1. Introduction

Introduction

What happens when someone dies

When someone dies in the United Kingdom (UK) (excluding Scotland for the purpose of this survey) the death needs to be registered with the state and formal documents issued so that funeral arrangements can take place. In order to register, there must be a recorded cause of death. In the majority of cases, a medical practitioner is able to sign a medical certificate indicating, to the best of his/her knowledge and belief, the cause or causes of death. The medical practitioner is also indicating that, as far as he/she is aware, there are no features in the death that suggest foul play, an accident or a scenario that makes the death appear to be suspicious or unnatural (i.e. not the result of a natural disease)[1].

However, a doctor may not know the cause of death, or there may be factors that suggest an unnatural death. Alternatively, a doctor may complete a medical certificate of the cause of death, which the Registrar of Birth and Deaths regards as not natural or appropriate. In these cases, in England, Wales, Northern Ireland and the offshore islands, the death is referred to a coroner who then decides whether or not to investigate the case further. Following discussion with the reporting doctor and any knowledgeable or interested parties, the coroner forms a view on this. The coroner may decide, in discussion with the reporting doctor, that there is sufficient information to permit a natural cause of death to be recorded and registered. If following discussion between the coroner and the doctor the death is regarded as 'natural', the coroner may issue a certificate (referred to as Pink Form A) that enables the Registrar of Deaths to register the death, without autopsy. If the cause of death is unknown, the coroner may arrange for an autopsy to be performed by a registered medical practitioner (nearly always a pathologist) who will write a report for the coroner that gives a cause of death and if the cause of death is 'natural', the coroner may issue a certificate (referred to as Pink Form B) that allows the death to be registered following the autopsy (but without inquest). A coroner may also decide to hold an inquest into the death at some later date.

How autopsies take place

Autopsies in England, Wales, Northern Ireland (NI) and the offshore islands take place under two main circumstances: the coronial autopsy and the consented autopsy. That requested by a coroner - under circumstances indicated above and described in more detail in 'The Coronial System' - does not require consent from the next of kin. Its purpose is simply to determine a cause of death. In governance terms, it is nothing to do with the National Health Service or hospital practice. Conversely, consented autopsies take place when a clinician requests consent from the next of kin for an examination after death. The clinician will have already signed, or be about to sign, a medical certificate of cause of death. The purpose of the consented autopsy is then to study the conditions that the person suffered from, in order to better understand the medical and pathological chain of events that led to death. These consented autopsies are

usually performed in hospital mortuaries and come under NHS governance regulations.

Currently, about 55% of deaths in England and Wales are certified directly by doctors and 45% are directly referred to a coroner[2]. If the coroner accepts the case for investigation, he/she provides the cause of death for registration purposes, usually confirming the pathologist's cause of death as the basis for this. The net result is that in 2005, 22% (114,600) of the people who died in England and Wales (513,000) were examined after death through a coronial autopsy[2]. On average there are 14,500 deaths in Northern Ireland per annum and in 2005 approximately 1,500 autopsies were performed for the coroner in Northern Ireland[3]. In terms of the offshore islands, there are approximately 2129 deaths per annum with, on average, 300 coronial autopsies being performed[4-6].

Audit of the autopsy

In the UK, the overall quality of the coronial process has never been audited. One of the key components of this process is the coronial autopsy and the resulting report. The autopsy report is a source of information to inform and assist a detailed investigation of individual cases by coroners and their staff, particularly those that are subject to a public inquest within the coronial system, or for cases that go on to become the object of civil claims. A small and unknown proportion of coronial autopsy cases are discussed at mortality meetings within hospitals as part of clinical governance[7], where the autopsy report often reveals information about the deceased that was unknown or unrecognised to clinical staff prior to death. Beyond anecdotal observation there has been no national overview of the quality of coronial (or other adult) autopsies and the associated reports[8,9].

The value of the autopsy

Increasingly, with advances in diagnostic procedures[10] the value of the autopsy has been challenged over the years. Even so, studies from all over the world have revealed the true value of autopsies by highlighting rates of discrepancies between clinical and postmortem diagnoses, and their use as an educational tool for the medical profession[8].

A recently published meta-analysis examining English language articles published between 1980 and 2004 which studied discrepancies between clinical and postmortem diagnoses showed that there has been little improvement in the overall rate of discrepancies between the 1960s and 2005. The authors concluded that 50% of autopsies produce findings unsuspected before death and at least a third of all death certificates are likely to be incorrect[11]. This figure has been supported by other investigators examining the accuracy of death certificates[12]. The office responsible for registering all deaths is the General Registrar's Office (GRO). In governance terms, it answers to the Office for National Statistics (ONS), which analyses causes of death and publishes data. The ONS comes under the auspices of Her Majesty's Treasury (not the NHS).

Individual studies examining the rates of discrepancies between clinical and autopsy diagnoses vary. In the United States, Goldman et al (1983)[13] examined 100 randomly selected autopsies from each of the academic years 1960, 1970 and 1980 to determine whether advances in diagnostic procedures have reduced the value of autopsies. They found that in all three decades, about 10% of the autopsies revealed a major diagnosis that if known before death "might have led to a change in therapy and prolonged survival". It was concluded that advances in diagnostic technology had not reduced the value of the autopsy. A similar study examining

missed clinical diagnoses in trauma patients dying in an American intensive care unit (2002)[14] found a missed major diagnosis that may have affected outcome if recognised clinically in 3% of cases in their sample. Another autopsy study examining critically ill patients in a UK teaching hospital found major missed diagnoses in 39% of cases[15]. In Australia, a systematic review of reports from 1996-2002 found autopsies detected, on average, 23.5% of clinically missed diagnoses involving the principal or underlying cause of death[16]. Finally, a Japanese study found that in 1,044 patients autopsied between 1983 and 1997, 7% of cases had a clinical diagnosis that differed from the autopsy findings[17].

These studies all highlight the value of autopsies in not only providing an accurate cause of death but also their value as an educational tool, serving to advance the understanding of diseases and disease processes. However, it is important to note that the purpose of the coronial autopsy, within the confines of the coronial system, is only to provide a cause of death. One reason why there is necessarily more interest in the coronial system now is because the numbers of consented autopsies have declined dramatically over the last 20 years. In adult practice, coronial autopsies now comprise >95% of all adult autopsies in England & Wales and Northern Ireland. It raises the question, posed throughout this report, of whether the coronial system is the appropriate vehicle to bear all the other potential roles of an autopsy such as education, a deeper understanding of disease processes, and questions from the family.

NCEPOD

NCEPOD has, since 1989, reviewed samples of hospital deaths, 15 of which have included evaluations of autopsy reports. Some of the evaluations have been critical of the standard of coronial autopsy practice[18,19] and other confidential enquiries have drawn the same conclusions[20,21]. Of the reports produced by NCEPOD during this time that have included reviews of available autopsy reports; in all cases the majority of the autopsies being performed at the request of a coroner. The reviews have been undertaken by actively practising pathologists and the conclusions and recommendations emerging have mirrored many of the concerns that come out of this current study.

The first NCEPOD report (1989)[22], which focussed on perioperative deaths in children, found a high standard of autopsy reports with 114/170 (67%) cases being of 'high' or 'very high' grade and only 6/170 (4%) being 'unacceptable'. The only criticism was that an autopsy was not sought by a clinician or coroner, yet the clinical evidence for the cause of death was inadequate based on premortem information (the clinical records being available).

In the next report, on adult deaths (1990)[23], many of the issues for the next 15 years of NCEPOD reports were established:

- New information about the patients' diseases and prognosis came from the autopsy in 32% of cases.
- The surgical team were informed of the date and time of the autopsy in only 31% of cases, and therefore many did not attend the autopsy.
- Information was fed back to the clinical team in only 78% of cases.
- Clinical history was given in the autopsy report in 76% of cases.
- Tissue samples for histopathology were retained in only 13% of the coronial autopsy cases; this increased to the range 19-55% in the various subsequent reports.

- A clinicopathological correlation was provided to explain the death in 39% of all autopsies.
- The coronial autopsies were graded as 'poor' or 'unacceptable' in 25% of cases.

In reports published between 1992 and 1995, the key issues over coronial autopsies on perioperative deaths were:

- The number of postmortem examinations should be increased.
- They provided valuable audit by confirming surgical findings.
- The overall quality of the autopsies was good, but more clinicopathological correlation and greater precision in statement of the cause of death were desirable.
- The widely used preprinted proformas for coronial autopsies limited the space available for description and interpretation.
- Wider observance of the Royal College of Pathologists Guidelines for Post-mortem reports[24] would improve the quality of the examinations.
- The cranial cavity should be examined in all coronial autopsy examinations: in the 1995 report, 7% of the cases reviewed did not have the head opened.
- Critically, 'contacts between the Royal College of Pathologists and the Coroners' Society of England and Wales should be developed to address issues of common interest'.
- Introduction of a system of audit, which includes coroners' autopsies, should be considered.

In 1998, the NCEPOD report[25] considered certain surgical procedures and the final key message was that "variation in coronial practice makes it impossible to build a single logical framework for deciding whether a case should be referred to a coroner".

By the time of the report published in 2001[26], the decline in the rate of consented ('hospital') autopsies was marked, with 95% of the cases considered coming from coronial authorisation. The quality of the autopsy reports was satisfactory or better in 69%, but the overall quality was not as good as in previous years. Lack of histopathology examination detracted significantly from the quality of the autopsy reports in 28% of cases. Encouragingly, the proportion of cause of death statements that included the operation had risen to 76% of cases.

The most recent of the NCEPOD general reviews of perioperative deaths, including pathology, was published in 2002[18]. The key issues that emerged were imperfect communication between clinicians and pathologists, and between pathologists and coroners. Particularly in the transfer, quality and completeness of information concerning events leading up to a death. Regular multidisciplinary audit mortality meetings were endorsed, in part to enable continuing professional development for pathologists as well as enabling clinical review.

Inconsistency in the way individual coroners order autopsies was criticised, particularly considering the demands of the large numbers of deaths being reported to them. There was a call for changing the coronial system and a strong plea that autopsies, like all other branches of medicine, should be subject to the formal scrutiny of external audit by interested groups including clinicians. Finally, the problem for coroners in identifying appropriately specialist

pathologists for certain cases (particularly paediatric) was noted.

The previous NCEPOD autopsy reviews have not been representative of all deaths occurring in the population, since deaths in the community and (until recently) non-perioperative deaths have not been within the NCEPOD remit. This changed in 2004, when the remit of NCEPOD was broadened to encompass all deaths that were not, related to pregnancy, or from homicide related to mental illness. This was reflected in the name change, from National Confidential Enquiry into Perioperative Death, to National Confidential Enquiry into Patient Outcome and Death.

The present study

This study is more truly representative since it is a review of the autopsy reports of all deaths accepted for autopsy by a coroner across the participating states over a particular period, whether occurring in hospitals, nursing homes or elsewhere in the community, the only exception being suspected homicide cases. A further significant change in the review process was the inclusion of coroners as well as pathologists among the Advisors. Since by virtue of the coronial system, the autopsy report is currently intended only for the coroner, it was considered useful to obtain their assessments of the product in conjunction with those of pathologists. Previous NCEPOD reports have included organisational questions that pertained to operations and medical practices, such as provision and staffing of operating theatres. For the present study, a similar investigation was made into some aspects of the provision of facilities and staffing of the mortuaries wherein the autopsies take place.

To understand the context of this report and its findings, the following sections provide a brief overview of the current legislative framework for coroners and the role of pathologists in the coronial process.

1. Introduction

The coronial system

In 2005 in England and Wales, 513,000 deaths were registered, of which 232,400 (45%) were reported to coroners. This proportion of reported deaths is an increase of 7,000 (3.1%) from the figure reported in 2004[2].

Governance of the coronial system

In England, Wales, Northern Ireland and the offshore islands there are approximately 120 coronial jurisdictions (ongoing amalgamations change the exact number, there were 137 at the time of running this study). The coroners and their deputies, are appointed by local authorities and are answerable to the Lord Chief Justice. They are managed by the Dept of Constitutional Affairs. Thus, coroners, the coronial system, and coronial autopsies are independent of the NHS, even though they are concerned with causes of death in patients who, for the most part, have been managed in the NHS.

The number of autopsy examinations as a proportion of deaths being reported to coroners has declined over recent years, (49% of deaths reported to coroners were autopsied in 2005 compared to 51% in 2003). It should be noted that the 49% of cases reported to them for which coroners request an autopsy is an average. There is enormous variation nationally; among the jurisdictions with over 1000 cases referred to them per year, the range is actually 28-77%[2].

As a proportion of all registered deaths, the autopsy rate through the coronial system is 22% in England and Wales, but notably, in Northern Ireland it is less than half that in England and Wales, at 9%. In Scotland, where the Procurator Fiscal takes the role of the coroner for medicolegal investigations, the rate is about 10%, as it is in other English speaking countries that have taken their legal framework from the UK (e.g. North America, Australia, and New Zealand). Only certain central European countries (Austria, Hungary) have traditionally had a higher autopsy rate than England and Wales. Therefore it is appropriate that a survey of the outcomes of this autopsy process be undertaken.

In England and Wales, the number of inquests into death has remained relatively stable, with approximately one in eight deaths being reported to coroners resulting in inquest. The most common verdicts following inquest have consistently been found to be accident/misadventure (35%), natural causes, (23%) and suicide (12%); the remaining 30% include death from industrial disease, an open verdict, and all other verdicts[2].

1. Introduction

Why autopsies are performed

The Coroners Act 1988[27] (the Act), sections 8, 19 and 20, prescribes that in England and Wales' coroners shall investigate the body of a person lying within their jurisdictions where they have reasonable cause to suspect that the deceased:

- has died a violent or an unnatural death;
- has died a sudden death of which the cause is unknown; or,
- has died in prison or in such a place or in such circumstances as to require an inquest under any other Act.

A coroner will request an autopsy if there is reasonable cause to suspect that the person has died a sudden death where the cause of death is unknown, i.e. a medical practitioner does not feel able to provide a natural cause of death, 'to the best of his knowledge and belief' or because they have not seen the patient for more than two weeks[1].

For the purpose of the investigation, a coroner will decide whether an autopsy is necessary and, if so, direct any qualified (i.e. fully registered) medical practitioner to make an autopsy of the body, and to report the results of the examination to the coroner in writing. For the format of that autopsy report, Section 10 of the Coroners Rules 1984[28] states that:

"The person making a post-mortem examination shall report to the coroner in the form set out in Schedule 2 or in a form to the like effect".

A copy of Schedule 2 is provided as an Appendix. It lists the information that should be contained within an autopsy report. (The equivalent Schedule in the Northern Ireland coronial system is similar to that of England and Wales. Minor deviations as noted in the Statutory Rules and Orders of Northern Ireland[29] are highlighted where applicable throughout this report). (The offshore islands also have their own equivalent of the Coroners Rules[4,5]).

What is the autopsy for?

The coronial autopsy examination should identify how the deceased came by his/her death in cases where an unnatural death is suspected. For natural causes of death, under existing legislation, the standard of proof required is only the 'balance of probability', rather than 'beyond reasonable doubt' as required under criminal law, and for certain categories of coroners' verdicts (suicide, unlawful killing). In summary, the purpose of the coronial autopsy is to assist the coroner in carrying out their duties in establishing who the deceased was, and how, when and where the deceased came by their death. In most cases, the level of diagnostic accuracy is expected to be 'probably true' rather than 'accurate beyond reasonable doubt'. It is important to recognise that under existing legislation, the purpose of the coronial autopsy is interpreted differently by coroners as well as pathologists. At the basic level, it is to identify or exclude unnatural or violent deaths (e.g. homicide) and provide a cause of death. At the other end of the

spectrum, others may consider that the purpose of the coronial autopsy is to confirm or refute clinical diagnoses, and/or to ensure that the autopsy report meets 'best practice' guidelines (discussed further under 'The Royal College of Pathologists' section).

The autopsy results may obviate the need for an inquest, as occurs in nearly 90% of cases (England and Wales) where the cause of death proves to be 'natural' rather than 'unnatural'. There is no statutory definition of what constitutes a natural cause of death, however, it is generally taken to be the consequences of old age or a disease that did not (for example) involve a third party, drug toxicity, industrial complications, trauma, self injury, or medical malpractice. Over the years there has been accumulated guidance on the types of death scenarios that should be reported to a coroner, with such lists printed in the books of medical certificates of causes of death, and recent advice from the General Registrar's Office[1]. The conditions described therein constitute the conditions considered potentially unnatural and are to be investigated by the coroner.

If an inquest is to take place, the resulting autopsy report may become part of the evidence. Often, but not always, this is supported by the presence of the pathologist at the inquest. The Act prescribes that at inquest, the coroner shall set out, so far as such particulars have been proved, who the deceased was and how, when and where the deceased came by his/her death.

The communication between coroners and pathologists is critical to the operation of the system for autopsies, and comes under scrutiny in several places within this report. The size of coronial jurisdictions and numbers of deaths reported varies hugely[2], and in the busier jurisdictions there are officers employed on behalf of the coroner in most aspects of referred cases. They apply the policies laid down by the coroner and do most of the communicating with pathologists.

There are approximately 700-800 pathologists in the UK who perform autopsies for coroners but there is no central register. The Royal College of Pathologists is the professional body that supports pathologists, and a summary of their work is provided in the next section.

1. Introduction

The Royal College of Pathologists

The Royal College of Pathologists (RCPath) is a "professional membership organisation... concerned with all matters relating to the science and practice of pathology"[30]. The RCPath has previously outlined a number of problems with the current coronial system[24], some of which are discussed here.

First, the RCPath contend that there is often a lack of adequate information presented to pathologists before the autopsy, and that in most cases the pathologist will not have the patient's medical records, a finding which has been supported by previous research[31].

Second, the RCPath has expressed the view that performing many autopsies in a short space of time can lead to an inadequate amount of time being spent on problematic cases. Attitudes of pathologists have also been highlighted as a problem, as they may be under pressure to provide a cause of death quickly, leading to inadequate investigations into the cause of death. These findings have been replicated by the Shipman Inquiry[32], which also highlighted the issue of histology, whereby the coroner may not allow for histology to be taken, even where the pathologist feels it is necessary. Following The Royal Liverpool Inquiry[33] and the Bristol Royal Infirmary Inquiry[34] there has been a 'sea change' in the attitude of most coroners to retaining tissues for analysis, with increasing restriction. The attitude of government toward all autopsy tissue retention also changed and the specific regulations governing tissue retention at a coronial autopsy were amended with effect from June 2005 (see 'Tissue retention' in the 'Results' section).

Third, the RCPath has highlighted a lack of audit leading to a possible fall in standards. They argue that it is important to have a baseline overview of what is actually done at autopsy.

In the late 1990s, the RCPath commissioned the development of practice guidelines for autopsies of all kinds (i.e. coronial as well as consented hospital autopsies) which was published in 2002. The minimum data set applicable to all autopsy examinations includes:

- Demographic details;
- Type of autopsy;
- Clinical history;
- External description;
- Internal organ examination;
- Histological report (if histology is taken);
- Summary of findings;
- Clinicopathological correlation;
- Cause of death[24].

These guidelines are for 'best practice' and have no direct influence on how coronial autopsies are performed. The RCPath recognises that in addition to providing a cause of death, autopsies that are conducted within and outside the coronial system are useful to gain further understanding of disease, to evaluate the effects of treatment and to identify other information about the deceased which may be relevant to the death. Autopsies may incidentally be used for audit of clinical care, teaching, and are occasionally used in research.

Role of the RCPath

The RCPath is a professional and advisory body; it is not a regulatory body that has powers to enforce standards of practice in any area of pathology. It produces best practice guidelines, across all areas of pathology, that derive from expert groups which are then subject to consultation with the membership and other relevant bodies, to arrive at a consensus. These guidelines are not binding upon practitioners, but are incorporated into specialist practice development and reviews (e.g. cancer networks). It has a Professional Standards Unit (PSU) that can become involved in investigating pathologists and departments where allegations of substandard practice have been made, usually at the invitation of medical directors of trusts and other hospitals. It organises a Continuing Professional Development (CPD) scheme for pathologists, which is voluntary, to document practice and continuing education in the specialist fields. This can be part of the regular appraisal of pathologists by their employers.

However, coronial autopsy practice is, by definition, privately contracted work that lies outside the National Health Service (NHS). Whether the pathologist is employed by a hospital trust, a medical school, or is an independent practitioner, the standards of practice in performing coronial autopsies do not come under the clinical governance prescriptions of the NHS. Thus this activity is essentially unaudited (the autopsy reports belong only to the coroner and may not be disclosed without the consent of the coroner[27]), is not part of the annual appraisal (as long as the time taken doing coronial autopsies does not conflict with agreed job plans), and does not come under CPD inspection. Further, the RCPath PSU has specifically indicated that, for the moment, coronial autopsy practice is not within its remit for investigation.

Initiating this study

In 2004, NCEPOD received a proposal from the RCPath, which called for a study to examine the quality of coronial autopsy reports. It will be the first of its kind to audit the quality of the product of coronial autopsies: the autopsy report. NCEPOD hope that the findings from this study will be useful to coroners, pathologists and other key stakeholders, particularly during the proposed coronial reform[35]; and that the results of the study will be used as a baseline for future quality audits, be that on a local, national or international level.

1. Introduction

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