Trends in CO₂ Monitoring for Patients on Home Ventilation

Expert Interviews
Summary of Key Findings

December, 2016
Executive Summary

The SearchLite recently completed an investigation to understand the challenges and opportunities in the field of home-vent CO$_2$ monitoring. The goal of the investigation was to understand the trends and the commercial viability of the home-vent CO$_2$ monitoring technology. The scope of the investigation included 12 subject matter expert interviews, extensive secondary research, online discussion forum engagement, surveys and final report synthesis and analysis.

Based on the study, The SearchLite discovered that there is currently no home-vent CO$_2$ monitoring solution currently available for patients. There is a market need for cost-efficient home-vent CO$_2$ monitoring. The biggest challenges for such product to go to market are: 1) obtain reimbursement by insurance, 2) educate the caregivers at home, 3) ensure patient compliance, 4) manage and integrate data, and 5) adapt to all major home ventilators on the market. Comprehensive research, product development and clinical trials are required to overcome those challenges and fulfill the market need.

This report is being provided as an exclusive courtesy to the experts who volunteered their time to speak with The SearchLite directly and offer their perspectives on emerging trends, future challenges as well as opportunities of home-vent CO$_2$ monitoring. We hope that you find the report useful and want to extend our thanks to all who generously donated their time and expertise.

If you have any questions or further comments on the report, we would like to hear from you. You can direct your inquiries to:

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**Home-vent CO₂ Monitoring**

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## Industry Experts:

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<td>Product manager</td>
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<td>Respiratory Therapist</td>
<td>Community Surgical Supply</td>
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<td></td>
<td>President</td>
<td>Heinz Ventures, LLC</td>
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<td>CEO</td>
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<td>Respiratory therapist</td>
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<td>VP, Health Market Access</td>
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Subject Matter Expert Interviews: Summary of Key Takeaways

- **There is a market need for capnography in home care setting**
  - Large amount of patients are on home ventilators, which does not adjust according to patients’ CO\textsubscript{2} production automatically
  - A significant proportion of post-op surgical patients, still on pain medication (IV & orally administered), are being discharged earlier and in need of home ventilation and respiratory monitoring
  - The use of pulse oximetry is widespread, however, delays in responding to patient sleep apnea and adequate O\textsubscript{2} levels are continuing problems

- **Market adoption challenges**
  - Price
  - Durability and reliability of 24 hr use
  - Introduction to various manufacturers to incorporate the CO\textsubscript{2} monitor into their equipment – Hospitals today do not purchase stand-alone monitors, all of their monitors are integrated into their patient monitoring
  - Convince doctors: until some doctors who feel very strong about the ventilators with capnography recommend and prescribe it over other ventilators without capnography, there is really not a business case behind it

- **The existing solutions for in-home CO\textsubscript{2} monitoring**
  - In-home visit from respiratory therapists
  - Clinic visit by patients
  - Currently for pediatric patients, depending on their insurances, some medical equipment companies provides them a clinical-use machine on emergency-use bases
  - Pulse oximetry

- **Foreseeable challenges in Home-vent CO\textsubscript{2} remote monitoring**
  - Educate the caregivers at home, e.g. proper calibration and understand capnography reading
  - Patient compliance issues, e.g. increase comfort of the mask on patient’s face, especially decrease the weight
  - Obtain reimbursement on ETCO\textsubscript{2} monitoring, including disposables and tubings
  - Data collection and management

- **Current market size**
  - Home-vent is not a huge market from a volume standpoint
  - Home care has shifted from small business to larger organizations
Home-vent CO$_2$ Monitoring

- The cost of entry is higher than the ROI currently

**Current reimbursement situation**
- No Medicare reimbursement code for capnography
- Patients are charged per capnometer use
- It would be very surprising to see capnography covered by insurance in the next 5 years
- Capnography fee is not broken out in hospital setting. Providers typically bill the whole treatment
- Challenges to get covered by CMS
  - Demonstrate clinic value and improved outcome to home care patients
  - Unsolved technical issues
  - Issues with patient remote assessment

**Buying process to purchase items such as the home-vent CO$_2$ monitoring system (stand-alone CO$_2$ monitoring is not reimbursable today)**
- Home care
  - Physicians recommend/prescribe home care capnometers to the patients
    - Procedure, coverage and support are discussed before discharge
    - The discharge physicians at the hospital and the primary care physicians sometimes don’t specify the brand when prescribe
  - Respiratory therapists, care givers, home care agencies and online publishers can influence the decision
  - Patients purchase the equipment
- Clinical care
  - Purchasing department at the hospital decides which brands they will use through bidding process
  - Some large hospitals have value analysis committees to determine the procurement
  - Hospital purchase from bid winner
  - Purchase processes are different from hospital to hospital

**Challenges in new medical devices marketing and sales**
- Strategic Marketing: What is your product roadmap and what it will look like over a number of years
- Some of the factors to be considered: players, regulatory pathways and reimbursement pathways
- Understand competitive landscape to find technologies used in competitor devices
- Find a way to fit in large companies’ portfolio
Home-vent CO₂ Monitoring

- Target right sales channel in the market

**Challenges of capnography in institutional setting**

- Technical usage of the product. The main screen can become fogged. For side-screen product, we must remove the moisture from the stream with moist filtration.

- Interpretation and reaction to the capnography value. E.g. respiratory depression in hospitalized patients due to post-op narcotics pain management. Capnography would be an excellent tool to monitor these patients.

- Currently capnography is fairly isolated from the critical care areas, emergency department because it requires an intensive nurse/physician-to-patient ratio.

**Current situation with remote monitoring**

- The problem is how the sensor will connect to a monitoring location. 1) If the device uses patient home Wi-Fi, older patients might not have network, 2) Interruption of services, 3) patients may not be technical-savvy enough, 4) who manages the instruments at home, 5) if the patients is in apnea, how you would notify the patient’s family through remote monitoring.

- Current usage of remote monitoring in home care: pulse oximetry (daily summary), non-invasive blood pressure and remote ECG monitor.

**Polysomnography (sleep study) in home care market procedure**

- Home sleep study procedure
  - The company will ship an overnight sleep package to the customer
  - The customer puts it on overnight
  - Ship the package back to the company
  - The company will be able to tell if the customer has sleep apnea
  - A sleep physician will schedule a visit if the customer is detected to have sleep apnea
  - A prescription is given

- Last 4-5 years, reimbursement dropped drastically, big sleep centers shrink and conduct more home sleep studies.