Appendix A: Additional Tables and Figures

Appendix Table 1 – Studies reporting rates of persistent diagnostic uncertainty after autopsy

Institution	Autopsy Rate	Case Mix (Number of Autopsies)	Persistent Uncertainty After Autopsy (95% CI)
Paddington General Hospital (UK): 1958[90]	53%	General inpatients[a] (265)	21.1% (16.5-26.6%)
Woodend General Hospital and Aberdeen City Hospital (Scotland): 1972-74 [77]	37%	General inpatients (1,000)	5.1%[b] (3.9-6.7%)
Oulu University Hospital (Finland): 1972-74[292]	24%[c]	Oncology (377)	1.1% (0.3-2.9%)
Holstebro Central Hospital, Denmark: 1974 [199]	85%	General inpatients (266)	0.4% (02-2.4%)
University of Bergen (Norway): 1975[293]	75%	General inpatients (742)	4.3% (3.0-6.1%)
Huddinge University Hospital (Sweden): 1977-78, 1987-88)[53, 294]	76%, 42%[d]	General inpatients (3,042)	2.4% (1.9-3.1%)
Salford Health Authority (UK): 1981[295]	35%	Inpatients age >65 (332)	3.6% (2.0-6.4%)
University of Colorado (Denver, CO): 1981-83[91]	81%	Fetal deaths (64)	46.2% (32.5-60.4%)
University of Colorado (Denver, CO): 1981-83[91]	80%	Neonatal/infant deaths (108)	23.0% (14.9-33.5%)
White River Junction VA Medical Center (White River Junction, VT): 1983[78]	60%	General inpatients (111)	3.6% (1.2-9.5%)

[a] Presumed from description of study and results, but not explicitly stated
[b] The authors reported that "the solution of a clinical problem proved impossible despite an adequately performed and reported autopsy" in 71 cases. The rate listed in the table derives from these cases, but excluding the 20 cases in which this failure to solve the clinical problem involved failure to perform biochemical or hematological tests.
[c] This rate reflects cancer patients only, which was focus of study
[d] The rate of indeterminate autopsies was reported for the study overall and not separated by time periods.

Hospital Central de la Cruz Roja (Spain): 1983-85[125]	51%	ICU (100)	6% (2.5-13.1%)
Sumitomo Hospital (Japan): 1983-97[296]	40%	General inpatients[a] (1,044)	0.6% (0.2-1.3%)
Leiden University Hospital (Netherlands): 1984 [118]	47%	Medicine patients (133)	9% (5-16%)
Northwestern Memorial Hospital (Chicago): 1985 [130]	36%	General inpatient (151)	6% (3-11%)
Institute Jules Bordet (Belgium): 1985-86 [297]	69%	Adult Oncology ICU (34)	17.6% (7.4-35.2%)
Johns Hopkins Hospital (Baltimore, MD): 1985-95[94]	24%	Adult cardiac surgery (147)	25.2% (18.6-33.1%)
Women and Infants Hospital (Providence, RI): 1991-92[93]	83%	Fetal deaths (77)	37.7% (27.1-49.5%)
Women and Infants Hospital (Providence, RI): 1991-92[93]	74%	Neonatal deaths[e] (47)	2.1% (0.1-12.7%)
Lund University Hospital (Sweden): 1991-92[92]	50%	Fetal deaths[f] (54)	42.6% (29.5-56.7%)
Lund University Hospital (Sweden): 1991-92[92]	50%	Neonatal and infant deaths (31)	3.2% (0.2-18.5%)
Lund University Hospital (Sweden): 1991-92[92]	90%	Medical abortions (19)	0% (0-20.9%)
248 Departments of Pathology (USA): 1993 [298]	-----[1]	General inpatients (2,479)	5.2%[2] (4.1-6.6%)
Prince of Wales Hospital (Hong Kong): 1997[211]	18%	General inpatients and forensic cases (332)	1.8% (0.7-4.1%)

[e] Defined by authors as deaths within 48 hrs of birth.
[f] Included 40 spontaneous abortions and 14 intra-uterine deaths
[1] Rate not calculable given study design in which each of 248 institutions contributed a small, consecutive sample of its autopsies.
[2] This study reported the number of clinical questions answered by the autopsy, with each of the 2,479 cases having a mean of 2.6 associated questions. The listed figure for "persisted uncertainty" after autopsy reflects the percentage of the cases in which the autopsy did not establish the cause of death (The answer to this question was provided by respondents for 1,330 of the total of 2,479 autopsies.)

Appendix Table 2 – Studies Reporting "Class I" or "Class I Equivalent" Error Rates (These error rates and 95% confidence intervals are displayed graphically in Appendix Figure 5.)

Institution	Autopsy Rate	Case Mix (Number of Autopsies)	Error Rate (95% CI)
Peter Bent Brigham Hospital (Boston): 1960 [51]	75%	Adult inpatients (100)	8% (4-16%)
Christian- Albrechts University Hospital (Germany): 1959 [54]	88%	General inpatients (100)	7% (3-14%)
Christian- Albrechts University Hospital (Germany): 1969[54]	82%	General inpatients (100)	12% (7-20%)
Peter Bent Brigham Hospital (Boston): 1970 [51]	71%	Adult inpatients (100)	12% (7-20%)
Zurich University Hospital (Switzerland): 1972[55]	94%	Adult medical (100)	16% (10-25%)
Winnipeg Health Sciences Center (Canada): 1978-79[299]	26%[3]	Adult inpatients (200)	1.5% (0.4-4.7%)
Royal Adelaide Hospital (Australia): 1979[300]	45%	Adult inpatients (99)	2.0% (0.4-7.8%)
Christian- Albrechts University Hospital (Germany): 1979[54]	58%	General inpatients (100)	12% (7-20%)
Peter Bent Brigham Hospital (Boston): 1980[51]	38%	Adult inpatients (100)	11% (6-19%)
39 Connecticut institutions performing autopsies: 1980[14]	14%	General (272)	4.0% (2.1-7.3%)
Belgrade University School of Medicine (Yugoslavia): 1981-84[301]	12%	General inpatients (2,145)	29% (26.9-30.8%)
Zurich University Hospital (Switzerland): 1982[55]	89%	Adult medical (100)	9% (4-17%)

[3] Rate reflects "teaching cases" only, with medicolegal cases excluded; overall autopsy rate for this period including medicolegal/forensic cases was 44%.

32 US hospitals (21 university and 11 community non-teaching): 1984 [70]	30%	General inpatients (2,067)[4]	13% (12-15%)
Brigham & Women's Hospital (Boston, MA): 1984-85 [129]	37%	Adult inpatients (175)	11% (7-17%)
Emerson Hospital (Concord, MA): 1984-85 [129]	26%	General inpatients (58)	12% (5-24%)
Medical Center of Delaware: 1988-91 [210]	17%	General inpatients (145)	3% (1-8%)
St. Vincent's Hospital (Australia): 1988[160]	22%	General inpatients (139)	6% (3-11%)
Christian- Albrechts University Hospital (Germany): 1989[54]	36%	General inpatients (100)	11% (6-19%)
Zurich University Hospital (Switzerland): 1992[55]	89%	Adult medical (100)	7% (3-14%)
Ben Taub General Hospital (Houston, TX): 1992-3 [116]	16%	Adult medical[5] (110)	10.9% (6.3-16.8%)
San Francisco General Hospital and 31 hospitals in Orange County, CA: 1974-75[6] [302]	100%	Adult and pediatric motor vehicle accident fatalities (182)	12.6% (8.3-18.6 %)
Mason F. Lord Nursing Home (Baltimore, MD):1981-88[303]	3.5%[7]	Nursing home residents (34)	32.4% (18-50.6%)
Hospital Central de la Cruz Roja (Spain): 1983-85[125]	51%	Adult ICU (100)	7% (3.1-14.4%)

[4] Not clear how many pediatric patients included as study states only that 2,067 autopsies reviewed included 360 cases under 20 years of age.
[5] Patients with Acquired Immunodeficiency Syndrome (AIDS) were reported separately; these data are presented in the line below this entry.
[6] The authors of this study were focused primarily on demonstrating the difference in quality of care between a region with a Level 1 trauma center (San Francisco County) and a region (Orange County) where trauma patients are sent to nearest available facility. Chart reviews were conducted by the authors and were not blinded to patient location. Because of the significant potential for bias introduced by non-blinded peer review, the results for the two regions were combined rather than presenting separate Class I error rates for the two regions.
[7] This value represents an average over the study period, with yearly rates ranging from 1.6-10.8%. In fact, all but the last year had rates under 3%, with the increase in the final year attributed to targeted efforts to increase autopsies.

Six Department of Veterans Affairs Hospitals: 1986-87[131]	43%	Adult medical ICU (172)	12% (8-18%)
Hartford Hospital (New Haven, CT): 1986-92[304]	29%	Adult surgical ICU patients (149)	11% (6.5-17.1%)
Gloucestershire Royal Hospital (U.K.): 1996-99[3]	40%	Adult ICU patients (97)	4.1% (1.3-10.8%)
University of Massachusetts Medical Center (Worcester, MA): 1984-88[120]	32%	Adult ED patients[8] (244)	1.6% (0.5-4.4%)
University of Texas Medical Branch (Galveston, TX): 1984-88[305]	73%	Adult and pediatric surgical patients (409)	7.8% (5.5-11%)
Royal Victoria Hospital (Northern Ireland): 1986-88[306]	23%	Adult and pediatric perioperative deaths (213)	20.7% (15.6-26.8%)
Ben Taub General Hospital (Houston, TX): 1992-3 [116]	16%[9]	Patients with AIDS (42)	9.5% (3.1-23.6%)
Lutheran General Children's Hospital (Park Ridge, Ill): 1984-93[128]	36%	Pediatric inpatients (107)[10]	6.5 % (2.9-13.5 %)
Children's Hospital of Western Ontario (Canada): 1985-89[307]	75%	Pediatric deaths in the ED (52)	0%[11] (0-8.6%)
Toronto Hospital for Sick Children (Canada): 1985-90[124]	62%	Neonatal ICU (338)	2.1% (0.9-4.4%)
North Shore University Hospital (Manhasset, NY): 1985-92[132]	26%	Pediatric ICU (50)	10% (3.7-22.6%)
Royal Alexandra Hospital for Children (Australia): 1991-97[308]	40%	Neonatal ICU (91)	5.5 % (2.0-12.9 %)

[8] Study focused on patients who died in the Emergency Department (ED) or within 7 days of hospitalization after admission through the ED; forensic cases were included.
[9] Listed autopsy rate is for all medical patients; specific autopsy rate for AIDS patients not stated.
[10] Deaths in neonatal ICU were excluded
[11] As noted by the authors of this study, the lack of Class I errors likely reflects the high proportion of deaths due to cardiac arrest in the ED, making changes in outcome unlikely even in the presence of major unrecognized diagnoses.

General Hospital Celje (Slovenia): 1998-99[320]	47%	Medical ICU (126)	9.5% (5.2-16.4%)
Ryder Trauma Center (Miami): 1997-98[321]	97%	Adult & pediatric trauma/burn patients dying in ICU (153)	2.6% (0.8-7.0%)
King Edward Memorial Hospital (India): 1995-96[319]	82%	Neonatal ICU (197)	12.2% (8.1-17.8%)

As explained in the text, inclusion as a "Class I" error rate required that the study explicitly reference the classification scheme of Goldman et al [51] or the modification of this scheme by Battle et al.[70] "Class I equivalents" included missed diagnoses that "would," "could," possibly" or "might" have affected patient "prognosis" or "outcome" had they been detected during life. (At a minimum, such impact involved discharge from the hospital alive). Errors for which expected impacts on patient outcomes were explicitly identified as being restricted symptom palliation were excluded from this category and included with major errors (Appendix Table 3).

Studies with fewer than 50 cases were included only if they involved a specific patient population (e.g., perinatal autopsies, ICU patients, oncology, etc.). Such studies are listed in the table below.

Appendix Table 3 – Autopsy Studies Reporting Major Error Rates

Institution	Autopsy Rate	Case Mix (Number of Autopsies)	Error Rate (95% CI)
Peter Bent Brigham Hospital (Boston): 1960 [51]	75%	Adult inpatients (100)	22% (15-32%)
Peter Bent Brigham Hospital (Boston): 1970 [51]	71%	Adult inpatients (100)	23% (15-33%)
Zurich University Hospital (Switzerland): 1972[55]	94%	Adult medical (100)	30% (21.4-40.1%)
South Lothian District hospitals (Scotland): 1975-7 [155, 156]	25%	General inpatients (1,152)	38% (36-41%)
University of Edinburgh teaching hospital (Scotland): 1978 [123]	64%	General inpatients (154)	15% (10-22%)
Peter Bent Brigham Hospital (Boston): 1980[51]	38%	Adult inpatients (100)	21% (14-30%)
Zurich University Hospital (Switzerland): 1982[55]	89%	Adult medical (100)	18% (11.3-27.2%)
White River Junction VA Medical Center (White River Junction, VT): 1983[78]	60%	General inpatients (111)	12.6% (7.3-20.6%)
Chandigarh Postgraduate Institute of Medical Education and Research (India): 1983-88[309]	23-27%[12]	Adult inpatients[13] (1,000)	31.7% (28.8-34.7%)
32 US hospitals (21 university and 11 community non-teaching): 1984 [70]	30%	General inpatients (2,067)	34% (32-36%)
Brigham & Women's Hospital (Boston): 1984-85 [129]	37%	General inpatients (175)	23% (17-30%)
Northwestern Memorial Hospital (Chicago): 1985 [130]	36%	General inpatients (142)	23% (17-31%)

[12] Stated range for annual autopsy rates during study period; overall autopsy rate not stated
[13] Aged 15 years and older

Medical Center of Delaware: 1988-91 [210]	17%	General inpatients (145)	12% (7-18%)
Peterborough District Health Authority (England): 1990 [310]	13%	General inpatients (63)	19% (11-31%)
Zurich University Hospital (Switzerland): 1992[55]	89%	Adult medical (100)	14% (8.1-22.7%)
University of Pittsburgh Medical Center (Pittsburgh): 1994 [152]	19%	General inpatients (172)	34% (27-42%)
Prince of Wales Hospital (Hong Kong): 1997[211]	17.7%	General inpatients and forensic cases (332)	23.5% (19.1-28.5%)
Mason F. Lord Nursing Home (Baltimore, MD):1981-88[303]	3.5%[14]	Nursing home residents (34)	47.1% (30.2-64.6%)
Leiden University Hospital (Netherlands): 1984[118]	47%	Adult medical (133)	41% (33-50%)
Ben Taub General Hospital (Houston, TX): 1992-3 [116]	16%	Medical patients[15] (110)	23.6% (16.3-32.9%)
Ben Taub General Hospital (Houston, TX): 1992-3 [116]	16%[16]	Patients with AIDS (42)	33.3% (20.0-49.6%)
Salford Health Authority (UK): 1981[295]	35%[17]	Inpatients over 85 yrs old (129)	31% (23.3-39.8%)

[14] This value represents an average over the study period, with yearly rates ranging from 1.6-10.8%. In fact, all but the last year had rates under 3%, with the increase in the final year attributed to targeted efforts to increase autopsies.
[15] Patients with Acquired Immunodeficiency Syndrome (AIDS) were reported separately; these data are presented in the line below this entry.
[16] Listed autopsy rate is for all medical patients; specific autopsy rate for AIDS patients not stated.
[17] The autopsy rate is for patients aged 65 and over; the rate specifically for the group over 85 years is unclear.

Beth Israel Hospital (Boston, MA): 1981-83[158]	27%	Adult inpatient deaths after undergoing CPR[18] (130)	13.8% (8.6-21.3%)
University of Massachusetts Medical Center (Worcester, MA): 1984-88[120]	32%	Emergency patients[19] (244)	4.1% (2.1-7.6%)
Johns Hopkins Hospital (Baltimore, MD): 1985-95[94]	24%	Adult cardiac surgery (147)	38.8% (31.0-47.2 %)
Royal Victoria Hospital (Northern Ireland): 1986-88[306]	23%	Adult and pediatric perioperative deaths (213)	49.8% (42.9-56.6%)
Hospital Central de la Cruz Roja (Spain): 1983-85[125]	51%	Adult ICU (100)	22% (14.6-31.6%)
Hartford Hospital (New Haven, CT): 1986-92[304]	29%	Adult surgical ICU (149)	23% (16.5-30.6%)
Hershey Medical Center (Pennsylvania, PA): 1994-5[117]	31%	Adult ICU (41)	27% (15-43%)
Cleveland Clinic (Cleveland, OH): 1994-95[2]	23%	Medical ICU (91)	19.8% (12.4-29.7%)
Gloucestershire Royal Hospital (U.K.): 1996-99[3]	40%	ICU patients (97)	23.7% (15.9-33.6%)
University of Rochester Medical Center (Rochester, NY): 1989-94[126]	74%	Pediatric inpatients including forensic cases (157)	6.4% (3.3-11.7%)
Children's Hospital of New Jersey (Newark, NJ): 1992[133]	29%	General Pediatrics[20] (23)	13.0% (3.4-34.7%)
University of Texas Medical Branch (Galveston, TX): 1984-88[305]	73%	Adult and pediatric surgical patients (409)	30.3% (26-35.1%)

[18] Study autopsies drawn from inpatients who died after undergoing cardiopulmonary resuscitation (CPR); patients experienced cardiac arrest outside the hospital, in the Emergency Department or ambulatory clinics were excluded.
[19] Study focused on patients who died in the Emergency Department or within 7 days of hospitalization after admission through the Emergency Department; forensic cases were included.
[20] Deaths in the Emergency Department were excluded.

Lutheran General Children's Hospital (Park Ridge, Ill): 1984-93[128]	36%	Pediatric inpatients (107)[21]	13.1% (7.6-21.3%)
Children's Hospital of Western Ontario (Canada): 1985-89[307]	75%	Pediatric Deaths in the Emergency Department (52)	15.4% (7.3-28.6%)
Hospital for Sick Children (Canada): 1985-90[124]	62%	Neonatal ICU (338)	18.9% (15.0-23.6%)
North Shore University Hospital (Manhasset, NY): 1985-92[132]	26%	Pediatric ICU (50)	28.0% (16.7-42.7%)
Ryder Trauma Center (Miami): 1997-98[321]	97%	Adult & pediatric trauma/burn patients dying in ICU (153)	15.7% (10.5-22.6%)
King Edward Memorial Hospital (India): 1995-96[319]	82%	Neonatal ICU (197)	26.9% (21.0-33.8%)

As explained in the text, "major errors" included missed diagnoses that, while important, likely had no effect on patient outcome. Changes in management could be assessed as possible or even expected, but impacts on outcome for errors in this category were judged to have been "equivocal," "doubtful," "unlikely," or otherwise unexpected. (Errors for which expected impacts on patient outcomes were explicitly restricted to symptom palliation were included in this category.) This category also included the sum of Class I and Class II errors from articles that explicitly reference the classifications of Goldman et al [51] or Battle et al.[70]

[21] Deaths in neonatal ICU were excluded

Appendix Table 4 – Studies Reporting Autopsy-detected Diagnostic Errors in terms of Discrepant Major ICD Disease Categories

Institution	Autopsy Rate	Case Mix (Number of Autopsies)	Error Rate (95% CI)
Serafimerlasarettet (Sweden): 1970-1[122]	96%	General inpatients (383)	7% (5-10%)
Holstebro Central Hospital (Denmark): 1974 [199]	85%	General inpatients (266)	10% (6.9-14.6%)
University of Bergen (Norway): 1975[293]	75%	General inpatients (742)	18.7% (16-21.8%)
South Lothian District hospitals (Scotland): 1975-7 [155, 156]	25%	General inpatients (1,152)	22% (20-24%)
Anonymous community teaching hospital (New York State): 1977-78[15]	37%	General inpatients (130)[a]	17.7 % (11.8-25.6%)
University of Sao Paulo (Brazil): 1978-80[311]	84%	General inpatients (997)	33.7% (30.8-36.7%)[b]
39 Connecticut institutions performing autopsies: 1980[14]	14%	General (272)	26.8%[c] (21.8-32.6%)

As explained in the text, studies included in this table reported the prevalence of cases for which major clinical and autopsy diagnoses fell in different disease categories in the International Classification of Diseases (ICD). Although this classification of clinical-autopsy discrepancies makes no mention of changes in outcome or treatment, such changes would be likely in many, if not most cases. Moreover, the classification scheme is well defined and likely involves less subjectivity than the other two error categories above.

[a] This study was primarily focused on the accuracy of death certificates. Two anonymous hospitals were involved. At one of the hospitals, 130 of the 229 autopsies had death certificates that the treating clinicians had completed prior to autopsy. The data from these 130 autopsies at one of the two study hospitals provide the basis for the rate of diagnostic discrepancies indicated in the table. The autopsy rate listed for this study is based on all of the autopsies, as it is not possible to calculate a rate applicable to just the 130 cases for which the death certificate was competed prior to autopsy.

[b] This outlier result is largely attributable to the high misclassification rate involving cases of Chagas' disease, which was quite prevalent in this Brazilian autopsy series. Clinical diagnosis was regarded as having missed 71 cases of Chagas's disease, so that 71 cases were assigned to some major disease grouping other than "infectious"– most often the "circulatory" category.

[c] This relatively high result partially reflects the shift of all of 13 cases in the "ill-defined" category to the trauma category and failure to code 15 deaths as due to alcoholism, all of which then counted as missed "mental disorders." Excluding all 28 of these cases lowers the observed error rate to 16.5% (95% CI: 12.4-21.6%).

Appendix Table 5 – Studies Addressing the Issue of Clinical Selection Bias in Referral for Autopsy

Study	Major Findings
75 hospitals in England and Wales (U.K.): 1959[127]	Autopsy rates inversely related to clinicians' diagnostic certainty Rates of disagreement between autopsy and clinical diagnoses increased as clinicians became less certain of the cause of death. Significant clinical-autopsy disagreements still noted in 16% of cases clinicians rated with the high level of confidence.
Serafimerlasarettet (Sweden): 1970-1[122]	Rates of autopsy detected diagnostic errors higher in cases with clinical uncertainty Major diagnostic discrepancies still noted in 15% of clinically confident cases under age 70 years of age and 34% of confident cases over age 70.
University of Bergen (Norway): 1975[293]	Autopsy rated as "essential" in only 45% of cases identified by clinicians as diagnostically "uncertain" Clinicians appeared to base their impression of autopsy necessity on more than just diagnostic confidence
South Lothian District hospitals (Scotland): 1975-7 [155, 156]	Autopsy rates and error rates inversely correlated with clinical confidence Failure to confirm clinical diagnoses still noted in 25% of clinically certain cases
One University of Edinburgh teaching hospital from above study (Scotland): 1978 [123]	Study again documented that clinicians pursue autopsies less frequently and make fewer diagnostic errors when they are confident of their diagnoses By contrast, there was no difference in diagnostic error rates between autopsies clinicians viewed as necessary and those they viewed as unnecessary
Leiden University Hospital (Netherlands): 1984 [118]	Clinicians identified cases as certain (185), probable (54) or uncertain (50). Major diagnostic errors were identified in 4% of the first category, 15% of the second and 46% for the third.
Brigham & Women's Hospital (Boston, MA) and Emerson Hospital (Concord, MA): 1984-85 [129]	Clinicians' prospective impressions of the likelihood of unexpected findings at autopsy showed no significant relationship to the occurrence of major unexpected findings (Class I or II errors)

Appendix Table 6 - Unsuspected complications of care detected at Autopsy

Institution	Autopsy Rate	Case Mix (Number of Autopsies)	Unsuspected complications (95% CI)
Peter Bent Brigham Hospital (Boston): 1960[51]	38%	Adult inpatients (100)	1% (0.05-6.2%)
Peter Bent Brigham Hospital (Boston): 1970[51]	38%	Adult inpatients (100)	3% (0.8-9.2%)
Evanston Hospital (Evanston, IL): 1973-82	Not stated	General inpatients and forensic cases (2,537)	3.1% (2.5-3.9%)
Peter Bent Brigham Hospital (Boston): 1980[51]	38%	Adult inpatients (100)	0% (0-4.6%)
Brigham & Women's Hospital (Boston, MA): 1984-85 [129]	37%	Adult inpatients (175)	0.6% (0.03-3.6%)
Emerson Hospital (Concord, MA): 1984-85 [129]	26%	Adult inpatients (58)	0% (0-7.7%)
Hospital for Sick Children (Canada): 1985-90[124]	62%	Neonatal ICU (338)	15.4% (11.8-19.8%)
Johns Hopkins Hospital (Baltimore, MD): 1985-95[94]	24%	Adult cardiac surgery (147)	1.4% (0.2-5.3%)
Royal Alexandra Hospital for Children (Australia): 1991-97[308]	40%	Neonatal ICU (91)	4.4% (1.4-11.5%)
Prince of Wales Hospital (Hong Kong): 1997[211]	17.7%	General inpatients and forensic cases (332)	3.6% (2.0-6.4%)
Central Hospital of Akershus (Norway): 1993-95[312]	78%	Adult medicine (572)	7.7%[d] (5.7-10.3%)

[d] This rate refers to adverse drug events (ADEs) only, not all complications. On the other hand, it is not clear how "unsuspected" these complications were. The authors stated that the autopsy was "decisive for identifying fatal ADEs" in 44 autopsies (from a total of 572).

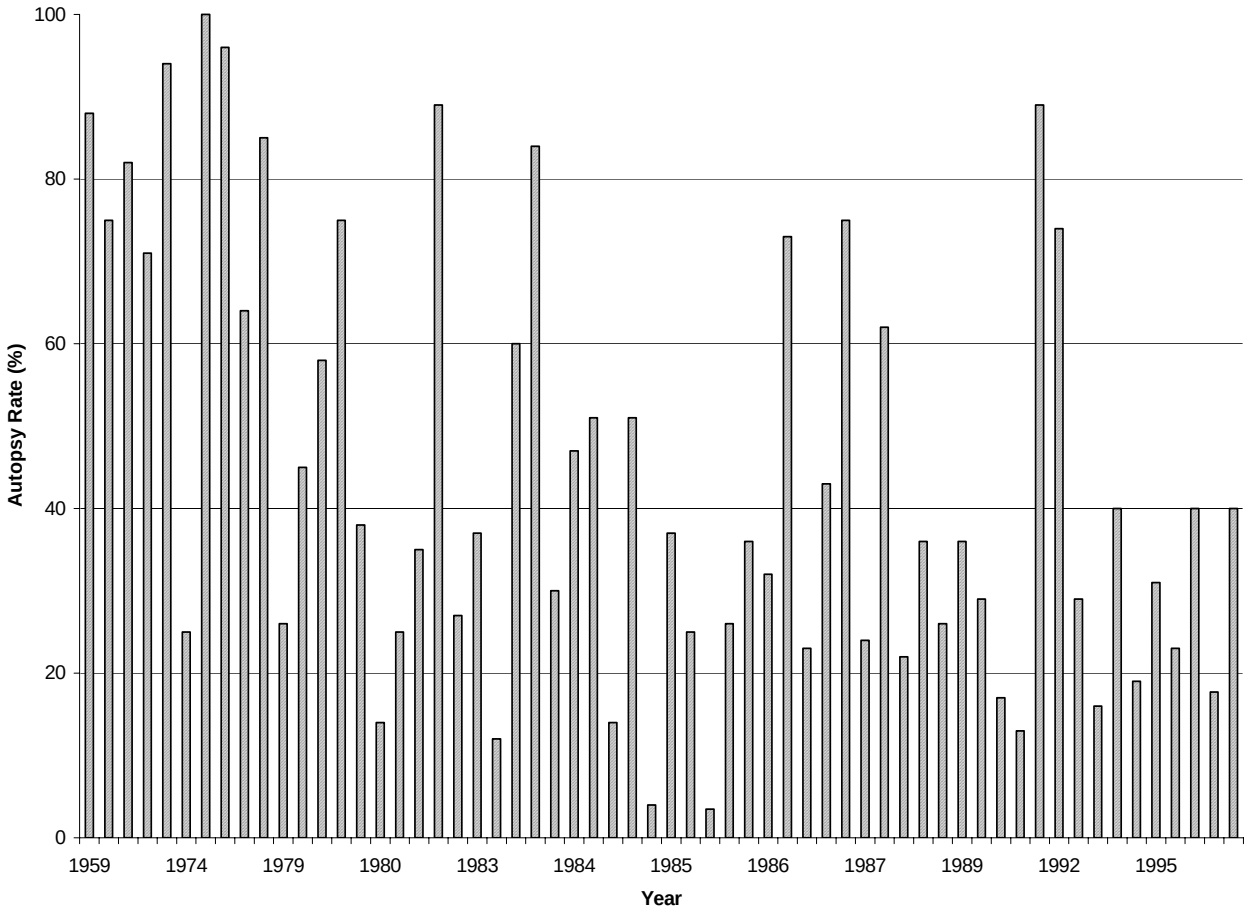
Appendix Table 7 – Sensitivity Of Clinical Diagnosis For Patients with Five Target Conditions

Condition	Estimated Sensitivity of Clinical Diagnosis	Source of Estimate
Acute PE	87-97%	A prospective clinical registry of 2,454 patients with suspected or confirmed PE, included 61 major PE cases first detected at autopsy. [177] As a high proportion of the remaining cases were diagnosed with high probability, these data permit a reasonable estimate of the sensitivity of clinical diagnosis in detecting acute PE. (The assumptions required to generate this estimate are discussed in the text.)
Acute myocardial infarction	96-98%	Four large cohort studies of patients presenting to the hospital[189-192] have reported that 2-4% with acute MI or unstable angina are clinically missed and inappropriately discharged from the emergency department.[e]
Acute appendicitis	~ 98% ~ 90%	This estimate comes from the one autopsy study[155, 156] that includes data on discharge diagnoses for all patients, not just those who died. The high sensitivity listed here does not take into account whether or not perforation had already occurred by the time the clinical diagnosis was made. This estimate reflects the false-negative rate for physicians assessing patients with acute abdominal pain in the office or ED – i.e., it does not take into account eventual clinical diagnosis by consulting surgeons or other physicians seeing these patients after hospital admission. As explained in the text, the study included a cohort of 1,118 consecutive patients with abdominal pain, 44 of whom proved to have appendicitis.[194]

[e] As explained in the text, population level studies of "unrecognized MI" were not included here, because the majority of patients with this entity have minimal or no symptoms and so do not seek medical attention.

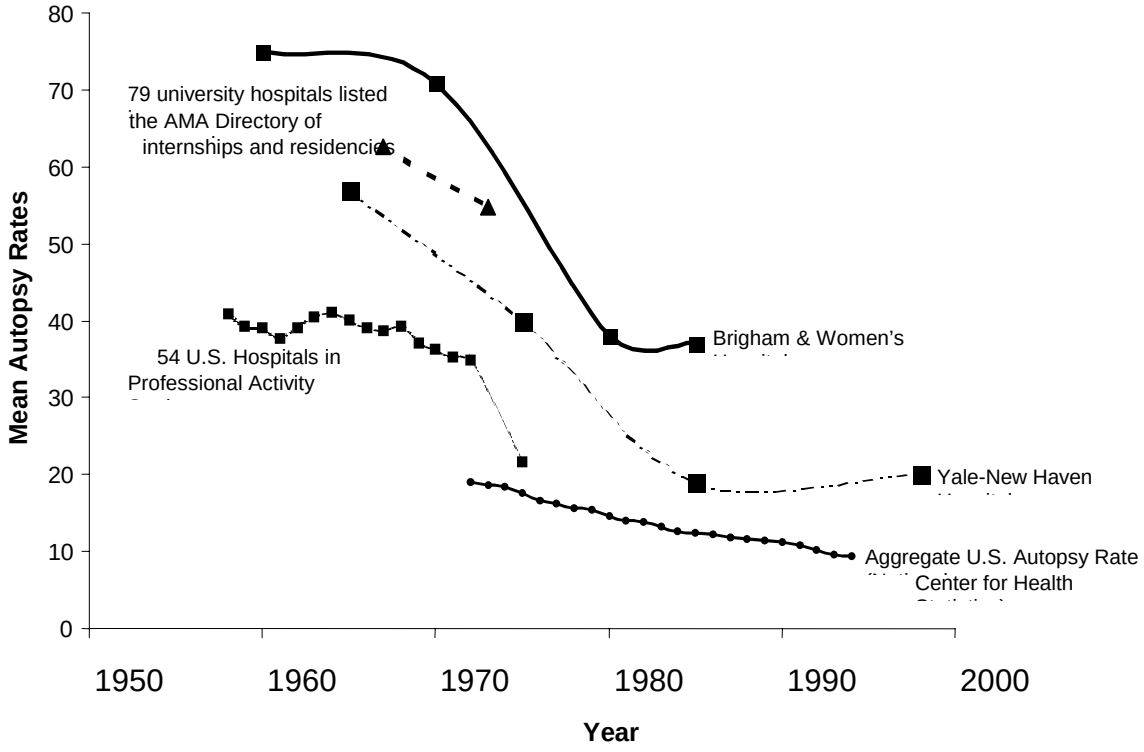
Acute dissection of the aorta	45-90%	Data from two large clinical series indicate that 10-55% of patients with aortic dissection are not identified until autopsy.[204, 205]
Active tuberculosis	>83% 39-96%	One autopsy study[155, 156] included data on discharge diagnoses for all patients, not just those who died, allowing estimation of the sensitivity of clinical diagnosis using reasonable assumptions discussed in the text. Data from a department of health indicated that the diagnosis of TB followed death in 4% of 3,102 reported cases.[219]

Appendix Figure 1 - Autopsy Rates Over Time Based on Autopsy Studies of Diagnostic Errors



Legend: these autopsy rates are those reported from all included studies of autopsy-detected diagnostic errors and thus reflect rates from institutions around the world. Appendix Figure 2 shows US data only and is limited to institutions with more than one time point, so that the general trend toward fewer autopsies is more apparent.
NB: This figure does not include the 3 most recent studies,[319-321] though these studies were used in the regression analyses and have been included in several of the other figures and tables.

Appendix Figure 2 - Trends in U.S. Autopsy Rates



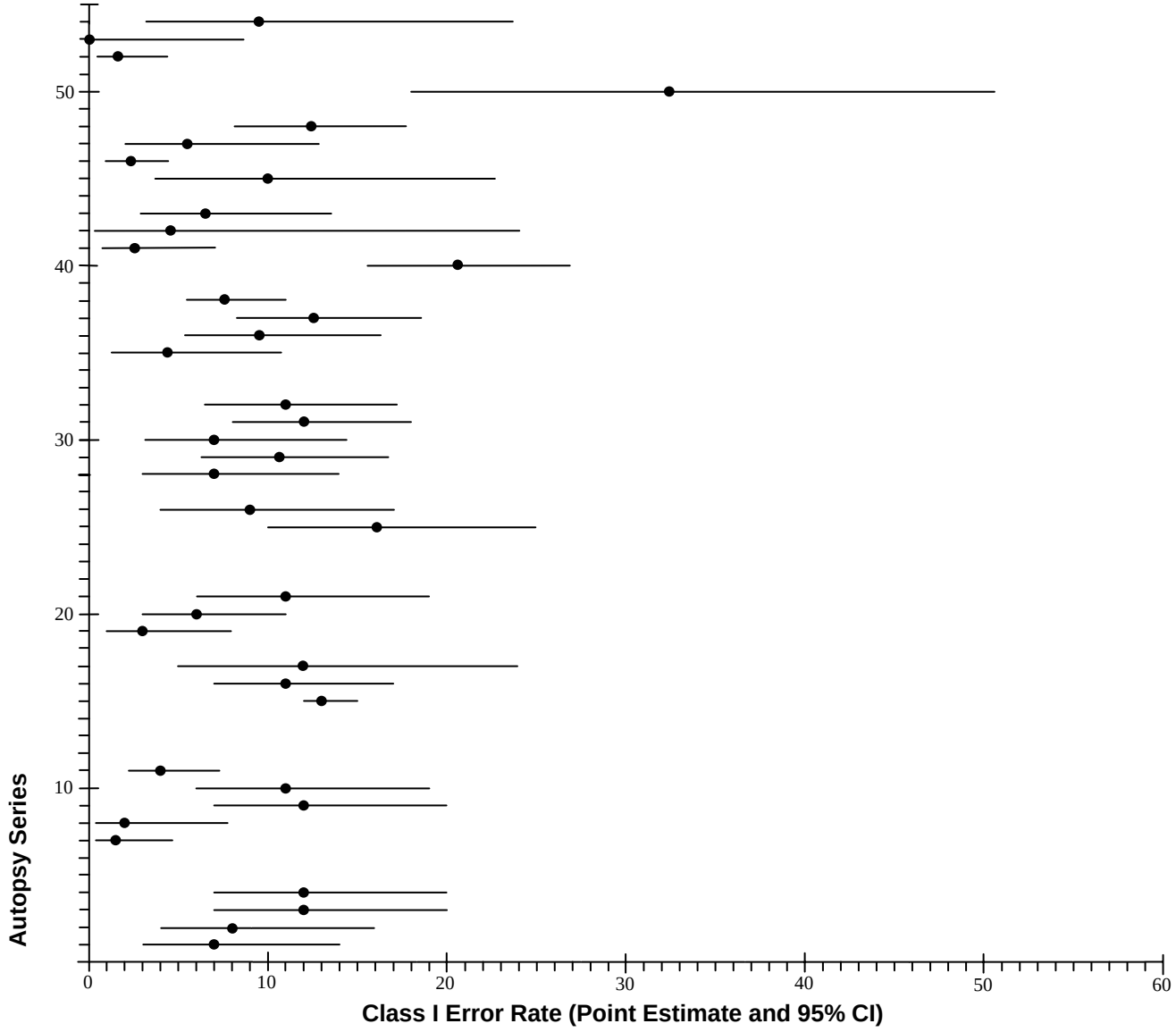
Legend: Trends derived from the following sources: 54 US Hospitals in Professional Activity Study (PAS)[313]; aggregate US autopsy rate[32]; 79 university hospitals listed in the American Medical Association directory of approved internships and residencies[314]; Yale-New Haven Hospital (New Haven, CT)[28, 315]; Brigham & Women's Hospital (Boston, MA)[51, 129]

The table on the following page shows additional data on US autopsy rates.

Addendum to Appendix Figure 2: Trends in Autopsy Rates - Studies from a single time period, but involving more than 2 US institutions

Place/Institution	Observation Period	Mean Autopsy Rate
18 States[316]	1967	26.7%
19 States (only partial overlap with above)[316]	1968	20.2%
1,828 US Hospitals in Professional Activity Study (PAS)[317]	1975	21.7% (28.4% for teaching hospitals)
21 university teaching hospitals[70]	1984	32%
11 community non-teaching hospitals[70]	1984	20%
Six Veterans Affairs Hospitals[131]	1986-7	43%
256 Pathology departments in College of American Pathologists Q-probe study (49% teaching hospitals)[318]	1993	12.4% (median 8.5%)

Appendix Figure 3 – Class I Error Rates with 95% Confidence Intervals



Legend for Appendix Figures 3 & 4

The numbering of the autopsy series here corresponds to the vertical axis in Appendix Figure 3 and in Appendix Figure 4

Autopsy Series	Year	Autopsy Rate	Case Mix (No. of autopsies)	Major Error Rate (95% CI)	Class I Error Rate (95% CI)
1. Christian-Albrechts University Hospital (Germany)[54]	1959	88%	General inpatients (100)	----	7% (3-14%)
2. Peter Bent Brigham Hospital (Boston)[51]	1960	75%	Adult inpatients (100)	22% (15-32%)	8% (4-16%)
3. Christian- Albrechts University Hospital (Germany)[54]	1969	82%	General inpatients (100)	----	12% (7-20%)
4. Peter Bent Brigham Hospital (Boston)[51]	1970	71%	Adult inpatients (100)	23% (15-33%)	12% (7-20%)
5. South Lothian District hospitals (Scotland)[3, 4]	1975-77	25%	General inpatients (1,152)	38% (36-41%)	----
6. University of Edinburgh (Scotland)[5]	1978	64%	General inpatients (154)	15% (10-22%)	----
7. Winnipeg Health Sciences Center (Canada)[299]	1978-79	26% [22]	Adult inpatients (200)	----	1.5% (0.4-4.7%)
8. Royal Adelaide Hospital (Australia)[300]	1979	45%	Adult inpatients (99)	----	2.0% (0.4-7.8%)
9. Christian- Albrechts University Hospital (Germany)[54]	1979	58%	General inpatients (100)	----	12% (7-20%)
10. Peter Bent Brigham Hospital (Boston)[51]	1980	38%	Adult inpatients (100)	21% (14-30%)	11% (6-19%)

[22] Rate reflects "teaching cases" only, with medicolegal cases excluded; overall autopsy rate for this period including medicolegal/forensic cases was 44%.

11. Thirty-nine Connecticut institutions performing autopsies [14]	1980	14%	General autopsies (272)	----	4.0% (2.1-7.3%)
12. Belgrade University School of Medicine (Yugoslavia)[301]	1981-84	12%	General inpatients (2,145)	29% (26.9-30.8%)	----
13. White River Junction VA Medical Center [78]	1983	60%	General inpatients (111)	12.6% (7.3-20.6%)	----
14. Chandigarh Postgraduate Institute (India)[309]	1983-88	23-27% [23]	Adult inpatients[24] (1,000)	31.7% (28.8-34.7%)	----
15. 32 U.S. university and community hospitals [70]	1984	30%	General inpatients (2,067)[25]	34% (32-36%)	13% (12-15%)
16. Brigham & Women's Hospital (Boston)[129]	1984-85	37%	Adult inpatients (175)	23% (17-30%)	11% (7-17%)
17. Emerson Hospital (Concord, MA)[129]	1984-85	26%	Adult inpatients (58)	33% (21-46%)	12% (5-24%)
18. Northwestern Memorial Hospital (Chicago)[130]	1985	36%	General inpatients (142)	23% (17-31%)	----
19. Medical Center of Delaware [210]	1988-91	17%	General inpatients (145)	12% (7-18%)	3% (1-8%)
20. St. Vincent's Hospital (Australia)[160]	1988	22%	General inpatients (139)	----	6% (3-11%)
21. Christian- Albrechts University Hospital (Germany)[54]	1989	36%	General inpatients (100)	----	11% (6-19%)
22. Peterborough District Health Authority (UK)[310]	1990	13%	General inpatients (63)	19% (11-31%)	----

[23] Stated range for annual autopsy rates during study period; overall autopsy rate not stated
[24] Aged 15 years and older
[25] Not clear how many pediatric patients included as study states only that 2,067 autopsies reviewed included 360 cases under 20 years of age

23. University of Pittsburgh Medical Center[150]	1994	19%	General inpatients (172)	34% (27-42%)	----
24. Prince of Wales Hospital (Hong Kong)[211]	1997	17.7%	General autopsies (332)	23.5% (19.1-28.5%)	----
25. Zurich University Hospital (Switzerland)[55]	1972	94%	Medical patients (100)	30% (21.4-40.1%)	16% (10-25%)
26. Zurich University Hospital (Switzerland)[55]	1982	89%	Medical patients (100)	18% (11.3-27.2%)	9% (4-17%)
27. Leiden University Hospital (Netherlands)[118]	1984	47%	Medical patients (133)	41% (33-50%)	----
28. Zurich University Hospital (Switzerland)[55]	1992	89%	Medical patients (100)	14% (8.1-22.7%)	7% (3-14%)
29. Ben Taub General Hospital (Houston)[116] [26]	1992-93	16%	Medical patients (110)	23.6% (16.3-32.9%)	10.9% (6.3-16.8%)
30. Hospital Central de la Cruz Roja (Spain)[125]	1983-85[27]	51%	Adult ICU (100)	22% (14.6-31.6%)	7% (3.1-14.4%)
31. Six Department of Veterans Affairs Hospitals[131]	1986-87	43%	Medical ICU (172)	27.9% (21.5-35.3%)	12% (8-18%)
32. Hartford Hospital (New Haven, CT) [304]	1986-92	29%	Surgical ICU (149)	23% (16.5-30.6%)	11% (6.5-17.1%)
33. Cleveland Clinic[2]	1994-95	23%	Medical ICU (91)	19.8% (12.4-29.7%)	----
34. Hershey Medical Center (Hershey, PA)[117]	1994-95	31%	Medical-Coronary ICU (41)	27% (15-43%)	----
35. Gloucestershire Royal Hospital (UK)[3]	1996-99	40%	Adult ICU (97)	23.7% (15.9-33.6%)	4.1% (1.3-10.8%)
36. General Hospital Celje (Slovenia)[320]	1998-99	47%	Medical ICU (126)	----	9.5% (5.2-16.4%)

[26] Patients with Acquired Immunodeficiency Syndrome (AIDS) were reported separately — series 54, the last entry in this table.
[27] May, 1983-Dec.1985 —> in calculating midpoint, was roundd to nearest year or mid-year so became 1984.5

37. San Francisco General Hospital and 31 hospitals in Orange County, CA[302 28]	1974-75	100%	Motor vehicle fatalities (182)	----	12.6% (8.3-18.6 %)
38. University of Texas Medical Branch (Galveston)[305]	1984-88	73%	Adult and pediatric surgery (409)	30.3% (26-35.1%)	7.8% (5.5-11%)
39. Johns Hopkins Hospital (Baltimore)[94]	1985-95	24%	Cardiac surgery (147)	38.8% (31.0-47.2 %)	----
40. Royal Victoria Hospital (Northern Ireland)[306]	1986-88	23%	Post-operative deaths (213)[29]	49.8% (42.9-56.6%)	20.7% (15.6-26.8%)
41. Ryder Trauma Center (Miami)[321]	1997-98	97%	Adult & pediatric trauma/burn patients dying in ICU[30] (153)	15.7% (10.5-22.6%)	2.6% (0.8-7.0%)
42. Children's Hospital of New Jersey (Newark)[133]	1992	29%	General pediatrics[31] (23)	13.0% (3.4-34.7%)	4.3 % (0.2-24.0%)
43. Lutheran General Children's Hospital (Park Ridge, Ill)[128]	1984-93	36%	General pediatrics[32] (107)	13.1% (7.6-21.3%)	6.5 % (2.9-13.5 %)
44. University of Rochester Medical Center (Rochester, NY)[126]	1989-94	74%	General pediatrics (157)	6.4% (3.3-11.7%)	----
45. North Shore University Hospital (Manhasset, NY)[132]	1985-92	26%	Pediatric ICU (50)	28.0% (16.7-42.7%)	10% (3.7-22.6%)
46. Toronto Hospital for Sick Children (Canada)[124]	1985-90	62%	Neonatal ICU (338)	18.9% (15.0-23.6%)	2.1% (0.9-4.4%)

[28] The authors of this study were focused primarily on demonstrating the difference in quality of care between a region with a Level 1 trauma center (San Francisco County) and a region (Orange County) where trauma patients are sent to nearest available facility. Chart reviews were conducted by the authors and were not blinded to patient location. Because of the significant potential for bias introduced by non-blinded peer review, the results for the two regions were combined rather than presenting separate Class I error rates for the two regions.

[29] "Perioperative" was defined as deaths during surgery or within 30 days after surgery. Thus, this sample essentially represents deaths among patients who have undergone surgery, as opposed to patients who die on the surgical service without having undergone operation.

[30] Age range 9-104; mean = 50 y.o.

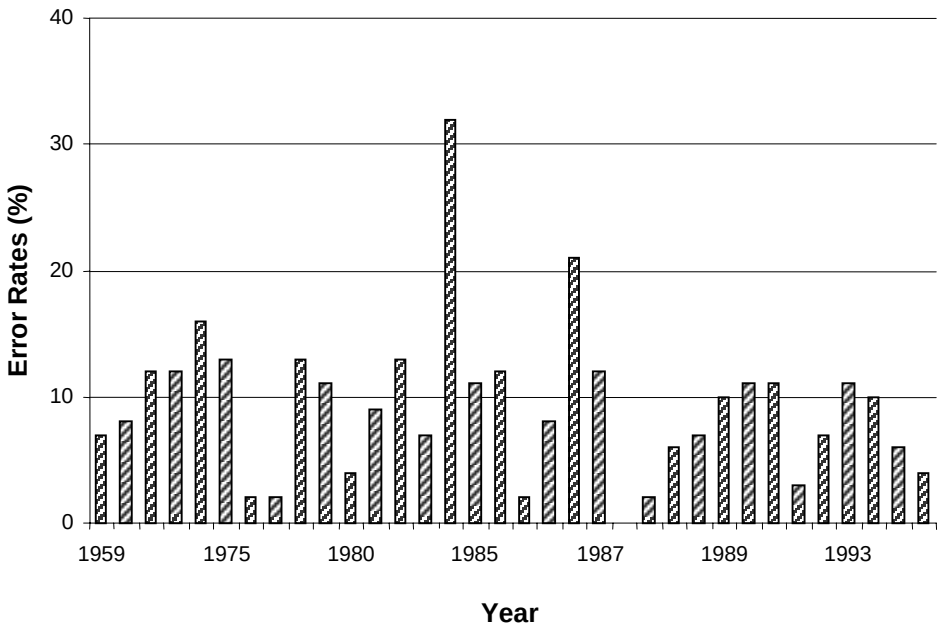
[31] Deaths in the Emergency Department were excluded.

[32] Deaths in neonatal ICU were excluded

47. Royal Alexandra Hospital for Children (Australia)[308]	1991-97	40%	Neonatal ICU (91)	----	5.5 % (2.0-12.9 %)
48. King Edward Memorial Hospital (India)[319]	1995-96[33]	82%	Neonatal ICU (197)	26.9 (21.0-33.8%)	12.2 (8.1-17.8%)
49. Salford Health Authority (UK)[295]	1981	35%[34]	Inpatients over 85 yrs old (129)	31% (23.3-39.8%)	----
50. Mason F. Lord Nursing Home (Baltimore)[303 35]	1981-88	3.5%	Nursing home residents (34)	47.1% (30.2-64.6%)	32.4% (18-50.6%)
51. Beth Israel Hospital (Boston)[158]	1981-83	27%	Adult inpatients post-CPR [36](130)	13.8% (8.6-21.3%)	----
52. University of Massachusetts Medical Center (Worcester, MA)[120]	1984-88	32%	Deaths in ED[37] (244)	4.1% (2.1-7.6%)	1.6% (0.5-4.4%)
53. Children's Hospital of Western Ontario (Canada)[307]	1985-89	75%	Pediatric Deaths in ED (52)	15.4% (7.3-28.6%)	0% (0-8.6%)
54. Ben Taub General Hospital (Houston)[116]	1992-93	16%[38]	Adult inpatients with AIDS (42)	33.3% (20.0-49.6%)	9.5% (3.1-23.6%)

[33] July 1995-August 1996, so only one year, but midpoint is January 1996
[34] The listed autopsy rate is for patients aged 65 and over; the rate specifically for the group over 85 years is unclear.
[35] This value represents an average over the study period, with yearly rates ranging from 1.6-10.8%. In fact, all but the last year had rates under 3%, with the increase in the final year attributed to targeted efforts to increase autopsies.
[36] Study autopsies drawn from inpatients who died after undergoing cardiopulmonary resuscitation (CPR); patients who experienced cardiac arrest outside the hospital, in the Emergency Department or ambulatory clinics were excluded.
[37] Study focused on patients who died in the Emergency Department (ED) or within 7 days of hospitalization after admission through the ED; forensic cases were included.
[38] Listed autopsy rate is for all medical patients; specific autopsy rate for AIDS patients not stated.

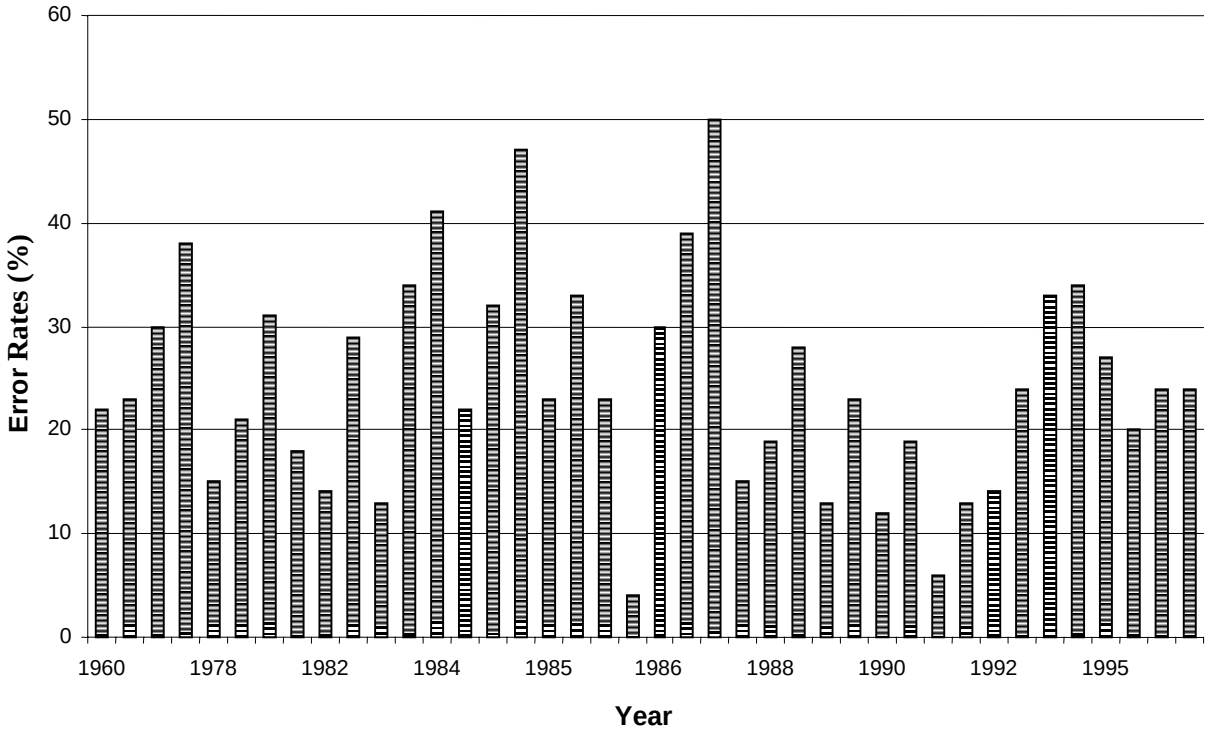
Appendix Figure 5: Class I Error Rates Over Time



Legend: Class I error rates reported in autopsy series included in review without adjustment from variations in autopsy rate or case mix.

NB: This figure does not include the 3 most recent studies,[319-321] though these studies were used in the regression analyses and have been included in several of the other figures and tables.

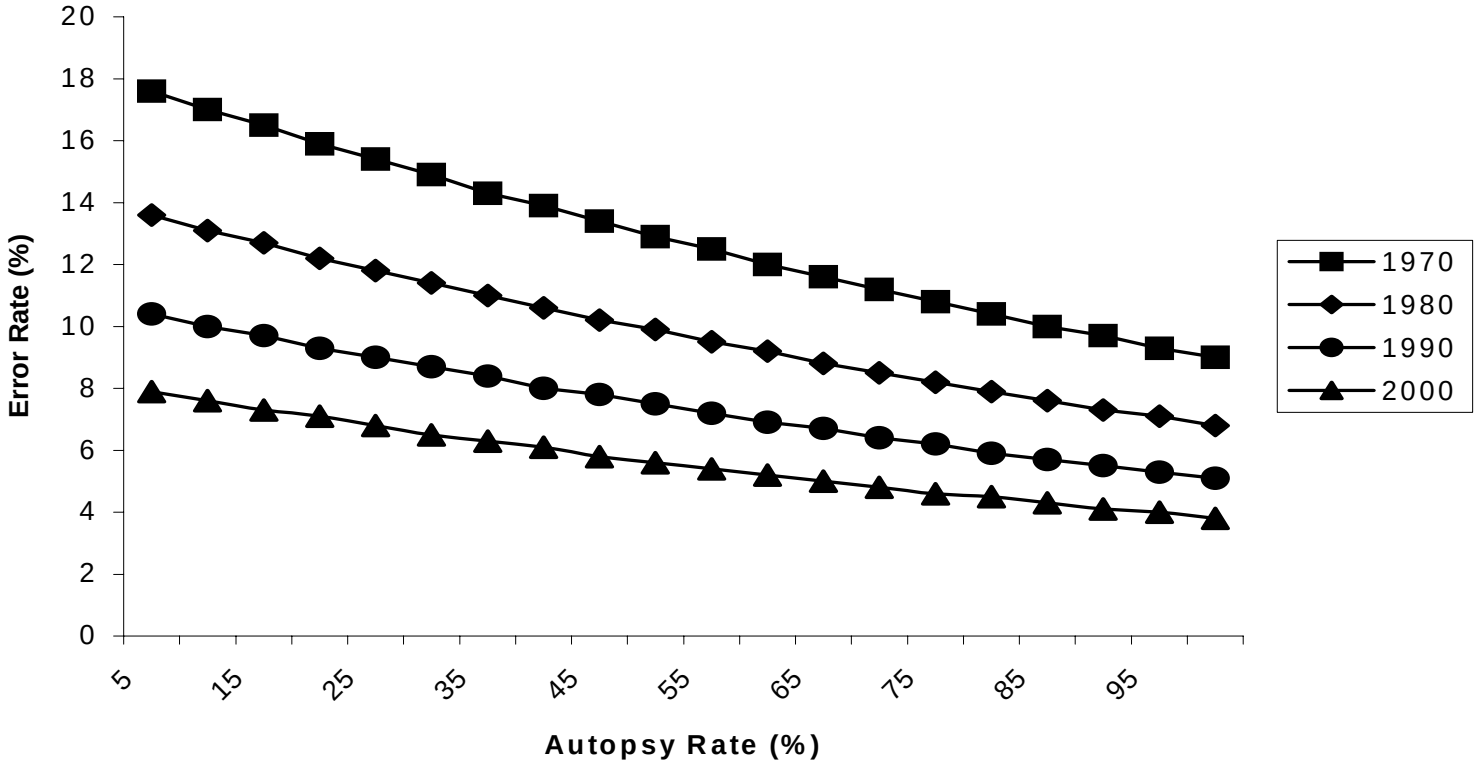
Appendix Figure 6: Major Error Rates Over Time



Legend: Major error rates reported in autopsy series included in review without adjustment from variations in autopsy rate or case mix.

NB: This figure does not include the 3 most recent studies,[319-321] though these studies were used in the regression analyses and have been included in several of the other figures and tables.

Appendix Figure 7- Class I Errors as a Function of Autopsy Rate for 4 Different Time Periods



Legend: Class I error rates derived from regression model over a range of autopsy rates in 4 different time periods with a case mix consisting of general inpatients.

Appendix Figure 8- Major Errors as a Function of Autopsy Rate for 4 Different Time Periods

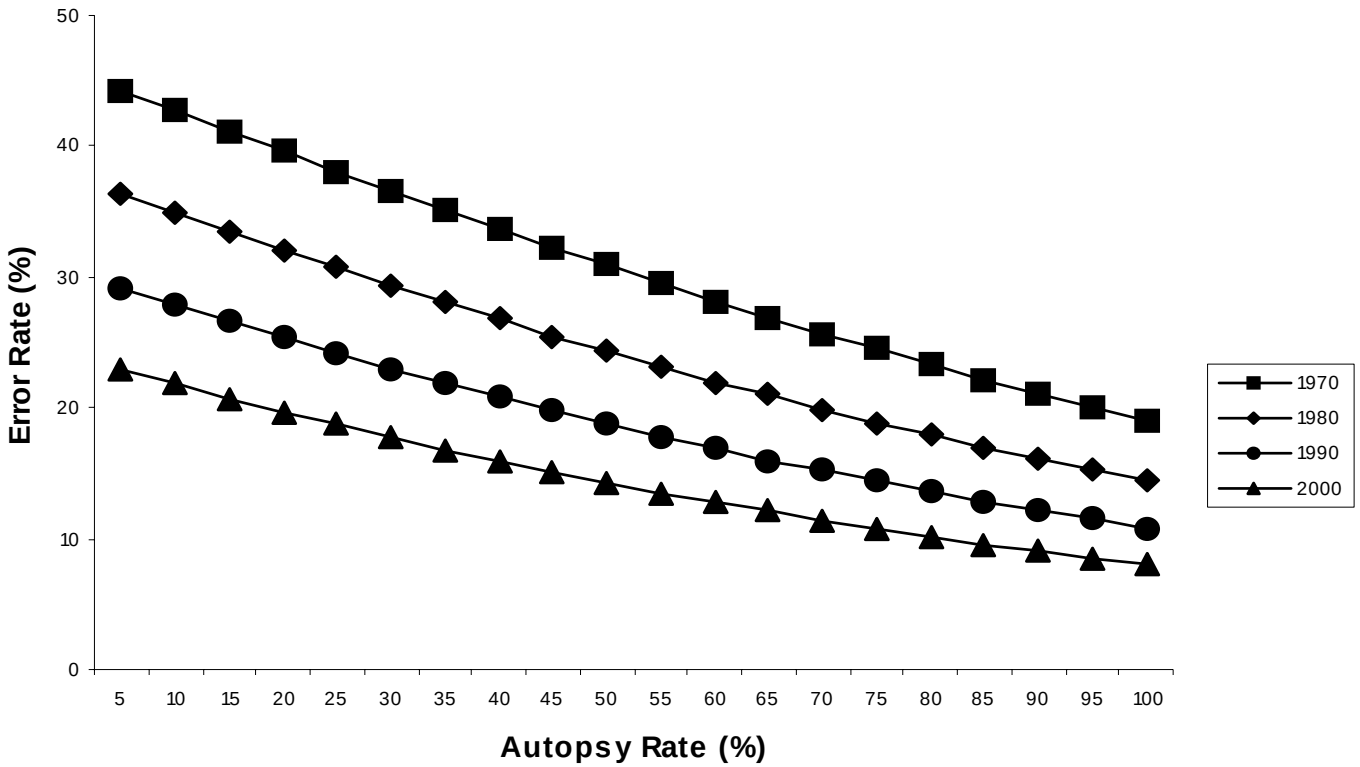
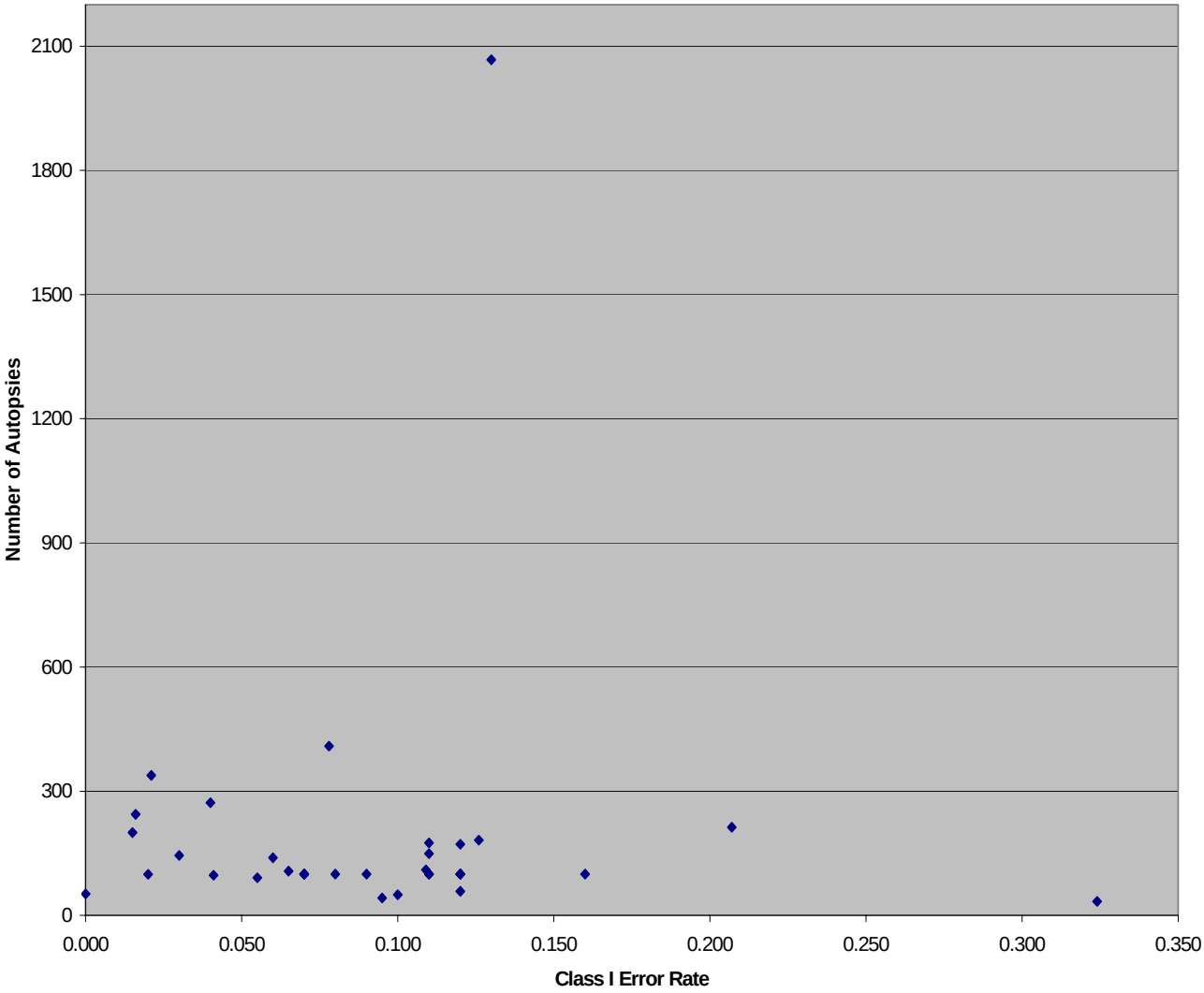


Figure 9a - Assessment of Publication Bias: Funnel Plot of All Studies Reporting Class I Errors



Legend: The above scatter plot graphs the observed error rate against sample size for studies reporting class I errors. For studies of therapeutic interventions, an inverted funnel distribution is expected if there is no publication bias, as the reported effect sizes are expected to be symmetrically distributed about the true effect. In this case, the inclusion of studies with different patient populations introduces additional asymmetry (e.g., the data point furthest to the right represents the only study involving nursing home patients). Therefore, we constructed a funnel plot limited to studies reporting autopsies among general inpatients, Appendix Figure 9b).

NB: Figures 9a & 9b and 10a & 10b do not include the 3 most recent studies,[319-321] though these studies were used in the regression analyses and have been included in several of the other figures and tables.

Figure 9b - Assessment of Publication Bias: Funnel Plot Restricted to Studies Reporting Class I Errors Among General Inpatients

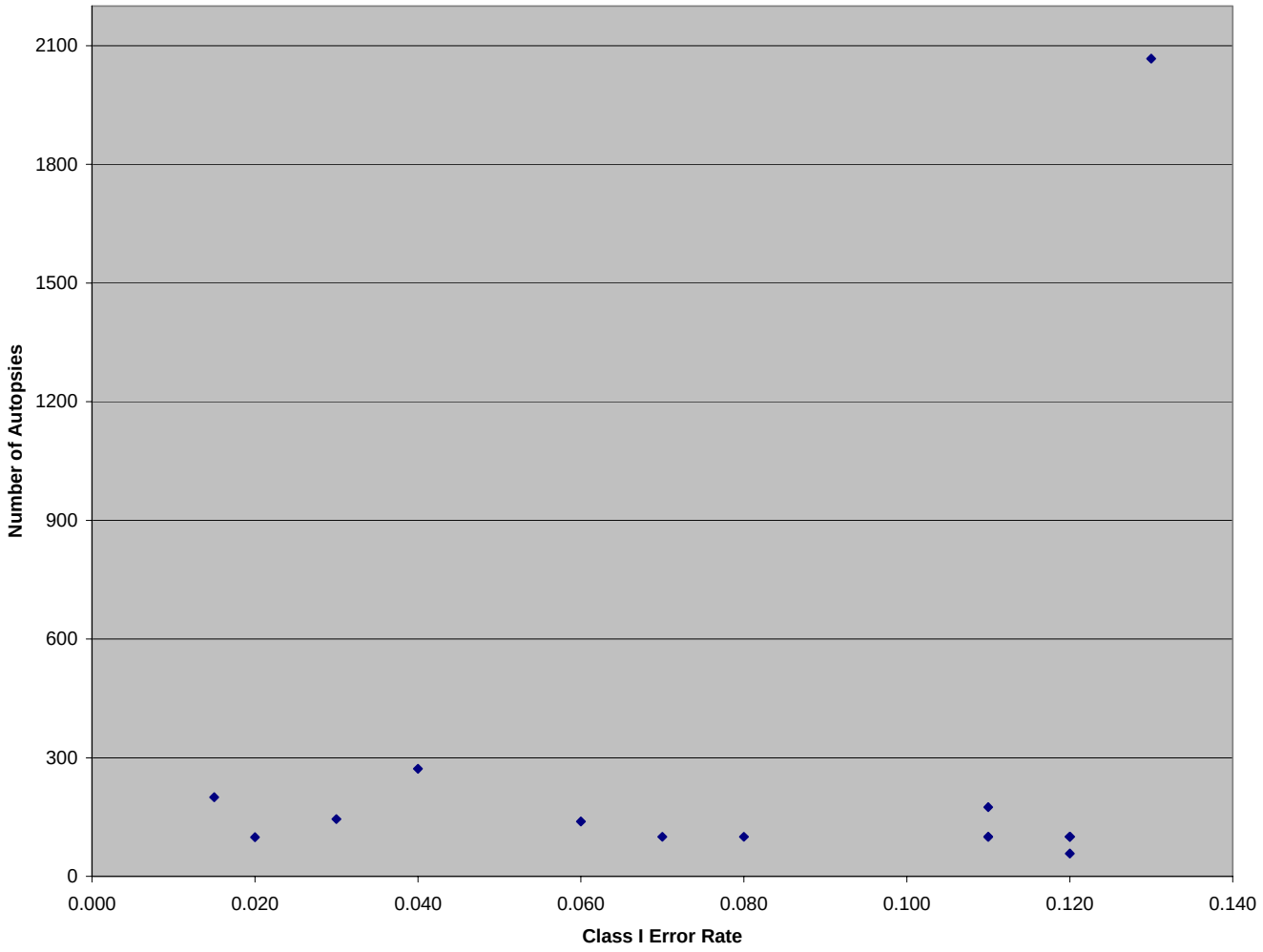
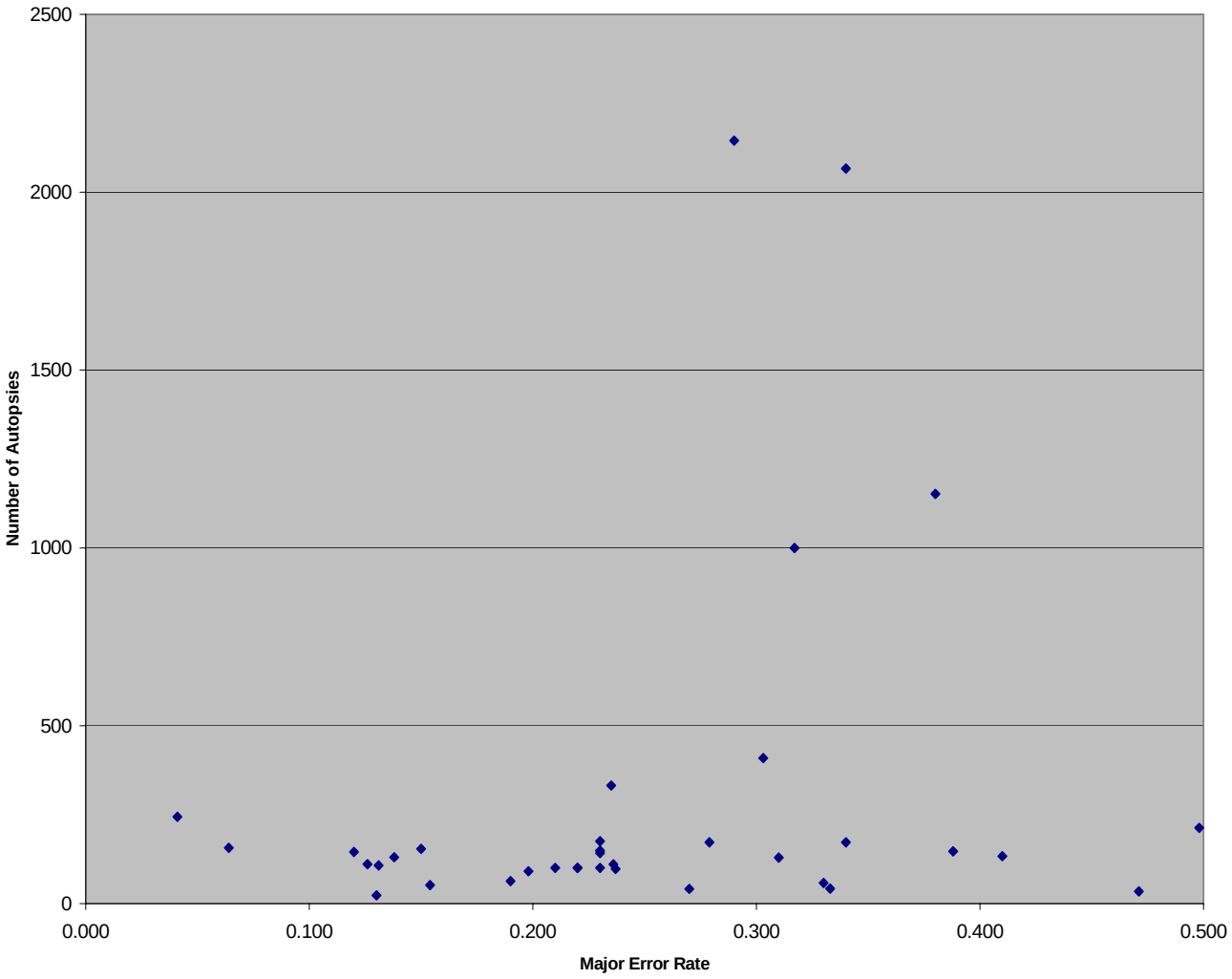


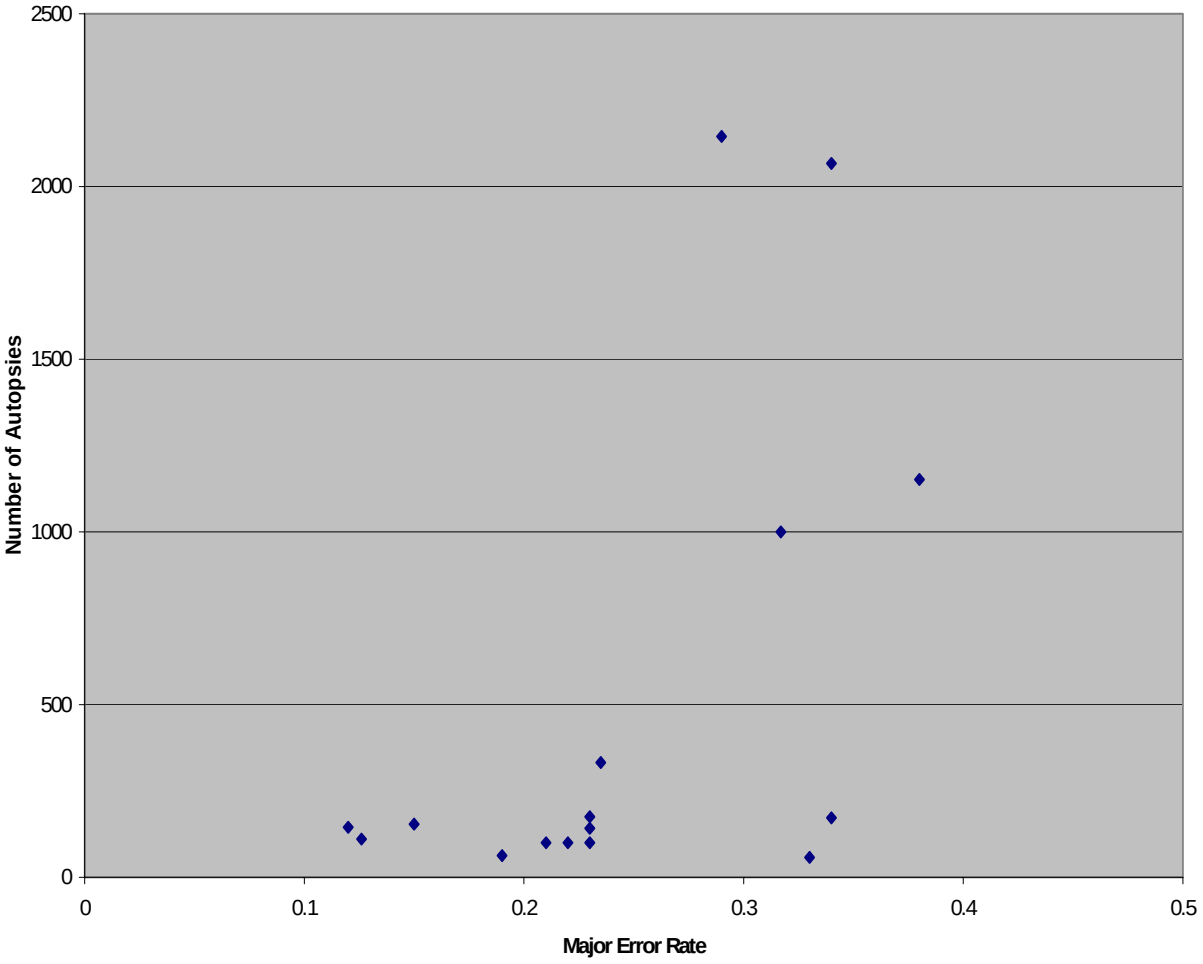
Figure 10a – Assessment Of Publication Bas: Funnel Plot For All Autopsy Studies Reporting "Major Errors"



Legend: This scatter plot is more symmetric appearing than that in Appendix Figure 9a. However, because the issue of asymmetry due to inclusion of different patient populations still applies, a separate plot involving general inpatient studies only was again created (Appendix Figure 10b).

NB: Figures 9a & 9b and 10a & 10b do not include the 3 most recent studies,[319-321] though these studies were used in the regression analyses and have been included in several of the other figures and tables.

Figure 10b - Assessment of Publication Bias: Funnel Plot Restricted to Studies of Major Errors Among General Inpatients



Legend: Restricting the funnel plot to studies reporting general inpatients (as shown above), indicates a relative absence of large studies with low error rates and small studies with high error rates. As explained in the text, the present review differs from systematic reviews of therapeutic studies in that publication bias might be operating in opposing directions (as suggested here). On the one hand, studies reporting very low error rates might be considered uninteresting and subject to publication bias in a manner similar to "negative" therapeutic trials. On the other hand, studies reporting high error rates might be self-censored by the institutions themselves. It is even possible that institutions with high error rates are less likely to conduct these types of studies in the first place (e.g., because they have less interest in performance measurement and improvement).

Appendix B: Statistical Analysis

The error rate was modeled from country, time, case mix and autopsy rate using a logistic model with a random study effect. Case mix and country were treated as categorical effects. More specifically, if X_1, X_2, ... are the above predictor variables, Ne the number of errors found for a study with Na autopsies, then the error rate p (Ne / Na) is modeled as $1 / (1 + e^{-\lambda})$ where $\lambda = \beta_0 + \beta_1 X_1 + \beta_2 X_2 + ... + u$ with the random study effect, u, having a normal distribution with mean 0 and variance σ^2. Computations were done using the SAS NLMixed procedure. [SAS software, version 8.2, SAS Institute: Cary, NC.]

In the tables and analysis below, Case Mix (CM) was categorized as follows:

1. General inpatients or general adult inpatients
2. Adult medical
3. Adult ICU
4. Adult or pediatric surgery
5. Pediatric inpatients
6. Neonatal or pediatric ICU
7. Other

Country was treated as a dichotomous variable, with U.S. studies assigned the value –1 and non-U.S. studies =1.

Time was defined as the midpoint of the study period (using whole or half years) and centered with 1980 as T=0. Thus a study reporting autopsies over the calendar year 1979 would be centered at –0.5; a study with a 2-year study period including 1982 and 1983 would be centered at +3.

Autopsy rates were also centered, using the unweighted mean autopsy rate for the included studies, which was 44.3% for studies reporting Class I and major errors.

For each of the error definitions (Class I, major errors, discrepant major ICD disease classifications), the analysis began with a model that included all predictors–study period, autopsy rate, case mix (general adult inpatients, medical patients, surgical parents, pediatric, etc.) and country (U.S., non-U.S.). We then compared this model with models in which one variable at a time was dropped.

The differences between the results produced by these models and the more complete model above were not statistically significant for Class I errors, but they were for the other two error definitions (data not shown). Even for Class I errors, the contributions of these other factors (autopsy rate, country, case mix) were noticeable, even if not statistically significant, and were

clearly plausible. Therefore, we used the more complete model to compute the mean error rate and the range of error rates shown in the analyses and tables below for all three error definitions.

A. Class I Error Rates

Model 1: Time, Autopsy rate, Country and Case Mix

Variable	Estimate	Standard Error	Odds Ratio	Lower 95% CI	Upper 95% CI	P-value
Intercept	-2.2622	0.2175	0.10412	0.06699	0.1618	<.0001
Time	-0.8122	0.6007	0.44389	0.1313	1.5008	0.1848
Autopsy rate	-0.03041	0.01825	0.97005	0.9348	1.0066	0.1044
Country	-0.09338	0.1322	0.91085	0.6967	1.1909	0.4844
CM 2 vs 1	0.4969	0.3513	1.64370	0.8061	3.3516	0.1658
CM 3 vs 1	0.1985	0.3121	1.21955	0.6476	2.2968	0.5289
CM 4 vs 1	0.3589	0.3449	1.43173	0.7114	2.8815	0.3050
CM 5 vs 1	-0.3306	0.6389	0.71850	0.1966	2.6254	0.6080
CM 6 vs 1	0.03348	0.3634	1.03405	0.4948	2.1610	0.9271
CM 7 vs 1	-0.4348	0.4007	0.64742	0.2873	1.4592	0.2851

I. Time Trend

Coefficient for Year = -0.03041 → -0.3041 to use decade as unit of analysis instead of single year

Odds ratio = exp (–0.3041)= 0.7378

<Subtract above from 1.0 to obtain relative decreases>

→ 0.2622

Class I error rates showed relative decrease of 26.2% per decade (p=0.1044)

95% CI = exp (-0.3041 ± 2*0.1825)

= exp (-0.3041 ± 0.3650)

= exp (0.0609, -0.6691)

= (1.0628,0.5122)

<Subtract above from 1.0 to obtain relative decreases>

→ (-0.0628,0.4878)

→ Class I error rates showed relative decrease of 28.0% (95% CI: 48.8% decrease to 6.3% increase) per decade

II. Relationship to Autopsy Rate

Coefficient Autopsy Rate = -0.8122

(-0.8122/10 = -0.08122 to calculate relationship as per 10% change in Autopsy Rate

Odds ratio = exp (-0.08122) = 0.9220

<Subtract above from 1.0 to obtain relative decrease>

(0.0780)

For every 10% increase in autopsy rate, Class I error rate decreased by 7.8% (p=0.1848)

95% CI = exp (-0.08122 (2*0.6007/10)

= exp (-0.08122 (0.12014)

= exp (-0.20136, 0.03892)

= 0.8176, 1.04

<Subtract above from 1.0 to obtain relative decreases>

(-0.0400, 0.1824)

(Class I error rate exhibited 7.8% relative decrease (95% CI: 18.2% decrease to 4.0% increase) for each 10% increase in autopsies.

III. Calculation of "mean" Class I error rate

Because error rates varied with time and autopsy rate (as well as case mix, though to a lesser extent), a true "mean" error rate does not exist. However, we can estimate a "base error rate," if the predictor variables are all set to their base values (i.e., time=1980, autopsy rate = mean rate of 44.3%, country=U.S., and case mix=general autopsies).

A point estimate for the base error rate can then be obtained from the regression equation,

Prob (Class I error) = $1 \;/\; (1 + e^{-\lambda})$ where $\lambda = \beta_0 + \beta_1 X_1 + \beta_2 X_2 + \ldots + u$

Intercept= -2.2622 and, for the base probability, the terms for time, autopsy rate and case mix all equal zero, because the equation is centered on these values.

Therefore,

λ= -2.2622 + (1980-1980)(–0.03041) + (-0.8122)(0.443-0.443) + (-0.09338)(-1), where the –1 in the country term reflects the value assigned to U.S. (non-U.S.=+1).

Thus, λ= -2.16882, so that base prob (Class I error) = $1 / (1 + e^{-(-2.16882)})$

→ Base prob (Class I error) = 0.10258→ 10.2%

Base error and 95% CI obtained from software were: 0.1023 and (0.06701, 0.1532)

Therefore, base rate of Class I errors was: 10.2% (95% CI: 6.7-15.3%)

Because the trends over time and the relationship to autopsy rate were not statistically significant for Class I errors, this base error rate provides a reasonable overall mean rate for Class I errors. It is clear, though (as shown in Table below), that the effects of study period (time) and autopsy rate are noticeable enough (even if not statistically significant for Class I errors). Therefore, a true "mean error rate" is not meaningful in the absence of stipulated values for time and autopsy rate. The table below shows how the Class I error rate varies with time and autopsy rate using the regression model above, with country equal to U.S. and case mix equal to general autopsies.

Autopsy Rate	**1970**	**1980**	**1990**	**2000**
5%	17.6%	13.6%	10.4%	7.9%
10%	17.0%	13.1%	10.0%	7.6%
15%	16.5%	12.7%	9.7%	7.3%
20%	15.9%	12.2%	9.3%	7.1%
25%	15.4%	11.8%	9.0%	6.8%
30%	14.9%	11.4%	8.7%	6.5%
40%	13.9%	10.6%	8.0%	6.1%
50%	12.9%	9.9%	7.5%	5.6%

Autopsy Rate	1970	1980	1990	2000
60%	12.0%	9.2%	6.9%	5.2%
70%	11.2%	8.5%	6.4%	4.8%
80%	10.4%	7.9%	5.9%	4.5%
100%	9.0%	6.8%	5.1%	3.8%

B. CLASS I ERRORS: U.S. ONLY

Model 1: Time, Autopsy rate and Case Mix

Variable	Estimate	Standard Error	Odds Ratio	Lower 95% CI	Upper 95% CI	P-value
Intercept	-2.0678	0.2501	0.12647	0.07477	0.2139	<.0001
Time	-1.6629	1.2590	0.18958	0.01346	2.6703	0.2031
Autopsy rate	-0.05501	0.02860	0.94647	0.8913	1.0051	0.0704
CM 2 vs 1	0.1857	0.5808	1.20405	0.3554	4.0796	0.7529
CM 3 vs 1	0.3223	0.3966	1.38027	0.6000	3.1754	0.4270
CM 4 vs 1	0.5144	0.6996	1.67261	0.3846	7.2734	0.4717
CM 5 vs 1	-0.2763	0.5884	0.75861	0.2204	2.6113	0.6443
CM 6 vs 1	0.01320	0.6391	1.01329	0.2646	3.8802	0.9837
CM 7 vs 1	-0.3228	0.4533	0.72410	0.2794	1.8769	0.4855

Coefficient for Time is –0.05501

→ -0.5501 to use decade as unit of analysis instead of single year

odds ratio = exp (–0.5501)= 0.57689

<Subtract above from 1.0 to obtain relative decrease>

→ 0.42311

→ Error rate showed relative decrease of 42.3% per decade, but this relationship was not statistically significant (p=0.07)

Coefficient Autopsy Rate = -1.6629

→ -1.6629/10 = -0.16629 to calculate relationship as per 10% change in Autopsy Rate

odds ratio = exp (-0.166291) = 0.8468

<Subtract above from 1.0 to obtain relative decrease>

→ For every 10% increase in autopsy rate, error rate decreases by approximately 15.3%, but this relationship was not statistically significant (p=0.2).

Prob (Class I error) = $1 / (1 + e^{-\lambda})$ where $\lambda = \beta_0 + \beta_1 X_1 + \beta_2 X_2 + ... + u$
Intercept= -2.0678

For base probability, time, autopsy and case mix terms all equal zero and there is no country terms in the analysis restricted to U.S. only, so

$\lambda = -2.0678$

Therefore,

→ Base prob (Class I error) = $1 / (1 + e^{-(-2.0678)})$

→ Base prob (Class I error) = 0.1117→ 11.2%

The value calculated using the statistical software corroborated this estimate and provided the corresponding confidence interval.

Thus, the mean Class I error rate using data from U.S. only is 11.2% (95% CI: 6.9-17.5%).

Summary

In the model adjusting for study period, variations in autopsy rates, differences in case mix and study country (U.S. vs. non-U.S.), the probability of the autopsy detecting a Class I error in a given case was 10.2% (95% CI: 6.7-15.3%). Restricting the analysis to data from U.S. institutions only, yielded a similar point estimate, but a slightly wider confidence interval, 11.2% (95% CI: 6.9-17.5%).

The expected inverse correlation between error rate and study period (i.e., the more recent the study the lower the error rate) was modest and statistically significant. Specifically, the probability of a Class I error showed a relative decrease of 28.0% per decade (p=0.1; 95% CI: 48.8% decrease to 6.3% increase).

The expected inverse correlation between error rate and autopsy rate (i.e., the higher the autopsy rate, the lower the error rate) was relatively weak and not statistically significant. Specifically,

for every 10% increase in autopsies, the Class I error rate exhibited a relative decrease of 7.8% (p=0.2).

C. MAJOR ERRORS

Model 1: Time, Autopsy Rate, Country and Case Mix

Variable	Estimate	Standard Error	Odds Ratio	Lower 95% CI	Upper 95% CI	P-value
Intercept	-0.9773	0.1238	0.37633	0.2931	0.4831	<.0001
a_rate	-1.2846	0.3211	0.27677	0.1448	0.5291	0.0003
year	-0.03288	0.01131	0.96766	0.9458	0.9900	0.0058
country	0.08833	0.07323	1.09235	0.9423	1.2663	0.2345
cm2	0.2505	0.2024	1.28464	0.8538	1.9329	0.2228
cm3	0.09321	0.1796	1.09770	0.7639	1.5773	0.6065
cm4	0.7518	0.1969	2.12083	1.4254	3.1555	0.0004
cm5	-0.7406	0.2842	0.47680	0.2687	0.8461	0.0126
cm6	0.01956	0.2773	1.01975	0.5827	1.7847	0.9441
cm7	-0.2192	0.1781	0.80320	0.5607	1.1506	0.2253

<u>I. Time Trend</u>

Coefficient for Time is –0.03288 → -0.3288 to use decade as unit of analysis instead of single year

Odds ratio = exp (–0.3288) = 0.719787

<Subtract above from 1.0 to obtain relative decrease>

→ 0.2802

→ Major error rates showed decrease of 28.0% per decade (p=0.0058) relative to the base time period of 1980.

Coefficient Autopsy Rate = -1.2846

10% change → -1.2846/10= -0.12846

Odds ratio = exp (-0.12846) = 0.879449

<Subtract above from 1.0 to obtain relative decrease>

→ 0.120551

For every 10% increase in autopsy rate, major error rate decreases by 12.0% (p=0.0003)

The models dropping case mix, country and autopsy rate (one at a time) produced results with statistically significant differences from the above. Consequently, we used Model 1 (including autopsy rate, country, case mix as predictors of major errors) to compute the mean error rate and the range of error rates shown in the table below and the mean major error rate of 25.6% (95% CI: 20.8-31.2%). The point estimate can be obtained manually using the calculation shown below and was compared with the value generated by the statistical software. (The software was required to calculate the confidence interval.)

Prob (major error) = $1 / (1 + e^{-\lambda})$ where $\lambda = \beta_0 + \beta_1 X_1 + \beta_2 X_2 + ... + u$

Substituting in Intercept (β_0)= -0.9773

and base values of time (1980), autopsy rate (overall mean rate of 44.3%), country (U.S.=-1) and case mix (general autopsies, so that case mix terms CM2,…,CM7 all equal zero), then

λ = -0.9773 + (–0.02223)(1980-1980) + (-0.9603)(0.443-0.443) + (0.08833)(-1)

λ = -1.06563

→ Base prob (major error) = $1 / (1 + e^{-(-0.88867)})$

→ Base prob (major error) = 0.256235 → 25.6%

Calculation performed with statistical software confirmed this estimate and provided the corresponding confidence interval of (0.2077, 0.3116).

Thus, base probability of major error was: 25.6% (95% CI: 20.8-31.2%)

Autopsy Rate	**1970**	**1980**	**1990**	**2000**
5%	44.3%	36.4%	29.2%	22.9%
10%	42.7%	34.9%	27.9%	21.8%
15%	41.2%	33.5%	26.6%	20.7%
20%	39.6%	32.1%	25.4%	19.7%

Autopsy Rate	1970	1980	1990	2000
25%	38.1%	30.7%	24.2%	18.7%
30%	36.6%	29.4%	23.0%	17.7%
40%	33.7%	26.8%	20.8%	15.9%
50%	30.9%	24.3%	18.8%	14.3%
60%	28.2%	22.0%	16.9%	12.8%
70%	25.7%	19.9%	15.2%	11.4%
80%	23.3%	17.9%	13.6%	10.2%
100%	19.0%	14.5%	10.8%	8.1%

D. MAJOR ERRORS: U.S. STUDIES ONLY

Model 1 – Time, Autopsy Rate, Case-mix

Variable	Estimate	Standard Error	Odds Ratio	Lower 95% CI	Upper 95% CI	P-value
Intercept	-1.1499	0.2002	0.31666	0.2098	0.4779	<.0001
Time	-1.0411	0.5382	0.35306	0.1168	1.0673	0.0640
Autopsy rate	-0.02460	0.01844	0.97570	0.9394	1.0134	0.1937
CM 2 vs 1	-0.00791	0.4640	0.99212	0.3823	2.5750	0.9865
CM 3 vs 1	0.1429	0.2625	1.15363	0.6726	1.9787	0.5908
CM 4 vs 1	0.6615	0.3243	1.93774	0.9950	3.7738	0.0516
CM 5 vs 1	-0.7628	0.3381	0.46637	0.2328	0.9344	0.0327
CM 6 vs 1	0.2219	0.4953	1.24850	0.4510	3.4561	0.6578
CM 7 vs 1	-0.2093	0.2599	0.81118	0.4754	1.3841	0.4281

Coefficient for Time is –0.0246 → -0.246 to use decade as unit of analysis instead of single year

Odds ratio = exp (–0.246)= 0.78192

→ Error rate exhibited relative decrease of 21.8% per decade, but this relationship was not statistically significant (p=0.2).

Coefficient Autopsy Rate = -1.0411

10% change → -1.0411/10 = -0.10411

Odds ratio = exp (-0.10411) = 0.90113

For every 10% increase in autopsy rate, the major error rate decreased by 9.9% (p=0.06)

Summary

In the model adjusting for study period, variations in autopsy rates, differences in case mix and study country (U.S. vs. non-U.S.), the base probability of the autopsy detecting a major error in a given case was 25.6% (95% CI: 20.8-31.2%). Using data from U.S. institutions only, the base probability of the autopsy detecting a major error was slightly lower at 24.0%, but with an almost entirely overlapping confidence interval (95% CI: 17.3-32.3%).

The expected inverse correlation between error rate and autopsy rate (i.e., the higher the autopsy rate, the lower the error rate) was relatively weak, but in contrast to the results for Class I errors, this relationship was statistically significant. Specifically, for every 10% increase in the autopsy rate, the major error rate decreased by 12.0% (95% CI: 6.2-17.5%).

The expected inverse correlation between error rate and study period (i.e., the more recent the study the lower the error rate) was modest and, in contrast to the results for Class I errors, this relationship was statistically significant. Specifically, the probability of a major error exhibited a relative decrease of 28.0% per decade (95% CI: 9.8-42.6%).

E. ICD Disease Category Discrepancies

Nb: for the analysis below, time was centered at 1975, rather than 1980, as the study periods ranged from 1970-1980. Also, all of the studies using this error classification involved general inpatients or adult inpatients (Case Mix = 1), so case mix was not included in the models below.

Model 1: Time, Autopsy Rate, Country (Error definition 3)

Variable	Estimate	Standard Error	Odds Ratio	Lower 95% CI	Upper 95% CI	P-value
Intercept	-2.0252	0.1024	0.132	0.103	0.170	<.0001
Time	0.2468	0.02098	1.280	1.216	1.347	<.0001
Autopsy rate	-0.2642	0.1541	0.768	0.527	1.119	0.1373
Country	0.4187	0.08126	1.520	1.246	1.854	0.0021

Intercept= -2.0252; Standard error = 0.1024

95% CI= -2.0252 ± 2*0.1024 → -2.230, -1.8204

probability of error = 0.1166 (95% CI: 0.0971 -0. 1394)

Coefficient for Time is 0.2468

Odds ratio = exp (0.2468)= 1.2800

→ Error rate increased by roughly 28% per year (p<0.0001).

Coefficient Autopsy Rate = -0.2642

5% change → -0.2644/20 = -0.01321

Odds ratio = exp(-0.01321) = 0.9869

For every 5% increase in autopsy rate, error rate decreases by approximately 1.4%, but this relationship was not statistically significant (p=0.1)

Summary

In the model adjusting for study period, variations in autopsy rates, study country (U.S. vs. non-U.S.), the autopsy and clinical diagnoses fell in different major ICD in 11.7% (95% CI: 9.7% - 13.9%) of cases in this base time period and country and at the base autopsy rate.

In contrast with the other two definitions of errors, ICD discrepancies showed an increase over time, and this relationship was statistically significant. Specifically, the error rate increased by roughly 28% per year (p<0.0001).

The relationship between the ICD discrepancies and autopsy rate did have the expected inverse correlation (as with the other two definitions of errors), but the relationship was weak and not statistically significant. For every 5% increase in autopsy rate, error rate decreases by approximately 1.4%, but this relationship was not statistically significant (p=0.1).

Appendix C: Index of Study Topics

One of the fields in the reference database was used to index articles according to the study topics addressed and the specific type of information provided.

TOPICS

1. Diagnostic Errors ("Dx errors") – studies of clinical-autopsy diagnostic discrepancies

Because of the complexity of this topic, articles tended to be indexed with one or more of the following sub-headings.

Spec Dz's – studies reporting diagnostic discrepancies for specific diseases or diagnoses.

Examples

Bobrowitz ID. Active tuberculosis undiagnosed until autopsy. *Am J Med*. 1982;72:650-8.

Zarling EJ, et al. Failure to diagnose acute myocardial infarction: the clinicopathologic experience at a large community hospital. *JAMA*. 1983;250:1177-81.

Goldhaber SZ, et al. Factors associated with correct antemortem diagnosis of major pulmonary embolism. *Am J Med*. 1982;73:822-6.

Population - studies providing data relevant to clinical diagnostic performance in a general population, not just at among deaths or autopsies (e.g., by providing discharge diagnoses for the same time period, or de facto, by achieving an autopsy rate close to 100%.)

Examples

DeRiemer K, et al. The epidemiology of tuberculosis diagnosed after death in San Francisco, 1986-1995. *Int J Tuberc Lung Dis*. 1999;3(6):488-93.)

McCarthy BD, et al. Missed diagnoses of acute myocardial infarction in the emergency department: results from a multicenter study. *Ann Emerg Med*. 1993;22:579-82.

Flum DR, et al. Has misdiagnosis of appendicitis decreased over time? A population-based analysis. *JAMA*. 2001;286:1748-53.

Selection – studies assessing clinical selection bias of cases for autopsy (e.g., by prospectively asking clinicians about their expectation of new information at autopsy

Example

Cameron HM, McGoogan E. A prospective study of 1152 hospital autopsies: I. Inaccuracies in death certification. *J Pathol* 1981; 133: 273-83).

Predictors – studies reporting factors other than clinical selection (above) and time of study (below) that predict the occurrence of diagnostic errors. Examples include demographics (age, gender, race, socioeconomic status, religion), hospital length of stay (LOS), clinical service (service), clinical diagnosis (Dx), and presence of a DNR order.

Examples

Landefeld CS, et al. Diagnostic yield of the autopsy in a university hospital and a community hospital. *N Engl J Med* 1988; 318: 1249-54.

McFarlane MJ. Clinical diagnosis is not a source of bias in selection for necropsy. *Arch Pathol Lab Med*. 1989;113:64-7.

Setting indicates that diagnostic error rates were compared in different settings (e.g., teaching vs. non-teaching hospital, nursing home vs. hospital)

Examples

Landefeld CS, et al. Diagnostic yield of the autopsy in a university hospital and a community hospital. *N Engl J Med*. 1988;318:1249-54.

Time indicates that diagnostic error rates were assessed compared in different time periods

Examples

Goldman L, et al. The value of the autopsy in three medical eras. *N Engl J Med*. 1983;308:1000-5.

Kirch W, Schafii C. Misdiagnosis at a university hospital in 4 medical eras. *Medicine (Baltimore)*. 1996;75:29-40.

Sonderegger-Iseli K, et al. Diagnostic errors in three medical eras: a necropsy study. *Lancet*. 2000;355:2027-31.

Error analysis - studies including some sort of analysis of why misdiagnoses were made (anecdotal discussion of selected cases did not count as sufficient)

Example

Middleton K, et al. An autopsy-based study of diagnostic errors in geriatric and nongeriatric adult patients. *Arch Intern Med*. 1989;149(8):1809-12.

Dx tests - studies examining the impact of antemortem diagnostic testing on autopsy-detected errors

Goldman L, et al. The value of the autopsy in three medical eras. *N Engl J Med*. 1983;308(17):1000-5.

Kirch W, Schafii C: Misdiagnosis at a university hospital in 4 medical eras. *Medicine (Baltimore)* 1996; 75: 29-40.

Complications – studies of the role of the autopsy in detecting complications of care, including many of the general autopsy series that happen to mention complications as a specific type of missed diagnosis, but also other studies focused specifically on this issue.

Examples

Ebbesen J, et al. Drug-related deaths in a department of internal medicine. *Arch Intern Med*. 2001;161:2317-23.

Gotti EW. Adverse drug reactions and the autopsy. Prevalence and perspective. *Arch Pathol*. 1974;97:201-4.

Medicolegal – studies including any information on the impact of autopsy-detected errors on legal actions

Examples

Juvin P, et al. Postoperative death and malpractice suits: is autopsy useful? *Anesth Analg*. 2000;91:344-6.

Nichols L, et al Are autopsies obsolete? *Am J Clin Pathol*. 1998;110:210-8.

Performance - studies containing information on the “test characteristics” of the autopsy itself (e.g., quality of the autopsy, number of cases in which a diagnosis could not be established despite adequate autopsy)

Examples

Veress B, et al. The reliability of autopsy diagnostics: inter-observer variation between pathologists, a preliminary report. *Qual Assur Health Care*. 1993;5:333-7.

Schned AR, et al A comprehensive quality assessment program on the autopsy service. *Am J Clin Pathol*. 1986;86:133-8.

Fowler EF, et al. Evaluation of a teaching hospital necropsy service. *J Clin Pathol*. 1977;30:575-8.

2. Attitudes - articles describing attitudes towards the autopsy on the parts of patients, their family members, or the general public clinicians (including students, post-graduate trainees and practicing physicians), and pathologists.

Examples

McPhee SJ, et al. To redeem them from death. Reactions of family members to autopsy. *Am J Med*. 1986;80(4):665-71.

Wilke A, French F. Attitudes toward autopsy refusal by young adults. Psychological Reports. 1990;67(1):81-2.

Sanner M. A comparison of public attitudes toward autopsy, organ donation, and anatomic dissection. A Swedish survey. JAMA. 1994;271(4):284-8.

Rosenbaum GE, et al. Autopsy consent practice at US teaching hospitals: results of a national survey. Arch Intern Med. 2000;160(3):374-80.

Stolman CJ, et al. Attitudes of pediatricians and pediatric residents toward obtaining permission for autopsy. Arch Pediatr Adolesc Med. 1994;148(8):843-7.

Trelstad RL, et al. The role for regional autopsy centers in the evaluation of covered deaths. Survey of opinions of U.S. and Canadian chairs of pathology and major health insurers in the United States. Arch Pathol Lab Med. 1996;120(8):753-8.

3. Autopsy rates – observational studies of trends in autopsy rates over time or intervention studies attempting to increase the autopsy rate

Examples

Cameron HM, McGoogan E, Clarke J, Wilson BA. Trends in hospital necropsy rates: Scotland 1961-74. *BMJ*. 1977;1:1577-80.

Sinard JH. Factors affecting autopsy rates, autopsy request rates, and autopsy findings at a large academic medical center. *Exp Mol Pathol*. 2001;70:333-43.

4. Epidemiology - studies describing the role of the autopsy in tracking the epidemiology of target conditions

Examples

Welch HG, Black WC. Using autopsy series to estimate the disease "reservoir" for ductal carcinoma in situ of the breast: how much more breast cancer can we find? Ann Intern Med; 1997. p. 1023-8.

Rakar S, Sinagra G, Di LA, Poletti A, Bussani R, Silvestri F, et al. Epidemiology of dilated cardiomyopathy. A prospective post-mortem study of 5252 necropsies. The Heart Muscle Disease Study Group. *Eur Heart J*. 1997;18:117-23.

McFarlane MJ, Feinstein AR, Wells CK, Chan CK. The 'epidemiologic necropsy'. Unexpected detections, demographic selections, and changing rates of lung cancer. *JAMA*. 1987;258:331-8.

5. Death Certificates - studies addressing the correlation between diagnoses on death certificates and autopsies and/or formal chart review

Examples

Kircher T, Nelson J, Burdo H. The autopsy as a measure of accuracy of the death certificate. *N Engl J Med*. 1985;313:1263-9.

Jordan JM, Bass MJ. Errors in death certificate completion in a teaching hospital. *Clin Invest Med*. 1993;16:249-55.

Appendix D: Article Abstraction Form for Autopsy Studies

The first half of the form applies to all of the study topics (Appendix C), but the second half (Results section) is tailored to studies addressing the rate of autopsy-detected diagnostic errors. The heterogeneity of studies addressing other topics precluded the development of a practical template. Thus, for these other topics, reviewers summarized the results as free text.

First Author		
Title		
Journal		
Year of Publication:		Database Ref #:

Language of Publication	**English**	Non-English without English abstract Language:_____	Non-English with English Abstract Language:_____
Country of Study	US	Non-US (Specify)	
Author affiliations *(Circle all that apply)*	Department of Pathology Office of Coroner or Medical Examiner Department of Medicine Department of Surgery Other Clinical Department of Radiology Department of Public Health Other Not Stated		

Principal Topics or Study Questions addressed by study *(Circle all that apply)*	▪ Diagnostic yield of autopsy ▪ *Role of autopsy in detecting complications* ▪ *Test characteristics of the autopsy (autopsy quality, accuracy, reproducibility)* ▪ *Reproducibility of classifications of autopsy-detected diagnostic errors* ▪ *Costs or cost-benefits of the autopsy* ▪ *Factors affecting autopsy rates* ▪ *Attitudes of clinicians, patients or others towards autopsy* ▪ *Autopsy assessments of vital statistics of death certificates* ▪ *Other*_____
SETTING	
Time span from which cases were drawn	*State month/year range - for all time periods if article included more than one (begin with most recent)* *1) ___/___ to ___/__* *2) ___/___ to ___/___* *3) ___/___ to ___/___* *Not Stated*
Name of Institution:	

Institution Type: circle one item per row					
Acute Care Hospital	*University-affiliated*	*Non-University Teaching*	*Non-teaching*	*Unclear*	
	Tertiary care (Referral center)	*Urban community*	*Rural*	*Unclear*	
	Private for-profit	*Private non-profit*	*Public (Gov't-subsidized, non-military)*	*Veterans Affairs*	*Other*
Non-Hospital or Non-Acute care	*Coroner's Office*	*Medical Examiner's Office*	*Forensic Institute (non-US)*	*Other (explain)*	
Forensic Cases Included	Not Stated	*No*	*Yes* ____ *%* ____ *some, but not clear how many*		
Types of Forensic Cases	Not Stated Not applicable	Natural ____ *% (or not clear)*	Unnatural *Trauma* ___ *% of total*		

			____ *some, but not clear how many* *Homicide/ Suicide* ___ *% of total* ____ *some, but not clear how many*
Outpatients included	Not included____ Not clear_____	<u>Natural</u> ____ *%* ____ *some, but not clear how many*	<u>Unnatural</u> *Trauma* ___ *% of total* ____ *some, but not clear how many* *Homicide/ Suicide* ___ *% of total* ____ *some, but not clear how many*
METHODS			
Case Mix (potential types of patients, based on study setting or design)	Not Stated Not clear	Unselected patients	Medicine Surgery Oncology Pediatrics Ob-Gyn Other (explain)

Study design	Not stated	Prospective series	Retrospective series	Case-control	Other (explain)

Patient Selection	Not stated	Random sample	Consecutive series	Other (explain)
Method of random selection	Not applicable	Not stated Unclear	Pseudorandom (e.g., by patient record number, calendar date)	True Random Selection
Procedure for obtaining autopsy	Not Stated Unclear	Request to family from treating physician(s)	Request to family from pathologist(s)	Automatic unless permission denied by family or other special circumstances
Types of Autopsies performed	*Limited autopsies* *Definition _____or" not stated"* *Number performed _____ or "none" or "not stated"*		*Complete autopsies* *Definition _____or" not stated"* *Number performed _____ or "none" or "not stated"*	
Source of premortem diagnoses	▪ Not Stated ▪ Diagnoses suggested by chart review performed for the study			

	▪ Diagnoses listed in death/discharge summary ▪ Clinical summary submitted with autopsy request/protocol ▪ Death certificates ▪ Not clear			
Framework for presenting or defining "diagnostic errors"	Not Stated	Goldman Classification of Class I-IV errors	Modification of Goldman scheme (explain)	Other (Please state classification system)
Method for determining disagreement b/w clinical and postmortem diagnoses	Not Stated Decision by one study participant Decision/consensus by more than one study participant Other (explain)			
RESULTS				
Autopsy rate	*Not Stated*	*Number of autopsies (n) _____* *Number of deaths in study period ____* *Autopsy rate reported as ____%, but numerator and/or denominator unclear*		
	Not Clear because _____			

Age ranges Circle all that apply and list percentages of total sample or write unclear	*Not Stated* *Stillborns _____%* *Neonatal (<28 days) _____%* *Infants (28 days to <1 year) _____%* *Pediatric (1 to<18yrs) _____%* *Adult (≥ 18 yrs) _____%*		
Gender	*Not Stated*	*Female ___ %*	*Male ___ %*
Race	*Not Stated*	US Studies *Caucasian _____%* *African-American _____%* *Latino _____%* *Native American _____%* *Asian _____%* *Other _____%*	Non-US *Please list racial demographics with percentages as stated by authors*
Socioeconomic class	*Not assessed*	*Summarize any demographic information addressing this characteristic*	
Ethnicity /Culture	*Not assessed*	*Summarize any demographic information addressing this characteristic*	
Religion	*Not assessed*	*Summarize any demographic information addressing this characteristic*	
Reproducibility of autopsy findings	*Not assessed*	*Kappa score_____*	*Other measure of agreement _____*
Reproducibility of error	*Not assessed*	*Kappa score*	*Other measure of agreement _____*

classification			
Prevalence of Diagnostic Errors	*Class I* _____	*"Major"*_____	*Other:*
	Class II _____	*"Minor"*____	

Infections by Site

Patient Population

CNS

TB

Fungal Infection

CMV Infection

PCP

Immuno-competent

Pts.

HIV+ patients

Transplant patients

Other immuno-compr.

No such distinctions made

Immuno-competent

Pts.

HIV+ patients

Transplant patients

Other immuno-compr.

No such distinctions made

CNS

Lung

Abdomen

Other

CHRONIC

Diabetic nephropathy_____

Non-Alzheimer's dementia (Vascular__ ; Lewy Body Dz__; C-J Dz_; Other___)

Parkinson's Disease_____

COPD/emphysema_____

Chronic CHF_____

*Cirrhosis*_____

Breast CA (Stage II or higher?)_____

Colon CA (Duke's B or higher?)_____

Metastatic Prostate CA_____ Metastatic Melanoma_____ Other Metastatic CA_____ HIV/AIDS_____ Vasculitis_____ OTHER_____	
Predictors of Diagnostic Errors	*For each predictor, choose: Yes, No, Not analyzed, Analyzed but not Reported, or Unclear* Age_____ Gender_____ Race/Ethnicity_____ Presence of DNR_____ New DNR_____ Death in ER_____ Death in ICU_____ Death on General Hospital Ward_____ Nursing Home Residence_____ MD prediction of “unexpected findings” _____ Major chronic illnesses: dementia_____

	end-stage renal disease (on dialysis)_____ end-stage liver disease_____
Use of Conventional tests	*Plain x-rays* *Number of tests* *CT* *w/o contrast*_____ *with contrast*_____ *total*_____ *Ultrasound (excluding echocardiograms)* *Echocardiograms* *MRI*

	Angiogram (incl. R-heart cath as an agiogram) *Tissue Biopsy or Diagnostic Body Fluid Aspiration w/o operation* *Open Biopsy (brain, lung, laporotomy)*

Appendix E: Interviews and Other Input From Advisory Panel

A Technical Expert Advisory Group was assembled to provide guidance to the project team. The Advisors included pathologists, internists, a surgeon, and researchers with expertise in critical appraisal of the literature, health economics, patient perspective, and ethnicity. The Advisors were provided with the original project proposal and study questions, as well as a set of questions tailored to their areas of expertise. These questions were formulated to allow the project team to gather background from a variety of perspectives in order to inform a feasible and worthwhile direction for the systematic evidence review of autopsy. The responses to these questions therefore provide important background to the project, and are summarized broadly below.

1. On reviewing the study questions proposed for the project, were there any clear gaps or omissions?

Most of the advisors thought that the study questions covered important topics. Gathering data concerning the diagnostic yield of the autopsy, factors influencing selection of cases for autopsy, and documentation of complications of care were considered to be most salient if incorporated into the broader question about "How can this information be used in quality improvement, outcome analyses, performance measurement initiatives and error reduction?" In other words, the critical question that this entire study should answer is "Does the autopsy have the potential to improve quality and reduce errors?"

Additionally, one of the clinician advisors discussed the issue of distinguishing instances in which diagnostic errors would have affected therapy, but would likely not have altered patient. This issue was illustrated with two cases from this advisor's recent experience. In the first case, a patient had been transferred from another hospital with altered mental status and fever and underwent several lumbar punctures that were unrevealing. The patient progressively deteriorated and died after a respiratory arrest led to anoxic brain damage. Because of the patient's cachexia, the clinical team presumed an underlying malignancy or undiagnosed HIV infection. Autopsy revealed tuberculous meningitis. Although knowing the diagnosis would have resulted in more appropriate treatment, the outcome would have likely remained the same given the advanced state of his CNS infection. By contrast, the second case was a patient who had Noonan's Syndrome and a variety of chronic problems including a seizure disorder and recurrent pulmonary infections. His terminal hospitalization for an acute febrile illness was presumed to reflect another pneumonia. Autopsy revealed endocarditis. This was not only undiagnosed, but also completely unsuspected and untreated. In this case knowing the diagnosis would not only have altered therapy, but also would very likely have changed the outcome.

2a. Regarding the "diagnostic yield of the autopsy," many clinicians will undoubtedly believe that cases taken for autopsy are "pre-selected" (by the treating physicians) to represent a high

potential for unexpected or erroneous diagnoses. We know of only one study that specially asked clinicians prospectively whether or not the clinical diagnoses were particularly uncertain prior to autopsy performance. (No correlation was found between clinicians' expectation and the finding of significant errors.) Because of the importance of addressing this significant potential for bias, we would like to know if you know of any other studies relevant to this question. (We also know that "diagnostic error rates" are significant even at institutions with higher autopsy rates, but institutions with higher autopsy rates tend to be non-US centers, and so clinicians may wonder if these patients undergo fewer sophisticated diagnostic tests.)

One Advisor noted that the Royal College of Pathologists (UK) in their August 1991 report entitled "The Autopsy and Audit" (available on their web site www.rcpath.org or from their offices at 2 Carlton House Terrace, London SW1Y 5AF) addressed sampling of hospital deaths. They suggested that autopsies should be done in all "problematic" deaths and, in addition, autopsies should be performed on 10% of random general hospital deaths in which there is no perceived "problem". Another Advisor suggested that clinicians ask for autopsies in cases of diagnostic uncertainty, but also emphasized that is it is not uncommon to uncover diagnostic errors in cases that clinicians regarded as routine, as noted in the article by Landefeld et al from the New England Journal of Medicine. Similarly, another Advisor agreed that some selection is likely occurs, but strongly believed that the observed error rates could not be explained solely as an artifact of this selection – i.e., the autopsy does detect important quality problems in clinical diagnosis, even when selection is taken into account. In contrast, the surgical Advisors believed strongly that diagnostic uncertainty was the main, if not only, reason for requesting autopsy.

2b. What do you anticipate to be the major challenge in conducting a systematic review such as this one in which the target literature consists entirely of observational studies? Are there some special concerns regarding the observational nature of the literature given that we are trying to evaluate the performance of what amounts to a diagnostic test?

The biggest challenge for both of the above questions will be avoiding publication bias. Observational studies tend to be far more subject to publication bias than randomized control trials.

2c. Because of the importance of addressing this significant potential for bias, we would like to know if you could suggest any other means of assessing the degree to which persistent significantly high rates of "diagnostic errors" can be explained by selection bias.

The only hope of errors related to pre-selection is if, within the US, you have differential autopsy rates across studies that are not totally confounded with time. Then, you can use rate meaningfully as a factor in your regression.

3. Do you think that the current autopsy rate in the U.S (or in US hospitals) is appropriate? If so, why so?

Some Advisors thought the current rate is too low to allow detection of important quality problems at a given institution. The literature fairly consistently indicates important diagnostic errors in small, but still a significant proportion of deaths. Autopsy rates < 5% (as occur at many hospitals) clearly do not permit one to notice trends in such errors that might alert one to local quality problems. Others pointed out that a specific or required rate is inappropriate, and supported JCAHO's having dropped this as a regulatory requirement since there is a lack of necessity of performing autopsy in "most" cases.

4. What do you think the autopsy rate should be - higher, lower or about the same as current rates?

One Advisor agreed with the Royal College of Pathologists that autopsies should be performed on a minimum of 10% of random deaths and on all "problematic" cases. These could be defined locally such as all perinatal deaths, all deaths following new or experimental treatments and also all deaths which have educational or research value. (Of course often one does not know that a case is interesting until after an autopsy is performed, thus the rationale for the 10% random, unsolicited autopsies.) Another Advisor could not state a specific rate (or offer any evidence for such a rate), but thought that the "right rate" was around 30%. The major factor in offering this target was capturing diagnostic errors. Also, at the current rate at this Advisor's institution (20%), it is difficult to achieve the requirement that pathology residents participate in 50 autopsies over the 2 years of training anatomic pathology. Therefore, 30% would remove the current difficulties in achieving this educational goal. The current 20% rate also makes it difficult to achieve the goal of having each medical student see one autopsy. Medical students attend autopsies in groups of 6-8 students, but are not available all year, and are not invited to cases where there are major infectious risks (e.g., known TB) or to fetal cases. One other opinion was that, although a "right rate" cannot be defined, the rate clearly needs to be higher than it is now.

5. If you do think increasing autopsy rates (or at least preventing further decreases) is important, which if the following issues do you regard as crucial to address - physician understanding of the persistent importance of the autopsy? Patient perceptions of requests for autopsies? Support for activities related to the autopsy within pathology departments? Reimbursement for autopsy performance?

All are considered important, although clearly each present their own problems. Residents also do not know how to request autopsies, but an in-service could easily be put together in which the recommendations in the literature (e.g., from the Archives of Internal Medicine series on the autopsy) regarding answers to commonly asked questions from patients were presented to house staff. Reimbursement could be an issue, with a belief that declining rate of autopsies is a victim of our current financial system. It is a problem for clinical medicine in general because there are times when one really does learn from patients. There is some downside also with regards to research, and perhaps to education. The big issue relates to quality within an institution and in the management of a particular problem. Addressing the decline is important for both clinical

medicine and for quality of care within an institution. An Advisor noted that community pathologists have no financial incentive to perform autopsies and may even find the procedure itself "distasteful," compared to other pathology procedures.

Another Advisor also added that pursuit of the autopsy out of academic interest has to be tempered by recognition of the potential for malpractice, and that the legal environment is an important consideration with respect to obtaining autopsies.

6. Are there certain groups that you think are under-represented in selection of autopsy cases (e.g., in terms of age, gender, socioeconomic class, ethnicity, religion)?

Advisors were not aware of any groups that are under-represented, except perhaps some religious groups, and possibly Chinese patients. In addition, one Advisor thought there is over-representation of perinatal autopsies, due in large part to local or state laws and regulations mandating such, probably based on the reaction to SIDS.

7. Do you think selection biases (based on patient or provider factors) or missed opportunities for quality improvement are significant enough to warrant random selection of autopsy cases? Do you think such a system could be developed in the US?

While one Advisor favored such a system, others pointed out a number of logistic and patient-related barriers.

8. Do you think clinicians benefit from autopsy findings? To your knowledge, has the impact of autopsy findings on clinicians ever been studied?

Of course clinicians could benefit from autopsy findings, but it requires a well-trained, knowledgeable pathologist working with a concerned clinician. Advisors knew of no studies to document this. Clinicians probably do not derive optimal benefit from current autopsies, and Advisors believed this should be addressed. Advisors did not think that the quality improvement impact of the autopsy has ever been studied.

9. What could be done to increase the benefits/impact of autopsy findings for clinicians?

One Advisor suggested improving the training of pathologists in autopsy performance, as well as updating the methods and techniques used in the autopsy. Modern and up-to-date techniques of molecular pathology and immunohistochemistry as well as imaging, probe and physico-chemical methods should be incorporated in the performance of autopsy. Because of the inherent costs of such advances, innovative solutions might include centralization or regionalization of both training and performance of autopsies. Another Advisor pointed out that clinicians may not

benefit from the current system in place because of time delays between autopsy request and reporting. An alternative to focusing on time would be to have periodic conferences with clinical departments in which the cases with diagnostic errors could be reviewed. One Advisor's department already has such conferences on a regular basis with the Coronary Care Unit. All deaths are reviewed and cases in which an error has occurred are always presented. In addition, the chief of the medical service is notified whenever important diagnostic errors are detected on autopsy, but there is no formal mechanism for ensuring that these cases are presented at Department of Medicine's Morbidity and Mortality (M&M) rounds.

10. From a policy or economic point of view, would you place greater emphasis on autopsy rates or the use that is made of autopsy information as currently performed?

Advisors felt that both could be considered. The current low rate only provides information for individual families or clinicians. The numbers are too small for any valid statistical evaluation about quality, outcomes or performance.

11. As a practicing clinician, what would you like to see changed/improved about procedures and protocols related to reporting the results of autopsied cases?

Key features would include: detailed descriptions of clinical and demographic characteristics of consecutive autopsied and non-autopsied deaths autopsied and not autopsied cases (in order to clarify selection bias and other features distinguishing these two groups); assessments of reproducibility for judgments of diagnostic errors (i.e., discrepancies between clinical and autopsy diagnoses demonstrated); better quantification of the likely impact of autopsy-detected errors on patient outcome (not just antemortem therapy).

12. Are there factors that make surgeons more or less likely to request autopsies than their non-surgical clinical colleagues? Do you think timing of death (e.g., soon after surgery) exert a special effect on surgeons' tendency to request autopsy?

The main factor is the unexpectedness of death or complication, and the adequacy of the diagnostic evaluation the patient had undergone prior to death.

13. In surgery, do you think that autopsies play an important role in Morbidity and Mortality (M&M) conferences, or do discussions center more on aspects of antemortem care (i.e., use of appropriate diagnostics, aspects of surgical care, etc.)?

Although the Surgeon Advisor strongly supports the continued role of M&M rounds a part of surgical quality assurance, he believes that autopsies play a very minor role in these proceedings, with patient care problems generally apparent prior to death or autopsy. He based this opinion

primarily on advances in diagnostic imaging. As a result of this comment, the analogy with unexpected findings at laparotomy was discussed. Anecdotally, surgeons generally believe that advances in diagnostic imaging have made discrepancies between pre-operative and post-operative diagnoses less common. Moreover, the "diagnostic laparotomy" has become a very uncommon operation. One of the other advisors confirmed these impressions, but none of the advisors (nor the core project team) could find any studies documenting this trend.

14. How do you think patients' attitudes towards requests for autopsy performance might be affected by ethnicity or culture?

One Advisor pointed out that ethnicity should be defined based on self-identification, and that Defining "culture" is a major challenge. Perhaps thinking of it in terms of individual's national origin, religious background, social class would be one approach. This Advisor suggested that not violating the physical remains of a deceased person might be important to many people (e.g., Catholics who want an open casket funeral). In decision making about consenting to an autopsy, one has to consider cultural roles and norms. In the Latino culture, for example, the extended family or family members would need to be agreeable that an autopsy is important. This kind of groundwork may need to be established ahead of time if possible, but clearly would not just be a simple "let's go in and consent for an autopsy" approach. Much respect and consideration has to be given to this decision, which is often a collective one, not an individual one. Similarly, the trust in the physician and respect for the physician having taken care of the deceased family member would in the view of this Advisor, play a major role in consenting or not.

15. In considering the above question, is there a particular aspect of the autopsy that you think is most relevant - e.g., what the procedure entails, its purpose?

One Advisor thought that the altruistic goal of defining what we can learn from it – how can we do this better next time – how can the system learn from it is probably the most compelling argument. Clearly, nothing can be done to help the individual. However, there are benefits for the system, the public, and the clinicians. Taking another perspective, as eluded to in Steve McPhee's study, it may be very relevant to know what the diagnosis really is because of the concerns about genetic susceptibility or infectious diseases. Another Advisor noted that unsuspected hemochromatosis (and other genetic diseases) are detected and impacts family members.

16. Are there any areas of research involving the impact of ethnicity on patient attitudes that might shed light on attitudes towards the autopsy (e.g., requests for organ donation)?

One Advisor suggested consideration of attitudes about family and how collective decision making is important in certain cultures. This may be particularly true in Asian and Latino immigrant cultures, but to some extent is universal. This is not an individual decision or an individual family member's decision much of the time. A second area is what degree of trust

and respect the family has for the clinicians and the institution taking care of the patient. There is wide spread perception that African Americans have less trust in the system, and although less documented, it probably is also true for other groups such as Latinos and Asians. However, individual physicians with a strong therapeutic relationship can overcome this. Trust and respect would seem to be important areas to pursue.

The following studies were suggested relevant to this and related questions:

Connell C, Avey H, Holmes S. Attitudes about autopsy: Implications for educational interventions. Gerontologist. 1994 Oct. 34 (5) p. 665-673.

Sanner M. Attitudes toward organ donation and transplantation: A model for understanding reactions to medical procedures after death. Social Science & Medicine. 1994 Apr. 38(8): p. 1141-1152.

Kotch J, Cohen S. SIDS counselors' reports of own and parents' reactions to reviewing the autopsy report. Omega: Journal of Death & Dying. 1985-1986. 16(2): p. 129-139.

17. Are there any areas of research on patient attitudes to other medical requests or procedures that you think might shed some light on patients' attitudes towards the autopsy?

The Patient Perspective Advisor commented that important patient factors to consider regarding autopsy consent processes might include the existence of a prior relationship with the requesting clinician (e.g., primary care physician versus attending physician versus unknown covering physician), religious/spiritual beliefs, and trust in the healthcare system, which in turn is very likely to be affected by ethnicity and economic status.

The two areas of study of patient perspectives mentioned were organ donation and cancer screening, with organ donation obviously being the more directly related area. The notable difference between organ donation and autopsies that the Advisor pointed out was that patients probably do not regard autopsies as having a clear goal (e.g., helping people). The general area of patient perspectives of healthcare choices could also be researched.

18. One of the questions that the existing literature probably will not answer is whether or not there is a "right rate" for the autopsy? As a health economist, how might you frame this question or consider answering it?

Agreed with general approach of the report, that one has to identify quantifiable benefits and then demonstrate cost-effectiveness in achieving these benefits with a certain autopsy rate.

19. The literature will almost certainly furnish evidence that the autopsy provides multiple benefits for different "users" of the autopsy, including patients' family members, clinical staff,

pathologists, researchers, public health officials, hospitals and health care organizations, and health care payers. Unfortunately, the information for families regarding heritable diseases, the use of the autopsy as a means of detection for public health officials in monitoring important trends, the multiple roles in medical education, and other benefits attributable to the autopsy have no clear " dollar value." Do you have any thoughts on how we might attempt to quantify the benefits of the autopsy?

Benefits other than improved diagnosis and more accurate vital statistics are difficult to quantify, and even the latter benefit is not easily quantified.

20. The costs of the autopsy are presumably more straightforward: other than the time spent by the pathologists performing and interpreting autopsies and associated use of supplies/equipment, are there any significant costs associated with autopsy performance? Do you think medicolegal exposure for society/hospitals/physicians represents a substantial cost of the autopsy?

One Advisor noted that there are anecdotal reports of autopsy findings actually helping hospitals/MDs in defending the care they delivered, but no real data addressing the issue of costs incurred or saved by routine autopsy performance.

Another Advisor pointed out that the College of American Pathologists has done some work on specifying the cost elements for autopsy. Baseline costs include: 1.) Space - detail original cost, depreciation and maintenance; 2.) Utilities (i.e., Air - Pressure Gradient Requirements, Filtration - Laminar Flow, Venting, Plumbing, Waste disposal - liquid and solid); 3.) Capital Equipment (i.e., Depreciation, Interest loss, Lease or rental costs, Maintenance, Insurance, Licensing fees for computers and other equipment); 4.) Supplies (i.e., Disposables, Cleaning Supplies, Histology, Secretarial and computer, Photography and educational); 5.) Personnel – Technical (i.e., Salaries, Benefits, Pension; Autopsy Assistants; Histopathology Technicians; Laboratory Assistants; Nurses - in Decedent Affairs Office); 6.) Personnel – Professional (i.e., Pathologists; Residents; Autopsy Assistants - if employees of the Professional Group; Costs of Autopsy Performance -- Chart Review, Gross Dissection, Microscopic review, Dictation, Formulation of Final Diagnosis; Costs of Educational Services -- For attending physician, For Hospital/Medical Staff); 7.) Indirect Costs (i.e., Laboratory Administration and supervision; General Laboratory and Office Supplies; General Maintenance; Computer services; Continuing Education - including subscriptions, dues and travel; Licensing fees; Quality control, quality assurance and laboratory accreditation costs; Other); and 8.) Allocated Expenses from Hospital. Additionally, Special Costs Related To OSHA Regulations: 1.) Personnel Protective Equipment; 2.) Decontamination and Housekeeping; 3.) Ducted exhaust and air ventilation system; 4.) Waste disposal; 5.) Containment Equipment (biologic Safety Cabinets); 6.) Employee Vaccination; 7.) Employee Education; 8.) Construction and Capital costs; 9.) Other Personnel costs; 10.) Other Supply Costs; and 11.) Indirect and allocated costs.

21. In conducting this analysis, from a policy perspective, would you recommend targeting research toward determining an optimal autopsy rate, or instead considering the strategy of

directing resources at increasing the impact of the information derived from autopsies obtained under the current system, or both?

All of the Advisors agreed that both are important.

22. Most of our analysis will be from the societal perspective, but can you think of any financial incentives for institutions or payers to maintain their current autopsy rates (or increase them) under the current reimbursement system? For example, can autopsy results be used to modify discharge diagnoses so as to increase hospital reimbursement for individual patients?

The Health Economics Advisor knew of no data addressing this possibility. (We subsequently identified two papers that discuss this issue, but no good studies demonstrating a systematic impact on DRGs—and therefore reimbursement—by routinely including autopsy findings.)

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