

Adherence and Concordance

EPF Position Paper

March 2015



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1 Introduction

Effective use of medicines is an important part of self-management of chronic conditions. However, many patients do not take their medicines as intended by the prescriber. Estimates vary, but it may be that only half of patients with chronic diseases adhere to their long-term medications¹, and perhaps only a third follow general lifestyle recommendations, such as diet advice. A 2008 study by the community pharmacists' association, PGEU, estimated that 20-30% of patients do not adhere to medication regimens that are curative or relieve symptoms, and 30-40% do not follow regimens designed to prevent health problems.²

Non-adherence (sometimes called non-compliance; see [chapter 2 "Terminology"](#)) can mean, for example: not taking the prescribed medicine at all; taking a different dose than prescribed, or at different times; taking the medicine irregularly; or stopping the course early.

Non-adherence carries enormous costs, not only to patients but also to the health systems. This can be seen in increased need for further treatment, emergency hospitalisations, reduced productivity, and simply waste of resources funded by public healthcare systems. Each year, millions of people get sick or die as a result of not taking medicines correctly; in the EU, around 194,500 deaths each year are due to mis-dosing or other type of non-adherence. Non-adherence is estimated to cost the European Union some €1.25bn each year.³ A recent overview is available from the EU-funded ABC project.⁴

"Increasing the effectiveness of adherence interventions may have a far greater impact on the health of the population than any improvement in specific medical treatments."

- Haynes RB (2001) in WHO (2003)

Rational prescribing of medicines is on the policy agenda as many European health systems struggle with limited resources while facing increasing need due to ageing populations and increase in chronic conditions. However, policy makers, health managers and healthcare professionals often underestimate the opportunity to improve health outcomes and use health resources more efficiently by monitoring what happens *after*

medicines are prescribed.

Improving adherence is a key factor in improving patient safety and quality of care tailored to patients' needs⁵, in reducing unused and improperly used medications, increasing the effectiveness and cost-effectiveness of healthcare, and so improving the financial sustainability of European health systems.⁶

Adherence is closely linked to, or a key element of, several policies and initiatives at EU level, including the recent EU legislation on pharmacovigilance; plans for combating anti-microbial resistance; European initiatives on health literacy, patient safety and quality of care; eHealth; and the European Innovation Partnership on Healthy and Active Ageing.

¹ WHO (2003) *Adherence to long-term therapies. Evidence for action*, p. 22

² "Targeting Adherence" report, PGEU (2008)

³ *Ibid.*

⁴ Ascertaining Barriers for Compliance (FP7), final report. <http://abcproject.eu/img/ABC%20Final.pdf>

⁵ But see caveat regarding mental health, below.

⁶ Horne et al. (2005) *Concordance, adherence and compliance in medicine taking*. Report for the National Co-ordinating Centre for NHS Service Delivery and Organisation R&D.

Adherence is an important issue when it comes to antibiotics. This is because misuse of antibiotics leads to the emergence of resistance. In addition to reducing inappropriate prescribing and use of antibiotics, it is important that patients take their prescribed antibiotics correctly: with the correct dosage, dose intervals and duration of treatment. Improper use of antibiotics includes taking them for the wrong reason – for example for cold and flu, which are normally caused by viruses against which antibiotics are not effective; using someone else’s “leftover” antibiotics; stopping antibiotics early; taking a lower dose; or taking the drug less frequently than directed.⁷

EPF has argued that adherence should be a priority at EU level, both in policy and in research under the Health Programme and Horizon 2020. In our view, future actions need to be framed within the organisation of the healthcare system as a whole and should involve all the stakeholders, from patients to health professionals, policy makers and the pharmaceutical and medical device industries.

In 2011, we co-organised an awareness-raising seminar at the European Parliament with PGEU, CPME and EFPIA – the EU-level organisations representing community pharmacists, doctors and pharmaceutical industry. Information on this event is available on our website.⁸ We contributed comments to the “ABC” project (Ascertaining Barriers to Compliance, FP7 2009-2012), which provided a comprehensive evidence-base on adherence and developed an educational framework for health professionals.

Feedback from EPF members indicates that the level of priority accorded to adherence by Member States varies significantly. There is also divergence between disease-areas: In respiratory diseases and diabetes, for example, it is seen as a very high priority. In cancer adherence is an emerging issue due to the fact that cancer is increasingly a chronic disease, and treatments are becoming available in oral form, many of which need to be taken for life.

Caveat concerning inappropriate medication and mental health

Whilst addressing over-medication and inappropriate prescribing in detail is beyond the scope of this paper, it is important to bear in mind that adherence is not by definition always a positive thing. Over-medication, or inappropriate medication, can be as much of a problem as under-medication. Inappropriate prescribing is often a problem associated with polypharmacy and complex conditions.

Moreover, the situation in the mental health field cannot be compared with other fields of medicine. The causes of major mental health conditions are still unknown, and psychiatric medications have been argued to be in some cases detrimental to health and quality of life.⁹ Many patients prefer non-pharmacological approaches, and a number of patient and professional organisations are critical of the biomedical approach to mental health conditions. Regrettably, patients with mental health issues often do not have access to holistic treatment approaches, which systematically combine psychotherapy, psycho-education and psychological rehabilitation with pharmacological treatment (if the latter is chosen). The reader should therefore bear in mind that the views on adherence to medications described in this paper are not necessarily applicable to mental health conditions.

⁷ A wide range of information, data and other resources on anti-microbial resistance is available at the ECDC website, www.ecdc.europa.eu/en/healthtopics/antimicrobial_resistance/basic_facts/Pages/factsheet_general_public.aspx

⁸ <http://www.eu-patient.eu/whatwedo/Policy/Adherence-to-therapies-Compliance-Concordance/>

⁹ Ho, Andreasen, Ziebell, Pierson, Magnotta (2011); Whitaker (2002, 2010). Further information available from www.enusp.org/

2 Terminology

Adherence and compliance are both terms used to describe the extent to which a patient takes their medication as prescribed. **Compliance** is defined as the extent to which the patient's behaviour matches the prescriber's recommendations. **Adherence** in turn is the extent to which the patient's behaviour matches the *agreed* recommendations from the prescriber.

- Compliance implies passivity, following demands and direction. Patient beliefs are not interacting in this process or are seen as an obstacle to treatment. Non-compliant patients are seen as rebellious, incompetent or a nuisance, as challenging the "status quo" of the doctor-patient relationship. Patient acceptance is based on the doctors' status.
- Adherence implies a more active role: collaboration with the physician with no place for blame; self-motivated decision to adhere to the advice; a tacit self-regulation of illness and treatment. Patient acceptance is based on trust.

Compliance and adherence both describe medicine-taking behaviour by the patient. Adherence is nowadays preferred by many to compliance because of its emphasis of the need for agreement.¹⁰ **Concordance** is a more recent term which focuses on the patient-prescriber relationship and interaction, and the degree to which the prescription represents a shared decision. In a concordant process the beliefs and preferences of both the prescriber and the patient are taken fully into consideration, with the recognition that the patient's views are paramount. Concordance also increasingly refers to a wider concept of patient support in medicine taking.¹¹

Concordance recognises that in the interaction between professional and patient, two sets of health beliefs are involved – that of the patient and that of the doctor – and that these may be different but they are equally valid in the concordant process. In the interaction, the task of the patient is to convey his or her health beliefs to the doctor; and of the doctor, to enable this to happen and to respect the patient's point of view. The task of the doctor or other provider is to convey his or her health beliefs to the patient; and of the patient, to entertain these. Patients should be in a position to make as informed a choice as possible about the diagnosis and treatment, the benefits and risks, and to take full part in a therapeutic alliance. A therapeutic alliance, "[a]lthough reciprocal ... is an alliance in which the most important determinations are agreed to be those made by the patient".¹²

¹⁰ Horne, R: Compliance, adherence and concordance: implications for asthma treatment. *Chest*, 2006;130;65-72; *Concordance, adherence and compliance in medicine taking*. Report for the National Co-ordinating Centre for NHS Service Delivery and Organisation R&D, December 2005.

¹¹ *Ibid.*

¹² *Partnership in Medicine Taking: A Consultative Document*. London: Royal Pharmaceutical Society of Great Britain and Merck Sharpe and Dohme; 1997

EPF believes the term adherence should be used instead of compliance as a neutral description of the patient's medicine-taking behaviour, assuming that the medicine prescribed is appropriate. **Health professionals should move towards concordance** and the respect for a patient's "free and informed choice of treatment" as the foundation for supporting patient adherence.

Although our members broadly consider that patients have certain responsibilities in the context of managing a chronic condition, failure to adhere should not be a reason to "blame" the patient but rather an opportunity to find solutions to support the patient through giving information, promoting empowerment, enhancing capacity and creating motivation – an approach which needs to be adapted to the unique situation of each individual patient.

Terms used to describe a patient's adherence behaviour:

Initiation = the patient takes the first dose of a prescribed medication (start)

Discontinuation = the patient stops taking the prescribed medication (finish)

Execution = the extent to which a patient's actual dosing corresponds to the prescribed dosing regimen (from start to finish). Weak execution can mean, for example, that the patient is taking the medicine but doing so irregularly, or at different times than prescribed.

Persistence = the length of time between initiation and discontinuation of dosing. Weak persistence means that the patient stops taking the medicine earlier than prescribed. (Source: [ABC project](#))

"Coeliac is unique because of the "funny" therapy – which is the lifelong gluten-free diet. Many parents/patients do not trust the diagnosis, because they are waiting for a "traditional" medicine so they do not keep to the diet prescribed by doctors and dieticians. One man was diagnosed with the skin form of gluten-intolerance, for which the treatment is the same: lifelong gluten-free diet. This condition is unusual, and he did not want to accept it. There is a special medicine to alleviate the itchy rashes but it should not be used for a long time as it has side effects. Sometimes the patients misunderstand this as a treatment for the condition itself and are convinced that the diet is not the "right" treatment. In many cases our association was able to convince the families that there is no other treatment and the best way for the children to recover is to accept the diagnosis and follow the rules." - Patient representative, coeliac disease

3 Reasons for non-adherence

The reasons behind non-adherence are complex and related to many factors. Non-adherence can be either intentional or unintentional. *Unintentional* non-adherence happens, for example, when the patient forgets to take medicine, is not able to open the packet, or does not understand the instructions. Change in routine can also result in unintentional non-adherence. As an example, some key factors in unintentional non-adherence in chronic obstructive pulmonary disease (COPD) include: impaired vision or musculoskeletal problems (affecting patients' ability to use inhaled medications); complex medication regime and multiple devices; poor awareness and understanding of the nature of the condition; confusion about prescribed medication regimes; and high rates of depression.¹³

Intentional non-adherence happens when the patient decides to take the medicine at different times, different doses, or not at all (for example, because they are feeling better or have concerns about long-term use). Patients can also overestimate their own adherence.¹⁴ Reasons for non-adherence, whether intentional or not, can be related to:

- lack of or poor of information given to patients (e.g. regarding treatment choices and their relative benefits/risks, the clarity of communication, evidence-base and source of information)
- the impact of treatment on daily life, (burdensome, painful, big social impact)
- factors related to the disease (although severity of disease is not necessarily correlated with higher adherence)
- adverse effects (desire to manage/reduce physical, psychological, emotional side-effects)
- complexity of the treatment, such as many different medications (polypharmacy)
- patients' beliefs (about medicines generally and about the treatment specifically, for example when there is no visible benefit from taking the medicine)
- health system-related factors (e.g. lack of care integration) or
- healthcare team-related factors (e.g. lack of data sharing, poor communication)
- access considerations (e.g. lack of reimbursement, co-payments, medicine shortages)
- physical or mental incapacity or emotional issues, e.g. depression
- social isolation or lack of support network.

These reasons are reflected in EPF members' responses to this position paper (with the exception of some organisations representing persons with mental health issues, see above Chapter 1). Complexity of treatment and the burden it imposes on everyday life is often mentioned: "people with chronic diseases often have to dedicate significant time, energy and resources to dealing with multiple medical appointments and treatments. This high burden of treatment of living with the long-term condition can have a negative impact on quality of life as well as resulting in poor adherence to treatment". Adverse effects are also frequently mentioned, as is lack of health literacy and good information – see Chapter 5 for more details on these.

¹³ Source : European Federation of Allergy and Airways Diseases Patients' Associations (EFA)

¹⁴ CML Advocates, "Non-adherence In Chronic Myeloid Leukemia: Results of a Global Survey of 2546 CML Patients in 79 Countries". Abstract submitted to EHA 2014 available at <http://www.cmladvocates.net/news/3-news/newsflash/250-eha-2013-adherence>

Health inequalities

Anecdotal evidence suggests strongly that financial/socio-economic factors may be a significant contributor to non-adherence, but this area has not yet been comprehensively studied. For example, recent studies in Finland showed that doctors and pharmacists frequently encounter patients who face financial difficulties as a result of the treatment costs, but patients are often ashamed and reluctant to talk about this.¹⁵ The financial crisis may have worsened the already existing inequalities through cuts in health insurance coverage and increased out-of-pocket costs.¹⁶ Some comments were received from EPF members in the Central/Eastern European region indicating that especially older and poorer people often cannot afford their prescribed medicines and thus have to forego necessary treatment. Shortages of health professionals, resulting in services under too much pressure and professionals with less capacity to respond to patients' needs, were also mentioned several times.

Older patients

Although non-adherence is common in all age groups, it is particularly pertinent for older patients, many of whom live with more than one chronic health problem and are on multiple medications.¹⁷ Such patients often experience disjointed services, with multiple specialists focusing on their "own" condition and patients have little support to manage the interactions. "Listening to [the patients'] experience offers valuable insight, advice and support to help improve these services."¹⁸

"The majority of people who do not adhere to treatment report that they do not have the capacity, skills and knowledge to do so, which would indicate a greater need for self-management support."

- Study by ALLIANCE Scotland

Older patients may also face specific physical or cognitive issues. In this context, EPF is participating in the European Innovation Partnership on Active and Healthy Ageing (EIP-AHA) action groups A1 (adherence) and B3 (integrated care). EPF has also developed a position paper "The rights and needs of older patients" (2013), which calls for specific health literacy strategies and a shared decision-making approach.¹⁹

Gender

There are differences in adherence behaviour based on gender. Men, especially from low income groups, tend not to report adverse effects – which are known to be linked to non-adherence. Men are also less likely to consult a doctor.²⁰ Women face specific issues, including pregnancy. Health-related information needs, beliefs and behaviours can also be different. There is thus a need to bear in mind gender-specific aspects when developing solutions for adherence.

¹⁵ Finnish Medicines Agency magazine *Sic*, February 2011 at http://sic.fimea.fi/koyha_saastaa_laakehankinnoistaan.aspx

¹⁶ See for example EPHA briefing note "Impact of the financial crisis on public health", September 2014, at http://epha.org/IMG/pdf/Economic_Crisis_and_Health_Facts_Figures_2014_10-09-2014_.pdf

¹⁷ See for example EU Reflection on Chronic Disease: EPF consultation response, [May 2012](#)

¹⁸ ALLIANCE Scotland. See "Many conditions, one life: an action plan to improve care and support for people living with multiple conditions in Scotland" at <http://www.jitscotland.org.uk/resource/many-conditions-one-life-living-well-multiple-conditions/>

¹⁹ <http://www.eu-patient.eu/whatwedo/Policy/Ageing/>

²⁰ White A et al., Report "The State of Men's Health in Europe", (2011) at http://ec.europa.eu/health/population_groups/docs/men_health_report_en.pdf See also <http://emhf.org/publications/>

4 Strategies to support patient adherence

Patients are the main actors: it is they who take (or not) the medicine, and it is their life and well-being that is at stake. Patients are non-adherent for a variety of complex, sometimes interlinked reasons, and no “one size” solution will fit all patients. Because adherence is so complex, and because the patient plays a key role in the long-term (self-) management of chronic disease, EPF believes that strategies to tackle it need to take a multi-stakeholder and, importantly, a patient-centred approach.

Difficulties with adherence should be used as an opportunity to explore how therapy can be made to fit better to the patient’s personal circumstances and needs; not to label the patient as “non-compliant” or “difficult”.

A patient-centred approach requires patient empowerment, including shared decision-making regarding the treatment in which the patient’s values and preferences are effectively integrated. It also requires certain skills, knowledge and attitudes by health professionals; and the availability of accurate, relevant and easily understandable information to patients. Health professionals, meanwhile, need appropriate training and working conditions.

4.1 INFORMATION AND HEALTH LITERACY

EPF considers that accurate, unbiased and understandable information about their health, condition(s), therapies, self-management, and social and peer support is a fundamental patients’ right. Health literacy is a critical strategy towards patient empowerment and an aspect of empowerment.^{21,22}

Well-informed, health-literate patients have been shown to be more discerning about their health, in a position to make more informed choices and decisions, and more likely to seek earlier diagnosis and recover faster. The converse is also true.²³

There is a clear need for patient-friendly information about medicines generally, and about specific medicines, including their potential benefits and potential risks. However, medical professionals tend to overestimate the information they provide, and patients’ understanding of it, while patients tend to want more information.^{24,25} Low quality information is a source of medication errors, adverse events and poorer outcomes.²⁶

“The information on medicines should be discussed rather than presented, making sure that the patient understands the treatment and has an opportunity to express concerns that may arise *after* reading the information leaflet.”

- Patient representative

The EU **pharmacovigilance legislation** (2011) mandated the European Commission to undertake a review on the shortcomings of the standard “patient information leaflet” (PIL) which is included in every

²¹ <http://www.eu-patient.eu/whatwedo/Policy/Health-Literacy/>

²² EMPATHIE – Empowering Patients in their Health Management in Europe, final report (unpublished).

²³ “Health Literacy – part 2: evidence and case studies”, World Health Communication Associates, 2010, pp. 20-22. Available online at www.whcaonline.org/uploads/publications/WHCAhealthLiteracy-28.3.2010.pdf

²⁴ Coulter, A (2007) “Evidence on the effectiveness of strategies to improve patients’ experience of cancer care”, Cancer Reform Strategy Patient Experience Working Group. At www.pickereurope.org/Filestore/PIE_reports/project_reports/Cancer_reform_strategy_Macmillan.pdf

²⁵ Fédération française des associations et amicales de malades insuffisants ou handicapés respiratoires (FFAAIR)

²⁶ *Health Literacy: the Solid Facts*. WHO 2013, p. 54.

medicine package. This leaflet is widely agreed not to be patient-friendly and many patients do not read it. A recent study in England found that a third of older adults had difficulties reading and understanding the instructions on a packet of aspirin. Poorer understanding was associated with higher mortality.²⁷ The Commission was to consult stakeholders and present proposals on how the PIL could be improved in order to better meet the needs of patients and health professionals. A study was indeed undertaken in 2013, but the results of that study have not as yet been published.

Patients want information that is accurate, relevant, short, legible and understandable. It should be offered both verbally and in written form. Information should cover the basics including:

- the diagnosis itself and the reasons for the prescribed medicine
- what it is prescribed for (what it is supposed to do)
- how likely it is that it will be effective
- correct dosage and how to take it
- possible interactions
- whether the course needs to be completed
- why is it important to be adherent – especially if the impact is not immediate or noticeable
- what would be the consequences of sub-optimal adherence
- what adverse reactions may be expected, and how to manage these
- whether further courses of treatment will be needed and how to renew a prescription.

One suggestion is that a “core package” of therapeutic education should be available to patients with chronic condition; this could start at the moment of diagnosis and be repeated with more in-depth discussions 2- 3 months after diagnosis and subsequently at regular intervals.

However, while information should be optimised, even more important is a full and honest and ongoing dialogue between prescriber and patient, so that the patient fully understands the importance and relevance of the medicine and adherence to the prescription, and the prescriber fully understands the patient’s perspective, her/his concerns if any, and her/his personal goals regarding disease management. Information is merely a support tool. In other words, *shared decision-making* leading to *concordance*.

4.2 SHARED DECISION-MAKING

In the beginning of this paper, we emphasised the importance of concordance. In our view, concordant prescribing is vital to promote optimal adherence. In turn, to achieve concordance, medical professionals and patients need to engage in shared decision-making about therapeutic options.²⁸

Concordance requires a radical change in doctors’ consulting styles and a deeper understanding of patients’ health-related beliefs and their experience and knowledge. This means health professionals must engage with patients as valued partners, respecting their beliefs and concerns. The professional should approach the patient as a whole person, not only as a medical problem. The treatment regimen

²⁷ Bostock S and Steptoe A (2012) “Association between low functional health literacy and mortality in older adults: longitudinal cohort study.” *BMJ* 2012;344: e1602.

²⁸ Some patients may choose not to take part in the decision-making process and prefer to delegate decision-making to their clinician. This is their right and should be respected.

needs to be tailored to the individual life circumstances of the patient, taking into account the patient's life goals (not just treatment outcomes).

The uncertainties of benefits and risks for many treatments means that most decisions are subject to preference to some extent – whether those preferences of the doctor or those of the patient. Both physicians and patients need to be able to manage uncertainties and communicate openly and honestly about these.

Shared decision-making implies that both doctors and patients recognise the uncertainties of different treatment options. Doctors are urged to be both “patient-centred” and “evidence-based”, yet these two goals can conflict with each other. Professionals should respect the right of patients to decide whether or not to take a specific therapy, but in some cases the patient may have incorrect information and beliefs, which need to be addressed carefully and sensitively.

“When I walk into the clinic I get asked: How have you been? What does my doctor really want to hear? About my clinical well-being (tests, infections, etc.)? **OR** the real burden in my life? ... Most patients instinctively know the answer.”
-Patient representative

It is the health professional's responsibility to provide all the available information, including benefits and risks involved in particular treatments, and all available treatment options. The right to refuse treatment should remain the patient's fundamental right. Patients also have the right at any time to change their mind about the treatment; in this sense, shared decision-making takes place along the continuum of care.

“Pressure from the hospital management to ensure shared decision-making is adopted at every level could help – especially in countries where the doctor-patient role is rather old-fashioned.”
- Patient representative

Patients need to be involved in the process of setting the goals (both of the treatment and the personal goals of the patient), deciding the treatment path, and planning ahead. Patients should also be able to feel safe and comfortable discussing all aspects of their treatment, including dosing, side effects, lack of effectiveness, any

concerns they may have regarding the treatment, etc.

One of the key barriers to patient empowerment identified in the EMPATHiE study²⁹ was lack of time for discussion between patient and professional. Conversely, having enough time is seen as a key facilitator. Clearly, pressures on the health workforce such as staff shortages have implications for the ability of professionals to meaningfully engage with patients.

4.3 HEALTH PROFESSIONALS' TRAINING

The flip side of empowering and informing patients is the need for training and education of health professionals. Professionals need to be trained for better communication with patients, and for creating an enabling environment for dialogue, concordance and a partnership approach. This requires integration and communication within the whole multi-disciplinary health team, involving not only doctors but also pharmacists and nurses. Fundamentally, it involves a change in medical culture.

²⁹ Tender study “Empowering Patients in the Management of Chronic Diseases”, Final report (September 2014) available at http://ec.europa.eu/health/patient_safety/docs/empathie_frep_en.pdf

Our members identified the following as most important barriers on the part of professionals:

- Lack of time to discuss with patients
- Attitudes
- Workload, resulting in “overloaded” professionals
- Lack of training
- Lack of incentives/funding for providing therapeutic education
- Stigma, particularly in mental health conditions.

“Long-standing tradition of paternalism and lack of motivation to change”

Key skills, knowledge and attitudes professionals must have to implement shared decision-making include:

- “Really” listening to the patient
- Asking the right questions
- Empathy and respect
- Communication skills
- Training to assess patients properly
- An open mind

“It is important for professionals to *believe* that involving patients in decision-making promotes trust and honesty and leads to better outcomes.”

The guideline “Managing and Supporting Medication Adherence. A framework for the education and training of health professionals in Europe”, developed by the EU-funded ABC project in 2011³⁰ integrates many of the principles of patient-centred healthcare, including: recognising the patient as an individual; listening actively to the patient; communicating; defining objectives and purpose with the patient; exploring options and deciding together; and supporting the patient. We do not know, however, whether this framework has been taken up and implemented by professional bodies and educational institutions.

The OSCE Guidelines for Human Rights Education for Health Professionals (2013) is another existing reference point for professional education specifically to instil a human-rights based approach.³¹

4.4 ONGOING, INTEGRATED SUPPORT

Although doctors are the primary professional actors in the decision-making regarding treatment, other professionals – particularly pharmacists and nurses – are often closer to the patient in the ongoing management of a condition and should be considered as integral to the care process. Moreover the roles of non-medical professionals, for example psychologists, social workers, therapists, and peers in the care process are underestimated and possibly under-researched.

Nurses not only increasingly prescribe medicines, but they can also provide valuable support to patients on how to “live with” the treatment, given that they are often more approachable and have more time to spend with the patient. Specialist nurses play an important role in the management of many chronic

³⁰ www.abcproject.eu

³¹ <http://www.osce.org/odihr/105053>

conditions, integration and supporting patients’ self-management.³² Nurses need to engage with patients to ensure that they and their carers understand the full implications of the prescription. “Nurses might have more time for patients; they could ask more questions about how patients are doing with their medicines.”

Pharmacists are a valuable source of information on adverse effects, contraindications and interactions of combinations of different medications, they can remind patients of the importance of regular tests if necessary. Patients often feel more comfortable discussing problems they experience with medication with their pharmacist than with their doctor.

“Most countries still focus on the doctor as the only person responsible for interactions with patients; but there are many roles that can be played by nurses and pharmacists, which will help address capacity issues in the health system and also make these roles more interesting and relevant to the patient journey.”
- Patient representative

There are differences between EU member states both in the way pharmacists’ role is perceived and the extent of their engagement in supporting patients’ medicine-taking. There are, however, many examples of adherence support schemes managed by pharmacists. These include for example regular consultations with pharmacists, follow-up interviews by telephone, and disease-specific programmes. Schemes similar to the UK’s

New Medicines Service (see “Links to further information”) have been implemented in some other EU Member States, including at least France and Belgium.

In Scotland a government action plan was adopted in 2013 with the aim to expand the role of pharmacists in delivering healthcare services. Objectives include building the capacity of pharmacists to work with patients and identify issues such as burden of treatment or low health literacy; to increase the number of “independent prescribers”³³; to increase continuity of care by registering patients with a “named pharmacist” who will support their needs throughout their journey; and to increase information sharing between pharmacists and other health and social care professionals.³⁴ EPF member ALLIANCE is closely involved with developing the programme of work to ensure that it is developed around the real-life needs of patients and integrates a strong patient voice, including people with disabilities and unpaid carers.

“Nurses and pharmacists should be encouraged to speak up, especially when they have traditionally not been given such a role, which will present a challenge in some systems.”
- Patient representative

For pharmacists to be able to play an enhanced role effectively, they need to be appropriately trained for the shift to a guidance and advisory role.

4.5 SELF-MANAGEMENT SUPPORT

Self-management by patients is a key element of patient-centred chronic disease care. In chronic conditions, the management of the condition is mostly handled by the patient in the home and in the

³² See for example EPF paper on chronic diseases (2012), p. 6 available at <http://www.eu-patient.eu/whatwedo/Policy/Chronic-disease/>

³³ Pharmacists who can monitor, adjust, start and stop medicines.

³⁴ “Prescription for Excellence: A Vision and Action Plan for the right pharmaceutical care through integrated partnerships and innovation” at www.scotland.gov.uk/Resource/0043/00434053.pdf

community, so one could say that patients already “self-manage”. For more about self-management, please see EPF papers on “chronic diseases”³⁵ and “patient-centred healthcare” (forthcoming).

“If I can be working in partnership with clinicians I could have much more success at avoiding mistakes and reducing the negative. Clinicians are full of good intentions and highly trained, but they are never going to be as committed to me and my health and wellbeing as I am.”

- Patient representative

Self-management does not mean leaving the patient to cope on their own, but rather a holistic approach providing the appropriate support and tools according to each person’s individual needs and preferences. Through this patients can develop the confidence, self-efficacy and skills to take control of the daily management of their illness and attain the greatest possible quality of life. It also aims to make the best use of all available resources. Evidence indicates that self-management support increases

patients’ quality of life and health outcomes, and may have an impact on reducing healthcare costs, though more research is needed.^{36, 37}

The importance of self-management support has long been understood, and in many disease areas (e.g. diabetes, respiratory diseases) models and tools have been promoted and researched for decades. In some disease-areas a so-called guided self-management approach is widely used.³⁸ Yet, overall, these services are still not available to patients consistently across countries and disease areas.

The role of technology

Technology can provide self-management support and motivation to patients and carers; patients can, for example, monitor their condition at home through wearable technology, and add information from their own observations to their shared electronic health record.

ICT-based tools, such as mobile phone apps with reminders to take medicine, can be helpful to some patients. The website “Myhealthapps” lists a number of apps under the topic “medication and treatment”, including reminders.³⁹ Still, current surveys indicate that mHealth solutions are currently used by a minority of people and many solutions are geared more towards

“There is something incredibly powerful about being able to see all your results over time in the one place. It allows a sense of reflection and lets you see patterns that you may not get when you are on the spot sitting in front of a healthcare professional.”

- Patient representative

consumers rather than to support self-management of chronic conditions. It is not easy for patients to find the right app for them, or to ascertain whether an application is safe and of good quality. Other barriers include differential access to the Internet across the EU, and lack of skills to use apps and monitoring tools.

The **electronic health record** is key to patient empowerment and self-management. EPF believes that patients should be *co-owners* of their health data, together with health professionals. Patients should not only have free access to their own health records, but the record – including mental and physical health

³⁵ <http://www.eu-patient.eu/whatwedo/Policy/A-Z-list-of-topics/>

³⁶ EMPATHiE literature review (2014) unpublished

³⁷ www.alliance-scotland.org.uk/what-we-do/self-management/self-management-impact-fund/

³⁸ E.g. in management of allergy, asthma and COPD in the Nordic countries and the UK (source: EFA).

³⁹ <http://myhealthapps.net/> Please note the information available on myhealthapps is not endorsed or checked by EPF.

data⁴⁰ – should be designed so that it is at least partly controlled and ‘owned’ by the patient, who should have the ultimate say regarding access to their data and any secondary use. This is already a reality in some parts of EU member states; in others, patients cannot even access their own records easily, or they are charged fees for this.

Some innovative examples exist. The “*My Diabetes My Way*” information portal for diabetes (NHS Scotland) contains educational materials, videos and interactive tools supporting education and self-management; it allows patients direct access to their data via a novel electronic personal health record.⁴¹

“The overriding advantage of Renal PatientView is being able to check my blood test results the morning after an appointment, without having to ring the hospital or wait until my next appointment ... when my kidney is reaching the end of its ‘shelf-life’ my test results are even more significant and, added to advice from my consultant, will help me to decide when it would be appropriate to start dialysis.”

- Patient representative

Through *PatientView*, British patients with certain conditions can access their healthcare records, including information about diagnosis and treatments. This now covers 90% of UK renal units and is now becoming available in some places for people with inflammatory bowel disease and Diabetes. The service, which has a small fee, has 30,000 registered users.⁴²

Although technology allows patients to get information traditionally held by doctors, this in itself is not enough to empower patients. As monitoring devices that can record patients’ activities and transfer information to health providers become more wide-spread, issues of consent and privacy need to be addressed. Fundamentally, to realise empowerment changes are needed in the healthcare system at all levels (e.g. embedding shared decision-making and comprehensive self-management support).

4.6 PATIENT REPORTING OF SUSPECTED ADVERSE EVENTS

Adverse reactions to medicines (ADRs), or fear of these, are an important reason why patients do not take medicines as intended. ADRs are also a big problem in themselves: they are the fifth largest cause of deaths in hospital – and yet only around 10% to 25% of all adverse reactions are reported.⁴³

Patients are best placed to assess the impact of a treatment on them and their life; patients’ reports have been shown to be of equal quality to professional reports, and they actually add value because they are based on the direct experience of patients and often provide richer detail. Patients’ reporting also leads to earlier detection of adverse reactions and the discovery of new reactions.⁴⁴ However, sometimes patients do not feel comfortable discussing side effects with their doctor or another health professional. This can lead to a patient simply stopping the medicine.

The recent EU rules on pharmacovigilance are aimed at improving the collection of information on adverse reactions. They also bring new options for patients to report suspected reactions directly to the national authorities (via an online tool). Some member states already have a long-standing system of collecting patient reports – for example the UK’s “Yellow Card Scheme” and similar schemes in The

⁴⁰ The conditions of access to “psychiatric records” are not always the same as to other medical records.

⁴¹ www.mydiabetesmyway.scot.nhs.uk

⁴² <https://www.patientview.org/#/>

⁴³ European Commission, http://ec.europa.eu/health/files/pharmacovigilance/ga_pharmacovigilance_2011_en.pdf

⁴⁴ See EPF Guidance on the EU Pharmacovigilance legislation, available at www.eu-patient.eu/globalassets/policy/pharmaceuticalpackage/epf-guidance-pharmacovigilance-for-patient-organisations.pdf

Netherlands and Denmark, whose impact has been positive.⁴⁵ Underreporting still remains a problem: in the UK it is estimated that only 10% of serious suspected reactions and 2-4% of non-serious ones are reported.⁴⁶

For the national reporting systems, it is important to provide a system of follow-up for patients who submit reports. It is essential for the individual patient who reports a reaction to have personalised feedback, confirmation of the value of their report, and further information about the medicine in question, as this can play a role in adherence to the treatment or the choice of an alternative therapy.⁴⁷

5 The role of patient organisations

Patient organisations can play a role in supporting adherence to therapies. They may be involved in direct peer support, as well as developing and implementing actions on adherence, information to patients, health literacy, etc. Patient organisations also play an important advocacy role in health policy, and many are already active in the field of adherence. Patient organisations can raise awareness in the patient community on the importance of reporting of suspected adverse reactions, and disseminate information about the availability of direct patient reporting and how to do it.

Patient organisations, whether at national or European level, need support to fulfil their role effectively. As many of them function on purely or almost voluntary basis, they need core funding and in addition potentially earmarked funding for specific projects. Patient organisations would also benefit from having access to scientific literature (through *pro bono* access to scientific journals, for example) as well as existing support tools and best practices.

Professional groups should engage with patient groups, for example in the development of “information templates” to explain the risks of non-adherence /benefits of adherence, adapted to their specific disease-context.

Industry should also engage with patient groups to develop more patient-friendly packaging; this should be considered early in the drug development process before manufacturing decisions have been taken without patient input.

Case study: EFA

In 2014 EFA* launched project to develop recommendations for education of adolescents with asthma in order to support their adherence to treatment. The target group are young people with asthma aged 12-17, which is the majority of patients and professionals consider one of the most difficult age groups to evaluate for adherence. The University of Maastricht, a partner of the project, produced a literature review exploring the reasons for non-adherence of young adolescents in order to assess what is already known in this field and where further research is needed. The project includes an adolescent patient-centred survey, which will be translated into three languages and distributed among 200 adolescent patients in four EU countries. Recommendations for education will be elaborated by combining the findings of the literature review and the outcomes of the survey.

* European Federation of Allergy and Airways Diseases Patients' Associations www.efanet.org

⁴⁵ See for example documents from the second pharmacovigilance stakeholder forum, European Medicines Agency, available [here](#); and the “Monitoring Medicines” project (FP7) on www.monitoringmedicines.org

⁴⁶ “Evaluation of patient reporting of adverse drug reactions to the UK ‘Yellow Card Scheme’: literature review, descriptive and qualitative analyses, and questionnaire surveys” at http://aura.abdn.ac.uk/bitstream/2164/2957/1/mon1520_YCS.pdf

⁴⁷ See [EPF recommendations](#) for patient-centred implementation of the pharmacovigilance legislation.

Policymakers should adopt adherence strategies with the collaboration of patient organisations, and provide political support/funding. EU funding should be available for developing effective and patient-centred adherence support programmes, and funding for implementation should be made at national level. Excellence centres or reference centres with specialised teams should be considered to spread best practice.

6 EPF principles and recommendations

Below EPF sets out a series of principles to guide policymaking on adherence and concordance and the development and implementation of adherence support programmes.

EPF principles on adherence and concordance

1. Strategies to promote adherence should be based on the concept of *concordance* and encompass health literacy, user-friendly information, and shared decision-making by patient and health professional.
2. Patients should not be blamed for non-adherence on forced to adhere.
3. Patients should be supported with all possible means to adhere to their (appropriate) treatments, or to change treatment if desired, through regular medication reviews.
4. Patients' personal goals – life goals as well as treatment goals – should guide the treatment decision. Treatment should be tailored to individual patients' needs, and doctors should always elicit the patient's preferences.
5. Communication about medicines should be based on full and comprehensive information, be accessible and tailored for individual patients as well as specific groups, such as older patients and patients with low health literacy.
6. High-quality, easy-to-understand information about medicines, including their benefits and risks, should be easily accessible, e.g. through online portals.
7. Health professionals should work in integrated teams with effective flow of information, especially during handovers/transitions.
8. Self-management support (e.g. CDSMP courses, peer-led support services) should be integrated into all chronic disease-management programmes.
9. eHealth and mHealth adherence support tools should be developed with patients' identified needs as the starting point and with patient involvement from the outset.
10. R&D on new treatments should specifically address the concept of concordance and adherence support. Patient representatives should be meaningfully involved in designing research and prioritising topics for research.

EPF policy recommendations

For EU policy-makers, national policy-makers, researchers and stakeholders.

Professional education and training

- a. Training in shared decision-making should be integrated into all medical training and continuous professional education.
- b. Existing patient-centred tools, such as the ABC competency framework should be implemented and used in professional education.
- c. A common set of professional competences (skills, knowledge and attitudes) for patient-centred healthcare should be developed at EU level with patient involvement and with tools for adaptation to different national and professional contexts.

Good practice sharing

- d. Good practices in adherence support based on concordance, and involving pharmacists and nurses, as well as doctors, should be identified, implemented and integrated into the care pathway. The platform of the Innovation Partnership on Active and Healthy Ageing should be used to share good practices.

Information to patients

- e. Member states should implement and/or further develop the national medicines information portals required by the EU pharmacovigilance legislation, with the involvement of patient organisations to ensure that information is relevant, easily understandable, accessible and useful.
- f. The outcomes of the study into the readability of the patient information leaflet should be published and appropriate action taken by the European Commission and the European Medicines Agency together with patient organisations.

Access and health inequalities

- g. The impact of the financial crisis, including co-payments, cuts in coverage, and shortages of healthcare staff, on adherence should be mapped, and steps taken to address the persistent health inequities, including access to medicines, across and within EU Member States.

Support to patient organisations

- h. Patient organisations, peer and self-help groups should be involved in developing advocacy strategies and providing information. They should be adequately and sustainably resourced to carry out their functions at EU, national and local levels.

Research

- i. Existing research related to adherence under EU programmes should be taken forward to implementation.
- j. The Health Programme and Horizon 2020 should prioritise studies on educational and training pathways on how to involve patients in treatment, targeted to both physicians/pharmacists/nurses, and patients.

7 Links to further information

This section will be regularly updated with more information.

Information about medicines

“Master your medicines campaign” (Ireland) Support materials for older patients to give information about medicines, help patients manage their medicines, and prevent unnecessary hospitalisation. It includes an information booklet available at pharmacies; a Patient Medication Record; a poster campaign in pharmacies; and a Medicines Reminder Chart. National radio was used for infomercials. Source: [IPHA](http://www.ipha.ie) (the Irish Pharmaceutical Industry Association) <http://www.ipha.ie/alist/consumer-patient-resources.aspx?article=81eb9422-80bf-4da7-bf74-cbd888ef5dea>

“A patient’s guide to fake medicines”. A leaflet produced by the European Alliance for Access to Safe Medicines (EAASM), this guide gives practical information to ensure the quality and safety of medicines. http://www.eaasm.eu/cache/downloads/8mrifvencpkw8s4kc8s4cwggw/EA677_EAASM_A4_Patient_Info_Leaflet_FINAL.pdf

Adherence support tools and services

Universal Medication Schedule. A tool developed by the Institute of Medicine (IOM) for standardising (written) medication instructions and supporting patient adherence. This tool describes the taking of medicines in a simple way (for example, “take two pills in the morning and take two pills in the evening” rather than “take two tablets by mouth twice daily”). See for example: <http://bmjopen.bmj.com/content/4/1/e003699.full>

New Medicines Service (UK). Patients with certain long-term conditions who have been prescribed a new medicine can benefit from a session with a pharmacist, either face-to-face or by telephone, to help identify any problems, side-effects, concerns related to the new medicine. The pharmacist provides guidance and advice, or refers the patient to their GP if needed. Source: PGEU. Information: <http://psnc.org.uk/services-commissioning/advanced-services/nms/>

Self-management

Self-Management Network Scotland: <http://smns.alliance-scotland.org.uk/>

ENOPE – European Network on Patient Empowerment (providers of chronic disease self-management programmes based on the “Stanford model”): www.enope.eu

Mental health

Paper written by a member of EPF member organisation ENUSP (European Network of (ex)users and survivors of psychiatry) on “involvement of users and survivors of psychiatry in issues relating to psychiatric drugs.” http://www.psychiatry.univr.it/page_eps/docs/2005_1_lehman.pdf

Guide for withdrawal from psychiatric drugs by the US-based user/survivor organization: <http://www.willhall.net/files/ComingOffPsychDrugsHarmReductGuide2Edonline.pdf>

Blog: <http://beyondmeds.com/>

8 Selected references

Ascertaining Barriers for Compliance: policies for safe, effective and cost-effective use of medicines in Europe. Final report, June 2012. <http://abcproject.eu/img/ABC%20Final.pdf>

Bostock S and Steptoe A (2012) "Association between low functional health literacy and mortality in older adults: longitudinal cohort study." *BMJ* 2012; 344:e1602

CPME, EFPIA, EPF, PGEU (2011) "Improving the sustainability of healthcare systems through better adherence to therapies: a multi-stakeholder approach" Joint briefing paper
<http://www.pgeu.eu/en/events/details/5-improving-the-sustainability-of-healthcare-systems.html>

CPME, EPF, MSD (2013) "Making health literacy a priority in EU policy", consensus paper, June 2013.
http://www.eu-patient.eu/globalassets/policy/healthliteracy/health-literacy-concept-paper_final.pdf

PGEU (2008) "Targeting adherence. Improving patient outcomes in Europe through community pharmacists' intervention." <http://www.pgeu.eu/policy/5-adherence.html>

European Centre for Disease Control (2014) Factsheet on antimicrobial resistance
www.ecdc.europa.eu/en/healthtopics/antimicrobial_resistance/basic_facts/Pages/factsheet_general_public.aspx

European Commission (2011) "Questions and answers: pharmacovigilance"
http://ec.europa.eu/health/files/pharmacovigilance/qa_pharmacovigilance_2011_en.pdf

Horne, R (2006) "Compliance, adherence and concordance: implications for asthma treatment" *Chest*, 2006; 130; 65-72.

Horne, R et al. (2005) *Concordance, adherence and compliance in medicine taking*. Report for the National Co-ordinating Centre for NHS Service Delivery and Organisation R&D, December 2005.
http://www.nets.nihr.ac.uk/_data/assets/pdf_file/0007/81394/ES-08-1412-076.pdf

Finnish Medicines Agency magazine *Sic*, February 2011
http://sic.fimea.fi/koyha_saastaa_laakehankinnoistaan.aspx

Kickbusch et al. (eds.) (2013) *Health Literacy: the Solid Facts*. World Health Organization
http://www.euro.who.int/_data/assets/pdf_file/0008/190655/e96854.pdf

World Health Organisation (2003) *Adherence to Long-Term Therapies. Evidence for action*.
<http://whqlibdoc.who.int/publications/2003/9241545992.pdf>

