

Payer Demands for Clinical Data; Hurdles and Opportunities

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Current Environment

Payer

- Value
- Low costs
- Price

Industry

- Rigorous R&D
- Fast approvals
- Timely coverage
- Transparency

- Inconsistent policies
- More clinical data
- Higher standards
- No transparency

Patient

Physician

- Safety/efficacy
- More data
- Early technology access
- Cost-conscious

Regulator

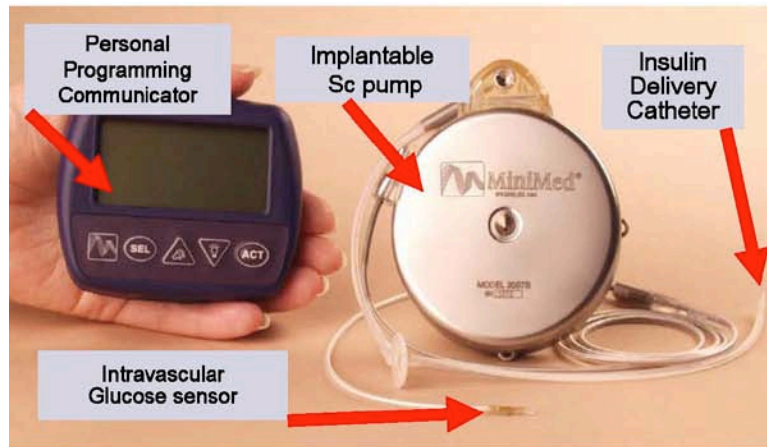
- Safety/efficacy
- Post-market surveillance
- Faster approval
- Implanted devices, more complex
- Younger patients, longer follow-up
- More devices, more recalls
- Global Harmonization

Congress

- Increased oversight/hearings
- Little risk tolerance

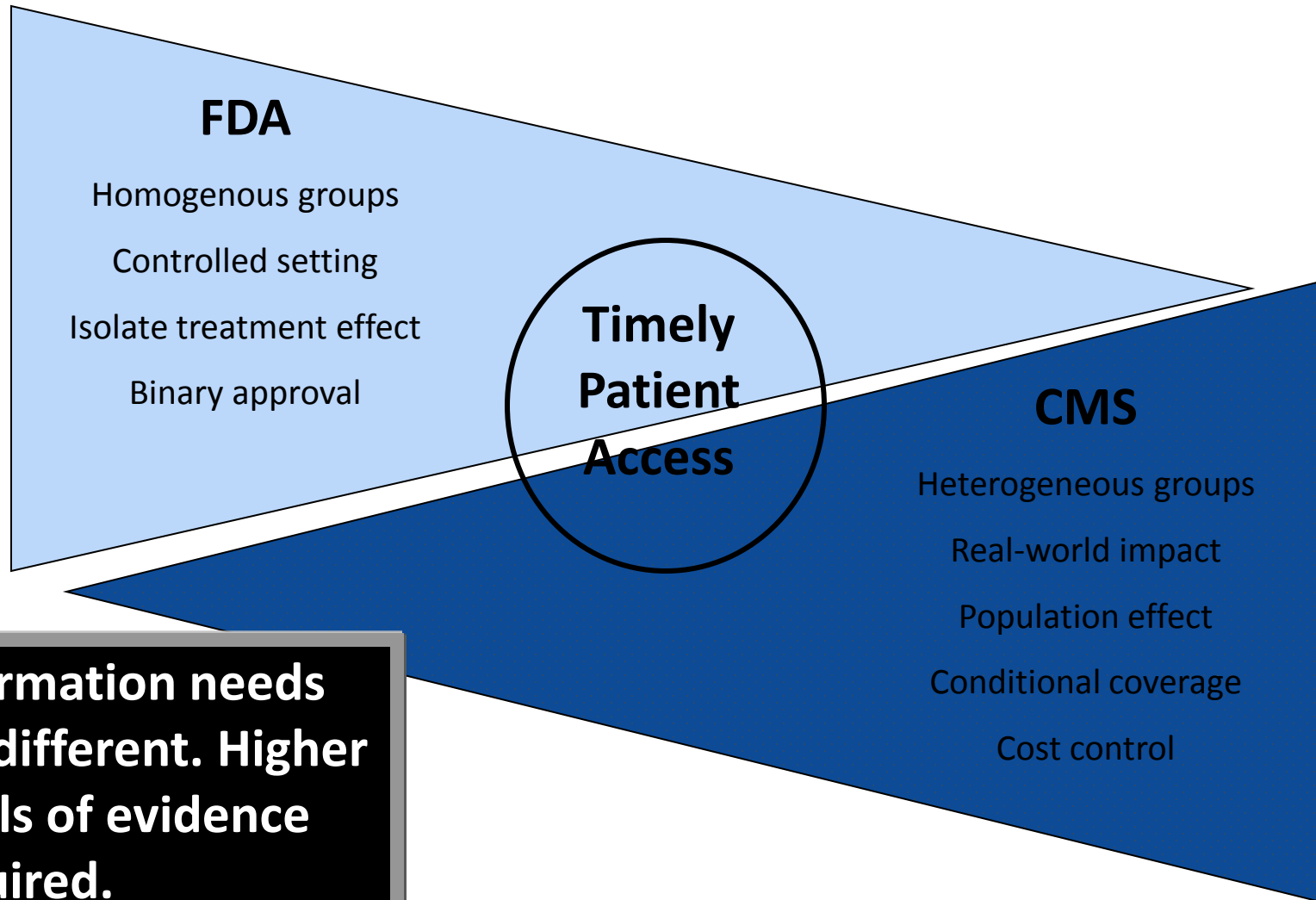
New, Innovative and Complex Technologies

- **Devices are getting smarter and are providing more information**
 - Intelligent devices
 - Biotechnology Revolution
 - Personalized Medicine
 - Combination Products
 - Information-Rich Therapeutics



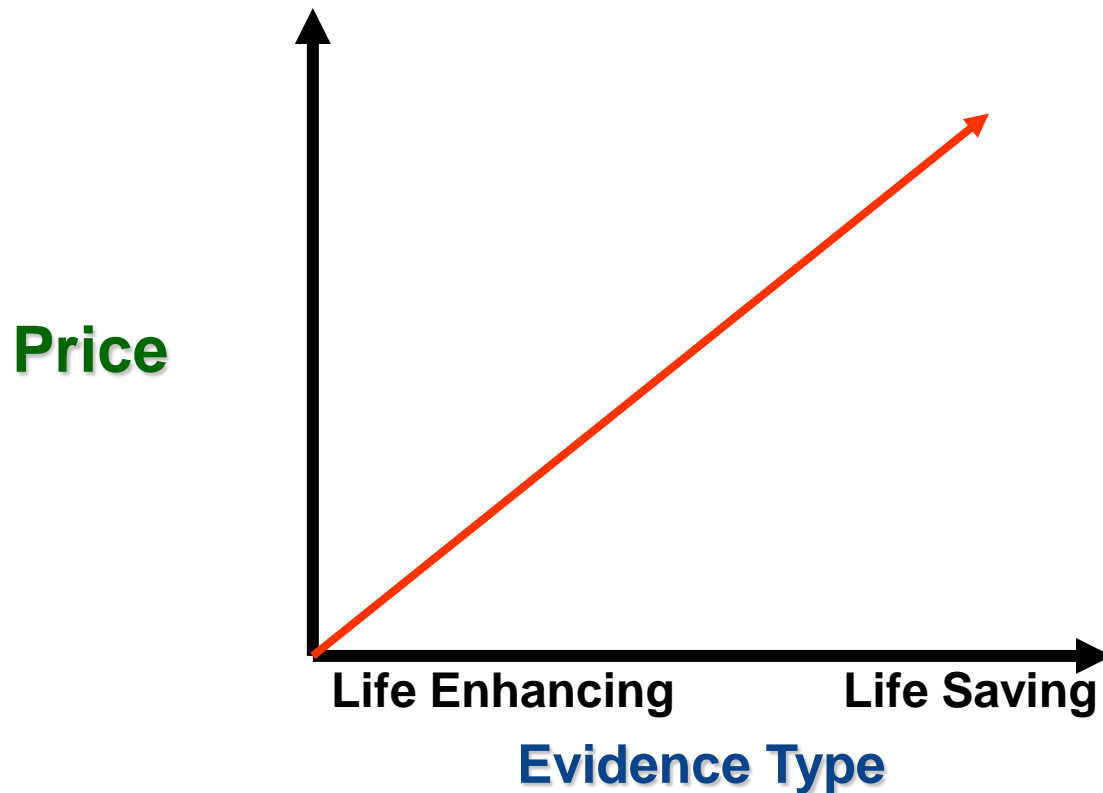
*Information provided by
FDA/CDRH

Higher Evidence Thresholds: Fundamental Disconnect Between Regulator and Payer



**Information needs
are different. Higher
levels of evidence
required.**

Challenge: Evidence Threshold for New Devices and Indications



Value to Provider or Payer

- Higher Payment Category can create more “head room” for premium product price
- Payments to hospitals (inpatient or outpatient) includes ALL costs such as beds, nursing, overhead, medical equipment, etc.)
- Margins vary by site of service. Physician payment will not change

Payers Want More Evidence

- Criteria used is becoming more stringent – higher threshold
- **Evidence-based medicine** strength/robustness
- Burden of proof on innovators is increasing:
 - Better data earlier in product life cycle
 - Comparisons to next best or least expensive alternatives
 - Study perspective & scope changing

Payer Health Technology Assessments

HTAS: Comparative evaluation of a diagnostic or a therapeutic requiring clinical, regulatory, economic, clinical, economic and epidemiological data.

- **Expect greater scrutiny and barriers if:**
 - **high cost**
 - **high volume**
 - **high visibility**
 - **clinically controversial**
 - **new indication**
- Responses include:
 - more intense health technology assessment
 - request for more data/evidence
 - limit coverage (e.g., coverage with evidence development)

How Private Payers Review Technologies

- Evidence relating to a technology undergoes scrutiny by plan medical directors and their staff to determine
 - Whether the evidence demonstrates a benefit
 - Whether the evidence is rigorous enough to support policy decisions, eg, peer-reviewed publications and studies with sufficient number
- Outside organizations who conduct independent technology assessments are the AHRQ, ECRI, Hayes and the Blue Cross/Blue Shield Technology Evaluation Center (TEC)
- Criteria for a favorable assessment by the TEC includes
 - Evaluating whether a technology improves health outcomes such as length of life, quality of life and functional ability
 - TEC produces 20-25 evidence-based assessments each year
- Payers monitor European studies and assessments

Blue Cross and Blue Shield Association Technology Evaluation Center (TEC)

- **Evaluates drugs, devices, procedures and biological products using the following criteria:**
 - Technology must have final approval from the appropriate governmental regulatory bodies
 - Scientific evidence must permit conclusions concerning effect of technology on health outcomes
 - Technology must improve net health outcome
 - Technology must be as beneficial as any established alternatives
 - Improvement must be attainable outside the investigational settings

Complexity of Environment

- Products need a “boutique” approach for success.
- Multivariable perspectives:
 - Clinical, regulatory, coding, business, policy, data analytics, epidemiology, statistics;
 - Global health care payment systems (private and public), health economics, decision analytics, reimbursement law, pricing.
 - ***Must have the ability to integrate into a successful commercialization plan***

Threats to Imaging

Turf Wars in Radiology: The Overutilization of Imaging Resulting from Self-Referral

David C. Levin, MD^{a,b}, Vijay M. Rao, MD^a

A recent report by the Medicare Payment Advisory Commission to Congress indicated that the utilization of diagnostic imaging is growing more rapidly than that of any other type of physician service. This has engendered concern among those who pay for health care. In this article, the authors review the role of self-referral in driving up imaging utilization.

J Am Coll Radiol 2004;1:169-172.

Insurers Hire Radiology Benefits Managers To Ensure Physicians Use High-Cost Scanning Technology Appropriately

Medical News Today, 2008

Changing payments for expensive imaging services

A Congressional Budget Office report suggests a savings of \$220 million between 2010 and 2014 and about \$1 billion between 2010 and 2019 with radiology benefit managers who would block unnecessary scans.

The Secretary should start by adopting a standard of 45 hours per week for all diagnostic imaging machines that cost at least \$1 million and should explore applying this standard to imaging equipment that costs less. This change would reduce PE RVUs for costly imaging services and increase RVUs for other physician services.

MedPAC, March 2009

- High cost and utilization has made imaging a major cost control target
- Key policies - DRA, MIPPA and reports MedPAC, CBO have placed blame on imaging services as key cost driver
- Ongoing efforts to manage utilization in government and private sectors.
- Provider response has been to define appropriateness

criteria and quality metrics.

Complexity of reimbursement

Depend on product attributes

	"Me Too" Minor Modification	Next Generation or Fast Follower	Game Changer (1st to Market)
Regulatory	<ul style="list-style-type: none"> • Class II: 510(k); tech file • Class III: PMA supplement; update design dossier 	<ul style="list-style-type: none"> • Class II: 510(k), possibly with clinicals; tech file • Class III: PMA, possibly without panel meeting; design dossier 	<ul style="list-style-type: none"> • Novel technology most likely Class III • PMA with Panel • Country specific clinical data requirements
Clinical	<p>Clinical data not likely required to meet regulations; but may be desired for customer acceptance</p>	<ul style="list-style-type: none"> • Non inferiority likely • Scaled trial cycle • Feasibility • Pivotal 	<ul style="list-style-type: none"> • Superiority Studies, full trial cycle • Feasibility • Optimization • Pivotal • Expansion
Reimbursement	<ul style="list-style-type: none"> • May require product differentiation • Funding efforts likely only in OUS 	<ul style="list-style-type: none"> • Obtain/improve/defend funding • Evidence for payers: • Real world efficacy • Economics • Quality of life • Differentiation: • Customer economics • QoL 	<ul style="list-style-type: none"> • Obtain/improve/defend funding • Evidence for Payers: • Real world efficacy • Economics • Quality of life • Positioning: • Customer economics • QoL

Pricing and Value

- Pre-launch Analysis
 - Investigate the coverage, coding and payment issues
 - Develop precise strategies for addressing these issues, e.g. applying for new codes, developing alliances
 - Develop materials and data that are both credible and compelling for distribution and presentation to providers and payers
- Post-launch: Customer and Reimbursement Support
- Build the Value Story
 - Develop data to demonstrate the financial impact of the technology under realistic assumptions of coverage, coding and payment by Financial Gatekeeper

Translating clinical into economic value

- WILL the clinical benefit of the technology TRANSLATE into cost reductions? (Examples)
 - LOS, procedure time or complication rates **REDUCED**
 - Anesthesia **ELIMINATED**
 - Re-intervention rates **LOWERED**
- Consider different TYPES of COSTS:
 - **DIRECT** medical costs (hospitalizations, ER & MD visits, home health care)
 - **INDIRECT** costs (lost productivity, absenteeism)
 - **CAREGIVER** costs (direct & indirect costs)
- Perspective ...WHO SAVES THE MONEY?
 - Good economics for **PAYERS** but less not for **PROVIDERS?**

Possible Study Designs

CMS: “following is a representative list of study designs (some of which have alternative names) ranked from most to least methodologically rigorous in their potential ability to minimize systematic bias:”

- Randomized controlled trials
- Non-randomized controlled trials
- Prospective cohort studies
- Retrospective case control studies
- Cross-sectional studies
- Surveillance studies (e.g., using registries or surveys)
- Consecutive case series
- Single case reports
- Source:CMS. Decision Memo:Ventricular Assist Devices as Destination Therapy (CAG-00119N), 10-1-03

Registries: More Important and Useful

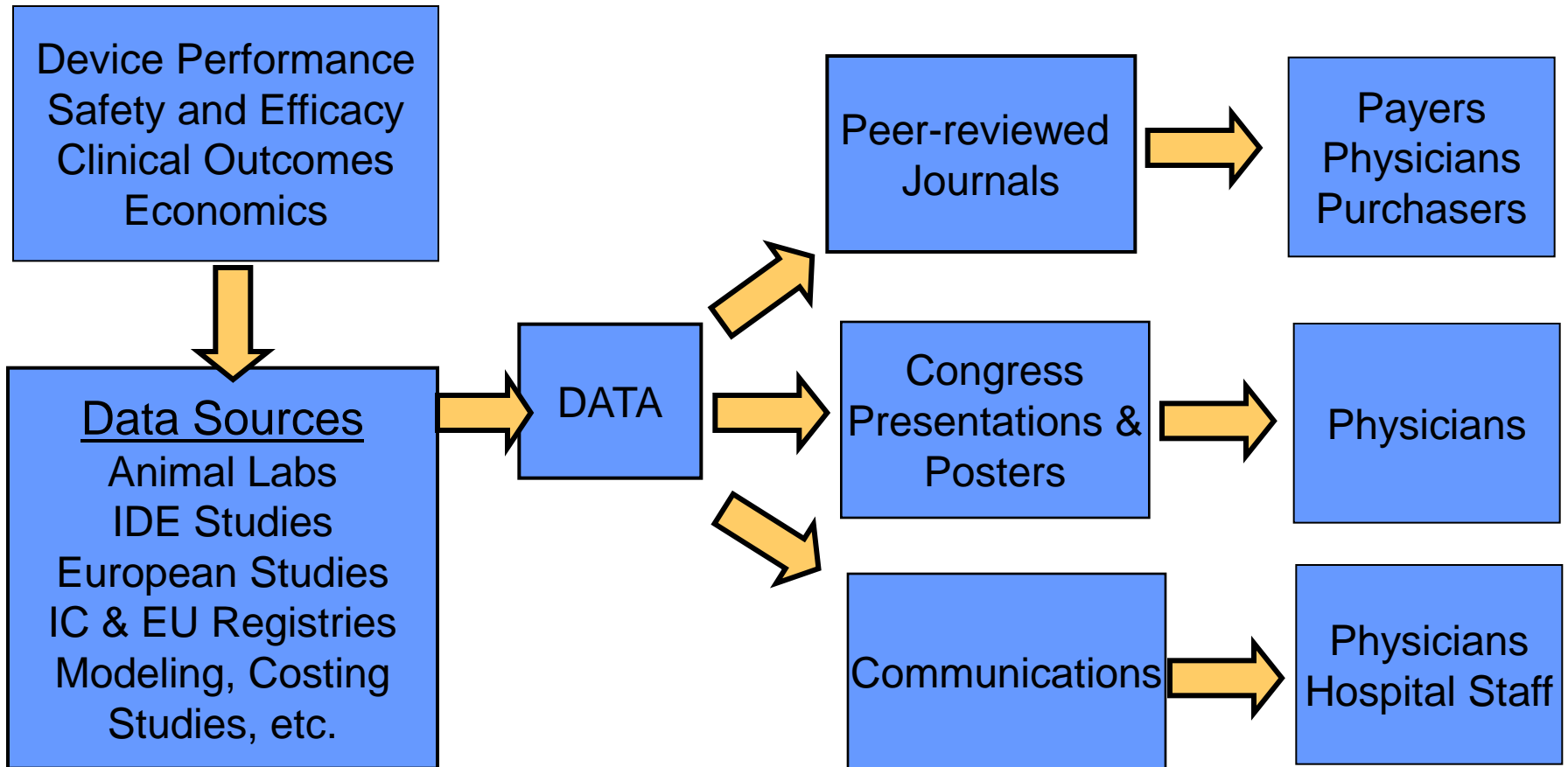
- Prospective, observational cohort studies of patients with a particular disease and/or receiving a particular treatment
- Used for understanding natural history, assessing or monitoring real-world safety and effectiveness, assessing quality of care and provider performance, and assessing cost-effectiveness

Use of Registries (CMS Language)

- Info to be used for CAD and/or CSP determinations...and *to be of great interest to other government and non-government researchers* for many purposes.
- Patient safety and health benefits
- Comparative effectiveness
- Utilization and diffusion of the item or service
- Variations in outcomes among providers or patients
- Long term outcomes and patient management issues,
- Mortality and post-coverage utilization of services
- Data can be used to conduct controlled observational studies
- Use of this data will meet all conditions of the Privacy Act, HIPAA, and patient protections set forth in 45 CFR Part 46.

Publish, Publish, and then Publish some more...

*Hospital, MD, Providers
Demand This!*



Summary

- Plan early
- Include economics in trial planning
- Use creative approaches to study design
- Publish, publish and publish some more



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