Digital Health & Medication Adherence

How medical device and pharma companies can cut through complex issues to develop well-targeted adherence solutions
A review of digital design, service solutions, strategies, processes and approaches, such as *Human-Centered Design*, that medical device and pharma companies can use to control the business risk associated with medication adherence.

There is no shortage of statistics and studies related to the issue of patients not adhering to their medication regime - from high drop-out rates for specific prescription regimes, increased suffering and mortality risk, to the huge financial burden on the healthcare system and payers. The latter fact is hard to ignore; for the US alone according to a 2012 study, direct costs for medication non-adherence is estimated to be as much as $300 billion dollars annually.

Fortunately, ample awareness of this issue has fuelled entrepreneurs, companies and providers to develop new ways to improve adherence such as low to hi-tech organised pill boxes, some integrating wireless technology (Fig.1) and the many mobile device apps to help patients to stick to a regime. There is a growing array of **design guidance** for building effective medication reminders that support the daily routines of the consumer.

Given the business risk of less-than-expected sales and payers’ scrutiny of drugs associated with adherence problems, pharma companies are, unsurprisingly, engaged with this issue also. This engagement varies from joining patient groups and industry forums to better understand the issue, to integrating electronic monitoring capabilities in their drug delivery devices, to helping develop cutting-edge adherence technologies such as the Proteus smartpill system.

Part-funded by Novartis, the Proteus smartpill system comprises of miniature ingestible sensors embedded in pills that send signals wirelessly to a body-worn patch when swallowed - removing any doubt that someone has taken their medication.

Landscape of issues and opportunities

Understanding this complex issue naturally begins with the patient-related challenges as illustrated in Figure 2. This shows that medication non-adherence is not necessarily about a lack of patient discipline. There are many psycho-social factors at play. Academics have published many theories on **medication adherence**, as well as interventions that can positively change behaviour (e.g., the *behaviour change wheel*). These theories provide the basis for the effectiveness of digital design and service solutions.

Another aspect relates to adopting a systems approach. Figure 3 illustrates the complex landscape of stakeholders, interactions and therefore the potential issues that need to be considered in the development and provision of digital solutions and pharmaceutical therapies. If medical device and pharma companies develop adherence solutions that only respond to their direct issues and interactions, it might not be enough. For example, the effectiveness of solutions may be compromised if healthcare teams do not play their part.

Table 1 shows a non-exhaustive list of headline recommendations collated from several reports on this subject. In light of this, a potentially effective business strategy for companies to consider is direct to consumer models that are enabled by digital technology. For example, taking greater responsibility for the overall care of their consumer (including adherence).

**Table 1: Recommendations collated from adherence reports**

![Figure 1: Glowcap wireless pill bottle and router](image1)

![Figure 2: Patient-related issues](image2)

It’s just not about my discipline...

- “I can’t afford my care and medication costs”
- “I don’t speak the language of healthcare teams very well”
- “My doctor’s words are too complicated and technical for me”
- “The instruction leaflet seems to be written for a lawyer rather than me”
- “I don’t like having to remember to take all these different pills at different times”
- “I feel too physically sick”
- “I am too distressed or depressed”
- “I hate the side effects”
- “I still feel bad - I don’t believe I’ll get better”
- “I am not comfortable to ask questions”
- “There’s stigma associated with my medical condition - I don’t want other people to know”
- “I hate needles”
- “Pills are too hard to swallow”
- “Lack of convenience is a big issue”

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The approach

A highly effective approach to navigate the complex landscape of needs is Human-Centered Design - an approach where solutions are created and tested against a deep understanding of the sensitivities, needs, and abilities of people and the interplay between products, services, systems and cultures. Another approach is to use the Transtheoretical model illustrated in Figure 4 to create motivations for behavioural change in patients (alongside the broader toolkit provided by the Centre for Behaviour Change - CBC). This approach can offer an effective structure to manage positive and negative actions and beliefs of patients for sticking to a regime. The advantages of Human-Centered Design and using the Transtheoretical model are that they can identify many untapped opportunities, highlight the fact that relapses need to be managed and help to address the needs, or barriers to adoption, of multiple stakeholders.

The process: understand, conceive and validate

With these two approaches in mind, the process of understanding the landscape of needs can start in different ways. Desktop research into the issues, joining industry groups and learning through “e-patients” portals such as patientslikeme.com can be good first steps. We have published another white paper on this topic.

However the research process needs to be structured and enabled by a set of highly effective and well-proven techniques to gain insights of the cognitive, practical, financial, cultural and emotional challenges felt by patients and other stakeholders. Likewise there are environmental, legislative, regulatory and political dimensions related to medication adherence and digital health solutions. To extract some of these deep insights, this set of methods includes naturalistic observation, journal studies, in-depth interviews and heuristics reviews. Likewise Human-Centered Design helps frame and prioritise the research data with methods such as affinity clustering, experience diagramming and persona profiling.

Powered by this understanding, teams would discover, during the idea generation stage, that there are many types of potential digital and non-digital interventions to consider as shown in Table 2. Given the varied nature of the potential interventions, workshops with teams from different disciplines, such as product design, engineering, service design, behavioural psychology, usability engineering and business analysis can be very effective - especially when grounded by research insights. This has the advantage of bringing different perspectives, identifying new opportunities, driving creativity and importantly increasing patient advocacy within the team.

<table>
<thead>
<tr>
<th>Paper Media including IFU’s</th>
<th>Digital Media</th>
<th>Shipping packaging, storage container and/or administration device</th>
<th>Service</th>
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<tbody>
<tr>
<td>Use of plain language</td>
<td>Text messaging</td>
<td>Size minimisation</td>
<td>Reminder call service</td>
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<tr>
<td>Multi-language communications</td>
<td>Emails</td>
<td>Reduce operational steps</td>
<td>Multi-language advice line</td>
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<tr>
<td>Reward coupon</td>
<td>Website</td>
<td>Increase number of doses to reduce refills</td>
<td>Respond to questions seen on peer/social websites</td>
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<td>Map of local pharmacies</td>
<td>Mobile applications</td>
<td>Embedded electronics for counting, reminding</td>
<td>Online reordering</td>
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<td>Barcoding for transmission of product ID and quantity</td>
<td>Video</td>
<td>Wireless comms for monitoring and automatic refill order</td>
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<td>Electronic behaviour tracking</td>
<td>Wireless sensor integration</td>
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<td>Creating peer/social media sites for people living with conditions</td>
<td>Electronic reward (discount and/or gamification)</td>
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<td>Big data analytics</td>
<td>Implantable drug-release devices</td>
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Table 2: Potential patient intervention opportunities

Figure 3: Stakeholder map

Figure 4: Transtheoretical model

Human-Centered Design offers a range of research techniques which can look at this problem from many angles. Categorised as ethnographic, participatory and evaluative,
It also gets around the silos that can exist in large multinational corporations (described here). With concepts generated, early-to-late stage user studies and consultation with stakeholders are recommended to ensure solutions are well targeted and adoption barriers are avoided.

**Connected health & adherence**

Exploring wirelessly-connected packaging and digital apps as potential solutions is understandable and expected. The enabling technology is ubiquitous, digital interfaces have become easier to use and regulators, while remaining vigilant, are receptive to emerging concepts generated, early-stage user studies and consultation with stakeholders are recommended to ensure solutions are well targeted and adoption barriers are avoided.

Likewise, other stakeholders can be direct beneficiaries of Connected Health—like the digital Helius system being an example; it can report swallowing events of Proteus smartpills to family members of the patients who struggle with adherence.

Connected Health solutions for adherence can also serve as a platform to deliver other forms of value; to connect digitally with monitoring devices to improve drug therapy evaluations, to detect counterfeit drugs by sending serial numbers to suppliers, to sense when a drug is running out for auto-reordering, and to help promote lifestyle changes complimentary to drug therapy, e.g. more exercise for diabetes patients.

**Summary: delivering core business aspirations**

There are many digital product and service design opportunities to improve medication adherence but the landscape of patient and stakeholder issues is complex. However, there are many well-proven approaches and processes, such as Human-Centered Design, that can deliver well-targeted and effective adherence solutions.

Controlling commercial risk can be the main driver for developing adherence solutions but it can also deliver on medical device and pharma companies’ core business aspirations - an opportunity to innovate, to be closer to patients and an opportunity to deliver better clinical care to drug therapy, e.g. more exercise for diabetes patients.

Sources:

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Chris has experience of conducting formative and summative usability studies across a range of medical devices. He has experience across healthcare, defence and aerospace. Before joining PDD, he spent five years working on the EPSRC funded CH-IRED research project, investigating ways to make medical products safer.

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- **TECHNOLOGY & INVENTION ENGINEERING DESIGN & ANALYSIS**
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