

# The Informed Patient: Study Report

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## 1 Introduction

### Scope of the project

“The Informed Patient” project is a research initiative aimed at guiding future policy on the provision of information to patients in Europe. The objective is to produce a Consensus Statement (see Section 3) detailing recommendations for policy actions in the future, supported by a Study Report (this document) which explores the wider perspectives of what information patients require to be fully engaged in the management of their healthcare.

The project is led by Professor Don Detmer, Director of Cambridge University Health at the Judge Institute of Management of the University of Cambridge. Cambridge University Health is the name of the health policy and management research centre at the Judge Institute and is referred to variously as ‘CUH’ or ‘Cambridge Health.’

### Concept and Scope of ‘The Informed Patient’

The term, ‘Informed Patient’, presumes that people with illnesses (‘patients’, but not just those awaiting treatment) need appropriate information in order to be properly involved in their healthcare – be it to seek care, decide on the best courses of action with care professionals, or to follow through the agreed course of treatment.

The project deliberately focused on patients, excluding wider issues of health promotion and education, though these aspects may be critical in terms of preparing the public to avoid illness, or for any encounter with illness or the healthcare system.

The ‘informed patient’ concept as used here includes carers and family members, since they may serve as proxies for the patient when incapacitated and often are part of the social unit making decisions for the future.

### Approach used

The main outcome of the ‘Informed Patient’ project undertaken by Cambridge University Health is a **Consensus Statement** (see p7) from a conference held in Cambridge, UK, in early December 2002. The Cambridge Consensus Conference was attended by invitees, broadly representative of stakeholders from across the EU to identify policy approaches for developing information provision to the public in order to improve healthcare.

The Conference was supported by work from an earlier **Literature Survey** by CUH and advice and opinions from five **Expert Panels** held in Brussels in November 2002 (see Appendix 2 for the list of attendees). The output from these parts of the project is summarised in Appendix 1.

The project followed a four-stage model for problem identification and resolution:

1. What are the issues/problems?
2. What is the environment/structure/world model?
3. What are possible options/ policy levers?
4. What are practical options/approaches to address the most immediate needs?

The Literature Survey and Expert Panels stages of the project addressed the first two steps; while the Consensus Conference sought to progress the latter two parts. The goal was to move policy forward in the near future and not necessarily create recommendations for the distant future since the topic and related technology are so dynamic.

This document presents the Consensus Statement, followed by some explanatory notes and a detailed discussion section that brings together comments from all stages of this project.

## Acknowledgements

The project and its dissemination has been supported by the Nuffield Trust, a UK charity for research and policy studies in health services, and Johnson & Johnson, a global pharmaceutical company. The CUH team is grateful to Johnson & Johnson, particularly Dr. Scott Ratzan, for its unrestricted research grant, its assistance with the logistics of organising the Expert Panel meetings in Brussels, and its scrupulous observation of the independence of this study. We thank the Nuffield Trust for its support in hosting and funding the UK launch event.

The CUH team is also grateful to all the attendees at the Consensus Conference and the Expert Panels for the significant contribution of their valuable time and expertise in the support of this project and its aims. However, all responsibility for the accuracy of materials in this document rests with CUH.

Cambridge Health thanks those who could not come to the meetings, but who contributed by finding a replacement from within their own organisation or from a related body or by submitting useful comments. We also thank the College of Europe in Brussels and the Møller Centre in Cambridge. A special thank you goes to Jane Ewart for her able assistance in helping run six very successful meetings.

## Limitations

As noted above, all responsibility for the accuracy of materials in this document rest with the CUH team: Professor Don Detmer, Peter Singleton, Dr. Alison MacLeod, Dr. Suzanne Wait, Marie Taylor, and Jolyon Ridgwell.

As mentioned above the project has been limited in its reach and so should be viewed as an early stage in bringing together evidence and opinion to inform future policy decisions. Further work will need to be done (as recommended by the Consensus Conference) in order to take the vision of the Informed Patient forward and Cambridge Health will remain committed to this line of research since it is so important to the future of better health care.

We would also note that the outcome of this study may have been affected by the decision to conduct the meetings in English, which may have limited those choosing to participate in meetings and the subsequent range of materials available from across Europe. We hope that any such restrictions can be avoided in future wider studies.

**Illustration: 'Informing' in action?**

To help illustrate some of the issues to do with 'The Informed Patient', we describe below a vignette that shows the difficulties encountered in a simple real-life scenario:

The parents of a 20-month old baby girl know that she is allergic to eggs, and are worried about the severity of her reaction, which includes a facial rash and vomiting. Occasionally she reacts to other foods.

The mother, worried about the reactions, talks to friends. One friend, who happens to be a nurse, suggests that she seeks help. The mother takes the toddler to her GP, and asks for allergy testing. The GP is reluctant to refer her, suggesting that egg allergy is extremely common in babies, and allergy testing is unpleasant for small children. The mother perseveres, and is referred to a specialist clinic at the nearby teaching hospital.

At the referral, three months later, the toddler undergoes skin-prick tests for common allergens. 10 minutes later, the tests reveal that not only is she allergic to eggs, but she is also allergic to nuts – an extremely serious allergy that is usually lifelong.

The doctor explains that the toddler must now totally avoid all nuts, but, given that reactions to nuts have been mild, suggests that an adrenaline pen is not necessary. Mother and toddler are ushered out to see the nurse. The clinic nurse, who is friendly and supportive, basically repeats the advice about the child not eating nuts or products containing nuts, and gives them a 1-page information sheet and the name of an allergy support group.

The mother has access to the Internet, and looks up nut allergy on the search engine, Google. The search turns up many different sites, including medical sites, patient group sites, food manufacturer pages, university dermatology departments, and more. Much of the information concerns the risk of an anaphylactic reaction, which can be fatal. The parents are very frightened by all this, and are unsure how to apply it in their own case.

**Question: How well-informed are the parents? How could the process be better?**

## 2 Executive Summary

### Main conclusion

The major conclusion from the “Informed Patient” study is the conviction that the future of health care in Europe demands far greater health-related information for patients and citizens. The information and knowledge support must be available at the level of the EU/member states and also at regional/local levels to assure sufficient education and support.

### Main Objectives

‘The Informed Patient’ study addressed the key question of how to provide appropriate information to patients/citizens across the European Union in order to:

- ?? Deliver impartial, sound (evidence-based), and accessible information and knowledge support to address the generally inadequate provision to patients/citizens noted today
- ?? Ensure that such support will mitigate some of the burden for the growing numbers of elderly people with chronic illnesses on the already constrained healthcare systems across Europe
- ?? Help patients and healthcare professionals better evaluate treatment choices as medical science and health care become increasingly complex
- ?? Increase transparency and accountability of the healthcare system so that choice and cost-effectiveness are evident
- ?? Adopt, on an on-going basis, new information and communications technologies such as the Internet and digital TV, so that healthcare operations will promote best practices, adopt new effective treatments and discard ineffective and/or unsafe old treatments.

### Consensus Statement

The Consensus Statement, coming from a conference held in Cambridge in early December 2002, recommends a four-part European initiative including creation of a framework for the future, support of implementation, coordination of the suppliers of information, and continuing leadership and education.

Each component requires action as follows:

- ?? **Create a Framework for the Future.** This can be accomplished by convening key stakeholders in the near future to develop the set of initiatives outlined in the Statement;
- ?? **Support Implementation:** Focus the EU and member state governments and the private sector explicitly on accessibility, availability, and quality of structured information for patients/citizens;
- ?? **Co-ordinate the Suppliers of Information:** By developing and using agreed standards, promote the effective provision of quality information;
- ?? **Leadership and Education:** Provide critical support to patient health education and continued professional development.

The Consensus Report calls on the European Commission to take the lead in moving the agenda forward by building on and co-ordinating existing initiatives into a broader framework, bringing together both private and public sector interests to assist developments for the benefit of patients and the healthcare industry in member states and regions and localities as appropriate.

### Inputs to the Consensus Conference

The Consensus Conference drew upon on earlier work by CUH, including five Expert Panels held in Brussels, which brought together representatives from the range of stakeholder groups to provide perspectives and views drawn from both extensive experience and research.

The Consensus Report is supported by additional information developed by CUH (including evidence from the literature and expert sources) to inform further work in this area.

### 3 Consensus Statement

#### Basis of the Consensus Statement

The basis of the Consensus Statement is that:

- Participants at the Conference were invited as individuals because of their own expertise
- While the participants agree to the statement as presented here, no participants came to represent their respective organisations
- All of panel participants' views were sought to inform the debate, however since the final recommendations emerged from the entire group, they are not attributable to any particular individual or organisation.

The attendees, while expert in their own way, noted that knowledge was incomplete, that opinions had often been expressed elsewhere, and their experience built on the work of others.

#### EU 'Informed Patient' vision and recommendations: Summary:

The Cambridge Consensus Conference Vision:

**Europe will have a framework to ensure the ongoing availability of timely, high-quality, accessible, understandable, reliable and relevant information for patients and their carers.**

Recommendations and Conclusions:

#### **Creating the Framework:**

- 1: Key stakeholders, including patients, professionals, private sector and EU and member state governments, should be convened for the purpose of stimulating a set of initiatives, which may include policies, procedures, and demonstration projects to address the Informed Patient vision.**

#### **Supporting Implementation:**

- 2: We recommend EU and member state governments and the private sector to focus explicitly on accessibility, availability and quality of structured information to patients, utilising the networks recommended above.**

**We also conclude that:**

#### **3: Assuring the suppliers of information**

**An EU-financed research and evaluation process is needed; this would entail a systematic review of information from multiple sources looking at 'good practice' and drawing upon this analysis, create and test a variety of quality and accessibility processes and standards for their practicality and usefulness.**

#### **4: Meeting the challenge through leadership and education**

**EU member governments and the EU institutions as consistent with the Treaty should invest specific additional resources to improve continuing education and entry level communications skills of care professionals to inform and engage patients better in their own healthcare.**

Each component of the Consensus Statement is discussed in more detail on the following pages.

Cambridge Consensus Conference ‘Informed Patient’ vision:

**Europe will have a framework to ensure the ongoing availability of timely, high-quality, accessible, understandable, reliable, and relevant information for patients and their carers.**

The conference believes that such a vision will improve patient quality of life, health status, patient satisfaction and the quality and efficiency of care.

The goal of this framework is to facilitate:

- Involving patients
- Understanding patient expectations
- Informed and supported decision-making
- Improving patient awareness of treatment options
- Patient self-care
- Performance management and quality improvement
- Public engagement in improving health, healthcare and outcomes.

The conference draws attention to key challenges in achieving this vision, including issues of equity of access, literacy (health information and numeracy), socio-economic status, culture and language differences, creating incentives and reducing barriers to change.

To address these challenges requires substantial efforts in education of information providers, including knowledge acquisition and development of interpersonal skills of health professionals and providing tools and techniques that may enable patients to engage where they wish to.

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#### **Notes:**

##### ***Terminology***

It was agreed that the term ‘patient’ as a person experiencing some condition or disease (possibly undiagnosed) was sufficiently understood not to require further development and was the most appropriate single term to use amongst various related options such as consumer, user, client, etc.

Selecting the most appropriate term for a ‘healthcare professional’ (e.g. doctor, nurse, pharmacist, physiotherapist, etc.) was debated and ‘healthcare professional’ was felt to be both sufficiently precise yet broad enough without being too cumbersome. It was noted that, on the one hand, that this might imply the exclusion of ‘healthcare workers’ who were not part of a recognised professional body and, on the other hand, ‘social workers’ who provided ‘care’ but not ‘healthcare’ as such. Where such distinctions are necessary, a more precise phrase can be used. The intention is to include (rather than exclude) all those involved in care provision to patients that have, at the minimum, some training for their role.

##### ***Need for a European lead***

It was felt to be crucial that the EU takes a lead in promoting activities in this area, rather than leaving developments to nation states or private funding. A lead by the EU would ensure that:

- efforts, public and private, are well directed towards improving public health, rather than being wasted in poor quality, ill-directed, or duplicated efforts;
- there is greater inclusion of minority groups across Europe;
- quality, evidence-based, information is distributed more efficiently across Europe;
- broader research programmes are supported (existing studies have generally been small and localised); and
- long-term benefits to public health actually accrue, e.g., evaluation and monitoring for actual impact be pursued over time.

## 1: Recommendation - Creating the Framework

**Key stakeholders, including patients, professionals, private sector and EU and member state governments, should be convened for the purpose of stimulating a set of initiatives, which may include policies, procedures, and demonstration projects to address the Informed Patient vision.**

The components of the initiatives include:

- Capturing best practices over time
- Guidelines that define what information should be provided regardless of the disease area and applicable across all languages and cultures
- Encouraging evidence-based patient information (in content, design, and delivery)
- Agreeing on quality standards for patient information.
- Recommending specific further actions in terms of regulation, public health, information needs, and deregulation
- Developing a “model of good information”
- Addressing how to incorporate guidelines most effectively into practice
- Stimulating initiatives, including demonstration projects that help implement the Informed Patient vision throughout the EU
- Recommendations to appropriate government bodies in member states

To address these objectives, we request that an appropriate EU group or body convene in the near future a high-level roundtable of the key parties identified above to develop an action plan that secures these objectives, including a discussion of its implementation.

Elements for implementation may include:

- o Developing policy initiatives to implement the Informed Patient vision throughout the EU
- o On-going responsibilities for evaluation of demonstration projects
- o Advising on and monitoring the quality of information according to established standards.
- o Identifying continuous streams of funding within EU resources to create and fund accessible evidence-based information networks for patients to realize this vision, including:
  - EU-wide networks accessible in local languages
  - Local networks that respond to frequently asked questions (FAQs) from patients
- o Committing to the ongoing change management challenge that this represents.

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### Notes:

The recommendation sought to create a cross-interest representative body that would be resourced in order to drive the agenda forward. It seemed most efficient to build upon the existing G10 Committee, which had been effective, but with a broader representation to include patient groups and suppliers.

This new group might develop into a longer-term body, or simply help in the formation of such a body by providing an early platform for discussions, the determination of objectives, and the finalising of funding and future review.

It was hoped that this new body could address issues such as quality standards for information, providing a forum for the exchange and promotion of best practice, as well as supporting change in the member countries of the EU.

## 2 : Recommendation - Supporting Implementation

**We recommend EU and member state governments and the private sector to focus explicitly on *accessibility, availability, and quality* of structured information to patients, utilising the networks recommended above.**

This means helping those addressing patient information needs using a variety of traditional media, such as print, brochures, etc., and a forward-oriented focus on the Internet and other emerging communication technologies, such as hand-held devices and secure computer-based health records. Further, it means that all current models of good practice should be evaluated and supported. Examples that arose during the conference discussion included:

- **Cochrane Consumers and Communication Review Group**

This international collaboration looks at issues concerning communications with patients and their involvement in the provision and management of healthcare, looking at promoting evidence about interventions in this area.

The Consensus conference discussed the option of a similar initiative to create a central repository for patient information with public access. It was felt that this would be extremely beneficial, both to patients who can access the system, and to healthcare professionals in order to access effective communication tools and techniques.

- **Awards for the best patient information leaflets**

The National Council on Patient Information, a US charity, has awards to individuals on work done to support medical communication about medications.

The Plain English Campaign works across many areas, including healthcare, to promote clear public information through its Plain English and Golden Bull awards.

The Focus Awards are a joint initiative between the Department of Health and the British Dental Association, set up to recognise and reward patient-focused innovations within dental practices.

Similar activities at the European level would help identify best practice and promote the publication and sharing of innovative initiatives, including other media such as compact discs, websites, and films.

- **“Doctor-Patient Partnership”**

The DPP is a UK charity ([www.dpp.org.uk](http://www.dpp.org.uk)), which aims to: encourage better communication between patients and healthcare professionals, promote the responsible use of NHS services, and offer practical advice on self-medication. They provide a repository of patient leaflets and promotional items and work closely with other bodies such as patient groups.

One of the current activities is ‘Ask about Medicines’ week in October 2003 in conjunction with PECMI (Promoting Excellence in Consumer Medicine Information) and the Medicines Partnership to promote awareness and the safe use of medicines.

- **Patients Forum**

The Patients Forum is a network of organisations in the UK concerned with the healthcare interests of patients and their families and carers. Its aim is to provide a forum for national and regional organisations representing the interests of people who use health services to share experiences, information and ideas, to strengthen their work and to participate in informing and influencing decision-makers. Its membership consists mainly of patient groups though with mainly of the medical professional bodies as associate members. It has commissioned a number of studies concerning patient involvement in the provision of healthcare services.

- **BMJ Best Treatments**

This initiative developed since the project concluded, but its features are so consistent with the conclusions of the stakeholders and consensus group that the CUH team believes it deserves mention. (see Nash B, Hicks C, Dillner L. Connecting doctors, patients, and the evidence. *BMJ* 29 March 2003, 326:674.)

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### Notes:

The EU treaty acknowledges ‘national subsidiarity’ for health policy matters in Europe, so much of the change in practice would require initiatives within member states, but aided by central collaborative initiatives at the EU-level. This would require commitment and funding to develop and support change.

### 3 : Conclusion – Assuring the suppliers of information

The conference concludes that there are numerous important issues relating to those who serve the patients' information needs, including the pharmaceutical industry, equipment manufacturers, care providers, health professionals, patient organizations and others.

Amongst these issues are several relevant dimensions, including the quality and balance of information, credibility of sources, objectivity, supporting patient safety including personal and public health risks, completeness, appropriateness and timeliness.

Two controversial yet important dimensions include the distinction between education and advertising and the issue of accountability and jurisdiction across EU member states supporting the provision of quality information to patients.

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#### Notes:

The distinction between 'advertising' and others forms of information provision ('education') needs to be addressed, though the Consensus Conference was not able to offer reliable definitions of each. On balance it was felt more important to be able to identify 'quality information' though the application of suitable definitions, guidelines or 'standards' and hence not focus *per se* on the origins or use of data whether from 'advertising' or educational settings. The criteria from the Institute of Medicine 'Crossing the Quality Chasm' report and from The King's Fund 'Informing Patients' book were both mentioned as possible starting points for standards for the evaluation of the appropriateness of patient information.

These standards might include some form of Kite-marking (vetting or accreditation system) and would be equally applicable to all suppliers of information.

Standards should be directed toward "controlled permissiveness" as opposed to strict control. We must allow for creativity, as opposed to binding something so strictly that it precludes experimentation and innovation. Reference was made to the difficulty of pharmaceutical companies being unable to offer any information on their drugs other than that on the patient information leaflets set as part of the approval process when they possess substantial additional information that they perceive would be a substantial value to patients. Simple 'linear approaches' are very unlikely to work well in systems as complex as healthcare.

Quality criteria from Institute of Medicine: 'Crossing the Quality Chasm' (National Academy Press 2001):

- ?? **Safe** – avoiding harm to patients from the healthcare system
- ?? **Effective** – avoiding under-use and overuse
- ?? **Patient-centred** – respectful and responsive to individual patient preferences
- ?? **Timely** – reducing waits and potentially harmful delays
- ?? **Efficient** – avoiding waste of resources
- ?? **Equitable** – providing quality care irrespective of aspects, such as gender, ethnicity

## 4 : Conclusion - Meeting the challenge through leadership and education

The conference draws attention to key challenges in achieving The Informed Patient vision, including issues of literacy (health information and numeracy), socio-economic status, culture and language barriers and patients' individual needs.

To address these challenges will require substantial efforts in a variety of subject domains and locations. Including are the education and training of care providers, including knowledge acquisition and effective curricula for enhancing interpersonal and communication skills of health professionals, as well as education and training for patients so that those who wish such engagement know how to be effective.

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### **Notes:**

The core of this recommendation is that the problem needs to be addressed holistically. Producing policies that focus on only limited dimensions are not likely to produce much benefit and could potentially do more harm than good.

It may only be necessary to make improvements in existing processes in order to generate much benefit to patients – evolution rather than revolution.

Greater education of clinicians in communication skills is a key area for supporting change. The EU should help member countries develop appropriate criteria and curricula in association with relevant professional bodies, such as World Medical Association (WMA), Comité Permanent des Médecins Européens (CPME), International Council of Nurses (ICN), etc. It would then remain for member governments to review and adopt the recommended criteria/curricula depending upon the response of the professions to such an initiative.

The EU should expand on the models of good practice identified by the Consensus Statement (see next page) and seek to promote best practice throughout the EU.

## Some models of good practice:

The Conference identified and discussed various sources and examples of good practice to guide progress in meeting the educational challenge for health professionals and patients. Amongst the items discussed were:

- Sharing best practice and Curriculum development

While no specific existing initiatives were highlighted at the Conference, it was felt that a more explicit effort to share expertise and effort in the production of effective tools could only lead to cost-savings as well as quality improvements, while still being consistent with the policy structure of the EU.

It is important that any EU initiatives to improve professional communication skills tie in with wider activities, including those of the World Federation of Medical Education and any other similar organisations, since they are likely to prove a useful resource.

- Learning from nurses in communicating and listening skills

Generally it was felt that there was a greater emphasis on communications with patients in the training of nurses than the curricula of other health professions. All professions need to be able to communicate effectively with patients as well as listen to their needs and perspectives.

- Learning from patients

There have been a number of excellent initiatives where patients have been involved in the development of communication tools as well as wider healthcare policy. This approach should be taken forward more generally.

Equally, patients are the experts in their experience of a condition and coping with it. Capturing this experience and using it to benefit others as well as improve the quality of care is vital to improving the whole healthcare process. The development of e-health utilising the Internet could be pivotal in this regard.

- Work on “concordance” and shared decision-making

The concept of *concordance* (as opposed to *compliance* where ways are sought to persuade people to take their medicines) focuses on the need to adopt a different model of the patient/prescriber relationship and shared decision-making. This has been strongly promoted by the Royal Pharmaceutical Society of Great Britain (RPSGB), including a report ‘From compliance to concordance’ published in 1997 and a report by the All-Party Pharmacy Group to Health Ministers in July 2000.

- European Union Health Policy Forum

The EU Health Policy Forum is an information and consultation mechanism involving stakeholders in the health field, which aims to ensure that the European Commission’s health strategy is transparent and responds to the public concerns. It is composed of three complementary elements: a Health Policy Forum, an Open Forum and a Virtual Forum. This was felt to be a key initiative to help build the Informed Patient vision.

- The “Expert Patient” experience in the UK

The UK Department of Health set up an ‘Expert Patients Task Force’ in 1999, under the leadership of the Chief Medical Officer, Professor Liam Donaldson, to bring together the work of patient and clinical organisations in developing self-management initiatives for those with chronic conditions. Detail is available at [www.doh.gov.uk/cmo/ep-report.pdf](http://www.doh.gov.uk/cmo/ep-report.pdf).

- Dutch “Personal Budget Management” initiatives for chronic disease patients.

In the Netherlands, chronically ill patients are provided with a ‘personal budget’ so that they can choose how they wish to be supported from additional treatments (possibly alternative medicines) to modifications to cars and homes to better support the quality of life. This allows supportive treatment to be tailored by the patient rather than prescribed by the healthcare system.

- Clinical Evidence journal ([www.clinicalevidence.com](http://www.clinicalevidence.com))

This journal was cited as giving physicians options (based on firm evidence rather than hearsay) as opposed to prescriptive behaviour. This supports change in practice without imposing a straitjacket, allowing clinicians to respond to the particular circumstances.

It was felt that there is a need to do the same for patients – viz. provide information about treatment options (couched in suitable language) and let the patients and their clinicians decide what is most suitable in the circumstances.

The Conference considered that there was a need to identify partnerships with people who have a vested interest in the objectives, albeit coming from different perspectives (e.g. physicians and payers) to ensure that there were the right incentives for change.

## Membership of Consensus Conference

Name	Title	Organisation
Dr. Jim Appleyard	President Elect	The World Medical Association
Mary Baker	President	European Foundation of Neurological Associations (EFNA)
Prof. E. Andrew Balas	Dean, School of Public Health	St. Louis University
Abraão Carvalho	Head of Unit F3	EC Commission, DG Enterprise
James Copping	G10 Secretariat	EC Commission, DG Enterprise
Prof. Angela Coulter	Chief Executive	Picker Institute, Europe
Prof. Don Detmer	Director	Cambridge University Health
Rodney Elgie	President	GAMIAN Europe
Christine Hancock	President	International Council of Nurses
Dr. Jane Henney	Senior Scholar in Residence	Association of Academic Health Centers, USA
Keith Krzywicki	President	Pharmacia Limited
Dr. Graham Lister	Chair	College of Health
Christine Marking	Director Health & Pharmaceuticals	Weber Shandwick Adamson
Hildrun Sundseth	Director European Community Affairs	Merck Sharp & Dohme (Europe) Inc.
Ele Visser	Secretary, International Affairs	Netherlands Federation for Patients & Consumers
Stephen Withers	Director European Affairs	British United Provident Association

**Table 1 - Consensus Conference attendees**

## 4 Discussion

### Introduction

Over the course of the project, issues relating to patients and information were developed, interrogated, and clarified, both in the discussions with experts and by reviewing literature in this area. The following section provides a longer account of the most important aspects.

### Issues Overview: the information gap and its consequences

There is evidence (Jones et al 1999, Coulter et al 1998) that patients do not feel that they are getting sufficient or appropriate information.

From a study in the UK, Coulter et al (1998) identified the main deficiencies of existing patient materials:

- ?? *Patients want information about treatment options and outcomes even if they do not want to participate in treatment decisions – most don't receive it.*
- ?? *The quality of most patient information materials is poor.*
- ?? *Many materials contain inaccurate and out-of-date information*
- ?? *Few provide adequate information about treatment risks and side-effects*
- ?? *Topics of relevance to patients are omitted.*
- ?? *Technical terms are not explained.*
- ?? *Coverage of treatment options is incomplete.*
- ?? *Uncertainties are ignored or glossed over.*
- ?? *Information about treatment effectiveness is often missing or unreliable.*
- ?? *Few materials actively promote shared decision-making.*

Content may not be targeted to patients' real needs. Panel and Conference attendees also identified that patients may be seeking information about living with a disease or condition, rather than the purely clinical detail provided by most professionally produced material

Beyond this general desire for more information, there are a number of factors which suggest that information provision to patients is going to become an increasingly important issue:

#### Changing public attitudes

In the Expert Panels, there were strong feelings that provision of appropriate levels of information was an ethical 'good' and necessary to support the principle of 'informed consent'. It was not something that state governments should opt out of simply to save money.

Generally, there have been moves away from a traditional 'paternalistic' relationship between the patient and the professional, and there is now more emphasis on individual rights as well as increasing expectations on the healthcare systems.

Coulter et al (2003) from a survey across eight European countries found that attitudes are changing:

*People wanted more information about health care than they tended to be given, and were looking to their health care professionals to provide it: use of the internet for health information was generally low. People wanted to be involved in decisions about their health care, and were enthusiastic about the idea of patient-held health care records. Most people wanted to have a choice of health care provider.<sup>1</sup>*

If people generally are seeking more choice, then they will need more information to support that choice, assuming that there are such options within their healthcare system.

<sup>1</sup> Reported at 'Hopes & Fears Conference', Cambridge 2002 - <http://www.jims.cam.ac.uk/research/health/polifutures/pdf/papers/consumer.pdf>

European policy-makers have recognised the importance of this debate on information to patients through the formation of the Open Forum, the Health Policy Forum, and the Virtual Forum to make healthcare in Europe more responsive to patient/consumer needs.

#### Inappropriateness of current information provision

Coulter et al (1998) have shown that much written patient information is too poorly designed and presented to be readable by most patients. Health literacy studies in the USA (Beaver and Luker 1997, Kellerman & Weiss 1999) have shown that readability levels of patient information often greatly exceed the reading skills of the general public, yet alone those of the average patient (who is often older, poorer and has had less formal education). In the largest US study of health literacy, (Williams et al, 1995) one third of English-speaking patients at two public hospitals were unable to read basic health materials.

Raynor and Knapp (2000) have highlighted the shortcomings of drug patient information leaflets (PILs) – while 83% of patients recalled seeing a PIL and 74% had kept it, only 40% had read any of it, and only 21% all of it. In further work (Berry et al. 2002) they showed that patients had difficulties properly interpreting the risk factors identified in the PILs – generally overestimating the risk and so possibly discouraging them from taking the medicines.

This suggests money being spent on producing written materials is not always producing the benefits intended. Written information needs to be clear, simple, and target patients' most pressing information needs. Conference attendees felt that more support should be provided for the direct training/guidance for authors and/or exemplars produced centrally.

Much of the work focuses on written, audio, video, or computer-based information provision. The most important area of clinician verbal provision is less well researched, probably through difficulties of maintaining a control group and consistency between consultations. There is evidence (Swan and Borshoff 1994, Cassileth et al 1980, Muss et al 1979, Priluck et al 1979, Leeb et al 1976) that patients remember relatively little of what a doctor may have told them during a consultation, and are reluctant to ask for more information, either through a fear of appearing foolish or consciousness that the doctor is pressed for time.

#### Increasing complexity of medicine

The increasing complexity of medicine puts an extra burden on the professional to keep pace with change. General Practitioners (GPs) are finding it increasingly difficult to perform their 'gatekeeping' role with ever increasing options and risks as medical knowledge continues to expand. It is also harder for patient or professional to find an 'expert' to help resolve rare disorders or to find alternative treatments.

IT systems, such as PRODIGY and NeLH in the UK or [www.clinicalevidence.com](http://www.clinicalevidence.com), are intended to help professionals access the necessary knowledge, but there are few, such as NHS Direct Online, that are similarly compiled by publicly funded bodies for access by patients. Even sites by patient groups can be forbiddingly technical for newcomers unfamiliar with the terminology of a disease.

There are also concerns (Kawachi I, Conrad P. 1996) about the growing 'medicalisation' of daily life with 'a pill for every ill' and the additional costs this puts on the healthcare payers – though the actual costs may be counterbalanced by broader economic benefits from better health.

#### Increasing burden of chronic care

Increasing affluence and improving medical technologies mean that people are living longer and, as a result, more are living with chronic conditions. This increases the economic burden on publicly-funded healthcare systems, as well as increasing the importance of lifestyle choices in terms of selection of treatment options – diabetes is a classic case where greater self-management of the condition allows the patient to suit the treatment around their lives rather than *vice versa*. This has led to initiatives such as the 'Expert Patient' by the UK Department of Health.

There is evidence (McCulloch et al, 1998) that patients with chronic conditions can manage their own health rather well, with support and training. This has several advantages. It provides human benefits to the patient, in terms of improved health and greater independence. It also provides economic benefits, by moving some responsibility for care back to the individual, and as such provides an alternative to rationing of care or greater emphasis on private provision.

#### Healthcare information on the Internet

Internet usage is increasing rapidly in Europe. Navigating the wealth of information already available and bringing it into perspective is the challenge. The ABPI report (Illman 2001) advocates patient education to enhance information-seeking skills as it was clear that few could grasp the range of material or know which sites provided reliable, quality information. This may be no different from any other encounter with a large body of knowledge which may be described in technical jargon – most people will seek help from a librarian when using a reference library for the first time - see the section on 'Infomediaries' on page 25.

Although used widely for health information and communication, the Internet remains limited in terms of accessibility. Some panel attendees felt that Digital Interactive TV (DiTV) was more likely to have wider access to some audiences than the Internet in the future.

At all the sessions, attendees raised concerns about the quality and appropriateness of health information on the Internet. The World Health Organisation (1999), amongst others, has produced guidance on assessing the content of health-related web-sites. EPFIA has also produced guidance for their members. More recently (Nov. 2002), the European Commission (DG Information Society, eHealth) has issued guidelines on 'Quality Criteria for Health Related Websites'<sup>2</sup>.

Equally, it was felt to be impossible to 'regulate' the Internet, though there are a number of initiatives to provide some form of 'quality marking' or 'kite-marking' (e.g. MedCertain/ MedCircle, Hill) or 'quality codes' (e.g. HONCode). Studies (Jadad & Gagliardi, 1998 & 2002) have shown that these initiatives can often be poorly developed and short-lived.

The issue here seemed to be to avoid unscrupulous promotion, creating unnecessary concern or even panic amongst the public, or the risk of dangerous self-treatment by the public. Quality marking and the use of evidential support ('evidence-based information' was a term used) should help information seekers identify reliable information.

It is not clear to what degree people distinguish reliable authoritative information from misreporting or untruths. Experience in advertising has shown that the public adapt remarkably quickly to 'sales ploys', identifying dissonances and inconsistencies. However, people are still susceptible to plausible suggestions, especially when in need and looking for hope (hence Charles Revson's quote "In the factory we make cosmetics, in the store we sell hope").

Some panellists noted that assessing poor information had always been a problem, and that the Internet was just a new manifestation. Examples cited were comments in the general media in the UK about MMR or risks from oral contraceptives, which had caused unnecessary withdrawal by the public and had actually been detrimental to overall public health.

#### Promoting change in healthcare practice

It was mentioned at the Conference that studies have shown that some new treatments/ medical technologies are only adopted at a rate of about 2% per annum (based on Balas and Boren 2000, where it is stated that on average it takes 17 years to implement 14% of new knowledge in clinical practice). While adoption rates are likely to vary with the level of benefit and difficulty of implementation, this highlights the difficulty of introducing new approaches to medicine.

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<sup>2</sup> [http://europa.eu.int/information\\_society/eeurope/ehealth/doc/communication\\_acte\\_en\\_fin.pdf](http://europa.eu.int/information_society/eeurope/ehealth/doc/communication_acte_en_fin.pdf)

However, Raftery 2001 and Rubin & Rubin 2001 have shown that regulatory approval (e.g. NICE/CHI authorisation in the UK) can promote adoption more rapidly if professionals are given firm directives, including re-imburement incentives, to do so.

#### Information provision fragmented and not standardised

Much of the formal written information is generated and provided on a local basis. There are few examples where good practice has been identified and then implemented on a wider or national basis. The Cochrane Collaboration is probably a notable exception, but is geared mainly towards information for doctors. Most of the studies are based on small local experimentation, so that generalisation can be difficult, which in turn makes it hard to justify the investment for wider implementation.

Even where information provision is standardised, it may not be well tested and proven to be effective (O'Connor 2001, Edwards and Elwyn 2001, Coulter 2002). By shortening and simplifying a standard industry consent form used for clinical trials, Dresden and Levitt (2001) increased both readership and retention of content by patients.

#### Direct-to-Consumer (DTC) Information

Some panellists identified the need to distinguish between 'information' and 'advertising', where the former should be unrestricted and the latter avoided (or even proscribed). However, discussions failed to reveal a clear way to distinguish between the two, though there was a preference favouring 'pull' over 'push' forms of information provision, in which the individual can choose what they wish to receive.

Direct-to-consumer advertising (DTCA) is permitted in the USA and New Zealand, but presently forbidden in the EU under Council Directive 92/28/EEC. There have been a number of studies on the effects of DTCA on consumer behaviour and other outcomes in the USA, though there is still much debate about the interpretation of the results and whether the overall outcome from DTCA is positive or negative.

In the European Union, this is perhaps one of the more prominent issues at present given the European Commission's proposals for amending the EU pharmaceutical legislative framework, *Pharmaceutical Review 2001*, and the current consideration of the Review by the European Parliament and the Council of Ministers. However, the Review did not support DTCA, quite the opposite, it recommended that the existing ban on DTCA should continue. It did propose to allow industry to provide more *information* on prescription medicines to the public in three disease areas.

The Council of Ministers will make its decisions and propose alternatives during 2003. If the Commission and Parliament fail to reach agreement following the consultation process, conciliation procedures will be adopted. The Commission aims to have the procedures adopted before enlargement in 2004.

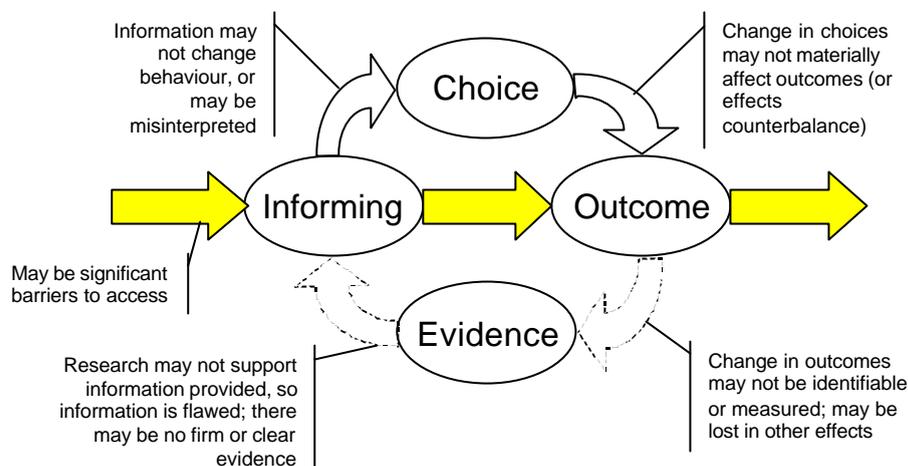
This project sees value in shifting the present DTCA debate to a wider context of overall provision of information to patients and away from the very polar positions taken by some parties on this topic.

The need is to support innovation and the adoption of new beneficial technologies without advancing ill-judged promotion or incomplete information on selected new treatments.

## Patient Information needs

### Informing patients to affect choices and improve outcomes

At several Panel sessions, the point was raised that simply providing more or better information would be just a ‘displacement activity’ unless it altered choices of treatment and ultimately affected outcomes (for the better):



**Figure 1 - Informing may affect choice and outcomes**

The difficulty is in the multiple and tenuous links that typically separate informing and outcomes, especially when there is little data generally recorded about outcomes or agreement about what outcome measures are appropriate. Clinical measures may not relate to the patient’s own perception of ‘quality of life’, nor to economic benefits outside the healthcare system (O’Connor 2001, Edwards and Elwyn 2001). As an example, more information to breast cancer patients may reduce anxiety and depression for some patients, while it may not affect the clinical outcome in respect of the removal of the carcinoma or ultimately long-term survival.

Two recently published reviews (Eysenbach et al 2002, Bessel et al 2002) attempted to identify empirical studies assessing the quality of web-based healthcare information or its impact on patient outcomes against more traditional means of communication. They concluded that empirical evidence is weak due to small study size and variable scope and definitions.

In one of the panels, discussions focussed on the benefits of providing information through the workplace, involving employees and employers over decisions for treatment and recovery, as well as general health education.

While there is evidence (NeLH) that good information helps to reduce patient anxiety, the effect on actual outcomes is much harder to identify. Alleviating anxiety about a patient’s prognosis seems to have positive effects, though there are some patients for whom ‘ignorance is bliss’. Much may come down to the individual patient’s attitude to risk and uncertainty.

### Informing as a necessary precursor to consent

In panel discussions, it was felt to be an ethical requirement that patients were properly ‘informed’ by professionals about their treatment to respect their rights to autonomy and choice.

It was suggested that perhaps only the patient could actually determine how much information was sufficient to leave them ‘fully informed’. Equally, some patients might choose not to be ‘fully informed’. There was a danger of treating ‘informing’ as a process to be done to the patient, rather than a dialogue involving the sharing of information and the support of choice.

Patient needs for information vary with individual characteristics and across/within cultures

Patient needs are driven by many individual factors. These are summarised below:

Factor	Comments
Age	Older people are prone to different conditions and may also be used to a more 'paternalistic' relationship with doctors. A high proportion of illness occurs in older people, so it is important that information provision reflects this. Older people may find modern technologies less accessible.  Younger people may be less experienced and require simpler delivery of information – they may not be the sole decision-maker (viz. with parent/guardian)
Gender	Generally, women are the care-seekers for their family; men are notoriously bad at seeking treatment. Conditions can be gender-related
Culture	Some cultural differences exist across Europe, e.g. Northern Europeans may be more individualistic and rights-based, whereas Southern Europeans may be more family-based exhibiting collective decision-making and greater reliance on the clinician's opinion.  Equally, religion or culture may affect perceptions about disease, e.g. mental health in Asian cultures. Different views and/or taboos may apply and need to be accommodated. Richards et al (1995) and Beaver et al (1996) show that cultural differences affect engagement in decision-making in cancer patients – a finding supported by the panels.
Education	Education levels affect individual ability to assimilate information, and, to some degree, questions that may result. This would cover formal education, acquisition of general knowledge about health-related issues gleaned from the media, and social contacts may be involved.
Language	Information must be accessible, and so information provision must reflect variations across Europe and within countries with different local and immigrant languages. Older people in immigrant populations are likely to be less adept at the host language.
Socio-economic status/literacy	Lower socio-economic status and low literacy are associated with increased ill-health and poorer diet.
Disability	Those with learning difficulties or sense impairment may need special formats to access relevant information.
Personality	There are indications that some patients find better information reduces anxiety by giving a greater sense of control, while for others it may only increase anxiety when they would prefer to leave matters to the clinician
Acute versus chronic conditions	In acute or emergency conditions, there may be less time for detailed communication and fewer options. For chronic conditions, options can recur and may have greater effects on quality of life; there is also time for discussion, reflection, and research.
Stage of condition	People need different information at different stages – see Patient Journey below
Individual receptiveness to information	Patients may not always be ready to accommodate information, e.g. they will have to go through stages of understanding and acceptance similar to Kubler-Ross (1969) 'Seven Stages of Grief'.

These factors must be taken into account, both in individualised patient information as well as wider communication efforts. Ratzan (1998) noted the challenge of reaching a diverse audience through different channels and formats as a consequence of differences in gender, age, educational level, ethnic/cultural beliefs, language ability, and disability.

Hoek et al (2001) argue that consumers' ability to understand information conveyed in DTC advertisements depends on prior knowledge, the actual details provided, and the format in which these are presented. Wogalter et al (2002) found that, where risk statements are not separated or made explicitly distinct from benefits, then patient recall of risk is lower. This suggests that the development and design of appropriate communication tools is far from easy, will require considerable expertise to be effective, is likely to be costly, and so may be an activity that is best shared in order to spread the cost.

Patient needs vary over the course of the Patient Journey

This model was found useful by a number of the panellists, and, while simplistic, brought out some of the different types of information that patients may require:

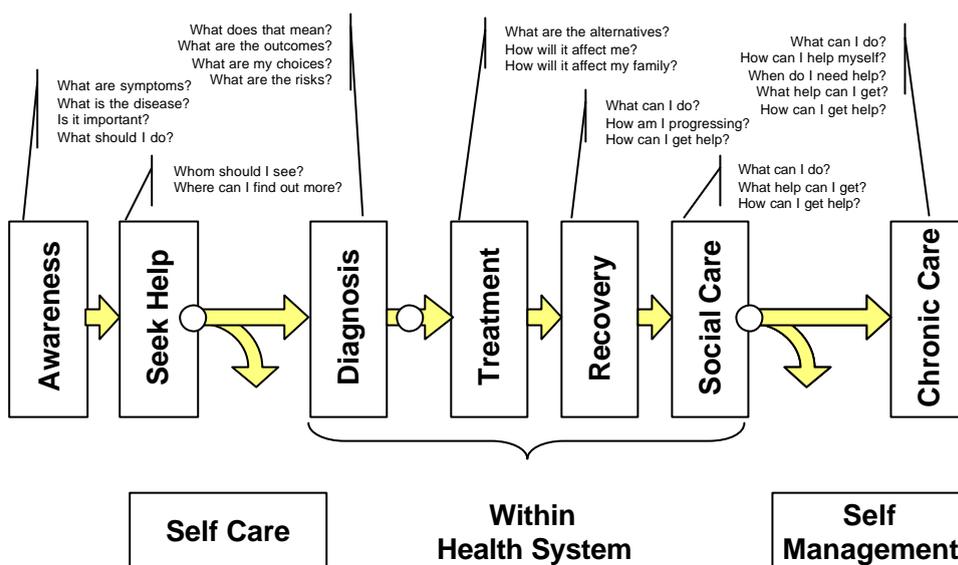


Figure 2 - The Patient Journey

This presents a oversimplified 'linear' view of healthcare – diagnosis may to some degree lie outside the healthcare system, and may not necessarily precede treatment, being provisional and subject to revision. Patients may relapse and need to pass through the system many times, either with the same or different conditions.

However, the model does highlight some different information needs:

Information about:	Need
Disease/symptoms	To know that there is a problem, that the condition is treatable
Access to the health system	Where to go, whom to see, what to ask for – should one call/see ambulance, GP, specialist, pharmacist, or alternative healer?
Disease/prognosis	What does the disease mean – what are the outcomes without treatment?
Treatment options	What different treatments are available? Which are covered under public funding, insurance, or need to be paid for privately?
Outcomes	What are likely outcomes? What will they mean in terms of recovery and future life?
Personal involvement	What will patient need to do – either in adherence to the agreed treatment or in future lifestyle to remain healthy?
Lifestyle	How do I live with the condition or disability?
Support options	Where do I seek social care and what technologies are available to help me cope with the condition?
Self-management education	Can I self-treat? This is the basis of the UK 'Expert Patient' initiative.

## Information Provision

### Information Channels

Patients receive information in many different ways:

?? Through personal interaction with:

- Family and friends (informal networks)
- Doctors, nurses, and other healthcare professionals
- Pharmacists
- Patient groups

?? Through what they see, hear, and read

- Supplied in the course of contact with the healthcare system:
  - o Product literature, including PILs
  - o Patient Leaflets (from clinic or surgery)
  - o Government information (possibly through the above)
- Media (Broadcast: TV, Radio; Written: Press, journals, health magazines) – this may be documentary, drama/soaps, as well as advertising
- Education (programmes at school, work, or elsewhere, e.g. pre-natal classes)

?? By actively seeking information from:

- Internet
- Books and magazines
- Patient groups
- On-line triage (e.g. NHS Direct)

Two recently published reviews (Eysenbach et al 2002, Bessel et al 2002) attempted to identify empirical studies that compared the quality of web-based healthcare information and its impact on patient outcomes to more traditional means of communication. They concluded that there is a need for further research comparing the relative effectiveness of different channels of information as the empirical evidence is weak due to small study size and variable scope and definitions.

These channels each have their own features and potential biases reflecting the interests of those providing or funding the information.

One key feature is the ability of channels to provide a ‘full’ range of information – the ‘bandwidth’ of the following diagram:

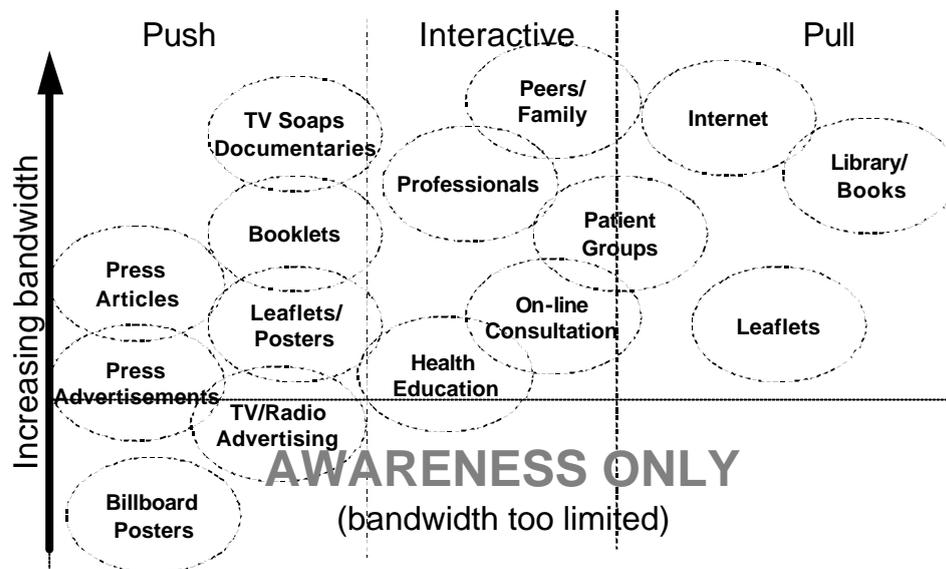


Figure 3 - Information channels and bandwidth

It should be noted that this diagram does not properly allow for the time-frame of presentation, the complexity of the message, or the context in which the information is provided.

#### Advertising vs. Information

There was discussion at the Panel meetings about ‘information’ or ‘education’ versus ‘advertising’. ‘Advertising’ was seen as promotional (attempting to influence on the basis of emotions as well as facts), potentially biased (may omit or de-emphasise information about adverse factors), and primarily geared to increasing sales. For these reasons, advertising was seen generally as ‘bad’. However, it was also pointed out that all sources of information generally had biases. For example, governments might suppress information about alternative treatments in order to cut costs.

The definition of ‘advertising’ has been a complex issue. For example, the attempt to redefine the scope of advertising within the latest EU proposals for the pharmaceutical industry has included information developed by patient groups and media commentary.

The distinction between ‘search goods’ and ‘experience goods’ in relation to prescription medicines is explored by Rosenthal, Berndt, et al (2002), including the corresponding use of ‘informational’ versus ‘persuasive’ advertising with the latter required to persuade potential users to try the ‘experience’. There may also be parallels with the ‘Intel Inside’ campaign where the ultimate PC consumer is informed in order to influence the behaviour of the actual corporate buyer of computer systems – equally patients are encouraged to influence, rightly or wrongly, doctors’ choice of treatment.

In this sense, ‘advertising’ is necessarily limited, as print advertising or conventional 30 or 60 second commercials can only convey limited information to the recipient. If loaded too heavily with ‘negative’ information, they may fail to gain the attention required. This has been noted in various public health campaigns, e.g. anti-smoking or AIDS, where overly negative messages may be rejected. The key may be to ensure that the ‘call to action’ to the recipient is to seek more information from a suitably qualified source, such as a physician or pharmacist. This is often a key requirement of ethical codes for product promotion (e.g. American Medical Association).

No studies have been found which indicate that advertising of pharmaceutical products is more or less obtrusive than advertising by other industry sectors, though the subject of nail fungus or bladder problems may produce viewer discomfort on prime-time television. There was some anecdotal commentary that it is often crass, suggesting that DTCA is still in an experimental phase, that pharmaceutical companies are inappropriately advised, or, perhaps, that those making such comments are not the target audience.

Some US studies (Calfee 2001) have suggested that advertising increases compliance though a greater sense of choice, or provides general information that stimulates a relevant visit to a doctor. The Prevention Magazine Survey (1999) also suggests that the better the information is conveyed through an advertisement, the more likely a patient will raise a question with a doctor, i.e. poor or biased advertisements are not as effective as more balanced ones.

## Infomediaries/Suppliers of information

### Package Leaflets/Patient Information Leaflets (PILs) from medical suppliers

Nearly all the Panel sessions raised the issue of inadequacy of the formal provision of information from pharmaceutical companies to patients which is constrained by regulation of authorised medicines.

Patient groups complain that the format of PILs is inaccessible to most patients. Professionals indicated that, in some cases, they had to instruct patients to ignore the leaflets. Pharmaceutical companies were concerned that they are blamed for the poor format when their hands were tied by regulation and they are prevented from providing more accessible information that would help with compliance. This is reinforced by recent evidence (Raynor & Knapp 2000, Berry et al 2002) – see p16.

On the positive side there are initiatives to review this type of information – in particular, Agence Française de Sécurité Sanitaire des Produits de Santé (AFSSAPS) in France has a taskforce addressing this issue. The European Commission produced a *Guideline on the Readability of the Label and Package leaflet of Medicinal Products for Human Use* in September 1998, which aimed to improve PILs, but still left the basic position of 'one size fits all' (large fonts are encouraged, but it is not possible to have different versions for different literacy levels) and limiting the options available to provide useful information to patients.

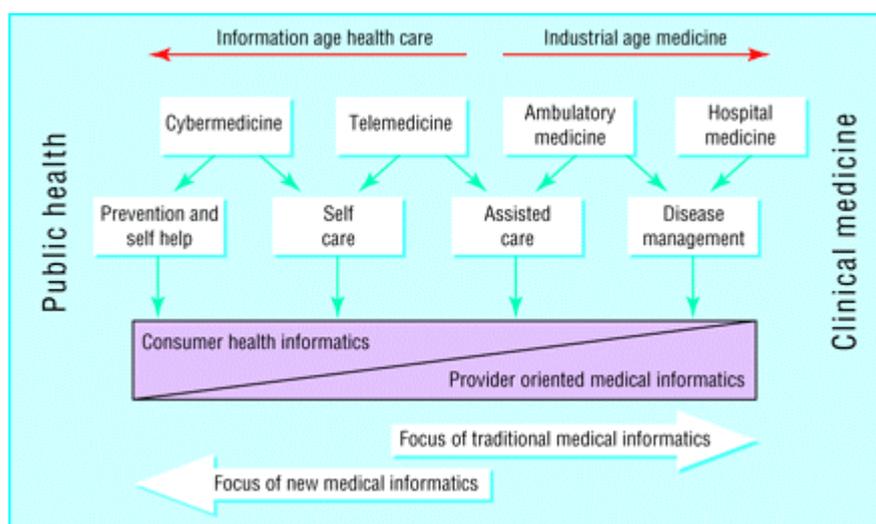
### Changing Roles and relationships

The richest form of information provision is conceded to be interactions between the patient and healthcare professionals, and all Panels recognised that this was often the most appropriate channel, but the key difficulty was reconciling this with the increasing pressure on clinicians' time. Several experts have advocated increasing the role of other professionals (nurses, pharmacists) or of changing processes, e.g. e-mail with pre-processing by software to respond to frequently asked questions. In the UK, the 'Expert Patient' initiative seeks to create an additional role/channel of the 'expert patient'/'patient trainer' who is not a clinician, but an appropriately trained lay person to support patients with chronic conditions.

Indeed, the changing relationship between patients and physicians was discussed at a number of the Expert Panels, mainly with the view that the relationship was changing over time, but would vary depending on the individuals concerned and the situation, e.g. emergency heart surgery does not allow for much variation from a 'passive patient' and a hopefully expert and controlling physician. Culture too is a major factor, affecting the social norm of the country or region (Coulter 2003).

Healthcare professionals need support in their need to understand and use communication and listening skills when dealing with patients. It was noted that this was only a fairly recent introduction into medical curricula. This need was further emphasized by the Consensus Panel and is reflected in its recommendations.

The patient-physician relationship is also being affected by broader changes of focus within the delivery of healthcare, as is reflected in the diagram below (Eysenbach, BMJ 2000):



**Figure 4 - The focus of traditional medical informatics is shifting from health professionals to consumers (Eysenbach 2000)**

### Infomediaries

This portmanteau word, short for 'information intermediary', arose several times in the panels, suggesting that patients will increasingly require some form of agent (human or software) to help them find the information they need. The agent will have to understand both the patient's needs and the information available; it will also have to use this knowledge to effectively filter out irrelevant material as well as providing information in a suitable form to be accessible to the patient.

If the agent is to be human, then greater training will be required for all clinical staff to be better at sourcing information for the patient, helping to guide them to a reliable source, and presenting information appropriately. Alternatively, some element of role specialisation may need to occur. Panel members suggested that this was already happening with nurses often being left with the task of supporting patients.

If the agent is to be software, then it will need to know more about the patient, both in terms of medical history in order to filter relevant information and also health literacy/preferences for presentation/accessibility. Links to Electronic Health Records (EHRs) may be one requirement, both to access medical data and to record preferences. Data Protection issues will be a consideration, both as a necessary defence for the individual and as a potential impediment to desirable innovation in personal information services.

### Economic Arguments

The drive to inform patients is partly prompted by the assumption that better-informed patients will not only achieve better health status, but also that they will make more efficient use of health care resources through more appropriate treatment decisions, better adherence to the agreed treatment, and better understanding of the ramifications of clinical decisions. Better health status, while a valuable social good in its own right, may also lead to higher productivity and better economic performance for individuals, corporations, and countries.

Constraints on funding in most healthcare systems may limit the levels of information provision below the ideal. This is both through seeking a trade-off between the costs of care and information provision, and also as a form of rationing to constrain demand.

There is little information within most public care systems to identify which care treatments reflect best practice and whether providing more appropriate information to patients would engender better practice and a more cost-effective system. If this were so, it might provide the necessary incentive for better information provision).

There are some studies that explore the economic ramifications of DTCA following deregulation in the United States. Despite their specific context, findings from these studies may also provide some useful insights into the economic implications of providing other forms of information to patients.

#### Does informing patients lead to improved health outcomes?

Some studies support the notion that better-informed patients may achieve better health status and quality of life. A study of the treatment of hypertension (Schulman 1979) showed that such patients benefited from actively participating in their treatment decisions. Similarly, Fallowfield et al (1990) found that patients with breast cancer suffered less anxiety and depression if clinicians allowed them to participate in their treatment.

There is little clear evidence that information alone generates better outcomes. Murray et al (2001) indicate that it may reduce decisional conflict and increase satisfaction with the decision made, but not offer any clear health improvement. Stewart (1995) evaluated 8 studies and concluded that there was a correlation between effective physician-patient communication and improved patient health outcomes.

The Cochrane review (O'Connor et al, 2001) suggest that decision aids do improve knowledge, reduce passivity, and lower decisional conflict, but have no great effect on anxiety, decision outcomes, or satisfaction with the decision. Importantly, they recommend that standards should be developed.

According to NeLH, good information helps to reduce patient anxiety, though the effect on actual outcomes is harder to identify. Alleviating anxiety about the patient's future seems to have positive effects, though there are some patients for whom 'ignorance is bliss'. Much may come down to the individual patient's attitude to risk and uncertainty. Finally, there is some evidence (Kiley 2002) that poor information can have adverse effects on health.

There seems to be no firm answer to the question posed above as the effects of structured information provision (leaflets, videos, etc.) can be overwhelmed by patient-physician interactions.

#### Does informing patients lead to increased demand for healthcare?

There are concerns that better informed patients will also be more demanding of new and possibly more expensive treatments, with the risk of higher healthcare costs. It should be added that these fears, often raised in the context of DTCA, are not always balanced by consideration of possible reductions in overall care costs through earlier diagnosis and treatment.

There is evidence (Kaiser Foundation study 2001, DTC Monitor 2000) that DTCA increases patient referrals to clinicians. The Dutch Health Ministry reported that a 3-month media campaign for a nail fungus treatment - which carried neither the company nor the product name - led to patient consultations for this condition rising from an average of 2 per month per doctor to 20 per week per doctor.

Such increases in consultation rates may address unmet needs, e.g. patients maybe unaware that unsightly nails and discomfort could be due to infection and were treatable, or increased 'hypochondria' as public concerns are raised unnecessarily. There is also the possibility that patients will be encouraged to visit doctors with a self-limiting minor illness, e.g. common cold, that will naturally rectify itself. Early diagnosis and management of diseases like diabetes and heart disease can improve health status and longevity and reduce long-term expenses from sequelae such as stroke and amputation.

### Does more information lead to increased healthcare expenditure?

Clearly, providing additional or simply better information is likely to incur extra direct costs, but how this affects overall healthcare expenditure through changed treatment patterns is less clear.

One panellist noted that clinicians' families tend to have lower levels of intervention than the general public. On the other hand, female obstetricians often have higher than average elective Caesarean rates. The Ticino study (Domenighetti et al 1988) indicates that a better informed patient may choose less risky or less invasive intervention. A better informed patient, who is more likely to be engaged in the decision-making, may prefer a wait-and-see attitude rather than adopting a more assertive regimen suggested by a clinician. This suggests lower healthcare costs as a possible result of better informed patients, though there could be correspondingly higher social care costs from supporting the patient through the wait-and-see period.

There are concerns that promotional activities, including DTCA, are used to promote new drugs at the expense of equally effective older drugs, especially generic alternatives, thereby increasing the overall healthcare budget. While it is self-evident that promotion will be targeted at newer or more profitable drugs, in order to gain or maintain market share, there are limitations to this strategy since drugs will normally only be adopted onto formularies if there is an increased effectiveness or reduction in adverse side-effects. Whether these improvements are properly reflected in the premium cost of a new drug is harder to tell.

There is evidence that DTCA spend has increased alongside a rise of expenditure on pharmaceuticals in the USA (Rosenthal, Berndt, et al 2002, NIHCM study 2001). There has also been a true increase in the average cost-per-drug. New formulations also account for a large share of the real increase in drug expenditure. However, Wosinska (2001) shows that the major correlation with increased sales is higher promotion to physicians rather than DTCA.

Indeed, there are many factors that may account for the rise in drug expenditure, irrespective of the role played by advertising:

- ?? the aging of the population leads to increased prevalence of chronic conditions, for which long-term treatment with an increasing number of agents is more common
- ?? doctors are using a wider array of drugs more often in preference to more costly and/or risky surgical interventions
- ?? it may be easier and cheaper to meet the increasing demand for healthcare through increased drug prescribing than through increasing surgical interventions
- ?? Health insurance in the USA has increased the coverage for drugs over the past decade – thus eliminating a potential financial barrier.

It is difficult to resolve whether DTCA has merely supported the adoption of new technologies to the benefit of all or is a tool that exploits the system and the public at large. Not surprisingly with something so new and dramatic, there are advocates for both positions.

Finally, given the predominance of US studies in the English-language literature, it is important to voice caution at extrapolating evidence from one culture to another without considering the baseline cultural issues or differential patterns in purchasing behaviour and expectations regarding healthcare consumption between countries. This caveat is supported by cross-cultural comparative studies by Mintzes et al (2002). Panellists and conferees clearly held the view that US-style DTC advertising would not be considered appropriate in Europe.

## Can information help manage demand for healthcare?

Providing more relevant information about how to use the healthcare system properly might lead to improved utilisation of resources by the public.

Some information may reduce demand on the healthcare system by encouraging self-care and a more appropriate use of resources. In a controlled trial, Heaney et al (2001) showed no significant change in health service utilisation through use of patient information leaflets, though one leaflet did reduce consultation rates suggesting that some unnecessary consultations were avoided.

Information campaigns can be effective. In the USA, a public health campaign, known as the Partners Health Initiative in Anderson, South Carolina, have showed overall savings by reducing GP and emergency clinic visits through provision of a healthcare manual to households. Similar programmes were introduced in the states of Idaho (the Healthwise program, Kemper 1997) and Rhode Island, with compelling results. In Rhode Island, a 35% reduction in primary care consultation rates was observed (Vickery et al, 1983). The US Agency for Health Research and Quality (AHRQ) has issued several consumer guides on particular illnesses to foster patient education. This experience might not carry through to Europe as many people in the USA have to pay for such consultations, so there is a clear incentive on the part of the consumer to restrict consultations.

For better or worse, most information is provided at the point of care, so the patient has probably already made their choice about access. To change patterns of access requires a pro-active campaign to inform the public and this needs to be sustained over time to be effective.

Only a few major public health campaigns in Europe have sought to inform the public about how best to use the system and there may be difficulties in changing public behaviour in accessing the healthcare system. In the UK, NHS Direct (a telephone triage system) is promoted to divert callers from using more expensive primary-care or emergency resources and to improve access to information. Reports (National Audit Office 2002) suggest that it may have increased demand and patient satisfaction rather than having reduced operational costs overall.

Some panellists noted that there may be incentives for triage systems, such as NHS Direct, to be even more risk-averse than patients themselves and hence they recommend visits to GPs or emergency services when the patients might not have self-referred.

## Direct-to-Consumer Advertising (DTCA)

In economic terms, if one views the healthcare sector as a 'zero-sum game', then any advertising expenditure on prescription medicines will take money out of the system and will either reduce profits, take money from other factors of production (e.g. clinicians' pay). Alternatively, it will force an increase in national budgets.

Increased prescribing of drugs (possibly supported or instigated by DTCA) may substitute for other forms of treatment which could be more expensive (when total healthcare costs are considered) or scarce (e.g. skilled staff), thus reducing overall expenditure or increasing healthcare capacity. If one can improve overall health status, there may be substantial benefits to other sectors of the economy, e.g. reduced costs of social care, or earlier return to work which may generate wider economic benefits.

There have been studies, e.g. Rosenthal, Berndt, et al, 2002, NIHCM study 2001, which relate DTCA to overall spend on drugs and note a positive correlation, suggesting that DTCA increases drug expenditure for those drugs where it is used. They also concur with Wosinska (2001) that '*DTCA, unlike detailing, affects individual drug market share only if that brand happens to have preferred status on the third party payer's formulary*'. This suggests to us that payer approval may be a more significant factor than DTCA in changing clinician prescribing practice, and that pharmaceutical companies use DTCA to support an approved change in practice (viz. the causality may be reversed – that DTCA follows likely future spend on specific drugs).

These studies, while showing a correlation between DTCA and drug expenditure, do not indicate what the ultimate effect on overall healthcare spend was after allowing for substitution of treatment options (e.g. drugs and home care rather than surgery and expensive hospital care).

The 2001 Prevention Magazine survey commented that DTCA may prompt subjects to discuss a drug with their physician, but may ultimately lead to non-drug treatments. For example, in the cases of diabetes, high cholesterol, or obesity, the physician recommended a diet or exercise in 72% of cases. This is the basis for the argument that DTCA can have 'positive externalities' and thereby promote better healthcare.

On the other hand, it may also lead to longer and more expensive consultations to deal with the issues raised by patients who have seen the DTCA and so increase the costs of consultation. Evidence for this is based mainly on clinician opinion surveys rather than direct measurement. Prevention Magazine (1999) indicates that in the USA 81% of consumers reacting to a DTC advertisement wait until a regularly scheduled appointment to raise their concern (with 10% calling to enquire by phone, and 7% making a special appointment), but it is not clear whether this may have increased (or even reduced) the consultation time.

US surveys by Prevention Magazine indicate that patients exposed to DTCA may be more likely to adhere to the prescriptions they receive either because of prompting by the advertisement or because it increases confidence in the treatment. Panellists commented that a greater emphasis on 'concordance' through greater discussion of treatment options might be a better place to start.

Studies (Cramer et al 1989) indicate that up to 50% of medicines are taken incorrectly and up to 10% of medicines discarded, so if DTCA prompts patients to improve compliance, then it may reduce drug wastage and improve health outcomes.

#### Reduced litigation

There is evidence in the USA that better communications can reduce patient litigation against doctors (O'Connell & Keller 1999). This seems to reflect greater shared decision-making and increased trust. While there are strong cultural and legal differences between the USA and Europe in respect of litigation, there is likely to be some economic benefit through better communications.

There are few facts to support an estimate of potential savings in this area. Indeed, there are indications that better incident management, including apologies and commitment to improvements, might do even more to reduce litigation claims.

### Policy Options

Health policy options for the European Commission are dependent on the wording of the Amsterdam Treaty (Article 152), which acknowledges that sovereignty for healthcare provision and finance remains with the nation states. EU-level competence is limited to public health matters, for instance co-ordinating public health matters between member countries.

The pharmaceutical industry is subject to EU law which has the primary objective (as supported by the European Court of Justice) of protecting public health by ensuring that medicines placed on the market are safe, of good quality and effective. It is also regulated under Treaty Articles applying to industry in general (including intellectual property), 'freedom of services', research, and indirectly in a number of other ways. Responsibility is divided among various relevant Commission Directorates, with DG Enterprise often taking the lead. In these contexts, some pan-European policy options can be developed, notably in terms of restricting or promoting 'trade' rather than relating to 'health' *per se*. The main body supporting the European licensing procedures through the provision of technical and scientific advice is the EMEA (European Medicines Evaluation Agency), which works closely with national regulatory authorities and the European Commission.

## Legislation

Legislative changes at the EU level take a number of years to develop, whether via ‘Directives’ for national implementation in due course or ‘Council regulations’ that can be implemented at once. Otherwise, initiatives can be based on existing legislation where EU-level improvements to patient information provision are desirable, competence may be found in a number of ‘cross-border’ issues, in supporting ‘open coordination’ of voluntary agreements between governments, in consumer protection, fair trading, research, informatics and a number of incidental areas. There may be assistance too from other areas of EU law, the Council of Europe that deals with Human Rights, or international agreements, e.g. Helsinki Agreement. Organising support for initiatives typically takes a number of years, unless a suitable or adaptable ‘Action Line’ (Budget) already exists..

## Regulation

Where regulation deriving from EU legislation is implemented by independent agencies set up for the purpose it may be more flexible, since regulations can be adapted more readily by the regulatory body. This too depends on the constitution which sets its objectives and ensures funding to meet these obligations. Any pan-European body would require new EU legislation, or a reinterpretation of existing legislation and this seems unlikely. This might just apply to the pharmaceutical industry, since it is viewed as a sector with distinctive concerns involving several Treaty provisions, but even that does not address the broader areas of information provision to patients.

Clearly, regulations that prove ineffective or to have adverse unintended consequences should be reviewed and modified to achieve their original policy objectives. The current position over patient information leaflets (PILs) under labelling regulations would seem to be a clear case, in which the policy objective of informing patients is not being adequately achieved.

## Self-Regulation

Self-regulation has been a model adopted by the pharmaceutical industry for several decades in individual EU countries. Several panellists proposed this as a viable model for “vetting” the content of DTC advertising and overall provision of information emanating from the pharmaceutical industry.

There are many stakeholders within healthcare, most of whom provide information. It is unlikely that all could be brought together to support consistent self-regulation, or be subject to a single body.

## Guidelines/Standards

A standard-setting rather than a legislative or regulatory role at the European level is far more likely to succeed. This would require funding a central body to determine standards, certify conformance to the standards, or provide authorisation for other certification bodies or information suppliers who meet requirements or codes of practice. Standards should be applicable to all providers of information equally.

Solutions to the setting of technical standards have been found by a number of other sectors in the EU’s ‘CEN’ (Comité Européen de Normalisation) structure, which unites national bodies such as British Standards Institution (BSI), Deutsches Institut für Normung (DIN), Association Française de Normalisation et de Certification (AFNOR), Nederlands Normalisatie-instituut (NNI) etc. Stakeholders can be represented by their national bodies and may also participate in CEN processes, including an official voting structure in which stakeholders are fully represented. Resulting CEN standards are supported by EU Procurement Directives and CEN itself has well-established funding mechanisms, with a Commission contribution. CEN only facilitates the establishment of standards. There are separate industry-specific structures are needed for subsequent conformance testing, and accreditation. Such standards are not in principle mandatory, but those not using them can expect difficulties in procurement and public acceptance

The question of funding may otherwise be tricky, either by direct grant from the EU, by common subscription from nation states, or funding from other sources such as charitable foundations, or some combination of fees from information providers if there is a business reason to conform to the standards and pay fees. This needs exploration.

Setting standards for quality requires a review body with representatives drawn from across the stakeholders groups including patients. Examples of possible quality requirements are given in Coulter (1998) drawing on earlier work by Jadad & Gagliardi (1998) and Ambre, Guard, Perveiler, Renner, and Rippen (1997). These include:

- ?? Accessibility
- ?? Acceptability
- ?? Readability and comprehensibility
- ?? Style and attractiveness of presentation
- ?? Accuracy and reliability of content
- ?? Coverage and comprehensiveness
- ?? Currency and arrangements for editorial review
- ?? Reference to sources and strength of evidence
- ?? Location of further information
- ?? Credibility of authors, publishers and sponsors
- ?? Relevance and utility.

Clearly these require more detailed work to serve as quality standards since terms such as 'credibility' require definition and delineation into acceptable levels for adoption or certification. Some work of this kind has been addressed within CEN and can be tracked in the papers of CEN Technical Committee No 251 'Medical Informatics' (CEN TC251) and in committees (CEN and ISO) with a more general remit for research citation.

#### Incentives/Grants/Support

An alternative approach is for organisations to support or fund completely 'Informed Patient' activities. Specific bodies could act as portals and/or exemplars of good practice.

The College of Health in the UK is used by the Department of Health to provide telephone help-lines for patients, and to provide materials in different languages (tailored for cultural aspects – 'transculturisation'). A similar model, but extended across the EU would have economies of scale as well as allowing minorities in individual countries to be better supported through sharing across the whole EU. This could also support expatriates working across the EU.

Within the European Court of Justice, the recent cases of Geraets-Smits and Peerbooms, after Kohll and Dekker and with Müller Fauré and Van Riet impending, there is a growing understanding of the conditions under which patients can move across Europe to receive care. It is well recognised by governments and the Commission that measures will need to be in place to help EU citizens get access to their rights, compare treatments and costs and be aware of treatment options on an EU-wide basis. In the European interest, better patient information seems fundamental to these goals.

A panellist suggested that patient groups needed support in running their web-sites, so that a common resource with quality accreditation might be a possible approach.

#### Co-operation amongst national agencies

All national agencies will experience problems providing appropriate information to patients with cultural or linguistic differences from the host country. Rather than each seeking to resolve these problems individually, it would make sense to co-operate to share costs and also to share existing resources to support expatriate and immigrant communities.

The European Union is in a strong position to help support co-operative activities that serve cross-border trade and public health provision.

#### Educational Initiatives

Comments at the Panel meetings and the Consensus Conference suggest that additional education of professionals and other intermediaries is needed if they are to provide appropriate information to patients. The development of guidance and guidelines to support such education would stimulate change, though without real incentives, e.g. financial or legislative, uptake may be slow.

#### Public-Private Partnerships

EU authorities use 'Public-Private Partnerships' (PPP) to describe a generally collaborative approach, possibly including the joint funding mentioned above. (This should be distinguished from the more specific meaning of PPP in the UK and some other countries, where it refers to joint ventures in the structuring of major public projects).

In the EU, a number of PPP options could be considered, although the ideals need to be tempered with the realisation that 'commercial' funding will generally only be available if there is a likely commercial benefit at some point in the future.

Hopefully, clear 'win-win' arrangements can be identified which will support public health, improve safety and quality, cut waste in healthcare systems, and generate revenue for the commercial supplier. 'Commercial' operators, like all systems, need a 'profit' incentive for innovation, and it is reasonable that profits should be proportionate to business risk and eventual benefits to consumers. This is no different from any other market.

A common thread in all Panel and Consensus Conference discussions was the need to encourage collaborative initiatives to support the provision of suitable, high-quality information to patients in Europe. Given the complexity of health care provision, the changing role of health care professionals, the increased power of the Internet and the increased focus on chronic care, a collaborative approach will ensure that patients receive information in a timely and clear manner.

There are areas, such as 'off-label use'<sup>3</sup> of medicines, where information provision is poor and the responsibility for proper provision is unclear. Indeed, regulations prevent pharmaceutical companies from providing relevant information. A General Accounting Office (USA) survey revealed that a third of all prescriptions for anticancer drugs had off-label uses. Another study of AIDS patients (Brosgart et al 1996) showed that up to 40% of all drugs prescribed were off-label. Co-operation across organisations should permit a more rational approach to support these uses of medicines.

These collaborations could take many forms, as described in some of the examples of "models of best practice" given in the Consensus Statement (Section 3). However, some illustrations or models described in the literature may also be used to guide these initiatives.

#### Proposing further research

The literature survey and comments from experts show that there is little evidence identifying what information provision is most effective in improving health outcomes. More research is needed in this area to support appropriate development of both evidence-based content and effective delivery. This would require studies assessing the effectiveness of different formats, mode and timing of delivery, as well as the collation of results from these trials to identify which approaches work most effectively.

There is a need to bring together current initiatives across Europe so expertise and experience can be shared. There should be further work to co-ordinate sharing of patient literature in different languages and to support different cultures across Europe to avoid duplicated efforts. It would also permit joint funding to support 'orphan' minorities where no one country can justify the expenditure of specific materials.

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<sup>3</sup> Sometimes referred to as 'unlabelled use', where the drug is used in a clinically approved and evidence-based protocol under the physician's prerogative, but not one approved by the regulating authority.

### Recommendations in the Literature

Ratzan (1998) identifies four strategic building blocks to improve health communication:

- Effective infrastructure to ensure technical and interpersonal capacity
- Quality standards to ensure a sustained level of quality and build a supporting evidence base through research.
- Strengthening the capacity/ability of the health consumer/audience to access, understand and use communication by building capacity to discern the quality of information
- Promoting the critical appraisal and thinking capacity of professionals through education and training, to improve their ability to be effective communicators of health information.

Lister (2001), a proponent of public engagement, highlights the need to change culture to support patient and public involvement in the NHS in the UK.

He argues for :

- commitment and training at all levels to effect behaviour change;
- a legal basis for patient rights;
- a network organisation to support local initiatives;
- technical resources to support training and information (for example through the creation of a digital TV resource);
- regular measurement of patient perception, and
- development of expertise to engage communities across ethnic and social divides.

New approaches should also draw from existing models and from the experience in other countries. For example, in the Netherlands, patient rights are enshrined in law, supported by the Netherlands Federation of Patient Consumer Organisations (NFPCO), which has equal status with government in a triangular relationship between the purchasers and providers of health services and patients and carers. In Australia, active programmes exist to promote consumer participation in healthcare, some of which are mandatory. These are funded by government.

## Reflections by CUH Team

This section represents some conclusions of the CUH team separate from those of the Consensus Conference or Expert Panels.

Areas requiring Investment and Education

### **Improving readability and relevance of existing materials**

This was recommended both in the literature and in the Expert Panels. It may require additional funding as well as guidance, similar to the Plain English guidelines, on how best to present material to patients to create awareness and understanding of conditions, treatment options, risks, and likely outcomes.

### **Better Public Health funding and information**

The Panellists described a demand from patients for better availability of information on new treatments and to help patients identify potential illnesses earlier. This requires some form of health promotion and public funded 'education' to create awareness is considered preferable to DTCA by the industry to avoid commercial bias. However, it is unclear how this will occur without a significant policy impetus and funding.

### **Health literacy and education in schools**

Strictly speaking this is outside the boundaries of our study. However, the topic came up repeatedly as a prerequisite of information pertinent to the majority of the EU populations. If information is only accessible to the better educated or advantaged, then health inequalities can be expected to increase and economic benefits, yet alone quality of life considerations, would be limited to those populations that are already comparatively healthy.

The advent of the Internet is important in providing ready access to information for some, but at present the 'digital divide' will result in the better-off having access to better information. It is anticipated that in time the Internet, or equivalents such as digital TV or 3G mobile phones, will be more generally available.

Aspects concerning regulation

Regulation offers a number of options. These include 'industry self-regulation', 'statutory regulation', outright ban, authorisation (of a company or body to produce or approve activities), certification of individual actions put forward, and/or post-event policing possibly with active monitoring.

The advantages of industry self-regulation is that part of the cost is factored into the industry concerned, and can be tuned to be as fast and responsive as is required, provided the industry is prepared to meet the requirements. Any self-regulatory body tends at the margin to serve the interests of the industry rather than the wider public, unless sanctions can apply.

Statutory regulation tends to be slow and inflexible. Some regulatory bodies, such as film censorship boards, can be quick to move with the times and responsive, despite increasing workloads. One must determine the level of discretion to be given to the regulator and the funding model to apply

A 'hybrid' approach of an industry self-regulatory body subject to sanction by a statutory body may allow both the flexibility and speed that the industry needs while maintaining effective and smooth public control.

### **Information - quality and balance of output**

It is peculiar that information to the public is restricted in the absence of clear evidence of harm. Indeed, there is evidence that some aspects of present regulations prevent the 'good' that they are intended to promote. Strikingly, package leaflets are so regulated that they may seem irrelevant and inaccessible to the very people they are supposed to help.

There are risks of excessive competitive advertising which could be detrimental to the healthcare industry as a whole, so some 'regulation' may be justified, but it should be appropriate and proportional.

One approach may be a two-stage model: first a 'pre-event' self-regulating body to approve proposed advertising, with a statutory 'post-event' regulator similar to the approach used by the FDA. Both regulators must have effective powers of sanction to ensure compliance. The statutory regulator should have the power to revoke the authorisation of industry 'self-regulator' in order to ensure proper practice. This seems to have been necessary in New Zealand.

In the EU context, it might be necessary to have a framework for such regulation at national level, supported by an EU-wide structure for 'mutual recognition' of national rules. The position is complicated by access to advertising from other states outside the EU and from widely-accessible electronic media

### **Inconsistencies in regulation**

There exist some fascinating and important inconsistencies in current European regulation. For example, it seems inconsistent that OTC drugs can be advertised, but prescription drugs cannot, especially as there is a stringent clinical trial process and a 'gatekeeper' in the form of the clinician to whom pharmaceutical companies are allowed to promote their goods directly, subject to accuracy requirements. There are few restrictions on 'traditional medicines', either in requiring approval or restricting advertising or promotion, though new proposals seek to introduce more controls. Private medical companies are allowed to promote medical services, e.g. cosmetic surgery, with no specific restrictions, apart from normal advertising regulations. Equally, there are far fewer restrictions on food products which these days also include a wide variety of additives.

Panel and Conference experts noted that patients cannot get more details about drugs from pharmaceutical companies because of regulatory restrictions, especially when the pharmaceutical companies are a key potential source of research information, though the firms may not choose to release all such information. In nearly all Panel sessions, it was noted that all sources of information have biases, deliberate or otherwise with governments and the media being no exceptions. It would be better to improve the motivation of all parties to provide quality information, rather than focusing on possible motivations that may or may not exist to provide poor information.

Areas requiring further research and development

### **Securing a better understanding of the information needs of patients at differing times in their illness**

While there have been studies assessing the appropriateness of existing materials, there is little to help guide how information should be packaged, either in form, content, or staging, to provide the public in all its diversity with appropriate information. This would require a far closer and more comprehensive study of what has been done, as well as field studies to explore what is effective in particular clinical areas.

### **Better information on healthcare outcomes**

There has been work assessing whether patients and physicians feel that providing better information helped in treatment. There have been too few studies that link to ultimate health outcomes rather than surveys of general opinion. It is vital that information be available on actual patient outcomes, such as return to work.

### **Incorporating information provision in treatment protocols**

By including action points within treatment protocols for the appropriate informing of the patient, it will be possible to ensure that adequate information is provided consistently (though care will still be needed to ensure that the information is appropriate to the individuals needs and wants).

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#### Web-sites

Organisation/Publication	URL
Clinical Evidence journal	<a href="http://www.clinicalevidence.com">www.clinicalevidence.com</a>
Cochrane Collaboration	<a href="http://www.cochrane.org/">http://www.cochrane.org/</a>
Cochrane Library	<a href="http://www.update-software.com/cochrane/default.htm">http://www.update-software.com/cochrane/default.htm</a>
Health Improvement Institute (HII)	<a href="http://www.hii.org/">www.hii.org/</a>
Health on the Net (HON) HONCode	<a href="http://www.hon.ch/HONcode/Conduct.html">www.hon.ch/HONcode/Conduct.html</a>
MedCertain/ MedCircle	<a href="http://www.medcircle.org">www.medcircle.org</a>
National electronic Library for Health (NeLH)	<a href="http://www.nelh.nhs.uk">www.nelh.nhs.uk</a>
Pharmaceutical Review 2001: European Commission/DG Enterprise	<a href="http://pharmacos.eudra.org/F2/review/index.htm">http://pharmacos.eudra.org/F2/review/index.htm</a>
American Medical Association – ethical codes for promotion	<a href="http://www.ama-assn.org/ama/pub/category/2732.html">http://www.ama-assn.org/ama/pub/category/2732.html</a>

## Appendix 1 - Project Overview

“The Informed Patient” project is a research initiative aimed at guiding future policy on the provision of information to patients in Europe. The objective is to produce a Green Paper exploring the wider perspectives of what information patients need to be fully engaged in the management of their healthcare, developing possible policy approaches for the future.

The project is led by Professor Don Detmer of Cambridge University Health at the Judge Institute of Management.

The scope of the project is limited to aspects concerning ‘patients’ with illnesses requiring treatment and care, rather than the wider question of informing the ‘citizen’ on health promotion, disease prevention, and healthy lifestyles.

Project structure:

The overall approach to the project is summarised in the flowchart below (Figure 5).

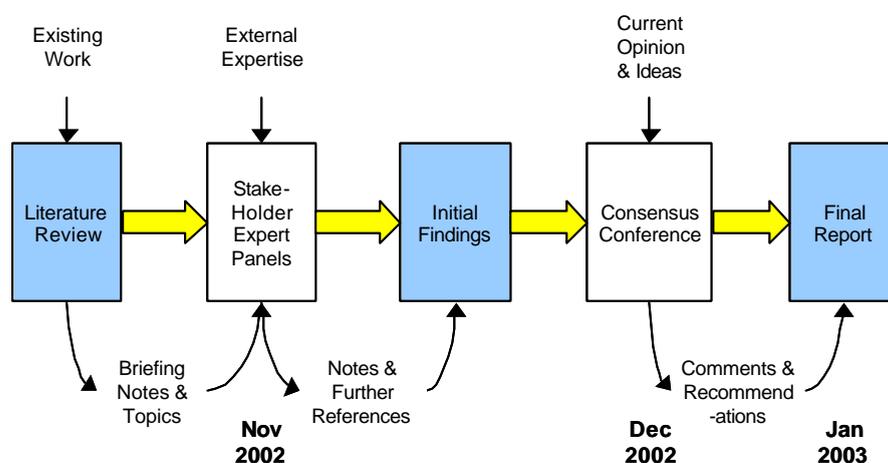


Figure 5 - Project Structure

The first stage was to identify relevant literature and to gather evidence from it.

The next was to gather different stakeholder Expert Panels. These helped the project team bring together the views of all relevant parties, review existing evidence, and identify possible ways forward to help further the appropriate provision of health information to patients.

The key stakeholder panels were:

- Payers/Insurers/Employers
- Pharmaceutical industry
- Patient & Carers
- Professionals (Clinicians, Pharmacists, Social Care)
- Policy-makers

The Interim Findings Report summarised key conclusions drawn from the published literature as well as from the Expert Panels who were convened as the preparatory phase of this project. The report sought to identify the main issues of concern to policy development, as well as supplying a summary statement of present thinking and evidence. It acted as a briefing note for delegates attending the Consensus Conference.

Consensus Conference:

The purpose of the Consensus Conference was to review the evidence and discuss possible policy options, producing recommendations for the future. One key outcome from the Consensus Conference is the ‘Consensus Statement’, setting out the areas where all participants at the conference agree, noting where there is disagreement and why.

## Literature Survey

The objective of this search was to review primary and secondary research evidence and expert opinion contained within the published and grey literature and information sources on the topic of patient Information.

### Search strategy

The following sources of information were used:

- ?? search databases, including: BMJ, NEJM, IOM, Medline, Reuters Business Insights, and WHO
- ?? searches within relevant web-sites (e.g. HAI, European Commission)
- ?? general searches through the Google search engine
- ?? references from a press-clipping service on pharmaceutical promotion (mainly on DTCA and trade journal reports)
- ?? bibliographies in relevant reports, specifically a Wirral (ERDIP) report<sup>4</sup>.

Key phrases and search terms used to search within databases and the internet were:

- ?? “informed patient”,
- ?? “expert patient”,
- ?? “health literacy”, and
- ?? “patient information”.

Some searching by author was performed where a piece of primary research was identified. Where relevant articles were cited in the reference sections, efforts were made to include those articles where appropriate.

Searches were made using primarily English-language terms. Any bias thus introduced was moderated by invitations to all experts involved to submit references known to them.

For the purposes of this survey, findings were organised under four main headings that represent the main themes explored in the literature. These are:

- ?? Characteristics of the ‘Informed Patient’
- ?? Channelling information to patients
- ?? Direct-to-consumer advertising (DTCA)
- ?? Economic impact of information provision.

The results of the Literature Survey are recorded in a Bibliography spreadsheet to accompany the Report (see [www.jims.cam.ac.uk/research/health/tip/tip\\_f.html](http://www.jims.cam.ac.uk/research/health/tip/tip_f.html)).

The weight of the literature was disproportionately (in our opinion) weighted towards DTCA. This could be both that our search strategy made it disproportionately easier to find relevant (or not so relevant) articles, or that there has been a lot of funding (both from pharma and public sources, mainly FDA) in the USA to assess the recent changes, whereas other studies have mainly been driven by individual research interests and limited to standard research budgets.

It was noticeable that we received large numbers of references to material from pharma attendees at the Expert Panels (for which we are grateful), but perhaps showing that they are better organised to access and promote this material. Certainly, DTCA has been a ‘hot’ topic in the English-language pharmaceutical trade journals, increasing the number of available references, whereas the more general ‘informed patient’ has been a persistent but far lower profile topic in the general medical press.

<sup>4</sup> Wilson S. ERDIP Cancer Project Literature Review: Patient Information. Wirral: Wirral Health Authority: 2001. Available at URL: [http://www.nhs.uk/erdip/pages/demonstrator/wirral/wirral\\_\(1\).pdf](http://www.nhs.uk/erdip/pages/demonstrator/wirral/wirral_(1).pdf)

Despite this preponderance of DTCA references, the evidence from DTCA studies may help show what effects providing information to patients (or the public) may have, even if the preferred channel is not DTCA.

## Expert Panels

### Panel Structure

As the second part of our project, we identified five main stakeholder groups, shown below:

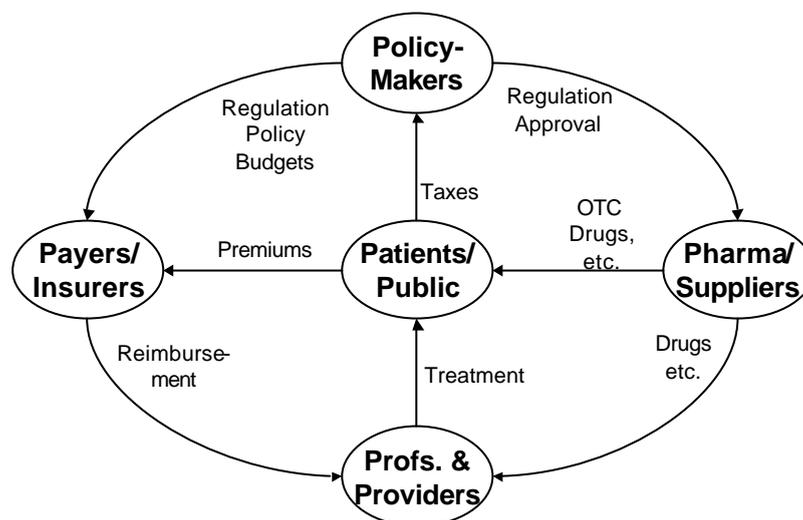


Figure 6 – Main Healthcare Stakeholders

As part of information provision, we also identified two other possible stakeholder groups: Academics (as a source of evidence) and Media (as intermediaries in the presentation and channelling of information to patients).

Each of the Panels was based around one of the main stakeholder groups with additional academic and media representation in different panels. The detailed structure and attendee list are shown in Appendix 2.

### Key questions addressed

The Expert Panel sessions considered 5 main themes:

- ?? **The informed patient**
- ?? **The gap between the informed patient and reality**
- ?? **Issues and considerations in providing information**
- ?? **Economic considerations**
- ?? **Trust and the balance of power**

The panels also considered what the critical issues are and what is realistic and achievable in the medium and longer term in the context of major changes in healthcare systems:

- ?? Aging populations
- ?? Expanding technologies
- ?? Reducing practitioner: patient ratios
- ?? Modern culture and the changing model of care
- ?? Need to promote innovation
- ?? Moves towards ensuring cost-effectiveness.

## Key Points raised in Panels

While it is difficult to summarise in a short space the range of topics and opinions covered in each of the Expert Panels, to give a flavour of what emerged from the sessions, some of the comments were:

### **Summary of findings from Payers/Insurers/Employers panel**

- ?? Appropriate timing for delivery of information is imperative - you cannot communicate information effectively if a patient is not ready to accept it (in "denial" or just focussed on other priorities).
- ?? Information provision, like treatment should be patient-centred, not an inflexible process-centred activity.
- ?? Cultural differences of educating / working with employees exist and create barriers to information communication; employers must be aware of boundaries and scope.
- ?? Primary move should be towards behaviour change (prevent rather than cure).
- ?? Where information designed for patients already exists, take advantage of it (e.g. translate leaflets) but there is a need to invest more in patient information and to ensure it is relevant to the culture and needs of patients and attractive to users.
- ?? Information to meet the needs of minority ethnic groups needs to be rethought in the culture language and traditions of the community, this approach to transcultural health goes beyond simple language translation.
- ?? Role of agents in information delivery will have an increasingly important role, especially as information proliferates and beneficial information has to be separated from the less useful material. This is where an infomediary plays a role with more extensive access to information and clearer understanding of the information itself. Patients should seek appropriate information. If they do not, cannot or will not, then 'agents' should be identified who will do so *on their behalf*. These agents are agents of the patients in 'acquisition', not intermediaries in 'delivery'
- ?? As healthcare takes on an increasingly consumer-service profile, the need for 'want optimisation' (viz. providing customer satisfaction in addressing their 'wants' not just their 'needs') arises as indicated by US and some other experience; empowerment enables a fuller understanding of the options available.
- ?? Patients differ, as do their conditions and capabilities / education level. One solution cannot fit all - a matrix of needs and benefits should be devised to optimise delivery and appropriateness of information.
- ?? A structured information delivery mechanism should be devised. Patients would benefit further if they have a reasonable understanding of information and become used to using it.
- ?? Sources of bias in information can impact many aspects of the treatment including misconceptions of efficacy, pain, benefit, cost, duration etc. Elimination of bias is vital, but improbable.
- ?? Health systems vary tremendously across Europe so needs for patient information may, at some levels, be correspondingly different. Where there may be common features, the official 'method of open coordination' may be found useful in comparing best practice and harmonising any necessary regulation.
- ?? Informal systems *do* work and help certain patients to benefit from their "informed" status. They should attract at least equal attention in any suggestions for process-revision.
- ?? Death: we are increasingly likely to face long pre-death stretches of relative incapacity, maybe spending long periods of costly time in residential care settings, and possibly without the resources to die in the setting we would wish. Health professionals still have problems in explaining options around death and need the support of good information. There are also problems to resolve in most countries about the status of 'living wills'.
- ?? Genetic testing and genome issues, in the present state of knowledge, are unlikely to have a huge impact on insurance and health provision as the information cannot reliably predict much more than existing expectations based on family history.

- ?? Some diseases are more "fashionable" than others for open discussion. Where openly acknowledged and admitted, more patient groups form, which provide access to more easily accessible information. With others e.g. depression and mental health, fears of stigma appear to reduce widespread communication and information sharing.
- ?? The role of the pharmacist becomes increasingly important for information provision; technology could play a part in this.
- ?? Drug information leaflets probably do provide sufficient information (how much information do patients really want / need?), but drug recommendation is largely dependent on accurate advice from doctor. Other areas around drug information provision are suggested, including easier channels to trial drug information and availability of information about prescription pharmaceuticals (which often come in brown containers with minimal guidance only). Information leaflets are full of data but it is often poorly communicated - if you read many leaflets you would probably feel very unsafe in using the drug.
- ?? Orphan diseases must not be ignored nor underrated in the patient information debate - by their nature they often attract the least amount of interest / information generation.

### **Summary of findings from Pharmaceutical/Suppliers panel**

- ?? The strategic outcome needs to encourage working across players to improve healthcare outcomes.
- ?? The Informed patient demands a range of solutions and method of communication with recipients is key
- ?? The pharmaceutical industry needs to fund research into what information patients need and want and make the research publicly available. Public may not, however, view pharmaceutical research as unbiased and credible.
- ?? Information on EU mandated package leaflets is not achieving its potential to inform currently.
- ?? Information should be "layered" to permit patients of different educational levels to use medicines safely and effectively. The informed patient is one that is educated in being a discerning patient able to assess information regarding their condition.
- ?? Information is not just facts that can be readily applied but evidence and data
- ?? Consistency of interpretation as to what information is and how it can be given is key
- ?? Information of itself doesn't change behaviour.
- ?? The model of delivery and balance of power needs to be addressed.
- ?? The boundaries of information and conduct of the range of information providers is a key influence on patient confidence.
- ?? Defining information and what constitutes advertising consistently across EU is an issue requiring legal clarification. European Court of Justice case law may help do this.
- ?? Education should be provided irrespective of the status of a treatment as OTC or prescription
- ?? The strategic intention of payers in governments needs to be made explicit and defined to inform long-term strategy across EU.
- ?? Focus on regulation of new products is insufficient and need wider consideration of current products, OTC products and off label use (although off label use cannot be regulated).
- ?? Bibliography is useful and little suggestion of any other research
- ?? In the DTCA for and against - would like to see these referenced with evidence. Are some against that are questionable? Are some for that are questionable?
- ?? Need to be clear when referring to DTCA and when to information provision more generally.
- ?? Needs to be an evidence base to inform strategic policy and regulation - need to be based on what patients want and not on what others say they want.
- ?? Wide dissemination of the resulting paper is required with launch conferences or workshops in Brussels/London.

- ?? Clear academic paper needs to be issued and further research undertaken to inform the debate and strategy. This may be impeded by the question of sponsorship, authorship and accountability, which are significant to achieving academic standing.
- ?? Self-regulation or codes of conduct should be introduced for the industry that applies across member states and has a legal basis with specific sanctions for infringement.
- ?? Need to focus on a single market as key to making the process of information giving, regulation and access to healthcare as key.
- ?? In delivering this, the commission need to improve their processes for consultation leading to conclusions.
- ?? Overriding issue is one of trust building between players with different goals and partnership creation. (There are common objectives and need to build on them)
- ?? Communication of ongoing work is key- who should lead, define and implement these ideas/work?
- ?? DTCA is only a small part of the wider debate of the informed patient and shouldn't overwhelm it

### **Summary of findings from Patients/Carers panel**

- ?? Terminology is not clear; it appears that we possibly need to define patients as healthcare consumers.
- ?? Redefine unpopular label of patient as expert in some chronic cases (these are really people that live their lives with a condition).
- ?? Involve patients more in the decision making process; this builds on informed consent and allows them to understand the impact of the choices they are making, which also has an ethical advantage.
- ?? Involve patients' families / carers in the decision-making and care process.
- ?? Pan European differences exist around treatment, attitudes and role of family.
- ?? A clear policy /mechanism for information sharing of clinical trial information would be useful and ethical issues around early trials for orphan drugs simplified.
- ?? Guidance on good/approved web sites could help users search through the information minefield; patients / patient organisations could play a role here.
- ?? Management of information can be difficult for various different groups.
- ?? For rare disorders, patients become experts in their own condition, even before it has been diagnosed. These people need advice but can also be used to advise others - use their experience to produce leaflets etc.
- ?? Informal information channels are still important and doctors don't always know hugely more than patients who may actually be quite knowledgeable.
- ?? Funding is key to beneficial information flow.
- ?? Patients come with different personality types - some may be active information seekers, others more passive.
- ?? Doctors do have a legal obligation to provide options and advice on treatments, although they not be properly trained to provide this type of advisory role.
- ?? Patient groups can play a vital role in helping patients to cope with a condition through information, advice, support and community.
- ?? Sudden news about a health condition can prompt a shock and denial reaction - further information cannot be absorbed straight away.
- ?? Person making diagnosis has a very dynamic role in the care process including guidance. Counselling should accompany diagnosis.
- ?? Immigrant communities / ethnic groups often face additional difficulties over health management.
- ?? Stigmas can add difficulties to acceptance of a condition.
- ?? Enlargement of EU will add extra strain on health systems, including cultural differences that will have to be addressed.

- ?? Patients want information in order that they feel partners in the process
- ?? The role of gatekeepers in accessing treatments is key for patients as free choice of treatment and healthcare professional is not usual in many European countries.
- ?? The range of methods for information transfer is wide-ranging and varied, therefore potentially variable.
- ?? There is a need to define terms e.g. patient groups? - A generic term used to describe an organisation who has as one of its primary aims, the provision of information to its users with potential health conditions (or the family members/carers thereof) and which is considered to advocate on their behalf in policy making fora.
- ?? Resourcing is not just about set up but ongoing support for web based providers of information as obsolete information is of little use. Groups advising patients need resources to improve and sustain information.
- ?? Accessibility through provision of information in different languages and education of citizens to identify what is quality information is key across all information sources. (Concept of being a knowledgeable traveller).
- ?? The context in which people receive information is important, as is the stage of the patient journey in which they receive the message.
- ?? The degree of base education regarding health and functioning of the body influences how accessible condition specific information is for patients.
- ?? Pharmaceutical funding and identification with particular pieces of work affects trust whether that be in funding patient organisations themselves, promoting drugs, supporting academic research etc
- ?? Clinician training needs to include issues of handling patient communication sensitively and accepting the more empowered patient who wants to be in control of their care and knowledgeable about their condition.
- ?? Ethical and legal requirements regarding patient consultation need to be made clear to patients.
- ?? Patients are not an amorphous group and diagnosis and treatment are influenced by content, context, the physician-patient relationship, culture and language or other factors affecting accessibility.
- ?? Different levels of trust are ascribed to different information sources – amongst the group no one trusted the pharmaceutical industry to provide impartial, accurate information.

### **Summary of findings from Professionals panel**

- ?? A clear distinction between informed patients and expert patients must be made.
- ?? Is a specific level of “being informed” sought, and if so what is the purpose of being informed and what type of responsibilities accompany the changed status?
- ?? Healthcare systems vary across Europe and the level of involvement varies accordingly.
- ?? A clear assessment /survey to uncover the types of information that patients say they need / want should be used or conducted.
- ?? Guidance is necessary around rights of informed patients including role of family / carers etc. Right to information is fundamental.
- ?? Drugs tend to be released with the minimum legal amount of testing and accompanying documents tend to indemnify against legal liability rather than provide beneficial information for the drug users.
- ?? Empowerment of patient occurs when they have sufficient information to understand their condition, needs, options available and sources of information.
- ?? Patient / doctor relationship is delicate. Patients need to know that they are being offered the best care, not just the lowest cost option. Information can help patients to see whether they are being given the best alternative.
- ?? The importance of primary health promotion (although outside the scope here) is still the key driver for informed patients.

- ?? As patients access more information, professionals<sup>5</sup> need to perform an information filtration role. There's also scope for an agent to identify appropriate, screened information.
- ?? Health is a consumer purchase (we all pay for it one way or another) and we distinguish between choices and preferences.
- ?? Paternalism of professional still dominates, although a partnership between professional and patient is increasingly seen and accepted. We are far from a true partnership and that suits many patients' attitudes.
- ?? Chronic diseases and acute diseases have different information needs - these must both be addressed.
- ?? Ultimately, information could lead to responsibility. This theoretically means that in extreme cases patients who do not comply with their treatment could be ignored by the system.
- ?? The patient is often the best source of information.
- ?? Patients do not merely need information but education in how to appraise information when they have it.
- ?? Is the strategy for engaging with patients 'push' or 'pull'? A seeming degree of discomfort with a 'push' strategy where patients are told they will become informed - the option not to be informed is a valid one.
- ?? The role of family and Culture are important in accessing information and doing so through different media and access points.
- ?? Content needs to be clear, at the level of the patient and provided in different forms
- ?? Assessing whether someone is well informed is complex, relating to their view of the world, their desire to be informed and the role/influence of gatekeepers between the information and the patient.
- ?? Harmonisation of information to identify what is credible. Also, build information bases that are regulated to a defined quality and content standard with a system of endorsed approval which includes practice standards.
- ?? Education of patients and practitioners to both interrogate and produce information is key.
- ?? Information should identify the probability / likelihood of successful treatment, and increase the ability of patients to make informed enquiries, including access to information that presents the negative aspects of particular treatment, the basis of the particular trials and the consequences of not accepting a recommended treatment.
- ?? Evidence based medicine needs to be explained and the reality of post approval drug "trials" made clear to patients.

### **Summary of findings from Policy-makers/Regulators Panel**

- ?? Patients go to the doctor for advice and his ability to act on it. What purpose should patient information serve if the responsibility is with doctor?
- ?? Indicators of quality become particularly important as European mobility increases and no standards exist across the EU.
- ?? Holding back information can be as important as providing it, but patients have a right to know the truth. Positive psychological aspects arise around open, truthful information provision.
- ?? Providing information may not make much difference - it's the way it is presented that can cause benefits.
- ?? There is no shortage of information, but quality of information is key. More information is not always a positive.
- ?? Definition of "Patients" - these people could be labelled healthcare consumers.
- ?? Segmentation of consumers could be used to identify information needs more effectively.

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<sup>5</sup> The term 'professional' has led to considerable debate. It was taken to include all staff who provide care or treatment for patients (including doctors, anaesthetists, midwives, nurses, health visitors, physiotherapists,) or have the professional training to be involved with patient care indirectly (e.g. pathologists, pharmacists)

- ?? More information can lead to a better doctor / patient partnership. Symmetry / balance of power is often a good thing.
- ?? If information helps to move away from a paternalistic model, than it should be seen as a good thing.
- ?? Change in behaviour is key.
- ?? PIL is often seen as a waiver of liability, providing little useful information for patients, although it may be their main source of information.
- ?? EU (article 152) is more interested in citizens and in disease prevention than cure. This represents a wider audience than patients and would be of greater interest to the EU.
- ?? Cultural differences around Europe must not be forgotten - advertising campaigns, role of family etc all vary and will increase with enlargement of EU and adding to the debate on information.
- ?? Patients should drive the type and quantity of information they want, not have it imposed by a professional.
- ?? Greater promotion of health information should not lead to greater use of medicines; it should help earlier, possibly preventive intervention.
- ?? Patient psychology (e.g. over risks / benefits) often leads to sub optimal behaviour.
- ?? Effective advertising uses emotion behind a decision to prompt awareness.
- ?? Harmonisation of rights and regulation across the EU is difficult but differentials need to be identified and addressed.
- ?? Issue of data ownership and the effects of changes in technology on service delivery and degree of patient information is changing and needs both clarification and systems/processes to address issues of technological advancement where they arise.
- ?? Enlargement will exacerbate the issues of accessibility in terms of literacy, in common languages used in Europe, provision of information in different forms and the need to design culturally appropriate methods of communication and engagement.
- ?? There are mixed views regarding the role of DTCA with on the one hand a desire to have existing patients made aware of new treatments and on the other a sense that pharmaceutical industry motives are incompatible with those of patients/potential patients to the extent that greater freedoms could create even more over prescribing and unnecessary use of medication.
- ?? Information provided by pharmaceutical companies is selective and designed to protect the industry therefore a wider stakeholder group needs to be involved in determining information content.
- ?? A collaborative approach is required where pharmaceutical companies share more information regarding side effects and trial details and a public body such as public health produce comprehensive information on conditions.
- ?? The range of treatments available and the limitations/risks of those. That this information is covered by regulation defined by a multidisciplinary group of stakeholders.
- ?? Pharmaceutical companies could create a general education/information fund to be used in Europe
- ?? Information leaflets should include side effects, long term effects and effects of non-compliance. Clinicians should discuss effects of non-compliance and of refusing treatment.
- ?? Involvement of Governments is key in delivering changes in legislation that will facilitate information exchange across media and remove state regulations that hinder provision of information to the wider public.
- ?? Positive engagement of the media and presentation of both sides of an issue in an open way is key to building trust between providers / prescribers and the public. There is a spectrum from information to sensationalism and the goal needs to focus on moving towards balanced information every time as far as healthcare reporting is concerned.
- ?? Education of medical professionals in how to engage positively with the media and communicate complex information objectively and well.

- ?? Relationships in medicine and between medical professionals and other stakeholders are key to this debate.
- ?? The engagement of others in the debate on the framework of information provision and the funding of it requires effective communication and a willingness to share information openly and appropriately.
- ?? Expert patients who have experience of their condition have a role to play in educating/informing others including medical staff and pharmaceutical.

Recurrent Themes from all Panels

- ?? The focus should be on the patient
- ?? Information needs vary considerably
- ?? Ability to access & understand vary
- ?? All information subject to bias/influence
- ?? Need quality process to support info
- ?? Controlling Media, including the Internet, is difficult
- ?? Provision of care & roles changing
- ?? Is healthcare a special case?

## Appendix 2 – Panel Structure and Attendees

Each panel comprised 10-15 people in order to allow a reasonable level of round-table discussion. This immediately limited the choice to invitees from ‘European-wide’ organisations or bodies, rather than a selection of national organisations from across Europe.

In the event, a number of attendees had multiple interests: many were involved with policy-making within their own organisation, and most were also patients (or with close relatives experiencing chronic conditions) to a greater or lesser extent.

Details of the individuals attending the Panels is shown below, but the overall analysis of specific interests is:

Panel:	1	2	3	4	5	Total
Payers/Insurers	4					4
Employers	2					2
Patients & Consumers			8	1	1	10
Healthcare Professionals				10		10
Pharma & other suppliers		12				12
Policy/Govt/Regulators					9	9
Academics	1	1		4	2	8
Media			1	1	3	5
<b>TOTAL</b>	<b>7</b>	<b>13</b>	<b>9</b>	<b>14</b>	<b>15</b>	<b>58</b>

Table 2 - Expert Panels - Stakeholder Panel Analysis

Note that some attendees wore ‘two hats’ so that the total represents the number of persons attending.

### Patient and consumer groups

Name	Title	Organisation(s)
Pascale Blaes	CEO	Belgian Federation Against Cancer
Michael Griffiths		Fighting Blindness
Jorma Koskinen	Co-Chair Policy Group	EATG
Rod Mitchell	Treasurer - IAPO	Chairman – EFCCA
Mie Moerenhout		Vlaams Ouderen Overleg Komitee & AGE
Dr. Paulo Lucio Morselli	Secretary General	Gamian-Europe
Phil Riley	Project Manager	International Diabetes Federation
Françoise Salama	Secretary General	EuroRDis
Hannu Vanhanen	Medical Director	Finnish Heart Association
Adrian von Bellen	Board Member	Dutch Genetic Alliance of Patients Organisations

Pharmaceutical and medical technology industry

<b>Name</b>	<b>Title</b>	<b>Organisation(s)</b>
Martin Anderson	Director of Commercial Affairs	ABPI
Tony Garlick	Technical Director	British Association of Pharmaceutical Wholesalers
Richard Horne		Eli Lilly
Shelagh Kerr	European Representative	PhRMA European Representative
Sophie Leyman	Director Medical and Regulatory Affairs	Wyeth Pharmaceuticals
Carole Lochman	Representing the Novartis Foundation for Gerontology	Novartis
Dr. Jacques Mascaro	Director European Regulatory Affairs	Johnson & Johnson
Eduardo Pisani	Director International Policy & Government Affairs Europe	Bristol-Myers Squibb
Dr. Mark Sampson	Medical Director UK & Ireland	Amgen
Helen Shaw	Head of Clinical and Medical Affairs	Boots Healthcare International
Dr. Jeffrey Sturchio	Vice President, External Affairs, Europe, Middle East & Africa	Merck & Co., Inc
Maurice Wagner	Director General	Eucomed

Healthcare Professionals

<b>Name</b>	<b>Title</b>	<b>Organisation(s)</b>
Dr. Reiner Brettenthaler	Chief Executive	CPME
Prof. John Copeland		Institute for Aging
Dr. Vincenzo Costigliola		European Medical Association
Mr. Paul de Raeve	Secretary General	Standing Committee of Nurses
Anne-Marie Felton	Chairman	Federation of European Nurses in Diabetes
Dr. Flora Giorgio	Secretary General	PGEU
Ian Hodgson		EANAC
Ton Hoek	C.E.O.	International Pharmaceutical Federation
Eileen Neilson	Head of Policy Support	Royal Pharmaceutical Society of Great Britain
Judith Oulton	Chief Executive	International Council of Nurses
Brian Rogers		Community Psychiatric Nurses Association

Media (Press and Marketing)

<b>Name</b>	<b>Title</b>	<b>Organisation(s)</b>
Linda Davidson	Editor	E-Health Media
Fibi Duke	Business Development Director	Saatchi & Saatchi Health
Christine Marking	Director Health & Pharmaceuticals	Weber Shandwick Adamson
David Sharp	Former Editor	Lancet

Payers, Insurers, and Social Security

<b>Name</b>	<b>Title</b>	<b>Organisation(s)</b>
Dr. Peter Brosch	Head of Unit	Federal Ministry for Social Security and Generations
Dr. Gunter Danner	Deputy Director	Permanent Liaison Bureau of German Statutory Social Insurance
Dr. Philippe Swennen	Project Manager	Association Internationale de la Mutualité
Stephen Withers	Director, European Affairs	BUPA

Employers

<b>Name</b>	<b>Title</b>	<b>Organisation(s)</b>
Veerle Hermans	Research Co-ordinator	Prevent
Dr. Gabriele Nigemeier		Ford A.G.

Health Organisations

<b>Name</b>	<b>Title</b>	<b>Organisation(s)</b>
Kees de Joncheere	Regional Adviser for Pharmaceuticals	WHO

Academics/Researchers

<b>Name</b>	<b>Title</b>	<b>Organisation(s)</b>
Prof. Angela Coulter	Chief Executive	Picker Institute
Dr. Anna Donald	Chief Executive	Bazian Ltd.
Dr. Livio Garattini	Director, CESAV	L'Instituto di Ricerche Farmacologiche Mario Negri
Professor Jeffrey Levett	Director International Affairs	National School of Public Health
Dr. Graham Lister	Chairman	College of Health
Professor Theo Raynor	Professor of Pharmacy Practice, Medicines & Their Users	Leeds University
Dr. Alexandra Wyke	Managing Director	Patient-View

Policymakers, Government & Regulatory Authorities

<b>Name</b>	<b>Title</b>	<b>Organisation(s)</b>
Björn Beermann		Swedish Medical Products Agency
Nils Behrndt	Enterprise DG Pharmaceuticals	European Commission
James Copping	DG for Enterprise	European Commission
Dr. Sunjai Gupta	Senior Medical Officer & Team Leader	UK Department of Health
Daniel Klein	Assistant to Frau Rosemarie Mueller MEP	European Parliament
Dr. Philippe Lenoir		AFSSAPS
Lyndsay Mountford	DG for Health & Consumer Protection	European Commission
Octavi Quintana Trias	Director for Health DG Research	European Commission
Dr. Mike Tremblay	Health Advisor	Council of Europe