Managing Medical Technology

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Advanced Medical technology has a great impact on healthcare delivery and patient outcomes, but it can also be...

- Expensive
- Hard to predict clinical adoption
- Hard to predict usage rates
- Hard to predict clinical or economic value
- Operationally disruptive
- A source of significant hidden costs
- An (expensive) dust collector
- A runaway expense
- A source of conflict between clinical and business stakeholders
Advanced technology adoption can be wildly different from many different perspectives

Note: ICD – Primary Prevention curve reflects indication expansion which occurred ~7 years after launch of ICD therapy in secondary prevention

Penetration of Gross Incidence
5%: ICD - Primary Prevention
2%: ICD - Secondary Prevention
3%: CRT-D
7%: Balloon Sinus Dilation
10%: LVAD
3%: Endovascular Stroke - Stent Retriever
2%: Bariatric Devices

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Warum?
WHY?
Por qué?
なぜ?
Perché?
為什麼?
왜?
Tại sao?
Pourquoi?
Not to mention many medical technologies fail to take off or live up to the hype/promise

- Capnography
- Fluid status management monitors
- Robotic surgery
- Uterine prolapse implants
- Ablation for BPH
- Renal denervation
- Deep Brain Stimulation
- Uterine Fibroid Embolization
- Ibot mobility system
- Wearables
- Home hemodialysis
- Lung navigation technologies
- And on and on…
Even on for the same technology – adoption can vary widely by country and by region

- The dynamics of medical device adoption on a penetration or per capita basis is markedly different between the US and Europe with the ICD market serving as a prime example
  - ICDs are a developed market with robust clinical evidence, treating a cardiac condition with a mortality consequence
  - EU ICD market has only achieved ~44% of the penetration observed in the US (37% penetrated in the EU vs. 84% in the US)

- The underlying causes of the EU adoption dynamic are likely diverse and multifactorial:
  - Capitated healthcare budgets constrain procedure volume with high tech equipment
  - Allocation of resources limits use in older patients > 75yo (EU has older population)
  - Different philosophy on end of life care

EU-6 = UK, Germany, Spain, France, Italy, Netherlands
In addition procedure/patient volumes are not uniformly distributed.

294 Hospitals perform 50% of Carotid Procedures, However the Remaining 50% of Procedures Are Spread Across 1905 Hospitals.
THE ADOPTION OF MEDICAL TECHNOLOGY
Technology adoption actually follows a classic “S” adoption dynamic (Sometimes it doesn't look like it)

- It’s **predictable** based on understanding the underling dynamics
- If it’s predictable, it can be **influenced**

Historical Technology Adoption Curves

Source: NY Times, 2008
Adoption follows a well-understood path to Standard of Care

• Milestone 1 is the gateway to broad market adoption
• Milestone 2 is a strategic inflection point that can happen soon after Milestone 1
• Milestone 3 is the fully realized market—which can take many years to achieve

M1: Completion of Infrastructure & Technology barriers
M2: Penetration of "easily accessible" segments
Rate of growth dictated by Indication Attractiveness

R = Revenue ($M)
I = Investment ($M)
T = Time (years)
Clinicians: First & foremost, adoption is about changing behavior

- What will cause clinicians to stop doing what has been working for them, and do something new?

Rogers Innovation Adoption Curve

Pillars of Adoption

<table>
<thead>
<tr>
<th>INFRASTRUCTURE</th>
<th>TECHNOLOGY</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Condition Management</td>
<td>1. Operational Disruption</td>
</tr>
<tr>
<td>2. Triggers for the technology</td>
<td>2. Set-up Scalability</td>
</tr>
<tr>
<td>3. Body of Evidence</td>
<td>3. Ease of Use/Usability</td>
</tr>
<tr>
<td>5. Reimbursement &amp; Coverage</td>
<td>5. Performance Reliability</td>
</tr>
<tr>
<td>7. Provider Capacity</td>
<td>7. Industry Engagement</td>
</tr>
</tbody>
</table>
Each group plays an important role in the adoption of medical technology

<table>
<thead>
<tr>
<th>Rogers Group</th>
<th>Attitudes</th>
<th>Behaviors</th>
<th>Influence</th>
<th>Risk Tolerance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Innovators (3%)</td>
<td>Want to be pioneers of something new</td>
<td>Partner with new technology companies</td>
<td>Early Adopters</td>
<td>Very high – understand they are experimenting on pts.</td>
</tr>
<tr>
<td>Early Adopters (12%)</td>
<td>Want to lead change</td>
<td>Early users of the technology. Partner with Innovators</td>
<td>Innovators (validate their hypotheses)</td>
<td>High – understand that the technology is not fully baked</td>
</tr>
<tr>
<td>Early Majority (34%)</td>
<td>Want to practice good medicine</td>
<td>Willing to use proven new technologies, not wedded to current SOC</td>
<td>Late Majority</td>
<td>Moderate – Understands no perfect tech. but needs to be able to set Pt. expectations</td>
</tr>
<tr>
<td>Late Majority (34%)</td>
<td>Want to be absolutely sure</td>
<td>Wait and see if it’s ‘real’</td>
<td>Need to see Early Majority adopt</td>
<td>Low – Likes to practice in a very comfortable and ‘safe’ zone</td>
</tr>
<tr>
<td>Laggards (15%)</td>
<td>See change as both a threat and work</td>
<td>Hold onto the current SOC as long as possible</td>
<td>Shame, Policy, Compensation</td>
<td>Very low – likes things just the way they are</td>
</tr>
</tbody>
</table>
The overwhelming importance of evidence

• It’s not news that every medical technology requires supporting clinical evidence; what is universally under-appreciated is just how much is required to actually access the total market opportunity

• There is no bigger “hammer” in the tool box of med tech companies
  – It is also the biggest headwind if not addressed head on

• There are three major “thresholds” for clinical evidence
  – Minimum: government clearance (FDA/CE)
  – Practical: payor coverage decisions (CMS/Privates)
  – Commercial: enables full physician adoption

• Clinical evidence is one of the most expensive and time consuming Pillars to address
  – But often the one that returns the greatest ROI for the industry

  – *We live in an ever increasing world of evidence-based medicine. Ignoring this fact is not a viable option*
Patients: Adoption rates will vary significantly across different segments

- “Perfect Patients”
  - That group for whom your technology/therapy will offer the greatest consistent benefit
  - Beachhead indication for standard of care

- Subsequent Indications
  - Based on logical sequencing of how clinicians would think about patients
  - Typically decreasing benefit/harder to identify
  - Slower adoption

If you don’t define them, physicians will...
Sizing: Quantify the market size based on the “dynamic calculus” of patient populations

Prevalence = Incidence \times Duration

Diabetes
- Incidence
- Duration = 50 years

Common Cold
- Annual Incidence
- Duration = 1 week

Prevalence
Indication Attractiveness: Describes the strategically important differences between patient segments

- **Benefits:** Patient, Clinician, Bother
- **Clinical condition/situation** (e.g., emergency)
- **Gap vs. SOC**
- **Patient situation** (diagnosis, symptoms, acuity)
- **Patient density/visit rate**
- **Clinician/Provider economics**
- **Referral network maturity**
- **Technology bias**

**Strategic Segment Attractiveness**

**Rate limited:**
- **Technologies** (Tech A, Tech B)
- **Choosing candidates**
- **Patient flow and candidate identification**
- **Getting patients to a decision-maker**
- **Identifying good candidates**

**Highest Possible Adoption Rates**
Adoption is a function of Patient Journey, Provider Behavior Change and Patient Segments

**Patient Journey**

**Provider Segments**

(Patient Location)

**Total Disease Population**
- Fourth Tier Candidates
- Third Tier Candidates
- Second Tier
- Perfect Patients

More complex, comorbid, older

**Inside Each Segment**

Rogers Innovation Adoption Curve

- Innovators 2.5%
- Early Adopters 13.5%
- Early Majority 34%
- Late Majority 34%
- Laggards 16%

**PATIENT SEGMENTS**
- More Accessible
- Less Accessible

**PROVIDER SEGMENTS**
- More Compelling
- Less Compelling

Full Opportunity

Tier 2 Opportunity

Easy Opportunity

<50%?

<5%?

More Accessible

Less Accessible

80%

50%

20%

76%

20%

1.0% Target Product

Enter

Refer

Diagnose

Treat

Patient Journey

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The synthesis of adoption across ALL provider and patient segments yields surprisingly accurate forecasts.
EXAMPLE
The Net Treatable Opportunity for Endovascular Stroke Therapies is 95K (from an original incidence of 800K)

- The ASA/AHA guidelines recommend stent retrievers in ICA and M1 occlusions.
- IFUs indicate usage in large, proximal anterior occlusions (ICA, MCA, ACA).

Note: This does not include an assessment of patient eligibility based on timing from onset to hospital presentation.
Endovascular Treatment of Stroke – Clinical Timeline

- **2004**: IMS
- **2005**: MERCI Clearance, MERCI Trial, CLOTBUST
- **2007**: IMS II, Penumbra Clearance
- **2008**: Multi MERCI
- **2009**: Penumbra
- **2010**: Solitaire Clearance
- **2012**: Trevo Clearance, Trevo 2 SWIFT
- **2013**: SWIFT PRIME, REVASCAT, MR CLEAN, EXTEND-IA
- **2014**: SYNTHESIS, IMS III, MR RESCUE
- **2015**: SWIFT PRIME, REVASCAT, ESCAPE, MR CLEAN
- **2016**: REVASCAT, EXTEND-IA
- **2017**: New Trevo & Solitaire Clearances
- **2018**: PENUMBRA 3D, Penumbra 3D Clearance

**5 Key RCTs, Other Studies, Clearances, Guidelines**

Initial ASA/AHA Guidelines for Endovascular Stroke Therapy
Revised ASA/AHA Guidelines for Endovascular Stroke Therapy
Approximately 20k Mechanical Thrombectomy Procedures Were Performed in 2016

Annual Procedure Volume - Mechanical Thrombectomy ± Stent Retrievers
In 2016, Mechanical Thrombectomy Reached ~20% Penetration of the Indicated Incidence Due to Resolution of Key Market Barriers

- Rapid acceleration in the adoption of stent retrievers required the publication of 5 successful RCTs showing a clinical benefit over using the current standard of care alone (i.e. IV-TPA) in order overcome the impact of the three preceding negative trials.

- These positive trials led to an AHA guideline update and a Class IA recommendation for the use of stent retrievers in selected patient populations, and resolved major barriers to the adoption.

Penetration of Net Incidence

- Milestone 1: Resolution of all major market infrastructure and technology barriers.

Ref: 26-33
TAKEAWAYS
Adoption of medical technology requires both strategic and tactical factors that can be easily confused, overlooked or ignored.

### Pillars of Adoption

<table>
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<th>TECHNOLOGY</th>
<th>ACCESS</th>
<th>ACCELERATION</th>
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<tbody>
<tr>
<td>2. Triggers for the technology</td>
<td>2. Set-up Scalability</td>
<td>2. TDM Adoption Status</td>
<td>2. Referral Dynamics</td>
</tr>
<tr>
<td>5. Reimbursement &amp; Coverage</td>
<td>5. Performance Reliability</td>
<td>5. Local HC System</td>
<td>5. Local Pricing</td>
</tr>
</tbody>
</table>

- **Validate**: Assess Opportunity
- **Launch**: Develop Product
- **Foundation**: Enable Adoption
- **Std of Care**: Accelerate Adoption
- **Manage Maturity**: Foundation

### Factors

- **Patient indications**
- **Market assessment**
- **Technology assessment**
- **IP strategy**
- **Business plan**
- **Funding**
- **Proof of concept**
- **Marketing plan**
- **Design for manufacture**
- **Regulatory**
- **Reimburse**
- **Clinical strategy**
- **Launch planning**
- **Cost controls**
- **Pricing discipline**
- **Service & support**
- **Iteration**
- **Global expansion**
- **New threats**

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Some new things to think about…

• Structural barriers to adoption

• Net indicated patients and clinical value-proposition

• The needs for medical technology are very different in different regions

• Patient journey/flow

• Patient concentration

• Behavior change vs. technology acquisition

• Implementing protocols and procedures to codify change

• Advanced medical technologies are just tools to improve outcomes:
  – Patient related
  – Operational
  – Financial
  – Societal
GLOBAL LUNG CANCER INCIDENCE INCREASES FROM 2.27M IN 2013 TO 2.8M BY 2028
Implications for Hospitals

- One-off decisions on advanced medical technology cannot be the foundation for comprehensive approach to acquiring and managing medical technology to advance operational effectiveness, patient outcomes, clinical support and competitive positioning.

- There is an opportunity to instill a much more systematic approach to the acquisition and management of advanced medical technology.
  - There are proven and effective tools that can be used to more effectively understand, categorize and prioritize advanced medical technology to aid decision-making and resource allocation.
  - There is a common language that can be used between clinical and business stakeholders to more effectively communicate and develop shared objectives and decision-making around advanced medical technology.

<table>
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<tr>
<th>Type</th>
<th>Emerging</th>
<th>Developing</th>
<th>Scaling</th>
<th>Globalizing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Score = Barriers + VP + Econ.</td>
<td><em>New to the world</em></td>
<td><em>Second or third generation</em></td>
<td><em>Proven technology</em></td>
<td><em>Mature in devel. markets</em></td>
</tr>
<tr>
<td>Monitors</td>
<td>Tech A: Score</td>
<td></td>
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<tr>
<td></td>
<td>Tech B: Score</td>
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<tr>
<td>Diagnostics</td>
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<td>Tech C: Score</td>
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<tr>
<td>Therapies</td>
<td>Tech D: Score</td>
<td></td>
<td>HD: Score</td>
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<tr>
<td>Facilitation / Tools</td>
<td></td>
<td></td>
<td>Tech E: Score</td>
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Questions?