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## ADHERENCE

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## MOSTLY COMPLEX AND NOT VERY EFFECTIVE

The situation with medications adherence at the turn of the millenium was epitomised by the conclusion of a Cochrane systematic review<sup>1</sup> that read, 'The full benefits of medications cannot be realised at currently achievable levels of adherence.'

A repeat Cochrane review<sup>2</sup> undertaken in 2014 concluded that, '[then] current methods [...] are mostly complex and not very effective, so that the full benefit of treatment cannot be realised.' Fourteen years later, yet the problem remained the same.

Latterly though, what has most certainly changed is the awareness of, and eagerness to address, issues of nonadherence through a plethora of incentives and initiatives; albeit, as yet, seemingly to little avail.

### Medications compliance (synonym: adherence):

the act of conforming to the recommendations made by the provider with respect to timing, dosage, and frequency of medication taking

### Medications persistence:

the act of conforming to a recommendation of continuing treatment for the prescribed length of time

How big is the problem? Well, nonadherence is prevalent across all clinical conditions and populations,<sup>3</sup> and evidence suggests that it has been that way for over 50 years.<sup>4,5</sup> In developed countries, adherence among patients suffering chronic diseases averages only 50%; levels in developing countries are thought to be considerably lower.<sup>6</sup> Given that nearly half of adults have a chronic condition – one in four having more than one – it's fair to say that the problem is huge.<sup>7</sup>

### How big is the problem?



average level of adherence among patients suffering chronic conditions<sup>7</sup>



nearly half of adults have a chronic condition<sup>7</sup>

# 1 in 4

have more than one chronic condition<sup>7</sup>

## 'A worldwide problem of striking magnitude'

So, what does this mean for healthcare stakeholders? The concept of foregone therapeutic benefit on the part of the patient is relatively easy to appreciate, but, despite this, the facts surrounding the frankly frighteningly low levels of adherence remain.

That said, I will be the first to admit that I don't take every medication as prescribed. How can we begin to explain this behaviour in the

knowledge that nonadherence has been linked to a number of deleterious health outcomes<sup>8-11</sup> and claims the lives of over 200,000 people in Europe annually.<sup>12</sup>

Fascinatingly, some evidence has shown that **a high level of adherence to a placebo can confer a benefit similar to that seen when adherent to an effective active drug;** in said

study<sup>13</sup> the benefit common to both was a 50% reduction in mortality risk. Put another way, **low adherence, even to a placebo, is independently associated with an increased risk of death.**<sup>13</sup>

Further studies have also shown that this effect is not adequately explained by considering good adherence a surrogate marker of broader healthy behaviours.<sup>14</sup>

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For patients, nonadherence<sup>3,8-12</sup>:



**worsens treatment outcomes**



**increases risk of adverse medical events**



**necessitates further consultations**



**raises rates of hospitalisations**



**claims the lives of over 200,000 people in Europe annually**

To healthcare professionals (HCPs), a patient failing to benefit from drug treatment may require additional consultations, further diagnostic testing, or hospital admission. Compounding matters, **clinicians tend to overestimate levels of patient adherence.**<sup>15-17</sup> This tendency, when combined with a patient's apparent lack of clinical improvement that is actually due to nonadherence, may lead to dosages being increased or additional drugs being prescribed – driving medication costs up even further.

At the level of the healthcare service, nonadherence unsurprisingly affects the NHS in a big way too. Most apparent may be the monetary cost of medicines which, through nonadherence, are wasted and don't lead to their intended clinical benefit. So, there is the opportunity cost associated with the lack of a beneficial effect, but secondary to this lack of effect, patients then also require additional treatment leading to them re-presenting and taking up further healthcare resource.



**Nonadherence costs the NHS at least**

**£500m**

**a year in forgone health benefit<sup>18</sup>**

At a time when NHS efficiency is rarely not a headline, it seems appropriate to represent the sum of nonadherence as a monetary cost to the NHS; a 2010 estimate of the cost of health gains forgone across just five therapeutic areas was in excess of £500 million per annum<sup>18</sup>; adjusting for inflation up to 2018 this figure is likely to have grown considerably.

In addition, **there is a trend among payers and policy-makers to demand increasing levels of real-world evidence in an attempt to evaluate effectiveness on the ground, rather than relying purely upon clinical trial-based efficacy.**

The penny has dropped in terms of the savings potential in no longer funding the provision of medicines for which the efficacy is unquestionable, but that suffer from poor adherence or poor persistence due to, for example, a high prevalence of adverse drug reactions (ADRs) or complicated dosing regimens. Indeed, the observed variation in levels of achievable adherence and persistence to drugs on the basis of tolerability goes a long way to explain the difference between trial-based efficacy and real-world effectiveness.<sup>19</sup>



**Nonadherence costs pharma around**

**\$637bn**

**per year<sup>20</sup>**

Expect to see the demand for real-world evidence increase further as a function of attempts to deal with adherence and generally improve health outcomes per unit spend.

**To pharma, global revenue loss associated with medication nonadherence was recently estimated to be an eye-watering \$637 billion per annum,<sup>20</sup> which puts the issue very much on their radar and makes it a behaviour worthy of efforts to change.**

Somewhat encouragingly though, in a recent survey of pharma industry stakeholders, money wasn't the highest concern on their agendas; improving patient outcomes was actually the most compelling goal in addressing adherence, followed by increased patient persistence, and improved patient engagement.<sup>21</sup>

But what's driving the issue? Why don't we take our medications, as prescribed, 100% of the time? We'd benefit personally, free up HCPs' time, save the NHS money, and the pharma wheel would continue merrily turning. It should be a no-brainer, right? Unfortunately not.

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## Into the fifth dimension

As with most issues rooted in human behaviour, the reasons for nonadherence are complex, many, and varied. So, I find it helpful to first simplify them using the dichotomy of 'unintentional nonadherence' and 'intentional nonadherence'.

**Unintentional nonadherence** incorporates what can be thought of as practical barriers to adherence that reduce the patient's capability or

opportunity to adhere; for example, physical and cognitive problems, or a patient misunderstanding instructions.<sup>22</sup>

**Intentional nonadherence** is more about personal and perceptual barriers, such as illness perceptions, personal health beliefs, and levels of activation, that affect a patient's motivation to adhere.<sup>22</sup>

In considering all of the factors that comprise nonadherence, intentional or otherwise, the World Health Organisation (WHO) also volunteered a useful taxonomy involving five sets of factors, or 'dimensions'.<sup>6</sup> A basic understanding of the determinants of adherence are fundamental to leveraging the potential benefits of improving medications adherence and affecting positive change.



Adapted from: Sabaté E, et al. 2003.<sup>6</sup>

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## The ideal intervention

Interventions that have been shown to positively affect both adherence and clinical outcomes frequently include enhanced support from family, peers, or allied health professionals, who often deliver education, counselling, or daily treatment support. But overall, even the most effective interventions rarely lead to large improvements.<sup>2</sup>

Crucially, **the most effective approaches to date have tended to target more than one dimension with more than one intervention.**<sup>19,23,24</sup> Let us consider each dimension in turn, with particular focus on any practical insights.

### Socioeconomic factors

Government officials and policy-makers involved with shaping the healthcare environment seem best placed to deal with the socioeconomic factors affecting adherence, such as literacy and poverty. Having said that, actionable and meaningful contributions can also be made on a smaller scale, at the societal or community level, by facilitating social support networks. **There is a wealth of evidence to show that patient-to-patient peer support networks can improve adherence and increase health literacy, while also reducing the amount of necessary HCP input.**<sup>24-28</sup>

Networks for patients already exist, which to a variable extent see involvement and/or investment from pharma. However, where pharma and such groups meet, there will always be close scrutiny of the former's motives. Nonetheless, the provision, by pharma, of objective medical information can go some way to address low levels of health literacy in this sphere and, when communicated patient-to-patient, this information is more likely to be trusted.

Where socioeconomic status is a rate-limiting factor in the acquisition and utilisation of health information provided by HCPs,<sup>29</sup> this seems not to be the case for information perceived to have come from peers, even if its genesis lies elsewhere. Calls for trusted repositories of understandable, factual and peer-reviewed health information, funded by pharma, signposted by HCPs, and used by patients are both well-documented and longstanding.

### Health system factors

**Lack of awareness and a lack of clinical tools to intervene have been cited as major barriers to HCPs effectively tackling adherence.**<sup>6</sup> In order to weave nonadherence management into the daily practice of HCPs, resources need to be made available that highlight how to tackle these issues. Any such resources must address the following three topics<sup>6</sup>:



#### Information on adherence

- summary of factors reported to affect adherence
- effective interventions available
- epidemiology of adherence
- the economic case for addressing adherence
- behavioural mechanisms driving adherence



#### Strategies

- how to broach adherence with patients
- how patients' progress can be followed up and assessed



#### Patient-tailored interventions

- train HCPs to deliver and share such interventions and incorporate into daily practice

**The broader preferences of HCPs should also be taken into account with regards to how any material addressing adherence is received.** For example, eCPD provisions are likely to be welcome, especially where there is the opportunity to follow up with an expert after completion, as well as pieces designed for the HCP to directly share with the patient in front of them, perhaps in the form of printable assets, or a website to signpost to.

### Condition-related factors

Condition-related interventions can also be viewed as ideal targets for the efforts of HCPs. It seems that they may exert the largest effect by identifying and dealing with issues such as troublesome symptom burden, as well as treating co-morbidities that are known to affect adherence, for example, depression.<sup>23</sup> However, attempts to make this top-of-mind for HCPs in the context of an already overstretched 7-minute consultation are likely only to work secondary to highlighting the benefits of addressing adherence for each stakeholder i.e. the patient, the HCP, and the healthcare system.

### Therapy-related factors

Interventions addressing therapy-related factors have been said to be most aptly addressed at the level of the pharmaceutical company, in conjunction with HCPs and researchers, given that factors affecting adherence include dosing frequency and side effect profiles. Innovation to address these issues is paramount and ongoing.<sup>6</sup> Meanwhile, small improvements could be made by providing HCPs and patients with informative educational pieces addressing common ADRs, in the hope that by handling expectations and signposting to appropriate services for their management, the patient is less likely to become nonadherent as a result.

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## Patient-related factors

Finally, we come to factors relating to patients, which enjoy proportionately more research secondary to the misconception that adherence is a patient-driven problem.

**Some attempts to deal with nonadherence at the patient level enjoy modest success but can be criticised for being reductionist in their narrow focus and should, at most, form part of an adherence solution.**

Some such methods currently employed include practical provisions like dosette boxes, while others are more intelligent and sophisticated, such as so-called 'digital pills' that incorporate tiny sensors that travel through the body harmlessly and communicate data back to an external device; some of that data pertaining to tracking levels of adherence.

However, under the surface, **further barriers for patients exist, including a lack of information and skills required to self-manage, lack of motivation and self-efficacy, and lack of support for behavioural change.**<sup>6</sup>

When it comes to patients' lack of information, we rely upon patient education and patient empowerment efforts. But for such efforts to be compelling they first need to be understood. I would wager that most people wouldn't guess that the average reading level in the UK hovers around that of a child of 9 years,<sup>31</sup> so understandability is obviously key.

Furthermore, almost one in ten people in the UK do not class English as their main language.<sup>32</sup> The result – studies show that those **patients with lower levels of education and those of mixed ethnicity are more likely to report having less confidence in managing their own health.**<sup>33</sup>

Could we then do more in alternative language formats, or try to create universal collateral that relies more upon graphics than the written word? Could we turn flat, printed, instructive literature into engaging, interactive, bitesize digital content using gamification while incorporating learnings from psychology and behavioural economics? We could, and we should. We need approaches that increase the perceived importance of adherence, and that activate not just the patient, but also the community that supports him or her.<sup>6</sup> A lofty goal, I appreciate.

Patient education is often treated simply as an exercise in imparting information, but evidence suggests that traditional patient education in its current format does not go far enough. Not least because it presumes that the patient is motivated to learn and that they are ready to change their behaviour, as described by the Transtheoretical Model of Change (see below).<sup>30</sup>

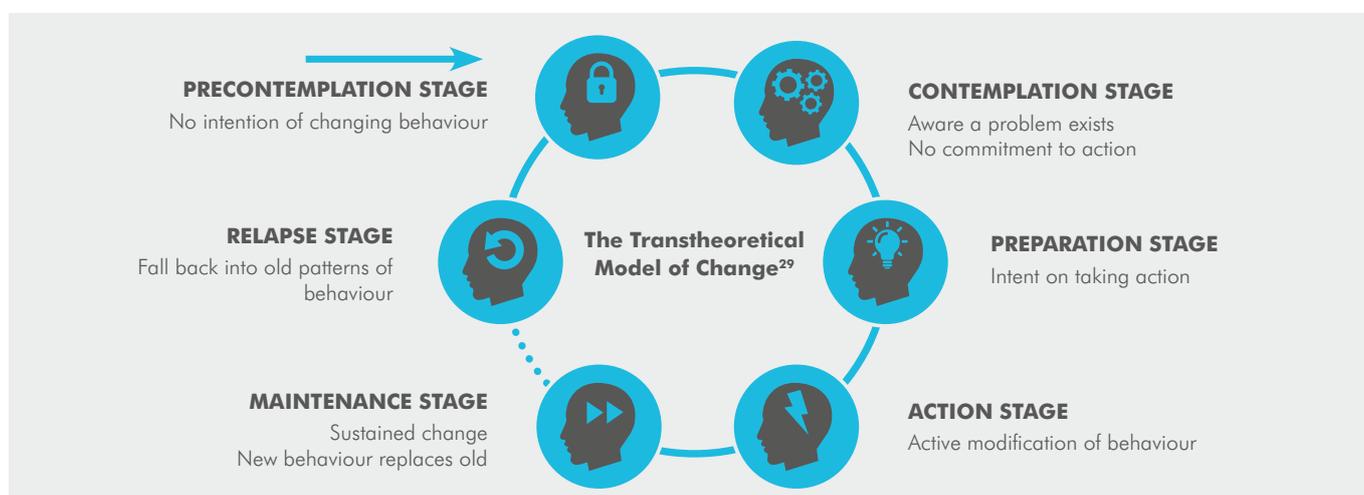
**There is unquestionably a place for patient education, but it requires a more holistic proposition that addresses multiple dimensions.** For example, a patient education asset could also prime patients to consider what

they wish to discuss at a future HCP consultation, thereby addressing the health system factor of short consultation times by making any communication more efficient. This might also give HCPs the time to broach symptom burden or adherence directly with the patient.

In addition, an understanding of how our choice of words may be perceived is increasingly important as we drive up levels of health literacy – one size really does not fit all. The term 'patient' has come under close scrutiny in recent years, implying for some a passiveness that threatens one's intrinsic autonomy, and fits more with the paternalistic model of healthcare from which we are moving away. **Some patients do not consider themselves to be 'ill', so why would 'disease awareness' materials resonate and motivate behavioural change?**

Should we use terms embedded within consumer culture, such as 'client' or 'consumer'? This is yet another nuance that makes an understanding of our target audience essential – the same patients (apologies!) that desire autonomy, also want a caring, human relationship with their physician.<sup>34</sup>

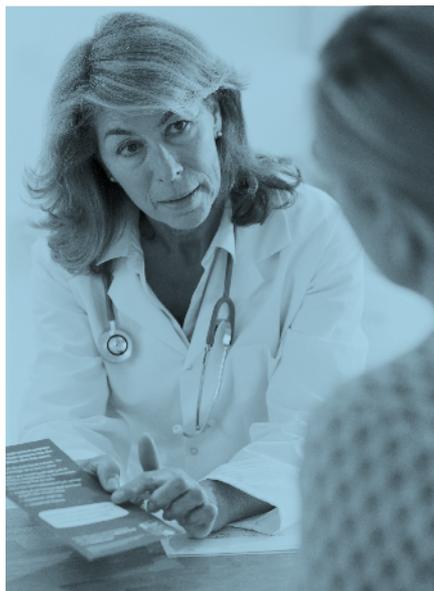
Are there ways that we can kickstart patient education to incorporate what's been highlighted as missing and create the 'responsible patient'; a patient that appreciates the effects of nonadherence both to themselves and in the broader sense, and so changes their behaviour?



Adapted from: Prochaska JO, et al. 1983.<sup>30</sup>

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## Patient adherence programmes



As mentioned previously, the increasing pressures on healthcare systems has led to payers demanding solutions that go beyond clinical trial efficacy. Notice the word solutions in there, rather than drugs? I think that's representative of what has changed over the last 5–10 years.

**Marketing standalone drugs is working less and less, as payers want more health benefit in exchange for their ever-dwindling budget.**

We're at the stage now where a less efficacious, less expensive drug, delivered with a proven bolt-on adherence programme, can win out against the first-line, gold-standard medications. Of course, nobody is standing still in the patient support space, so it is likely that the most efficacious brands will also react by addressing their proposition in terms of value-adds.

But how is this demand for better healthcare value evolving? On the ground, a popular approach has been the utilisation of patient support programmes, the first iteration of which have been with us for some years now.

**Usually built to support a particular brand, rolled out by nurses or allied health professionals, focussing on patient education, and utilising a fairly rigid bundle of content, they can only really be described as a step in the right direction with many not actually affecting health outcomes in a meaningful or long-term way.**

Such programmes have also been retrospectively described as expensive, notoriously difficult to get approved and to manage, whilst often being underutilised and becoming obsolete in short spaces of time.

In short, they were, and to a variable extent still are, effective within their scope, but they have many limitations.

In more recent years there has been a massive uptake of digital concepts into such programmes, in a concerted effort to both increase reach and generate useable real-world data, effectively closing the loop and allowing the programmes to make their own case for return-on-investment. There has also been a drive to include more patients at the inception of any such project, often through collaboration with patient advocacy groups, thereby increasing their relevance and perceived benefit at a grassroots level.

**It would seem as though patient support programmes are starting to move in the right direction by looking beyond the issues of the drug, looking instead at issues facing patients.**

Some programmes recognise the bewildering task of navigating our healthcare ecosystem, mapping touchpoints for specific groups of

patients with similar needs. Others focus on the provision of support through peer-to-peer networking or improving access to physicians outside of formal parameters.

Giving a nod to patient centricity, patient support programmes are starting to make an honest and transparent attempt at understanding the needs of patients, such that every aspect delivers holistic and relevant patient-focussed benefit. But this approach is understandably a huge undertaking, drawing on the experience of a multitude of stakeholders and professionals alike.

**With this in mind, it seems that there is scope to go back and really get to grips with the root causes of nonadherence, because whether you have the resource to commission a large-scale, all-encompassing patient support programme, or not, meaningful change in adherence is firmly anchored in an understanding of its behavioural roots.**

Theories are to this day emerging and others being expanded upon in order to comprehensively describe adherence behaviours. But, we can't all be experts in behavioural science; all we can hope to do in this regard is to keep abreast of any big developments.

In the meantime, the WHO's five dimensions serve as a template to better approach nonadherence as the complex behaviour it is; that is, any adherence intervention, great or small, should begin with a commitment to exploring and understanding as many dimensions relevant to that population of patients as possible, and should seek to address as many as possible.

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## To a more holistic healthcare proposition

What's in store for the future? Well, as I've talked about elsewhere, overt drug promotion is gaining less-and-less traction, losing ground to genuine attempts at patient education and empowerment. Patient support programmes can nicely complement, and become integral to, this approach.

What can be taken from all of this? Well we would say that unless you're committing to building a support programme from the ground up that wholly focusses on the needs of patients, your time (and budget!) might be better placed attempting in earnest to get to grips with the real pinchpoints of a predefined group of patients.

This will increase our understanding of the roots of their nonadherence, for which we can provide smaller, cost-effective bundles of interventions, while being mindful not to fall into the trap of being reductionist in our approach by tackling only one dimension of nonadherence. Learning from large-scale patient

support programmes, there is no reason why carefully planned, well-researched, small-scale adherence interventions can't also have an impact. But, **large or small, buy-in from HCPs is crucial – they should feel supported rather than circumnavigated and should be made to feel included in, and necessary to, the solution.**

Such undertakings may then snowball into larger, longer-term projects with scope for longevity and can be furthered with careful planning to mitigate the risk of becoming obsolete. **Patient support cannot be something that you dabble in, particularly if you're going to set up something comprehensive and you want to reap the rewards of real-world evidence along the way.** It needs to have the budget and manpower to last long-term, and it needs to be continually assessed, improved and evolved to ensure relevance and benefit. It's a learning curve, not a tick-box exercise.

This approach then feeds into a continued pursuit of being sincerely patient-centric. It's no longer a matter of just telling the HCP we understand the patient's perspective, that we appreciate what they're going through, and that we empathise with them. **It seems pharma really is now starting to move in the right direction to truly understand patients and support them appropriately, beyond what is needed for the business.**

IGNIFI's Business Development Director, Jan Reiss, recently attended the Eyeforpharma conference in Barcelona, and relayed that there was a much more tangible and genuine shift towards patient centricity. We are starting to go to the patient directly now, through early involvement via co-creation, 1-to-1 interviews, ethnography and field studies, rather than solely asking HCPs about patient behaviours and beliefs and gathering information 'second hand'.

Importantly, when we refer to our customers it is no longer a given that we are talking about the prescriber; both patients and HCPs have a seat at the table, and both offer equally important perspectives and insight, regarding all elements of patient care, adherence included. As marketers, this might make our job more complex and challenging, but it also makes it far more effective and rewarding.

There is no question that tackling nonadherence is a key ingredient of patient centricity, and as pharma begins to truly embrace this concept the likelihood is that we will only see efforts in this area increase. So, perhaps when the next Cochrane review comes around, we might just begin to see a different picture. Let's hope so.



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Michael is a trained biomedical scientist who went on to read medicine at Durham University.

Choosing not to pursue a career in medicine, Michael began working in medical writing; first in medical information and, upon joining IGNIFI, medical copywriting.

Michael draws on first-hand clinical experience and ongoing research to explore issues facing patients, the pharmaceutical industry and the healthcare sector.

