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Patient adherence to medicines

Summary of a joint meeting held on 03 December 2014 hosted by the Academy of Medical Sciences and the Faculty of Pharmaceutical Medicine

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Disclaimer

This document reflects the views of participants expressed at the meeting and does not necessarily represent the views of all participants, the Academy of Medical Sciences or the Faculty of Pharmaceutical Medicine. For further information, please contact Dr Claire Cope, Senior Policy Officer at the Academy of Medical Sciences (claire.cope@acmedsci.ac.uk, (0)20 3176 2164).

All web references were accessed in March 2015.

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Executive summary

Adherence to medicines is vital for effective treatment regimes. A lack of adherence can render treatments ineffective and even harmful in some cases. Additionally, poor adherence represents an economic loss to the healthcare system and to society. It is estimated that between 30-50% of patients taking medicines for chronic conditions do not take their medicines as prescribed, and wasted medicines are thought to cost the NHS in England around £300 million per year, a figure which does not take into account the resultant costs of avoidable illness, further treatments and hospital admissions.[1,2]

On 03 December 2014, the Academy of Medical Sciences, in partnership with the Faculty of Pharmaceutical Medicine, convened a meeting to identify the key challenges and opportunities of better adherence to medicines. The meeting brought together key stakeholders from academia, the pharmaceutical industry and the healthcare sector, along with ethicists, economists and patient representatives to explore stakeholders' roles and responsibilities in improving adherence to medicines, facilitate interactions between them, and work towards identifying solutions to this issue.

The meeting was divided into two sessions:

- The morning session consisted of five short talks outlining the background to the meeting.
- The afternoon session provided an opportunity for delegates to devise and discuss potential solutions to tackle non-adherence with colleagues from across the healthcare landscape.

The meeting highlighted several key considerations for enhancing adherence to medicines. These included:

- The need for greater priority to be given to tackling the challenge of non-adherence if the healthcare system is to succeed in ensuring best outcomes for patients.
- The need to better acknowledge that the problem of non-adherence lies within the wider healthcare system and not just with patients. As such, a coordinated response from the whole community will be necessary to address this issue.
- The importance of carefully examining how to best allocate effort and resources in addressing non-adherence. A better understanding of the root causes will help in this regard.
- The importance of engaging and better communicating with patients, and developing a deeper understanding of their experiences and expectations. Where possible, patients should be involved in shared decision-making with their healthcare provider, should they wish to participate more in their treatments options.
- The necessity to incorporate messages on medicines adherence into medical training. Increased emphasis should also be put on developing communication skills and on highlighting the importance of considering patients' values and preferences in treatment decisions.

[1] York Health Economics Consortium and the School of Pharmacy, University of London (2010). *Evaluation of the Scale, Causes and Costs of Wasted Medicines*. http://eprints.pharmacy.ac.uk/2605/
[2] Royal Pharmaceutical Society (2014). *New Medicines, Better Medicines, Better Use of Medicines*. http://www.rpharms.com/promoting-pharmacy-pdfs/nmbmbu---full-report.pdf

- The necessity to develop and implement tools capable of more accurately monitoring adherence, in order to better estimate the prevalence and nature of the problem.
- The utilisation of new technologies to improve adherence to medicines, complementing – not substituting – the work of healthcare providers. Various new technologies, such as reminders, automated pill boxes and mobile phone applications to name a few, are already on the market and should be used to their full potential to enhance medicines adherence.

The challenges and proposed solutions identified in this report represent the views of the participants at this meeting, and will need to be carefully considered in devising efficient ways to address non-adherence to medicines. Further dialogue between all the stakeholders involved will be crucial in ensuring a coordinated approach, which puts the patient at the centre of the discussions.

Introduction

Adherence to medicines is vital for effective treatment regimes. A lack of adherence can render treatments ineffective and even harmful in some cases. The former US General Surgeon, Dr C. Everett Koop's quote '*drugs don't work in patients who don't take them*' neatly encapsulates the problems of poor adherence.[3] Not only does it waste medicines, but it also makes it impossible to know what the best treatment for a particular patient would be. Opportune periods for treatment during which a correctly prescribed and adhered to medicine would most likely be effective may also be wasted, potentially leading to reduced treatment options once the patient's health has declined and the disease worsened.

In addition to its impact on patient outcomes, poor adherence represents an economic loss to the healthcare system and to society. Indeed, it is estimated that between 30-50% of patients taking medicines for chronic conditions do not take their medicines as prescribed, and wasted medicines are thought to cost the NHS in England around £300 million per year, a figure which does not take into account the resultant costs of avoidable illness, further treatments and hospital admissions.[4,5] Poor adherence can also contribute to the emergence of resistance to antimicrobials, which has both individual and broader population health implications.[6,7,8]

In an effort to increase adherence, emphasis has been put on communicating effectively with patients to best inform them about how to make the most of their prescribed treatments. Other schemes include improved prescribing, new approaches to administration, and the use of new technologies to monitor or remind patients to take their medicines appropriately.

On 03 December 2014, the Academy of Medical Sciences, in partnership with the Faculty of Pharmaceutical Medicine, convened a meeting to discuss these issues. The meeting was chaired by Sir Alasdair Breckenridge CBE FRSE FMedSci and Professor Tim Higenbottam FRCP FFPM and brought together key stakeholders from across the health and research system. Short presentations were delivered by:

- **Professor Rob Horne**, Professor of Behavioural Medicine, University College London
- **Professor David Taylor**, Professor of Pharmaceutical and Public Health Policy, University College London School of Pharmacy
- **Professor John Urquhart**, Senior Scientific Advisor and Co-Founder, AARDEX-MWV Healthcare

[3] Osterberg L & Blaschke T (2005). *Adherence to Medication*. New England Journal of Medicine **353**, 487-497.
[4] York Health Economics Consortium and the School of Pharmacy, University of London (2010). *Evaluation of the Scale, Causes and Costs of Wasted Medicines*. http://eprints.pharmacy.ac.uk/2605/
[5] Royal Pharmaceutical Society (2014). *New Medicines, Better Medicines, Better Use of Medicines*. http://www.rpharms.com/promoting-pharmacy-pdfs/nmbmbu---full-report.pdf
[6] Vrijens B & Urquhart J (2005). *Patient adherence to prescribed antimicrobial drug dosing regimens*. Journal of Antimicrobial Chemotherapy **55**, 616-627.
[7] Thomas JK, *et al*. (1998). *Pharmacodynamic evaluation of factors associated with the development of bacterial resistance in acutely ill patients during therapy*. Antimicrobial Agents and Chemotherapy **42**, 521–527.
[8] Guillemot D, *et al*. (1998) *Low dosage and long treatment duration of ß-lactam: risk factors for carriage of penicillin-resistant Streptococcus pneumoniae*. JAMA **279**, 365–370.

- **Professor Richard Ashcroft**, Professor of Bioethics, Queen Mary University of London
- **Dr Keith Ridge CBE**, Chief Pharmaceutical Officer, Department of Health

This report provides a summary of the speakers' presentations and the lively discussion session that followed.[9]

[9] The speakers' slides are available to download from our website: www.acmedsci.ac.uk.

Session I Speakers' presentations

Sir Alasdair Breckenridge CBE FRSE FMedSci launched the meeting by giving an overview of the issues associated with poor adherence to medicines. He outlined its negative impact on patient outcomes but also the concerning economic loss it causes and which cannot be ignored in these times of austerity. He questioned why non-adherence is still common in practice, raising the ethical and economic implications, and the role of detection, monitoring and new technologies in tackling this issue. He highlighted motivation and behaviour as two important factors affecting adherence to treatment, with patient populations requiring extensive behavioural change and with little motivation to adhere to therapy perhaps being the most challenging to address.

Behavioural aspects of patient adherence

Professor Rob Horne, Professor of Behavioural Medicine, University College London

Professor Rob Horne emphasised that patient behaviour is the final link for effective treatments to translate into health gains and outlined the Perceptions and Practicalities Approach (PAPA) to understanding non-adherence. Non-adherence can be both intentional and unintentional, driven by overlapping conscious processes (e.g. decisions about whether and how to take the medicine), and unconscious processes (e.g. effects of environmental cues and habit that one does not think about). Adherence/non-adherence is a variable behaviour, rather than a trait characteristic, and is best understood in terms of the individual's encounter with the specific treatment. To facilitate optimal adherence, support needs to address both the perceptual factors (e.g. beliefs, preferences and incentives) and the practical factors (e.g. capacity and resources), influencing the individual's motivation and ability to initiate and persist with the treatment.

The patient's beliefs about the treatment are a crucial factor, often neglected in clinical care. A recent meta-analysis of 94 studies spanning 24 long-term conditions and involving over 25,000 patients from 18 countries showed that a patient's decision to take a medicine is often a balance between their perceptions of personal need for the medicine (necessity beliefs) and concerns about potential adverse consequences of taking it.[10] Such concerns go well beyond side effects and include primarily worries about the long term effects of medicines, and fears over how regular use will affect long term efficacy and potential dependency. These concerns can be influenced by a variety of factors including beliefs, misinformation and shared experiences, which are easily disseminated over the internet.

Professor Horne suggested that to be convinced of a treatment's necessity, patients need to perceive a 'common sense fit' between their illness and the proposed treatment. However, there is a mix of beliefs around medicines amongst the public that range from the view that medicines are over-prescribed, harmful or addictive, to the view that the

[10] Horne R *et al*. (2013). *Understanding Patients' Adherence-Related Beliefs about Medicines Prescribed for Long-Term Conditions: A Meta-Analytic Review of the Necessity-Concerns Framework*. PLoS ONE **8(12)**, e80633.

benefits of medicines outweigh the risks of taking them. These more general negative views about pharmaceuticals and the pharmaceutical industry often fuel concerns about specific medicines prescribed by the doctor.

These concerns are reinforced by product information leaflets that are required by law to list every possible side effect, further enhancing perceptions of danger. These can be difficult to process by patients. To facilitate informed treatment decisions, and not those based on misplaced concerns, risk needs to be communicated in a way that is understood and can be balanced against the potential benefit. Added to this, patients with high levels of baseline concerns about side effects are more likely to suffer from their ill-effects than patients with low level concerns, the so-called 'nocebo' effect.

Professor Horne suggested that interventions to support optimal adherence to appropriately prescribed medicines need to span from the patient, to patient-provider interactions, and ultimately to the policies and practices regulating the healthcare system. Patients, the pharmaceutical sector and healthcare providers will need to collaborate more innovatively to achieve this.

To support adherence, efforts need to be put into:

- The content – better engaging and communicating with patients regarding the necessity of treatments, addressing concerns about side effects, and making the treatment as convenient as possible to adhere to.
- The channels used – considering cost-effective solutions to medicines delivery, involving healthcare professional such as doctors, pharmacists and nurses working synergistically and supported by new technologies.
- The context – a 'no-blame' approach to non-adherence is essential to enable patients to disclose their beliefs and behaviours, and have honest discussions with their healthcare practitioner (HCP). It needs to be recognised that patients may trust the prescriber but not the prescription and that there is frequently a disparity between patient choice and evidence-based medicine.

Professor Horne suggested that to tackle non-adherence to medicines, tailored interventions to support optimal engagement and use of medicines are essential, and that there needs to be a greater understanding of how to value and cost support for better adherence to medicines.

The economics of adherence in medicines taking

Professor David Taylor, Emeritus Professor of Pharmaceutical and Public Health Policy, University College London

Professor Taylor gave an overview of the economics associated with improved healthcare and optimisation of the use of medicines. By defining the situations in which improving adherence to medicines is most likely to generate economic benefits, he warned against simplistic 'economies', that do not take into account the wider benefits of improving patient health and wellbeing.

The key economic concepts associated with health economics include marginal costs (costs of production), average costs (which are often quoted and can be misleading), fixed and variable costs (of research for example), incremental cost effectiveness ratios (ICERs) and quality-adjusted life years (QALY). However, these concepts fail to consider the wider economic gains associated with a healthy, productive population.

Professor Taylor suggested that adherence is particularly important when:

1. An appropriate and effective therapy corresponding to patient requirements is available.
2. Therapeutic tolerances and/or windows are narrow.
3. The marginal costs associated with the supply and the use of a medicine is high.

On balance, the welfare costs associated with lost lives and lost clinical benefit are normally far greater than the financial costs of inappropriately used or wasted therapies.

Two recent studies have demonstrated the value of initiatives aimed at better communicating with patients and supporting them with their treatments. Firstly, the New Medicines Service (NMS), introduced in 2011 to provide support for patients using newly prescribed medicines to treat long-term conditions such as hypertension, asthma and type 2 diabetes, was found to be highly cost-effective in a recent service review.[11] Adherence rates were found to have increased by 10% under the scheme, which was projected to have generated additional QALYs at an estimated cost per QALY of approximately £3,000. Secondly, a recent study demonstrated that text messaging was effective in improving adherence to cardiovascular disease preventive treatment.[12] In fact, the positive impact of automated text messaging was greater than that reported by the NMS evaluation. Combined, these studies and other data suggest that benefits in the order of £500 million per annum can be generated in the cardiovascular disease area alone by improving patient adherence.

Professor Taylor stressed that the value and cost of medicines should not be confused, as the value of medicines does not lie uniquely in its cost. As such, improving adherence to medicines should be pursued as part of a holistic patient/consumer-oriented approach to care and health outcome improvement, the benefits of which should be evaluated in a rigorous manner.

Measurement of patient adherence in ambulatory drug trials

Professor John Urquhart, Senior Scientific Advisor and Co-Founder, AARDEX-MWV Healthcare

[11] Nottingham University School of Pharmacy & University College London School of Pharmacy (2014). *Department of Health Policy Research Programme Project 'Understanding and Appraising the New Medicines Service in the NHS in England (029/0124)'*. http://www.nottingham.ac.uk/~pazmjb/nms/downloads/report/

[12] Wald DS, *et al.* (2014). *Randomised Trial of Text Messaging on Adherence to Cardiovascular Preventive Treatment (INTERACT Trial)*. PLoS ONE **9(12)**, e114268. http://www.plosone.org/article/fetchObject.action?uri=info%3Adoi%2F10.1371%2Fjournal.pone.0114268&representation=PDF

Professor Urquhart highlighted that accurately-measured adherence is essential to determine the entirety of a medicine's effects and that variability in adherence to a treatment regimen contributes to the variation observed in drug responses. He stressed not only that *'drugs don't work in patients who don't take them',* but that drugs can be hazardous if not taken appropriately, even when under-dosed.[13,14]

Accurate measurement of adherence to medicines depends on a combination of reliable, non-biased methods, which provide richly-sampled data. Examples of unreliable, biased methods that are used to monitor dosing histories include patient diaries, pill counts and retrospective questionnaires, methods that all allow patients to adjust their dosing history. More reliable, unbiased methods include therapeutic drug monitoring and pharmacy refill data, although these measurements are usually made too infrequently to be fully reliable indicators of ongoing drug action. Electronic monitoring methods on the other hand can provide a rich, reliable, unbiased method to measure medication adherence. Although they were introduced in the late 1980s, their use for evaluation of adherence is not routine, and less reliable methods as described above are still used today.

Adherence to medicines describes the process by which a patient takes a medicine as prescribed by their HCP. Initiation of treatment occurs when the patient takes the first dose of a prescribed treatment, and discontinuation when the patient stops taking the prescribed medicine. Implementation describes the extent to which the patient's dosing history echoes the prescribed dosing regimen, from initiation to discontinuation of treatment. Deviation in the initiation, implementation and/or discontinuation of a medicine from that prescribed by a HCP can all impact on a given treatment's efficacy, and therefore on patient outcomes and the economics of treatment.

Multiple studies show that 40% of patients discontinue medicines prescribed for long-term use during the 12 months following the initial prescription.[15] Additionally, the extent and pattern of medicines being taken incorrectly (also known as non-execution) can vary between patients. For example, the same amount of medicines can be taken over a 12 month period through different adherence patterns, such as when:

- The treatment initiation is delayed, but once initiated the medicine is taken as prescribed.
- Originally the medicine is taken as prescribed, but the treatment is discontinued earlier than prescribed.
- Single doses are frequently missed.
- The treatment is discontinued for a single more extended period, in between two periods of taking the medicine as prescribed.

[13] '*Drugs don't work in patients who don't take them*' is a quote from the former US Surgeon General, Dr C. Everett Koop. Osterberg L & Blaschke T (2005). *Adherence to Medication*. New England Journal of Medicine **353**, 487-497.
[14] Blaschke T, *et al.* (2012). A*dherence to medications: insights arising from studies on the unreliable link between prescribed and actual drug dosing histories*. Annual Review of Pharmacology and Toxicology **52**, 275-301.
[15] Blaschke T, *et al.* (2012). *Adherence to medications: insights arising from studies on the unreliable link between prescribed and actual drug dosing histories*. Annual Review of Pharmacology and Toxicology **52**, 275-301.

Analysis of the citations of the 670 peer-reviewed papers which report electronically compiled drug dosing history data via 'smart packages', shows that these papers have been cited over 46,000 times, resulting in an *h*-index of 108 for the set.[16,17] These figures attest to the impact of well-validated, objective measurements of ambulatory patients' exposure to prescribed drugs in a wide variety of clinical settings. These metrics should be applied to other methods for quantifying patient adherence.

To conclude, Professor Urquhart suggested that the reliability of adherence data should be improved by using unbiased reliable electronic methods, as opposed to self-reporting and pill count. Inclusion of adherence data in the regulatory review of medicines could provide valuable information on the efficacy and safety of new medicines, thereby highlighting at an early stage the potential harm of non-adherence.

Ethics and patient adherence to medicines

Professor Richard Ashcroft, Professor of Bioethics, Queen Mary University of London

Professor Ashcroft gave an overview of the ethical implications associated with adherence to medicines and a personal account of the importance of considering a patient's decision not to take, to discontinue, or to ask for an alternative medicine. This decision may be due to personal reasons or unbearable side effects, sometimes despite an initial willingness to adhere to a course of treatment.

The language used in this area has evolved from early discussions about 'compliance', a term which suggests that patients should simply do as they have been instructed, to the preferred term of 'adherence', which suggests that patients should follow an *agreed* course of treatment. Nevertheless, language associated with the notion of compliance is still, in many respects, employed in conversations about adherence, and it was thought that a more collaborative dialogue and co-productive approach should be pursued.

Non-adherence can lead to treatment failure, extended illness, severe complications as well as a reduction in cost-effectiveness. In the case of antimicrobials, drug resistance can even emerge, which has health implications for both the individual and the population. Therefore, why would a patient not adhere to a treatment regimen? Reasons may be multiple and varied, and include factors such as misunderstanding or lack of information, side effects, impact on quality of life, distrust in the medical professions, misalignment of treatment goals, or reluctance to accept a disease state.

To encourage adherence, more effective communication and support for patients, in conjunction with an increased understanding by HCPs of the underlying reasons for non-adherence, would be valuable. Behaviour change interventions and inclusion of patients' preferences in treatment decisions also have a role to play by ensuring patient support for the proposed treatment and raising awareness of potential alternatives, should a regimen

[16] The full bibliography can be found at www.iadherence.org.
[17] The *h*-index is a measure of the scientific output of a researcher [see Hirsch JE (2005). *An index to quantify an individual's scientific research output*. PNAS **102**, 16569–16572]. The metric can also be applied to a journal, university, or country, among others.

not be effective or suitable. Additionally, a treatment's administration route could be modified to best suit patients' needs where possible, for example, by prescribing longer acting medicines or therapies directly administered by HCPs. 'Contracts of adherence' established between patients and their HCPs could be envisioned, although these would have to be used with caution.

Professor Ashcroft concluded his talk with four points for consideration:

1. It is important to understand the reasons for non-adherence, a significant proportion of which is done voluntarily.
2. Interventions to address adherence may not be successful and may themselves have knock-on effects. It will be important to consider alternative plans should this be the case.
3. Informing patients about third party effects of non-adherence, for example in the case of antimicrobial resistance (AMR), will be important but may not drive a real change in practice.
4. Negotiated commitment with patients may be more effective than enforced adherence measures.

Policies surrounding patient adherence

Dr Keith Ridge CBE, Chief Pharmaceutical Officer, supporting NHS England, Department of Health and Health Education England

Dr Ridge highlighted that non-adherence to medicines is a worldwide problem of growing magnitude, illustrated by the number of past and present policies aimed at addressing this issue in the UK and beyond (please refer to the tables below).

The New Medicines Service (NMS) implemented in the UK in 2011 has been shown to be highly cost effective, as evidenced by a recent evaluation of the service.[18] However, there is a concerning lack of robust evaluation of the impact of other initiatives aimed at improving adherence. Evidence to demonstrate the success of these schemes is invaluable to support their widespread adoption and implementation. Dr Ridge also suggested that the UK may be able to learn from other countries, such as Australia, which incorporates medicines adherence into a broader national medicines policy, helping to ensure awareness at the highest level.

The NHS in its recently published *Five Year Forward View* outlined three gaps to be addressed:[19]

1. The health and wellbeing gap, which will require a radical upgrade in preventative measures.
2. The care and quality gap, for which new models of care will be required.

[18] Nottingham University School of Pharmacy & University College London School of Pharmacy (2014). *Department of Health Policy Research Programme Project 'Understanding and Appraising the New Medicines Service in the NHS in England (029/0124)'*. http://www.nottingham.ac.uk/~pazmjb/nms/downloads/report/

[19] NHS (2014). *Five Year Forward View*. http://www.england.nhs.uk/wp-content/uploads/2014/10/5yfv-web.pdf

3. The funding gap, where efficiency savings and investment will be needed.
Tackling issues pertaining to non-adherence to medicines will help to address aspects in all three of these areas.

Despite growing recognition of the scale and scope of the issue of non-adherence to medicines and of its impact on patient outcomes, awareness is still variable across Governments. A recent report by the Royal Pharmaceutical Society, *Medicines Optimisation: Helping patients to make the most of their medicines*, has made some progress in raising its profile at the highest levels of the NHS and UK Government. However, there is still scope for adherence to be more centre stage.[20]

To encourage improvements in this field, Dr Ridge suggested that adherence policies could be better aligned to broader health and medicines policy, with which they share mutual aims. Systematic evaluation of the effectiveness of these initiatives should be championed to support their widespread adoption. It will be important for any future policies to be centred on the patient and encourage a holistic, team-based approach involving multiple stakeholders from across the healthcare system, unlike current policies which tend to rely solely on community pharmacies (please see tables below). There is also scope to review public and professional education on these matters. Given the broad scale of the issues, public-facing campaigns aimed at improving medicines adherence may need to be considered. This has started to happen in some countries.[21]

[20] Royal Pharmaceutical Society (2013). *Medicines Optimisation: Helping patients to make the most of medicines*. http://www.rpharms.com/promoting-pharmacy-pdfs/helping-patients-make-the-most-of-their-medicines.pdf
[21] For example, the National Consumers League's '*Script Your Future campaign*' in the USA. http://www.scriptyourfuture.org

Summary table of medicines and adherence policies in the UK (references in Appendix III)

World Health Organisation (WHO): Adherence to Long Term Therapies- Evidence for Action (2003) [1]				
Cochrane: Haynes *et al.* (2014). Interventions for enhancing medication adherence [2]				
	England	**Scotland**	**Wales**	**Northern Ireland**
Government level recognition	1. Medicines Taking Partnership (2002) [3] 2. Community Pharmacy Contractual Framework (2005) [4] 3. Pharmacy in England (2008) [5] 4. NICE Guideline 76 (2009) [6] 5. Evaluation of the scale, causes and cost of waste medicines (2010; action plan 2012) [7] 6. Medicines optimisation (2013) [8] 7. Innovative Medicines and Med Tech Review (2014) [9]	1. The Right Medicine (2002) [14] 2. Effective Therapeutic Partnerships (2010) [15] 3. Prescription for Excellence (2013) [16]	1.Getting the Best Outcomes from Medicines (2006) [18] 2. Tactical Paper: Optimal Use (2008) [19] 3. All Wales Medicines Strategy Group Strategy (2013-2018) [20]	1. Making it Better (2003) [22] 2. Report on the regional steering group on medicines adherence (2012) [23] 3. Making it Better Through Community Pharmacy (2014) [24]
Policy development	1. Medicines Use Review (MUR) (2005) [10] 2. Targeted MUR (2011) [11] 3. Discharge MUR [11] 4. New Medicine Service (NMS) (2013) [12]	1. Chronic Medication Service (2010) [17]	1. MUR [21] 2. Targeted MUR [21] 3. Discharge MUR [21]	1. Managing your medicines service (2003) [25] 2. Targeted MUR (2013) [2)]

Implementation	National	National	National	National
Impact / Evaluation	NMS Evaluation [13]	-	-	-

Summary table of medicines and adherence policies beyond the UK (references in Appendix III)

WHO: Adherence to Long Term Therapies- Evidence for Action (2003) [1]					
Cochrane: Haynes *et al.* (2014). Interventions for enhancing medication adherence [2]					
	USA	**Australia**	**New Zealand**	**Canada**	**Europe**
Government level recognition	1. Medicare Prescription Drug, Improvement and Modernization Act 2003 [27] 2. Agency for Healthcare Research and Quality – Medication Adherence Interventions: Comparative Effectiveness (2012) [28] 3. Issue Brief: Medication Adherence and IT (2014) [29]	National Medicines Policy (1999; includes "Quality Use of Medicines") [37]	1.Medicines New Zealand (2007) [41] 2. Actioning Medicines New Zealand (2010) [42]	1. National Pharmaceuticals Strategy (2004) [44] 2. Progress report (2006 [45]; 2009 [46]) 3. Time for Transformative Change (2012) [47]	1. EU Horizon 2020: ABC Compliance Project (reported 2012) [49] 2. Council of Europe: Pharmaceutical Care Policies and Practices for a Safer and Cost Effective Health System (2012) [50]
Policy	1. Rand Corporation – A Review of Barriers to Medication Adherence: A Framework for Driving Policy Options (2009) [30] 2. Issue Brief: Medication Adherence and IT (2014) [29]	1. 5th Community Pharmacy Agreement (2010) [38] E.g. a. MedsCheck b. Diabetes MedsCheck c. Home Medicines Review d. Residential Medication Management Review	Community Pharmacy Programme [43] E.g. 1.Community Pharmacy LTC Service 2.Community Pharmacy Anticoagulation Service	National Pharmacare Programme	Examples in various countries

		2. NPS Medicines Wise [39] E.g. Medicines List App [40]			
Implementation	Some national initiatives, some local/insurer based 1. Script Your Future campaign 2011 [31] 2. 2103 Prescriptions for a Healthy America [32] 3. Various IT initiative E.g. PHARMACeHOME [33], Southern Piedmont "Closing the Gap" [34] E.g. Kaiser Permanente [35]	National	National	E.g. Pharmacare British Columbia [48] E.g. Pharmacy Led Medication Review: 5 or more medicines	Examples in various countries: France, Belgium, Netherlands, Denmark
Evaluation	NIH Adherence Network [36] Evaluation of specific initiatives E.g. Kaiser Permanente [35]	R&D Programme in parallel [38]	-	-	-

Session II Discussion session

The speakers' presentations were followed by a discussion session, chaired by Professor Tim Higenbottam FRCP FFPM and Sir Alasdair Breckenridge CBE FRSE FMedSci. During this session, delegates drew on the important issues raised in the morning presentations to further explore the key challenges and opportunities associated with patient adherence to medicines, and reflected on solutions to drive improvements in this area. A summary of the day's discussions is provided below.

Adherence to medicines as a priority for the healthcare system

Delegates highlighted that the overarching priority for the healthcare system lies in ensuring best outcomes and treatments for patients. In working to achieve this goal, non-adherence to medicines was identified as a significant challenge that can no longer be ignored. Inevitably, given the multitude of factors that can lead to non-adherence, it was suggested that a whole-system approach would be needed to tackle it. This effort should not be taken in isolation from broader initiatives promoting lifestyle changes as a means of preventing ill-health, as the two initiatives are complementary, and could even be synergistic in some instances.

In addition to the impact on patients' health, delegates acknowledged that non-adherence represents a waste of NHS resources. Its damaging effects to the overall economy were also considered, reflected for example, in the increased number of sick days and decreased productivity. Tackling non-adherence to medicines is therefore not only an issue in terms of heath losses, but also for the economy.

Conversation and shared decision-making

Participants felt that the quality of dialogue between patients and HCPs is a crucial factor in determining adherence to medicines. Whilst they acknowledged the time constraints of medical consultations, they emphasised the need for finding ways to enhance this dialogue and for HCPs to develop a better understanding of the patient's experiences, expectations, preferences and values. Improved understanding of these factors would valuably inform HCPs on the appropriate treatment.

Increased dialogue with the patient was also recognised as part of a more general need for a holistic approach in treating patients, through which greater emphasis would be given to the overall wellbeing of patients rather than purely on the treatment of their medical condition. Consideration should also be given to tailoring the treatment, where possible, in line with patients' preferences about their involvement in the decision-making process. On the one hand, some patients may respond well to shared decision-making about treatment options, feeling more in control of their condition and empowered to choose treatments that are best suited to them, ultimately leading to improved adherence. On the other hand, some patients may prefer to play a less active role in their treatment options by relying on their HCP's expertise for choosing the best treatment.

Providing information

Participants pointed out that the emphasis during consultations and in drug information sheets is on the side effects of drugs, while their benefits are in comparison poorly communicated. It was suggested that the value of medicines for disease management and wellbeing, but also the recognition of time, effort and thorough scientific process invested into their development, should be emphasised to a greater degree. These efforts should be coupled to better communication of the risks linked to non-adherence, both in terms of personal health but also broader public health issues, for example in the case of AMR.

It was agreed that these messages should be disseminated consistently by all HCPs, as part of drug information sheets, and more generally throughout society, including for example in schools and in the workplace. Crucially, they should be conveyed in a language appropriate for the lay public.

It was also highlighted that the portrayal of drugs in the scientific and general media can be unhelpful at times. Whilst it is important for these channels to expose the potential harmful effects of medicines when these are well-founded, misrepresenting medicines and their effects can be unhelpful and could potentially have harmful consequences for patients who alter their treatment as a consequence. There may be merit in better engaging with journalists on these issues.

Education and changing attitudes

Incorporating messages on the importance of drug adherence into medical training was thought to be one of the first steps in tackling non-adherence. It was suggested that medical training should also put increased emphasis on developing communication skills and establishing the importance of understanding patients' values and preferences, which can be incorporated into treatment decisions where possible. A culture of openness and honesty between patients and their HCPs should be encouraged, such that patients feel comfortable to discuss any underlying reservations about treatment options. This more constructive relationship, in which patient and HCPs are equal partners, could help prevent non-adherence by considering at an earlier stage alternative treatments to which the patient would be more likely to adhere.

Delegates also questioned whether the overall health literacy of the public, including a basic understanding of diseases and crucially disease management and treatments, should be broadened. It was suggested that healthcare messages should be taught from an early age.

A change in culture and attitudes contributing to non-adherence will be required, although it was recognised that this is likely to be a slowly-evolving process, as was the case with changing attitudes towards smoking. Delegates highlighted that the public's sense of entitlement to NHS services, rooted in the perception of the NHS as a system that can be used without limits, might contribute to the issues. This could be mitigated by raising

awareness of the NHS as an asset with limited resources, which are being wasted by non-adherence. This could also be complemented by informing the public on the costs of medicines. A community-wide approach would be required in disseminating such messages, to ensure that specific patient populations do not feel discriminated against.

The importance of adherence was also raised in the context of AMR, where ensuring full and appropriate adherence to an antibiotic regimen is critical not only for an individual's health, but also for the health of the wider community. AMR could be used as an example to illustrate how non-adherence to medicines could be harmful on a broader societal scale, and used to reinforce the importance of adherence to medicines by resonating with the public's sense of social responsibility.

Integrated healthcare

The structure of the current healthcare system was recognised as one of the factors contributing to non-adherence and an obstacle in ensuring a coordinated response against it. One proposed solution was to introduce a 'healthcare facilitator', whose role would be to provide a link between different HCPs and communicate more effectively with patients, thereby providing some from of continuity in the healthcare pathway in relation to medicine prescribing and adherence. A second solution would be to link records in general practitioners' (GPs) surgeries, hospitals and pharmacies, and enable them to communicate with one another. This could be used for example to develop a system that would alert GPs when prescriptions have not been collected. Interoperable IT systems could also help tackle issues associated with problematic polypharmacy, which is often linked to non-adherence and can result from a lack of cross talk between pharmacies and different HCPs. Introducing central dispensing of drugs could also help in this regard.

The fragmented healthcare system was also noted as a barrier to a coordinated response to non-adherence by its different components; as noted before, it is crucial that HCPs transmit and reinforce similar messages on the importance of adherence to medicines, if this issue is to be tackled appropriately.

Need for involvement of all relevant stakeholders

Delegates noted that responsibility for better adherence to medicines is shared by multiple stakeholders and that system-wide changes would be needed to address non-adherence. A crucial step in this endeavour would therefore entail aligning the incentives of all different stakeholders. Delegates described the ideal system as one in which adherence to medicines would be given high importance, becoming part of organisational objectives supported by structures that would encourage and promote attitudes to address issues associated with non-adherence.

In turn, participants considered how each of the relevant stakeholders could contribute to addressing non-adherence.

The regulatory sector

Regulatory bodies, such as the Medicines and Healthcare products Regulatory Agency (MHRA) or the National Institute for Health and Care Excellence (NICE), may have a further role to play in improving adherence. The MHRA, for example, could ask for adherence data as part of submissions for regulatory approval. It was however questioned whether this would add an undesirable layer of complexity and bureaucracy to the current submission process. NICE, with its power to directly influence healthcare provision and practice, could have a prominent role to play. It is planning on reviewing its guidelines on medicines adherence in early 2015, and it will be important for it to consider the various aspects raised in these discussions.[22]

The pharmaceutical industry

Participants felt that the pharmaceutical industry could also play a greater role in tackling non-adherence to medicines. It was suggested that industry could collect post-marketing authorisation feedback on drugs, and correspondingly, seek to improve their design and delivery in order to improve adherence. It was acknowledged, however, that this would be a costly and relatively slow process. It was also pointed out that the question of adherence should be considered early in the drug development process.

Healthcare practitioners

As mentioned previously, delegates thought that increased integration within the healthcare sector would enhance adherence. Specifically, in addition to the role of physicians, it was highlighted that nurses could take part in the dialogue with patients. However, it was acknowledged that nurses, similar to other HCPs, have limited time resources. Delegates considered the possibility of introducing 'field nurses', who would be responsible for visiting groups of patients in their homes to monitor and advise on taking medicines appropriately. It transpired that some pharmaceutical companies had already hired nurses specifically for this purpose.

Pharmacies

It was also noted that pharmacies could play a greater role in supplementing medicine dispensing with patient-tailored advice. Setting up pharmacies as part of GP surgeries was put forward as a way of enabling better communication between GPs and pharmacies; although it was acknowledged that due to lack of physical space in surgeries and potential financial burden to GPs, this might not be easily feasible, particularly in smaller GP surgeries.

Patients

Whilst it was noted that the problem of non-adherence did not lie solely with patients but also in the wider healthcare system, it was recognised that patients do have a role to play. For example, as highlighted before, education and communication with HCPs would help to develop greater recognition of the value of the healthcare system, which has limited resources that should be used responsibly. Better awareness of the issues relating to non-adherence would also help. It was emphasised that all actions to address non-

[22] National Institute for Health and Care Excellence (2009). *Medicines adherence: Involving patients in decisions about prescribed medicines and supporting adherence*. http://www.nice.org.uk/guidance/CG76

adherence should be undertaken in close collaboration with patient groups. For example, the views of patient representatives on NICE's Citizens Council could be sought when it undertakes its review of its medicines adherence guidelines in 2015.[23]

Technology

Participants recognised that digital technology has the potential to transform healthcare; some even described it as the 'blockbuster drug of the 21st century'.

There are various technologies currently available that could help improve adherence. For example, systems have been developed to remind people to take their medicines, including watches, automated pill boxes and mobile phone applications (apps). Trials have demonstrated that text messages sent to remind patients to take their medicines can improve adherence.[24,25] Additionally, a variety of technologies offer the possibility of monitoring adherence. Examples include micro-chipped pill containers or pre-loaded blister packs programmed to dispense the correct medication at the correct times, and sensors which once ingested emit a signal received by a patch on the skin.[26,27]

Mobile healthcare may also contribute to better communication between patients and HCPs. For example, it was mentioned that health apps could be used to provide information to patients and help them better manage their condition. At the same time, these technologies could supply HCPs with a richer source of information about their patients, beyond the limited information that can be obtained through short medical consultations. However, the use of digital applications should be carefully considered and individually tailored: there is a fine line between feeling cared for and being monitored, and this threshold varies between different individuals.

Overall, whilst delegates recognised the great potential technology holds in improving adherence to medicines, it was emphasised that it should not be used as a substitute for personal contact between HCPs and patients.

Research

It was recognised by all the sectors represented at the meeting that more research into the extent and underlying causes of non-adherence is needed to design intelligent solutions. To achieve this, delegates noted that research groups specifically dedicated to

[23] https://www.nice.org.uk/get-involved/citizens-council
[24] Broomhead S & Mars M (2012). *Retrospective return on investment analysis of an electronic treatment adherence device piloted in the Northern Cape Province.* Telemedicine and e-Health **18**, 24-31.
[25] Wald D *et al*. (2014). *Randomised Trial of Text Messaging on Adherence to Cardiovascular Preventive Treatment (INTERACT Trial)*. PLoS One. **9**, e114268.
[26] Arnet I, Walter P & Hersberger K (2013). *Polymedication Electronic Monitoring System (POEMS) – a new technology for measuring adherence.* Frontiers in Pharmacology **4**, 26.
[27] http://www.proteus.com/technology/digital-health-feedback-system/

this area should be established, and appropriate sources of funding made available to support their research.

Participants discussed the sources and tools for conducting research on adherence, and emphasised that more real-world data on drugs should be collected, following post-marketing authorisation. This could include information on adherence as well as on patients' perspectives and experiences, all of which should be rigorously analysed. Equally, developing reliable measurement tools for tracking adherence is needed, as a necessary prerequisite for obtaining meaningful data. Participants were keen to emphasise that while accurate measurement of adherence is important, ultimately the major criterion in evaluating treatments remains the patient outcomes.

Specifically in relation to randomised clinical trials (RCTs), delegates suggested that RCTs should explore producing a standardised set of outcomes that would enable reliable comparison of results of different trials. The COMET (Core Outcome Measures in Effectiveness Trials) Initiative was listed as an example of enterprise that seeks to develop such a standardised set of outcomes.[28] Delegates also considered the importance of collecting data on patients' perspectives of taking part in trials, which could be informative in predicting drug adherence in the real world. The MRC North West Hub for Trials Methodology Research is one of a number of organisations looking at designing patient-centred trials, and this work offers possible avenues for exploring this idea further.[29]

Concluding thoughts

The meeting concluded with each of the speakers highlighting what they considered to be the key priorities to make progress in improving adherence to medicines. It was thought that greater priority should be given to tackling the challenge of non-adherence, should the healthcare system wish to succeed in ensuring best outcomes for patients. It was also suggested that all stakeholders needed to acknowledge that the problem of non-adherence lies within the wider healthcare system – not just with patients – and that a coordinated response from the whole community would be necessary to address this issue. A deeper understanding of the root causes would inform how to best allocate effort and resources in addressing non-adherence. Enhanced engagement and communication with patients was deemed to be vital, as was involving patients in choosing treatment options, should they desire to participate more in their own healthcare. Incorporating into medical training messages on medicines adherence, communication with patients, and including patients' choices in treatment decisions, was thought be a first step in tackling non-adherence. It was also suggested that tools to better assess the prevalence and nature of the problem, and new technologies, such as reminders, automated pill boxes and mobile phone applications, should be utilised to their full potential to enhance medicines adherence. These technologies should complement, not substitute, the work of healthcare providers.

[28] http://www.comet-initiative.org/
[29] http://www.liv.ac.uk/translational-medicine/departmentsandgroups/nwhtmr/

Appendix I Programme

03 December 2014 at the Academy of Medical Sciences, 41 Portland Place, London W1B 1QH.

09:30 - 10:00	**Registration with tea/coffee**
Session 1 – Introduction **Chair:** Sir Alasdair Breckenridge CBE FRSE FMedSci	
10:00 - 10:10	**Welcome** Sir Alasdair Breckenridge CBE FRSE FMedSci, Former Chairman, MHRA
10:10 - 10:30	**Behavioural aspects of patient adherence** Professor Rob Horne, Professor of Behavioural Medicine, University College London
10:30 - 10:50	**Economics of patient adherence** Professor David Taylor, Professor of Pharmaceutical and Public Health Policy, University College London School of Pharmacy
10:50 - 11:10	**Measurement of patient adherence** Professor John Urquhart, Senior Scientific Advisor and Co-Founder, AARDEX-MWV Healthcare
11:10 - 11:30	**Ethics of patient adherence** Professor Richard Ashcroft, Professor of Bioethics, Queen Mary University of London
11:30 - 11:50	**Overview of current policies surrounding patient adherence (globally)** Dr Keith Ridge CBE, Chief Pharmaceutical Officer, Department of Health
11:50 - 12:00	**Summing up** Sir Alasdair Breckenridge CBE FRSE FMedSci, Former Chairman, MHRA
12:00 - 13:00	**Lunch**
Session 2 - Discussion session **Chair:** Professor Tim Higenbottam FRCP FFPM	
13:00 - 14:30	**Group session to discuss key challenges, opportunities and implementable ideas, including discussion around the following topics:** • Is addressing the issue of non-adherence to medicines a priority for the healthcare system? • What are the key challenges and how can they best be tackled at the level of: 1. The individual? 2. Organisations? 3. Society? Solutions may include for example enhanced communication, system change, advances in technology, amongst others. • How can we develop integrated strategies that can operate at all three levels?
14:30 - 15:00	**Tea/coffee break**
15:00 - 15:30	**Feedback**

	Chair: Professor Tim Higenbottam FRCP FFPM, Director of Research and Development, AllergyTherapeutics Ltd
15:30 - 15:50	**Plenary discussion session** Sir Alasdair Breckenridge CBE FRSE FMedSci, Former Chairman, MHRA
15:50 - 16:00	**Summing up and next steps** Sir Alasdair Breckenridge CBE FRSE FMedSci, Former Chairman, MHRA
16:00	**Close**

Appendix II Delegates

Dr Dipti Amin, Senior Vice President and Chief Compliance Officer, Quintiles
Professor Richard Ashcroft, Professor of Bioethics, Queen Mary University of London
Professor Nick Barber, Director of Research, Health Foundation
Ms Nina Barnett, Consultant Pharmacist, Care of Older People, Northwick Park Hospital
Dr Paula Boddington, Stipendiary Lecturer in Philosophy, University of Oxford
Mr Matt Bonam, Pharmaceutical Project Director, Intelligent Pharmaceuticals, AstraZeneca
Professor Christine Bond, Chair in General Practice & Primary Care, University of Aberdeen
Dr Keith Bragman PFPM, President, Faculty of Pharmaceutical Medicine
Sir Alasdair Breckenridge FMedSci (Chair), Former Chairman, MHRA
Ms Mair Davies, Chair, Welsh Pharmacy Board
Mr Simon Denegri, Senior NIHR National Director for Public Participation and Involvement in Research, NIHR
Mr Mark Duman, Non-Executive Director, Patient Information Forum
Dr Sarah Edwards, Senior Lecturer in Research Ethics and Governance, University College London
Professor Andrew Farmer, Professor of General Practice, University of Oxford
Professor Albert Ferro, Professor of Cardiovascular Clinical Pharmacology and Honorary Consultant Physician, King's College London
Mr Bruce Hellman, CEO and Co-founder, uMotif
Mr Mark Hicken, Managing Director UK & Ireland, Janssen
Professor Tim Higenbottam (Chair), Director of Research and Development, AllergyTherapeutics Ltd
Professor Rob Horne, Professor of Behavioural Medicine, University College London
Mr Alan How, Head of Devices and Digital Health, Merck Serono
Dr Ian Hudson, Chief Executive, MHRA
Ms Joanna Hulme, Associate Director – Medicines Advice (Medicines and Prescribing Centre), NICE
Dr Charles Lowe, President Telemedicine and e-health section, Royal Society of Medicine
Dr Andrew Makin, Head of Clinical Strategy – Europe, Otsuka
Dr Isabelle Moulon, Head of Patients and Healthcare Professionals, European Medicines Agency
Dr Mine Orlu-Gul, Chair, Academy of Pharmaceutical Sciences Age Related Medicines Focus Group
Dr Mitesh Patel, NIHR Academic Clinical Lecturer in Respiratory Medicine, University of Nottingham
Dr Charles Phillips, Advocacy Committee, Faculty of Pharmaceutical Medicine
Dr Bina Rawal, Director of Medical, Innovation and Research, ABPI
Dr Sian Rees, Director, Oxford Health Experiences Research Group
Dr Keith Ridge, Chief Pharmaceutical Officer, Department of Health
Dr George Savage, Co-Founder, Chief Medical Officer, Proteus
Mr Ed Tallis, Director of Customer Solutions, GSK
Professor David Taylor, Professor of Pharmaceutical and Public Health Policy, UCL School of Pharmacy

Professor Stephanie Taylor, Professor in Public Health and Primary Care, Queen Mary University of London
Professor John Urquhart, Senior Scientific Advisor and Co-Founder, AARDEX-MWV Healthcare
Dr James Wilson, Lecturer in Philosophy and Health, University College London

Secretariat
Dr Claire Cope, Policy Officer, Academy of Medical Sciences
Dr Ben Cottam, Policy and Communications Officer, Faculty of Pharmaceutical Medicine
Mr Nenad Medic, Policy Intern, Academy of Medical Sciences
Dr Rachel Richardson, Policy Intern, Academy of Medical Sciences
Dr Naho Yamazaki, Head of Policy, Academy of Medical Sciences

Appendix III References for the tables describing medicines and adherence policies in the UK and beyond

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