Interventional Pain Management - What the Next Few Years Will Look Like

Laxmaiah Manchikanti, MD

Disclaimer

Laxmaiah Manchikanti, MD
Chairman of the Board, and Chief Executive Officer, ASIPP and SIPMS
Board Certified: ABA, ABA Pain Medicine, ABIPP

Medical Director, PMCP, ASC, PCS

Member: Kentucky CAC; AMA delegate

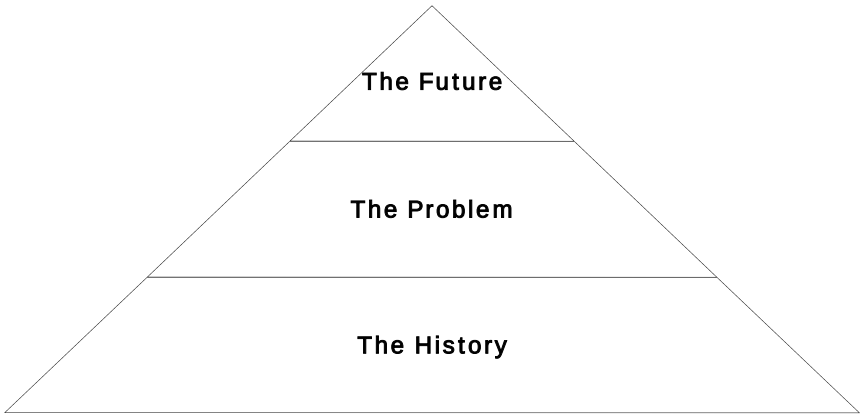
Served on Board of Regents, Murray State University, KY; KBML; MCAC

Publications: Over 300 articles and 8 books

Receives Royalties for Publications
Paid Consultant to Centene Corporation – Medicaid Managed Care
Paid Reviewer for Maximus

No outside funding, no grants, no support from industry

Key Concepts for Future



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Important Issues for IPM

1. Misconceptions
2. Increasing Heath Care Costs
3. Physician & Office Procedure Reimbursement
4. Facility Payment Issues
5. Compliance, Fraud & Abuse
6. Memberships – CAC / BML etc.
7. Controlled Substance Abuse
8. Politics of Representation and Preservation
9. Who is Providing IPM?
10. Motivational Deficiency Syndrome

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ASC Issues: Looking Back


federal register

Friday
June 12, 1998

Part II

Department of Health and Human Services

Health Care Financing Administration

42 CFR Parts 416 and 488
Medicare Program; Update of Ratesetting Methodology, Payment Rates, Payment Policies, and the List of Covered Surgical Procedures for Ambulatory Surgical Centers Effective October 1, 1998; Proposed Rule

Added: 422 Procedures
Deleted: 203 Procedures

60% of interventional procedures to be deleted
Remaining 40% faced cuts

Proposed Rule, June 1998

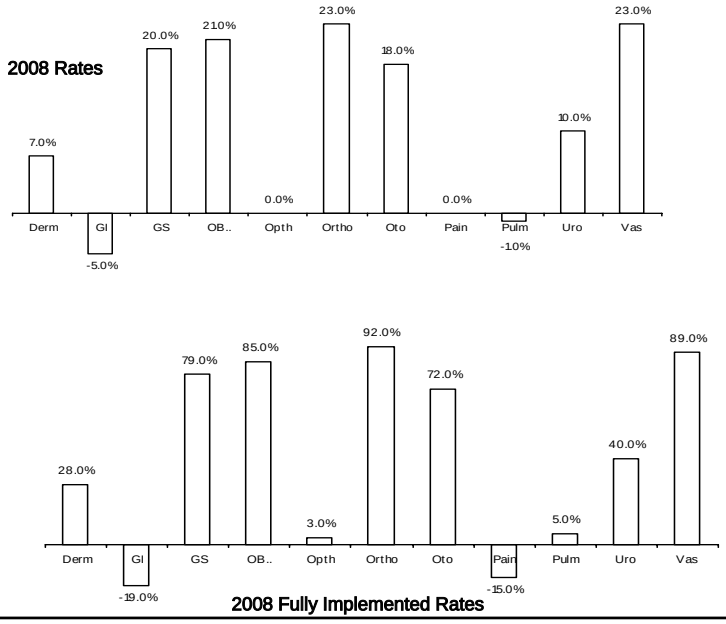
ASC Issues

- 2000: Nine replacement codes added to ASC-covered list
- Aug. 2000: HOPD PPS implemented
  - IPP APCs inconsistent with the mandate that groups include services that are alike both clinically and in resource utilization
  - Hospitals refusing to schedule OR time for IPP
- Feb. 2001:
  - ASIPP testifies before APC Panel, presents new APC groupings of IPP
- Nov. 2001: HOPD IPP APCs regrouped

ASC Issues: **Medicare Modernization Act**

- **Signed into Law, December 2003**
  - Payment rates to be frozen at 2003 rates
  - New ASC payment methodology to be implemented between January 2006 and January 2008
  - GAO should recommend whether to use the outpatient PPS procedure groups and relative weights as the basis for the ASC payment system
    - GAO report released in 2006
    - 84% of HOPD expense

ASC Issues: Impact by Specialty

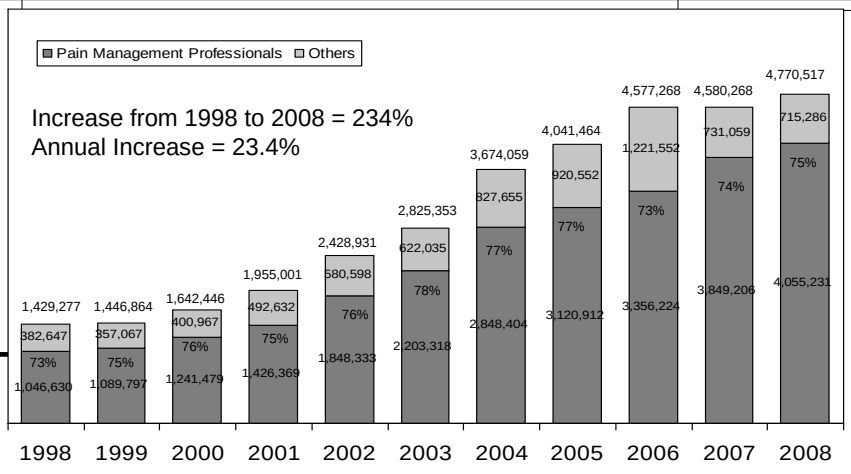


The Problem: Declining ASC Payments

- 2007-2011 **Interim and Final (for top 9 IPM codes)**
  - ↓ 3% to 18% - 2008
  - ↓ 8% to 36% - 2009
  - ↓ 11% to 69% 2010
  - ↓ 12% to 71% - 2011 and after
- TRICARE etc. may pay same or less
- Medicare Advantage Plans
  - 10% - 20% less than Medicare
- Medicaid
  - 20% or more less than Medicare
- Third Party
  - 30% Payers higher than Medicare
  - 40% Payers same as Medicare
  - 30% Payers less than Medicare

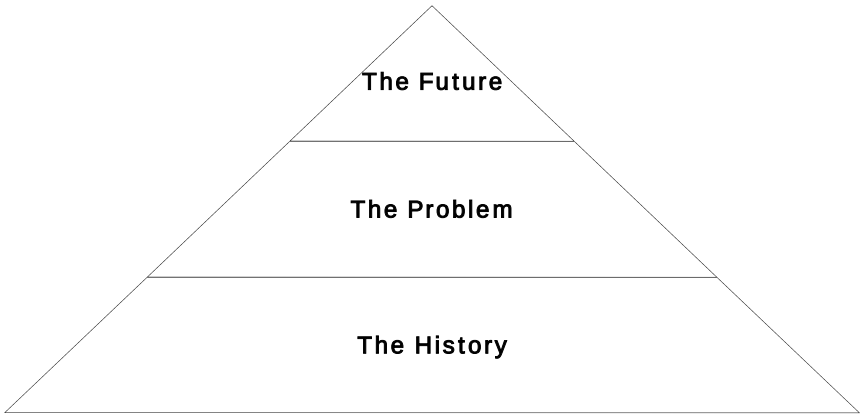
…. … and unfunded mandates

Explosive Growth



Increasing utilization of interventional techniques excluding continuous epidurals, intraarticular injections, and trigger point and ligament injections from 1998 to 2008

Key Concepts for Future



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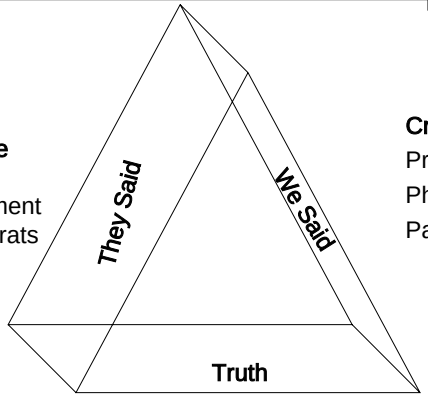
The Problem

Three Sides to Health Care Crisis



Sick care
Payors
Government
Bureaucrats

Crisis care
Providers
Physicians
Patients

Expensive critical care
Working harder
Getting paid less
More out-of-pocket expenses

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Health Care Issues: Regulations

- Wasted dollars
  - $1 trillion
- Cost of regulations $169 billion without benefit
  - Total cost $339 billion
- Unfunded mandates
  - Compliance programs:
    - Start-up $60 - > 100,000
    - Annual $30,000
    - ICD -10
    - Single dose vials
    - Separate waiting room
- Insurance interactions total
  - $ 30 billion annually
  - $60-88,000 per physician
  - Prescription management $16,000 per physician
- EMRs - Under funded
  - Another Y2K
- Fraud and Abuse
  - RACs
  - OIG

Major Issues of Obama Care

- **Patient-Centered Outcomes Research Institute -(PCORI)**
- **Independent Payment Advisory Board (IPAB) (Recommendations due to Congress Jan. 2014)**
  - Unelected board with authority to make Medicare spending decisions re: providers
  - Each year Medicare spending exceeds annual targets, Board must propose ways to reduce payments to providers
    - Board could put proposals into effect unless Congress modifies or rejects proposals
    - Board cannot change benefits and out-of-pocket costs for beneficiaries

Worst Case Scenario: What President Wants

- New Rule May Push Almost 70 Million Out of Employer-Sponsored Program
  - Range 17 – 120 million
- Medicaid and Exchanges
  - How many?
  - Original 32 million
  - By 2019, Congressional Budget Office estimates 24 million Exchange enrollees will receive $144 billion in subsidies
- Bureaucracy
  - Less coverage
  - Higher premiums
  - Higher out of pocket expenses
  - Lower reimbursement
  - Comparative effectiveness
- Single Payer Medicare-Like or Medicaid for All

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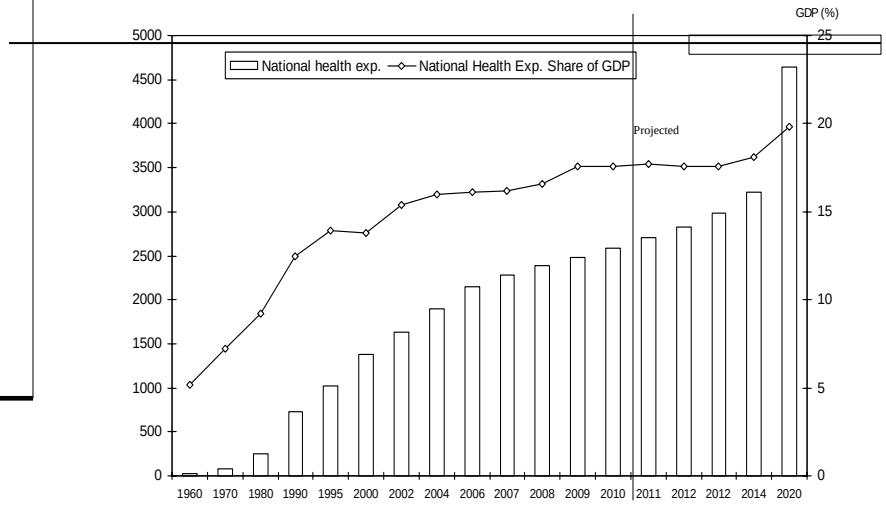
The Problem: State of Healthcare Industry

- Expensive
  - $2.3 trillion per year 2008 in the U.S. and growing
- Pervasive problems with the quality of care that people receive
- Large variations and inequities in clinical care
- Uncertainty about best practices involving treatments and technologies
- Translating scientific advances into actual clinical practice and usable information both for clinicians and patients

National health expenditures and their share of the Gross Domestic Product (GDP), 1960 - 2020



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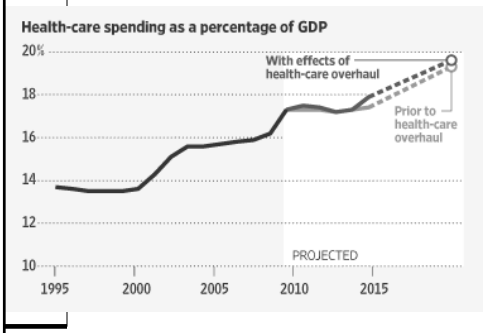
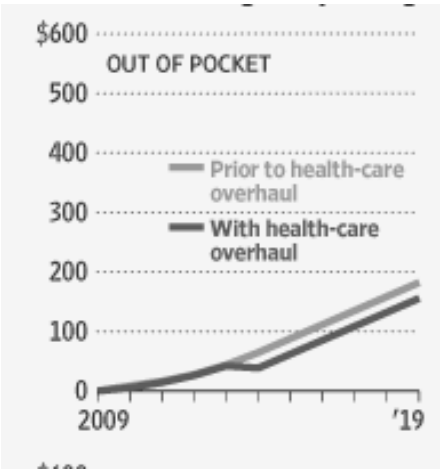
Health Outlays Still Seen Rising: CBO

Law's Effect – Change in billions





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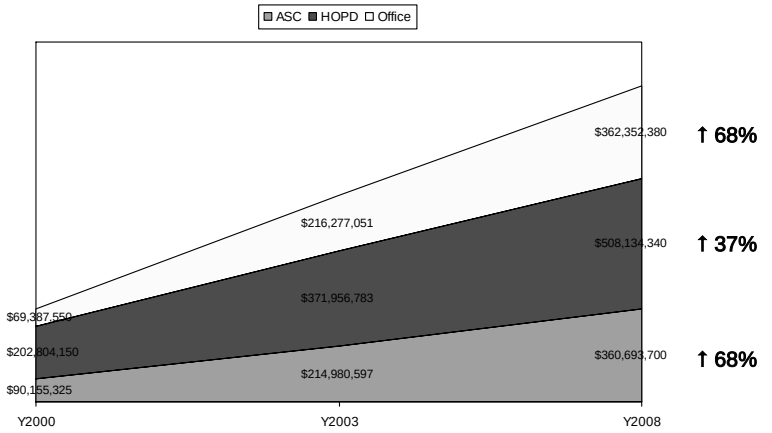
Total Allowed Charges by place of service* from 2000 to 2008



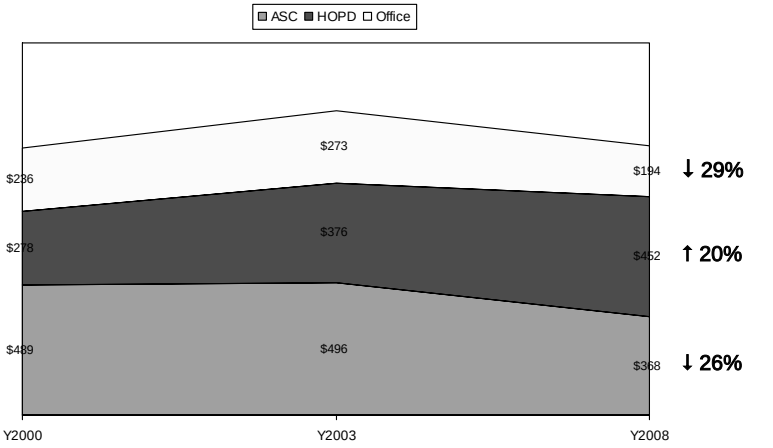
↑ 68%

↑ 37%

↑ 68%

* Spinal Interventional Pain Management Services - (transforaminal, interlaminar - caudal, and adhesiolysis procedures, facet joint interventions and sacroiliac joint injections.

Total Allowed Charges per Procedure* by place of service from 2000 to 2008



↓ 29%

↑ 20%

↓ 26%

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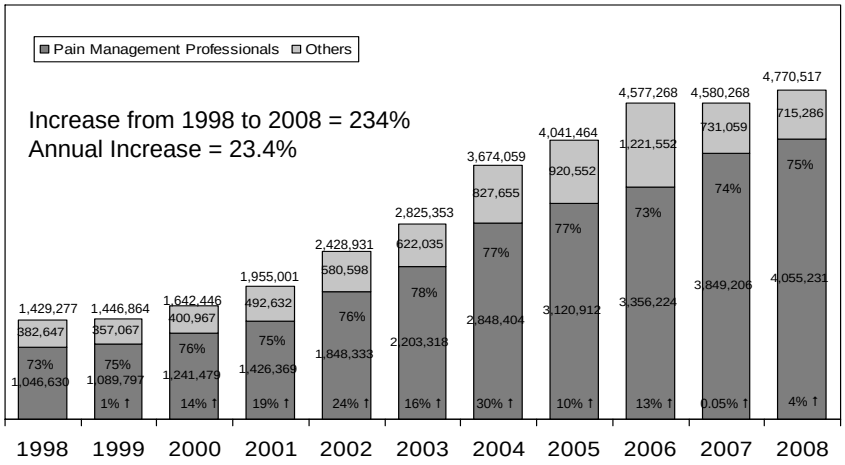
Explosive Growth: IPM



Increasing utilization of interventional techniques excluding continuous epidurals, intraarticular injections, and trigger point and ligament injections from 1998 to 2008

Department of Health and Human Services
Office of Inspector General

Medicare Payments for Facet Joint Injection Services

- Medicare claims for facet joint injections increased by 76% from $141 million in 2003 to $307 million in 2006.
- Sixty-three percent (63%) of facet joint injection services allowed by Medicare in 2006 did not meet Medicare program requirements.
- $96 million in improper payments to physicians.
- Additional $33 million in improper payments for associated facility claims.

Daniel R. Levinson
Inspector General

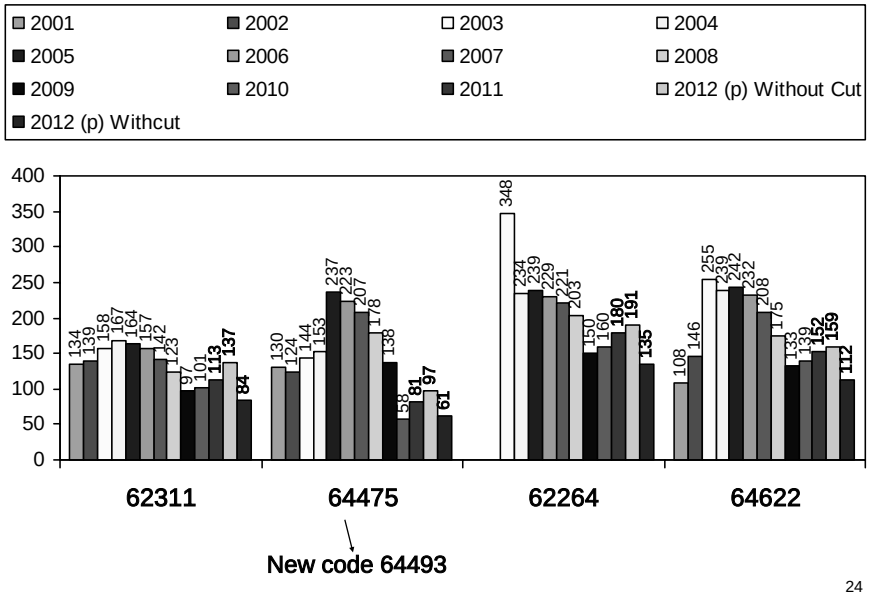
September 2008
OEI 05 07 00200

INAPPROPRIATE MEDICARE PAYMENTS FOR TRANSFORAMINAL EPIDURAL INJECTION SERVICES

FINDINGS

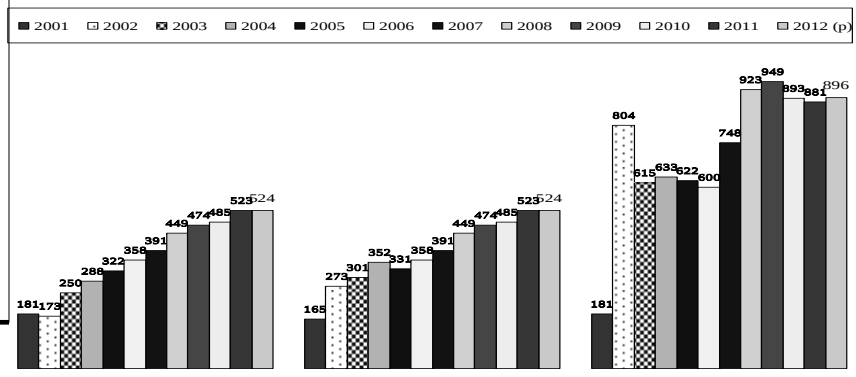
- **Thirty-four percent of transforaminal epidural injection services allowed by Medicare in 2007 did not meet Medicare requirements, resulting in approximately $45 million in improper payments.**
  - Medicare allowed an additional $23 million in improper facility payments associated with physician services in error. Nineteen percent of transforaminal epidural injection services had a documentation error.
- **Documentation errors were more likely to occur in office settings.**
  - Thirteen percent of transforaminal epidural injection services had a medical necessity error.
  - Eight percent had a coding error. Seven percent had an overlapping error.
- **In 2007, 9 of 14 contractors had an LCD for transforaminal epidural injection services, but reported limited use of other safeguards.** Nine of the fourteen contractors had an LCD for transforaminal epidural injections. However, only one contractor enforced all LCD requirements through edits.
- **No contractor staff reported performing a medical review**

Office Overhead Payments



HOPD Payments

- Nov. 2001: ASIPP proposes new classification



(62310, 62311) (64470*, 64475*) (62264, 64622)

APC 0207 APC 0207 APC 0203

Increasing HOPD Payment Rates

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For 2010: 64470=64490 and 64475=64495

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…. … and unfunded mandates

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ASC Game Changer

May 14, 2009
New Conditions of Coverage (CfC)
Effective May 18, 2009

Changes in ASC Oversight

- New Conditions:
  - Quality Assessment/Performance Improvement
  - Patients' Rights
  - Infection Control
  - Patient Admission, Assessment & Discharge

Changes in ASC Oversight

- Revised Conditions:
  - Governing Body (Contract Services, Hospitalization & Disaster Preparedness Plan)
  - Surgical Services (Anesthetic Risk & Evaluation)
  - Laboratory & Radiologic Services

Result = Frequent, extensive and intense surveys

Core Infection Control Components

- Hand hygiene
- **Injection practices**
- Instrument reprocessing
  - High-level disinfection
  - Sterilization
- Environmental cleaning
- Point of care devices (e.g., glucometers)

Unsafe Injection Practices
Outbreaks

Acute Hepatitis C Virus Infections Attributed to Unsafe Injection Practices at an Endoscopy Clinic — Nevada, 2007

Outbreak of *Burkholderia cepacia* Bloodstream Infection at an Outpatient Hematology and Oncology Practice

Transmission of Hepatitis B and C Viruses in Outpatient Settings — New York, Oklahoma, and Nebraska, 2000–2002

Outbreak of *Serratia marcescens* Bloodstream and Central Nervous System Infections After Interventional Pain Management Procedures

Single-dose and Multi-dose Medications

- Single-dose medications
  - One patient
  - One procedure
- Multi-dose medications
  - Ideally dedicated to one patient
  - If used for more than one patient, must follow strict parameters

Pain Physician 2011; 14:425-434 • ISSN 1533-3159

Prospective Evaluation

Infection Control Practices (Safe Injection and Medication Vial Utilization) for Interventional Techniques: Are They Based on Relative Risk Management or Evidence?

Laxmaiah Manchikanti, MD, Yogesh Malla, MD, Bradley W. Wargo, DO, and Bert Fellows, MA

Background: Recently, multiple regulations and recommendations for safe infection control practices and safe injection and medication vial utilization have been implemented. These include single dose and multi-dose vials for a single patient and regulations. It is a well known fact that transmission of bloodborne pathogens during health care procedures continues to occur because of the use of unsafe and improper injection, infusion, and medication administration. Multiple case reports have been published illustrating the occurrence of infections in interventional pain management and other minor techniques because of lack of safe injection practices, and noncompliance with other precautions. However, there are no studies or case reports illustrating the transmission of infection due to the use of single dose vials in multiple patients when appropriate precautions are observed. Similarly, the preparation standards for simple procedures such as medial branch blocks or transforaminal epidurals have not been proven to be essential. Further, the effectiveness or necessity of surgical face masks and hats, etc., for interventional techniques has not been proven.

Objective: To assess the rates of infection in patients undergoing interventional techniques.

Study Design: A prospective, non-randomized study of patients undergoing interventional techniques from May 2008 to December 2009.

Study Setting: An interventional pain management practice, a specialty referral center, a private practice setting in the United States.

Methods: All patients presenting for interventional techniques from May 2008 to December 2009 are included with documentation of various complications related to interventional techniques including infection.

Results: May 2008 to December 2009 a total of 3,179 patients underwent 12,000 encounters with 18,472 procedures.

A total of 12 patients reported suspicion of infection. All of them were evaluated by a physician and only one of them was a superficial infection due to the patient's poor hygienic practices which required no antibiotic therapy.

Limitations: Limitations include the nonrandomized observational nature of the study.

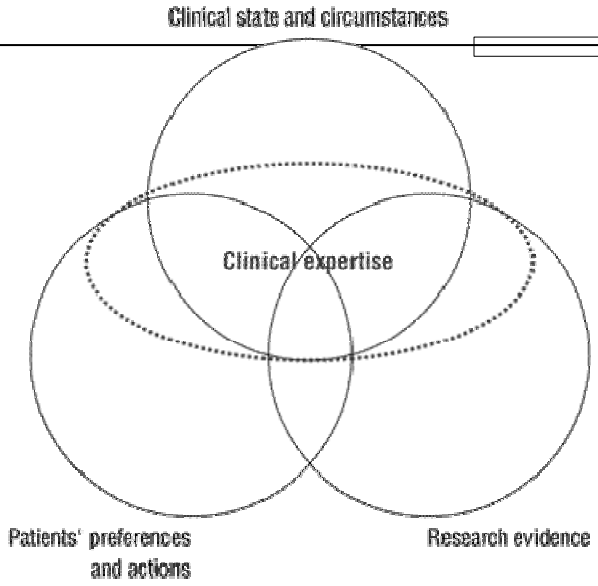
Conclusion: There were no infections of any significance noted in approximately 3,200 patients with over 18,000 procedures performed during a 20 month period in an ambulatory surgery center utilizing simple precautions for clean procedures with the use of single dose vials for multiple patients and using safe injection practices.

Clinical Trial Registrion: NCT00625248

EBM/CER

Patient-Centered Outcomes Research Institute !!!

Is EBM the Science of Methodology or Patient Care?



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Guidelines Preparation

- **Four aspects of lack of integrity**
  - **Pre-possession**
    - The mental phenomenon whereby, when we seek the evidence of our preconceptions, we find it.
  - **Vagary**
    - The obsessive pursuit of a particular conclusion, decided upon early, whatever the contrary evidence.
  - **Rationalization**
    - The intellectual art of piecing together valid evidence in such a way as to produce an invalid conclusion.
  - **Congeniality of conclusion**
    - Whereby we reach the conclusion we *like* rather than the one dictated by evidence and logic.

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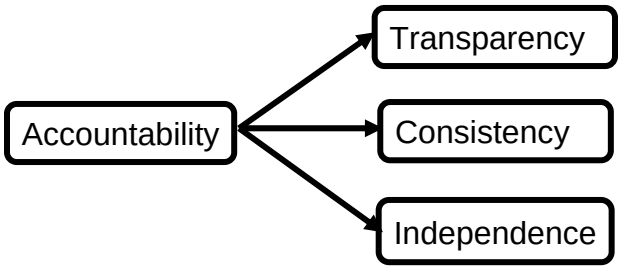
Guidelines Making



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Is it essential to understand technical and physiological aspects of an intervention?

Not just intentional inaccurate interpretation of Methodology!

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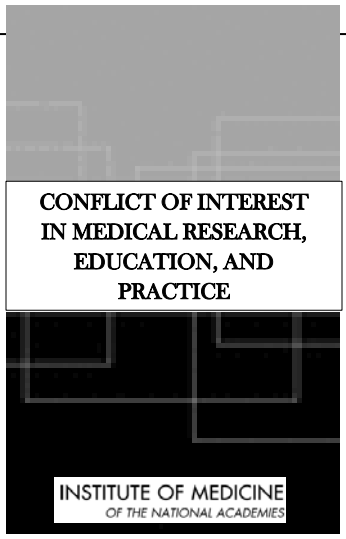

What is missing?

Conflict of Interest
In Systematic Reviews
and Guideline
Preparation !!!

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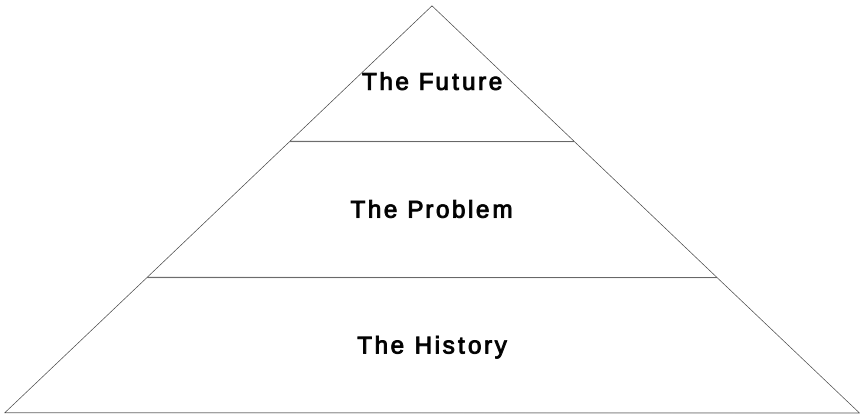
Key Concepts for Future



IPM

Issues are surmountable

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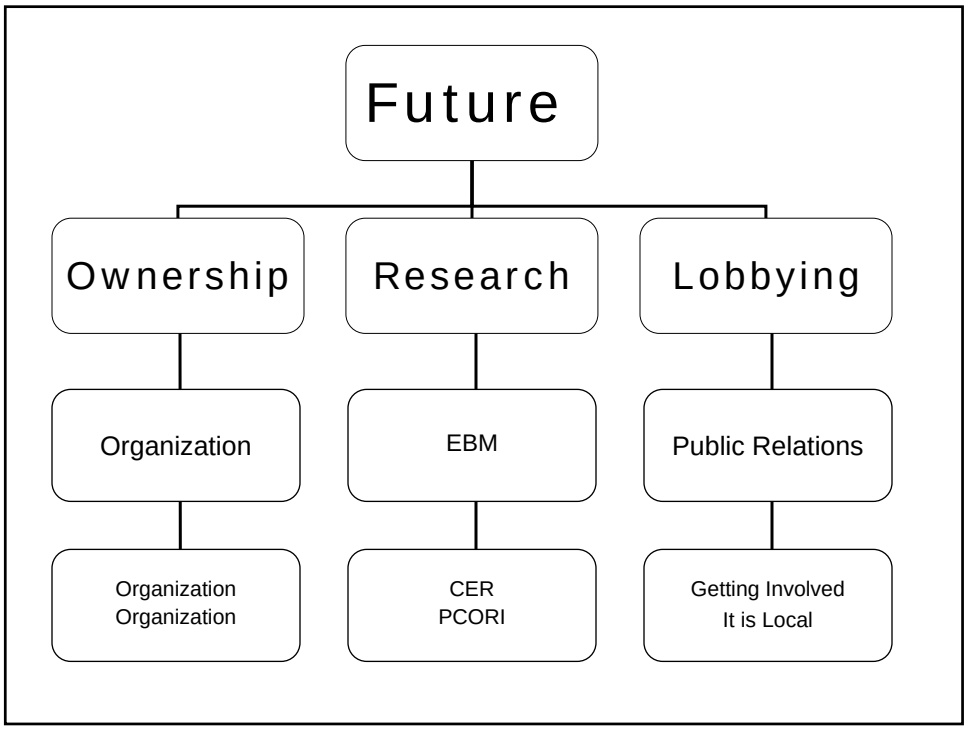

Organization: Why Bother?

- Determines Productivity
- Reduces Frustration
- Reduces Rework
- Optimizes Perception of Service
  - Excellence in the minds of your customers
- Optimizes performance
  - Income
  - Satisfaction for all

How Do You Organize?

- Organization is a vehicle for successful enterprise which requires:
  - Leadership
  - Motivation
  - Decision making and delegation
  - Time management

Organization: Mastering Your Time

- Remember that Murphy's Laws apply to everything you do:
  - Everything takes longer than you expect.
  - Everything costs more than you originally plan.
  - Whatever can go wrong, will go wrong.
  - Of all the things that can go wrong, the worst possible thing will go wrong at the worse possible time and cost far more than you ever expected.

"Murphy was an optimist."

Top 10 Considerations for Future

1. Facility
2. Personnel
3. Scheduling
4. Evaluation & Management Services
5. Procedures
6. Documentation
7. Billing and Coding
8. Public Relations
9. Outcomes
10. Publications and Politics

To assure survival with profitability

Provide Evidence-Based Medicine

Why Outcomes?

- To make marketing decisions
- To provide accountability
- To improve the knowledge base of medicine

"Physicians control 70% of health care cost expenditures"

Outcomes are where the Treasures can be found.

Robert L. Kane, Understanding Health Care, Outcomes Research. 1997

Why Publish?

- Desire to share your exciting research findings with others in hope of fame and fortune
- Remember: *if it hasn't been published it hasn't been done*

Don Bowen, Bedford Institute of Oceanography, Dartmouth, Nova Scotia

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Public Relations and Lobbying

Why Public Relations?

Engaging in PR = Win/Win situation

- Good for the profession
- Good for your professional association
- Good for your business
  - More and satisfied patients
  - Profitable
  - Family referrals are the best
- Pass “yo mama test”

ATC Annual Conference, Chris Durbin

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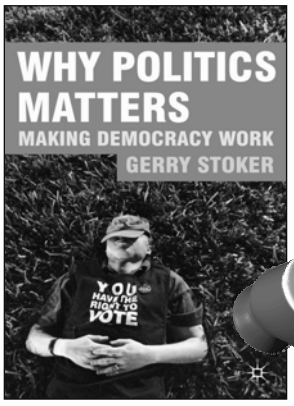
Why Politics?



Making Your Voice Heard

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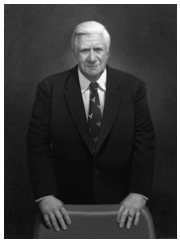
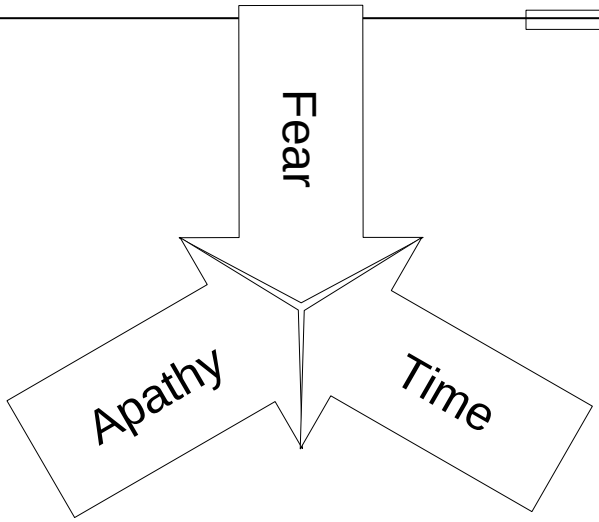
Why?

"All politics are local"

Tip O'Neil



We have met the enemy...



The cost of inaction

To our patients

To our practices

To our profession

The Steps to Take

- Be an activist
- Value your Organization
- Give to the PAC
- Know your congressional delegation

Advocacy and Legislative Action

- Local
- Washington

Success has many fathers, but failure is an orphan.
Tacitus

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