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Use of "Therapeutic Complication" as a Manner of Death

ABSTRACT: Analyses of deaths due to therapeutic complications (TCs) provide important quality of care information for medical providers. In New York City, 463 deaths were investigated by the Office of Chief Medical Examiner and certified with TC as the manner of death in 2003. The TC manner of death is used for fatalities due to predictable complications of appropriate medical therapy. All death certificates and select autopsy, hospital, and investigation reports were reviewed. Data concerning cause of death, contributing conditions, age, race, and sex were extracted. The types of complications and the causes of death were classified into various types of surgical and nonsurgical categories of complications. These included: postoperative infections, pulmonary emboli, and technical and medication complications. The use of TC as a manner of death has benefits and limitations. Without the TC option, one is forced to certify certain deaths (e.g., penicillin anaphylaxis) either as natural or accident. The TC option allows easy identification and tracking of medical complications for public health purposes and also allows more consistent reporting of natural and medical-accidental deaths. In general, complications that occur during emergency surgeries/procedures for natural disease, tend to be certified with a natural manner. The "but for" test may be used to distinguish natural from TC deaths. There are criteria for distinguishing TC from accidents and homicides. TCs that occur during treatment of a potentially life-threatening injury, are superceded by the manner dictated by the circumstances of the initiating injury. The certification of TC usually does not address errors of omission, clinical judgement/management, or missed diagnoses.

KEYWORDS: forensic science, forensic pathology, therapeutic complication, fatality

A report by the Institute of Medicine of the National Academy of Sciences in 1999 stated that up to 98,000 patients die of preventable medical errors in American hospitals each year (1,2). In 2004, HealthGrades, a healthcare quality company, stated that as many as 195,000 people per year could be dying in hospitals due to preventable errors. These reports have enhanced public awareness of the need to reduce medical errors and subsequent deaths (3–6). One of the Institute's recommendations called for a mandatory reporting system for deaths and serious injuries (1). Medicolegal death investigation systems are one component of this approach. Specific guidelines are needed, however, to clarify which deaths should be reported and how they will be classified.

In addition to the standard manners of death (natural, homicide, suicide, accident, and undetermined), medical examiners in New York City (NYC) have the option to certify a death as therapeutic complication (TC). The TC manner is not part of a New York statute but is accepted by the NYC registrar of vital statistics. The TC manner of death is used for fatalities due to predictable complications of appropriate medical therapy. For death certification purposes, death during medical care for a disease falls into one of three categories. The first category is deaths exclusively due to natural disease. In these deaths, neither medical therapy nor injury plays a role in causing or contributing to the death. The second group is those due to predictable complications of appropriate medical therapy. The third category is deaths due to unanticipated complications and/or inappropriate therapies. In general, these three categories correspond to the following three manners of death: natural, TC, and accident.

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With the current trend of decreasing rates of hospital autopsies (7), medicolegal death investigation systems play an increasingly important role in the detection, evaluation, and documentation of deaths that occur under medical care (8). Consistent death investigation and certification guidelines used by medicolegal death investigation systems help identify and track medical trends. In NYC, all deaths that occur during diagnostic or therapeutic procedures or from complications of such procedures must be reported to the Office of Chief Medical Examiner (OCME). In addition, all deaths due to injury (including chemical injury such as medication errors) must be reported to the OCME. In this study, we review only the TC deaths. Deaths certified as accidents are not examined.

Materials and Methods

The NYC OCME investigates all unexpected, violent, and suspicious deaths in NYC. In addition, all deaths that occur during diagnostic or therapeutic procedures (or from complications of such procedures) must be reported to the NYC OCME. In 2003, there were 8848 deaths certified by the NYC OCME. Of these, 463 were TCs, of which 328 (71%) underwent autopsy. Also investigated and certified were the following manners: 5013 natural, 2014 accident, 665 homicide, 487 suicide, and 206 undetermined. Of the 2014 accidents, 81 occurred in a medical facility.

All death certificates and select autopsy, hospital, and investigation reports were reviewed. Data concerning cause of death, contributing conditions, age, race, and sex were extracted. The causes of death were classified independently by two reviewers (J. R. G. and L. B. G.) into various types of surgical and nonsurgical categories of complications (see Table 1). This classification system was based on the types of adverse events from a study by Leape et al. (9).

Contributing conditions were additional disorders listed on the death certificate as contributory to death but unrelated to the un-

TABLE 1—*Categories of therapeutic complications.*

Complication	Example
Operative:	
Postoperative infection	Bronchopneumonia, wound infection, line sepsis, urinary tract infection
Technical	Dehiscence, bleeding
Nontechnical	Ileus, cardiac arrhythmias
Late/delayed	Adhesion, splenectomy associated infection
Anesthesia related	Hyperthermia, ventilation problems, anesthesia reactions
Pulmonary embolism	Postoperative
Transfusion	Complication of transfusion that was needed due to surgery
Nonoperative:	
Nonoperative infection	Line sepsis, urinary tract infections
Procedure: technical	Gastric tubes (leaks/bleeding), bleeding with cardiac catheterization, bronchoscopy, or invasive radiologic procedures, perforation during colonoscopy
Procedure: Nontechnical	Arrhythmia during stress test or catheterization
Medication	Anaphylaxis, infection during steroid therapy, toxic epidermal necrolysis, gastrointestinal hemorrhage (nonsteroidal anti-inflammatory medication), and pseudomembranous colitis (following antibiotic therapy)
Anticoagulation	Bleeding complications with anticoagulation therapy
Hemodialysis	Bleeding, shunt problems, electrolyte disturbances, subdural hemorrhages, infected shunt
Pulmonary embolism	Nonsurgical inactivity, medications
Radiation therapy	Fibrosis/infection
Transfusion	Transfusion reactions, viral hepatitis, or HIV infection

derlying cause of death. Typically, contributory conditions are listed in part 2 of the death certificate. In some instances, the contributing condition was woven into the primary cause of death statement (part 1) along with the proximate cause of death.

The cause of death is defined as the etiologically specific disease and/or injury responsible for initiating the lethal sequence of events. A competent cause of death includes the proximate (underlying) cause, defined as that which in a natural and continuous sequence, unbroken by any efficient intervening cause, produces the fatality and without which the end result would not have occurred. The manner of death is determined from the cause and circumstances of death. The manners of death listed on the United States Standard Certificate of Death include: natural, accident, suicide, homicide, and undetermined.

Results

There were 463 deaths certified as TC by the NYC OCME in 2003. The majority (58%) were surgically related (Table 2). The age of the decedents ranged from 7 days to 95 years with a mean of 59 years. The majority were female (57%).

TABLE 2—*Complications in therapeutic complication deaths.*

	Total	%
Operative		
Nontechnical	74	16
Technical	71	15
Postoperative infection	59	13
Pulmonary embolism	32	7
Late/delayed	28	6
Anesthesia related	5	1
Transfusion	1	<1
Total	270	58
Nonoperative		
Procedure: technical	65	14
Medication	49	10
Anticoagulation	26	6
Hemodialysis	24	5
Procedure: nontechnical	12	2
Procedure: wound Infection	6	1
Transfusion	5	1
Radiation therapy	3	<1
Pulmonary embolism	2	<1
Undetermined	1	<1
Total	193	42

Atherosclerosis and/or hypertensive cardiovascular disease (21%) and diabetes mellitus (9%) were common contributing conditions (Table 3). Diabetes mellitus was the contributing condition or proximate cause in 53 (12%) of the TC deaths. Obesity was a contributing condition or proximate cause in 48 (10%) of the deaths. There were 328 deaths that underwent autopsy, and 135 did not have an autopsy. The total number of deaths with contributing conditions were: 121 (37%) for the autopsy and 52 (39%) for the nonautopsy deaths.

Pulmonary emboli (PE) deaths were predominantly (32/34) associated with surgical procedures (Table 4). The two nonoperative deaths from pulmonary embolism were due to estrogen medications and both patients were obese. One decedent had a congenital abnormality of the uterus that may have resulted in a partial venous obstruction. Overall, contributing conditions for the PE deaths included: 13 obesity, nine neoplasms, three cardiovascular disease, two anatomic uterine abnormalities/enlargements, one sickle cell disease, and one membranous glomerulonephritis. The neoplasms included five carcinomas (two renal, two lung, and one rectal), two meningiomas, and one oligodendroglioma. All of the PE deaths with neoplasms were postoperative. The time range of the PE from surgery to death was: 1–73 days with a mean of 12 days (the date of surgery was not known in two deaths). 14 of 32 (44%) postoperative PE deaths occurred after discharge from the hospital.

TABLE 3—*Contributing conditions.*[*]

	Number	%
Total number of therapeutic complications	463	100
Total number with one or more contributing conditions	173	37
Atherosclerotic and/or hypertensive cardiovascular disease	99	21
Diabetes mellitus	44	9
Obesity	25	5
Chronic obstructive pulmonary disease	14	3
Liver disease/chronic ethanol abuse	13	3
End-stage renal disease	9	2
Congenital disease	2	<1
Prematurity	1	<1
Other disease	21	5

[*]Some decedents had more than one contributing condition.

TABLE 4—*Risk factors for pulmonary embolism.*

Operative		
General surgery	12	Appendectomy, cholecystectomies, hernia repairs, splenectomy, colon resections
Obstetrics/gynecology	4	Two hysterectomies for leiomyomas, two C-sections
Orthopedic surgery	4	Hammer toe, knee, spine, congenital leg malformation repairs
Neurosurgery	4	Subdural hematoma and three surgeries (two meningiomas, one oligodendroglioma)
Cardiothoracic surgery	3	Coronary artery bypass graft surgery, lung carcinoma resections
Obesity surgery	3	Gastric bypass, two liposuction with reduction surgery
Urologic surgery	2	Transurethral resection of prostate, renal oncocytoma
Total	32	
Nonoperative		
Estrogen therapy	1	Estrogen therapy in obese patient
Oral contraception	1	Drospirenone/ethinyl estradiol therapy in obese patient
Total	2	

Technical problems related to surgery or a procedure accounted for 136 deaths (see Table 2). Infections, both postoperative and those related to procedures, accounted for 65 deaths; these included bronchopneumonia, urinary tract infection, line sepsis, and wound infection. Complications of medications resulted in 49 deaths, and anticoagulation complications added an additional 26. The complications associated with medications included anaphylaxis, toxic epidermal necrolysis, neuroleptic malignant syndrome, gastrointestinal hemorrhage, pseudomembranous colitis, and infections due to immunosuppressive medications (e.g., steroids, azathioprine). There were 26 deaths due to complications of hemodialysis which included bleeding or infections of shunts and catheters (Table 5).

There were seven deaths due to perforations during colonoscopy. Two of these were screening colonoscopies and the others included diagnostic evaluations for GI bleeding, anemia, and obstruction. There were 21 deaths following bariatric (gastric-bypass) surgery including 16 due to technical complications, three late complications (incarcerated hernia, obstruction), and two nontechnical complications (cardiac events).

Of the 26 deaths complicating anticoagulation therapy, there were 10 gastrointestinal hemorrhages usually with underlying pathology (peptic ulcer disease or arteriovenous malformation), six intracerebral hemorrhages, five retroperitoneal hematomas (10,11), three subdural hematomas (without history or evidence of injury), and two others.

There were 81 accidents where the place of injury was a healthcare facility. The predominant cause of death was blunt injury (usually from a fall). Also included were inadvertent endotracheal extubations, incorrect administrations of medication (e.g., insulin), aspirations of food bolus, and an intraoperative mishap.

Discussion

Before the Institute of Medicine published its report on medical errors, "iatrogenic illness" had been a well recognized and described phenomenon for half of a century (12,13). Studies at Yale in 1964 and Boston University in 1981 describe TCs and the hazards of therapy (14,15). There remains a pressing need for a better understanding of these complications occurring when "sound therapeutic procedures had not been used" (12,15).

TABLE 5—*Numbers of deaths due to hemodialysis complications.*

Exsanguination	
Catheter site	5
Shunt/fistula site	10
Gastrointestinal	1
Subdural hematoma without trauma	2
Infections (catheter, sepsis, endocarditis)	5
Cardiac arrhythmia while on dialysis	1
Total	24

In 1964, the "hazards of hospitalization" were described by Schimmel in a review of complications that occurred with 1014 patients at a university hospital medical service (14). They documented every untoward event, complication, and mishap ("episode") if it resulted from acceptable diagnostic or therapeutic measures. Inadvertent errors by physicians or nurses (i.e., accidents) and postoperative complications were excluded. During the 8-month study, 20% of the patients had one or more medical complication. These episodes were categorized as reactions to diagnostic procedures, drugs, transfusions, or other therapies. In addition, they included acquired infections and miscellaneous hospital hazards. There were 16 fatal episodes and 5% of all patients had a fatal or life-threatening complication.

The Types of TCs

The complications were classified into subtypes of surgical and nonsurgical categories (see Table 1). PE occurred in both sets, however, the vast majority were associated with a surgical procedure. This finding may reflect a reporting bias due to the wording of the reportable death statute ("during diagnostic or therapeutic procedures") or due to a selection bias since we only examined the TCs. PE that were complications of injury (e.g., following surgery for a hip fracture) were not included because they were classified on the basis of the circumstances of the initiating injury. In instances of trauma, if the original injury is life threatening, the unnatural manner (accident, homicide, suicide) "trumps" a certification of TC. In addition, medical deaths due to PE complicating disease are natural deaths, and therefore not reportable to the OCME.

Among the PE deaths, the only similarity among all of the various surgeries (Table 4) was the operative and postoperative period of immobility. The efforts to prevent PE in each case are unknown, but even with prophylaxis, PE still occur (16). Therefore PE would fall under the classification of not completely preventable but predictable (9). Until there are further medical advances in the prophylaxis of DVT/PE, postoperative PE deaths can be expected to continue.

One criticism of the Institute of Medicine report on medical errors has been that it did not calculate excess mortality, that is "many patients . . . dying as the result of an adverse event would have died anyway" (2). The same criticism could be made of this study. Many of the patients had comorbid conditions ranging from cardiovascular disease to end-stage renal disease requiring hemo-

TABLE 6—*Definitions.*

Natural	Manner of death due to disease (100%) or old age
Therapeutic complication	Manner of death due to predictable complication of appropriate therapy
Accident	Manner of death caused by violent means that is not an intentional or criminal act. In medical circumstances, deaths from inappropriate therapy or from unanticipated complications that should not occur
Adverse event	Harm caused by medical management (rather than underlying disease) that prolonged the hospitalization, produced a disability at the time of discharge, or death
Error	Failure of a planned action to be completed as intended or the use of a wrong plan to achieve an aim
Negligence	Failure to meet the standard of care

dialysis. Logic would dictate that a critically ill person would be more prone to require any type of procedure and at the same time to be at greater risk to die of a TC. By reviewing only OCME cases, however, we miss some TC deaths because we must rely on physicians in NYC to properly report a suspected death (17,18). This deficiency is highlighted when a family requests us to investigate a hospital death that was not initially reported to our office by the treating physician. Since we honor all family requests for autopsies, some TCs (and the occasional accident) came to light by this route.

For anticoagulation therapy, the risks of the outcome of the disease without anticoagulation usually outweigh the risks of anticoagulation. Specialized anticoagulation monitoring clinics may further decrease the annual incidence of bleeding complications due to warfarin therapy which has a 0.5–1.1% rate of fatal hemorrhage (19). The low number of deaths associated with the high number of patients treated with anticoagulants has become an accepted and predictable risk of the therapy.

Similarly, screening colonoscopies carry risks but the number of deaths associated with colonoscopy is very low (0.01%) with most fatalities due to a colonic perforation (20). All seven deaths associated with colonoscopies in our study had perforations. This supports previous findings that bleeding and other complications of colonoscopy usually are survivable. If there is underlying pathology (e.g., inflammatory bowel disease, peritoneal adhesions) that renders the colon susceptible to perforation, the manner is best certified as TC. If the bowel is entirely normal (e.g., during a cancer screening colonoscopy) and a perforation occurs through normal tissue, an accidental manner is appropriate.

Heart disease, diabetes mellitus, obesity, and liver disease are common contributing conditions that could make a patient more susceptible to a variety of complications including cardiac arrhythmias, deep venous thrombosis, and infections. In some instances, these disease processes played such a dominant role that they were designated as the proximate cause of death in the part 1 cause of death statement with the complication designated as the contributing condition (part 2). For example, a patient with marked coronary artery disease dies of a myocardial infarct following a routine herniorrhaphy. This may be certified descriptively: myocardial infarct due to atherosclerotic cardiovascular disease following inguinal hernia repair; or separated into part 1 (myocardial infarct due to atherosclerotic cardiovascular disease) and part 2 (status-post inguinal hernia repair).

The TC as a Manner of Death

NYC is one of few jurisdictions in the country that has a "TC" manner of death category. King County, Washington uses "Complications of Therapy" and Cuyahoga County in Ohio adds TC to the cause of death statement but certifies the manner as natural. Even though the TC manner is used in a minority of jurisdictions, a majority of forensic pathologists favor the addition of such a category (21). Medical examiners in other jurisdictions (New Hampshire, Vermont) have attempted without success to implement the TC manner with the registrar of vital statistics. To the best of our knowledge, this manner of death originated in Cuyahoga County (Cleveland), Ohio in the 1960s as a replacement for "therapeutic misadventure" (22) because the latter term was deemed inflammatory.

A TC death is due to a predictable complication of appropriate therapy (Table 6). TC is not synonymous with negligence or a euphemism for accident or malpractice. It is a nonjudgemental recognition of the fact that every treatment or procedure carries a risk (23). The TC category protects the purity of the "natural" manner which is used only for deaths that are 100% due to disease. It seems intellectually inconsistent to classify a death due to physical or chemical injury as "natural" because the injury was sustained in a hospital or doctor's office rather than on the street. With or without the TC option, medical accidents are still certified with a manner of death as accident.

Each medicolegal death investigation system is an independent state or county jurisdiction and each has its own requirements as to which deaths must be reported to the Medical Examiner or Coroner. In addition since most jurisdictions do not have a TC option, there is wide variation in the certification of such deaths. Without the TC option, one is forced to certify certain deaths (e.g., penicillin anaphylaxis) either as natural or accident. Conferences on death certification and forensic pathologist list-serves demonstrate the lack of national consistency in the certification of these types of deaths (24). One cannot expect 100% consistency, since there always will be unusual cases whose certification is a matter of judgment. With the same set of facts, some certify TCs as natural while others classify them as accidents. To a family, treating physician, insurance company, or malpractice attorney, the difference between an accident and natural manner can have profound ramifications. The certification of a TC death as an accident may result in the inappropriate implication of malpractice when there is none. On the other hand, certifying the death as natural may give the appearance of covering up an obvious medical complication (23). Some may argue that the addition of a third option will further obfuscate such certification disparities. In practice, however, the TC option allows more consistent reporting of natural and accidental deaths. As surgical pathology has demonstrated, not every tumor is either benign or malignant; sometimes it is important to have a "borderline" diagnosis category to protect the purity of those clearly malignant and benign groups.

The "but for" test may be used to distinguish natural from TC deaths. This is done by asking the question: "But for the procedure/treatment, would the patient have died at that time?" If the answer is "yes," then the death is certified as natural. For example, if a patient presents to the emergency department with a ruptured abdominal aortic aneurysm and dies during emergency surgery, this would be certified as a natural death. If the risk of treatment is

comparable to the risk of the disease, or if a fatal outcome is anticipated in some circumstances, the manner usually is certified as natural (23,25).

In general, complications that occur during emergency surgeries/procedures for natural disease tend to be certified with a natural manner. Complications of elective procedures are either TC or accident. When a surgery or procedure is performed on a diseased organ system (particularly when it is acutely failing) and that same organ system subsequently results in death, it may not be possible to differentiate between the roles of the natural disease and the therapy in causing death. Sequence does not always imply consequence. In these instances, one needs an unequivocal complication (e.g., PE or myocardial infarct in patient undergoing lung surgery) in order to certify it as TC. If a patient has a lethal cardiac arrhythmia while undergoing emergency cardiac catheterization for an acute myocardial infarct, this would be certified as natural. If, however, it was an elective procedure due to stable angina, the manner would be TC. If a perforation occurs in a normal coronary artery during an elective angiography, an accidental manner is appropriate. If, however, that perforation occurs in a diseased artery, the manner would be TC. The clinical circumstances and the extent of any underlying pathology detected at autopsy provide important information in distinguishing among natural, TC, and accident.

Alternatively, a death due to a complication of a diagnostic or therapeutic procedure that is not an anticipated complication and/or due to inappropriate therapy would be certified as an accident or, in rare instances, as homicide. If a patient with nonoperable pancreatic carcinoma dies of an infected porta-catheter, this is a TC. If that same person dies due to a pulmonary embolism, it is certified as natural. The proximate (or underlying) cause in both scenarios is pancreatic carcinoma. If that patient inadvertently had been given 10 times the prescribed dose of a therapeutic agent that resulted in death, the manner would be certified as an accident. Rarely, if there is a gross and wanton disregard for a patient's health and safety, death due to the action or inaction of medical care givers may be certified as homicide (see *People v. Einaugler*, 618 NYS.2d 414 AD 1994). Also, death due to treatment by an unlicensed fraud is classified appropriately as homicide.

In general, the certification of TC does not address errors of omission, clinical judgment/management, or missed diagnoses. For example, if a patient died of meningococcemia that clinically had been missed, the manner of death would be certified as natural. If the same patient received an injection of penicillin and died of an anaphylactic reaction to the penicillin, it would be certified as TC. If the same patient were erroneously given insulin instead of penicillin, this would be certified as an accident. Deaths due to inadvertent administrations (e.g., administration of incorrect or too much medication), equipment problems (ventilator malfunction), or complications of therapy that are not predictable complications of appropriate therapy, are generally certified as accidents.

A study of errors in otolaryngology used a detailed classification scheme that includes several clinical management issues that are beyond the expertise of most forensic pathologists (26). A forensic pathologist is unlikely to know if there were errors in the selection of the type of surgical therapy or planning. TC manners actually underestimate errors since they do not include errors in clinical judgment, misdiagnoses, etc. It is often beyond the expertise of a forensic pathologist to judge the appropriateness of treatment, particularly when that judgment is through 20/20 hindsight. Therefore, a mechanism other than the medicolegal death investigation system must be in place to identify those errors and the other nonfatal errors and adverse outcomes.

Different criteria have been used to differentiate a TC from an accident. The definition of TC includes predictable complications and appropriate therapies. Therefore, unanticipated complications and inappropriate therapies would be accidents. What is a *predictable* complication? A potential problem for the forensic pathologist may occur due to varying levels of experience with and clinical knowledge of a particular procedure or treatment. At these times, consultation with a clinical expert in the field may assist in the determination of the manner of death. For example, a healthy patient electively donates a kidney to a family member. The healthy donor dies shortly after the surgery due to exsanguination from the recently ligated renal artery stump. After a review of the literature and discussion with a renal transplant surgeon, it became clear that this is not a reasonable, predictable complication of this surgery, and the death was certified as an accident.

Medical errors have been defined as the failure of a planned action to be completed as intended or the use of a wrong plan to achieve an aim (1). Types of errors described in the Institute of Medicine report include: "adverse drug events, improper transfusions, surgical injuries and wrong-site surgery, suicides, restraint-related injuries or death, falls, burns, pressure ulcers, and mistaken patient identities." This definition of error is broad and includes a variety of manners of death (accident, suicide, and possibly even homicide) in addition to TC. Few would argue with wrong-site surgery, mistaken patient identity, or incorrect medication as errors. But mixed among these "errors" are adverse events that may not necessarily be mistakes. Is an anaphylactic reaction to penicillin in a patient with no known drug sensitivity an error? It would be an error if the patient had a known history of a penicillin allergy. Adverse outcomes that are certified as TCs are not necessarily errors (e.g., pulmonary embolism). Deep venous thrombosis is preventable to a certain extent but even with venodyne boots and heparin, patients still die of PE. Not all "errors" are certified as an accident or TC. Errors in diagnosis usually are not certified as a TC, while treatment errors usually are. TC does not equate with negligence or malpractice. Some deaths due to negligence may even be certified as natural (*see below*).

In 1991, Brennan et al. (27) reviewed more than 30,000 randomly selected hospital records in New York State to examine the incidence of adverse events and negligence. An adverse event was defined as an "injury that was caused by medical management (rather than the underlying cause of disease) and that prolonged the hospitalization, produced a disability at the time of discharge or both." They further classified the adverse event by whether it was likely due to an error and whether there was evidence of negligence. Negligence was defined as the failure to meet the standard of care (4,27). Caution must be taken in the terminology used in these studies (28). In their study, they describe several cases with adverse events. One case involved a stroke during nonemergent coronary artery angiography and one involved complications of kidney failure due to intravenous angiographic dye for the evaluation of peripheral vascular disease. Both of these deaths would be typical TCs.

The final case involved a man with rectal bleeding. The physician performed a limited sigmoidoscopy which was negative and reassured the patient about continued rectal bleeding. Twenty-two months later, after a 30 lb. weight loss, he was admitted to the hospital and found to have metastatic colon carcinoma. This event was considered an adverse event and negligent. His death, which was due to cancer, however, would be certified with a natural manner. This case highlights terminology differences and the need for consistent criteria for the certification of these deaths and a clear understanding by all parties of this approach to the evalu-

ation of these deaths. It reiterates the medicolegal perspective compared with the purely medical or purely legal approach. Deaths due to acts of commission may be certified as TCs but deaths due to errors of omission are typically certified as due to the underlying disease. This does not, however, prevent civil legal remedies.

In 1993, Leape et al. (29) wrote about preventing medical injury and classified the types of errors as diagnostic, treatment, preventative, and other. Diagnostic errors included errors or delay in diagnosis, failure to use indicated tests, failure to act on results, or use of outmoded tests. None of these would necessarily result in a change of the manner of death from natural to TC. Errors in treatment included TCs and accidents. Other errors included failure of communication (natural) and equipment failure (accident).

Deaths related to hemodialysis highlight the changes of "modern day" medicine. Strictly abiding by the "but for test," any death related to hemodialysis could be considered natural. Exsanguination from an AV fistula or a fungal infection of a hemodialysis catheter are consequences of lifesaving hemodialysis, without which the patient would already have succumbed to the fatal renal disease. Although dialysis patients have an increased mortality, the average survival on hemodialysis is on the order of years (28,30). Patients expect to live long term on hemodialysis. In addition, kidney transplantation can allow a patient to stop hemodialysis. Of the 26 hemodialysis deaths, most (20/26) were a dramatic, yet expected complication of the dialysis access site: bleeding or infection (Table 5).

When invoking the "but for test," one must consider the physiologic mechanisms involved in the death. Mechanisms of death can help differentiate two competing potential causes of death. The "but for test" may be expanded to the "but for the procedure/treatment would the patient have died at that time *of that physiologic mechanism*." With this definition a death from hyperkalemia secondary to renal failure is natural. A death from dialysis-induced hypokalemia is a TC (30). In a sense, the hypokalemia caused by the hemodialysis (or the exsanguination from the AV fistula) is an intervening event that makes the death a TC. The mechanism (arrhythmia due to hypokalemia) inculpates the hemodialysis.

Since patients who require hemodialysis often have other marked medical disease, one needs an obvious immediate cause directly related to the hemodialysis in order to invoke it as part of the cause of death and thus make it a TC. Finally, if a patient decides to stop receiving hemodialysis and dies of kidney disease, the manner of death is natural. This would not be certified as a suicide because it is nonviolent; the patient simply allowed nature to take its course.

What role does a TC play in death certification when an injury (gunshot wound, blunt trauma) is the initiating event? TCs that occur during treatment of a potentially life-threatening injury are superceded by the manner dictated by the circumstances of the initiating injury. In other words, the death would be certified as homicide, suicide, or accident even if a TC contributed to the death. This is somewhat analogous to deaths in which pre-existing medical disease contributes to a death that has an injury as the proximate cause or contributing condition. The unnatural component (i.e., the chemical or mechanical injury) usually dominates. For example, a patient develops urosepsis due to a chronic indwelling Foley catheter. If that catheter were placed due to paraplegia from a gunshot wound, the manner is dictated by the circumstances of the gunshot wound (the proximate cause). If the initiating injury, however, is not life threatening, the TC will dominate (23,25). Therefore, if the Foley catheter were placed following surgery for a remote rotator cuff injury of the shoulder, the manner would be TC due to this efficient intervening cause.

With the certification of TC deaths, one common error is not to include the underlying condition for which the treatment was performed. The medical reason for the therapy is the proximate cause of death. The cause of death statement for a TC death should include three components: the complication, the therapy, and the underlying medical diagnosis. Rarely, there will not be an underlying disease (e.g., cosmetic surgery, screening colonoscopy). For example, a death from anaphylaxis due to penicillin should not be certified as "anaphylaxis due to treatment with penicillin," but rather "anaphylaxis due to treatment with penicillin for bacterial pharyngitis."

The death certification system is imperfect and incapable of documenting all cases of medical "errors" as defined by the Institute of Medicine or any other definition (17). Although some clinical errors may not be detected at autopsy, the autopsy still provides relevant positive (e.g., contributing conditions) and negative findings that may be useful in interpreting the entire context of a death (31). Because of the conventions of death certification, some TC deaths are not due to errors and some natural deaths are. Death certificates are not the entire answer and current medicolegal death investigation systems cannot identify all errors (particularly with the variable jurisdictional reporting and certification guidelines). During the past 5 years, the increased emphasis on error reporting appears to have resulted in an abundance of reports of minor events with an ongoing inability to attract serious events (28). A national uniform system of reporting and certifying the fatal complications could shift the focus to these serious events.

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