April 2018

Medical Adherence Consortium

Encouraging adherence initiatives: aligning individual, commercial, and social value

Compiled based on discussions of the CfBI Medical Adherence consortium by the Economic Sustainability Working Group: Sheena Macpherson of Miotify (group convener), Guillaume Nebout of Walgreens Boots Alliance, Carol Stafford of Vodafone, Matt Bonam of AstraZeneca, Jeremy Holland of CfBI.

Abstract

It is commonly understood that the most expensive medicines are the ones that are not used. Not only does failure to take prescribed medication correctly – or at all - cost up to US$290 billion annually in the US alone, it can have a major detrimental effect on patient health contributing to an estimated 200,000 deaths in Europe every year. Therefore, improving patient adherence should not be a peripheral consideration when managing patient health but a core priority that needs greater attention.

This paper, produced by the CfBI Medical Adherence Consortiuma, sets out to understand why medicines adherence is difficult to achieve and the barriers that limit success and identifies where efforts should be concentrated to improve adherence. In particular, the need to address 'value misalignment' on low cost high volume medicines, where low prices dis-incentivise manufacturer funded adherence programmes, though the cost and impact of non-adherence to the payer is significant because of the high volume. The consortium concludes by making five recommendations to policy makers, payers, healthcare professionals and manufacturers to recognise adherence in the development of policies and new services, to discover new ways of funding adherence, and to use existing funding more effectively.

Definition of medicines adherence

Adherence is the process by which patients take their medications as prescribed, composed of initiation, implementation and discontinuation. Initiation occurs when the patient takes the first dose of a prescribed medication. Discontinuation occurs when the patient stops taking the prescribed medication, for whatever reason(s). Implementation is the extent to which a patient's actual dosing corresponds to the prescribed dosing regimen, from initiation until the last dose. Persistence is the length of time between initiation and the last dose, which immediately precedes discontinuation.[2]

a The CfBI Medical Adherence Consortium (www.cfbi.com) brings together a wide range of organisations from across Europe, including stakeholders from industry, healthcare professionals, academics and patient groups, who have a common interest in obstacles to the improvement of medication adherence. Of particular focus is the issue that successful adherence initiatives all too often fail to be scaled up due to economic challenges. This paper aims to set out the nature of the economic challenges surrounding medicines adherence projects and suggest ways of overcoming these challenges

Impact of poor medicines adherence

The WHO calls poor medicines adherence "a worldwide problem of striking magnitude" and there are reports of up to 50% of medications for long-term conditions not taken as prescribed [1]. Poor medicines adherence can:

- **Lead to unnecessary expense to the healthcare system**: costs the US healthcare system $100 billion to $290 billion annually [2]

- **Be detrimental to patient health**: 10% of hospitalisations are attributed to the incorrect use of medicines and there are an estimated 200,000 deaths per annum in Europe as a result of non-adherence [3]

Medicines adherence initiatives

Addressing medicines adherence can lead to both improvements in patient health and savings to the healthcare system. In fact, the WHO stated that any intervention to improve medication adherence to existing treatments would have a greater benefit than the development of new drugs for most medical conditions.[2] Benefits may also be seen for other stakeholders, including carers (e.g. reduced anxiety), employers (healthier workforce), pharmacy (increased loyalty), pharmaceutical companies (improved brand) and Governments/insurers etc.

Adherence initiatives may be seen as any initiative that aims to improve adherence directly or as part of a larger activity. Examples include simple reminders (text, phone or app); increased patient 'activation' and 'engagement' through improved self-monitoring of condition and therapy; automated dispensers; enabling the patient's healthcare professional to better understand the required level of adherence leading to a shared approach with the patient (sometimes called concordance); and other still richer approaches to affecting behavioural change. These can be delivered by a variety of organisations including healthcare bodies, patient support consultancies, pharmaceutical companies, pharmacies, healthcare charities, technology providers and many others.

Barriers to adherence initiatives

However, addressing medicines adherence issues is not a simple task as there are many reasons why patients do not take their medicines as directed. Every meaningful initiative to manage medication adherence should work, but only if it is applied to the right person, for the right problem, at the right time. The complexity of the issue therefore precludes simple solutions, and can be viewed as either essential impediments, or structural complexity.

Essential complexity/impediments	Structural complexities/impediments
• **Intentional vs non-intentional**: whether a patient wants to adhere or not • **Behavioural/belief influences**: does the patient believe in the requirement/benefit of the medicine? • **Difficulty of measurement**: differing measures (e.g. patient-reported, direct observation, prescription monitoring, wearable/ingestible devices, electronic	• **Economic complexities**: mismatch between individual, commercial and social value of adherence activities – the commercial reward for improving adherence is not aligned to the social/personal value that improved adherence generates. In addition, the cost of poor adherence and the potential benefits to improvement are

pill box monitoring), no single agreed approach and difficult to have effective control groups • **Importance of therapy 'feedback'**: when patients can see no change to their health they may assume the medicine is not working and feel less urgency to take it	difficult to estimate and differ for each stakeholder involved. • **Regulatory impediments**: medicines adherence activities operate in a highly regulated environment

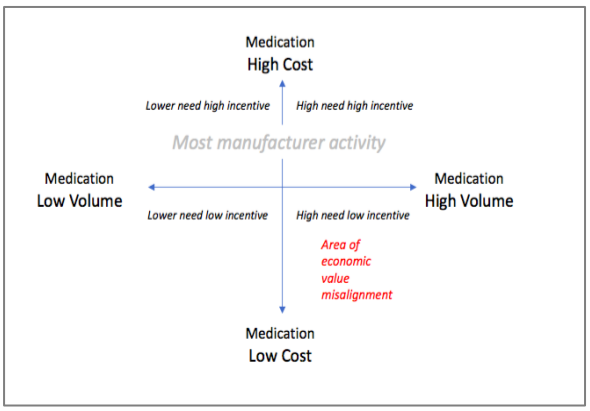
The adherence landscape

Adherence initiatives and patient support programmes are often funded by pharmaceutical companies acting to support individual products (around the pill) or therapies (beyond the pill) services. Indeed, there is often an expectation from payers and providers that pharmaceutical companies should fund the majority of adherence initiatives. However, regulations often restrict the engagement of pharma companies with patients and other stakeholders may have greater influence over patients in their treatment journey.

The consortium argues that there is a significant and vital set of adherence activities that cannot be undertaken, driven, or funded by pharmaceutical companies alone, but should be delivered from within the healthcare eco-system with all parties around the patient playing a part. For example, most patients and their carers interact frequently with pharmacies to have their drugs dispensed and pharmacists are seen as healthcare professionals who are 'therapy experts' by the general public. The consortium believes that pharmacies should take a larger role in adherence management via multichannel interventions. Pharmacists interact in a multi-channel way (face to face or digitally) and are in a position to provide accurate advice to patients. Experience from across Europe shows that pharmacists have been incentivised to take a more active role in the medication management of their patient population (e.g. Medicines Use Review in the UK and the anticoagulant interview in France).

Value misalignment

Although the costs of poor adherence are significant, commercial activity to address this is comparatively small, which could be a sign of economic misalignment (supply not meeting demand) or little demand despite a clear identified need. The consortium feels that there is often a mismatch between individual, commercial, and social value of improving adherence. The economic aspects of adherence initiatives vary greatly, depending on the nature of the condition, the therapy, and other characteristics of the patient and healthcare environment.



There are two key dimensions that describe (at a high level) the economic viability of adherence activities: the unit cost of the medication (high or low) and the total social impact of the condition (see opposite). Total social impact refers to the impact to society as a whole of the condition. This means that rare conditions, while possibly devastating to the individuals suffering with them, are unlikely to have as big a social impact to society as a whole as common conditions. Where the unit cost of the medication is high there is commercial justification for manufacturers to invest in initiatives which will drive sales, where the unit cost is low there is less commercial justification.

When a condition is serious and widespread we can say that it has a large total social impact. When the condition is widespread but less serious (such as a common cold) or is serious but not widespread, then the total social impact of the condition is (comparatively) low. Societal value is very difficult to gauge and goes beyond the cost to the payer. Greater public benefit in adherence would be seen where the societal impact is high but the unit cost of the medication is low and where there is little incentive for manufacturers to invest. This is where there is greatest misalignment of value.

Recommendation 1: The Consortium recommend that policymakers and influencers concentrate on addressing the area of greatest economic value misalignment for adherence initiatives – namely where the volume of prescriptions is high, and cost of drug is low – and focusing on those medications and conditions where non-adherence is considered a significant problem.

Approaches to economic sustainability

The consortium believes that in the case of misalignment of value, payment for adherence improvement initiatives and activities cannot come from pharmaceutical companies alone, but must come from the whole ecosystem including other major beneficiaries of improved adherence. This may include – but is not limited to – the public health system**.**

Recommendation 2: The Consortium recommends that stakeholders identify appropriate and innovative funding mechanisms and take steps to implement these.

Making successful adherence activities truly economically sustainable will require the development of new business models. The consortium believes that whatever the business model, it should be accessible to a broad set of suitable providers of adherence initiatives which could lead to increased innovation from new participants in the market. Funding models should avoid limiting funding by criterion so that only a small number of projects and initiatives are considered for funding. This 'silo solution' approach can act to prevent the emergence of truly inter-disciplinary and innovative approaches.

Recommendation 3: The consortium therefore recommends that any new route for accessing funding to support adherence initiatives be made clear by bodies responsible for setting compensation rules.

Measurement of benefit from adherence initiatives is difficult to derive and requires more work to understand the health outcomes link; however,

Recommendation 4: The Consortium recommends that the burden of proof for adherence activities should be lower than it is for the underlying medication

This is because the level of risk associated with adherence interventions is lower than that associated with the medicines themselves. The payment – and commercial return – for a successful adherence initiative is therefore likely to be aligned to service sector margins rather than to the actual measured benefit of the adherence measure itself.

The role of regulation

It is important to work towards reducing the cost of adherence activities, particularly those flowing from regulatory compliance. These include, regulatory complexity (variance between regions and who is funding the activity); regulatory burden (cost to address regulatory and compliance requirements

seen as a barrier); and regulatory obstruction (direct barrier to some adherence initiatives, e.g. control on patient communication). Maintaining patient safety through effective regulation is vital, but many of these costs are derived from the historic lack of consideration of adherence as a priority.

Recommendation 5: The consortium recommends that regulators, industry, payers, healthcare providers, patient and carer representatives and other stakeholders work together to:

- **Recognise the importance of increasing adherence, and take this into account when drafting regulations;**
- **clearly identify 'best practice' as well as 'minimum requirements' to guide existing and new organisations operating in this market; and**
- **encourage more engagement between the stakeholders in the value chain to work together on standards that meet the regulatory requirements, are usable in practice and reduce the barriers to encourage innovative approaches to be tested and validated.**

Conclusion

The Consortium recognises the widespread commitment and investment of many stakeholders to improve medicines adherence, and in doing so the health and wellbeing of patients. It understands the complex challenges involved but believes the economic case exists to invest in medicines adherence, especially for medicines and therapies that fall into the trap of economic value misalignment. It would encourage all stakeholders to take stock of its recommendations and co-create the solutions that are desperately required.

Recommendations of the Consortium

1. Policymakers and influencers should concentrate on addressing the area of greatest economic value misalignment for adherence initiatives – namely where the volume of prescriptions is high, and cost of drug is low – and focusing on those medications and conditions where non-adherence is considered a significant problem
2. Stakeholders should identify appropriate and innovative funding mechanisms and take steps to implement these
3. Any new route for accessing funding to support adherence initiatives should be made clear by bodies responsible for setting compensation rules
4. The burden of proof for adherence activities should be lower than it is for the underlying medication
5. Regulators, industry, payers, healthcare providers, patient and carer representatives and other stakeholders should work together to recognise the importance of increasing adherence, and take this into account when drafting regulations;
    a. clearly identify 'best practice' as well as 'minimum requirements' to guide existing and new organisations operating in this market; and
    b. encourage more engagement between the stakeholders in the value chain to work together on standards that meet the regulatory requirements, are usable in practice and reduce the barriers to encourage innovative approaches to be tested and validated.

References

1. Vrijens, B., De Geest, S., Hughes, D. A., Przemyslaw, K., Demonceau, J., Ruppar, T., ... & Matyjaszczyk, M. (2012). A new taxonomy for describing and defining adherence to medications. *British journal of clinical pharmacology*, *73*(5), 691-705.
2. Sabaté, Eduardo. Adherence to long-term therapies: evidence for action. World Health Organization, 2003
3. Rosenbaum, Lisa, and William H. Shrank. "Taking our medicine—improving adherence in the accountability era." New England Journal of Medicine 369.8 (2013): 694-695.
4. Pharmaceutical Group of the European Union "Targeting Adherence - Improving Patient Outcomes in Europe through Community Pharmacists' Intervention" PGEU policy statement on adherence to medicines 2008.

Further Information

For further information about this position paper or the CfBI Medical Adherence Consortium please send an email to MA@cfbi.com.