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About DCA...

- · Based in the UK,
- 130 strong development team
- One of the World's leading product development consultancies.
- Extensive experience in drug delivery device development
- We offer a support to our clients in activities ranging from product strategy and planning, through design development, to production support





1

The adherence problem

We are going to break the presentation down into three areas. We will start by putting the adherence problem it context by discussing its scale.

We will then discuss the importance of taking a systems view.

Finally, we will end by discussing what this could mean for device design.

2

The importance of taking a systems view

3

What this means for device design



The adherence problem So let's start with the wider adherence problem then...

2

The importance of taking a systems view

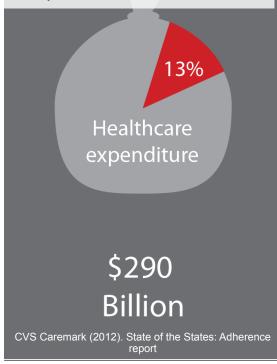
3

What this means for device design

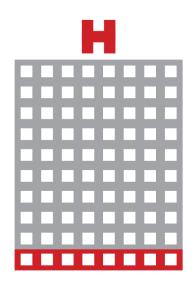


It is incredibly difficult to measure the impact of adherence as what is in, and out, of scope can be open to interpretation; however, if we start by looking at figures for the USA we can see that cost estimates are around the 300 billion dollar mark. To put this into perspective, this accounts for around 13% of the healthcare expenditure.

Or in slightly more human terms, estimates suggest that it accounts for 10% of hospital admissions and 125,000 deaths a year. And this is just the USA remember.

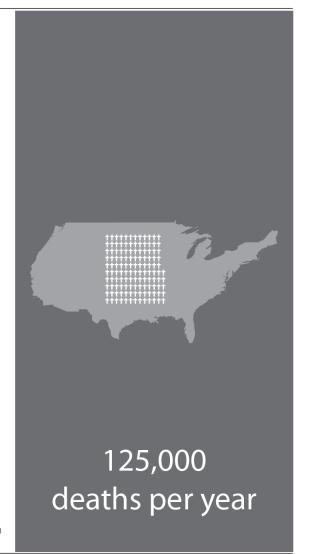


US estimates:



10% of hospital admissions

Smith DL. Compliance packaging: a patient education tool. Am Pharm. 1989;NS29(2):42–45. 49–53.





It's important to bear in mind that it's not a first world problem either, according to the World health organisation around 50% of patients around the globe with long term health issues don't take their drugs as prescribed.

50% of patients around the globe with long term health issues do not take drugs as prescribed

World Health Organisation report (2003). Adherence to long-term therapies: evidence for action. ISBN 92 4 154599 2





The most common approach to tackling adherence revolves around reminding patients when to take their medicine, or providing some feedback that the medicine has been taken. For example dose counters.

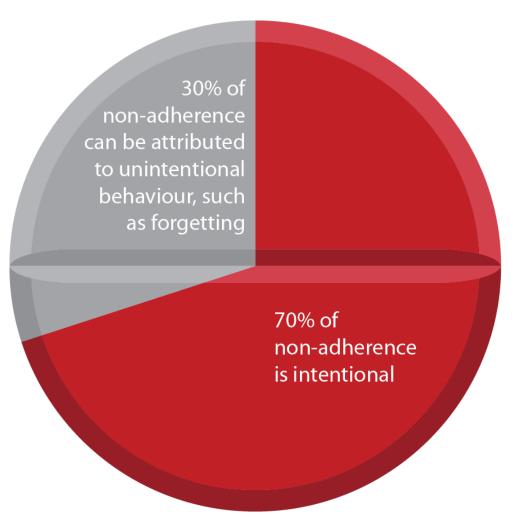
These are, of course, a very critical part of tackling the problem. They are particularly useful for patients with some form of cognitive impairment or simply those with very busy lives.





But they are just that one part of the problem. They only really address unintentional nonadherence, that is patients forgetting to take their pills.

They do nothing to address the patients who are electing not to take their drugs as prescribed. Like all things with adherence, it's very hard to measure; however, some estimates place intentional nonadherence as high as 70%



Reid. K (2012). The Heart Of The Non-Adherence Epidemic.



1

The adherence problem

So adherence is clearly a big problem; furthermore, we know that we can't fix the whole problem with reminders alone. Clearly we need some form of systems solution.

2

The importance of taking a systems view

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What this means for device design



It would be fair to say that the more parts of the system you have influence over, the easier it is to have a systems impact.

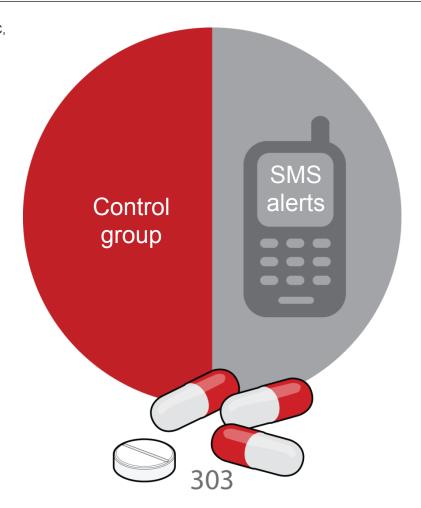
Accordingly, health providers are probably best placed to have a big impact on this issue. Those supplying drugs also have opportunities. Basic interventions such as simplifying treatments and discussing them in detail can be critical.

The way drugs are dispensed also has an important role to play and there are some very interesting solutions already in use.





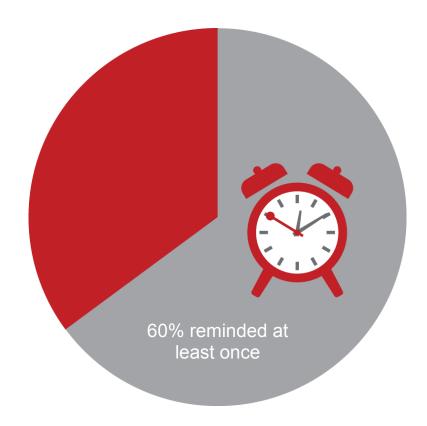
A recent study, picked up by the BBC, highlights the importance of systems thinking. The study involved 303 participants; half of which received SMS alerts prompting them to take their drugs, while the other half, the control group, received no intervention.







So what did it show, well first off the reminders were helpful. In fact, 60% reported that they were reminded at least once to take a dose that they may have forgotten. This is perhaps unsurprising.

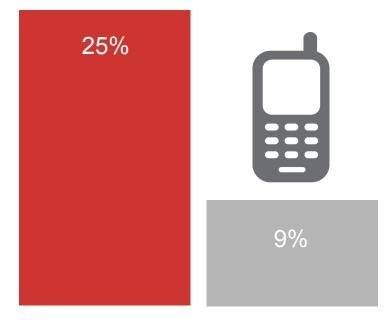






What gets a bit more interesting is what else the study found. When comparing drop out rates – that is those either stopping completely or taking less than 80% of their medication. We can see that this dropped from 25% in the control group, to 9% in the those receiving text messages.

The much lower drop out rate is attributed to the engagement after the users reported that they were not taking their drugs. Participants were asked to text back if they had decided to not take their drugs. They were then called back and a conversation was had.



Stopped taking medication or continued to take <80%





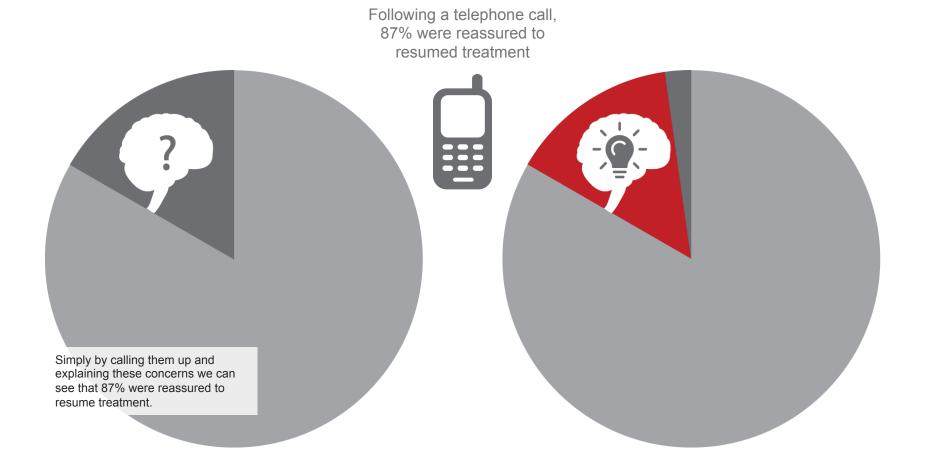
The study showed that 15% did not take their medication on at least one occasion, because of uncertainty over the need for treatment, concern over sideeffects, or another medical illness.



15% did not take their medication on at least one occasion, because of:

- uncertainty over the need for treatment,
- · concern over side-effects
- or another medical illness







1

The adherence problem

So it's clear that there are many opportunities at a systems level; however, what can device manufactures do to play their part?

2

The importance of taking a systems view

3

What this means for device design



As the study showed, perhaps the most powerful tool in tackling the issue of intentional non adherence is engagement.



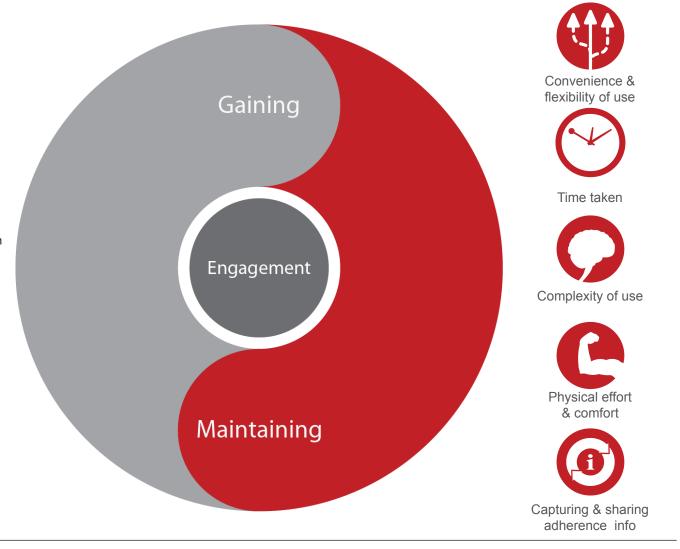


We can divide the task of engagement into two; gaining engagement and maintaining it. Gaining Engagement Maintaining

DCA

When it comes to maintaining engagement, products need to be convenient to use, it needs to be quick to set them up and deliver the drug, they need to be simple and intuitive, they should also be comfortable to handle and use and the forces required should be carefully considered.

Where practical products should also capture and potentially share information on adherence.





Turning our attention to gaining engagement, this can be broken down into three areas. Understanding the context, developing an emotional connection and providing information that the user can relate to. Understanding Convenience & flexibility of use Gaining the context Time taken Developing Engagement emotional Complexity of use connection Physical effort Information & comfort Maintaining that the users can Capturing & sharing adherence info



Understanding the context

... a journey

Understanding the context involves exploring the journey that the user goes on. This involves considering the condition and how it shapes users lives as well as the routine of drug delivery and how this interplays with the rest of the user's life.

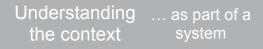
Taking a simple example, getting kids to brush their teeth is important for their oral hygiene. For those of you with kids, the concept that different things appeal to kids at different ages will be nothing new. However, this simple insight formed the basis of the development of Aquafresh's new range.

This steps from teething rings to engage parents on the need to consider oral care as soon as possible through to first toothbrushes with smaller heads, to characters with smiling teeth for infants, through to more grown up yet still playful brushes for older children.



Aquafresh is a brand of GSK consumer healthcare





Considering a product in its wider context of use is also critical. This involves considering the artefacts around it that it may have to interact with.



Falck

Falck



Developing an emotional connection

... out of the medicine cabinet

Developing more approachable products is a key part of moving products out of the medicine cabinet.



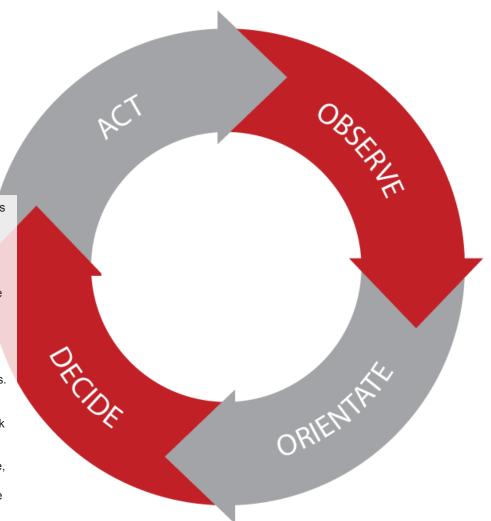
Clearasil is a brand of RB





Information that the users can relate to

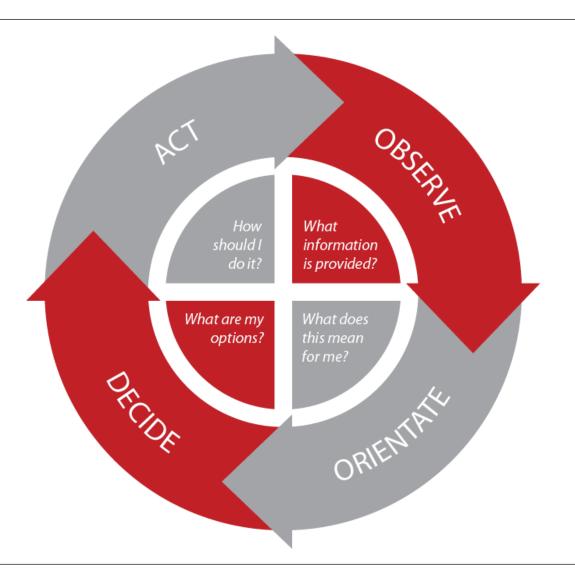
Intentional non-adherence involves the patient making a decision not to take their drugs as prescribed. One approach to tackling this is to view the patient as an irrational decision maker. With this view in mind, each perceived 'flaw' can be taken in turn and addressed to identify new ways to make people more motivated, to stop people doing something, or to persuade them to do something else. Fear tactics are just one example of this. Where the negative consequences of non-adherence are highlighted to patients to shock and scared them into changing their behaviour. The efficacy of these fear tactics are questionable, moreover, they can lead to patient anxiety, often in patients who have no issues with adherence.





The other approach is to consider the patient as a rational decision maker. Borrowing from other decision making models, it is possible to decompose the decision making activity into four stages.

The user starts by observing information, they then orientate this information to their specific case, this is then used to inform their decision about whether to take the drug and finally the act.





Information that the users can relate to

... directly addressing the patient

Information should be presented in a way that the user can relate to. Presenting information in terms that allow users to orientate it to their specific situation is an important part of this.

What this drug is for:

To make it easier to fall or to stay asleep

Who might consider taking it:

Adults age 18 and older with insomnia for at least 1 month

Recommended monitoring:

No blood tests, watch out for abnormal behavior

Other things to consider:

Reduce caffeine intake (especially at night), increase exercise, establish a regular bedtime, avoid daytime naps

Lunesta

(compared to sugar pill) to reduce current symptoms for adults with insomnia

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How long has the drug been in use?

Lunesta was approved by FDA in 2005. As with all new drugs we simply don't know how its safety record will hold up over time. In general, if there are unforeseen, serious drug side effects, they emerge after the drug is on the market (when a large enough number of people have used the drug).

Lunesta Study Findings

at difference did LINESTA make?

788 healthy adults with insomnia for at least 1 month – sleeping less than 6.5 hours per night and/or taking more than 30 minutes to fall asleep – were given LUNESTA or a sugar pill nightly for 6 months. Here's what happened:

People given

People given LUNESTA

what difference did LUNESIA make?	a sugar pill	(3 mg each night)
Did Lunesta help?		
LUNESTA users fell asleep faster (15 minutes faster due to drug)	45 minutes to fall asleep	30 minutes to fall asleep
LUNESTA users slept longer (37 minutes longer due to drug)	5 hours 45 minutes	6 hours 22 minutes
Did Lunesta have side effects?		
Life threatening side effects:		
No difference between LUNESTA and a sugar pill	None observed	None observed
Symptom side effects:		
More had unpleasant taste in their mouth	6%	26%
(additional 20% due to drug) More had dizziness	3%	10%
(additional 20% due to drug) More had dizziness (additional 7% due to drug) More had drowsiness	3% 3%	10% 9%
(additional 20% due to drug) More had dizziness (additional 7% due to drug) More had drowsiness (additional 6% due to drug) More had dry mouth		
(additional 20% due to drug) More had dizziness (additional 7% due to drug) More had drowsiness (additional 6% due to drug) More had dry mouth (additional 5% due to drug) More had dry mouth (additional 5% due to drug) More had nausea (additional 5% due to drug)	3%	9%

http://www.npr.org/blogs/health/2014/07/25/333726737/how-well-does-a-drug-work-look-beyond-the-fine-print



Information that the users can relate to

... providing the right options

More choice is not always a good thing. Too much choice can lead to decision paralysis, thus its important to consider and control the number of options available.

30% purchased when confronted with 6 choices

3% purchased when confronted with 24 choices – decision paralysis















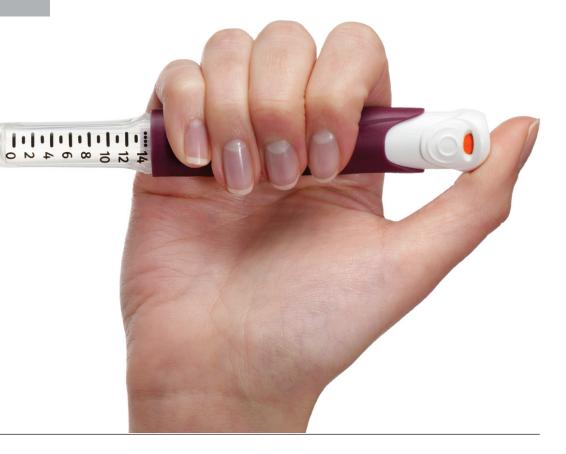
Iyengar., S.S. & Lepper, M.R. (2000). When Choice is Demotivating: Can One Desire Too Much of a Good Thing? Journal of Personality and Social Psychology, 79(6)995-1006



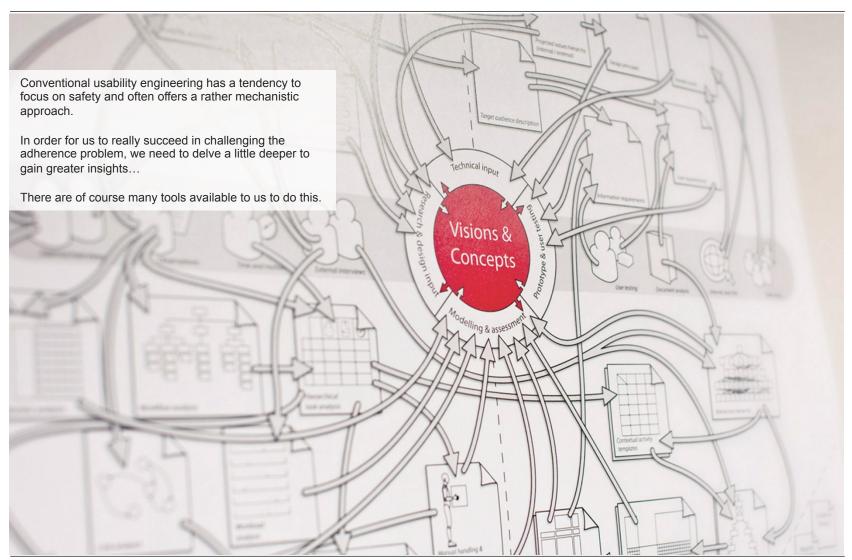
Information that the users can relate to

... providing the right options

Rather than requiring the user to select the defined dose and dial this up from a single device – the choice and range of options is simplified to picking a pen.





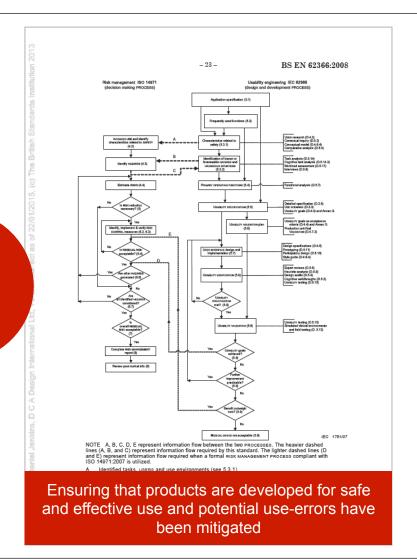




ISO 62366 focuses on safe and efficacious use and human factors plays a critical role in ensuring this.

Human factors can also play a critical role in getting them to use them.

Getting them to use it





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