

Conquering Market Access Challenges and Opportunities for Connected Devices

Presenters



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SCOPE – “Medical Device” focused (regulated) rather than “Health Products” (step counters). Products used in clinical settings (MRI, pacemakers, ...) are emphasized though principals may apply to durable medical equipment used in patient settings (wheelchairs, automatic blood pressure...) .

Conquering Market Access Challenges and Opportunities for Connected Devices

1. Meeting the triple aim of improving patient experience, population health, and reducing costs
 - Population Health – “Clinical Benefit”
 - Include individualized medicine and focus on evidence
 - Reducing Cost – “Economic Benefit”
2. Discussing the importance of setting reimbursement and regulatory pathways in order to obtain timely approval and payment
3. Applying ethnographic research to your user base to understand your market's expectations and identify opportunities to solve unmet needs

Proposition: #2 and #3 are methods of achieving #1

Connected Solutions

- High interest from AMA
 - How does this change healthcare delivery?
 - How does it impact physician practices and reimbursement?
- AMA “types” of connectivity
 - Synchronous – immediate and interactive
 - Asynchronous – one-way with expectation of review and action if needed
 - Disruptive – providing old services in new ways
- Telemedicine
 - Telemedicine – real-time audio and video to diagnose, consult, educate, treat, support care and self management of patients.
 - Tele-health – anything around remote healthcare in homes or group homes
 - Tele-monitoring (remote monitoring) – applications that enhance safety and security in a residential setting.

Follow the Money

What do Payers Seek?

Integrated

- Into the Care Continuum
- First patient contact throughout therapy

Easy to Administer

- Patient, hospital, payers
- Simpler than today's solution?

Engaging

- Will patients "use" it?
- Will caregivers?

Clinically Sound

- What is the level of evidence (LOE)
- For therapy? For the Product?

Outcomes and QoL

- Cure? Preventative?
- Patients independent longer?

Payer ROI

- Cost avoidance? Cost reduction? How?

R&D Strategy

Workflow

- Analyzed present user workflow
- Propose solutions that fit within and simplify that workflow

Ethnography

- Model the culture and tools
- Understand the "meaning" of tools
- Solve problems within meaning model

Reimbursement & Regulatory Pathways

- Regulated product? PMA or 510k?
- Seek reimbursement – or justify w/o?
- How do caregivers get paid?

Economic Story

- ROI for payer? Caregiver?
- Source of ROI: reimbursement? No reimbursement? Other

Simple Do's and Don'ts

Do's

- Front-end user research
 - Contextual, ethnography, ...
- Front-end technical feasibility
 - Reduce the risk of core technology
- Leverage outside resources
 - Often for ethnography and product definition
 - Consider regulatory and reimbursement
- Validate early and often
 - Check in with users – “Did we get it right?”
- Develop market as a side-effect
 - Partner with marketing for “validation”

Don'ts

- Don't rush into development
 - Do your homework first!
- Don't assume you know it all
 - Aggressively find your gaps
- Avoid “Build it and they will come”
 - You MUST know who will pay and why
- Don't seek perfection
 - Seek MVP and assume a version 2, 3, 4,
- Don't forget to build a business
 - Its more than “product”

Most important: Do you have a problem worth solving?

Early Debates You Should Have

- Where does the cloud fit?
- What is our customers' economic business case?
 - Include reimbursement? At launch, later?
- What degree do we “go standards”?
 - Confirm to create (be first, and only)
- Where is our initial market?
 - US, EU, Other?
- What is our connectivity MVP?
 - Prove commercial viability – then add?
- What is our version iteration goal?
 - Device time (years) or Internet time (quarters)
- How big a “bite at the apple”?
 - For each iteration?
- Who are the users?
 - HC Professionals, Patients, Payers, both?
- Privacy & Cyber-security
 - How much? How little?
- How do we avoid delaying sales?
 - When hospital IT “intervenes”
- Is there a non-connected version?
 - To get in the door
- What protocols?
 - Wi-fi? Bluetooth? Cellular? Landline?
- Who on the team should be able to speak for the vision, business case, customer and patient?

Case Study

Implanted medical devices require a quarterly “check up.” As most specialists are in urban centers, some patients have to travel over 100 miles. Most “checks” involve no reprogramming.

A new technology allows the physician to interrogate devices remotely and produce the same report. Patients only need to come to the office for reprogramming.

Is there ...

- A problem worth solving?
- Does the patient benefit?
- Does the physician benefit?
- Does the company benefit?
- Are there any barriers to adoption?

Consider ...

- Physician reimbursement equals an in-office visit
- Does this impact your thinking?

Consider

- There is no reimbursement to the device vendor.
- How does this affect your thinking?

Consider

- You led with a synchronous solution – but now competitors are in market with programs that took 3-4 years at high cost and produce reports asynchronously (no staff required) and physicians get the same reimbursement
- Now what?

Finally

- You now have an asynchronous solution with “alerts” that can detect silent events. Acting on this can reduce 30-day readmissions. You also have retrospective analysis showing high impact to mortality and morbidity. You are two years ahead of competition.
- What next?

Questions