Inhalation Technology - What might the future hold?

DDL23
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Contents

There are 3 areas I want to cover today

1. Background – the pressures on the industry, the issues and problem
2. The Question – is technology the answer and if so at what level?
3. The RDD survey – the findings and conclusions

The major emphasis will be on the results of the survey
Background - the pressures on healthcare

The cost of healthcare has to be reduced in the long term
- The growth in the cost of healthcare is not sustainable for reasons that are well known
- The industry is responding by vigorous cost cutting, defensive mergers and innovative business models

Payers need to improve the quality of healthcare
- Improve how they meet patient needs (patients are informed)
- Increase the effectiveness of existing drugs (screen and treat?)
  - Improve adherence to reduce wastage and reduce the massive consequential costs on non-adherence

Healthcare company diversification
- Pharma companies are seeing higher levels of project attrition and fewer successful submissions
- Shareholder value still needs to increase or at least be sustained
- Offering wider levels of service and support is one way to increase revenues and shareholder value

Cost Effectiveness of Companion Diagnostics

redrawn from Davis et al Nature Reviews Drug Discovery 8, 279-286 (April 2009).
redrawn from Centers for Medicare and Medicaid Services, Office of the Actuary, National Health Statistics Group

**Total Federal**

- Medicare
- Medicaid
- Other
- Federal

**Total 2008**

- $2.3 Trillion

**Total Healthcare Expenditure ($Tn)**

- Medicare
- Medicaid
- Other
- Federal
Do we have a problem?

- The cost of ineffective drug delivery (ineffective for whatever reason) is borne by all.

- The result of ineffective delivery of inhaled therapy is wasted drugs, more devices than necessary ‘consumed’, more frequent GP visits, increased exacerbations, more emergency room visits, greater hospitalisation, poorer patient health and increased mortality – and, the cost burden is crippling and cannot be sustained.

- Yet when we define drug delivery solutions we typically look at minimising the device and drug cost rather than looking at a more holistic cost benefit analysis that assesses the impact on the total patient care cycle cost.

- If I ask you “can we do more?,” the answer will be “yes”; quickly followed by “but who is going to pay?”

- Well, if we do not do more we will all pay…and a lot more than we expect!

- However, whilst better technology might be part of the solution it is not the total answer, we still need to provide better useability, more patient education, training, more liaison, monitoring and support – but this is out of scope for this presentation.
Could better use of technology help in the future?

- A significant proportion of the costs associated with managing asthma and COPD are due to ineffective delivery of medication due to:
  - poor patient adherence
  - poor technique and critical errors
  - and I suggest, outdated technology

- But it isn’t all the patients fault – drug delivery platforms can and must be improved

- In the last decade or so useability has achieved a welcome and increasing focus

However, the task we face in the future…

- to significantly reduce total healthcare costs (by addressing the consequences of sub-optimum drug delivery)

…will be immensely challenging and needs more than improved usability

Hypothesis - better use of technology throughout the patient care cycle can deliver more cost effective therapy and disease management than is currently achieved

* P Trueman, D Taylor et al. (2010) Evaluation of the Scale, causes and costs of Waste Medicines
Evidence of emerging technology offering cost benefits

- Research by Mass General Hospital/Harvard's Centre for Connected Health (CCH) on behalf of Vitality suggests monitoring can increase adherence in hypertension by 27%.
- Recent studies estimate that non-adherence results in an incremental 131,400 deaths per year in the U.S., and 194,500 in the E.U., and significantly higher healthcare costs (e.g., close to $300 billion annually in the U.S., and 125 billion Euros in the E.U.). Improved patient adherence will lead to improved health outcomes, significant cost savings for the healthcare system, and better revenue generation for the pharmaceutical industry. For these reasons, patient adherence is beginning to gain more focus among companies, health authorities, payers and providers.\(^1\)
- Kathy Calvin, chief executive of the UN Foundation, a founding member and host of the Mobile health mHealth Alliance, said that “wireless technologies have enormous potential to improve the efficiency and effectiveness of health programmes”. She claims that the report \(<mHealth: New Horizons for Health through Mobile Technologies>" provides the data that can help accelerate the strategic use and evaluation of mobile technologies as mHealth is taken to scale to help meet health needs\(^2\)
- Within the next 5 years, mHealth is expected to target 220 million diabetes patients and around 400 million obesity cases globally, resulting in savings of US$ 29 billion per year for health care providers, according to West Wireless Health Institute\(^3\)
- COPD – Remote monitoring of patients with severe respiratory illness. Reduced hospital admissions by 50%; reduced acute home exacerbations by 55%; reduced hospital costs by 17\(^%\)\(^4\)
- There are many more examples

3. Arthur D Little, Capturing Value in the mHealth Oasis, June 2011  
But does intervention help? Can we manage adherence and have an impact


<table>
<thead>
<tr>
<th>Disease</th>
<th>Drug</th>
<th>Length of study and number of patients</th>
<th>Method used to improve adherence</th>
<th>Adherence in control group/ at baseline (%)</th>
<th>Adherence in intervention group/end of trial (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Asthma</td>
<td>Fluticasone propionate</td>
<td>24 weeks 110 patients</td>
<td>Smartholer fitted with audio visual reminder function (AVRF)</td>
<td>66 (control)</td>
<td>88 (AVRF)</td>
</tr>
<tr>
<td>Asthma</td>
<td>Inhaled steroids</td>
<td>10 weeks 19 patients</td>
<td>Direct clinician-patient feedback</td>
<td>47 (control)</td>
<td>81 (treatment)</td>
</tr>
<tr>
<td>Asthma</td>
<td>Inhaled steroids</td>
<td>4 weeks 15 patients</td>
<td>Home visits using social learning theories</td>
<td>No data available</td>
<td>79</td>
</tr>
<tr>
<td>COPD</td>
<td>Ipratropium bromide or placebo</td>
<td>4 months 251 patients</td>
<td>Adherence feedback</td>
<td>68.8 (control)</td>
<td>88.8 (feedback)</td>
</tr>
<tr>
<td>COPD</td>
<td>Ipratropium bromide or placebo</td>
<td>24 months 231 patients</td>
<td>Adherence feedback</td>
<td>38.7 (control)</td>
<td>55 (feedback)</td>
</tr>
</tbody>
</table>

In UK

- Estimated 1.8 million asthmatics in England who are only partially compliant*
- The total net benefit associated with compliance is estimated to be £2,250 per patient*
- If interventions could make these people 80% more compliant, savings are estimated by the authors to be £130million p.a.*
- Thus the total potential saving is £4billion over the expected patient treatment spans

*P Trueman, D Taylor et al. (2010) Evaluation of the Scale, causes and costs of Waste Medicines
Is Technology the answer?

- Is better technology the answer or is cheapest best? We can’t afford to keep focussing on the cheapest delivery system if these systems are ineffective.

- However, there will always be a place for low-cost, simple technology devices

- But there is also an opportunity to achieve more effective drug delivery, more cost effectively, by employing better technology appropriately

- But how far should we go
  - Is a dose counter, reminder and logger enough?
  - Do we need full diagnostics, drug titration and integrated disease management?

*Let’s review what you, the industry believed, from the RDD survey this year*
The survey question—Where will inhalation technology be in 10 years?

We provided reference levels of technology one could expect in the future

<table>
<thead>
<tr>
<th>Level</th>
<th>Device Capability</th>
<th>Description of Technology</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>User aids</td>
<td>Breath actuation; dose counter (the past)</td>
</tr>
<tr>
<td>2</td>
<td>Adherence</td>
<td>Dose reminders; actuation sensors; adherence apps; web based data transfer (the present)</td>
</tr>
<tr>
<td>3</td>
<td>Successful device use</td>
<td>Combined user feedback (BAI/flow rate etc); event capture; transmission to HCP</td>
</tr>
<tr>
<td>4</td>
<td>Successful drug delivery</td>
<td>Device verifies that the drug was successfully delivered and indicates or transmits confirmation that the dose was in chamber, left the device, entered patient and that the flow rate used was appropriate</td>
</tr>
<tr>
<td>5</td>
<td>Diagnostic device</td>
<td>Device diagnoses some aspect of disease state through e.g. measurement of biomarker</td>
</tr>
<tr>
<td>6</td>
<td>Disease management</td>
<td>Fully, or partially, closed loop system that monitors condition and adjusts/recommends dose accordingly</td>
</tr>
</tbody>
</table>

Respondents were asked to select the level of technology they believed would be in use in 2022 and to discuss the reasons why.

This yielded considerable further information and views on the benefits, drivers and barriers in using more inclusive technology in inhalation therapy.
The Results

43 responses - Pharmaceutical, device companies, suppliers, regulators and academics

Range of views from little advance to those who believed technology would play a more significant role in pulmonary disease management in the future

Clear skew towards the use of more inclusive technology and that technology will play a stronger role in inhalation in the future…….but what else emerged
Benefits – opinion is that inclusive technology can and will deliver more

Many respondents felt this presents an opportunity to deliver the following benefits:

- **Reduction in the cost of healthcare** by improving
  - Adherence to reduce wastage and the consequential cost of non-adherence
  - Effectiveness of generic drugs – getting more from existing lower cost drugs
  - Effectiveness of new drugs (screen and treat – personalised medicine)

- **Improved quality of healthcare**
  - Better clinical outcomes, fewer exacerbations and fewer hospital visits/relapses
  - Improved patient services – better remote support in disease management
  - “De-hospitalisation” of treatment by allowing higher levels of care at home

- **Increased revenues for pharmaceutical companies**
  - Wider levels of service and support to increase revenues and shareholder value
  - IP protection and increased potential for line extensions
  - Improved approval of new products by better clinical data and secured revenue in payment by results scenarios

*Service and disease management based benefits requiring a more holistic view for realisation*
Drivers – but what are the primary drivers in reducing total cost

- **Improved clinical outcomes via**
  - Enabling better patient adherence through monitors, reminders, intervention
  - Advanced feedback to patients and GPs, as well as providing data to aid next generation product and service development
  - Improved technique

- **Improved product safety**
  - Reduced dose escalation through better outcomes, especially if through improving poor technique where escalation is not addressing the problem
  - Better patient awareness of the benefits of good technique and adherence
  - Technology has the potential to improve delivery consistency, reduce patient-critical errors, improve useability leading to improved patient health, acceptance and even better adherence

*A virtuous cycle that embraces and supports the patient, rewarding not admonishing*
Drivers continued

• **IP Capture**
  - Convergence between drugs and devices in general indicates that further convergence to include diagnostics and even ‘well-being’ products is presenting IP opportunities outside a company’s core skills but none-the-less, attractive.
  - Modern Pharma needs to look beyond the traditional revenue stream and seize the inclusive technology opportunities and not leave it to others like Sony and Nestlé.
  - A recent CambridgeIP study found that up to 89% of new medical device patents involve wireless but less than 8% of ~11,000 inhaler patents included wireless.*

• **Lifecycle management and product differentiation**
  - Both off-patent and proprietary products can benefit from differentiation and line extension improvements.
  - Pharma has the opportunity to extend the product lifecycle via enhancements such as simple breath actuation to monitoring to diagnostics and titration to improve the delivery of generics just as effectively as with NCEs.

*If they don’t, ‘add-ons’ will emerge to take the higher value revenue for improved benefits*
Barriers – so why isn’t it just happening

Well it is…but maybe not as fast as we would all like….what is holding us back?

- **Legislation**
  - Technology development is moving at a rapid pace, particularly in diagnostics, communications and connectivity and the inability of regulatory bodies to keep up was cited as a main barrier in approving technologically advanced products
  - The problem is as products converge to more inclusive solutions (drug combinations, device hardware, software, diagnostics, integration with consumer products etc. – how do we define the optimum regulatory pathway?
  - For example, Ford with Medtronic has developed Ford SYNC® to connect to a continuous glucose monitoring device or iPhone asthma management system using WellDoc® software* (AstraZeneca announced a collaboration with WellDoc® 4 yrs ago!)
  - So is the car a medical device? What regulatory pathway would you choose?
  - The spread of liability also complicates the regulatory landscape beyond that of FDA and EMEA
  - How can the medical closed, integrated development approach meet the open innovative common standards approach adopted by telecoms to deliver the e-health potential?

Barriers continued

- **Cost of Development**
  - Technology laden products may not be expensive but the cost of development to achieve low manufacturing costs and an integrated service is.
  - Does the value of the developed extended service offering outweigh the cost and can some of the downstream cost savings be directed back to the developer?
  - The business case must be both compelling and realistic but will be more ‘business’ than product oriented.
  - The necessary partnerships, collaborations will all need to share the available margins and thus the commercial model may need to change
  - At present it is likely that only large Pharma can form the partnerships to fund and develop inclusive technology solutions but smaller players are and will continue to provide elements and snap at large Pharma’s heels
  - The challenges and threats will not all be obvious as e-health attracts external players
Barriers continued

- **Payers and reimbursement**
  - The potential benefits are not in question but who pays is
  - The application of technology can deliver considerable downstream savings but the apparent cost benefit to healthcare payers may not be obvious or it may be non-existent
  - Business propositions requiring healthcare providers to pay more for increased benefit can only succeed if there is a mechanism for the provider to share the downstream benefit
  - The holistic cost benefit model may show substantial total savings but breaking the current mould and embarking on this path requires more than a leap of faith
  - In the short term, more privileged patients may add ‘new money’ to the mix enabling advances to be made but this may result in a 2 tier system
  - However, NICE is considering offering advice on the evidence needed in its assessments of cost benefit to perhaps better demonstrate the longer term value

- **Competencies**
  - The multidisciplinary needs of inclusive technology combination products is beyond the core competency of pharmaceutical companies meaning strategic partnerships are essential to deliver the true potential. This is initially another unfamiliar hurdle to climb.
Conclusions

- The previous benefits and the degree of technology needed may seem a distant dream to some.
- From a patient perspective they are more recognisable as desirable.

Mapping the emerging technology levels used for the survey to the patient care cycle shows that by adding technology to inhalers we can better control and influence the whole care cycle.
Conclusions – and Finally

- The potential savings of adopting more inclusive technology are shown by numerous studies to be significant and realisable together with other potential clinical and commercial benefits.
- The adoption of more inclusive technology will require Pharmaceutical companies to move from a product based supplier to a disease management based service model (indeed some companies are already embracing this change)
  - Assuming more responsibility for clinical outcomes
  - Embracing the potential of payment by results
- Payers are assessing drugs by value in the whole care pathway, including assessing reduced exacerbations, impact on quality of life etc. as well as primary clinical results
- Regulators, in assessing useability are beginning to see evidence of how technology can improve adherence, reduce user errors, overcoming stigma and fear resulting in better outcomes
- As developers of inhaled products we are in a unique position to create devices that are a gateway to better and more efficient care in the same way that mobile devices created a gateway to the world
- Will the future remain entrenched in the development and selling of drugs alone or will it be in being a provider of those drugs as part of an integrated healthcare service, embracing technology as part of a total care, cost benefit business model aiming to do more for less?
THANK YOU

http://www.youtube.com/watch?v=5-IZbpqRL0s