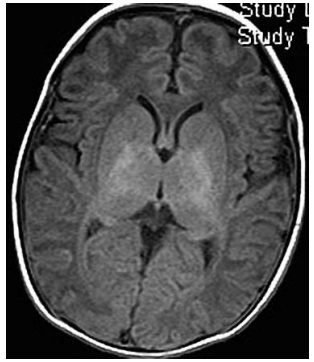
# Medicolegal implication of neonatal practice
# 'Pearls and Pitfalls'

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# Content

- Ethical principles and Duty of care
- Negligence
- Medical Litigation / Balance of probability
- Standard of care
- Managing risk

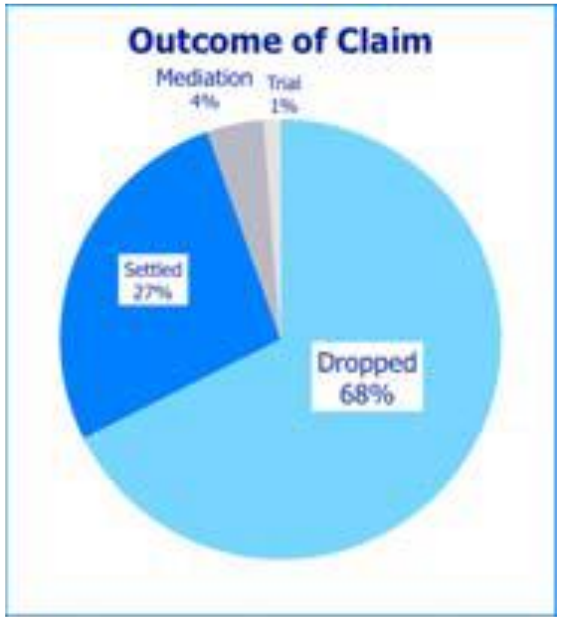
# Disclosure

There is a moral and ethical obligation for physicians to acknowledge medical error

Mechanism for advancement of medicine through risk reduction initiatives to minimise medical errors

I provide expert opinion in medical litigation cases

# Medical Liability Claim Frequency: A 2007-2008 Snapshot of Physicians




Source: AAP Periodic Surveys 2015

- 61% of physicians ≥55yrs old have been sued
- 1 In 4 Pediatricians are sued once during career
- 1 In 10 Pediatricians are sued for care provided while in training
- Defendant prevailed in 90% of trials

Source: Legal Health Organization (LHO) KSA

- Medical practice complaints against medical practitioners in Saudi Arabia had increased by 37% between 2011 to 2016

# Awareness of medical law - KSA

- 97% of consultants, senior registrars, interns, and residents had poor awareness of medical law
- Only 1.5% had adequate awareness of medical law, and only 1.5% had moderate awareness
- Age group between 25 and 34yrs/being from the central region/clinical practice for less than 10 years had increased awareness of medical law.

- Health care practitioners must be educated in laws /regulations of practicing health care in the country.
- Medico-legal education should be a required competence for undergraduate and postgraduate medical education.

Shihah ASB et al. Awareness of medical law among health care practitioners in Saudi Arabia. Saudi Med J. 2022 Aug;43(8):954-958. doi: 10.15537/smj.2022.43.8.20210920. PMID: 35964962

# Awareness of medical law

Knowledge of how judicial forums deal with cases relating to medical negligence is an absolute necessity for doctors

- Protects the public and physicians
- Principle of ‘minimum standard of care’ owed to a patient

Judicial laws aims to strike a balance between the *autonomy of a doctor* to make judgments and the *rights of a patient* to be treated fairly

Agrawal A. (2016). Medical negligence: Indian legal perspective. Annals of Indian Academy of Neurology, 19(Suppl 1), S9–S14. https://doi.org/10.4103/0972-2327.192889

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# Ethical Principles Guiding Medical Practice

- **Beneficence**- act of charity, mercy, and kindness/doing good to others
- **Non-Maleficence**- obligation not harm others “First do no harm”
- **Autonomy**- respect decisions of those with decision-making capacity
- **Justice**- equitably distribution of benefits, risks, costs, and resources
- **Sanctity of life-** act in interests of patients, preserve and protect life

# Medical Claims

Civil / Criminal  Litigation/Professional regulatory bodies

# Purpose of claim

- Monetary compensation/Civil courts
  - Medical negligence - Standard of care not met
- Disciplinary action/Professional Governing Bodies (GMC, IMC, CPSA etc)
  - Safety to practice

# Legal objective

- Provide justice
- Ascertain accountability
  - ❖Practitioner
  - ❖Institution
- Deterring harmful behaviour and future risk
- Appropriate allocation of loss

# Civil Litigation - Medicolegal Principles

- Medicine is not an exact science
- Satisfactory standard of care does not guarantee satisfactory results
- Perfection is not the standard of care
- Most common medico-legal actions against physicians are for **negligence** both for steps taken and actions that the physician has failed to take

https://www.cmpa-acpm.ca/en/advice-publications/handbooks/medical-legal-handbook-for-physicians-in-canada

# Negligence

1. Duty of care
2. Breach of that duty of care
3. Causation / Contribution of Harm or injury

The plaintiff must fulfill all the above criteria to succeed in a claim

# Duty of Care – What does it entail?

- Make a diagnosis and advice the patient / best interests of the patient
- Treat patient in accordance with current and accepted standards of practice
- Refer patient/obtain consultation when unable to diagnose /patient is not responding to treatment / condition is beyond capability or experience of the physician/centre
- Adequately instruct patients regarding treatment and follow up and when to seek immediate medical care

*A physician is not expected to be correct every time but **must** demonstrate reasonable care **always***

# Breach of Duty of Care

- Courts apply the ‘standard of care’ principle

“Every medical practitioner must bring to his task a reasonable degree of skill and knowledge and must exercise a reasonable degree of care. He is bound to exercise that degree of care and skill which could reasonably be expected of a normal, prudent practitioner of the same experience and standing and, if he holds himself out as a specialist, a higher degree of skill is required of him than one who does not profess to be so qualified by special training and ability.”

Ontario Court of Appeal

*Physicians are held to a* ***reasonableness standard and not a standard of perfection***

# The Bolam principle

The *Bolam* test was established in 1957 following the decision of the court in *Bolam v Frierm Barnet* in which the court concluded that a doctor might be able to avoid a claim for negligence if he can prove that other medical professionals would have acted in the same way

Bolam v Frierm Barnet HMC 1957 1 WRL 582

# Medical experts

- Expert puts before the court material with reasons which induce him to come to a certain conclusion
- The court may form its own judgment using its own observation of those materials
  - Titli v. Alfred Robert Jones AIR 1934 All 273.

- Experts should only render opinions that are “intelligible, convincing, and tested”
  - Ramesh Chandra v. Regency Hospital Limited (2009) 9 SCC 709.

# Standard of care

The plaintiff must prove, on a balance of probabilities, that the health care providers (usually physicians and nurses) failed to provide the appropriate level of care in the circumstances

‘Standard of care’ is based on existing standards at the time of care

# Litigation in Neonatology

Balance of probability

# What is different about Babies

- Errors in diagnosis can lead to severe and permanent injuries
  - Meningitis
  - HIE
  - Missed dx: congenital dysplasia of the hip; ROP etc.
- Lifetime costs of care can be staggering
- Enormous sympathy by courts
- Long hospital stay
- Long Statute of Limitations

- Legal claims for damages resulting in neurological injury from negligence - largest damages awards in personal injury litigation
- Physical and cognitive impairments may prevent working or functioning independently
- Lifetime dependence for care and supervision
- Assessment of damages in millions of dollars

# Birth related Injury and Impairment

- Idiopathic causes
- Antenatal causes
- Unpreventable causes
- **Potentially avoidable causes**

# Birth related injury

- Many cases of CP are unavoidable
- Few are avoidable
- It is legitimate to ensure that liability is not imposed where it is unjustified based on the best medical knowledge available
- It is unjust to deny compensation to injured infants and their families when the application of best medical knowledge establishes liability

# Balance of Probabilities


To distinguish between potentially avoidable causes and all other causes

# Liability and Compensation through litigation

- Proof on a balance of probabilities
  - Injury was due to a potentially avoidable cause
  - Plaintiff proves that applicable standard of care were not met
  - Intervention would have avoided **some or all** the harm

- Key to this exercise includes the use of differential diagnosis against all other causes of neonatal neurological injury

- Understanding timelines and applicable (existing)  standards of care

# Snell v. Farrell- Supreme Court of Canada (51% certainty)

The plaintiff does not need to show causation to a level of medical certainty, but rather only on a balance of probabilities.

The judge may draw an inference, where a medical expert would not, based on common sense and a consideration of all the circumstances.

Plaintiff bears the burden of adducing  evidence of causation

# Neonatal Resuscitation Claims

Pitfalls and Pearls

# Resuscitation - Claimed breaches

- Failure to have appropriate personnel at delivery
- Failure to appropriately ventilate baby
- Failure to initiate CPR and give epinephrine in right dose or route at the right time
- Failure to recognize and treat hypovolemia in a timely manner

# Post resuscitation pitfalls

- Failure to admit to appropriate care facility of ongoing care
- Failure to be vigilant for seizures
- Initiation/referral for Therapeutic Hypothermia with HIE
- Failure to recognize hypoglycaemia
- Failure to be vigilant for infection

# “Pearls” of Neonatal Resuscitation

The single most important aspect of neonatal resuscitation is effective

**Ventilation**

Be sure to document objective evidence of ventilation

# Resuscitation documentation - pearls

- Time of attendance at resuscitation
- Resuscitation care given by others prior to arrival
- Description of vital signs (don’t simply state Apgar scores)
- Time of onset of positive pressure ventilation even if only by bag and mask
- Time of intubation; comment on ease of intubation/compression/drugs
- Confirmation of colour change CO2 detector
- **Movement of chest wall and auscultation findings in response to IPPV**
- Timed sequence of changes in heart rate, onset of spontaneous breathing, change in colour/ saturation
- If re-intubation is needed, give reason

# Neonatal Litigation Hot Spots

Common and emerging conditions

- Neonatal Jaundice
- Neonatal Hypoglycemia
- Care of the Preterm Infant
- Failure/delay in recognition of sepsis
- Neonatal Safety (Drops/Falls) & Unexpected Perinatal Collapse

# Litigation risk with Jaundice

- Common condition
- Relatively easy to treat
- Often predictable
- Charts guide treatment thresholds – not thresholds for discontinuation of treatment
- Risk assessment for kernicterus requires some thought
- Kernicterus can be proven clinically and on MRI

# Case

- Mother is G2 PI L1
- Previous pregnancy with male infant had jaundice with G6PD
- 36 wk. male infant African origin 2.9kg
- Maternal pyrexia & PPROM 36 hours
- Admitted to NICU with grunting / tachypnea & hypoglycemia
- WCC 3.4 on CBC
- Treated with antibiotics for 48 hours and discharged home.

- Seen at Day 4 mild jaundice
- Day 8 poor feeding lethargy
- Bilirubin 559 mmol/L – G6PD
- Developed Kernicterus
- Plaintiff's claim, suboptimal neonatal care and monitoring for jaundice.
- Ruling in favour of Plaintiff – CAD 12M
  - Risk factors Late preterm/risk of sepsis/FH G6PD/ male infant
  - 5 day blood culture positive – corynebacterium ? contaminant
  - No follow up plan/advice provided to parents on discharge

Hypoglycemia

# Hypoglycemia- Concepts

- Significant hypoglycemia CANNOT be defined by a single number that is universal or can be applied to every patient (varies with disease states and physiology).

- There are no evidence-based guidelines that define glucose levels or ranges that cause or lead to irreversible brain injury.

- There is no evidence that treating asymptomatic hypoglycemia improves neurological outcomes.

# Pearls for managing hypoglycemia

- Always document that you are trying to correct significant hypoglycemia
- Inform parents what you are trying to do and explain the risks, difficulties, and complications.
- Err on the side of higher threshold lower-limit glucose values if unable evaluate a baby for clinical signs of serious hypoglycemia
- Initiate immediate Rx when serious signs or extremely low glucoses are seen.
- Follow established local guidelines

# Emerging areas for litigation

Risk with ELBW Care

# Case

- 700 gm Male born at 25 wks. by CS
- APGAR Score 5/3/6/7
- Born at level 2 NICU having presented 48 hours earlier
- Difficult intubation/bradycardia during 3 attempts
- Placed on CMV ventilation. Initial blood gas showed mixed respiratory and metabolic acidosis.
- CXR- consistent with RDS. Surfactant therapy – subsequent CBG $CO_2$ in 30s for several hours. Transferred to Level 3 NICU

- Initial HUSS bilateral grade 2 IVH, suspicion of PVL at 2 wks. with mild PHVD on subsequent HUSS's not requiring intervention.
- Several episodes of feeding intolerance with poor weight gain. No NEC. Feeds started on day 7. Not established till day 28
- Developed Staph. Epi sepsis while PICC in situ at 2 weeks of age.
- BPD - Discharged home on oxygen at 42wks CGA
- Not walking at 4 years with microcephaly
- PLAINTIFFCLAIM: BABY'S NDI CAUSED BY POOR NICU CARE

# Missed opportunities

- Antenatal steroids
- Maternal transfer to high-risk perinatal facility
- Hypocarbia
- Poor nutrition / central line related risk

# Sepsis

- Poor outcome for cognitive and motor impairment
- White matter abnormalities

# Caution about Head USS messaging

ELGAN/EPIPAGE Studies

- 4-6% of those with “normal” HUS diagnosed with CP
- 33-38% with CP had “normal” HUS

# Reducing your ‘Risk

Being knowledgeable and proactive

# Mitigating practitioner risk

- Maintain complete and accurate notes
- Keep up to date and practice evidence-based medicine
- Maintain procedural competence
- Maintain professional and effective communication with team – closed loop communication as needed
- Timely communication with patients/SDM
  - Be respectful
  - Compassionate
- Refer / obtain second or more opinions
- Discharge advice patients - follow up/indications to seek attention
- Follow up Lab reports you order

# Documentation

- Document all care – If it wasn’t documented it wasn’t done
- Document conversations with others – Include response, instructions, orders
- Never use the chart as a battleground
- Document use of the chain of command

# Keep Up to Date

- Keep informed about recent developments in the field — literature, conferences
- Incorporate current methods of diagnosis and treatment into your practice
- The practice of ‘evidence based medicine’ is not optional. It is a moral, ethical and legal responsibility of licenced practitioners

# Informed Consent

- Much more than a signature on a form
- Nature & Purpose of Treatment
- Risks
- Benefits
- Alternatives
- Informed Refusal

# Skill of Communication

"Health care communication is a critical, but generally neglected, component of paediatric and paediatric subspecialty practice and training and is a skill that can and must be taught."

Communicating with Children and Families: From Everyday Interactions to Skill in Conveying Distressing Information. Marcia Levetown and the Committee on Bioethics. Pediatrics 2008;121:1441-1460.

# Professionalism

- Case: Took at least three pages and over an hour to get the anaesthesiologist to respond
- While waiting for the anaesthesiologist uterus ruptured.
- The infant was born – Severely brain damaged with limited use of his legs, arms and head

# How can we mitigate institutional risk

- Guidelines and protocols
- Risk management and case reviews
- Practitioner certification and continuous professional development
- Simulation and testing
  - Individual performance
  - Team performance
  - Institutional/ systems performance
- Review and attention to Institutional accreditation processes.
- Safe scheduling

# Take home message

- Practicing evidence-based medicine is not optional
- Maintain skill and knowledge
- Be professional, compassionate and responsive
- Document - clear and complete notes
- Communicate with team and families
- Collaborate with colleagues
- If in doubt get a second or more opinions
- Management: Focus on improving care & reducing institutional liability