

An Overview of Policy, Data, Outcomes, Innovation, and Coding

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Disclosures:

- Strategic Vice President/Executive Board for Titan Spine
- Executive Operations Board: FDA's MD EpiNet
- White House Population Health Council:
 - End Stage Renal Disease
 - Chronic Pain and Narcotic Opioid Abuse

Duck Key, FL
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Changing Focus

Visibility and Tracking from:

- Health Systems
- Payers
- Patients

The Impact of back pain in the US

- #2 in reasons for MD visits (behind respiratory illness)
- 6+ million people are being treated for chronic back pain (pain lasts >3 months unresponsive to treatment)
- 149 million work days missed (\$28 Billion in lost productivity)

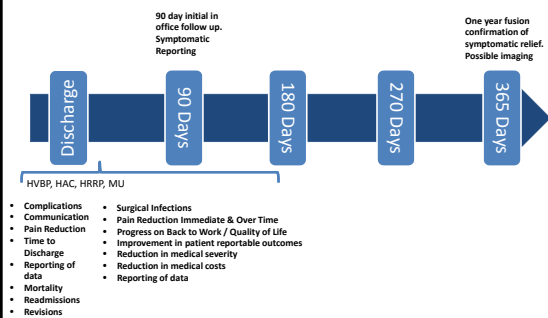
Numbers to Know:

- 2015 inpatient surgeries = 19,814,335
- 2015 spinal inpatient fusions = 398,942
 - This is a drop of roughly 30,000 inpatient procedures from 2014
 - 1762 facilities
 - 47% Medicare/Medicaid
- Highest Paid MD's
 - Orthopedist (Top of the group is spine)
 - Average spine surgeon delivers 5+ x average salary in revenue

Trends

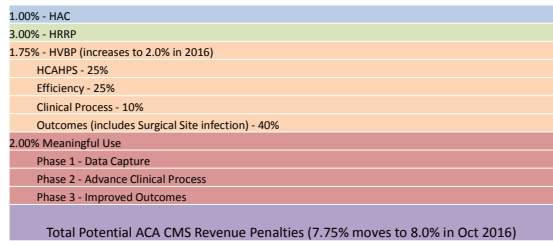
- 2016 OPSS
 - Eight CMS payment codes added for Outpatient Surgery
 - Post Surgical Nursing/Education (now billable)
- 2016 IPPS
 - Profit share with surgeons and hospitals (formerly kick-back)
 - Drop of Two Midnight

Changing Focus: New Model of Fusion Success



Changing Focus: ACA Review

Hospitals Top ACA Priority is to



Changing Focus

ACA Review: How did hospitals do from Oct 2014 to Oct 2015?

HRRP

- 79% of US hospitals penalized (2601 out of 3,400 hospitals)
- 38 hospitals will be subject to the maximum 3% reduction

HAC

- 22% lose full 1% for ranking in the bottom quartile nationally
- \$364MM in annual lost payment

MU

- Phase 3 being "canned" for "new outcomes measures" that are supposed to be released around July 2016

Two year stats:

- National drop in 150,000 preventable readmissions
- 15,000 fewer deaths
- \$4.1 billion in estimated savings from penalties, efficiency, or payment reductions

Current Surgeon Ranking Progression

Top Doctors – Madison

- Castle Connolly
- Super Doctors
- Consumers' Checklist
- City/Regional Magazine Top Doctors Issues

Media Advertising

Health Grades

- Launched October, 2014
- No malpractice claims found
- No sanctions found
- No board actions found
- Patient satisfaction (online responses)
- Years of Practice
- Insurance carriers
- Languages
- Procedures
- Conditions
- Hospitals
- 17 Million Unique Online Visitors Monthly

Propublica Surgeon Scorecard

- Launched July, 2015
- CMS patient data for 2.3 million procedures: hip and knee replacements, three types of spinal fusion, gallbladder removals, prostate removals and prostate resections
- 16,019 Surgeons rated in Propublica analysis
- 30 Day Complications
- 30 Day Readmissions (over 63,000 reported)
- 30 Day Mortality (over 3,400 reported)

Hospital.gov

- Launched Jan 2016
- Government Ranking of Hospitals for procedure type

Surgeonratings.org

- Launched July 2015
- Analysis of over 4 million surgeries done for hospital inpatients by more than 50,000 surgeons
- Rewards high surgical volumes
- Reports any inpatient adverse outcome (death or prolonged length-of-stay)
- Death within 90 days of discharge
- Any adverse within 90 days after discharge
- Readmission within 90 days after discharge

Rankings Everywhere

The Drive to "Patient Like Me" Concept

- Health grades – They have over 17 million unique online viewers every month. They note surgeons based on malpractice claims filed, sanctions, board actions, years of practice, etc. The data on outcomes is mostly absent and they track patient satisfaction through online responses. In my mind that makes those metrics skewed but with that many viewers it is hard to ignore. www.healthgrades.com/gr/thopedic-surgerv-directory
- Propublica – 0-30 day outcome data tracking used to rank surgeons based on complications, readmissions, mortality for voluntary procedures. This data comes directly from CMS metrics which influence how you and/or your hospital get paid. At some point, if you would like I can walk you through how they remove outliers, how they determine who is included and who is not, and how they determine a surgeon's adjusted risk. You were not listed on cervical or posterior lumbar but you were noted as #2 in your area for anterior lumbar. In some arguments you would be at the top based on no reported complications but the volume of surgeries alters the risk. <https://projects.propublica.org/surgeons/>
- Surgeon Ratings – gets data from CMS like Propublica. The difference is this assesses the scores based on 90 days and incorporates a few more categories associated with the ACA. They do a ranking system using stars (similar to health grades). In this one it groups all spinal exploration and fusion categories into one. www.surgeoratings.org
- Hospital.gov – not surgeon specific but gives ACA penalties comparing hospitals directly from the government. GREAT NEW TOOL for administration conversations. www.medicare.gov/hospitalcompare
- HIVE is a project that started at GW in DC (<https://hive.biochemistr.gov.edu/dna.cgi?cmd=main>) and has, at least for now, morphed into the future of predictive medicine. <http://www.bio-itworld.com/2014/10/22/inside-hive-ftlas-multi-omics-compute-architecture.html>

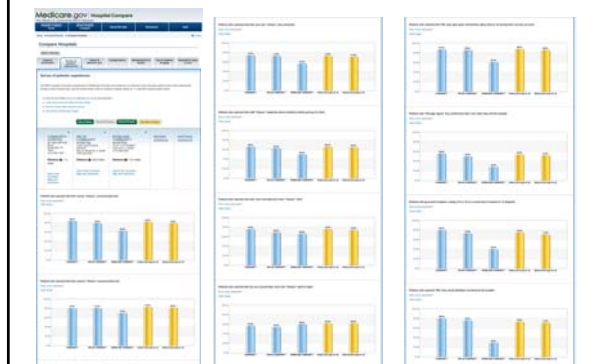
90 days = Rankings (Insurance)

Spinal Cord Exploration or Spine Fusion Surgery

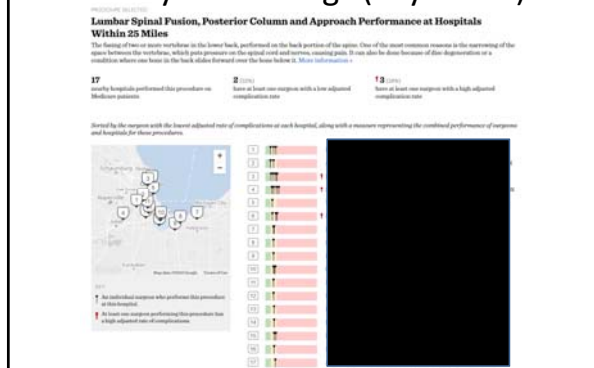
47 surgeons found within 50 miles of zip code 60638

| Select to Compare | Name (Click doctor name for more information) | Better Outcomes Fewer Deaths or Other Bad Outcomes | Recommended Most By Surveyed Doctors | Board Certifications | Surgeon's Hospitals (✓ = Hospital high-rated for outcomes for this surgery) |
|-------------------|--|---|--------------------------------------|----------------------|---|
| | [REDACTED] | ★★★★★ | — | Orthopedic Surgery | Proton Memorial Hospital, Al Health La Porte Hospital, St. Mary Medical Center |
| | [REDACTED] | ★★★★★ | No Not enough members | Orthopedic Surgery | Rush University Medical Center |
| | [REDACTED] | ★★★★★ | Yes 9 doctors recommended | Neurological Surgery | Rush University Medical Center |
| | [REDACTED] | ★★★★★ | No Not enough members | Neurological Surgery | Adventist Hinsdale Hospital, Adventist La Grange Memorial Hospital, Edmund Memorial Hospital |
| | [REDACTED] | ★★★★★ | — | Orthopedic Surgery | Proton Memorial Hospital, Englewood St. Anthony Health - Crown Point, St. Mary Medical Center |

Comparisons for Quarterly Compensation



30 days = Rankings (Payments)



Lumbar Spinal Fusion, Posterior Column and Approach

The image shows a table with columns for Patient ID, Age, Sex, Height, Weight, BMI, and various clinical parameters. Several rows are highlighted with colored circles: green for the first row, yellow for the second row, and red for the third row.

| Patient ID | Age | Sex | Height | Weight | BMI | Other Parameters |
|------------|-----|-----|--------|--------|------|------------------|
| [Redacted] | 55 | F | 157 | 68 | 27.2 | [Redacted] |
| [Redacted] | 55 | F | 157 | 68 | 27.2 | [Redacted] |
| [Redacted] | 55 | F | 157 | 68 | 27.2 | [Redacted] |

A Closer Look at HIVE
(High Performance Integrated Virtual Environment)

Comprehensive Evidence Synthesis is Dependent on Multidisciplinary Data Integration

- Device Description
- Device Procedure
- Surgeon/Hospital Characteristics
- Device Effectiveness Data
- Bench/Bio Compatibility Testing
- Patient Characteristics
- Device Safety Data
- multidisciplinary evidence
 - ✓ biological plausibility
 - ✓ clinical outcomes
 - ✓ regulatory applicability

Simulated Visualization of Patient Subgroups and Identification of Patient/Procedure/Device Characteristics Impacting Clinical Outcomes

- Underlying Disease
- Biomaterials
- Surgical Approach
- Patient Demographics
- Device Design or Device Attributes
- Spinal Orthopedic Procedures

Ranking Concepts

Assess Areas that Determine Outcomes or Rankings

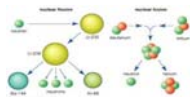
Direct (Measurable) Influence

- Selection of Patient
 - Demographic
 - Standard Measures
 - Comorbidities
- Selection of Device / Biologic / Pharma
- Selection of Procedure

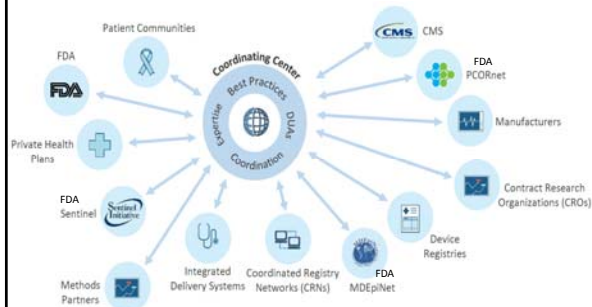
Indirect Influence

- Surgeon Skill
- Hospital Quality of Care
- Patient Education
- Patient Follow Up
- Post Discharge (now reimbursed)

Does a Marketing or a Product Name = Advanced Technology?



The Medical Device Landscape



Tricks to Product Selection

Recognize New **OR** Commoditize Me Too

We should we be looking for?

Differentiation in the Form of:

- **Product Specific Info** (Ask for written documentation that any studies were completed on the product being represented and not a different product)
- **Patient Outcomes Data**
- **Financial Total Cost of Care Data**
 - Reimbursement
 - Total Cost of Care Savings
 - Discharge
 - Long Term
- **Agency Differentiation**
 - PMA or FDA 510K PLUS OTHER DESIGNATION (Added Clearances/Codes)

Tricks: Avoid Outcome Based Penalties

(HVBP, HRRP, Rankings)

- High Focus on Pain
- Discharge Delight Push Final day in-room MD visit
 - Discharge quickly
 - Tablet rankings on-site
- Patient Variable Follow Up Targeting
 - Female elderly w/o close family
- Billing Adaptations Delay
 - No patients billed until day 31
 - Post Adjustment Billing (Avoid Sticker Shock)
