

Review of core quality criteria for information to patients

Report of a Survey conducted by EPF in 2016

December 2016



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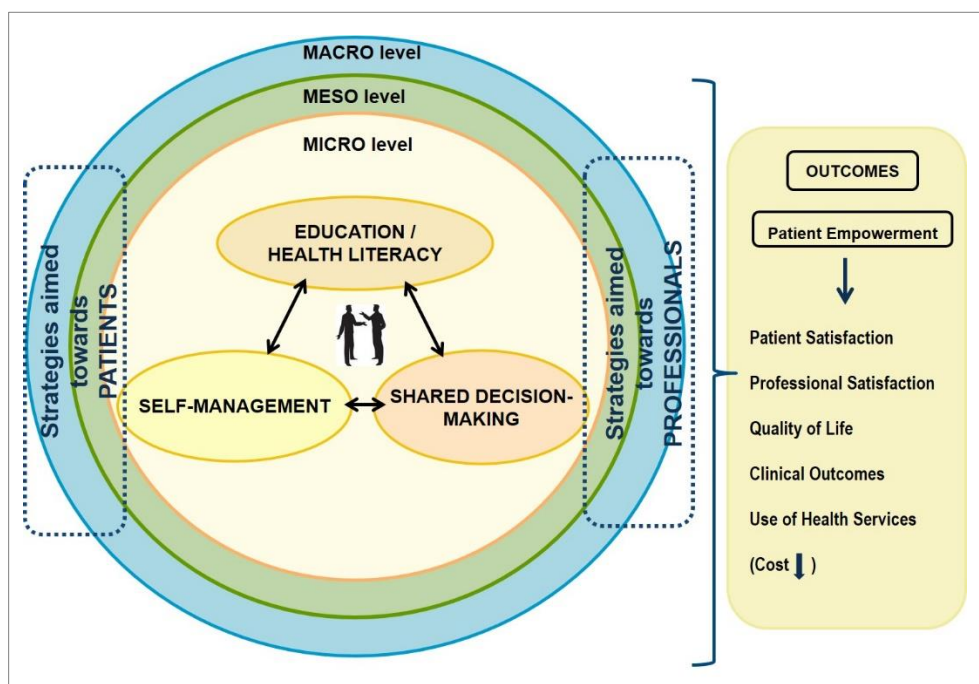
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1. Introduction

Information is both a right in itself and a fundamental prerequisite to exercising one’s rights. Information needs of patients are complex, and they often complain that they find the health (and social) care system difficult to navigate. Many patients and families experience having to “fight the system” just to get information about their rights and access to the services they are entitled to. This is even more of a problem for patients with low levels of health literacy or those in a marginalised or vulnerable situation.

Accessible, understandable and relevant information is a fundamental cornerstone of *health literacy*¹, itself a core dimension of *patient empowerment* as defined in the EMPATHIE study.² Although empowerment involves much more than becoming an educated or informed patient, the right information and resources are fundamental tools for empowerment. The knowledge and competence gained through health literacy leads to the strength and empowerment needed to manage well a disease and its impacts on quality of life.

The EMPATHIE conceptual framework of patient empowerment (2014)



¹ Health literacy definitions include the following: “the cognitive and social skills which determine the motivation and ability of individuals to gain access to, understand and use information in ways which promote and maintain good health” (WHO, www.who.int) and “the ability to make sound health decisions in the context of everyday life – at home, in the community, at the workplace, the healthcare system, the market place and the political arena.” (Kickbusch et al, 2005) a more recent definition comes from Sorensen and Brand (2013): “People’s knowledge, motivation and competencies to access, understand, appraise, and apply health information in order to make judgments and take decisions in everyday life concerning healthcare, disease prevention and health promotion to maintain or improve quality of life during the life course.”

² EMPATHIE study “Empowering patients in the management of chronic diseases” (2014). Final report available at http://ec.europa.eu/health/sites/health/files/patient_safety/docs/empathie_frep_en.pdf

Health literacy starts with good, easily understandable information: information is a tool towards improved health literacy. To make genuinely informed decisions about their health and treatment, it is vital that patients can access all the relevant information needed to make those decisions, in an easily understandable format.³ A particular challenge is finding the right balance between providing comprehensive information and information that is simple enough to be understood.

Good information is also critical to support *shared decision-making* and patient *self-management* as well as a critical pillar of *patient safety*.

Tools for patients, such as decision-aids, can help patients weigh the benefits and potential harms of different treatment options. A recent Cochrane review found that when patients use decision aids they improve their knowledge of treatment options; feel more informed and clear about what matters most to them; have more accurate expectations of benefits and harms; and participate more in decision-making. Patients also tend to choose less interventionist approaches to treatment.⁴

Self-management can be understood as a partnership between patients and the healthcare team: the team should support patients in “living with” their illness and in managing the conditions and their physical, psychological, emotional and social impacts. Through self-management support, patients can develop the confidence, self-efficacy and skills to take control of their daily life and attain the greatest possible quality of life. This also helps to make the best use of all available resources by, for example, improving adherence, reducing hospitalisation and emergency visits, and improving health outcomes.

Patients’ information needs are diverse and vary according to age, socio-economic status, gender, beliefs, preferences and coping strategies, and according to their general literacy, first language, skills and abilities. Needs often change during the patient’s journey, as does the empowerment “status” of the individual patient.

The EU Health Policy Context

The need for patients to play a more proactive role in their health, healthcare and in policy is recognised in order to ensure the high quality of our future health systems and addressing the combined challenge of chronic disease, budget constraints and rapid developments in technology. The concept of patients as “co-producers” of health hinges on empowerment. (The Health Foundation 2013, Mulley et al., 2012; Reflection Process on Chronic Diseases, Final Report, 8 October 2013)

The 3rd EU Health Programme states: “patients need to be empowered, *inter alia* by enhancing health literacy, to manage their health and their healthcare more pro-actively, to prevent poor health and make informed choices. The transparency of healthcare activities and systems and the availability of reliable, independent and user-friendly information to patients should be optimised. Healthcare

³ This is usually defined as “functional” health literacy. More advanced levels of health literacy are “interactive” health literacy (cognitive, literacy and social skills that enable active participation in healthcare) and “critical” health literacy (the ability to critically analyse and use information to participate in actions that overcome structural barriers to health). See for example Nutbeam D. “Health literacy as a public health goal: a challenge for contemporary health education and communication strategies into the 21st century”. Health Promotion International, 2000, 15(3):259–267. Cited in WHO, 2008.

⁴ Stacey et al. (2014) “Decision aids for people facing health treatment or screening decisions” Cochrane review. <http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD001431.pub4/abstract>

practices should be informed by feedback from, and communication with, patients.” (Regulation (EU) No 282/2014, recital 12)

Nevertheless, there is no consistent approach at European level to support patients’ right to comprehensive health-related information.

EU legislation

In certain areas, EU legislation has been passed that supports patients’ access to information, notably in the revised EU legislation on pharmacovigilance and falsified medicines, the Cross-Border Healthcare Directive (2011), and most recently the new Regulation on clinical trials (2014).

The EU Pharmacovigilance Legislation

The EU Pharmacovigilance legislation was revised to strengthen the EU pharmacovigilance system in order to prevent harm, promote safe and effective use of drugs, and to improve the provision of information to patients and the public.⁵ The new rules became applicable from July 2012.

The new rules introduced *direct, or spontaneous, patient reporting* as a mandatory provision for patients in all EU Member States. Such systems had already existed in some EU Member States and had proven their added value. Under the new system, patients (and professionals) can report all kinds of suspected reactions, including those resulting from off-label use, misuse, abuse, and medication errors. Patient reporting can be considered an empowering intervention, and it encourages patients’ engagement in their own health, awareness of and knowledge about medicines use, potentially also adherence to treatment.

The Eudravigilance, an EU-level database pooling information on suspected adverse drug reactions, is publicly accessible – although it has to be said that the database interface is not very lay-user-friendly. The legislation also required the creation of *national web-portals* by national competent authorities, with information on medicines presented in an understandable way and linked to EU resources. Furthermore, the Pharmacovigilance and Risk Assessment Committee (PRAC) was established at the European Medicines Agency, including two patient representatives. In connection with safety referrals the PRAC can organise *public hearings*; none have been held as yet but the EMA is now ready for such hearings.

The Cross-Border Healthcare Directive

The EU Directive on the application of patients’ rights in cross-border healthcare (Directive [2011/24/EU](#)) includes specific provision regarding information and transparency. A key novelty is the creation of *National Contact Points* (NCPs) for information to patients and the public. The NCPs must provide the information and practical assistance patients need to make an informed decision regarding treatment abroad, including on patients’ rights and entitlements. Member states are also obliged to make available information on the *safety and quality of healthcare*.

⁵ Directive 2010/84/EC and Regulation 1235/2010 revising Directive 2001/83/EC on the community code relating to medicinal products for human use and Regulation (EC) No. 726/2004 laying down community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, respectively.

The transparency provisions of the directive offer huge potential, not only to individual patients but also to patients' organisations and citizens, empowering them as advocates for improvements in the national healthcare provision. However, they need to be properly implemented and health literacy principles should be applied throughout. Implementation also needs to consider health and social inequalities in order to ensure that all people can benefit from better information about their rights and entitlements.

In our [recommendations](#) regarding the directive (2012) EPF recommended that Member States should apply the core quality principles of the Pharmaceutical Forum as a guideline for all information and disseminate those quality criteria to healthcare providers. From the state of the information available today, this does not appear to be the case.

Further work done by EPF through regional and national conferences and workshops involving patient communities across the EU, during 2013-15, has resulted in concrete recommendations regarding the provision of information, such as the development of EU guidelines on "core information" to be provided to patients and recommendations on good practices, such as applying health literacy principles; the use of standardised templates for application forms; and more engagement between NCP's and patient organisations.

Finally, patient feedback consistently indicates a need for better information about the national healthcare system, patients' entitlements and rights, which is not fully addressed by the Directive.

The EU Clinical Trials Regulation

In order to achieve meaningful patient involvement in research, and to increase public trust in research, it is crucial that at information is available to patients in a way that enables them to understand it. Patients will be more empowered to judge for themselves whether a summary of results is trustworthy when they know how to interpret clinical trials results. This means that patients should be able to understand the main principles and concepts of trial design and conduct, especially how to assess the evidence, and potential sources of bias.

The EU Clinical Trials Regulation (Regulation 536/2014) introduces a number of improvements to the transparency of clinical trial results: compulsory registration of all trials; the principle of public access to *the EU clinical trials database* developed and maintained by the European Medicines Agency; publication of all trial results, irrespective of the outcomes, on the EU database, as well as publication of clinical study reports for medicines seeking European marketing authorisation. All trials' summary results must include a *summary understandable to lay persons*.

In a position statement published in 2015, we called for a set of guidelines at European level to ensure the consistency and quality of the lay summaries. Subsequently, a working group was established to develop draft guidance, in which EPF participated along with several patient organisations. The guidance is expected to be published shortly, at the time of writing.

The “core quality principles” of the High-Level Pharmaceutical Forum

The EU High-Level Pharmaceutical Forum (2005-2008)

One of the working groups titled “Information to patients” developed a set of “core quality principles” for information aimed at patients, and the public.⁶ The principles were put through a public consultation process, and were subsequently endorsed by the EU Member States. A guide for using the principles is also available. The principles are available online, but they are not easily found unless a search is done using specific words.⁷

This background work led to the publication of a *legislative proposal* from the European Commission in 2008, as part of the so-called “pharmaceutical package”.⁸ However, unlike the other parts of the package, the draft Directive on information to patients never made it through to adoption, even though it was supported by the European Parliament.

EPF was supportive of the legislative proposal, with certain reservations. Primarily, we felt the scope of the proposal was too narrowly (only prescription medicines) and thus it would not have resolved the need of patients for comprehensive information on all aspects of health, from prevention and self-care to chronic diseases and their existing treatment options.⁹

We believed that Member States should play a key role in providing information to the general public, including statutory information about medicinal products, diseases and health conditions, and prevention, in accessible formats. EPF also called for a comprehensive EU strategy on information for patients, which would integrate information and health literacy aspects related to health and healthcare with the existing provisions regarding medicines-related information.

Regrettably, Member States were not willing to commit themselves. Even though the Commission published its proposal in a modified form in 2012, due to lack of agreement in the Council, the proposal was eventually withdrawn.¹⁰

Since then, the debate on information for patients has stalled at European level despite a growing recognition of the role of health literacy in patient empowerment, effective prevention and health promotion, self-management, patient safety and shared decision-making.

2. The EPF survey: rationale and methodology

EPF has continued to refer to the core quality principles of the pharmaceutical Forum as an example of good practice in all our work related to information for patients. However, it is unclear to what extent the patient community and other stakeholders are still aware of the existence of these principles, and whether they still consider them relevant given the changes in the health environment,

⁶ <http://bookshop.europa.eu/en/high-level-pharmaceutical-forum-2005-2008-pbND3008692/>

⁷ <http://ec.europa.eu/DocsRoom/documents/7593?locale=en>

⁸ The “pharmaceutical package” also comprised draft legislation to revise the EU pharmacovigilance system and a new Directive on falsified medicines.

⁹ Please see <http://www.eu-patient.eu/whatwedo/Policy/Information-to-Patients/>

¹⁰ COM(2008) 663 modified by COM(2011) 633, and COM(2012) 48. Proposal for a Directive of the European Parliament and of the Council amending, as regards information to the general public on medicinal products subject to medical prescription, Directive 2001/83/EC on the Community code relating to medicinal products for human use.

including technological developments, the emergence of the Internet as the primary source of information for many patients, since 2008.

This short survey, therefore, aimed to assess the level of awareness about the principles, their current use by various stakeholders providing information for patients, and perceptions about the usefulness or not of the principles.

EPF disseminated the survey to our member mailing, the target of which is patient organisations, and through our newsletter and mailing database, as well as individuals representing a wide range of health stakeholders. The survey was available online from 31 October until 15 December 2016 – a period of approximately six weeks.

3. Results of the EPF survey

A total of 45 responses were received. The majority of those identified as patients, family members or representatives of patient organisations.

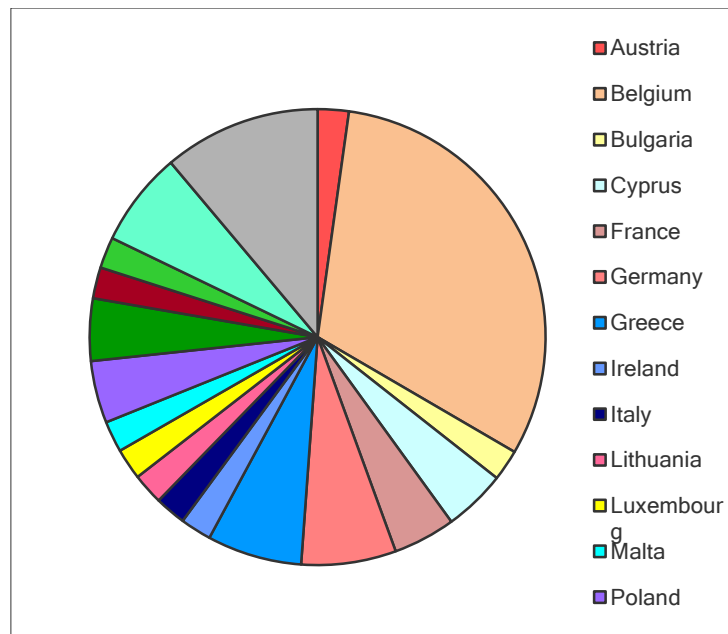
Table 1: Respondents by category (n=48)¹¹

Patients, family members or patient organisations: 25 (56%)
Pharmaceutical industry: 9 (20%)
Other organisation providing information to patients: 7 (16%)
Academic bodies: 3 (16%)
Other industry (med-tech, ICT...): 1
Regulators, either national or EU level: 1
Other: 1 organisation representing medical students and 1 communication consultancy

Somewhat predictably, most respondents were based in Belgium. Presumably this is because it is the seat of many EU level organisations, most of which would receive the EPF questionnaire. Thus, 14 answers were received from Belgium. Other countries represented were: the United Kingdom (5 answers); Germany, Greece, Spain (3 each); Cyprus, France, Poland, Portugal (2 each); Austria, Bulgaria, Ireland, Italy, Lithuania, Luxembourg, Malta, Slovakia and Slovenia (one each).

¹¹ There may be an error in this question, as the total responses comes to 48. It is possible that some of those who ticked "other" may have double-counted themselves.

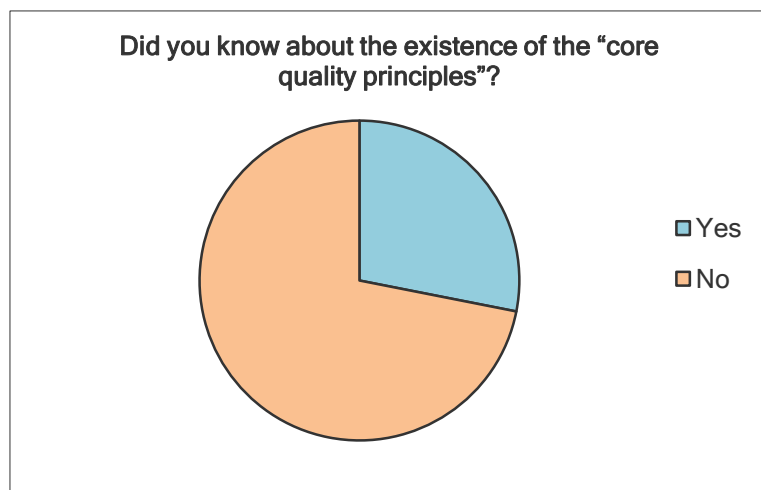
Chart 1: Geographic distribution of responses (n=45)



Awareness of the core quality principles

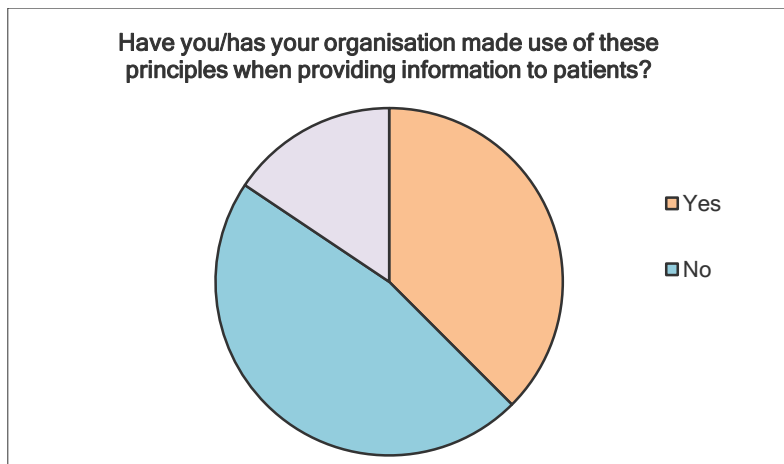
When asked about previous awareness of the core quality principles, 23 respondents (72%) answered no, and 9 respondents (28%) answered yes. However, 13 respondents did not answer the question.

Chart 2: Previous awareness of the core quality principles (n=32)



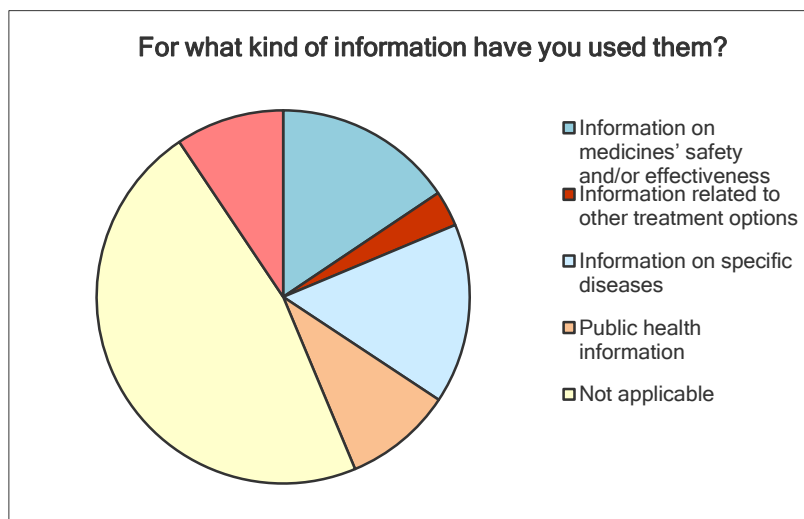
When asked if the respondent – or their organisation – had made use of the core quality principles, 12 respondents (38%) said yes, but 15 respondents (47%) said no, and five respondents (16%) did not know. Again, 13 respondents did not answer the question.

Chart 3: Previous use of the principles (n=32)



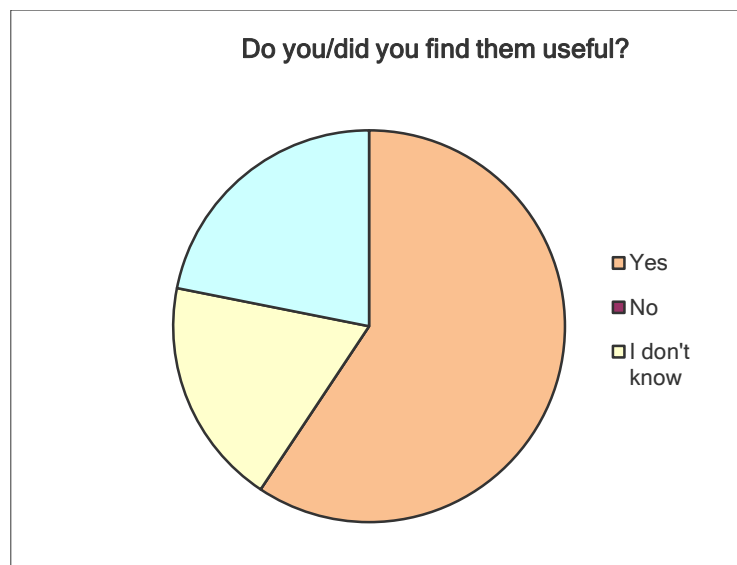
When asked what kind of use they had made of the criteria, the most frequently mentioned uses were information on medicines’ safety and/or effectiveness and information on specific diseases, both with five answers (16%); followed by public health information and “other” with three answers each (9%), whilst single mentions were made of information related to treatment options, patient empowerment, and information on policy. Fifteen respondents (47%) said the question was not applicable. One respondent said they were not aware of the principles and thus has not used them, but were using similar standards.

Chart 4: Previous use of the principles, part two (n=32)



Did the respondents find the quality principles useful? No-one felt they were not useful, whilst over half – 19 respondents (59%) said yes, and six (19%) said they did not know. Another seven respondents (22%) chose “not applicable”, presumably because they had not used the principles. Again, 13 respondents chose not to answer the question.

Chart 5: Usefulness of the principles (n=32)



Perception of the relevance of the principles

In the second part of our questionnaire, we asked the respondent to comment on the actual core quality principles, one by one. The core quality principles in their original formulation are as follows:

1. Objective and unbiased.

“Information is objective when it is based on facts and not influenced by prejudices or personal perceptions. Information is unbiased when it is impartial, non-directive and balanced.”

2. Patient-oriented.

“Information provided should be patient-centred taking into account patients’ needs and expectations in order to empower patients. Patients should be involved in the production and dissemination of information on diseases and treatment options wherever possible.”

3. Evidence-based.

“The evidence base for any information resource needs to be clearly stated, including making clear the level of evidence. Information should be verifiable, based on comparisons and backed up by scientific peer review where possible.”

4. Up-to-date.

“Information should be kept up-to-date and the date of publication should be included.”

5. Reliable.

“Information needs to be factually correct and not misleading. Information should be scientifically valid and reflect latest knowledge.”

(continued)

6. Understandable.

“Information provided should be comprehensible for a patient/citizen.”

7. Accessible.

“Information should be easily accessible via different mechanisms for example, through written documents, websites of certified official bodies etc. Information should also be accessible to people with disabilities.”

8. Transparent.

“Informed choice requires transparency. That entails transparency of what is known as well as what is not known. Funding, sources of information, evidence for that source and transparency when there is known controversy about a particular treatment, for example, all need to be made clear.”

9. Relevant.

“Information should include issues of relevance and importance to patients’ decision-making, e.g. including adverse effects. Impact on quality of life and the consequences of the disease on contribution of the patient to society/the work place are important elements of information on disease.”

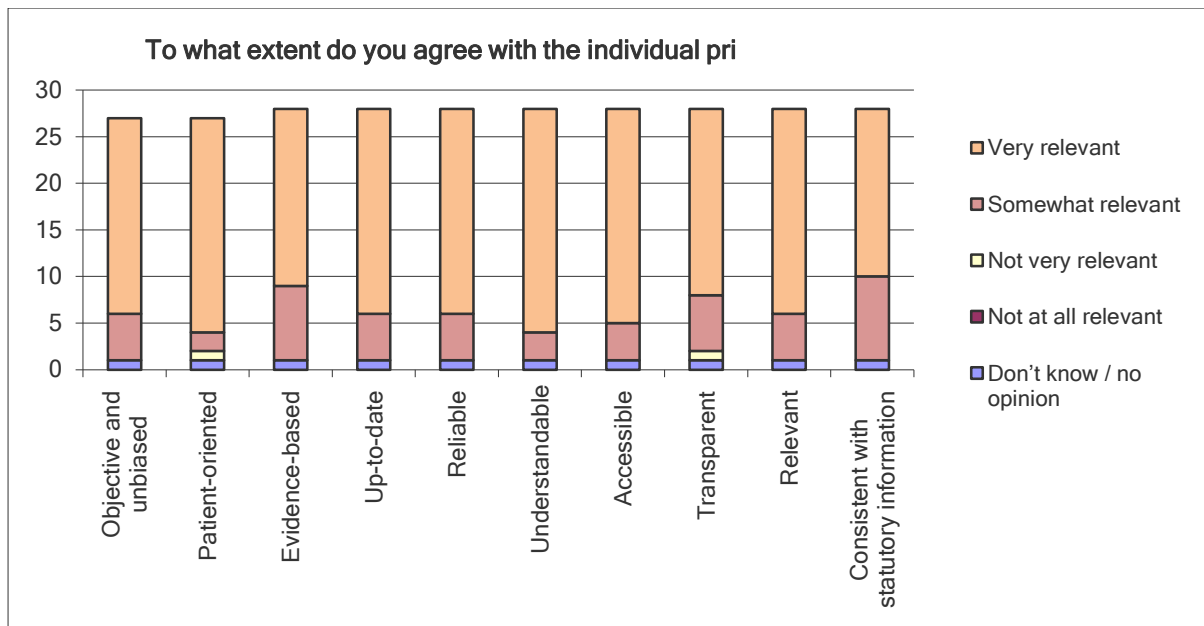
10. Consistent with statutory information.

“Information not regulated by statute should, nevertheless, be consistent with the legal requirements of European law (e.g. must not be designed to promote a prescription only medicine, reflecting the prohibition of direct to consumer advertising of prescription only medicines, must not be misleading etc.) and should refer, where appropriate, to statutory information approved through the process of regulation.”

We asked respondents to which extent they agreed with each individual principle, as to their relevance for improving information provided for patients. We asked respondents to answer the question even if they had not used the principles before, or did not know about them. We wanted their opinion on whether the principles would be potentially useful. While 17 respondents did not answer, nevertheless 28 respondents rated the principles.

Most principles were rated by a large majority of respondents as “very relevant”. The only two that were judged as “not very relevant” (though only by one respondent) were those relating to information being patient-oriented and transparent. No reason was given for this.

Chart 6: agreement with relevance of the principles (n=28)



To check the completeness of the principles, we asked respondents to state if there was anything important felt was missing. Of the 10 respondents who answered this question, four simply answered “no”. Other respondents gave some comments.

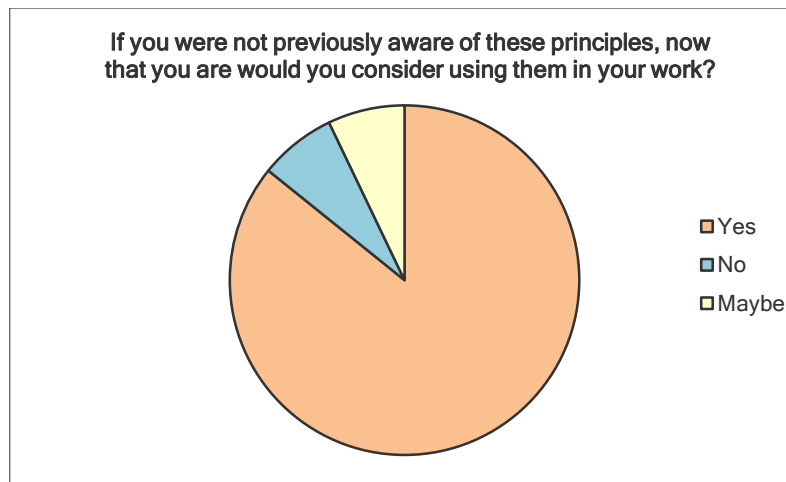
An important factor to consider is communication channels: one respondent said, that whilst the list describes quality of the information itself, it does not describe the channels by which information is communicated. “That seems out of scope of the principles as they stand. However, it is precisely those issues of communication which are currently the most challenging - and the information environment has changed substantially since 2008.”

Another commentator picked up on the potentially complex issue of evidence: “This list suggests there is always a clear body of evidence, [but] often there is contradicting evidence. In this case information must be balanced.” In a similar vein, “trying to produce entirely unbiased information is very hard - everyone brings a set of pre-conceptions to information. I would suggest balance as a better word than unbiased.”

Other commentators stressed the need for transparency and impartiality of information, “without any hidden suggestions”, and that information should be placed in the proper context.

Finally, one commentator suggested that the principles are not easy to find online.

Chart 7: Consider using? (n=28)



When asked if respondents would consider using the principles in their work – assuming they had not previously done so wondered previously aware of them – a majority of 24 (86%) said yes. Two respondents (7%) answered negatively, one because of their previous knowledge of the principles, and the other without giving any reason. Two respondents answered maybe. Seventeen respondents did not answer the question.

4. Discussion and conclusions

The survey was not intended to be scientifically robust. However, it should be noted that the number of responses does fall short of our ambition.

There are thus some important limitations. No responses were received from national, EU or regional government bodies, and most other stakeholders were represented with only one answer. Most countries, similarly, were represented with only one or two answers, and no responses were received from 12 of the countries (Norway and Switzerland as well as 10 EU member states).

In our communication and the survey, we did encourage responses by stating that the survey was not about the official opinion of any particular organisation, but rather about the personal views and experiences of respondents as representatives of a particular stakeholder group. We encouraged respondents to answer even if they had not heard of the core quality principles before; and if they felt they were not the right person within an organisation to fill in the survey, to pass it on to appropriate colleagues, or national members in cases of organisations at European level.

We felt the time period of six weeks would be adequate for people given the survey was fairly simple and not long. However, the low response rate could nevertheless be improved with more time, coupled with a more intensive, targeted follow-up.

Bearing the above in mind, the results indicate that

- There is low awareness of the core quality principles. This despite the repeated references EPF has made to these principles since their creation.

- The fact they are not easily found online may be compounding the issue.
- Most principles are considered very relevant for information targeted at patients.
- Those who were aware of the principles do find them relevant and useful.
- A clear majority of those who had not previously seen the principles, would consider using them.
- The principles are comprehensive; there are no important aspects missing.
- However, they only address the quality of the information itself. Another important factor to consider is communication channels. In this regard, it would be good to have an overview of the available channels through which different types of information are circulated to patients.
- The comment on contradictory evidence raises an important issue, in particular given that there is no wealth of online information available with very contradictory messages, so it is even more vital that the evidence base for a given piece of information is made very clear.
- Context of information should always be considered in communication.

EPF considers this information as useful for our advocacy on information and health literacy, bearing in mind that it is indicative. We may consider repeating the survey, subject to capacity, cascading it more effectively to different stakeholder groups and thus expanding the database of responses, in order to have more valid conclusions in the future.

We also believe it would be useful to have a further exploration of the issue of information for patients, placed in its wider context, at European level in order to see whether an EU-wide strategy on health-related information would be warranted given its importance for patient and citizen empowerment, health literacy, self-management capacity and potential impact on health outcomes. EPF has called for a European strategy for patient empowerment (see the EPF campaign “[Patients Prescribe E5 for Sustainable Health Systems](#)”); a strategy / action plan on information and health literacy would fit well as one part of such a strategy.



This report received funding under an operating grant from the European Union's Health Programme (2014-2020).

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