

THE INQUIRY INTO HYPONATRAEMIA-RELATED DEATHS

Belfast, Northern Ireland

Pathology commentary on the death ADAM STRAIN (1995), the autopsy performed by Dr A Armour, the contemporary medico-legal context, and critical aspects of coronial autopsy practice.

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Documents available and read

- The autopsy report by Dr Alison Armour (F. No 46,728; 29th Nov 1995)
- Two Witness statements 012/1 (2006), 012/2 (2012), by Dr Armour
- Brief for expert on paediatric pathology
- Statement 011-025-125, dated 8th Dec 1995 by ?
- Deposition of Dr Armour (handwritten + transcription) 18th June 1996.
- Resume (CV) of Dr Armour, dated 2011 or 2012
- The reports by Professors A Risdon & J Berry
- The Medico-legal report, Addendum and Supplementary reports by Dr Waney Squier
- The Coroners Act 1988
- The Coroners Act (Northern Ireland) 1959

COMMENT ON THE AUTOPSY AND ITS PERFORMANCE

In my opinion, the autopsy was performed competently, and achieved a diagnosis which, from the evidence in all the documents, appears to be the most likely to explain the death.

With one specific exception (the left neck veins) it is internally consistent, and given the clinical and laboratory information presented, it provides good support for the main conclusion: *death from cerebral oedema due to hyponatraemia during transplant operation for congenital obstructive uropathy*. I abbreviate the cause of death listing, since in my opinion, the pathologist should not be interpreting the peri-operative events in such a complex case (ie 'dilutional' should have been omitted - see below).

The 'ligated neck vein' issue

The 'impaired cerebral perfusion' (from purportedly a ligated neck vein) is contentious. The autopsy description of the ligature apparently found in the left neck is sub-optimal, since it was not then, and has not since become, clear whether or not there really was a ligature or whether it obstructed the venous outflow of the left internal jugular vein. This lack of clarity is a criticism of the autopsy and the report.

My impression from all the written material is that if there was such a ligature, it was probably in place prior to surgery and thus – being a chronic entity – may not have contributed to the acute demise of the patient. It would have been ideal practice to

photograph this ligature, but there was then and is no requirement in non-forensic (see below) autopsy practice to document such lesions or suspected lesions (see below). Nor was or is there any obligation to photograph the brain for later review of the swelling.

The report clearly states, in several places, that there was no cerebral venous thrombosis. The histology description of the brain does not mention venous thrombosis (and I believe it would have been obvious were it present).

Pathogenesis of death

Considering the limited range of pathogeneses for a peri-operative massive brain insult that led to failure to wake up and CT-diagnosed cerebral swelling at the cessation of the operation, I consider the *hyponatraemia* aetiology well founded. It is supported by a timely peri-operative low blood sodium measurement. No alternative diagnosis seems evident from the information available, including Dr Squier's exhaustive review of the pathology which specifically excludes hypoxic ischaemic encephalopathy. I have personally seen at least one death from acute cerebral oedema caused by dilutional hyponatraemia (in adults, not children).

The standard of diagnostic accuracy for Coroner Act 1988 s19 (non-forensic) coronial autopsies is 'balance of probabilities'. It is not 'beyond all reasonable doubt'; that pertains where 'unlawful killing' or 'suicide' are the verdict – which is not the case here. Accuracy in medico-legal work is considered below but, in summary, the diagnosis in this autopsy, in my view, certainly achieved the minimum standard. I am presuming that the same burden of proof criteria for autopsy diagnosis pertained and pertains in Northern Ireland.

Organ retrieval prior to autopsy

The heart was removed before autopsy for transplantation. Presumably the clinical data of the peri- and post-operative course indicated no abnormality of the heart function, and thus it was considered very unlikely that pathological examination would reveal significant pathology. In the context of current practice in London, this removal would not take place in a case that would be regarded as high profile: the unexpected post-operative death of a young child in hospital. For certainty (ie exclusion of cardiac disease), it would be examined at autopsy.

The heart weighed 120gm, which is large for a 4-year old child. However, chronic renal disease is associated with enlarged heart. The peri-operative records do not indicate that there was any cardiac malfunction (pressure, heart beat), so I do not think that this issue is significant.

Other criticisms, not relating directly to ascertainment of cause of death:

A second criticism is the omission of histopathological investigation of why the transplanted kidney had infarcted. Were the renal artery and/or vein obstructed? This is not an important matter in determining the cause of death; but it is important for the renal transplant programme to know why the transplant procedure itself failed. Professors Risdon and Berry confirm the infarction.

A third criticism concerns the weight of the brain, which is uncertain. However, we know that it was swollen (CT scan) from the end of the operation. And do we know whether the mortuary organ weight scales were accurate? I have seen the lengthy commentary on this issue by Dr Squier and have nothing useful to add.

The fourth criticism relates to the abundant non-pathology information provided in the autopsy report. There is, in my view, too much – in the context of this complicated case. The pathologist's role is to determine the pathology causing death, and the clinical information and fluid balance data included – obviously second hand – would be better omitted. In London practice, the coroner would almost certainly not want these data, given that HMC would be getting several clinician reports to prepare for the inquest. He/she would wish the pathologist to comment on the clinical stories presented in evidence, but in a complicated case like this that would come after their delivery, not before.

Overall, in comparison with many of the coronial autopsy reports which I regularly review, and others which were reviewed in detail by NCEPOD (see below), this report I would grade as 'satisfactory' or 'good'. It addressed the central issue of cause of death and produced a coherent answer.

Caveat:

I have not reviewed the histopathology of the autopsy samples (internal viscera and brain).

COMMENT ON THE BROADER ISSUES OF THE ROLE OF THE NON-FORENSIC CORONIAL AUTOPSY IN MEDICAL PRACTICE

The Coroner Act 1988 applied to England, Wales in 1995 (and still does); the main sections that relate to non-homicide coronial autopsies are s8 & s19.

In Northern Ireland, the Coroner Act (NI) 1959 pertained (and still does); the sections relevant to autopsy practice are 13, 26, 27, 28, 29, 30. This is broadly similar to that operating in England & Wales, though shorter, but does not appear to make the clear distinction between s19 (autopsy without inquest = 'routine; non-suspicious death') and s20 (autopsy with inquest, requiring 'special examination', and under which ?homicide deaths come).

The autopsy of Adam Strain was not a 'forensic autopsy', in that there was no issue of homicide in the case. Forensic autopsies are performed by pathologists on the Home Office registered list, who have experience of such work, and have passed one or more special examinations. The fact that a particular case is examined by a trainee or fully qualified forensic pathologist does not mean that the case is 'forensic' – that is determined by the nature of the case and the scenario of death, not the person doing it.

The NCEPOD report, 2006

In 2006, the National Confidential Enquiry into Patient Outcome and Death (NCEPOD) published its report into the E&W coronial system: "The Coroner's Autopsy: Do We Deserve Better?" I developed this study, chaired the discussions, and drafted most of the report. Prof Jack Crane was a member of the expert advisory group for the study. It can be downloaded at:

<http://www.ncepod.org.uk/2006.htm>

It examined one month (in 2005, before the new tissue retention regulations from the Human Tissue Act, 2004) of coronial autopsies across the UK (including NI) – excluding only forensic/homicide autopsies – to determine how well the autopsy reports were written, and implicitly how well the autopsies were done. The reports were reviewed by a panel of pathologists and coroners. Broadly the conclusions were:

1. One quarter of the autopsy reports (and implicitly the autopsies) were performed badly. Some were so appalling that they merited the equivalent of reporting the pathologist to the GMC for bad clinical practice.
2. In one fifth of cases, the review panel did not believe the stated cause of death (ie internal inconsistency of scenario of death, gross +/- histological/toxicological findings, and conclusions).
3. Paediatric autopsies were performed better than adult – reflecting increasing specialisation in autopsy practice

4. There was overall poor communication between coroners and pathologists at the time of autopsy
5. The purpose of the coronial autopsy is unclear, and there is no consistent approach taken by all coroners (ie they all differ in what they think it is for).

The public tend to regard coronial (medico-legal) autopsies as being of intrinsically high standard, because of their name. The reality is different. In the decade or so since I have taken an interest in the governance aspects of coronial autopsies, I have accumulated a large amount of information on what goes on, in London and UK generally.

Variation in standards of coronial autopsies

There is a huge variation in practice quality – as reflected in the NCEPOD report. In an unacceptable proportion of cases, in my view (and I am not alone), pathologists do not necessarily perform what should be their major role when examining a dead body: to address and answer (if possible) the question(s) raised by a death. They too often go through the motions of an anatomical dissection to produce a quick answer which may or may not relate to what actually happened to result in the death of the person. The consequences include wrong causes of death (affecting national statistics), incorrect information to families on what happened, and – often – inappropriate grounds for civil actions against doctors and health centres.

The three main drivers for this approach are:

1. The coroners' attitude to the autopsy (its purpose). See the NCEPOD report for the detailed range of potential purposes: from merely excluding homicide or unnatural death, to producing an excellent comprehensive report that could be the basis of a case report in a journal. The Coroner Act 1988 does not statutorily require a quality, true diagnosis; it requires a diagnosis that can enable the disposal of the dead and the relevant documentation. The s19 (standard) coronial autopsy is specifically targeted with providing a diagnosis that enables the coroner to dispense with an inquest. IE there is an in-built bias to producing natural cause death diagnoses, and – given the absence of an unnatural scenario – no requirement to produce the true natural diagnosis, which may be more complicated. Hardly an encouragement to do things well.
2. The remuneration scales for coronial autopsies (s19 and s20). This is historically and currently so poor, that it is hardly surprising that pathologists, who may depend on this income stream, wish to cut and run quickly so as to get through as many cases in as short a time as possible.
3. The indifference (until very recently) of the higher medical regulatory bodies to what happens during coronial autopsies, since – by definition – they are outwith the National Health Service. They are done as a private contract

between coroner and medical practitioner, and are not covered by NHS rules, guidelines and protocols. Medico-legal autopsies do – presumably – come within the general standards of medical practice enunciated by the GMC, but that organisation has only taken notice of bad practice since 2006, and only occasionally.

The Royal College of Pathologists

The Royal College of Pathologists (RCPATH) is a professional standards body, not a regulatory or disciplinary body. It has produced Guidelines on Autopsy Practice (2002 – on the web site) and updates for specific scenarios (2005-2010), but these are guidelines only, not mandatory performance standards. Historically it has ignored autopsy practice until about 1998, preferring to ignore problems in the coronial autopsy system and concentrate on diagnostic biopsy standards. I led the RCPATH committee that produced these Guidelines; and am involved in their re-writing to accommodate recent developments in consented and coronial autopsy practice (this is difficult since we still do not know which sections of the Coroner & Justice Act 2009 are going to be implemented).

The RCPATH has also produced codes of practice for forensic pathologists when performing suspected homicide and related autopsies (2004). At the time of the death of Adam Strain, Dr Armour was not an accredited forensic pathologist (ie she was not on the Home Office register); and the child's death was not a strictly forensic matter. Thus my comments relate to the autopsy of Adam Strain under s8 and s19 of the Coroner Act 1988 (ie a 'routine' medico-legal autopsy in a non-suspicious death) and the equivalent Northern Ireland Coroner Act section 13.

The training and supervision of non-consultant level pathologists in 1995 and now

On the subject of the training and supervision of non-consultant level pathologists (like Dr Armour), it is only in this millennium that curricula and protocols have been developed that address such issues (mainly from the RCPATH).

Up to the mid-1900s at least, training was entirely apprenticeship and/or self-taught by experience. Personally, I started performing autopsies, including coronial, in 1975, with a professor showing me how he did one, me doing the next – and thereon I was on my own. Advice was available to solve diagnostic problems, but not formal training or mentoring. I was put on the coroner's pathologist list within a few months, and carried on learning on the job. Local and national training days or sessions concerned with autopsy affairs were non-existent or rare then.

That has all changed. Training is now more rigorously managed, and trainees are now allowed much less opportunity to complete cases themselves and present evidence in coroners' courts. In 1995, my recollection is that trainees were expected to get on with the case load, asking for help if they felt they were out of their depth.

In 2012, the appointment of pathologists to be fit for working for coroners is still largely by word of mouth commendation from existing more senior pathologists. Few coroners have instituted a more formal review panel, with a written application form, CV and evidence of experience as expected processes.

Dr Alison Armour in 1995

By the time of this autopsy, she had been training and working actively in histopathology and autopsy pathology for 8 years, and had passed the MRCPATH diploma three years previously (in 1992). Having completed, satisfactorily, the standard 5-year histopathology training, she evidently wished to specialise in forensic pathology, and obtained the training post in Belfast. By 1998, she was on the Home Office List for forensic pathologists.

Once having obtained the MRCPATH diploma, a pathologist is deemed fit for a consultant post and fit for 'independent practice' in pathology. The latter was then and still is part of the RCPATH's depiction of a pathologist (in any speciality) once the MRCPATH (now FRCPATH) diploma has been obtained. IE there is no obligation to consult with superiors before signing out work – this includes diagnostic surgical histopathology and cytopathology, and autopsy work. True forensic, ?homicide, autopsy work comes into a different category, and does not pertain in this case. Of course, learning in pathology is life-long, and sensible people constantly show material to others for advice and guidance.

On the issue of knowledge of coronial law, whether Dr Armour was aware of the fine distinctions between the different coronial systems (E&W vs NI) is not known. She was initially trained in the E&W system. That said, I suspect she was not, for very

few trainees or even senior pathologists at that time knew much about coronial law (ie the Coroners Act 1988 and the Coroners Rules 1984). It was not made a mandatory component of the FRCPath diploma exam until 2005.

Consultation about pathological findings with colleagues.

This is variable – then and now – with no guidelines beyond the general injunction to seek advice when necessary. The RCPATH 2002 Guidelines on constructing autopsy reports do indicate the need to ‘record tissues sent to any third party for further investigation, such as genetic analysis’ [Guidelines, 8.8.4]. But they do not state the need to report what third parties actually said.

There is a further guidance: ‘Discussion with the responsible clinicians will yield optimal clinico-pathological correlation but frank discrepancies or disagreements must be noted’ [Guidelines, 8.10.6].

Thus, the report by Dr Armour cannot be criticised on these grounds. In my view, she was certainly senior enough for the particular case, did not require close supervision, and has demonstrated that she did consult with other pathologists.

Overview for the Inquiry.

There are some aspects of this specific case that can be used as support for recommendations on improving the practice of medico-legal autopsy work nationally. Although the NI Coroner Act is different from that of E&W, and the NI medico-legal autopsy work is now concentrated in a centre that is also a forensic centre in Belfast, with only a small number of pathologists doing the work (led by Prof J Crane), the following observations pertain across the UK:

1. Better documentation of what was seen grossly (ie the ligature business, the transplant kidney blood vessels, organ weights – though note that many pathologists believe that many of the latter are not important beyond indicating that the organ was actually looked at)
2. More precise indication of which professionals were involved in the autopsy and post-autopsy analysis, and what they said.
3. More careful consideration of how much clinical material to incorporate and to discuss in the report. Many coroners prefer the pathologists to include no clinical history and no clinico-pathological discussion in their autopsy reports; just state the findings and the cause of death where possible.

But to focus on these aspects is to miss the elephant in the room about coronial autopsy practice. It is important to recognise that in non-forensic coronial autopsy practice:

- there is no formal governance
- there is no standard of quality demanded by coroners
- each of the ~110 coroners has a different perspective on the purpose of the coronial autopsy and how they should be performed
- there is no obligatory linkage with audit or feedback of autopsy findings for correlation with pre-mortem clinical practice
- there no agreed level of investigations for particular scenarios of death
- there is no standardised minimum dataset presented by coroners to pathologists relating to the case to be examined, nor indication of specific questions to be addressed through the autopsy process

Coronial autopsy practice has, essentially, operated on a different planet from the less common and better audited consented (hospital) autopsy work, and from normal NHS clinical practice. Tissue retention issues, which now complicate the autopsy process and later review of pathology, did not pertain in 1995.

The Brodrick Report (1971 – one of many reviews of the UK coronial service that have periodically taken place and been ignored by governments) recommended that

medico-legal autopsy work should statutorily be brought within the NHS. I could not agree more, since that would force up standards overall, and make the coronial autopsy more fit for purpose (whatever that is eventually declared to be).

Professor Sebastian Lucas FRCP FRCPATH

A handwritten signature in black ink, appearing to read 'S. Lucas', with a long horizontal flourish underneath.

Statement of Truth

I understand that my duty as an expert is to provide evidence for the benefit of the Inquiry and not for any individual party or parties, on the matters within my expertise. I believe that I have complied with that duty and confirm that I will continue to do so.

I confirm that I have made clear which facts and matters referred to in my report(s) are within my own knowledge and which are not. Those that are within my own knowledge I confirm to be true. The opinions I have expressed represent my true and complete professional opinions on the matters to which I refer, having studied all the relevant documents supplied to me.

I confirm that I have no conflict of interest of any kind, other than any disclosed in my report(s). I do not consider that any interest that I have disclosed affects my suitability as an expert witness on any issue on which I have given evidence. I undertake to advise the Inquiry if there is any change in circumstances that affects the above. I have no personal interest in supporting any particular point of view.

I understand that I may be called to give evidence.

Signed:

A handwritten signature in black ink, consisting of a large, stylized initial 'S' followed by several loops and a long horizontal stroke extending to the right.

Date: 24th May 2012