Technology to enable telehealth in respiratory medicine

John Pritchard
The world is changing!

2005: The faithful gather at St. Peter’s Basilica to bid farewell to Pope John Paul II

2013: Pope Francis is installed at St Peter’s
What do we mean by telehealth?

TeleHealth & TeleCare Definitions

- eHealth
  - Integrated health information networks
  - Hospital information systems
  - Clinical information systems

- Telemedicine
  - TeleHealth (clinical content, educational programs)
  - TeleMonitoring (vital signs)
  - TeleDisciplines: Teleradiology, Telescreening, Teletherapy

- mHealth
  - On the go

- TeleCare
  - Ambient Assisted Living
  - (social alert)
The growth potential for mHealth applications

Compass Intelligence (2014) mHealth Market Analysis: Opportunities and Evolving Ecosystem.
Telehealth deployment

Chronic disease requires lifelong care

- COPD is the 4th leading cause of death worldwide [1]
- About 4% of men and 2% of women in the world have OSA Syndrome; an estimated 80% are still undiagnosed [2]
- The rise in chronic disease and co-morbidities combined with a desire for care on our own terms will drive demand for care in the home or on the go

Aging drives more demand for home care

- By 2050, the global population 65+ will triple in size to 1.5 billion [3]
- In 2010, 29% of people aged 65 and over lived alone in the USA [4]
- Older, isolated people have higher rates of mortality from breast cancer, high blood pressure, heart disease, and other chronic diseases

But to introduce telehealth requires

- **Effective stratification of patients to identify those who benefit the most**
- **Seamless integration with existing care structures**
  - Care coordination
- **Education of care providers**

Linking intervention to outcomes

Cochrane review of studies of >6 mo duration in respiratory diseases

<table>
<thead>
<tr>
<th>Adherence</th>
<th>Clinical outcome</th>
<th>Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>No change</td>
<td>No change</td>
<td>5</td>
</tr>
<tr>
<td>Improved</td>
<td>Improved</td>
<td>3</td>
</tr>
</tbody>
</table>

- Combining behavioral intervention with educational is better than educational alone
- Adherence improves most consistently when dosing regimens are simplified
- The most successful clinical outcomes were in the most severe events – e.g. hospitalizations

Intervention requires objective data

Objective versus reported adherence (completed doses) in CF patients

Interventions improve with feedback

How is as important as when

<table>
<thead>
<tr>
<th>At least 1 critical inhaler error</th>
<th>COPD (n=864)</th>
<th>Asthma (n=703)</th>
<th>Odds ratio ± SE</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Hospital admissions %</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Never</td>
<td>62</td>
<td>55</td>
<td>86</td>
</tr>
<tr>
<td>1</td>
<td>23</td>
<td>26</td>
<td>9</td>
</tr>
<tr>
<td>2-3</td>
<td>11</td>
<td>16</td>
<td>3</td>
</tr>
<tr>
<td>&gt;3</td>
<td>4</td>
<td>3</td>
<td>2</td>
</tr>
<tr>
<td>ER visits %</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Never</td>
<td>71</td>
<td>64</td>
<td>81</td>
</tr>
<tr>
<td>1</td>
<td>22</td>
<td>24</td>
<td>11</td>
</tr>
<tr>
<td>2-3</td>
<td>4</td>
<td>10</td>
<td>3</td>
</tr>
<tr>
<td>&gt;3</td>
<td>3</td>
<td>2</td>
<td>4</td>
</tr>
<tr>
<td>Infection treatments %</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Never</td>
<td>30</td>
<td>20</td>
<td>41</td>
</tr>
<tr>
<td>1</td>
<td>29</td>
<td>31</td>
<td>30</td>
</tr>
<tr>
<td>2-3</td>
<td>26</td>
<td>33</td>
<td>18</td>
</tr>
<tr>
<td>&gt;3</td>
<td>25</td>
<td>15</td>
<td>11</td>
</tr>
<tr>
<td>Steroid treatments %</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Never</td>
<td>37</td>
<td>29</td>
<td>35</td>
</tr>
<tr>
<td>1</td>
<td>22</td>
<td>19</td>
<td>30</td>
</tr>
<tr>
<td>2-3</td>
<td>30</td>
<td>26</td>
<td>22</td>
</tr>
<tr>
<td>&gt;3</td>
<td>11</td>
<td>26</td>
<td>13</td>
</tr>
</tbody>
</table>

AS Melani et al. (2011) Respir Med 105, 930-938
Most errors relate to breathing manoeuvre

### How can devices help?

<table>
<thead>
<tr>
<th>Device</th>
<th>Training</th>
<th>Sustaining</th>
</tr>
</thead>
<tbody>
<tr>
<td>Match inhaler to patient</td>
<td>Use the patient’s “language”</td>
<td>Provide reference material</td>
</tr>
<tr>
<td>Forgiving of poor technique</td>
<td>Check inspiratory maneuver</td>
<td>Electronic instruction</td>
</tr>
<tr>
<td>Provides feedback on dose emission</td>
<td>Check at return visits</td>
<td>Address motivation and beliefs</td>
</tr>
<tr>
<td>Provides feedback on technique</td>
<td>Training aids as alternative</td>
<td>Check adherence and reminders</td>
</tr>
</tbody>
</table>

**Technique Good/Poor Summary:**

- **Good:** Sub-optimal inhalation or flow rate of the inhaler was not assessed.
- **Poor/Improvement:** Not well-exhaled; timed inhalation held too short.
- **Good/Improve:** Inadequate inhalation with adequate inspiration volume and breath hold time.
This is not just about taking medicine

TORCH

3 yr mortality (%) Adherence >80%  Adherence <80%

<table>
<thead>
<tr>
<th></th>
<th>Adherence &gt;80%</th>
<th>Adherence &lt;80%</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n=4880</td>
<td>n=1232</td>
</tr>
<tr>
<td>Salmeterol</td>
<td>10.7</td>
<td>25.2</td>
</tr>
<tr>
<td>Fluticasone</td>
<td>12.9</td>
<td>28.7</td>
</tr>
<tr>
<td>Combination</td>
<td>9.5</td>
<td>24.9</td>
</tr>
<tr>
<td>Placebo</td>
<td>12.0</td>
<td>26.7</td>
</tr>
</tbody>
</table>

... there is an association of bad behavior!

Barriers to adherence

- **Socio-economic:**
  - Cultural & religious beliefs
  - Poverty
  - Illiteracy
  - Educational level
  - Substance abuse

- **The patient!**
  - Behavior
  - Motivation

- **Condition:**
  - Co-morbidities
  - Depression
  - Symptom severity
  - Rate of progression
  - Level of disability

- **Therapy:**
  - Effectiveness
  - Speed of action
  - Side-effects (real or perceived)
  - Multiple medications
  - Impact on lifestyle
  - Device complexity & technique

- **Healthcare system:**
  - Availability
  - Cost
  - Instruction
  - Support materials
  - Follow-up

## Attitudes change

<table>
<thead>
<tr>
<th>Healthy</th>
<th>Transition state</th>
<th>New state</th>
</tr>
</thead>
<tbody>
<tr>
<td>- great health</td>
<td>- A continuous battle</td>
<td>- Savor life as it is finite</td>
</tr>
<tr>
<td>- positive outlook</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- enjoy life</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- young at heart</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

| Frail                     |                                      |                                     |
| - sick                    |                                       |                                     |
| - frail                   |                                       |                                     |
| - dependent               |                                       |                                     |
| - homebound               |                                       |                                     |

<table>
<thead>
<tr>
<th><strong>Primary state</strong></th>
<th><strong>Transition state</strong></th>
<th><strong>New state</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Key driver</td>
<td>Empowerment</td>
<td>Reassurance</td>
</tr>
<tr>
<td>Aging</td>
<td>The time of your life</td>
<td>A continuous battle</td>
</tr>
<tr>
<td>Health</td>
<td>For ultimate well-being</td>
<td>For self-esteem</td>
</tr>
<tr>
<td>Future</td>
<td>Unlimited joy in life</td>
<td>Lifestyle adaptation</td>
</tr>
<tr>
<td>Empowerment</td>
<td>Rely on yourself</td>
<td>Fight for yourself</td>
</tr>
<tr>
<td>Reassurance</td>
<td>In control</td>
<td>Manageable</td>
</tr>
<tr>
<td>Connectedness</td>
<td>Acknowledgement</td>
<td>Self-development</td>
</tr>
</tbody>
</table>

**Big brother**               | **State support**                      |                                     |

**PHILIPS**
Types of non-adherence

**Unwitting**
- Misunderstands regimen
- Incorrect inhaler technique

**Erratic**
- Too busy
- Too stressed
- Costs too much
- Simply forgets

**Deliberate**
- Feeling better
- Perceived ineffectiveness of therapy
- Don’t like taking “too much” medicine
  - Side-effects

<table>
<thead>
<tr>
<th>Rationale for non-adherence</th>
<th>Asthma (%)</th>
<th>COPD (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unwitting</td>
<td>N=3618</td>
<td>N=2602</td>
</tr>
<tr>
<td>Complicated method</td>
<td>0.4</td>
<td>2.1</td>
</tr>
<tr>
<td>Difficult to use inhaler</td>
<td>2.5</td>
<td>7.9</td>
</tr>
<tr>
<td>Poor understanding of instructions</td>
<td>3.3</td>
<td>4.2</td>
</tr>
<tr>
<td>Long time to get new prescription</td>
<td>4.1</td>
<td>5.0</td>
</tr>
<tr>
<td>Erratic</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Forgetfulness</td>
<td>7.0</td>
<td>3.3</td>
</tr>
<tr>
<td>Shift working</td>
<td>9.1</td>
<td>7.1</td>
</tr>
<tr>
<td>Self-organization (haste)</td>
<td><strong>55.6</strong></td>
<td><strong>37.1</strong></td>
</tr>
<tr>
<td>Deliberate</td>
<td></td>
<td></td>
</tr>
<tr>
<td>High cost</td>
<td>2.5</td>
<td>5.4</td>
</tr>
<tr>
<td>Consciously not refill</td>
<td>2.5</td>
<td>3.3</td>
</tr>
<tr>
<td>Lack of prolonged efficacy</td>
<td>5.3</td>
<td>8.8</td>
</tr>
<tr>
<td>Desire to reduce medication</td>
<td>17.3</td>
<td><strong>23.3</strong></td>
</tr>
<tr>
<td>Fear of side-effects</td>
<td><strong>22.2</strong></td>
<td>13.3</td>
</tr>
<tr>
<td>Well-being (lacking symptoms)</td>
<td><strong>36.6</strong></td>
<td>21.7</td>
</tr>
</tbody>
</table>

Feedback provides empowerment

• Am I doing it right?
• Am I doing it often enough?
  • Am I seeing any benefit?

• Do I (we) need to intervene?

Traditionally, compliance with peak flow meters has been poor
Introducing additional tools
AZ blueprint for a modern patient support tool
Me and my COPD

Key Modules

- Patient Profiling based on behaviour and disease state
  - guides messaging strategy and other interventions

<table>
<thead>
<tr>
<th>Behavioural stages</th>
<th>Denial</th>
<th>Acceptance</th>
<th>Manage</th>
<th>Proactive</th>
</tr>
</thead>
<tbody>
<tr>
<td>Condition changes</td>
<td>Intermittent</td>
<td>Mild Persistent</td>
<td>Moderate Persistent</td>
<td>Severe Persistent</td>
</tr>
</tbody>
</table>

- Data Collection from Patients
  - Bluetooth devices for adherence support and detecting change in disease state
  - Devices to collect physiological data
  - Patient reported outcomes

- Supported self management
  - Individualised messages based on data collected
  - Content from medically valid sources
  - Goal setting and tracking
  - Decision support
  - Links to HCP and HCP services
Monitoring can also track symptoms


Early Therapy Improves Outcomes of Exacerbations of COPD

- 128 COPD patients (FEV$_1$ 1.07 L) with 1,009 exacerbations over 6 years

- Median time between exacerbation and treatment was 3.69 days

- Earlier treatment was associated with faster recovery
  - 0.42 days / day (p<.001)

Wilkinson et al (2004), Amer J Respir Crit Care Med 169:1298
Philips Respironics - achievements in cystic fibrosis

The problem
- Nebulized treatments place a significant burden on the lives of patients with respiratory diseases
- Cystic fibrosis patients also have to cope with multiple medications to manage diet, lung secretions, and lung infections
- Medication adherence in chronic disease is typically 50% of prescribed regimens. Multiple medications make this worse

The solution
- Nebulization is recorded and made available via I-neb Insight Online
- Patients can monitor and improve technique to shorten treatment times
- Patient support teams can coach
- Professionals can monitor adherence and improve behavior through motivational interviewing

Outcomes
- Patients and professionals found the system easy to use
- Treatment times were reduced
- Objective data were recorded
- The number of doses taken correctly improved by ~20%
- Improvements in adherence were sustained over 12 months
- Lung function was better in those patients with optimum adherence
- Poor adherence resulted in increased use of healthcare resources
- Motivational interviewing reduced the hospital use of IV antibiotics
- In the future, monitoring weight and activity may offer even greater benefits

The digital revolution

• There are > 20,000 healthcare apps available from > 300 companies devoted to digital health
  – By 2018, 70 % of healthcare organization swill have invested in digital technology (IDC Health Insights)
  – The US Healthcare device market is worth $ 3,000 Bn
  – There are > 13M users of health and fitness wearables in the UK (Kanta Media)
    ▪ Nearly 7M wearers use them to monitor heart rate, steps taken or fitness level.

• Are these the worried well ?
  – Already have a healthy attitude to disease

• Is this a passing craze ?
  – One third of uses stop using their device within first year of purchase

• Who owns and integrates the data ?
  – Multiple devices, platforms, Electronic Health Records
    ▪ Physicians do not wish to be limited in drug/inhaler options by the software/devices available

• Complex regulatory framework
  – Data privacy and security issues
  – Medical device classification
    ▪ Jan 2015: FDA draft guidance on Medical Device Accessories
    ▪ MHRA: Medical device includes “any software which is ‘standalone’ i.e. not a part of a physical medical device at its time of being first placed onto the market, and which is intended to be used in the treatment, prevention, alleviation or diagnosis of a medical condition”
Other areas of application

• Delivering healthcare services via an app

• Monitoring activity and sleep as Quality of Life measures

• Gamification for breath training or adherence
  • Need constant refreshing

• Using data to speed up drug development
  • April 2015: AstraZeneca partners with PatientsLikeMe
    • “We take the information patients like you share about your experience with the disease and sell it to our partners “
    • 5,000 patients who report having asthma, 1,200 with cystic fibrosis, and over 1,600 with COPD
Healthcare professional perspective

“I cannot really know if this patient is adherent” (Limited information about patient adherence, but trusting clinical judgment)

“I have no training in how to improve patient adherence”

“I have no time or resources to promote patient adherence”

“What good will it do anyway?”

A software tool to understand motivation

UNDERSTANDING THE REASONS FOR MEDICATION ADHERENCE

Perceptual/emotional
“I want to…”

Stress/ anxiety
Never

Disease severity
High

Hospital admissions
Frequent

Regimen complexity
Medium

Situational factors
“I am able to…”

Fear of side effects
Average

Condition

Cognitive decline
Very little

Health literacy
Average

Substance abuse
High

Financial resources
Low

Social support network
Enough support

Relationship with doctor
Bad

Larger is better, more enabled


Perception

Emotion

Coping skills
Emotional coping

Illness perceptions
Medium

Beliefs about medications
Negative

Self-efficacy
Average

Locus of control
Self-controlled

ACT: Advancing Care Coordination & Telehealth

“To identify ‘best practice’ organizational and structural processes supporting integration and implementation of telehealth in a care coordination context for routine management of chronic patients”

EU funded multi-country program
- Five leading regions in 4 countries
  - Experienced in delivering telehealth/coordinated care
  - At least 3000 CHF, COPD, DM patients per region
- Leading medical experts & key opinion leaders
- Iterative improvement to arrive at a toolkit for care coordination & telehealth use across EU
  - Spread plan to 15-20 other EU regions
Concluding thoughts

• Telehealth affords the opportunity to address two major healthcare issues
  • Medication non-adherence
  • Care of an ageing population
  • This will drive continuing development

• The technology already exists, but there are barriers to the introduction of services
  • A change in care provision
  • Patient ability
  • Regulatory challenges
  • Common software platform

• Most current activity is not focused on patients
  • Patients prepared to buy products are less likely to benefit
    • Opportunity for concerned relatives
  • Avoids the medical device regulations
  • Need trials to establish the value of outcomes
    • Outcomes generate payer engagement
## Potential payment sources

<table>
<thead>
<tr>
<th>TYPICAL FUNCTIONS AND ACTIVITIES</th>
<th>PAYERS</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Wellness and Prevention</strong></td>
<td>• Consumer/family</td>
</tr>
<tr>
<td>• Measure weight, exercise,</td>
<td>• Caregiver (adult child or parent)</td>
</tr>
<tr>
<td>calories consumed</td>
<td>• Employer/plan sponsor</td>
</tr>
<tr>
<td><strong>Chronic Disease Management</strong></td>
<td>• Health plan</td>
</tr>
<tr>
<td>• Diabetes: monitor blood</td>
<td>• Employer/plan sponsor</td>
</tr>
<tr>
<td>glucose</td>
<td>• Provider (pay-for-performance or</td>
</tr>
<tr>
<td>• CHF: track weight</td>
<td>bundled-for-condition)</td>
</tr>
<tr>
<td>• Hypertension: track blood</td>
<td></td>
</tr>
<tr>
<td>pressure</td>
<td><strong>Pharma industry</strong></td>
</tr>
<tr>
<td>• COPD: measure strength of</td>
<td></td>
</tr>
<tr>
<td>breath (spirometry)</td>
<td></td>
</tr>
<tr>
<td>• General: medication adherence</td>
<td></td>
</tr>
<tr>
<td>**Acute Care, Post-Acute Care,</td>
<td>• Medicare, under Accountable Care Act</td>
</tr>
<tr>
<td>and Rehabilitation</td>
<td>• Health plan</td>
</tr>
<tr>
<td>• Prevent hospital readmission</td>
<td>• Employer/plan sponsor</td>
</tr>
<tr>
<td>• Monitor physical therapy at</td>
<td></td>
</tr>
<tr>
<td>home</td>
<td></td>
</tr>
<tr>
<td><strong>Aging at Home</strong></td>
<td>• Health plan</td>
</tr>
<tr>
<td>• Medication optimization</td>
<td>• Consumer/family</td>
</tr>
<tr>
<td>• Remote monitoring of vital</td>
<td></td>
</tr>
<tr>
<td>signs and activities of daily</td>
<td></td>
</tr>
<tr>
<td>living</td>
<td></td>
</tr>
<tr>
<td>• Assistive technologies</td>
<td></td>
</tr>
<tr>
<td>(e.g., smart home, smart</td>
<td></td>
</tr>
<tr>
<td>wheelchair)</td>
<td></td>
</tr>
</tbody>
</table>

Identifying opportunities to improve: Lifestyle

<table>
<thead>
<tr>
<th>Marco Giorgi</th>
<th>Total Nebulizations per day</th>
<th>Expected Nebulization Time</th>
<th>1-neb Mouthpiece</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>3</td>
<td>5 mins</td>
<td>TBM</td>
</tr>
</tbody>
</table>

**Graphs:**
- **Nebulization Use over Time:**
  - Y-axis: Nebulizer Use
  - X-axis: Dates
- **Nebulization Time (min):**
  - Y-axis: Nebulization Time (min)
  - X-axis: Dates
- **Nebulization Time of Day:**
  - Y-axis: Nebulization Time of Day
  - X-axis: Times of Day
- Daily Nebulizations vs. Nebulization Time of Day

**Notes:**
- Confidential
- Teva meeting, 20 February 2014
Several systems exist to measure adherence

**Spiroscout™**
Records location of pMDI use as well as adherence, so patients can upload and map usage within the environment.

**adHaler™**
Records pMDI use and uploads data for remote access.

**MDILog™, DPILog™**
Records, stores, and wirelessly uploads both adherence and technique data from pMDI and Diskus™ for remote web access.

**Doser™**
Electronic device attached to a pMDI that counts and stores when the pMDI is actuated.

**Smartinhaler™**
Range of devices for different inhalers that provide reminders, monitor adherence, and upload for remote access.

**I-neb™ AAD System, I-neb Insight Online™**
Nebuliser that records device and breathing parameters. Option to upload for remote web access.
Which parts of adherence does this address?

**Psychological:**
- Comprehension of disease & treatment
- Cognitive functioning (e.g. memory, capacity for judgement)
- Executive functioning (e.g. capacity to plan)

**Physical:**
- Physical capability to adapt to lifestyle changes
- Dexterity

**Reflective:**
- Perceptions of illness
- Beliefs about treatment (e.g. necessity, efficacy, concerns)
- Outcome expectancies
- Self-efficacy

**Automatic:**
- Stimuli or cues for action
- Mood state/disorder (e.g. depression & anxiety)

**Physical:**
- Cost
- Access (e.g. availability of medication)
- Packaging
- Physical characteristics of medicine
- Regimen complexity
- Social support
- HCP-patient relationship/communication

**Social:**
- Stigma of disease, fear of disclosure
- Religious/cultural beliefs

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