Medical Necessity of Cardiac Implants:

The New Enforcement Priority

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Background

- Increased efforts over the last two years to combat Medicare/Medicaid false claims and fraud
  - Health Care Fraud Prevention and Enforcement Action Team
  - PPACA boosts funding for fraud investigations and enforcement by $300 million over 10 years

Background

- Increased focus on in the implantation of cardiac stents and Implantable Cardiac Defibrillator ("ICDs")
  - Scrutiny on
    - implant rates
    - documentation of medical necessity
    - timing
    - Medicare billing

Background

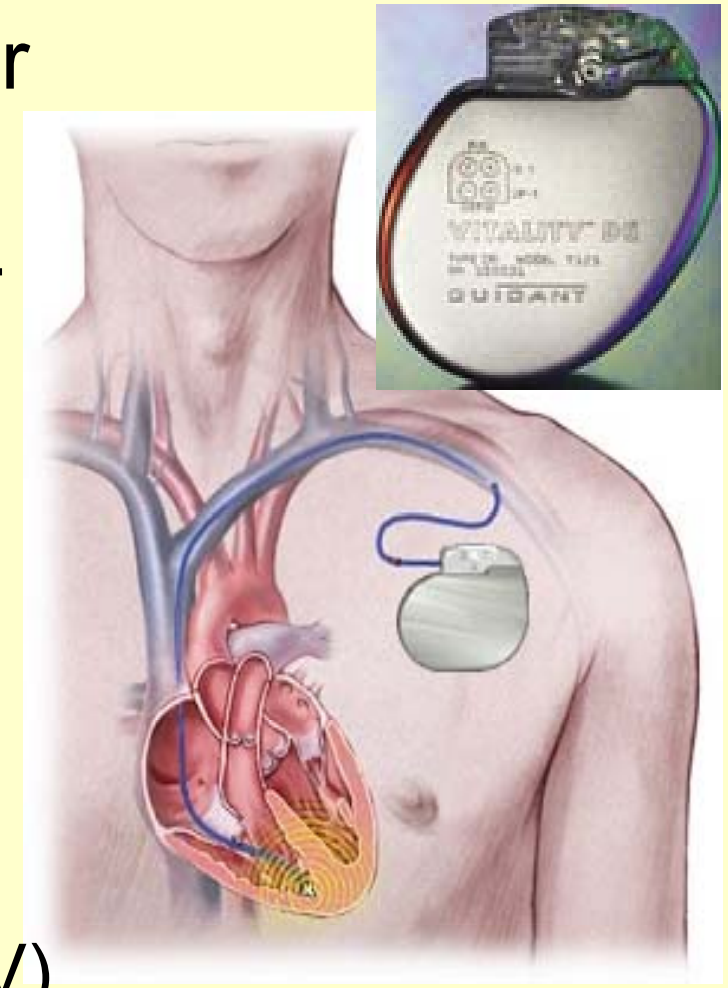
- Nationwide investigation specific to ICDs
  - Civil investigative demands
  - “Preserve and hold” notices
  - Production of medical records
  - Interrogatories

Cardiac Electrophysiology

- Subspecialty of cardiology involving the diagnosis and treatment of the electrical activities of the heart

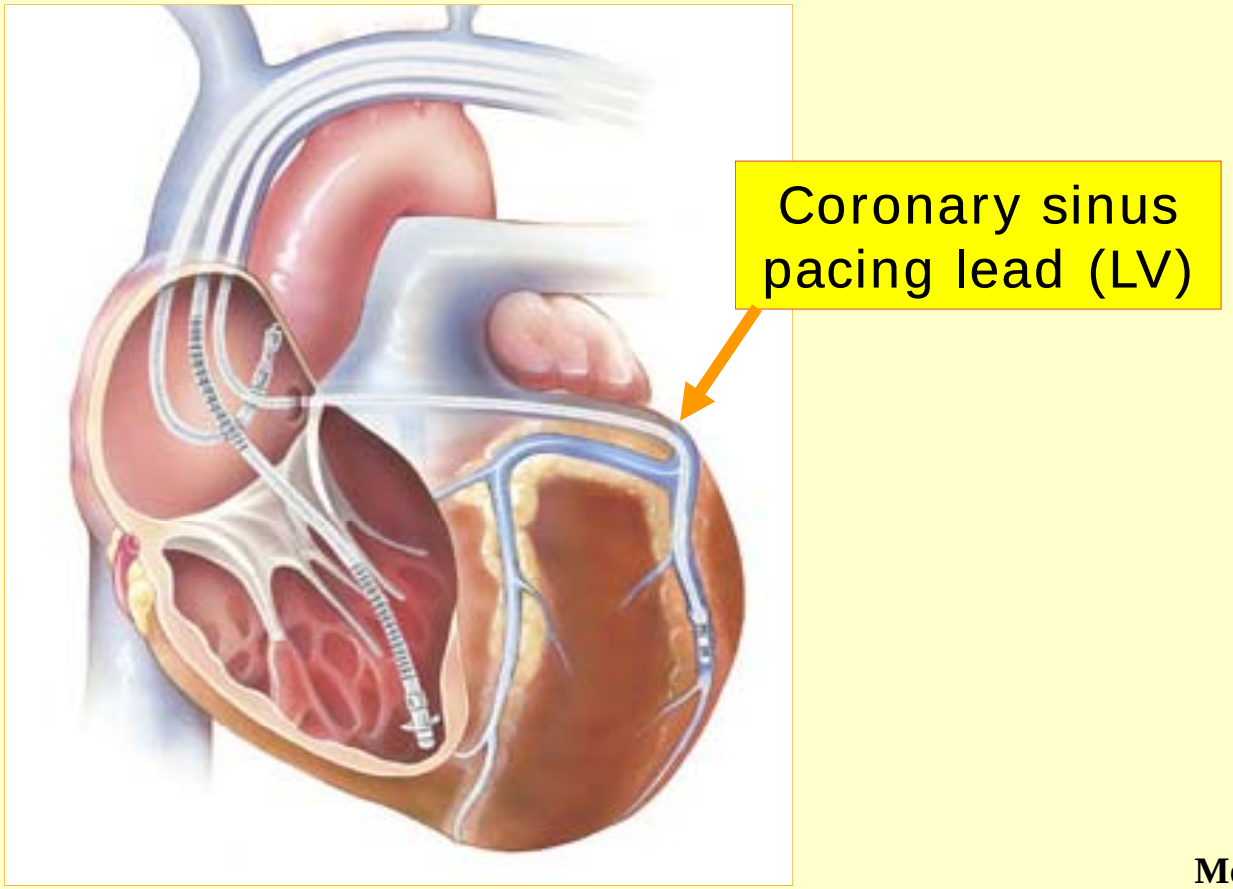
ICDs

- Implanted like a pacemaker
- Battery longevity: ~5 years
- Recognizes & stops VT/VF w/ pacing or shock
- All have pacing capability
- ICD types:
  - single-chamber (RV)
  - dual-chamber (RA + RV)
  - biventricular (RA + RV + LV)



Cardiac Resynchronization Therapy (CRT)

Biventricular pacemaker/ICD lead placement

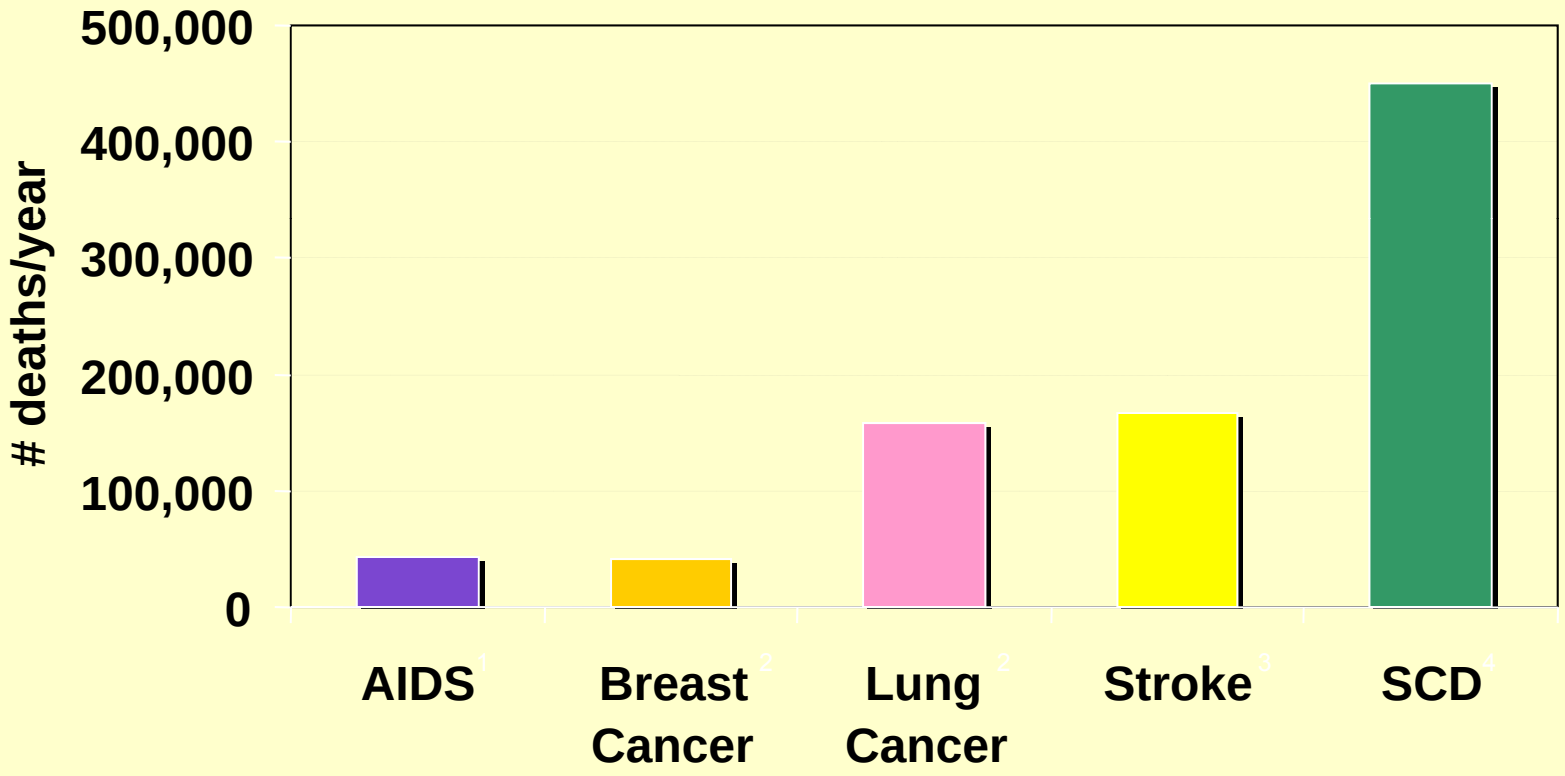


Evolution of the ICD

- 1980 - 1st human implant
- 1985 - FDA approval
- 1989 - Transvenous lead system
- 1997 - Dual chamber ICD
- 2005 - Biventricular ICD (CRT)

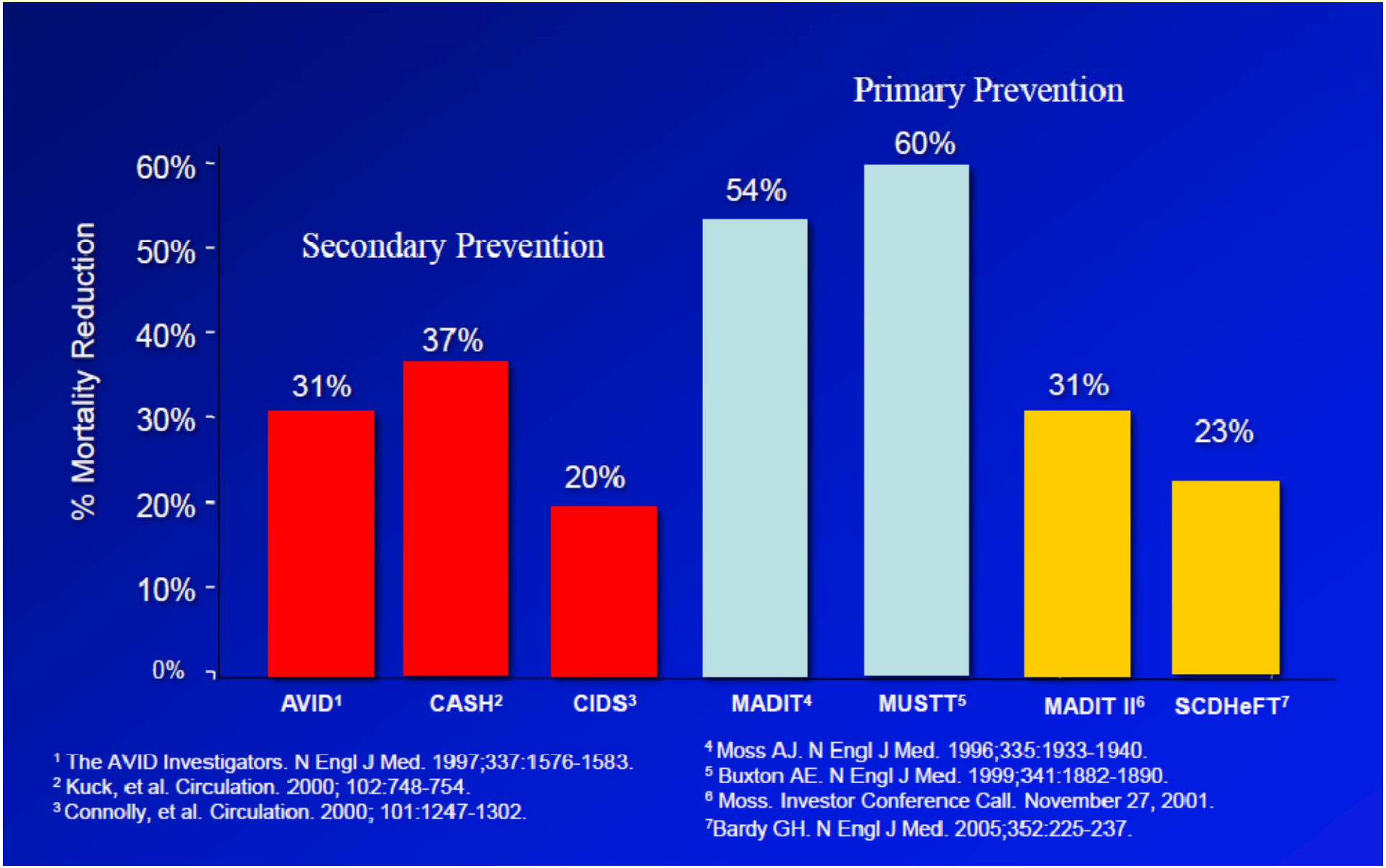
Sudden Cardiac Death in the U.S.

its impact relative to other major killers



1. U.S. Census Bureau, *Statistical Abstract of the United States*: 2001.
2. American Cancer Society, Inc., *Surveillance Research, Cancer Facts and Figures* 2001.
3. 2002 *Heart and Stroke Statistical Update*, American Heart Association.
4. *Circulation*. 2001;104:2158-2163.

Mortality reduction with ICDs



[1] The AVID Investigators. N Engl J Med. 1997;337:1576-1583.
[2] Kuck, et al. Circulation. 2000; 102:748-754.
[3] Connolly, et al. Circulation. 2000; 101:1247-1302.
[4] Moss AJ. N Engl J Med. 1996;335:1933-1940.
[5] Buxton AE. N Engl J Med. 1999;341:1882-1890.
[6] Moss. Investor Conference Call. November 27, 2001.
[7] Bardy GH. N Engl J Med. 2005;352:225-237.

Who Should Get an ICD: Prevention of Sudden Cardiac Death (SCD)

- Secondary Prevention
- Primary Prevention

Primary Prevention of SCD: Ejection Fraction (≤ 35%)

- Ischemic Cardiomyopathy
- Non-Ischemic Cardiomyopathy

Non-Evidence-Based ICD Implants in the U.S.

- January 4, 2011 study published in *JAMA*
- Retrospective review of 111,707 cases submitted to Nat'l Cardiovasc Data Registry-ICD Registry 1/1/06 – 6/30/09
- 22.5% of pts received non-evidence-based ICD implant (25,145 pts)
- Among 25,145pts: 62% newly diagnosed CHF, 37% w/i 40d of MI, 3% w/i 3mo of CABG, 12% w/ class IV CHF

Non-Evidence-Based ICD Implants in the U.S. (cont'd)

- Patients who received non-evidence based ICD
  - Were significantly older
  - Suffered more comorbid disease
  - Were more likely to have heart failure, atrial fibrillation or flutter, ischemic heart disease, cerebrovascular disease, chronic lung disease, diabetes, and end-stage renal disease
- Increased risk to patients
  - In-hospital death was significantly higher in patients who received a non-evidence-based device
  - Median LOS in the hospital was significantly longer

CMS NCD for ICDs

- Section 20.4 of Medicare NCD Manual (Pub. 100-03)
- Nine Covered Indications, including:
  - Documented episode of cardiac arrest due to ventricular fibrillation (VF), not due to a transient or reversible cause
  - Documented sustained ventricular tachyarrhythmia (VT) not associated with an acute myocardial infarction (MI) and not due to a transient or reversible cause

CMS NCD for ICDs (cont'd)

- Coronary artery disease with a documented prior MI, a measured left ventricular ejection fraction (LVEF) ≤ 0.35, and inducible, sustained VT or VF at EP study. (The MI must have occurred more than 40 days prior to defibrillator insertion. The EP test must be performed more than 4 weeks after the qualifying MI.)
- Documented prior MI and a measured LVEF ≤0.30 and patients must not have certain conditions (e.g., CABG or PTCA within last 3 months).

CMS NDC for ICDs (cont'd)

- Patients with ischemic dilated cardiomyopathy (IDCM), documented prior MI, NYHA Class II and III heart failure, and measured LVEF ≤ 35%
- Patients with non-ischemic dilated cardiomyopathy (NIDCM) > 9 months, NYHA Class II and III heart failure, and measured LVEF ≤ 35%

Enforcement Environment

- Civil Investigative Demands ("CIDs")
  - On March 24, 2010, Attorney General Holder authorized all United States Attorneys to issue CIDs for documents and testimony in connection with investigations of alleged False Claims Act violations
  - Six times as many CIDs were issued last year than had been issued before the 2009 Fraud Enforcement and Recovery Act

Enforcement Environment

- CIDs in practice: No stone unturned
  - Demand all documents relating to the NCD, all communications with physicians, all medical records, all applications and justifications made for “payment to CMS for the implantation of an ICD in contravention of the NCD”
  - Interrogatories demanding explanations of specific medical necessity determinations

Enforcement Environment

- Heart Rhythm Society
  - Leading international cardiac advocacy group
  - Announced earlier this year that it will advise DOJ in its False Claims Act investigation of the ICD market
    - Helping to determine if hospitals have improperly billed Medicare for defibrillator implants
    - Advising on “the field of electrophysiology”
    - Medical necessity

Enforcement Environment

- Senate Finance Committee
  - Has signaled that it will ramp up scrutiny into unnecessary use of stents and other implantable devices
    - Investigated a Maryland-based interventional cardiologist Mark Midei
  - Senate Finance Committee believes this is a trend of wasteful spending on stents and other devices that it intends to watch closely

Industry Enforcement Activity – Manufacturers

- Medtronic, Inc.
  - Received a CID from U.S. Attorney's Office for the District of Massachusetts under the False Claims Act on February 22, 2010.
    - seeking documents about the relationship of the company with a physician group
    - requesting production of documents relating to the company's cardiac rhythm medical devices, including revenue, sales, marketing and promotional documents
    - requesting reimbursement communications to customers pertaining to the devices, documents related to scientific studies and registries pertaining to the devices, and documents about payments to customers.

Industry Enforcement Activity – Manufacturers

- Ela Medical, Inc.
  - Announced November 2, 2010 that it will pay more than $9.6 million to settle a *qui tam* action alleging it engaged in a scheme to compensate physicians to use its pacemaker products in violation of the FCA and AKS

Industry Enforcement Activity – Manufacturers

- St. Jude Medical Inc. M1
  - DOJ announced on January 20, 2011 that the company agreed to pay $16 million to resolve allegations that the company used post-market studies and a registry to pay kickbacks to induce physicians to implant the company's pacemakers and defibrillators
  - kickbacks included alleged refunds retroactively applied to previous acquisitions and to purchases of heart device equipment sold by the company's competitors to induce future purchases of similar equipment from the company.

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M1 Not sure this one fits.
MP072714, 3/25/2011

Industry Enforcement Activity – Hospitals

- St. Joseph Medical Center
  - Agreed in November 2010 to pay $22 million and enter into a CIA to settle FCA, AKS, and Stark claims resulting from its relationship with a cardiology group
  - Service agreements in exchange for referrals to the hospital for cardiovascular procedures
  - Hospital submitted claims for medically unnecessary stent procedures

Industry Enforcement Activity – Hospitals

- Excela Health Westmoreland Hospital
  - As of Friday, March 25, 2011, 17 heart patient have filed medical malpractice lawsuits because of a coronary stent that hospital officials have acknowledged might not have been medically necessary.
  - Earlier this month, hospital officials sent letters to 141 patients informing them that they might not have had enough blockage in their arteries to need a stent.

Industry Enforcement Activity – Hospitals

- Tenet Healthcare Corp.
  - $59.5 million settlement in of state and federal government claims in 2003 regarding unnecessary heart procedures.
  - $395 million settlement agreement with 769 cardiac patients in 2004 to resolve allegations of unnecessary cardiac procedures.

Industry Enforcement Activity – Hospitals

- Tenet Healthcare Corp. (con't)
- On August 3, 2010 announced that DOJ is investigating whether one of its hospitals fraudulently billed Medicare for heart defibrillator implant surgeries.
- DOJ demanding documents detailing the hospital's Medicare submissions for ICD implants dating back to 2002.

Industry Enforcement Activity – Hospitals

- Peninsula Regional Medical Center
  - Medical malpractice action against the hospital claiming that its nurses, technicians, and staff knew or should have known that a surgeon was performing a vast number of unnecessary cardiac catheterization and stent placement surgeries at the hospital, and did nothing to prevent or report it.
  - Peninsula continued to extend privileges to McLean and rewarded him with large blocks of favorable scheduling time.
  - Hospital's motion to dismiss denied on August 12, 2010

Industry Enforcement Activity – Individual Physicians

- Dr. Mark Midei
  - Accused of implanting medically unnecessary stents at St. Joseph between 2007 and 2009
  - Senate Finance Committee investigated Dr. Midei, and on December 6, 2010 reported that these procedures cost Medicare $3.8 million.
  - In its report, the committee also raised concerns about the relationship between Dr. Midei and Abbott Laboratories, the manufacturer of many of the stents he used.

Industry Enforcement Activity – Individual Physicians

- Dr. John R. McLean
  - From 2003 to 2007, performed cardiac catheterizations on patients at Peninsula Regional Medical Center
  - Indicted on September 1, 2010 for submitting insurance claims for inserting unnecessary cardiac stents, ordering unnecessary procedures, and falsely documenting patient medical records

Industry Enforcement Activity – Individual Physicians

- Dr. Mehmood Patel
  - Sentenced in 2009 to 10 years in federal prison for implanting stents in patients that did not need them.
  - Convicted on 51 counts of billing private and government health insurers for unnecessary medical procedures and received the maximum sentence.

Industry Enforcement Activity – Individual Physicians

- Drs. Ehab Morcos and George Bou Samra
  - Resigned from Westmoreland Hospital in January following a determination by other cardiologists that they had implanted at least 141 stents that were probably not needed.
  - 753 stent procedures done in 2010 are currently under review.

Industry Enforcement Activity – Individual Physicians

- Drs. Chae Hyun Moon and Fidel Realyvasquez
  - Each agreed to pay $1.4 million in fines in 2005 related to a scheme to cause patients to undergo unnecessary invasive coronary procedures, such as artery bypass and heart valve replacement surgeries.

Compliance Considerations and Strategies

- Internal Reviews for Outliers
  - Self-generated lists to preliminarily risk-profile patient cases
  - Assess ICD application and individual patient placement within NCD categories

Compliance Considerations and Strategies

- Engage Outside medical experts
  - Case-by-case review of records for medical necessity
    - Complete medical, clinical, coding, and operational understanding of cases
  - Pre-operative documentation and review of ICD services, both emergent and elective
  - Independent assessment of LVEF

Compliance Considerations and Strategies

- Developing and implementing medical evidence-based compliance tools
  - NCD, American Heart Association, Heart Rhythm Society, American College of Cardiology standards and guidelines
  - Pre-procedure checklist
  - Post-procedure Q/A review

Compliance Considerations and Strategies

- Addressing problems
  - Risk management
  - Patient notifications
  - Government self-reporting
  - Malpractice

Compliance Considerations and Strategies

- Additional Considerations
  - Medical chart and coding reviews
  - Patient accounting
  - Government reimbursement policies and procedures
  - Voluntary self-disclosure

St. Joseph's Corporate Integrity Agreement

- OIG addressing issues of medical necessity
  - Requires the appointment of Physician Executives to oversee quality of care matters
  - Mandates the appointment of a Medical Director of the cardiac cath lab
  - Policies and procedures addressing
    - Appropriate medical record documentation
    - QA and performance improvement
    - Medical staff credentialing
    - Management and oversight of the cath lab

St. Joseph's Corporate Integrity Agreement (con't)

- OIG addressing issues of medical necessity
  - Expanded role of the IRO
    - Required to review
      - A sample of financial arrangements between the hospital and referral sources for compliance with the CIA
      - A sample of cardiac cath procedures for medical necessity and appropriateness
  - "Peer Review Consultant"

Questions?

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