New inhaler monitoring technologies: what they do and how they are used

Paul Colthorpe
Global Program Head, Novartis Pharma AG
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Content

1. Poor adherence – a key unmet need in respiratory disease
2. Smart inhaler technologies & their fit within a typical system architecture
3. How smart inhaler systems are being developed and commercialized
4. Value propositions for stakeholders
5. The evidence base for effectiveness of smart inhalers
6. The drivers and hurdles to more widespread usage of smart inhalers
7. Future use scenarios for smart inhalers
8. Conclusions

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“Drugs don’t work in patients who don’t take them.”

C. Everett Koop
Former Surgeon General of the United States
Improving adherence is a key unmet need in respiratory disease

- Adherence is defined as the extent to which patients follow the recommendations for prescribed treatments
- Adherence by patients with COPD is generally poor, with studies reporting adherence rates of 30–50%


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Patient barriers to adherence

Unintentional

Difficulty remembering

- "I forget to take them."
- "There are so many pills, I can't keep them straight!"

COMPLEXITY

Intentional

COST

- "I can't afford my medicine so I will only take half a pill today."

LACK OF UNDERSTANDING

- "Why do I need them?"

EMBARRASSMENT/STIGMA

- "I don't want my friends to know."

NOT FEELING SICK

- "I feel fine. I don't need them."

SIDE EFFECTS

- "The yellow pills make me feel sick."

BELIEF SYSTEMS

- "My sister took insulin then had her leg amputated."

Educational

HEALTH LITERACY

- "I can't understand these instructions!"
Provider barriers to adherence

LACK OF TIME
“The 15 minutes I have does not allow enough time to talk to my patients.”

LACK OF RESOURCES AND TRAINING
“I’m afraid to ask – don’t want to open up Pandora’s Box!”

LACK OF UNDERSTANDING
“Why don’t my patients just do what I tell them to do?”

LACK OF REIMBURSEMENT
“I don’t get paid to tell them how to take their medications and therefore cannot afford to make time.”

UNAWARE OF HOW TO SIMPLIFY REGIMENS
“How can I simplify – especially when my prescribing options are limited?”

UNAWARE OF OPTIONS FOR LOWER-COST MEDICINES
“I don’t know what to tell patients if they don’t have the money – I can’t tell them to take half a pill.”

Cardiovascular Prevention & Control Program and the Fund for Public Health in New York, 2010

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Adherence support requires intelligent design at all three points of the triangle.
Smart inhaler systems developed to help improve adherence (example architecture)

- **Inhaler with integrated electronics or add-on sensor**

- **Patient’s smart device**

- **Data transfer to secure cloud (with patient consent)**

- **Healthcare provider/carer**

- **Administer** inhaled therapy
- **Record use** (time and date of use) of inhaler
- **Remind** patients to use their inhaler
- **Motivate** patients
- **Educate** patients to use their inhaler correctly
- **Store Data**
- **Access/sharing** of data with stakeholders
- **Real-world insights**
- **Extended functionalities** like exacerbation prediction
The technology is rapidly advancing

Add-on sensors

Retro-fitted integrated electronics

Purpose-built, connected inhalers

SENSORS

- Accelerometers
- Microphones
- Pressure sensors
- Mechanical

GPS, global positioning system
The Novartis electronic Breezhaler® device

Integrated electronics

Similar appearance to native device

Unlocks smart device applications

Acoustic Detection Algorithm
Development driven by partnerships between pharma and technology/device companies

Smart inhaler landscape, HealthXL Feb 2017
Established providers such as Propeller Health offer a comprehensive solution
## Smart inhaler value propositions for stakeholders

<table>
<thead>
<tr>
<th>Patient</th>
<th>Clinician</th>
<th>Payer/Healthcare system</th>
<th>Smart inhaler provider/Pharma</th>
</tr>
</thead>
<tbody>
<tr>
<td>Improved self-management</td>
<td>Better informed clinical decision making</td>
<td>Improved quality of care</td>
<td>Product differentiation</td>
</tr>
<tr>
<td>Improved outcomes?</td>
<td>More efficient use of time (reimbursement?)</td>
<td>Improved outcomes: reduced burden on care facilities</td>
<td>Data on utilization</td>
</tr>
<tr>
<td>Facilitated peer support</td>
<td>New relationship with patient</td>
<td>New benchmarking opportunities</td>
<td>New revenue streams</td>
</tr>
<tr>
<td>New relationship with clinician</td>
<td></td>
<td></td>
<td>Seen as ‘innovative’</td>
</tr>
<tr>
<td>Improved device technique</td>
<td></td>
<td></td>
<td>Life cycle management</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Sensor in clinical studies</td>
</tr>
</tbody>
</table>
The global market for smart inhalers has the potential to grow rapidly; it is estimated that by 2024 it will be worth up to $3.56 billion.

DPIs segment is expected to emerge as the fastest growing category with a CAGR of 16.9%.

**Drivers**

- Prevalence of respiratory disease
- Addresses significant unmet need
- Proliferation of IoMT
- Increasing penetration of smartphones, tablets and wearables
- Population increasingly tech savvy
- Cheaper, smaller electronics; improved energy efficiency

**Hurdles**

- Lack of credible evidence base
- Lack of clear reimbursement pathways
- Security/privacy concerns
- Risk of information overload to HCP
- Lack of interoperability
- Additional user steps/human factors concerns
- Cost/benefit not proven

Digital dose inhaler market analysis by product, by type, and segment forecasts to 2024. Grand View Research 2016
CAGR, Compounded Annual Growth Rate; DPI, dry powder inhaler; IoMT, Internet of Medical Things; HCP, healthcare provider
Data protection keypoints

1. DATA QUALITY
   - Accuracy, reliability
   - Interactions and potential conflicts with other laws (regulatory, clinical trials, e-signature)

2. PURPOSE LIMITATION
   - Transparency
   - Secondary use of data

3. PROPORTIONALITY
   - Data minimization
   - Anonymization/pseudonymization
   - Personalized medicine and big data

4. CONSENT
   - Sensitive data
   - Withdrawal
   - Individual rights

5. THIRD PARTIES
   - Cloud
   - Data transfer
   - Data sharing

6. GOVERNANCE
   - Data security
   - Data Privacy by design and by default
Smart Inhalers as element of system for predicting disease worsening

Physician diagnoses COPD and prescribes inhaled therapy; informs John about Beyond the Pill solution.

John picks up smart inhaler from pharmacy, barcode on package to download app.

John scans barcode to download app, gets on-boarding call from telenurse; John puts on sensor patch.

Smart Inhaler monitors adherence, patch measures biomarkers indicating exacerbation risk. John answers patient-reported outcomes on app; app sends John medication reminders, motivation, and educational materials.

Based on risk factors, sensor, and PRO data, algorithm predicts risk of exacerbation. Alert sent to John and Physician. Physician contacts John and prescribes medication to address exacerbation.

John is back on stable treatment.

Physician intervention

Continued treatment
The relationship between healthcare provider and patient will be transformed

**TODAY:** “Next please”

1. FEV₁ Lab data
2. FEV₁ BP
3. ...
4. ...

- One patient at a time
- Barriers for effective patient-HCP engagement: sporadic visits, limited HCP time, inefficient interactions when HCP is reactive
- No evidence for adherence; only patient-reported
- Scattered data and difficult for HCPs to organize and make sense of at the patient level
- Lack of practice-level data to inform treatment

**TOMORROW:** “Bring them on”

1. HCP
2. ...
3. ...
4. ...
5. ...
6. ...

- All patients, real-time, through digital link
- Disease control with remote, real-time, continuous monitoring
- Objective and continuous adherence tracking
- Creates more efficient, effective, and proactive HCP-patient interactions
- Practice level data for epidemiology

BP, blood pressure; FEV₁, forced expiratory volume in 1 second; HCP, healthcare provider
Pharma would move to a new model...  

<table>
<thead>
<tr>
<th>TODAY</th>
<th>TOMORROW</th>
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<tbody>
<tr>
<td>Treating signs &amp; symptoms</td>
<td>Focus on overall clinical outcomes</td>
</tr>
<tr>
<td>Bronchodilators, ICS</td>
<td>Less exacerbations, fewer hospital admittances</td>
</tr>
<tr>
<td></td>
<td>Product offering</td>
</tr>
<tr>
<td>The product itself</td>
<td>Product plus offering</td>
</tr>
<tr>
<td></td>
<td>The product + measures to enhance outcomes:</td>
</tr>
<tr>
<td></td>
<td>diagnostics, telehealth technology, apps</td>
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<tr>
<td></td>
<td>Selling medicines &amp; devices</td>
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<tr>
<td>Customers with fixed budget</td>
<td>Partnering for better health</td>
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<tr>
<td>for pharmaceutical and</td>
<td>Partnering with customers to achieve good clinical</td>
</tr>
<tr>
<td>device spending</td>
<td>outcomes against sustainable healthcare spending</td>
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ICS, inhaled corticosteroid

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A model focused on patient outcomes: “digital health” is a key enabler
Key messages

Improving adherence in respiratory disease is a significant unmet need

The sensor technology is available now for smart inhalers

Clear value propositions for patient, healthcare provider, payer, smart inhaler provider/pharma

Smart inhaler use is currently not widespread. Enablers to drive uptake include:

- Robust evidence base (including outcomes data)
- Clear reimbursement pathways
- Interoperability
- Addressing data privacy concerns
“The future is here. It’s just not very evenly distributed yet.”

William Gibson
Cyberpunk author