week later, same GP locum: “viral illness” see local medical officer next am for blood tests
- 4 days later GP ? renal failure → hospital
- Kidney biopsy diagnosed Wegener’s granulomatosis
- Dialysis and renal transplant

# Case 1

- Sued hospital A&E and GP locum
- Expert report GP experienced as after hours locum
- Standard of care up to what expected
- Role of triage and referral
- A&E CMO report – hospital breached standard of care, failure to do simple tests – urine dipstick, FBE, U&E

# Few cases rely on guidelines

- Few judgments in Australian civil hearings rely on guidelines
- Why?
  - Few get to hearings (Avant 7 per year, win 70%)
  - Most settled or discontinued after exchange of expert opinions
  - Experts may refer to guidelines in support of their views
  - In-house expertise in defence (medical advisors in-house, medical Experts Committees, referral for opinion)

# Credibility of experts

- Expert should preferably be in current practice
- Have regard to standards prevailing at time of incident
- Backed up with supportive literature
- Impartial
- Experienced in court

## Case 2

- Complaint about a general surgeon
- Referred from Healthcare Complaints Commission → Medical Board Professional Standards Committee
- 55 year old male with right breast lump – excision biopsy showed carcinoma breast, axillae not explored
- 2 months later tumour diagnosed in left breast requiring radiotherapy and adjuvant chemotherapy
- Evidence of peer relied on NHMRC Guidelines requiring axillary exploration/sentinel node
- Surgeon guilty of unsatisfactory professional conduct

# Case 3

- GP practising “complementary and integrative medicine”
- 50 year old patient with chronic renal insufficiency
- 9 x 60 GM } Vit C IV
- 10 x 80 GM } 6 months apart
- Acute on chronic renal failure
- Birefringent crystals in collecting tubules
- Medical Board found that GP had breached the Board’s policy on complimentary healthcare and guidelines on dangers of high dose Vitamin C in renal insufficiency
- GP guilty of unsatisfactory professional conduct

# Disciplinary cases

- In investigation and determination of disciplinary cases, there is reliance on both expert peer opinion and reference to relevant guidelines
  - Boundary violations
  - Excessive prescribing of drugs of addiction (Schedule 8)

# Improving standard of care: anaesthetics

## **1987** Anaesthetics hypoxic injuries

- 60 incident reports
- 14 deaths and 6 'near misses' (average age 37)
  - 18 GAs
  - 11 elective
  - 1 spinal
  - 1 epidural
- 2 children permanent brain injury
- 4 full recovery
- >8 preventable
- 4 endotracheal tube mishaps
- 2 oesophageal intubations not recognised

# Improving standard of care: anaesthetics

## **1999 – 2003** Anaesthetics hypoxic injuries

- 1231 reports
- 143 deaths mostly associated co-morbidity
- 7 avoidable respiratory complications
  - aspiration
  - tube blockages
- No hypoxic injury deaths from oesophageal intubations

**1990** Australian and New Zealand College of Anaesthetists recommendations on routine use of pulse oximetry and capnography

# Summary

- Guidelines help to improve standards of care
- In medical negligence cases, defence organisations and courts rely primarily on expert evidence from peers; guidelines play a secondary role
- In disciplinary hearings, guidelines and codes of conduct may play a more central role

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# Guidelines a useful “starting point” in establishing appropriate standard of care

- Guidelines are increasingly influential in the way that health practitioners practice and the way that they are held accountable
- Guidelines provide courts (and experts) with one benchmark by which to assess clinical conduct
- Physicians who comply with relevant evidence-based guidelines will generally be found to have acted appropriately

# BUT guidelines are just that - guidelines

- However, guidelines:
  - do not set legal standards in isolation from professional practice
  - have not usurped the role of expert witnesses
  - must be supported by expert evidence re applicability, currency
- Slavish compliance with guidelines, disjointed from proper clinical judgement of the individual case, does not defend against allegations of negligence
- Some degree of discretion lies at the heart of clinical judgement, and a good physician will know when to depart from guidelines and will be able to justify that departure

## When departing from guidelines ...

- When departing from well-established guidelines, prudent to discuss decision with a senior colleague and clearly document reasoning:
  - GP accused of misconduct for prescribing injectable diazepam to heroin users, contrary to the then recommendations of the methadone guidelines
  - Initial finding of “infamous and improper conduct” reversed by the Supreme Court of WA, after it heard of a minority medical opinion that supported treatment of opiate users within a harm reduction framework as followed by the GP

*Cranley v Medical Board of Western Australia*

# In practice: Liability of individuals

- Health practitioners found in breach of appropriate standard of care through failure to comply with guidelines e.g.
  - Post-tonsillectomy child received >2500 mL of IV fluids in 9 hrs causing cerebral oedema
  - Febrile 4 week old baby discharged from hospital without investigation, later diagnosed with meningitis
  - 6 month old baby prescribed 3mg Maxolon, resulting in overdose which required hospital admission
  - Physician entered into sexual relationship with patient
- In each case, guidelines consistent with customary practice

# In practice: Liability of organisations

- Hospitals found in breach of appropriate standard of care through failure to have appropriate guidelines in place e.g.
  - Guidelines for sterilisation of equipment
  - Guidelines on seeking specialist assistance
- Guidelines should be seen as providing a “handrail” for safe care, not “handcuffs” constraining the appropriate exercise of clinical judgment

# No substitute for professional judgement

*“Guidelines and protocols are not a substitute for professional, clinical judgement, and need to be interpreted in the light of relevant circumstances.*

*A [health practitioner] faced with apparently inappropriate or contradictory guidelines or protocols should seek guidance from a senior member of the team rather than risk compromising patient safety by rigidly following a document.”*

NZ Health and Disability Commissioner

# The future

- Increasing reliance on guidelines
  - Australian equivalent of UK NICE?
- Failure to follow guidelines a form of “deemed negligence”?
- Experts on guideline methodology asked to advise the courts on quality and relevance of guidelines introduced in evidence?

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