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

Figure 1: Glowcap wireless pill bottle and router

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.

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"

Figure 2: Patient-related issues

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).

Recommendations to Improve Medication Adherence	
For Medical Device / Pharma companies	For Healthcare teams including pharmacists
Direct to consumer models	More cost-effective care regimes
Provide training and support	Simplifying drug combination regimes where possible
Integrate adherence solutions in packaging	Customise regime fit for patient type and profile
Engage with patient forums / monitor real world use	Increase plain language communication
Usability testing	Develop communication method to foster trust & elicit patient concerns
Increase plain language communication	
Educate more on conditions, risks, benefits and instruction	Understand patient barriers
Improve adherence measurement methods	Engage with patient care givers
Develop drug formats and formulations where prescription refilling is minimized	Improve follow-ups and counselling
	Improve adherence measurement methods

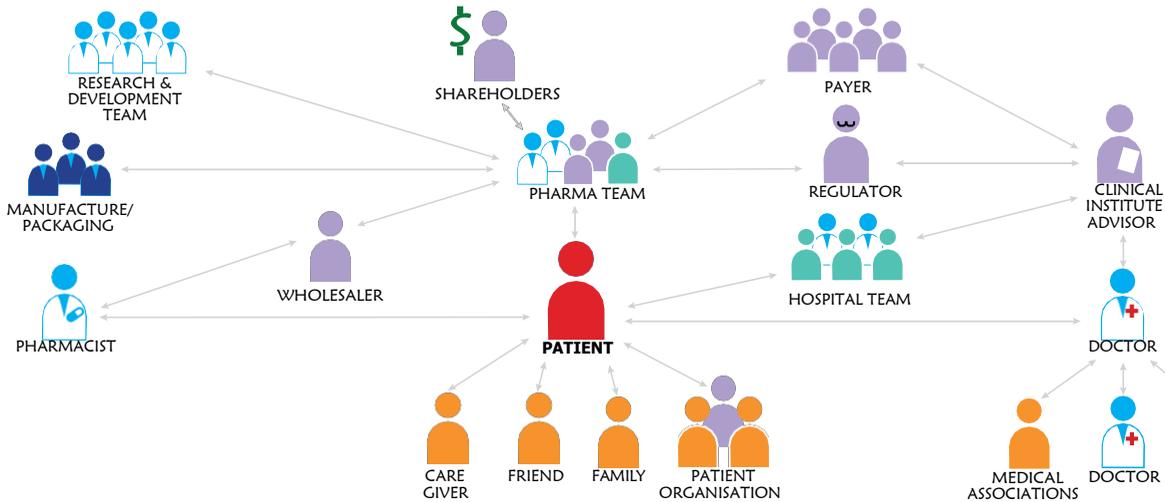*Table 1: Recommendations collated from adherence reports*

Figure 3: Stakeholder map

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,
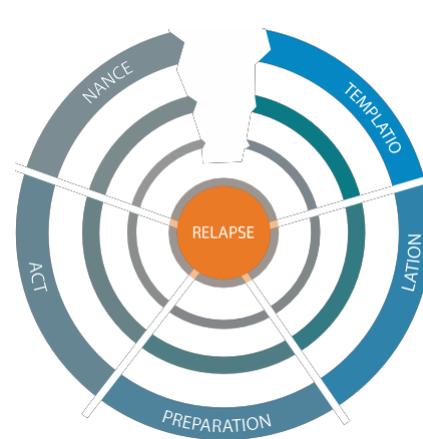

Figure 4: Transtheoretical model

Human-Centered Design offers a range of research techniques which can look at this problem from many angles. Categorised as ethnographic, participatory and evaluative,

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.

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

Table 2: Potential patient intervention opportunities

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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 digital solutions as seen by the FDA publication of its guidance document for Medical Mobile Applications (and more recent publications on cyber-security).

mHealth, or Connected Health, does need careful consideration. Patient information confidentiality, product cost, the use of uncontrolled third-party components, data ownership and physical portability

Figure 5: Electronic health data integration

must align to what regulators, payers and patients would accept. People that need most help with adherence may not be the most comfortable with technology. The potential for digital exclusion needs to be considered and mitigated

However, if the solutions are easy-to-use and targeted correctly, Connected Health has great potential to deliver impactful and customisable solutions for fostering behavioural change, education, communication and even deliver delightful solutions for better patient engagement.

Likewise, other stakeholders can be direct beneficiaries of Connected Health- with 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.

Figure 6: Helius digital app & Proteus smartpill system

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