Health Economics & Reimbursement: MythBusters Workshop

The 10x Medical Device Conference

May 1, 2017

DECISIONDRIVER analytics
a TTi company

MythBuster Speakers

- Beth Brooks, PhD
  - President, Decision Driver Analytics, Inc.
  - EVP, Health Economics & Outcomes Research, Translational Technologies International
- April Zambelli-Weiner, PhD
  - President & CEO, Translational Technologies International
- Nic Anderson, MA, MBA
  - Director of Market Access at PolarityTE
  - HE & reimbursement consulting with N C Anderson Consulting

Audience Introductions

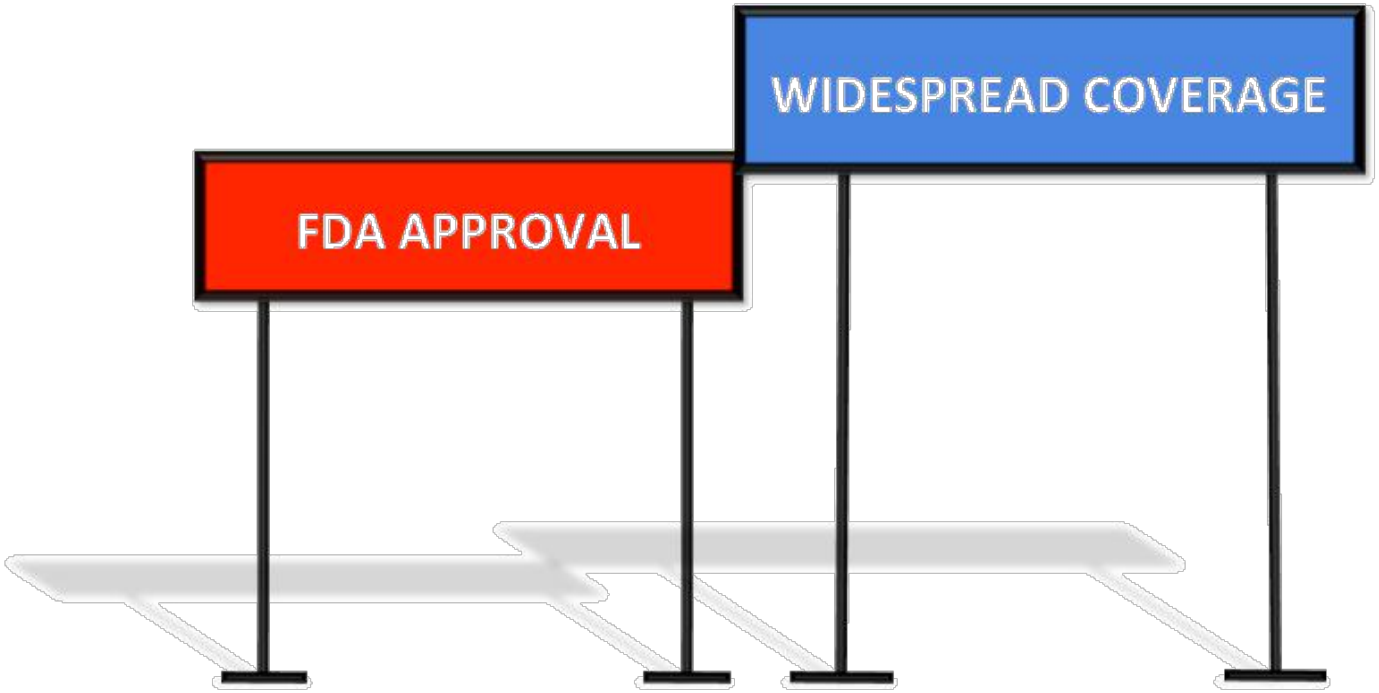
Welcome

Workshop Focus: Dispelling Reimbursement & Market Access Myths

- Myths abound with respect to reimbursement and market access for medical technologies
- Perpetuating these myths can lead to market failure
- Market access success depends on dispelling these myths and focusing on:
  - ✧ Executing a systematic reimbursement & market access strategy
  - ✧ Developing, proving, and articulating your product's value proposition
  - ✧ Collecting the right data via the right studies

Myth 1

FDA clearance equals market access



Myth 2

FDA clearance means that your technology is no longer considered investigational / experimental / not medically necessary

Myth 3

Our technology costs less, so payor coverage and payment will not be an issue. We're good to go!*

Myth 4

Clinical data from the FDA equals sufficient data for payor coverage and payment*

Myth 5

Immediately after obtaining FDA clearance, we are going to seek formal coverage determinations. Our technology is groundbreaking and this will eliminate any roadblocks with our customers.

Myth 6

Direct Facility Sales equals Easier Market Access

Myth 7

No one knows our technology's value story as well as, or better than, we do. After all, it's our technology!*

Myth 8

Randomized Clinical Trials (RCTs) are the only studies payors will consider when making coverage decisions. Providers prefer prospective RCT evidence, too.*

Myth 9

We are a start-up company. We cannot afford to conduct meaningful studies.*

Myth 10

Investigator-initiated (or sponsored) studies at high-profile sites will always provide the best data for market access.

Myth 11

At product launch, we must keep our market as large as possible*

Myth 12

When it comes to Health Economics analysis, big and complicated is better.*

Myth 13

Our technology will be paid based on its value to the healthcare system

Myth 14

It is much easier to demonstrate the value of a diagnostic technology versus a treatment technology*

Myth 15

We’re in good shape because our technology has a CPT code so we know it will be covered and paid!

Myth 16

Today’s reimbursement environment is tougher than ever

CASE STUDIES

Case Study 1: Understand your customer's needs & barriers to adoption

- Client type: Biopharmaceutical start-up
- Indication / Technology: Ophthalmology / drug-device combo
- Problem: Asked to conduct study to determine true facility-perspective costs associated with non-compliance with steroid eye drop regimen

Case Study 1: Understand your customer's needs & barriers to adoption (continued)

- Solution: Before conducting larger scale study, our team recommended a smaller, qualitative study to understand the real value story; involved interviews with nationally-representative sample of providers.
- Outputs: Client's value story upended; new story emerged; client's strategic research and marketing plan being overhauled.

Case Study 2: Importance of study design

- Client Type: Start-up medical device firm
- Indication / Technology: Uterine Fibroids / Minimally-invasive procedure
- Problem: Need to develop study design(s) to demonstrate value of technology as assessed by payors and provide physicians with reasons to adopt.

Case Study 2: Importance of study design (continued)

- Solution: Assembled multidisciplinary team to review and evaluate data to inform recommendations for study design
- Outputs:
  - Innovative composite endpoint (allows for unique market positioning)
  - Developed clinical plans for a series of small strategic studies
  - Strategic communication and publication planning

Case Study 3: The trouble with diagnostics

- Client Type: Start-up medical device firm
- Indication / Technology: Virtual biopsy with potential to eliminate need for physical biopsies
- Problem: Payors were concerned about increased utilization (i.e., virtual biopsy + physical biopsy)

Case Study 3: The trouble with diagnostics (continued)

- Solution: DDA developed payor cost-effectiveness and budgetary impact models as well as facility-focused health economic models to show the value of the technology. ***Focused on increased identification of cancer rather than on elimination of biopsies.***
- Outputs: All tools allow users to enter their own data and assumptions to increase buy-in
  - Payor-focused tools incorporated likelihood that physicians would still obtain physical biopsies
  - Facility-focused tools incorporated likelihood that technology would not be covered by payors

Case Study 4: Low cost technology meets high volume, high $$ indication

- Client Type: Medical device firm
- Indication / Technology: Asthma management / diagnostic tool
- Problem: Despite a low-cost, POC technology, payors were concerned about overuse in a highly prevalent patient population

Case Study 4: Low cost technology meets high volume, high $$ indication (continued)

- Solution: DDA recommended focusing on severe, uncontrolled asthma patients to reduce payor risk
- Outputs:
  - Multiple HE models to demonstrate benefit in severe, uncontrolled asthma patients
  - Active engagement in payor presentations
  - Pilot studies with Medicaid

Case Study 5: Simple, effective sales tool for medical supply

- Client Type: Start-up medical device
- Indication / Technology: Innovative small bowel feeding tube for use in critical care settings
- Problem: Feeding tube much more expensive than competitor; however, its placement had been proven to utilize fewer resources

Case Study 5: Simple, effective sales tool for facility supply (continued)

- Solution: Very simple facility sales tool was developed to demonstrate the value proposition for the innovative feeding tube
- Outputs: Facility sales tool that required little to no training for sales force to successfully utilize. Had immediate and profound impact on market uptake.

Case Study 6: Prepare for traditional & value-based reimbursement

- Client Type: Large, well-established medical device company
- Indication / Technology: Surgical supply used in complex abdominal aortic aneurysm procedures
- Problem: Purpose-driven supply more expensive than “cobbled together” solutions. No additional payment available to facility.

Case Study 6: Prepare for traditional & value-based reimbursement (continued)

- Solution: Demonstrate impact of technology on Triple Aim of Healthcare (reduce costs; improve population health; improve patient experience of care)
- Outputs: A facility sales tool which could be utilized to explore impact under fee-for-service or value-based reimbursement scenarios. Detailed User Guide to aid sales presentations.

Case Study 7: Maximize existing data

- Client Type: Established medical device firm
- Indication / Technology: Breast cancer / innovative radiation therapy
- Problem: Technology had been utilized for many years in US and in EU; however, very few publications and none clearly demonstrating 5-year recurrence rates to enable comparison to traditional radiation therapies

Case Study 7: Maximize existing data (continued)

- Solution: Used meta-analytic approaches to maximize existing data and project 5-year comparative recurrence rates.
- Outputs: Conference presentation and peer-reviewed publication (submitted) demonstrating that technology is as effective as current standard, while demonstrating significant improvements in toxicity and cosmesis.

Case Study 8: Utilizing database analysis

- Client Type: Large, well-established medical device company
- Indication / Technology: Surgical sealant used in gastric procedures to prevent post-surgical “leaks”
- Problem: Post-surgical “leaks” occur infrequently. Client having difficulty selling surgical sealant ”insurance policy” as an add-on cost to each case.

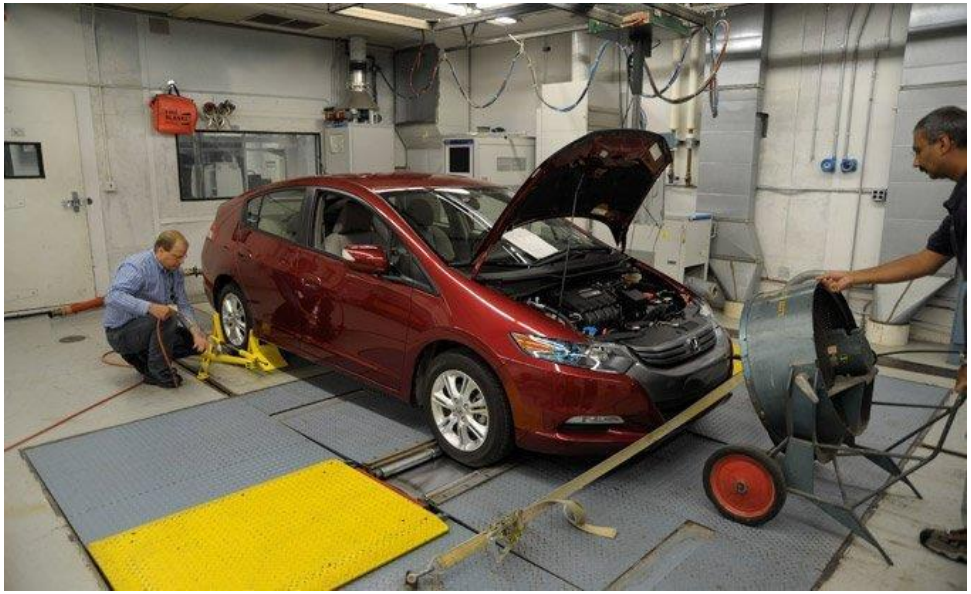
Case Study 8: Utilizing database analysis (continued)

- Solution: Use administrative claims data to estimate the frequency and costs of post-surgical “leak” events
- Outputs: Conference presentation and poster demonstrating that despite low occurrence rates, the cost of “leak” events to facilities justifies the use of prophylactic surgical sealants

Wax Philosophical

- Don’t care much about your clearance, Clarence.

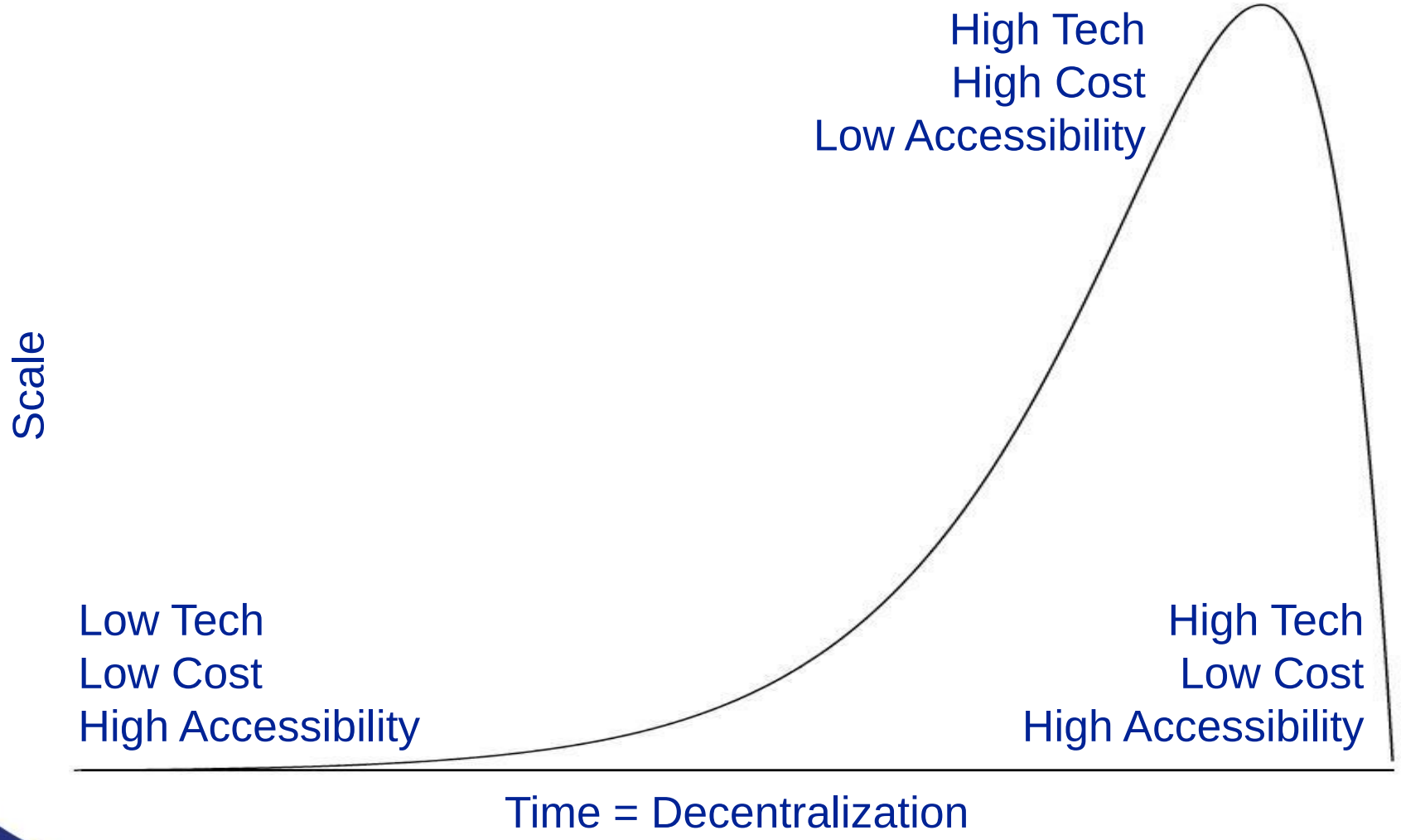
EPA Testing and Fuel Economy



Wax on…

- What is insurance?
- I believe healthcare costs will continue to escalate as we have more interventions covered by insurance.
  - Examples: Tuition, Big-O Tires, $10 tonsil Tuesday
- I believe we're in a healthcare bubble but what's going to pop it?

Enter…dHealth

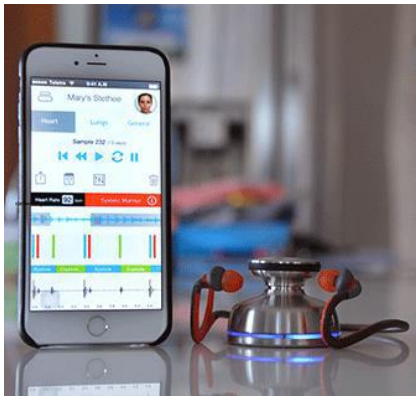


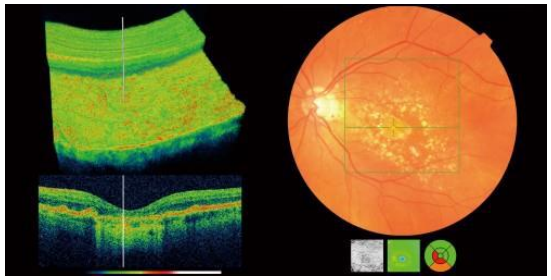
Examples

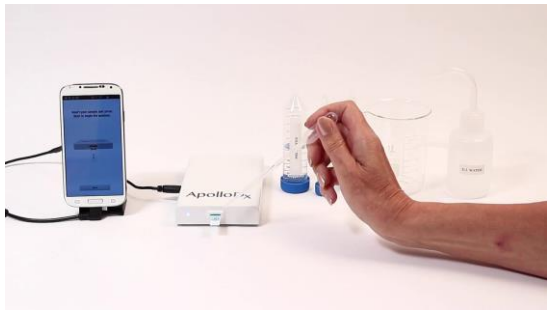
- Transportation
  Horseback→Steam Ship→Airport/Drone
- Education
  Country School→Modern Universities→Khan Academy
- Telecommunications
  Sealed Letter→Telegram/Telephone→Smartphone
- Computation
  Abacus→Mainframe→Calculator
- Entertainment (Entertainer Perspective)
  Theater→Movie Theater→Netflix/YouTube
- Medicine
  Home Doctor Visit→Modern Hospitals→dHealth

Examples of dHealth

- Stethee
- Visulytix (AI)
- Apollo DX
- Biomeme
- Nanosynth







The infrastructure is being built
(CROs like Evidation, IBM, etc.)

Conclusion

- My fear is that we'll lump mainframe payment into an abacus system
- My fear is that the healthcare industrial complex will eat up dHealth
- My fear is that we won't have an imagination
- If we want to get healthcare to the poor, should we build another hospital?
  - 1,000,000 people seeing 100 doctors or 1,000,000 people *being* doctors themselves?

Contact Us

- Elizabeth (Beth) Brooks
  - Decision Driver Analytics (DDA, a TTI company)
  - ebrooks@decision-driver.com
- April Zambelli-Weiner
  - Translational Technologies International (TTI)
  - aweiner@transtechint.com
- Nicholas (Nic) Anderson
  - N C Anderson Consulting
  - nicholas.c.anderson@gmail.com