Transcranial Electrostimulation for Analgesia

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Pain
Transcranial Electro-stimulation (TES) for Analgesia

WHAT IS IT:
• Non-invasive and non-pharmacological approach to relieving pain (analgesia)

HOW IT WORKS:
• Electro-stimulation is applied through two or more electrodes
  – The exact mechanism is unclear
  – Likely modulates the nerve fibers and nociceptors responsible for transmission of pain.
Two Niches

Obstructive sleep apnea surgery

Cervical spine injury
What is obstructive sleep apnea?
Epidemiology

• 20-30% of males and 10-15% of females have or will develop obstructive sleep apnea
• Increased risk through aging
• Increased risk if obese
• The most severe cases are indicated for sleep apnea surgery called uvulopalatopharyngoplasty

Source: UpToDate
Obstructive sleep apnea surgery

• General anesthesia has two major components:
  – Sedation
  – Analgesia

• TES provides an alternate to opioid induced analgesia
  – Roughly 20-25% of sleep apnea surgery patients have adverse reactions to opioids
The Need

• 33,000 sleep apnea surgeries per year in US
  – About 8,000 surgeries have adverse reactions to opioids
• $5-10k per surgery, covered by insurance
• Extended OR time resulting from complications is covered by the hospital
• Additional need from patients with undiagnosed sleep apnea who present for surgery for other conditions
Our Vision

• Use during operation for patients indicated for sleep apnea surgery
• Expand use for patients with less severe sleep apnea who present for surgery for other conditions
Benefits for Spinal Cord Injury Patients

- Quicker relief, and better maintenance
- Reduced overall costs
- Reduction of pain caused depression
- Increased energy level
- Better sleep
- No related deaths or overdoses
- Not addictive
- No side effects
- Most importantly – increased functionality and productivity
Current Alliance & Interest

• VA has set up a team to work with Dr. Nekhendzy and test the device
• Immediate funding for preliminary data findings – up to 1 year
• Estimate strong support from DOD to fund this project – up to $500,000 per year
Nearly $18 billion was spent in care of spinal cord injury (SCI) patients in the US, with an estimated $60 billion being spent globally.

Approximately 200,000 US patients
Benefits for Insurers and Manufacture of SCI Patients

**Value to Insurer:**
- Less Costly
- Easier set up
- Heathier
- Quicker pain relief
- Large variety of patient populations to benefit

**Value to manufacturer:**
- Holding initial patient, would open entire market
- Ability to tie device to future apps

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**Estimated Cost Comparison**

- Current SCI costs $90,000 per patient
- TES device $600
Wearable medical device
Metrics

• Patient safety
• Patient centeredness
• Outcomes
• Value
Transcranial Electrostimulation (TES) or Cranial Electrotherapy Stimulation (CES)

Substantially equivalent to a Class II device?
- Electrical Stimulation (CPT 97032):
  - Not substantially equivalent
- Cranial Electrotherapy Stimulation:
  - Not approved. Investigational only

Likely requires a PMA
Key Partners

- **key partners:**
  - Hospitals and individual doctors

- **key suppliers:**
  - Signal generator device manufacturer and electrode manufacturer

- **key resources we will acquire from partners:**
  - Electrical and mechanical components

- **key activities partners perform:**
  - Research, clinical studies, evaluation
Key Partners

• Motivations for Partnerships:
  – Facilitating patient treatment
  – Higher success rate in high risk surgeries

• Optimization and economy:
  – Attraction of higher number of patients
  – Higher cash flow

• Reduction of risk and uncertainty:
  – Obtaining endorsement from hospitals and doctors
  – Managing supply purchases based on customer’s orders
Revenue

• Revenue model
  – Start in hospitals/doctors’ offices
  – Move to home use
• Start up
  – Angel/Crowd Sourcing
• Mainstream
  – Partners/Venture Capital
• Pricing tactics (Estimated price customer willing to pay)
  – CPAP device currently selling for $450 - $900
  – EPAP devices (nasal devices) $15 - $30
  – Oral appliances for sleep apnea device $60 - $100
Funding options/sources

• Internal
  – Coulter
  – Bio-X

• External
  – NIH
  – DoD
Next Steps

• Closely monitor current studies at Stanford Hospital and VA.

• Learn Stanford's requirements for fundraising, how to set up account.

• Evaluate and arrange revenue streams for continued research: Crowd Sourcing or Mainstream Partner.

• Research FDA requirements and timelines.