



White paper:

Understanding the psychological blocks in medicine-taking: How pharma can help

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EXECUTIVE SUMMARY

Studies have shown that patients across all therapeutic areas, geographies, nationalities, levels of social status and any other variable, fail to take their medicines as prescribed. What this growing body of research cannot reveal, however, is how they might be persuaded to change their behaviour.

This white paper hones in on the psychological factors preventing patients from doing what the best medical evidence suggests and considers how pharma companies can help. After presenting a picture of the costs stemming from non-adherence that ricochet throughout healthcare, it looks at questions of trust in both the medical profession and the industry and how it is no-one's specific responsibility to work with patients to understand their particular self-management challenges.

The mechanisms of adherence are then explored in terms of both intentional and non-intentional behaviour, the former being not only far more prevalent but also harder to address. Three core factors are revealed. One relates to questions of motivation, addressed by the psychological consultant to the Great Britain Olympic rowing team. Others relate to a person's propensity to imagine the future, their general levels of defiance and their need for autonomy.

But perhaps most critical of all is that the factors affecting adherence are not exclusive to medicine-taking and secondly, that they revolve around patients understanding the need for medicines in terms that make sense to them. The collaborative efforts of both healthcare providers and the pharmaceutical industry to become more patient-centric could hardly be more timely.



White paper:

Understanding the psychological blocks in medicine-taking: How pharma can help

Key terms

Adherence: Following medical advice, e.g. taking medicines as prescribed. Conversely, non-adherence is the failure to adhere to such advice / take medicines as prescribed.

Non-intentional non-adherence: Passively failing to adhere to medical advice / taking medicines as prescribed, e.g. forgetting to take medicines.

Intentional non-adherence: Deliberately failing to adhere to medical advice / taking medicines as prescribed, e.g. adapting medicines use to suit personal needs.

Concordance: A shared agreement between physician and patient around appropriate treatment advice / taking of medicines – a key first step in tackling non-adherence.

Compliance: An older term, often used interchangeably with adherence, but implying a less empowered (and therefore less accurate) role for the patient in managing whether they take medicines as advised.

There are few assumptions in healthcare as erroneous, as damaging and as expensive as the idea that patients will, or even should, follow doctors' orders. Even when it is known that between a third and a half of all prescribed medicines are not taken as directed and 70 percent are discontinued within one year, most of the effort to understand why this is the case has implicitly assumed the patient is somehow at fault.

Dr Colleen A McHorney, Director of Patient-Reported Outcomes at Covance Market Access Services and a veteran researcher on the subject, has pointed out that more than 90 percent of the some 40,000 articles published on adherence focus almost entirely on what patients are, or are not, doing as regards their treatment rather than seeing it as a complex multi-dimensional problem where trust in healthcare professionals is critical.¹

“There is no way of knowing the extent to which these risks are personal to you so if your condition is not that serious and you read there is a risk, however small, of dying, it can easily seem that the side effects are simply not worth the risk”

There is also the question of trust in the industry and most people's inability to understand how to compute the risks and benefits of the medicines they are prescribed. Charles Abraham, Professor of Behaviour Change at the UK's Exeter University, says it can be an entirely rational response for patients not to take their medication after reading some of the patient-information leaflets, which our industry is obliged to produce as part of the regulatory process. “These are written in very small type and are a terrifying and destructive way of putting over the risks about taking drugs,” he says. “There is no way of knowing the extent to which these risks are personal to you so if your condition is not that serious and you read there is a risk, however small, of dying, it can easily seem that the side effects are simply not worth the risk.”

To compound matters, the language used in framing the discussion on adherence presents an interesting and unresolved paradox given that ideas of patient centricity and autonomy are simultaneously gaining traction. The fact that as many as 70-80 percent of patients are deliberately non-adherent illustrates this paradox and suggests a serious disconnect between healthcare systems (providers and the pharmaceutical industry) and patients, which has implications for all concerned.

Costs of non-adherence

In terms of the costs to society, the Council for Affordable Healthcare has estimated that poor adherence in the US accounts for \$290 billion and 125,000 deaths per year.² This figure comes from a 2009 New England Healthcare Institute study that also includes the costs of suboptimal prescribing, drug administration and diagnosis.

Adherence figures in the US for various conditions are shown in Figure 1.

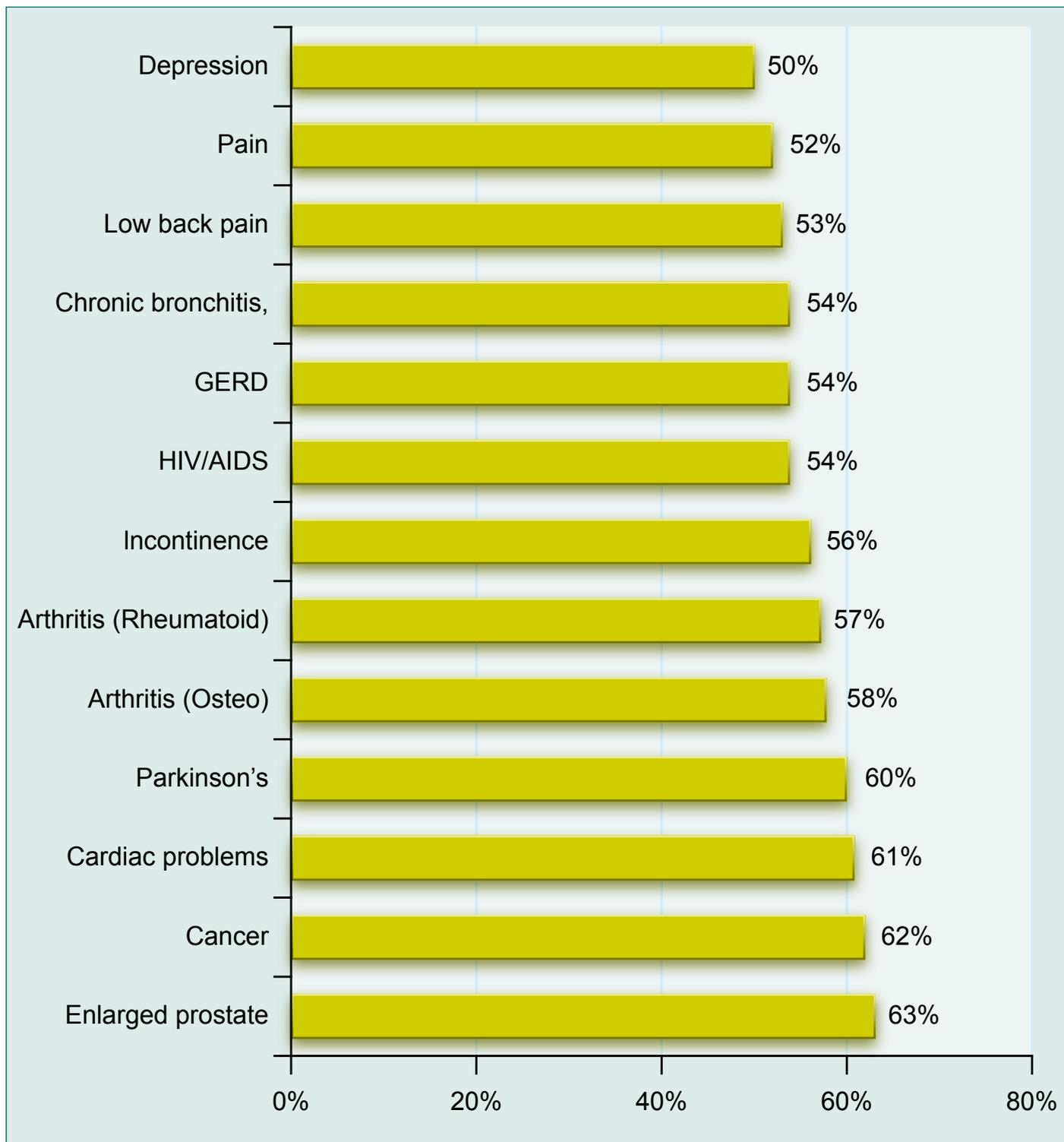


Figure 1: Adherence rates of selected conditions in the US³

A 2007 survey conducted by the National Community Pharmacists Association provides another perspective of the problem, revealing:⁴

- 49 percent of respondents have forgotten to take a prescribed medicine
- 31 percent of respondents have not filled a prescription
- 29 percent of respondents have stopped taking a medicine before the supply ran out
- 24 percent of respondents have taken less than the recommended dose.

Whichever way one looks at the problem, significant numbers of patients in all therapeutic areas are choosing autonomy over compliance with the directives for taking medicines as prescribed. If one takes the Medication Possession Ratio (MPR), which measures the ratio of the total days of the supply of medication dispensed divided by the number of days of the evaluation period, studies have shown insufficient adherence (MPR < 80 percent) in around 25 percent of hypertensive patients, 35 percent of diabetics and 63 percent of people being treated for hypercholesterolaemia.⁵

Non-adherence is not confined to the US either. Capgemini Consulting reports that in Australia, only 43 percent of asthma patients take their medication as prescribed and just 28 percent use prescribed preventive medication. The picture is the same in developing countries. In China, the Gambia and Seychelles, only 43 percent, 27 percent and 26 percent of patients respectively with hypertension adhere to their medication regimen.⁶

When patients decide not to medicate, the impact is detrimental to both them and the broader healthcare ecostructure. For the pharmaceutical industry, it has been estimated that non-adherence results in an average per-drug loss of 36 percent in potential sales.⁷ More importantly, as payers around the world increasingly make reimbursement decisions conditional on how medicines are taken in the real world rather than a controlled clinical trial; it is likely that the costs to pharma will rise as non-adherence means worse patient outcomes and therefore less likelihood of continuous reimbursement for medicines.

And it is the costs to patients from not receiving the best healthcare possible that is arguably the strongest motivating factor for addressing these issues around adherence.

Conventional understanding about how patients take medications

Conventional healthcare research sheds some light on this subject. From the numerous studies that have been conducted, various factors stand out, as grouped below:⁸

- **Concerns about the medication:** Studies have shown that around 45 percent of patients don't take their medication because of fears about their side effects. Other factors include the impression they are already taking too many medications, fear of addiction and worries about what others will think about the medication.
- **Impressions that the medication is unnecessary:** This can be either the idea that the medication was never needed or, after taking it for a while, the patient starts to feel better. This is about the psychology of prevention where, for example, a patient stops taking their blood pressure medication when they see it is under control, not understanding the drugs impact the readings. In some people, the non-adherence can be directly linked to denial of the underlying condition because each time they take their medicine they are reminded of it.
- **Financial worries:** Any out-of-pocket expenses can be a hindrance to adherence. A 2012 literature review in *Pharmacy & Therapeutics* of articles relating to adherence and the extent of the co-pay US patients are charged showed that "of those that evaluated the relationship between changes in cost sharing and adherence, 85 percent showed that an increasing patient share of medication costs was significantly associated with a decrease in adherence".⁹

- **Forgetfulness:** Some patients simply forget to take their medication properly or to renew their prescription.
- **Cultural or religious beliefs:** Some cultural or religious beliefs can make people hesitate or refuse medication. In many cases, patients don't tell their physicians and accept the prescription, but do not take the medication, or even fill the prescription.
- **Depression:** A number of studies have shown that depressed patients are not as adherent to treatment as those who do not suffer from depression, or other mental health conditions. This has obvious implications for anti-depressants but also applies to other medications they are prescribed.
- **Inability to follow treatment:** Some patients are simply unable to follow their treatment, for health literacy reasons. A 1995 study based on US patients found, for example, that 33 percent were unable to read basic healthcare materials; 42 percent could not comprehend directions for taking medicines on an empty stomach; and 26 percent were unable to understand information on an appointment slip.¹⁰ No official figures are available in the UK but GP and National Clinical Lead in Self-Management and Health Literacy for the Scottish Government, Graham Kramer, suggests 47 percent of working age people cannot calculate the safe dose of paracetamol to give to a child from the instructions. And that some would not be able to find an X-ray department when signposted as radiology.¹¹

While these various reasons remain perfectly valid, efforts to address them have not shown significant results except where unintentional causes of non-adherence are concerned. In cases of forgetfulness, for example, blister packs or reminders have been found to make a difference and are widely deployed in mobile apps, smart packaging initiatives and disease management programmes, where someone contacts the patient specifically to tell them it is time to take their drugs.

Mechanisms of intentional non-adherence

However, the far more challenging aspects of non-adherence revolve around intentional behaviour. To enable effective interventions in such cases it is important to understand the basic mechanisms of intentional non-adherence. Dr Gérard Reach of the Department of Endocrinology, Diabetes and Metabolic Diseases at Avicenne Hospital in Paris, France, believes that it must be seen as a general problem of human behaviour and not specific to taking medication. He asks why it is that even some doctors continue to smoke, for example, and for there to be an obesity epidemic when the premium on being thin could hardly be higher.

His research has therefore focussed on those psychological issues that he believes have a bearing on adherence. One is simply a question of will. A related factor is that patients can just get bored once the excitement of the initial diagnosis has worn off, leading to a gradual tapering of enthusiasm to take the medication, which can be demonstrated in any number of studies.

One example found the MPR decreases gradually to around 50 percent after two years of treatment, regardless of the medication.¹² And research by Capgemini Consulting shows in Figure 2 that average adherence rates are as high as 69 percent on the first prescription but this falls to 63 percent on the first refill, 53 percent by six months and 43 percent after the first six months.¹³

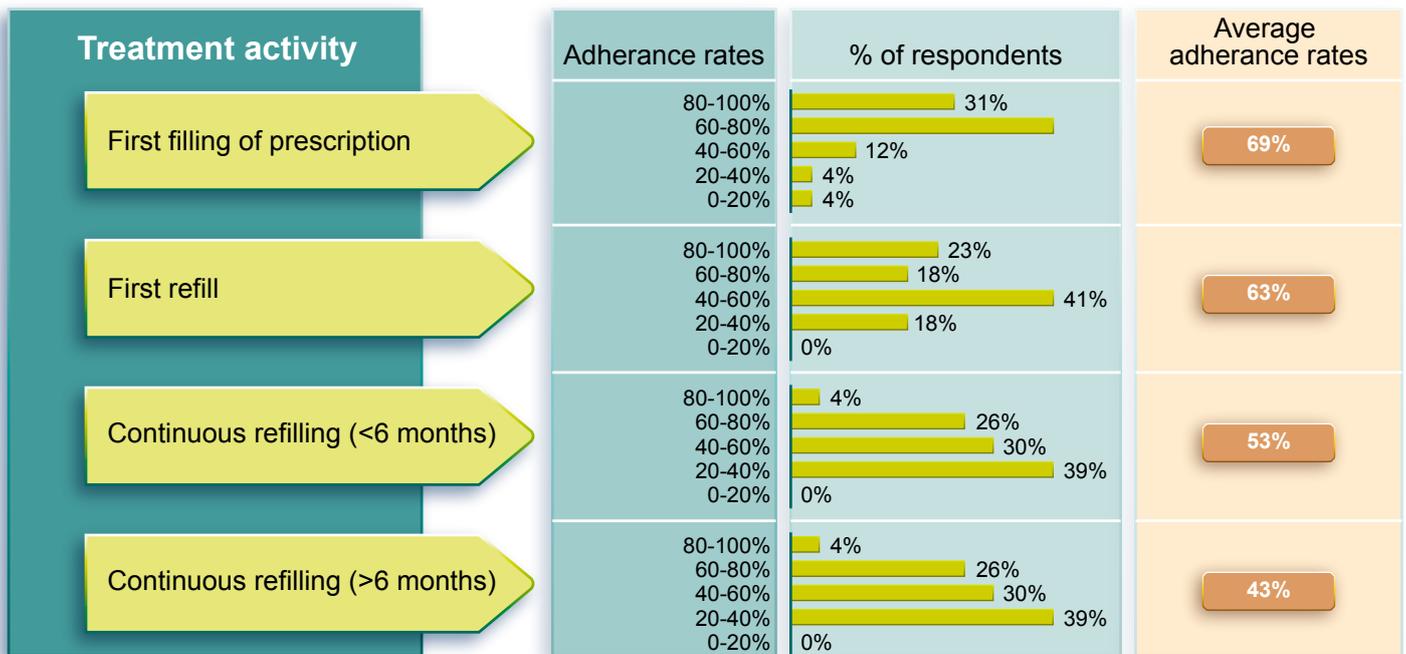


Figure 2: Adherence rates across the duration of therapy¹⁴

If boredom is recognised as a valid cause of non-adherence then Dr Reach says the solution is to create the habit to take medication. He cites the example of other ‘boring’ pursuits, such as brushing one’s teeth morning and night. This is not because people like cleaning their teeth but because it is so ingrained there is no effort involved. “People who have the habit to exercise do so,” he says. “It is like brushing teeth. Habits require no effort and people are lazy.”

Patience or, more accurately, the ability to prioritise the future, is another human factor he has identified as a mechanism affecting adherence. “People are impatient and want results in the short term,” he says. “This is why they continue to smoke and persist in other unhealthy behaviours. What is short term is concrete and what is long term is abstract. Another reason they are non-adherent is because they are disobedient. They don’t do what they are asked to do because they want to show they have free will.”

His research provides plentiful evidence of these points. Non-adherence is typically higher in younger patients, for example type 2 diabetics, who have been particularly shown to find it harder to visualise the future. And when it comes to ‘disobedience’, the percentage of obese diabetics who say they don’t fasten their seat belt when in the rear of a car is twice as high among non-adherers to medication as it is with the adherent group.¹⁵

“Research shows this is a general problem,” he continues. “A study shows women who are adherent to bisphosphonates are also adherent to statins and that they are more often non-smokers... Thus, a patient who is adherent to a recommendation, whatever it is, is also adherent to recommendations in general.”¹⁶

The implications of these revelations are that patients can be segmented accordingly. If non-adherence is due to a weakness of will, motivational techniques may help, aiming to help the patient clarify not only their barriers blocking the effective realisation of their treatment but also the advantages of that treatment.

If the non-adherence is due to the inability of patients to project themselves into the future, the solution could involve finding intermediate objectives that make sense to the patient. And if non-adherence is due largely to a defiant nature, presenting a treatment in a non-authoritative way and suggesting the final decision is in the patient’s hands could help.

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“Control, confidence and connectedness are the three key pillars in improving the quality of a person’s motivation”

Learning from the Great Britain Olympic rowing team

Chris Shambrook, director of UK-based K2 Performance Systems and a psychology consultant for the Great Britain Olympic rowing team since 1997, explains how self-determination theory works in honing personal motivation.

“We talk about control, confidence and connectedness,” he says. “These are the three key pillars in improving the quality of a person’s motivation. We want people to understand what motivates them and to have a sense of control or autonomy about that. We also want people to be clear about their confidence in being able to do what is being asked of them. And there is also a dimension of connectedness or shared purpose. If a person maximises these three things and takes individual responsibility for their performance, then their focus will be good, they will persist for longer and their energy will be of a high quality.”

But aren’t Olympic rowers in a different category to people who won’t take their medication properly? Shambrook insists it makes no difference. In terms of control, for example, where patients can feel it is doctors or pharma companies telling them what to do, he says it is important to take the time to discern what shared success looks like. “For one person, it might be having the best quality of life to enjoy their grandchildren,” he says. “Now you have some vested interests as to why they might seek to keep the medication going. But although we can break down goals for people, we need to understand how they are going to engage with them. People can be told how to set goals in the same way they can be told how to take medication. But it is absolutely absurd. I can’t tell anyone how to set a goal that is meaningful to their personality.”

Priming motivation means taking into account personality differences. “Some people are motivated by the long-term big picture, to achieve something that hasn’t been achieved before,” he says. “With some it is by gathering data so they have an accurate feedback link to keep them investing in personal effort and there are others who like the day-to-day challenge of finding out how effectively they can develop their own ability on a given day. It is important to know how an individual is going to engage with these different ingredients to drive them to keep on track.”

Olympic athletes like to exercise their free will just like patients. “There are people who don’t want to train like everyone else; they want to retain their sense of individuality and it is important they feel heard and understood, that their uniqueness is recognised,” says Shambrook. “This relates to retaining control and is where patients and athletes assert that despite all this support, ultimately they are in control of their destiny however perverse it may be. There is still a rationale there even though it may seem irrational to the majority and this is key to getting the best performance out of someone.”

“Most doctors do not proactively monitor whether medicines are taken and patients don’t tell them because they don’t feel they have permission to do so”

Doctor-patient relationship

The doctor-patient relationship is recognised as the best vehicle to help people overcome the psychological obstacles in taking medications appropriately. The trouble, says Charles Abraham, is that the conversations that need to take place rarely happen. Physicians rarely have the time or appropriate incentives to help motivate patients to take their medicines appropriately and pharma companies have traditionally seen this as beyond their remit, due to the potential for interfering with the doctor-patient relationship.

“The actual pattern of drug usage, particularly in chronic disease, is very individual and needs to be negotiated with individuals and in particular within the family context,” he says. “But this isn’t done. Most doctors do not proactively monitor whether medicines are taken and patients don’t tell them because they don’t feel they have permission to do so. They don’t say they feel fine even though they only take the drug once every five days instead of every morning and evening. Without this kind of negotiation, the doctors never get feedback. They never get to hear what makes the drug ineffective because they simply assume that patients are taking the drug as it was prescribed.”

What can pharma do to help?

We know that patient engagement and support are relatively new areas for pharma companies and are gaining traction partly because regulators are increasingly asking for care packages to accompany drugs before they will grant a marketing licence. Many pharma companies are now working to provide material to educate physicians, pharmacists, patients and their families / carers on the importance of adherence. Merck, for example, has produced a booklet, the Adherence Navigator, which goes out to physicians and pharmacists outlining the dimensions of the problem and suggesting practical strategies to improve adherence. And several other companies (including Boehringer Ingelheim) are running behavioural change programmes, usually in conjunction with third parties, to improve health.

But, as Kevin Dolgin, president of French healthcare company Observia explains, there is still a long way for us to go. He points out that while patient adherence budgets have quadrupled over the past five years (to roughly \$1 million on average per product per annum, according to US data), spending on traditional promotional channels are still 30 times higher, as shown in Figure 3.¹⁷

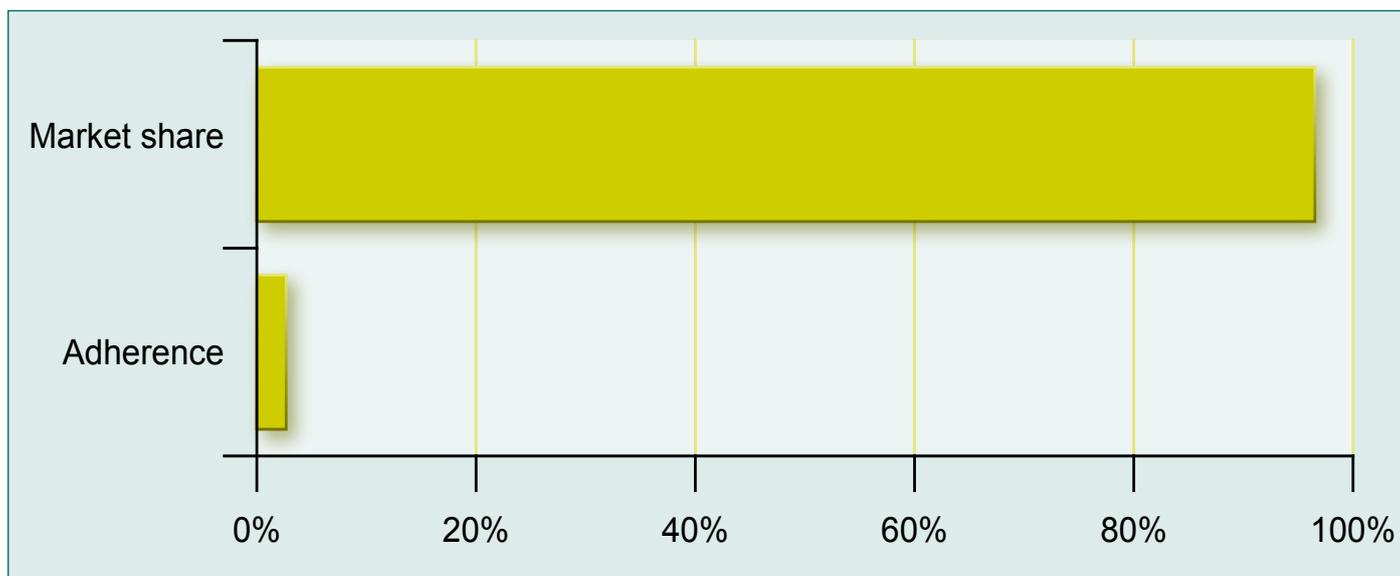


Figure 3: Pharma spending on market share and on adherence initiatives. Taken from: *The Business Case for Adherence Programmes*, Observia, October 2013.¹⁸

Moving beyond the patient information leaflet

Charles Abraham agrees there is more the industry can do. One suggestion is to address the patient information leaflet. Although it is a legal obligation for pharma companies to list all the side-effects of their products, he thinks the use of really small type and the language used is self-defeating.

“It can be seen as an attempt to hide the side effects, which really worries patients,” he says. “They should be written in lay language and in really large type. How pharma communicates to people about the risks of taking drugs as well as the personal risks to them is, I believe, a big part of the solution to the adherence issue.”

While the regulatory requirements around medically accurate patient information leaflets should be taken very seriously, the pharmaceutical industry can do more than just meet them. For example, a couple of initiatives we are rolling out at Boehringer Ltd at the moment are focussed on delivering more easily digestible information to patients, their families and carers about disease management, lifestyle, wellness and medications.

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Specifically, Boehringer Ingelheim Ltd is factoring in The Information Standard to all appropriate external communication, placing information on a number of Boehringer channels and platforms where patients can easily find it, to ensure what is presented is clear, accurate, balanced, evidence-based and up-to-date. The Information Standard is a certification scheme for all organisations producing evidence-based health and care information for the public, designed to simplify complex medical communication.¹⁹

Not only is this useful for patients, but there are benefits on all sides in disseminating information in this way (which links seamlessly with internal compliance systems, so the additional burden to pharma is minimal), specifically:

- Critically, improved engagement and feedback from patients and other healthcare stakeholders
- Better self-management of disease (78 percent of the public stated this could be achieved with quicker access to information they could trust)¹⁹
- Improved, more cost-effective and integrated pharma compliance processes, with clear differentiation between what is and isn't patient facing information
- Enhanced credibility, trust and reputation for the industry, with such activities acting as a point of differentiation and a way of driving positive change

Such multi-channel, regulated communication might sound like a sizeable task, but by adopting a lean, iterative development process whereby user feedback is quickly incorporated, it can be broken down into smaller, more manageable chunks. Of course, such initiatives also require changes to standard operating procedures and internal training, but the lessons that are being learnt by going through this process make it more than worthwhile.

Obstacles to pharma involvement

The regulatory environment can also be seen to inhibit direct contact with patients for those pharma companies not willing to invest in navigating it appropriately, something Amir Kishon, chairman and CEO of US-based healthcare company, Wellness Layers, believes is largely based on fear. He uses the analogy of skiing to highlight the fallacy of this approach. "When you are on a slope you have to lean forward," he says. "But one's instinct can be to bend backwards and then you lose control. To regain control you have to lean forward."

"Pharma may fear the risks but these are smaller than the benefits of engagement and adherence. If pharma wants to control its destiny it has to engage"

As an industry, we cannot be afraid to have these conversations, but there remains a certain level of fear within some pharma companies to engage digitally with patients because it may highlight adverse reactions to their drugs. This is akin to the skier who loses control by bending backwards. "Pharma may fear the risks but these are smaller than the benefits of engagement and adherence," he continues. "If pharma wants to control its destiny it has to engage."

But Dolgin quite rightly identifies a real win-win for those pharma companies brave enough to lean forwards and engage with patients to tackle adherence issues. If one views the issue in purely commercial terms, he points out that real-world outcomes are the new marker of success. "Pharma has traditionally considered revenue to be driven only by share of prescriptions, but prescribers only open the door to sales. Ultimately, it is the patient who determines the value to them and their value to manufacturers."

"So pharma companies can try to increase market share or market size via improved diagnostics or they can try to increase adherence. There are a lot of studies about the return on investment of adherence programmes and with such high rates of non-adherence, this is often the best option."

In reality, delivering patient benefit is just as important as a commercially successful industry that can reinvest in developing new medicines. Tackling adherence delivers clear and immediate benefits on both counts.

Patient engagement is only the start

Patient engagement to improve adherence rates is in fact only the start of a healthcare revolution as it responds to the digital world that has so profoundly changed other industries. Eric Dishman, general manager of Intel's Health Strategy and Solutions Group, recently gave a fascinating TED talk entitled 'Healthcare should be a team sport',²⁰ in which he outlines how patients are learning how to look after themselves via networked mobile technology interfacing with coordinated health teams and based on their own healthcare goals, which may or may not be the often assumed goal of longevity.

The missing mile

We recognise that the pharmaceutical industry, and its partners, needs to go further with tackling adherence and work together on this with patients. Without sufficient commitment in this way, pharma companies risk being like an architect who designs a great house for its conceptual look and feel, without checking that it can ever actually be practically lived in.

As an industry, we create great medicines that have the potential to transform patients by treating often terrible illnesses, but these medicines can sometimes have the potential to be even better, and have a greater impact on more people, if only compliance issues were tackled early on...compliance issues that can sometimes only be solved by truly involving patients in the process.

Without considering such 'patient-centred' medicines adherence, novel treatments - fresh from the researcher's bench after a decade or of hard work - will always feel like the beautiful designer house that no one can live in. This is the missing mile.

"The patient is critical," says Kishon. "The missing mile requires forward engagement. There are industries that know how to engage and pharma companies could learn from them." He mentions how the thinking behind Weight Watchers and the twelve steps programme to battle addictions can help with adherence and urges a three-pronged approach to engagement involving a so-called me-we-info approach based on:

- ME: Guided personal plans, incentives and apps to empower users
- WE: Brand-centric, closed social support networks
- INFO: Personalised and actionable content

In many ways, effective adherence programmes will lead to a kind of personalised medicine that is well within our grasp. "People talk about personalised medicine but that is about genetics," says Dr Reach. "There is a whole aspect of this that is possible now, which is about self-care, about taking medicines that suit patients' personal goals and their personal context."

Conclusion

As outlined above, the challenges around medicines adherence are many and complex, requiring coordination across numerous healthcare stakeholders to deliver meaningful impact. Critically, effective solutions cannot be applied 'to' the patient, but must actively involve them and secure their buy-in to work. This necessitates addressing the psychological aspects of both intentional and non-intentional non-adherence, with clearer communication playing a pivotal role here.

For the pharmaceutical industry, this means taking a more whole person view of adherence; working both directly with patients and families / carers themselves and broader healthcare systems to ensure the benefits of using medicines as intended are not only described, but taken on board. In broad terms this encompasses three key aspects. Firstly, information must be presented in such language that people can easily understand. Secondly, patients must be able to translate the clinical benefits of adherence to tangible personal benefits impacting them or their friends and families and, thirdly, they must trust the information being presented.

Adherence programmes are a start and the pharmaceutical industry is well positioned to move this along, delivering better outcomes from its new medicines, but also increasing trust by working more closely with the patient, the central and indisputed figure in modern healthcare systems.

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- Charles Abraham, Professor of Behaviour Change at the Exeter University, UK.
- Kevin Dolgin, President of Observia, France.
- Amir Kishon, PhD, Chairman and CEO of Wellness Layers, US.
- Professor Gérard Reach of the Department of Endocrinology, Diabetes and Metabolic Diseases at Avicenne Hospital in Paris, France.
- Chris Shambrook, Director of K2 Performance Systems, UK.

Some of the ideas discussed in this white paper will also be covered in the forthcoming book by Gérard Reach, *The Mental Mechanisms of Patient Adherence to Long Term Therapies*, in the Philosophy and Medicine series by Springer.



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Boehringer Ingelheim

Boehringer Ingelheim was founded in 1885 and is a family owned company. We are the largest privately owned pharmaceutical company.

Our vision, 'Value through Innovation', reflects our belief that, as well as being financially profitable, products should be pioneering and of genuine benefit to patients. Our independent status frees us from stock market expectations, and allows for long-term strategies, rather than short-term priorities.

We believe that we share one fundamental principle with the NHS: we both put patients at the heart of what we do.

Hannah is Patient Engagement and External Affairs Manager at at Boehringer Ingelheim, with responsibility for developing company insight into patients, their families and carers, and working with and learning from those who have the power to influence patients outcomes (e.g. public officials, politicians, professional medical bodies and the 3rd sector) as part of creating value beyond the pill.

Hannah currently Co-Chairs th ABPI Patient And Pharma Working Group and is a Trustee of a UK health charity in her spare time. Previous to being at Boehringer she worked at Marie Curie Cancer Care as their Public Affairs Manager and previous to this in the creative industries. As well as Hannah's professional insights into the UK Health and Social Care System, Hannah's passion and concern for this subject derives from her experience as a patient where her mother was her full time carer. Hannah's current work at Boehringer is to understand and work patients, families and carers in order that Boehringer can create the best information, products and services with them and for them and look beyond traditional Pharma model to new innovations to solutions.



To discuss the issues raised in this white paper, Hannah can be contacted by emailing Hannah.Gagen@boehringer-ingelheim.com or calling +44 (0)1344 746860.

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