How to Start Up a Forensic Toxicology Practice

Presented by:
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Clinical Professor of Medicine
University of Chicago Pritzker School of Medicine
Professor of Medicine and Pharmacology
Rush Medical College
EDUCATION

CHEMISTRY

INORGANIC

ORGANIC

BIOCHEMISTRY

BIOLOGY

PHARMACOLOGY

PHYSIOLOGY

PATHOLOGY

TOXICOLOGY
What is Forensics?

- “relating to the use of scientific knowledge or methods to solving crime; suitable in a court of law” – Merriam-Webster.com
- Reconstructing past events
- Non-clinical medical toxicology (no patient/physician relationship)
Advantages of Forensic Toxicology- Why Do It?

- Expands horizons – collateral benefits
- Demonstrates expertise in a variety of forums
- Leadership
- Promotes our subspecialty (and we NEED promoting)
- Creates opportunities
- Dependable revenue stream- once referral flow established
- Creates independence
- Medical Toxicology is uniquely prepared for Forensic Toxicology
- Networking (not an EM skill set)
- Makes one a better physician
Who does Forensic Toxicology?

• **Answer: Toxicologists** *
  - PhD (analytical)
  - Master Degree (online) MS
  - Toxicology bachelor’s degree – BS
  - First Responders
  - AACT members
  - Alternative Medicine Practitioners (e.g. American Holistic Medical Association which has > 800 members)
  - About 9000 Toxicology positions in the US & Canada

* Other than clinical pathologists

Where are the Toxicology Jobs?

Ref: Society of Toxicology at www.toxicology.com
The Four Disciplines of Forensic Toxicology

- Death Investigation Toxicology (Postmortem Toxicology)
- Human Performance Toxicology
- Doping Control
- Forensic Workplace Drug Testing

Ref: What is Forensic Toxicology?
Prepared by: The Forensic Toxicology Council, July 2010
SWGTOX.ORG
What is Forensic Toxicology

- PC reimbursement
- MRO
- IME
- Record Reviews
- Litigation
- Health Hazard Evaluations
- Industrial Contracted Work
- Surveillance evaluations
- Fitness for duty evaluations
- Research Protocol
- Law Enforcement & Pathology referrals (death investigations)
Toxicology fellows’ career goals and needs: a national survey – St. Onge M, Braden B, Connors N, et al.

- Forty participants (online)
- Career goals
- Areas of medical education (65%)
- Inpatient medical care (57%)
- Forensic Toxicology (57%)
- Working within Pharmaceutical Industry (41%)

“Participants felt less supported by their fellowship program in the areas of forensic toxicology, the pharmaceutical industry and addiction medicine.”

Note that only 14 of 290 NACCT abstracts do not deal with Poison Center/acute care/overdoses
Constructing a Financial Revenue Plan

Multiple Revenue Streams

- Personal
  - Forensics

- Employed
  - Forensics
  - Outpatient

- Inpatient
Case/record review: $360 per hour - 3 to 5 hour minimum ($180 written report)

Deposition: $480 per hour - 3 hour minimum

Trial: $600 per hour – 5 hour minimum (portal to portal?)

Consider getting a retainer from criminal defense and civil plaintiff attorneys
# Patient Care Fees *

<table>
<thead>
<tr>
<th>CPT Code</th>
<th>Charge $ $$*</th>
</tr>
</thead>
<tbody>
<tr>
<td>99245 Outpatient-Consultation</td>
<td>$533</td>
</tr>
<tr>
<td>99205 Outpatient-New Patient</td>
<td>$445</td>
</tr>
<tr>
<td>99245 Emergency Department</td>
<td>$533</td>
</tr>
<tr>
<td>99255 Inpatient Consultation</td>
<td>$461</td>
</tr>
<tr>
<td>99291 Critical Care</td>
<td>$575</td>
</tr>
</tbody>
</table>

* Charges will be reduced to Medicare approved rates for Medicare patients.
¤ Consultation code cannot be used for Medicare patients.
## My Practice – FY 2013
(NACCT Abstract # 227)

<table>
<thead>
<tr>
<th></th>
<th>CPT Code</th>
<th>Payments</th>
<th>Reimbursement Rate</th>
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<tbody>
<tr>
<td>Office</td>
<td>689</td>
<td>$245,808</td>
<td>77.4%</td>
</tr>
<tr>
<td>Inpatient</td>
<td>710</td>
<td>$70,011</td>
<td>51.2%</td>
</tr>
<tr>
<td>Observation</td>
<td>65</td>
<td>$5,711</td>
<td>56.2%</td>
</tr>
<tr>
<td>Emergency</td>
<td>128</td>
<td>$20,759</td>
<td>51.7%</td>
</tr>
<tr>
<td>Psych inpatient</td>
<td>174</td>
<td>$22,109</td>
<td>60.8%</td>
</tr>
<tr>
<td>Forensics</td>
<td></td>
<td>$159,707</td>
<td>98%</td>
</tr>
</tbody>
</table>
Payment per CPT Code (FY 2013)

- Office: $356.76
- Inpatient: $98.60
- Observation: $87.85
- Emergency: $162.17
- Psych: $127.06
- Forensic: $933.96
## FY 2014 - Payment per Work RVU

- Patient care: $67.85
- *Emergency Medicine (median): $44.95
- *Cardiology (median): $66.85
- Forensics: $1,413.71
- *Pathology (median): $75.89

### Poison Center

**A source for Forensic referrals**

<table>
<thead>
<tr>
<th>Service</th>
<th>Calls</th>
</tr>
</thead>
<tbody>
<tr>
<td>Information calls</td>
<td>1,025,547</td>
</tr>
<tr>
<td>Air quality calls</td>
<td>1,650</td>
</tr>
<tr>
<td>Hazmat planning</td>
<td>131</td>
</tr>
<tr>
<td>Mercury clean up</td>
<td>3,269</td>
</tr>
<tr>
<td>Interpretation of non-toxicology</td>
<td></td>
</tr>
<tr>
<td>Lab reports</td>
<td>131</td>
</tr>
<tr>
<td>Occupational information</td>
<td>1,303</td>
</tr>
<tr>
<td>Poison information (recalls, litigation, analytical toxicology)</td>
<td>63,096</td>
</tr>
<tr>
<td>Education presentation requests</td>
<td>721</td>
</tr>
<tr>
<td>Drug screen information</td>
<td>5,387</td>
</tr>
<tr>
<td>Administrative (expert witness</td>
<td></td>
</tr>
<tr>
<td>requests-33; product replacement/malfunction-2,249)</td>
<td>28,638</td>
</tr>
</tbody>
</table>

Only 2,477 (0.24%) referred to a private physician

Health Hazard Evaluations

• Health Hazard Evaluations (HHEs) and Health Risk Assessments (HRAs) are the processes that FDA follows to determine the risks of certain device problems and the actions firms should take to resolve them. HHEs and HRAs are designed to reflect the language in the recall regulations and are used specifically for recalls and related safety work. HHEs and HRAs follow the same process and use the same documentation, but they serve slightly different purposes:

  • **HHE** is a tool for classifying a voluntary recall by a firm. The evaluation guides FDA in determining the risk to the public from the defective product and appropriate actions for the firm and the FDA to take to protect public health.

  • **HRA** is a tool for predicting possible harm that can come from a defective or malfunctioning device. The assessment helps the FDA and the firm determine if any actions are necessary such as recalling the devices or notifying the public about the risk.

From: [www.fda.gov](http://www.fda.gov)
Pharmacovigilance - Health Hazard Assessment (HHA)

- Description of defect or contamination issues of a specific drug product.

- Memorandum Format:
  - Statement of problem
  - Therapeutic use of drug
  - Clinical Worst Case scenario
  - References
  - Root cause analysis may be addressed
  - Short turn around time
  - Used for product recalls

- 3 hour minimum plus report (same charges as for legal case reviews)
Example of HHE

....contracted Jerrold B. Leikin MD to perform a Health Hazard Evaluation (HHE) for the subject drug product. Specifically, to evaluate the impact of double the thickness of the 0.125 mg digoxin tablets from counter channels during packaging/filling operations on packaging line # 405 in November, 2007 (batch # -). A total of 15 tablets were removed.

Therapeutic use: Cardiac inotropic and anti-arrhythmic agent.

Root cause evaluation noted that the tablets found with double thickness might have been produced during the re-adjustment at start up. It was believed possible that the tablets might have been stuck in the tablet de-duster or metal detector and was not noticed by the press operator.

Clinical conclusion: Potential risks to the patient depend upon the constituency of the tablets. If the tablets contain double the dose, then it can be expected that digitalis toxicity can occur in individuals taking daily doses or in patients with renal insufficiency. Toxicity can include nausea, vomiting, dizziness, low blood pressure, cardiac instability and bradycardia. Death can result from excessive digitalis intake.

If the increased thickness is due to clinically inert substances, then a decreased amount of digitalis may be absorbed, leading to exacerbation of the underlying cardiac disease (congestive heart failure and arrhythmia) due to lack of therapeutic efficacy.
Actavis Totowa (formerly known as Amide Pharmaceutical, Inc.) recalls all lots of Bertek and UDL Laboratories Digitek® (digoxin tablets, USP) as precaution

FOR IMMEDIATE RELEASE -- Morristown, NJ -- April 25, 2008 -- Actavis Totowa LLC, a United States manufacturing division of the international generic pharmaceutical company Actavis Group, is initiating a Class I nationwide recall of Digitek® (digoxin tablets, USP, all strengths) for oral use. The products are distributed by Mylan Pharmaceuticals Inc., under a "Bertek" label and by UDL Laboratories, Inc. under a "UDL" label.

The voluntary all lot recall is due to the possibility that tablets with double the appropriate thickness may have been commercially released. These tablets may contain twice the approved level of active ingredient than it appropriate.

Digitek® is used to treat heart failure and abnormal heart rhythms. The existence of double strength tablets poses a risk of digitalis toxicity in patients with renal failure. Digitalis toxicity can cause nausea, vomiting, dizziness, low blood pressure, cardiac instability and bradycardia. Death can also result from excessive Digitalis intake. Several reports of illnesses and injuries have been received.

This recall is being conducted with the knowledge of the Food and Drug Administration.
From: www.fda.gov
Retrospective review of digoxin exposures to a poison control system following recall of Digitek® tablets.

BACKGROUND:
In April 2008, Digitek® digoxin tablets were recalled by the manufacturer as possibly containing double the labeled amount of drug. The recall to March 2006 involved 800 million tablets.

OBJECTIVE:
The aim of this study was to evaluate whether there was any increase in the number of calls to a poison control system, and any increase in the severity of exposures after the recall compared with before the recall.

METHODS:
A retrospective review of all digoxin exposures to a poison control system from March 2004 to February 2008 was conducted, with data extracted from an electronic database (California Poison Control System). Total numbers of exposures were identified. Cases with moderate, major, and death outcomes were also identified and tallied. Chi-squared analysis was performed.

RESULTS:
Prior to the recall, there were 679 digoxin exposures. 148 (22%) were listed with moderate, major, or death as outcome. After the recall, there were a total of 610 cases, 165 (27%) with moderate, severe, or death as outcome. There was a statistically significant increase in the total number of moderate, major, and death outcomes after the period of the manufacturing error compared with before (p = 0.028).

CONCLUSION:
During the period of manufacturing error, there was a statistically significant increase in digoxin exposures with moderate, major, or death outcomes. The recall of Digitek® tablets may have increased moderate, major, or death outcomes from digoxin exposures in a poison control system database.
Medical – Legal Consulting

• Criminal vs. Civil
• Civil cases dominated by environmental/impairment issues (rarely medical malpractice)
• Need to accept “all comers”
• An independent contractor with no contract
• Optimal: separate company to do billing/scheduling/light secretarial work/ insurance for expert witness/ one 1099
• Need to be in “active practice;” each state has different requirements. (for example, in Tennessee, the expert must practice in Tennessee or a contiguous state).
• Charge for time; not opinion
• Take MRO course & get certified
DEFINITIONS

- **Overdose**: Excessive dose in which there is no expected therapeutic benefit.
- **Impairment**: Increased risk in being involved in an accident.
- **Intoxication**: Nervous system abnormality due to a drug.
- **Inebriation**: Inability to perform activities of daily living (ADL) due to a drug.
- **Tolerance**: Increasing dose to achieve the same effect.
Medical-Legal: Accessing

- Contact local Bar Associations / Insurance Company offices
- National Search Firms of Limited benefit: TASA (Penn): [www.tasamed.com](http://www.tasamed.com) or 800-659-8464 (ask for Wendy Liu - [wliu@tasamed.com](mailto:wliu@tasamed.com) or Mary Calhoun – [mcalhoun@tasamed.com](mailto:mcalhoun@tasamed.com)
- Local search services are the best
Independent Medical Exam (IME)

- 2 types (medical records and physical examination)
- Requires outpatient clinic access/laboratory support for examination/secretarial assistance
- No physician/patient relationship
- Written report within 14 business days
- Payment within 10 business days upon receipt of invoice (Rule 1.360, Fla R. Civ P -2010)
IME (continued)

- **Key components:**
  - Diagnosis
  - Causation
  - Prognosis
  - Maximum Medical Improvement (MMI)
  - Impairment Rating (rarely)
  - Functional Ability (rarely)
  - Evaluate if Prior Care was Appropriate?
  - Future care recommendation

Ref: AMA Guides to the Evaluation of Permanent Impairment. Ed. Rondinelli RD. Sixth ed. Publisher AMA
Source of IME

- Attorneys
- Workman’s Compensation Insurance Carriers
- Self-insured employers
- American Board of Independent Medical Examiners (ABIME): 590 physicians listed - 6 report toxicology as one of their specialties
- SEAK- National Directory of Independent Medical Examiners
- Referral Services

Ref: Murphy C. Fear not the IME J Med Toxicol. 2012; 8(1): 3-4
Independent Medical Exams

• Companies that refer individuals for Independent Medical Examinations
  • ExamWorks (main office) 877-628-4703
  • MES Solutions (main office) 877-325-0091
Other Contractual Work *

- Industry Exposures / spills (i.e. mercury contamination)
- Labeling requirement review
- Marijuana decriminalization
- Environmental evaluations
- Protocol development

* Be prepared to respond promptly. (align with Occupational Medicine department)
Summation

• Take MRO course; become Certified
  • MRO Courses:
    • AAMRO: www.aamro.com
    • MROCC: www.mrocc.org or www.acoem.org
• Ultimate “Fee for Service” model- You set the rates
• Forensic Toxicology is an essential revenue stream and important component in any business plan.
• As leaders in Medical Toxicology, we may have a medical duty to answer appropriate inquires in legitimate forums.
• Improve awareness of our subspecialty.
• Can be integrated with clinical work.
• Will take years to develop
Summation (continued)

- Revenue can be sustainable, transferable, and reliable
- Creates professional independence/freedom
- Virtually no “fatal denials”
- Don’t pay to obtain referrals
- Little in the way of overhead
- Billing should be outsourced
- Always be prepared (Just don’t say no!)
- Network opportunities
- Don’t be intimidated
- Better to hit a bunch of singles than a single home run
- Makes one a better physician
Summation (continued)

- Consider contacting:
  - Expert referral services (focus on local)
  - IME referral services
  - Pharmaceutical companies (focus on regulatory affairs, pharmaco-vigilance, quality operations)
  - Poison Center
  - Local Bar Association/Insurance Firms
  - Industrial Hygienist group

- Start a website
Should You Ask a Question in Lecture?

Dr. Fizzy

Ref: The Journal of Irreproducible Results. June 2014; 52(3): 29
THANK YOU

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