

The European Patients' Forum Manifesto for the 2014 European Elections 22-25 May 2014

Patient involvement = healthier Europe Background Briefing No.4

The European Parliament Elections and new Commission 2014 offer a fresh opportunity for the European Patients' Movement to encourage politicians and policy-makers to commit to a healthier Europe.

We want to create a sense of urgency and real imperative to address the fundamental roadblocks to patients' access to proper healthcare and to demonstrate how patients can be part of the solution to make health systems more effective and quality-oriented. In other words, a healthier Europe, as outlined in our Manifesto "Patients + Participation = Our Vote for a Healthier Europe"



We, patients, as healthcare users, need to be involved in designing more effective healthcare and in research to deliver new and better treatments. Meaningful patient involvement in research will lead to treatments that provide real value. Patient-centred, integrated healthcare will lead to better quality of life for us and our carers, and more cost-effective, equitable and sustainable health systems for all. In other words, a healthier Europe.



Patient involvement is based on the premise that patients have a specific expertise derived from being patients, which is a valuable source of knowledge.

At **individual level** it can mean the extent to which patients – or their families or caregivers – participate in decisions related to their healthcare (e.g. through shared decision-making or self-management).

At the **provider level** (e.g. hospital), patients or their representatives play a role in improving healthcare using the specific experiences of patients as learning and educational tools to design better services.

At the **highest or policy level**, patients – through their representative organisations – contribute to shaping the healthcare system through their involvement in healthcare policy-making.

EVALUATING THE VALUE OF INNOVATION

Innovation, in all its forms – whether technology, process or social innovation¹ – is a crucial contributing factor to improving the health and well-being of patients, as well as the sustainability of care systems, and to enhancing Europe's global competitiveness and growth.

Innovative technologies and therapies promise to increase quality of care, but at least in the short-term they often represent an expense. Particularly innovative medicines are usually significantly more expensive compared to existing alternatives, and while they can result in important benefits for patients and thus contribute to overall societal objectives, at the same time they exert pressure on medicines budgets. The major challenge for European healthcare policy is to address and reconcile these conflicting objectives: *“to increase quality, to improve equal access to new technologies for those patients who need them, to guarantee equity and solidarity, and to control costs.”*²

From the patients' perspective, although access to new and improved medicines is crucial in many disease areas, innovation should not be defined purely in pharmaceutical terms. Often, unmet needs

¹ Operational plan of the European Innovation Partnership on Healthy and Active Ageing, 17 November 2011

² Belgian EU Presidency Background report, Ministerial Conference on Innovation and Solidarity (Sept 2010).

relate to how the health system is organised, or care delivered (e.g. lack of care coordination, lack of integration between social and health services, financial issues around cost of healthcare). Furthermore, specific groups of patients with unmet needs have been identified³ – e.g., patients with rare/neglected diseases, patients with mental health issues, older patients, children and women.⁴

“New” does not always mean better. Currently, innovation is mainly driven by pharmaceutical companies, and sometimes academic researchers; but how industry or academics define value in innovation is not necessarily how regulators, HTA, reimbursement bodies, physicians – or indeed patients – define it. Patients are in a position to the kind of innovation that would bring most value to them. One of the critical issues, therefore, is to bridge the gap between what patients, researchers, companies or regulators identify as priorities.

There is not as yet a common understanding of “valuable” innovation, or indeed how it should be encouraged and rewarded. At the same time, some urgent patients’ needs are still unmet. Innovation should be based on a patient-centred approach. Patients as healthcare users need to be involved in designing more effective healthcare of the future, including research to deliver new and better treatments (see also [EPF Manifesto Background Briefing No. 1, “Patients’ views matter”](#)). Patient involvement is needed to determine what innovation adds in terms of real value and improvement to people’s lives.

PATIENTS AND THEIR ORGANISATIONS SHOULD BE INVOLVED ACROSS THE ENTIRE INNOVATION CHAIN

Many patient organisations are already involved in developing new and better therapies for patients, for example identifying research issues not considered or not prioritised by academics, health professionals or industries, and initiating and (co-)funding research projects – particularly in rare diseases where no therapy exists.

There is growing evidence that patient involvement in clinical trials – starting from the question “What should be studied?” through to the design and evaluation of trials – leads to better quality and more relevant research outcomes.⁵ Patient-driven research is an untapped resource with the potential to greatly contribute to innovation. Moreover, being driven by patients’ needs, it has great possibilities to lead to innovative solutions that meet the real needs of patients. There is therefore a

UK surveys show that **48%** of inpatients and **30%** of outpatients want more involvement in decisions about their care than they have.

(Source:

<http://personcentredcare.health.org.uk/person-centred-care/shared-decision-making/why-do-shared-decision-making>)

³ See WHO report “Priority Medicines for Europe and the World”, by Warren Kaplan, Richard Laing et al. (2013 update), Chapter 7.

⁴ Older people, children and women are often excluded from clinical trials.

⁵ See, for example, the EPF position paper on clinical trials, http://www.eu-patient.eu/Documents/Policy/ClinicalTrials/EPF-position-statement_CTR_Feb-2013.pdf

need for increased policy attention and investment in this type of research. Research should be centred on patients' medical and social needs. This can only be achieved if patients are meaningfully involved throughout the research process, from the "idea" stage to the proven intervention. To ensure that research results in successful innovative solutions in healthcare, patients' involvement in the process is crucial. The involvement of patient organisations, and other civil society organisations, in research projects should be made easier with simpler rules, less bureaucracy, and adequate funding.

Empowering patients to get involved in research requires training to support their participation in scientific discussions and address the inherent imbalance of power between the "expert" and the "lay person". Those involving patients also need training and support. Some tools and good practices already exist, through the *Value+* and PatientPartner projects, and this is also the focus of the European Patient Academy on Therapeutic Innovation (EUPATI).⁶

But patient involvement is also needed at the other end of the chain, to ensure that cost/benefit assessment of innovative treatments takes into account their impact on patients' quality of life, and that they promote equitable access.

A recent randomised study found that patients who received enhanced support in treatment decision-making had **lower overall medical costs, fewer hospital admissions and fewer preference-sensitive surgeries.**

(Source: Veroff D, Marr A, Wennberg DE: "Enhanced Support For Shared Decision Making Reduced Costs Of Care For Patients With Preference-Sensitive Conditions". *Health Affairs*, February 2013, vol. 32, no. 2, 285-

HEALTH TECHNOLOGY ASSESSMENT

Patients should be involved in Health Technology Assessments, appraisals, prioritisation and reimbursement processes at national level. Patients' evidence needs to be better valued and incorporated at different stages in the HTA process.⁷ There is a lack of opportunities and structures for patients to give input in this area. Patients' unique experience and expertise on their diseases and treatments, as well as socio-economic and quality of life issues, is not always considered relevant and not adequately taken into account. Health Technology Assessments often focus on cost/benefit of a therapy for the healthcare system, instead of cost/benefits for patients' quality of life and ability to function in society – the latter are part of the wider societal benefits that often become apparent further down the line. Yet this has important implications for overall cost-benefit to society. There is a need to develop best practice on how to address societal benefits within Health Technology Assessment.

⁶ <http://www.eu-patient.eu/whatwedo/Projects/EPF-led-EU-Projects/ValuePlus/>; <http://www.patientpartner-europe.eu/>; <http://www.patientsacademy.eu/index.php/en/>

⁷ See EPF survey on patient involvement in HTA: <http://www.eu-patient.eu/Initatives-Policy/Initiatives/>

EHEALTH AND TELEMEDICINE

eHealth solutions, if implemented appropriately, can have huge potential for improving the quality of health services for patients, while serving the needs of the health professionals. For patients with chronic conditions, eHealth can significantly improve health outcomes and quality of life. Whether eHealth services will ultimately be adopted on a large scale is really going to depend on users, including patients' perceptions of the real benefits and safety of these services and interest in using them. Enhancing "e-health literacy" of patients and carers is a key requirement for the acceptance and confident use of ICT-supported services. Other barriers include low awareness of existing solutions by patients and health providers, lack of acceptance and trust on the part of end-users, organisational barriers such as 'silo' budgeting, lack of clarity concerning reimbursement, and the need for training on new skills and competences.⁸

BARRIERS TO PATIENT INVOLVEMENT IN INNOVATION

Barriers to patient involvement include:

- a general lack of recognition of patients' expertise and knowledge about what patients have to contribute;
- unequal power relations and researcher attitudes relating to who is allowed to "do science";
- poor understanding of patient involvement and how to work with them;
- (perceived) lack of scientific/medical knowledge on patients' part;
- and patients' lack of confidence and the resources to get involved.

There is a need for greater clarity about the roles and expectations of different actors, which can be supported by codes of conduct. Advocacy and awareness is needed to increase understanding of the patient's contribution. Capacity building for patient representatives is needed to address the inherent imbalances of power.⁹

⁸ One initiative to reduce such barriers was the two-year Chain of Trust Project entitled "Understanding patients' and health professionals' perspective on telehealth and building confidence and acceptance", which kicked off in January 2011.

⁹ One such initiative is the European Patients Academy for Therapeutic Innovation (EUPATI).

EPF KEY SOLUTION: A FRAMEWORK FOR PATIENT INVOLVEMENT ACROSS THE SPECTRUM OF HEALTH RESEARCH

We ask European decision-makers to:

- **Develop a clear framework for patient involvement across the spectrum of health research, through the entire cycle of the innovation chain.**
- **Ensure that patients' rights is part of the next Health Commissioner's portfolio.**

EPF calls for a clear framework for patient involvement in health research and innovation, with specific and concrete measures to enhance patient involvement across the spectrum of health research, across the innovation chain from start (ideas) to finish (implementation and evaluation). This framework should include:

- Identifying best practice and models for patient involvement in setting priorities for research and innovation – implementing the recommendations of the 2013 update of the WHO report “Priority Medicines for Europe and the World”¹⁰;
- Implementing patient involvement in clinical research – EU clinical trials regulation provisions on patient involvement in assessing trial applications;
- Implementing patient involvement in HTA – through the EU Network and in Member States;
- Implementing patient involvement in eHealth – through the EU Network and in Member States;
- Evaluating ongoing initiatives and identifying, collecting and sharing good practices on patient involvement in health research. Best practices and guidelines should be based on current knowledge e.g. that gained from previous European projects (e.g. *Value+* and PatientPartner).

¹⁰ http://ec.europa.eu/enterprise/sectors/healthcare/files/docs/prioritymedicines_report_en.pdf