Evidence Report

Chapter 1. Introduction

Background

The nomination for this report came from the College of American Pathologists (CAP), which sought a formal assessment of the extensive literature on the role of the autopsy as an outcome and performance measure. This literature, beginning in 1912[1] and continuing to the present,[2, 3] documents the prevalence of significant diagnostic errors discovered at autopsy, and forms the basis for regarding the autopsy as a potential tool in clinical audit and quality assessment. The autopsy has numerous other known and suggested benefits, [4-10] with specific examples including: more accurate vital statistics[11-16]; provision of accurate prevalence data for specific target conditions[17-22]; pathologic descriptions of new diseases[23-26]; teaching gross anatomy, disease progression and pathology in both undergraduate and graduate medical education[27, 28]; and comfort to family members in knowing the cause of death or allaying fears regarding heritable conditions.[29-31]

Despite the continued fulfillment of these roles, the frequency of autopsies has steadily declined in this country and elsewhere (Appendix Figures 1&2). In 1994, the last year for which there are national data, the autopsy rate for all non-forensic deaths fell below 6%.[32] A recent survey found that over half of all hospitals in one state reported performing no autopsies during a one year period.[33] The marked decline in autopsy rates from previous rates as high as 40-50% undoubtedly reflects various factors, including the lack of direct or indirect economic incentives and absence of regulatory requirements for minimum autopsy rates.[32-34] Other factors include the attitudes of clinicians regarding the utility of autopsies in the setting of other diagnostic advances, and general unfamiliarity with the autopsy and techniques for requesting it, especially among physicians-in-training.[28, 35-41]

Although the autopsy plays a number of potentially valuable roles, quantification of this value is difficult except in relation to the impact of autopsy performance on clinical diagnostics or therapeutics. In this way, assessments of the value of postmortem examination are handicapped in a fashion similar to assessments of the physical examination performed by clinicians. The act of examining patients has a number of benefits—focusing the clinician on the patient as an individual, reassuring the patient, and various roles in medical education.[42, 43] Nevertheless, assessments of the value of the physical examination inevitably focus on its impact on medical decision-making related to diagnosis or treatment.[44-50]

Recognizing at the outset, then, that our review would not take into account less quantifiable attributes of the autopsy (e.g., its value in medical education), we set out to assess the extent to which the autopsy provides a valid measure of clinical performance, especially as regards diagnosis.

An extensive literature has focused on the prevalence of clinically important diagnoses that remained undetected until autopsy. Several well-known studies from this literature have compared rates of “diagnostic errors” detected by autopsy from different time periods and found surprisingly little change.[51-55] It is important to note that the discrepancies between clinical and autopsy diagnoses discussed here and in these studies do not necessarily represent errors *per se*. In some cases, misinterpretation of test results, failure to respond appropriately to abnormal clinical findings and other such mistakes or ‘slips” in the diagnostic process do produce diagnostic discrepancies warranting the term “error.” In other cases, however, atypical clinical

presentations or the limits of current diagnostic techniques result in misdiagnoses without any true "errors" on the parts of clinicians. Despite this important distinction, we refer to "diagnostic errors" throughout this report because of the ubiquitous use of this phrase in the autopsy literature.

Selection of Patients for Autopsy

Discussions of the significance of autopsy-detected diagnostic errors have generally focused on the degree to which they reflect increased selection by clinicians.[56, 57] Given that autopsy rates have declined, it is quite plausible to suggest that cases for which clinicians request autopsy represent precisely those that have presented diagnostic difficulties. This question is obviously important (and one which we address in this report), but it is also important to clarify how autopsy-detected diagnostic error rates should be interpreted.

Patients undergoing autopsy represent a very select subset of patients, with selection of autopsy cases by clinicians constituting just one of several contributing factors (Figure 1).

Autopsied patients represent a nonrandom sample of all deaths, which in turn constitute a non-random sample of all patients. This non-random sampling is further complicated by the fact that most autopsy series involve hospital deaths only, adding a further level of selection. Thus, the interpretation of autopsy-detected diagnostic error rates is complicated by secular changes in the proportion and demographics of patients passing through these successive selections. Fewer and sicker patients are admitted to the hospital for shorter periods of time.[59-67] For many conditions, overall mortality has decreased, and, as already noted, fewer deceased patients undergo autopsy. Before attempting to unravel these complicating factors, it is worth considering the extent to which one ought to expect the rate of autopsy detected errors in clinical diagnosis to decrease over time (as commonly assumed in studies reporting these rates).

Patients who die generally fall into one of two categories – treatment failures (e.g., complications from treatments, ineffective treatment available, etc.) or diagnostic failures (e.g., missed or incorrect diagnoses).[1] While improvements in care reduce overall mortality for an increasing number of conditions, the proportion of deaths in these two categories may remain relatively unchanged. In fact, if the number of patients in the first category (treatment failures) decreases over time for many conditions, the relative proportion of deaths due to diagnostic failures might increase. Alternatively, if diagnostic advances outpace improvements in therapy, more patients will be diagnosed with a condition, but then not respond to treatment and therefore count as treatment failures. This issue is discussed in greater detail in the section on autopsy studies of the sensitivity of clinical diagnosis for pulmonary embolism.

The main point is that the relationship between diagnostic errors detected at autopsy and the overall performance of clinical diagnosis is quite complex. For a given condition it may be possible to predict trends in diagnostic error rates, but for clinical diagnosis taken as a whole, there is no reason to expect a decrease in error rates over time. The specific study questions below attempt to clarify the significance of autopsy-detected errors in clinical diagnosis in the context of this complexity.

[1] An increasing proportion of patients die while receiving treatment that focuses on palliation and comfort, so the term "failure" is not really appropriate in terms of diagnosis or treatment. We do not address this issue in this report, as the vast majority of autopsy studies do not capture data on advanced directives or "code status," let alone more detailed information on the kind of care patients were receiving in the days leading up to death.

Objectives

This report primarily addresses the following questions:

1) *To what extent does the autopsy reveal important diagnoses that were clinically unsuspected prior to death?*

2) *To what extent does the autopsy provide a useful performance measure or audit of clinical diagnosis in general?*

3) *What impact do autopsy findings have on clinical performance improvement?*

4) *Do autopsy findings have a role to play in generating accurate epidemiologic data (e.g., vital statistics)?*

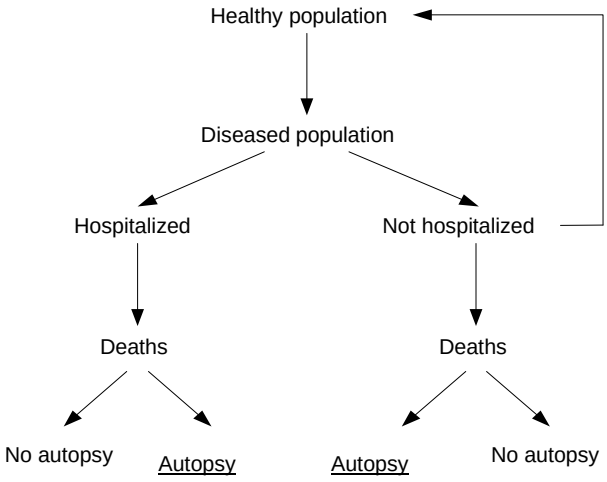
Although the first two questions are often considered the same, they are in fact quite distinct. The first question addresses the degree to which clinicians have correctly identified important potentially treatable diagnoses (e.g., pulmonary embolism, dissecting aortic aneurysm, bowel perforation) prior to death. Using the autopsy literature to answer this question requires assessing the extent to which the rate of diagnostic errors detected at autopsy simply reflects selection by clinicians of diagnostically challenging cases. Studies directly relevant to this assessment include autopsy series in which close to 100% of deaths were autopsied and studies in which clinicians explicitly state their diagnostic confidence prior to autopsy results becoming known.

The second question asks how common is it for important treatable diagnoses to escape detection during life and therefore first come to attention at autopsy. Answering this question requires taking into account performance of clinical diagnosis among all patients with conditions of interest, not just those who died. Precise evaluations of the overall performance of clinical diagnosis are complicated by the lack of a uniform diagnostic standard for (presumptive) clinical diagnoses among patients who survive. Nevertheless, long-term clinical follow-up of patients who survive combined with autopsy results for patients who die provides an estimate of the true sensitivity of clinical diagnosis for a given condition of interest.

The third question asks what impact the autopsy has on quality improvement. In other words, to what extent does knowledge of clinically missed diagnoses or unrecognized complications of care reduce the subsequent occurrence of similar quality problems. Many commentators have responded to studies of diagnostic error rates detected at autopsy by calling for an increase in the rate at which autopsies are performed. But, increasing autopsy rates without appropriate utilization of the information derived from autopsies may achieve little benefit. If hospitals are to invest in increasing current autopsy rates, there would also need to be simultaneous improvements in the utilization of the information derived from autopsies, in order to have a chance of realizing a clinical benefit for future patients.

The above questions focus on clinical applications of autopsy-detected errors, but the autopsy undoubtedly has multiple other values. One of the more quantifiable or tangible potential applications of autopsy-detected diagnostic errors is in generating accurate vital statistics, which is the target of the fourth question.

Figure 1 – Selection of Patients for Autopsy



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