Active Surveillance: Envisioning Surveillance

A perspective from Industry/MD EpiNet

Jeff Dunkel
Titan Spine Strategic Vice President & Executive Board
J&J (former) Diagnostics Presidents Advisory Council
MD EpiNet Executive Operations Board
WH Population Health Groups

The Medical Device Evaluation Landscape

Coordinating Center
Best Practices
DUAs
Coordination
Expertise

Patient Communities
FDA
Private Health Plans
Sentinel
Sentinel Initiative
Methods Partners
Integrated Delivery Systems
Coordinated Registry Networks (CRNs)
MDEpiNet
Device Registries
Contract Research Organizations (CROs)
Manufacturers
PCORnet
CMS

Who is Ready?

Ready. Set. GO!

- Government Agencies
- Academia
- Patients
- Creators of Acronyms

Ready. Set. WAIT!

- Device Manufactures
- Health Systems
- Insurance
- Electronic Health Companies

Changing Focus: ACA Review Hospitals Top ACA Priority is to Protect Revenue

1.00% - HAC
3.00% - HRRP
1.75% - HVBP (increases to 2.0% in 2016)
HCAHPS - 25%
Efficiency - 25%
Clinical Process - 10%
Outcomes (includes Surgical Site infection) - 40%
2.00% Meaningful Use
Phase 1 - Data Capture
Phase 2 - Advance Clinical Process
Phase 3 - Improved Outcomes
Total Potential ACA CMS Revenue Penalties (7.75% moves to 8.0% in Oct 2016)

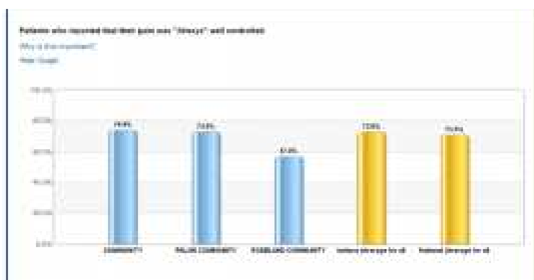
Comparisons for Quarterly Compensation

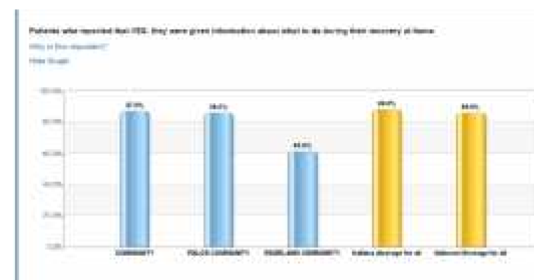
Medicare.gov | Hospital Compare

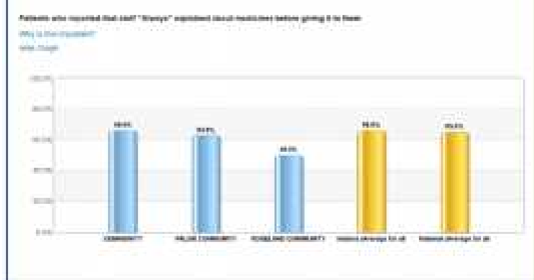
Compare Hospitals

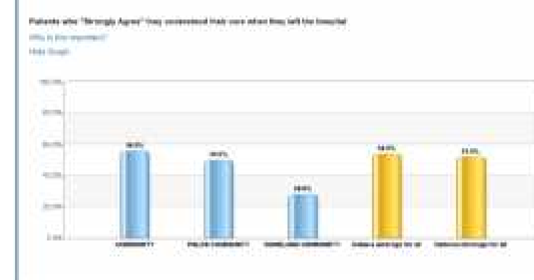
Survey of patients' experiences

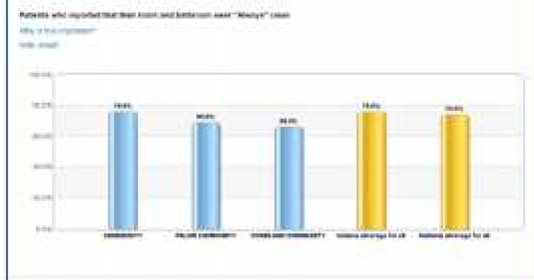
COMMUNITY HOSPITAL	PALOS COMMUNITY HOSPITAL	ROSELAND COMMUNITY HOSPITAL	INDIANA AVERAGE	NATIONAL AVERAGE

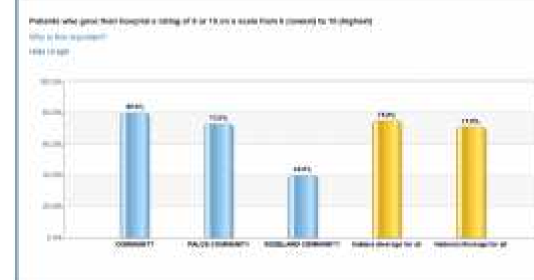


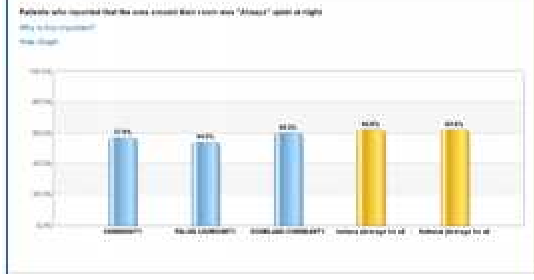


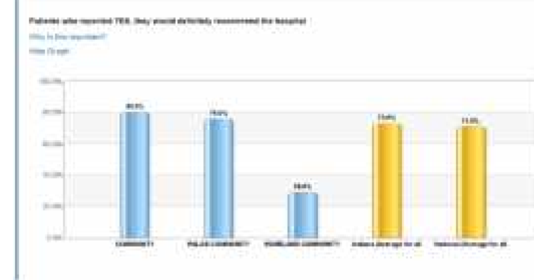




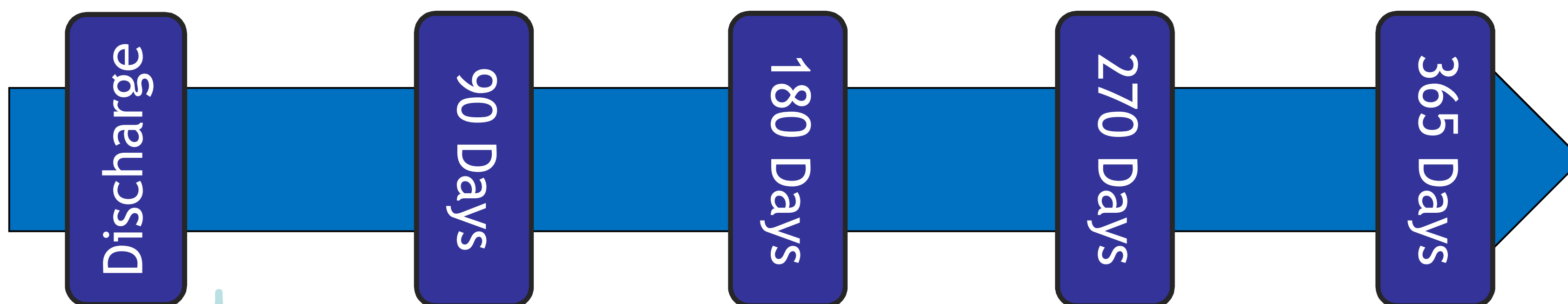








Changing Focus for Medical Providers



HVBP, HAC, HRRP, MU

- Complications
- Communication
- Pain Reduction
- Time to Discharge
- Reporting of data
- Mortality
- Readmissions
- Revisions

- Surgical Infections
- Pain Reduction Immediate & Over Time
- Progress on Back to Work / Quality of Life
- Improvement in patient reportable outcomes
- Reduction in medical severity
- Reduction in medical costs
- Reporting of data

U.S. Food and Drug Administration
Protecting and Promoting Public Health

www.fda.gov

Lumbar Spinal Fusion, Posterior Column and Approach

Fusing two or more vertebrae in the lower back; performed on the back of the spine, incision in the back (ICD-9-CM code 81.07)

The fusing of two or more vertebrae in the lower back, performed on the back portion of the spine. One of the most common reasons is the narrowing of the space between the vertebrae, which puts pressure on the spinal cord and nerves, causing pain. It can also be done because of disc degeneration or a condition where one bone in the back slides forward over the bone below it. More information

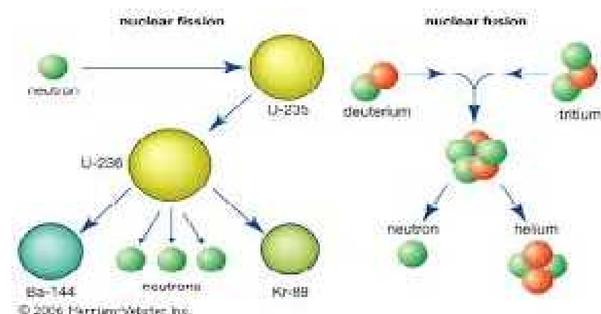
PERFORMED PROCEDURE	COMPLICATIONS	RAW COMPLICATION RATE	ADJUSTED COMPLICATION RATE
220 times	1-10	Redacted	2.7%
46 times	0	0	3.0%
38 times	1-10	Redacted	4.1%
24 times	1-10	Redacted	5.3%
44 times	1-10	Redacted	5.4%
71 times	11	15.5%	8.4%

The following surgeons perform this procedure less than 20 times in Medicare, lower than our threshold for display:

Compare to other nearby hospitals performing this procedure »

Industry Marketing Confusion

Fusion



Combustion

Meaningful Participation

- **Find a WIN for those screaming WAIT!**
  - Insurance
    - Improved Results with Decreased Costs
    - Patient – Symptomatic
  - Health Systems
    - Help with guidance, not mandated direction
    - Tie guidance to financials that are the focus
  - Manufactures – Motivate beyond status quo.
    - Reduce complicated channels and reporting.
    - Demonstrate that device value can increase from outcome data through FDA and CMS systems.
  - Electronic Health – Added requirements plus loss of revenue

- **Reassess those that are nervous to move forward to progress beyond Status Quo.**

In a perfect world

- UDI - Identify Device
- MU Data
- CMS Procedure Data
- CMS Penalties/ Outcomes data

- Registry Identification
- (HIVE)

- Patient Like Me
- Disease Specific Predictability

- Pre/Post Market Safety

- Predictive Medicine with Overlapping Financials
- Identify high level success, base line success, reduced success

- Use data to direct and reward
- Product Rankings
- Standard of Care - Indications and Claims (On-Off Label)

DEVICE SAFETY

What MDR?

FDA Last Tuesday

Technical Considerations for Additive Manufactured Devices

Draft Guidance for Industry and Food and Drug Administration Staff

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

Document issued on May 10, 2016.

You should submit comments and suggestions regarding this draft document within 60 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Identify all comments with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this document, contact the Division of Applied Mechanics at (301)

should be described, as these features may have reduced mechanical properties in comparison to a solid material. In the technical drawings of your device we recommend that you identify components made using AM.

B. Mechanical Testing

The type of performance testing that should be conducted on a device made using AM is generally the same as that for a device manufactured using a traditional manufacturing method. Depending on the device type, these may include material property testing such as, but not limited to, modulus, yield strength, ultimate strength, creep/viscoelasticity, fatigue, and abrasive wear. Performance testing should be conducted on final finished devices subjected to all post-processing, cleaning, and sterilization steps or on coupons, if the coupon undergoes identical processing as the final finished device. In addition, the worst-case combinations of dimensions and features (e.g., holes, supports, porous regions) should be considered when determining the worst-case devices for performance testing. You should also provide a discussion of how the worst-case devices were selected for each performance test conducted.

Due to the nature of AM, devices will have an orientation (i.e., anisotropy) relative to the build direction and location within the build space. The orientation and build location can affect the final properties and should be considered when conducting device mechanical testing. Specifically, the build orientation (including worst-case orientation) of devices or components should be identified for each performance test. If the orientation changes with device size or design, the worst-case orientation should be identified for each configuration. Since the effect of orientation can vary based on

	Current Value	Benefits	Concerns	Capabilities of MD EpiNet or those that MD EpiNet Influences
Educational Institutions	High	o Data & Science Access o Research and White Papers in controlled retrospective evaluations	o Controlling data and credibility of data	o Infinite data for medical

Industry	Med-Low	o Differentiation Opportunity
		o Outcomes leading to FDA Claims or Codes
		o Premarket 510K/PMA Influence?
		o Expanded Uses/Indications for existing devices
			o Risk of Loss/Commoditized Market
			o Diminished value for those that plan on being low dollar vendor
				o Replace the cost of the MDR
				o Can we get new indications/claims as a Beyond Compliance Measure?
				  o Post Approvals
				  o Post Market Exceptions
				o Lead registry studies
				o Self-enrollment in post market studies with Retrospective assessment
				o Impact of Data to CMS and FDA through these assessments that allow claims/reimbursements
				o Faster data reduces risk cost.

Private Patient Data Registries	Low	o Improvement of Data o Addition of Total Data into registries o Addition of Access of increased manufactures data that may have not been incorporated	o Loss of Revenue due to Client Transfer o Does MDEpiNet Availability create data without costs	

	Current Value	Benefits	Concerns	Capabilities of MD EpiNet or those that MD EpiNet Influences
Research Organizations	High	o Sustainability of Patient Outcomes o Good Data Payment	o	o
Additional Government Parties	High	o Increase of Visibility to Patient Care o Added data to increase visibility o Advancement of realized Evidence Based Medicine	o Challenges of Coordination and partnering necessary to drive ROi's for others	
Payers (Insurance)	Med	o Decision support on health care o Long term patient benefit vs short term benefit o Increase treatment protocol efficiency o Patient Like me approach o Ability to guide patient treatments to improved outcomes with cost effective models	o Need to see more than health systems can accomplish on their own	o Guidance with assistance from PCORnet
Health Systems	Med	o Ability to guide patient treatments to improved outcomes with cost effective models o Better Understanding of Cost/Patient Success Benefit	o Need to see more than health systems can accomplish on their own o Forced Change due to more big data	