



European Platform for Patients' Organisations,
Science and Industry

WORKSHOP ON PATIENTS' SAFETY

Best Practices on Communicating Risks and the Value of Safety to Patients with Chronic Diseases

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Communicating Risks to Patients

Introduction and Programme

- 1. The report and its aim
- 2. Summary and key messages
 - 3. The legal framework
 - 4. Informed consent
- 5. Optimising communication
 - 6. Case studies
- 7. Conclusions: basic assumptions and recommendations

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Communicating Risks to Patients

In the course of the 1980s and 1990s the haemophilia community globally was devastated by the impact of HIV and Hepatitis C transmitted via their treatments derived from blood.

The fear, anger and helplessness experienced by patients were greatly exacerbated by lack of understanding of the risks, lack of co-ordination in responding to the threat and poor communication. Lessons have been learned from this appalling tragedy.

Over the past number of years the World Federation of Haemophilia (WFH) has organised various communication mechanisms to ensure that information in relation to current and future threats will be communicated rapidly, responsibly and adequately to all National Member Organisations.

In the mid-nineties, the Variant Creutzfeldt-Jakob disease (vCJD), a rare and fatal neuro-degenerative condition, was first described. In 2001, at a time when the risk of vCJD transmission from blood or blood products was still theoretical, the WFH established a Task Force to ensure that if transmission occurred or if a case of vCJD was diagnosed in a person with haemophilia, the relevant information would be sent to member countries without delay.

This approach has been invaluable: in the small number of cases where vCJD was transmitted through blood transfusion, the Task Force was able to meet by conference call within 24 hours and send electronic bulletins to every member country.

In our era, communication has become instantaneous. Where there is a lack of proper information, the vacuum is filled by rumour, speculation, exaggeration or misinformation. It is vital therefore to have Task Forces or expert groups in place to deal with potential threats, ideally before the threat becomes real.

In this way participants are familiar with each other, can communicate quickly and effectively, and can disseminate the essential information in the rapid timeline required. Communication at this level should set out the facts which are known and also point out the facts which are still unknown or unproven, together with the further work being done.

Information should be updated as soon as required in the light of new information which becomes available.

The communication should be honest, open and transparent. This type of communication greatly reassures the National Organisations and persons with the condition and it can turn a crisis into a manageable situation. Based on the success of this Task Force the WFH has since set up a separate consultation mechanism which includes WFH lay-leaders, clinicians, regulators, and industry representatives.

This forum should be capable of responding to any future threat or crisis when rapid and accurate information is required by all the countries.

It should be recognized that a single way of communication will not be comprehended in the same way by all those who receive it. In order to deal effectively with a crisis, communication on a particular topic requires several tools and partnerships between all stakeholders as to ensure that information is accurate and non-sensationalist.

Brian O'Mahony

Chief Executive, Irish Haemophilia Society

Introduction

Patients have the right to adequate, timely and comprehensive information on all aspects of safety and risk associated with their medical treatment. The quality of the information provided will be optimised if patients, clinicians, industry and regulators join their efforts and cooperate to reach that goal.

All stakeholders now recognise the vital role played by patient organisations in communicating on safety and risk. The production of timely and audience-specific communication for national groups by their umbrella organisations on key issues relating to the safety and risks of therapies is vital. The perception and evaluation of the risks incurred by using a treatment is differently perceived by the patients according to their diseases and the prognosis given.

The risks which patients are willing to undertake as part of medical treatment will differ from the voluntary risks they are willing to take from other life activities. The perception of acceptable risk will vary depending on the communication and information available to the patient, the severity, consequences for quality of life and probable outcome of their medical condition, the economy of their country and the choices available to them. It will vary also depending on their past experience and the level of communication from and between all stakeholders.

Patients know their disease; they know their daily quality of life.

Communication to patients is vital in assisting patients in their decision taking process on treatment and the responsibility they take by accepting the communicated risks of their chosen treatment.

Through plenary lectures, case study presentations and discussion in break out sessions, key issues on communication of safety will be explored. These will include:

- How should we define risk in relation to benefit for specific therapies and how should such risk be assessed for one off as opposed to life long treatment.
- Discussion of the factors which affect perception of risk such as education, medical history, previous experience and perception
- Methods of communication including the relative merit of written, verbal, electronic communication or via the media.
- When to impart information and striking a balance between avoidance of unnecessary panic and undue withholding of information.

The workshop will bring together patients, clinicians, industry and officials to discuss on all these issues and lead to a broader understanding of this complex and interlinked topic among all attendees. The workshop aims to agree upon broad consensus recommendations on best practices in communicating the relevant risks and benefits of a therapy, which may form the basis of further actions.

Programme

PLENARY SESSION

Welcome Remarks

Michael Griffith, *Retina Europe, former EPPOSI Chair*

Legislation

Nick Fahy, *European Commission – DG SANCO*

Critical elements in informed consent for therapy

Glyn Elwyn, *Cardiff University, Department of Primary Care and Public Health*

Optimising communication on risk, safety and benefit of therapy

Paul Giangrande, *Oxford Haemophilia Centre*

Case Study 1: Foreseen Risk

Craig Ritchie, *Imperial College London*

Case Study 2: Unforeseen Risk: Lipodystrophy in HIV

David Haerry, *European AIDS Treatment Group (EATG)*

Case Study 3: Theoretical risk which becomes real: vCJD from Blood

Mark Brooker, *World Federation of Haemophilia (WFH)*

BREAK-OUT SESSIONS

1. Industry / Clinician

Chair: Detlef Niese, *Novartis*

Rapporteur: Ingrid Klingmann, *European Forum for Good Clinical Practice (EFGCP)*

2. Industry / Patient

Chair: David Watters, *International Patient Organisation for Primary Immunodeficiencies (IPOPI)*

Rapporteur: Jean-Marie Vlassembrouck, *Baxter*

3. Clinician / Patient

Chair: Vincenzo Costigliola, *European Medical Association (EMA)*

Rapporteur: Brian O'Mahony, *Irish Haemophilia Society (IHS)*

Open Forum and Discussion

Moderator: Christine Lavery, *Society for Mucopolysaccharide and Related Diseases (MPS), EURORDIS*

Final Recommendations

Co-Chairs: Ingrid Klingmann, Jean-Marie Vlassembrouck, Brian O'Mahony

1. The report and its aim

This report summarizes the discussion and conclusions of a workshop on patient safety held by EPPOSI in Luxembourg on 4 December 2007, entitled "Best Practices in Communicating Risks and the Value of Safety to Patients with Chronic Diseases".

With some 50 participants, this invitation-only workshop set itself the objective of achieving consensus on recommendations to all stakeholders about how to improve communication in this difficult and important area.

This report highlights the main points that emerged from this intensive discussion and sets out the conclusions. It was compiled by rapporteur Peter Wrobel in consultation with the meeting's co-chairs.

2. Summary and key messages

Ensuring that treatments are safe for patients is an important issue – and patients are not alone in their concern. Safety is high up on the list for pharmaceutical companies and policymakers as well. Yet however hard we try, some element of risk will always remain – known or unknown, quantifiable or unquantifiable.

But how should an issue at once so complex and personal be communicated to a patient with a chronic disease? What will a patient, or a clinician, see as acceptable risk? And how and when should health professionals discuss risk with patients?

These and other questions created the focus for discussion, and the workshop brought together clinicians, patient organisations, industry and officials from the European Commission to work for a broader understanding of this complex and interlinked topic.

The programme took the form of a series of brief presentations, including case studies, followed by three breakout sessions in which the same topics were discussed from the different perspectives of Industry/Clinician, Industry/Patient, and Clinician/Patient. The subjects:

defining acceptable risk; how best to communicate that risk; ascertaining whether patients understand the risks; and the role of communication in building or destroying trust.

Finally, the conclusions from the breakouts were discussed in plenary session, and a number of key recommendations agreed by consensus.

The three breakout sessions came up with remarkably similar conclusions, demonstrating the extent of shared interest, shared perspective and shared priorities across the stakeholders.

The key messages are these:

1. Patients with chronic diseases will decide what risks to accept, and need the highest-quality information on which to base their decisions.
2. Patient organisations have a vital role to play in discussions about how risk should be communicated.
3. All stakeholders need to work together to ensure that risks are clearly understood and communicated to patients in a coordinated and consistent way.
4. Health professionals must ensure that patients receive the information in appropriate forms and that the patients understand what is being communicated.

3. The legal framework

Europe's citizens give patient safety a high priority, and they want it improved. In response, the European Commission has formed a High-Level Group including representatives of member states and patients, professionals, providers, insurers and international organisations. Its aim: to look at systems that will identify the concrete and specific issues and enable them to be reported, so that we can learn from what goes wrong.

The High-Level Group is currently putting together a recommendation to the Council of Ministers and European Parliament, said Nick Fahy, head of the unit of health information at

DG Sanco. "That recommendation will deal with process, not content. Once we have that framework, we will need content linked into that," he said. "The more concrete examples we have, the easier it will be for member states and practitioners to implement."

Fahy issued a plea to the workshop for concrete recommendations: "Specific output in terms of bullet points...a page of your conclusions after today's discussions." His wish was fulfilled: see below.

4. Informed consent

The past decade has seen an increasing emphasis on involving patients in making decisions on healthcare, said Glyn Elwyn from Cardiff University, a general practitioner as well as an academic professor. "Sometimes feels like most of the responsibility has shifted over to patients," he said.

Surveys show that most patients want to take their own decisions on healthcare. And although they still want guidance from professionals, patients are more frequently informing themselves through information from the Internet – whether accurate or not.

Against this background, Elwyn said it was important to address the issue of uncertainty. There is, he said, collective professional uncertainty, which we address with more and better research; and individual professional uncertainty – many practitioners are simply unaware of the evidence. But there is another level: even when you as a patient know the evidence, whether or not the treatment works for you as an individual is a matter of chance. Communicating these different levels of uncertainty to patients, he said, will help in making them aware of what they are entering and will increase the patient safety factor.

How can communication be improved? Elwyn pointed to improved training for doctors and nurses, and also to the development of the new patient decision support technologies. Increasingly popular in North America, they are essentially tools – more and more Internet-based – providing information that enables

patients to understand options and risks. Several of these decision support tools are now being developed in Europe.

5. Optimising communication

The fact that communication is said to be a two-way process is repeated so often that it is almost in danger of becoming a cliché. It is, though, a central issue in communicating risk, as Paul Giangrande from the Oxford Haemophilia Centre, a practising haematologist, explained.

Giangrande presented research from a variety of sources on what patients actually understand when risk is communicated to them. Among his examples, a striking one affecting pregnant women: women told their risk of having a baby with Down's syndrome was 20 per cent were more likely to opt for an amniocentesis (which itself carries risks of termination) than those told there was an 80 per cent chance that the baby would not have Down's syndrome.

Similar misunderstandings emerged in research showing that people prefer to take a chance that they will pick a winning ball out of 90 balls when told that there are 10 winners than when told there is a 1 in 9 chance of winning. This subjective assessment of probability makes identical odds appear more favourable when expressed in terms of larger numbers. Similar confusion can reign when it comes to relative risk.

Against this background, Giangrande explained, former UK Chief Medical Officer Kenneth Calman had proposed a number of ways in which risk could be presented better to patients. These included using a numerical scale rather than descriptive terms wherever possible, and using consistent denominators for fractions. Giangrande also pointed to tools such as the Paling Palette and the Paling Perspective Scale, which present information graphically.

His conclusion: trust between doctor and patient is the bedrock of good communication. The way in which data are presented, he said,

can influence a decision. Hence it is important to reach consensus on how risks are defined, which means using absolute numbers. Graphical presentations of data and risk can help, too. Finally, he emphasised, make sure the patient has understood.

6. Case studies

A. Foreseen risk

Craig Ritchie from Imperial College London presented issues surrounding risk in using the drug Clozapine in treatment-resistant schizophrenia. Clozapine, he said, is one of the best drugs we have for schizophrenia, but unfortunately it carries with it the serious and predictable risk of neutropenia, a potentially life-threatening condition.

The risk is clear, and is backed up by evidence. In some regards, said Ritchie, the risk might be communicated easily. The problem is that the patients for whom it is best suited are often potentially suicidal and lack the capacity to make informed decisions. In the particular long-term case outlined by Ritchie, the patient was also HIV+, and evidence was lacking on the risks of the drug in someone with an underlying immune deficiency.

Ritchie concluded that in lifelong treatment the risk/benefit analysis will vary during the course of the illness. He also suggested considering recommending to psychiatric patients when well that they make an advanced directive about treatment in the event that they become unable to make informed decisions.

B. Unforeseen risk

In just 25 years, patients with HIV and their doctors have accumulated a wealth of experience with unforeseen risk – notably in the appearance in 1998 of a serious condition called lipodystrophy. As David Haerry from the European Aids Treatment Group (EATG) explained, it took about five years to find the cause and pin down the risks.

That, said Haerry, is why the EATG was very cautious when a new class of HIV drug, the so-called CCR5 inhibitors, was introduced this year – the first drug in this class was approved by the US Food and Drug Administration in August. The EATG's approach was to assume that there would be a risk, even it was not known now, and to plan for it, calling for the first 5,000 patients treated to be enrolled in a cohort and followed up. Indeed, both the US and the European Medical Agency have imposed a five-year patient registry.

Overall, Haerry stressed that risk perception is complex, and changes over time. The key is to understand the patient's own perception of risk. That, he said, needs an open dialogue between patients, physicians and industry, with all the facts on the table.

C. Theoretical risk which becomes real

Mark Brooker from the World Federation of Hemophilia looked at the risk of people with haemophilia contracting vCJD (popularly, the human form of "mad cow disease") from infected blood products. For years the risk was theoretical; then it was quantified. But, as Brooker related, the way in which a tiny marginal risk (1 per cent of a risk that was already just 1 in 300,000) was communicated caused unnecessary alarm. Fortunately, the Federation moved quickly to address the issue, issuing a commentary on the risks itself.

His advice was clear: patient organisations should be prepared, with a standing committee in advance ready to respond to statements of risk and ready to engage with industry and regulators on a permanent basis. Act quickly but calmly was his suggestion – and be as open as possible. "Some authorities are more open than others, but it is the patients that are at risk and they have the right to have all the information," he said. The biggest risk for people with haemophilia is not being treated.

7. Conclusions: basic assumptions and recommendations

Basic assumptions:

1. It should be recognised that:
 - The properly informed patient should be the final arbiter of acceptable risk.
 - Patients have a fundamental right to information.
 - Patients' decisions about what risks are acceptable can change over time.
 - Patients' decisions may vary with culture, religion, social factors, age and disease.
 - Information is a two-way process.
 - Honest, open and transparent communication on risk is required.

Deepening and sharing the understanding of risk

2. A regular consultation process should be established between industry, clinicians and patient organisations where risks are openly discussed and contextualised.
3. Patient organisations must be involved at the earliest possible stage in discussion on risk.
4. The European Commission should be encouraged to establish condition-specific Consultation Groups for chronic diseases, comprised of representatives from Regulators, clinicians, patient organisations and industry. These groups should agree parameters for acceptable risk calibrated to the relative impact of therapies on morbidity, mortality, patient safety and quality of life.
5. Unforeseen or theoretical risks: an agreed approach to communicating known and uncertain information should be established.

6. Better information sources are required to produce better patient materials, including appropriate use of terminology.
7. Clinicians and all other stakeholders require better continuing education on communication.

The communication of risk to patients

8. Potential risks and benefits of treatments should be communicated to patients in a coordinated and agreed manner by clinicians, industry, organisations representing patients and regulatory authorities.
9. Written texts should be used as part of any communication strategy.
10. Health professionals must seek feedback from the patient to ensure that the information provided has been received and understood as intended.
11. Ideally, clinicians should follow up oral consultations with patients with a letter to them, confirming what has been said.
12. The role of nurses in communicating with patients needs to be recognised and supported.

LIST OF PARTICIPANTS

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**A patient-led EU partnership of patients, academic science and industry,
working together to advance healthcare policies for the prevention and treatment of serious diseases**

EPPOSI was founded in 1994 on the initiative of patients' organisations, for the exchange of information and the discussion of human healthcare policies in the EU.

EPPOSI puts patients first in this dialogue, providing a forum for patients, academia, authorities and industry to discuss innovation and policies for healthcare, health technology, and the health outcomes for patients, especially those affected by chronic, life-threatening diseases – including rare diseases.

EPPOSI's ambition is to develop strategies that benefit present and future generations.

Objectives

- To encourage timely and regular exchange of information between stakeholders on the latest developments in human healthcare related to (bio-)medical research, policy and regulations; on the ethical, social, legal and political aspects of this type of research, and on biotechnology, notably for its application to human healthcare
- To promote a mutual understanding between patients' organisations, science, industry, and EU institutions
- To contribute to equal access for all to human healthcare products and services in the EU
- To support patients' organisations in presenting timely and effective contributions to the European political debate on all matters that concern them
- To raise public awareness in Europe on the opinion of patients and their organisations
- To help sustain a dialogue within society on progress in medical science through new technologies
- To advocate the development of therapies for unmet medical needs and to facilitate partnerships within society
- To function as an information coordination centre that encourages discussion, opinion-forming, and public debate in the area of human healthcare

Achievements

EPPOSI focuses on building dialogue, consensus positions and policy recommendations for the benefit of EU patients and consumers.

These consensus positions have provided building blocks for:

- the establishment of the European Orphan Medicinal Products Regulation
- the advancement of biomedical research and the value of innovation
- the timely access to innovative medicines
- several rare-disease therapy developments and partnerships
- East-West European collaboration among patient groups
- bio-banking

For more information, reports and publications, please visit our website or contact the EPPOSI office:

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