Medical Device Incidents and the Coroner

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+ # Types of Incident

- Defective device
- Incorrect implantation
- Training/Instructions
- Reviews/Updates
- Auditing

Coroners duties

1. To investigate unnatural deaths
2. Consideration of a report to prevent future deaths.

Duty to investigate

S1 Coroners and Justice Act 2009

1. Duty to investigate certain deaths

(1) A senior coroner who is made aware that the body of a deceased person is within that coroner's area must as soon as practicable conduct an investigation into the person's death if subsection (2) applies.

(2) This subsection applies if the coroner has reason to suspect that—

(a) the deceased died a violent or unnatural death,

(b) the cause of death is unknown, or

(c) the deceased died while in custody or otherwise in state detention.

Report to Prevent Future Deaths

Coroners Investigations Regulations 2013:

28.—(1) This regulation applies where a coroner is under a duty under paragraph 7(1) of

Schedule 5 (2009 Act) to make a report to prevent other deaths.

(1)

Where—

(a) a senior coroner has been conducting an investigation under this Part into a person's death,

(b) anything revealed by the investigation gives rise to a concern that circumstances creating a risk of other deaths will occur, or will continue to exist, in the future, and

(c) in the coroner's opinion, action should be taken to prevent the occurrence or continuation of such circumstances, or to eliminate or reduce the risk of death created by such circumstances,

the coroner must report the matter to a person who the coroner believes may have power to take such action.

Examples of PFD reports

1) Inquest touching the death of Samantha Ann Hopkins:

-Accidental death (died due to a head injury from fall)

-Given a dose of a trial drug when pregnant despite fact that trial expressly excluded pregnant women.

-Concern: warnings were inside of the packet. Had they been on the outside the oversight may have been avoided.

-Report sent to medical school responsible for the trial as well as the ambulance service. No guidance had been given to the ambulance service as to how exclusions were to be highlighted to trial participants.

2) Inquest touching the death of John William Rogers:

- Natural causes
- Found collapsed – resuscitation – defibrillator set on 2 joules rather than 150 joules. Operated by nurse using machine on manual setting for the first time and her advanced life support qualification had expired.
- Concerns: training/qualifications not up to date and was not appropriately trained

3) Inquest touching the death of Simon Harper

-Narrative (not possible to say what effect cardiac arrest had on the death)

-Portable oxygen cylinder not switched on during transfer – heart stopped – resuscitated but died 2 days later. Nurse didn’t turn valve to allow oxygen to flow.

-Concerns: training in that only 1 training session provided by external provider to a group of nurses and thereafter peer to peer training with no records made of who had received and no audits done in respect of the training. Issues extended to actual training, documentation and the processes in place.

4) Inquest touching the death of Nasar Ahmed

- Narrative as could not be sure whether earlier administration of adrenaline would have saved his life

- Pupil had severe asthma and multiple allergies. He ate a meal he was allergic to hours before his collapse. Possibility that if adrenaline had been administered by speedier use of Epipen he may have been saved.

- Concerns: not appreciated extent of medical condition, school unfamiliar with care plans. Lack of familiarity with medication box as school failed to administer before paramedics arrived.

5) Inquest touching the death of Billy Wilson:

- Narrative – died of brain damage due to oxygen deficiency
- Midwives failed to appreciate the CTG printout and stop drugs to induce labour. Newly qualified midwife had not received instructions or training during midwifery course at university and when she took up her first appointment she did not complete the 2nd part of the E-learning course. Evidence from exert that lack of training was common place. Concerns raised in respect of university, registering body and employer.

+ Other examples

- Suction machines: no training given re how to set up and use. No processes in place for inspection/maintenance.

+ Conclusions

- Collaborative approach between different organisation – inevitable overlap in responsibilities
- Need to provide clear training/instructions and updates
- Consideration of /availability of instructions – should there be any near to or on device?
- Need to provide inspection/maintenance
- Need to provide auditing
- If an issue arises undertake a thorough investigation and put steps in place to prevent/reduce risk of further incidents even if not causative of death

Any questions?