A Forensic Pathologist’s Experience with Therapeutic Complications in Medical Examiner and Coroner Jurisdictions: a proposal for guidelines

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Introduction

-a proposal for *usable, workable guidelines* for approaching deaths related to diagnostic and therapeutic procedures
-to be a resource for:
* forensic pathologists
* Medical Examiners/ Coroners
* medicolegal death investigators
* hospital pathologists
* hospital risk managers
* nurses and nursing supervisors
Objectives

1. To explain some of the reasons why therapeutic complications are so problematic for forensic and hospital pathologists.

2. To outline the problems with the definition of a therapeutic complication (a manner of death used to characterize predictable complications of appropriate medical therapy) - namely, the adjectives “predictable” and “appropriate”.

3. To propose a set of guidelines that could be implemented in periprocedural deaths between the hospital risk management department and medicolegal death investigation system.
Therapeutic Complication: Defined

a known, predictable (though possibly rare) consequence of an appropriately performed procedure or therapy
Therapeutic Complication as a Concept

• permits an alternative classification of deaths that:
  1) occur during or following or are somehow associated with diagnostic or therapeutic medical or surgical procedures
  2) are not exclusively due to disease (natural)
  3) are not due to error (accident) –

• Nonjudgmental because every procedure entails some degree of risk:

  THERAPEUTIC COMPLICATION ≠ MISADVENTURE
  (misadventure is an inflammatory term)
What Makes These Deaths So “Complicated”?  

• 1. They live in that uncomfortable “no man’s land” between hospital and forensic (medicolegal) death investigation.

• 2. The issues involved may be complex and technical → may exceed the expertise of forensic pathologists and medicolegal death investigators.

• 3. At least some forensic pathologists believe that these deaths belong more appropriately within the domain of the hospital autopsy → issues concerning standard of care and medical malpractice extend beyond the purview of forensic (“public”) interest.
Issues Associated with Hospital Autopsies

• The family may harbor mistrust of hospital, including the Pathology Department (“conspiracy theory” involving hospital clinicians and pathologists).
• Not all hospitals offer autopsies to patients’ families.
• Some hospital pathology departments conduct autopsies only upon a clinician’s request.
Issues Associated with Hospital Autopsies

- Some community hospitals charge patients’ families for performing autopsies.
- Some pathologists do not wish to perform autopsies and therefore, their involvement may be minimal.
- The decline in hospital autopsies has imposed additional burdens on medical examiners and coroners (and therefore, on forensic pathologists!)
Options Available for Families In Cases of Potential Therapeutic Complications

• 1. hospital autopsy →
  -if autopsy room and pathologists are available
  -if clinician offers autopsy to family
  -if family trusts hospital (pathologist) to perform autopsy

• 2. forensic (medicolegal) autopsy → if clinician refers death to the Medical Examiner’s or Coroner’s Office

• 3. private autopsy →
  -if neither hospital nor forensic autopsy is a viable option
  -if family is able to identify a private pathologist who will perform the autopsy
  -if family has sufficient money to pay for a private autopsy (several thousand dollars)
Disease, Treatment, and Death

• disease $\rightarrow$ complication(s) $\rightarrow$ death
  (untreated)  OR
Disease, Treatment, and Death

- disease → / Rx / → complication(s) → death

(treatment potentially alters sequence of events)
# Classification of Deaths Associated with or Accompanied by Medical Care

<table>
<thead>
<tr>
<th>Scenario</th>
<th>Manner of Death</th>
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<tbody>
<tr>
<td>1</td>
<td>Death due exclusively to natural disease</td>
</tr>
<tr>
<td>2</td>
<td>Death due to predictable complications of appropriate medical therapy</td>
</tr>
<tr>
<td>3</td>
<td>Death due to unanticipated complications and/or inappropriate therapies</td>
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Algorithm for Assessment of Risk in Procedure-Associated Deaths: Decision Point #1

• Critical question: does the risk of death from the procedure outweigh the immediate fatal potential of the disease process?

• **RISK OF DEATH FROM PROCEDURE** vs. **RISK OF DEATH FROM DISEASE at that point in time**

• But for the procedure or treatment, would the patient have died at that time?
Algorithm for Assessment of Risk in Procedure-Associated Deaths: Decision Point #1

• *If RISK OF DEATH FROM DISEASE > RISK OF DEATH FROM DISEASE at that point in time*

• But for the procedure or treatment, if the patient *would* have died at that time → the death is *natural*
Case #1 History

- 71-year-old man with known 8-cm-diameter abdominal aortic aneurysm
- Refused surgical intervention
- Suddenly became pale while riding inside of taxicab on way to 50-year college reunion → went into shock
- Rushed to hospital and brought to OR
- Exploratory laparotomy → 3 liters of blood within peritoneal cavity
- Goes into cardiac arrest before any repair can be started
- Pronounced dead in OR (intraoperative death)
intimal surface
Case #1: CAUSE OF DEATH

• 1A. Hemoperitoneum with retroperitoneal hemorrhage DUE TO
• 1B. Ruptured abdominal aortic aneurysm DUE TO
• 1C. Atherosclerotic cardiovascular disease

• Manner of death?
Case #1: MANNER OF DEATH

• Manner of death is *natural* because exclusively due to *disease*)

• “Intraoperative death” is artifact of modern medical resuscitation and transport technologies

• Therapeutic intervention/procedure plays no role in the death
Case #1: Risk Assessment

- **RISK OF DEATH FROM DISEASE exceeds (>)**
  
  **RISK OF DEATH FROM PROCEDURE at that point in time**
Algorithm for Assessment of Risk in Procedure-Associated Deaths:
Decision Point #1

• If RISK OF DEATH FROM PROCEDURE exceeds (>)
  RISK OF DEATH FROM DISEASE at that point in time

• But for the procedure or treatment, the patient
  would not have died at that time → the death is no
  longer natural
Case #2: History

- 58-year-old woman with primary biliary cirrhosis, portal HTN, and ascites was admitted for elective procedure to relieve her ascites and decompress the high portal pressures

- TIPS (transjugular intrahepatic portosystemic shunt) involves placement of a shunt via the internal jugular vein between the hepatic and portal veins of the liver

- During procedure she became hypotensive (BP: 51/28 mm Hg)

- Hypotension persisted with increased abdominal girth → peritoneal tap returned frank blood

- Remained refractory to resuscitative efforts → was pronounced dead ~5 hrs after initiation of procedure
Cause of Death (Case #2)

• (1a). Hemoperitoneum due to
• (1b). Laceration of portal vein branch complicating TIPS procedure for relief of portal hypertension and ascites due to primary biliary cirrhosis

• MANNER OF DEATH?
Indications for TIPS

Refractory or recurrent esophageal variceal hemorrhage
Refractory ascites
Acute esophageal variceal bleeding
Hepatorenal syndrome (HRS; types 1 and 2)
Refractory bleeding gastric varices
Portal hypertensive gastropathy
Hepatic hydrothorax
Hepatopulmonary syndrome (HPS)
BCS (Budd-Chiari syndrome)
Hepatic venoocclusive disease
Complications of TIPS

Technical complications
   Related to access
      Capsule puncture
      Intraperitoneal bleed
      Hepatic infarction
      Fistula
      Hemobilia
   Related to the stent
      Thrombosis
      Occlusion
      Stent migration
      Sepsis
   Related to portosystemic shunting
      HE
      Hemodynamic consequences
      Sepsis
Unique complications
   Intravascular hemolysis
   Endotipsitis

Algorithm for Assessment of Risk in Procedure-Associated Deaths: Decision Point #2

TC \quad \text{procedure-related death} \quad \text{ACCIDENT (death due to unanticipated complication that should not occur, inappropriate Rx, or unintentional error)}

TC = therapeutic complication

(death due to *known* or *predictable* consequence of *appropriate* Rx)
So what are “predictable” and “appropriate”?  

**Predictable:**  
- Capable of being foretold  
- Likely, expected, anticipated, or foreseeable

**Appropriate:**  
- Suitable for, fitting for, or compatible with a particular person, condition, occasion, or place
Problems with the terms “predictable” and “appropriate”?

**predictable:**
- How does one quantify “predictable”? (percentage)
- Does predictable mean more likely than not?
- Does a forensic pathologist have the necessary clinical knowledge of and/or experience with a particular procedure treatment *in order to decide if a complication is predictable*?

**appropriate:**
- What if the therapy is appropriate but for the wrong diagnosis?
  Ex. Steroid Rx for pulmonary hemorrhage diagnosed as lupus capillaritis (correct Dx is invasive pulmonary aspergillosis)
- What if the therapy is appropriate and for the diagnosis but the condition is incorrectly staged or prognosticated?
  Ex. Undertreatment for unfavorable histology neuroblastoma because mitotic-karyorrhectic index (MKI) was underscored
Example: Isoniazid (INH)-Induced Acute Liver Failure

Incidence of:
• antituberculosis drug-induced hepatotoxicity during standard multidrug TB treatment: ~2-28%
• INH monotherapy-related aminotransferase (ALT/AST) elevations: ~0.5%
• acute liver failure: ~0.01% (mortality rate: ~67%)

In clinical medicine (gastroenterology/hepatology/liver transplantation):
• Acetaminophen is an example of predictable (intrinsic) drug-induced liver injury → short latency, dose-related
• INH is an example of unpredictable (idiosyncratic) drug-induced liver injury → variable latency, dose-related
Additional Example: Isoniazid (INH)-Induced Acute Liver Failure

• Major points:
  1. rare can still be predictable!
  2. “predictable” in context of drug-induced liver injury (DILI) has an entirely different meaning/connotation than in a forensic pathologist’s evaluation of therapeutic complications
Case #3: The Importance of Consultation with Specialists/Experts (History)

- 54-yr-old man w/ longstanding history of type IV hiatal hernia (giant paraesophageal hernia w/ intrathoracic stomach and transverse colon)
- s/p laparoscopic reduction + repair w/ fundoplasty and biologic mesh placement
- Discharged on POD #3 w/ low-grade fever

- Found unresponsive in bed on POD #4 → EMS called → initial rhythm: PEA
- Transported to hospital ED but could not be resuscitated
- Case referred to ME → accepted jurisdiction
Liver
Xiphoid process
Stomach

Greater omentum

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Figure 2. Key operative steps. A, Crural dissection; (B), taking down the short gastric vessels; (C), crural closure; (D), complete crural closure; (E), wedge gastroplasty; (F), start of wrap; (G), completed wrap; and (H), biologic mesh placement.
left lung

left pleural cavity

???
1500 mL from peritoneal cavity
Case #3: Autopsy Findings

• Gross:
  - Perforation of anterior gastric wall w/1500 mL intraperitoneal fluid
  - Acute peritonitis
  - Bilateral serosanguineous pleural effusions (L: 725 mL; R: 270 mL)
  - Intact repair

• Microscopic:
  - Mucosal, mural and focally transmural gastric necrosis w/ fibrin thrombi, focal abscess formation, and bacterial colonization (“gangrenous” gastritis)
Case #3: Cause and Manner of Death

COD:
- Gastric necrosis and perforation complicating laparoscopic reduction and repair of paraesophageal hiatal hernia

MOD:
- Therapeutic complication vs. accident?
- Problem: forensic pathologist lacked proper background to interpret these findings!
- Solution: consultation w/ outside expert
Gastric Necrosis/Infarction

• Extremely rare due to rich arterial supply and collateral circulation
• Requires a critical \( \uparrow \) in intragastric pressure (> gastric mural venous pressure)
• Predilection for anterior gastric wall (reason unknown)
• Histopathologic features: mucosal, submucosal, mural, transmural necrosis

• What is explanation for gastric necrosis and perforation in the present case?
• Not entirely known, but consultant had a theory...
Acute Gastric Dilatation

- Incidence: rare (but first described in 1833)
- Pathogenesis: uncertain
- Risk factors:
  - abdominal surgery (postoperative complication)
  - anorexia/bulimia nervosa
  - diabetic gastroparesis
  - trauma

- Clinical presentation:
  - severe abdominal pain usually not a feature
  - massive abdominal distension is most consistent/reliable finding (seen on plain abdominal X-ray or abdominal CT)
  - often inability to vomit

- Prognosis:
  - grave if gastric perforation (>75% mortality)
Case #3: Manner of Death

• manner of death was determined to be therapeutic complication → natural on death certificate
What Does The TC Manner Not Address? (i.e., Limitations)

- Errors of omission
- Issues of clinical judgement and/or management
- Missed diagnoses
- Delayed diagnoses

- Result: TC manner of death likely underestimates the true incidence of medical errors because errors in diagnosis are usually certified as natural deaths
- Conclusion: the use of TC as a manner of death is insufficient to identify all fatal adverse reactions to diagnostic and therapeutic procedures
Responsibilities of the Hospital Risk Management Department

• to identify situations/practices that pose risk to hospital (losses or liability), including:
  1) breaches in patient privacy
  2) errors in diagnosis (i.e., failure to diagnose; incorrect diagnosis)
  3) medication errors (wrong medication, incorrect dose, incorrect route of administration, incorrect documentation)
  4) errors or adverse events in association with diagnostic or therapeutic procedures (therapeutic complications)
  5) potentially hazardous conditions either in the hospital or on the hospital grounds
What Role Can the Hospital Risk Management Department Play in Death Investigation?

- May serve as a liaison between the attending physician and the hospital pathologist or ME/Coroner’s office
- Can assist the hospital administrator in providing guidelines for death reporting
- Can develop an “open administration” of risk management in dealing with sudden, unexpected, and unexplained therapy-related deaths
Proposed Algorithm for Risk Management

All hospital deaths are reported to Risk Management

Does death satisfy criteria for ME/C case? (see next slide)

YES

Report case to ME/C’s Office

ME assumes jurisdiction

NO

Risk Manager initiates conference with attending physician/clinical team

ME declines jurisdiction
Criteria for Reporting of Case by Risk Management to ME/Coroner’s Office

• 1) Either the cause of death OR the sequence of events leading to death during or following a diagnostic or therapeutic procedure is unexplained

• 2) Confirmed or suspected major anatomic injury (perforation, laceration, incision, or obstruction) of a viscus, blood vessel, or duct during or following a diagnostic or therapeutic procedure

• 3) Confirmed or suspected act of commission, including:
   - incorrect medication administered
   - incorrect dose of medication administered
   - incompatible blood transfusion
   - improper placement of airway
Proposed Algorithm for Risk Management in Cases Not Reported to ME/Coroner’s Office

Risk Manager initiates conference with attending physician → the degree of risk is assessed and the family is offered the option of a hospital autopsy →

YES (family consents) → A brief preautopsy conference is conducted (Includes: -attending physician/clinical team -attending pathologist/pathology resident on autopsy service -risk manager assigned to case)

NO (family refuses) → autopsy → postautopsy conference
Conclusion: Potential Benefits of Proposed Algorithm

1. provides a more effective mechanism for addressing adverse events occurring in the hospital setting by allowing the Hospital Risk manager to play a more active role in these cases

2. facilitates communication among the clinical team, family, and the autopsy pathology service

3. *may help to relieve burden on the medicolegal death investigation system*