How Can Better Evidence Be Delivered?

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Abstract

Bias impacts all aspects of research: from the questions formulated in the study design to the dissemination of results and perceptions by different target groups. The implementation of evidence is not a simple, unidirectional pipeline, nor do target groups operate in a vacuum, eagerly waiting for any information. The information landscape can be likened to a crowded marketplace, with multiple vendors shouting at potential customers. People must be able to process information overload from multiple sources that strive to promote their interests actively in this pluralistic environment.

Recommendations are made to improve the evidence base and message design through (a) public funding of clinical trials, (b) development and reinforcement of information standards, (c) improvements in the delivery of information in continuing medical education, (d) support and development of information sources independent of commercial interests, (e) helping clinicians communicate uncertainty to their patients.

Information from many sources is exchanged between multiple audiences within a pluralistic environment. Messages from valid clinical trials addressing relevant questions must compete with ideas of obscure origin, often with the intent to manipulate clinicians, patients, and the general public. Recommendations are made to correct and/or avoid imbalances.

Powerful players can influence the production of evidence (research) as well as its dissemination. In most countries this poses a greater threat to pluralism than the suppression of individual opinions. The interplay between private sources (industry), voluntary and academic organizations, and a broad range of media and government regulation is necessary for a balanced expression and promotion of information. To ensure this, public regulation and intervention may be needed.

Introduction

In evidence-based medicine, the term “bias” is usually used to refer to a systematic error in the design, conduct, or the analysis of a study. We will use the
term in a broader sense to include manipulation of information, intentional or not. Bias can result during the production and dissemination of information as well as when it is received and interpreted.

We realize that the delivery of “unbiased” evidence, in the strict sense, is not possible, for this notion implies an objective truth, deviations from which can be defined unequivocally. This assumption can neither be justified from a philosophical point of view nor does experience with published clinical studies and reviews support the view that a single truth exists. Still, the concept of “biased” and “unbiased” evidence is useful as we attempt to understand and improve the dissemination of information to health professionals and patients/citizens at a pragmatic level.

In our discussions, emphasis was given to results derived from clinical studies as the paradigmatic content for the delivery of information. Given the amount of resources invested in formal research, as well as its potential to relieve human suffering, there is ample justification for this emphasis. However, this emphasis was not made to exclude ethical deliberations, personal insights and observations, qualitative studies, guidelines, etc.

Many actors are involved in the delivery of evidence: researchers (e.g., clinical, health services research, psychology, education, social science), professional societies, patient organizations, industry (pharmaceutical, devices), those who pay (e.g., insurance companies, patients), government institutions, and regulatory agencies (e.g., NICE, IQWiG, and Unabhängige Patientenberatung [independent patient advice]). All actors have their particular perspective which is likely to influence how they produce and disseminate information.

Information is disseminated through various forms of media. Over the past few decades, profound changes have impacted the media, as evidenced by the Internet which has revolutionized the information management of professionals and citizens alike. However, issues of access (technical as well as literacy) and provision (funding) remain as important today with electronic media as it was twenty years ago with print media.

The dissemination processes discussed here take place in the global capitalist environment. New drugs and devices are constantly being developed and marketed, and interconnected industrial, governmental, scientific, and media groups exist to promote their interests. Still, we wish to emphasize that “villains” and “heroes” are not always distinguishable. Plenty of examples exist of manufacturers who provide important and useful information, as well as non-profit organizations that distort evidence to promote their interests. In the case of individualized medicine, the research community often drives the premature adoption of new practices before effectiveness can be adequately evaluated.

In this chapter, we suggest measures to reduce the amount of bias in information for professionals and citizens. Where possible, we mention countries or organizations where they have already been adopted. More often than not, these measures have not yet been formally evaluated. Their impact, therefore,
is difficult to quantify. Whereas for some measures, scientific evidence on effectiveness is unlikely or even impossible to emerge in the future, for others, scientists are called to study the effects and unintended consequences.

**Origins of Bias**

**In Setting Research Questions, Study Design, and Reporting**

Conflict of interest can distort professional judgment. Defined as “circumstances that create a risk that professional judgments or actions regarding a primary interest will be unduly influenced by a secondary interest” (Lo and Field 2009), conflict of interest can be found in the setting of research, the design of its study, as well as in how it is eventually reported.

A large proportion of research relevant for clinical decisions is sponsored by the pharmaceutical industry. For instance, more than 75% of randomized controlled trials which are published in major medical journals are funded by manufacturers of drugs or medical devices (Smith 2005). Thus, research topics often reflect commercial interests or those related to requirements of regulating authorities. Issues of high importance to clinicians (Tunis et al. 2003) or patients (Gandhi et al. 2008) are all too often not addressed. Moreover, “seeding trials” (i.e., clinical trials or research studies where the primary objective is to introduce the concept of a particular medical intervention to physicians, rather than to test a scientific hypothesis) do not address relevant research issues but rather serve to promote particular treatments or strengthen networks of local opinion leaders (Hill et al. 2008).

A slightly different source for bias can be the tendency on the part of the investigator to reach a desired result. This phenomenon has been referred to by Wynder et al. (1990) as “wish bias.” They state that “from the initial hypothesis, through the design of the study, the collection and analysis of the data, and the submission and publication of the results, the possibility that the study may reflect the wishes of the investigator must be recognized if bias is to be adequately eliminated.” Wish bias appears to be a ubiquitous phenomenon. In the 17th century, Sir Francis Bacon described it (Bacon 1620) and it has also been referred to as “confirmation bias” (Nickerson 1998).

Separate to the formulation of the research question, study results can be limited or biased by design and/or analysis in many ways:

- selection of patients,
- selection of too low dose of the control drug (efficacy) or too high dose of the control drug (safety),
- measuring multiple end points and selecting those for which favorable results are obtained,
- analyzing subgroups and publishing results selectively,
- ending a study when the results are favorable,
interpreting results overoptimistically,
• withholding studies with “negative” results,
• multiple publication of positive results (Lexchin et al. 2003; Turner et al. 2008; Melander et al. 2003),
• overt fraud (Fanelli 2009; Lenzer 2009; Smith 2008).

Several of these points concern publication practices and lack of critical review. The integrity and usability of a medical journal is threatened when powerful interests (e.g., commercial, health service organizations, governments) are able to disseminate their bias, or when there is failure to correct for this bias.

In 2003, Bekelman et al. (2003) conducted a systematic review of quantitative analyses to see if financial conflicts of interest impacted clinical trial results. Assessing the relation between industry sponsorship and outcome in original research, a meta-analysis of eight publications showed a statistically significant association between industry sponsorship and pro-industry conclusions. Bekelman et al. also found that industrial funding is associated with certain methodological features of clinical studies (e.g., the use of inappropriately dosed controls) as well as with restrictions on publication and data sharing.

Lexchin et al. (2003) carried out a similar systematic review of quantitative analyses on the relation between source of funding and publication status, methodological quality, or outcome of research. They found that studies sponsored by pharmaceutical companies were more likely to have outcomes favoring the sponsor than were studies funded by other agencies. In a survey of commercially funded comparative trials of nonsteroidal anti-inflammatory drugs, the sponsor’s drug was shown, without exception, to be superior (Rochon et al. 1994). This result, although extremely unlikely, suggests bias in the design and/or analysis of comparison. Different analyses have shown that clinical studies financed by pharmaceutical companies frequently report favorable results for products of these companies when compared to independent studies (Bekelman et al. 2003; Lexchin et al. 2003; Bero and Rennie 1996; Schott et al. 2010b).

Pharmaceutical companies routinely withhold data of adverse drug reactions (Psaty et al. 2004; Psaty and Kronmal 2008). Despite efforts to improve public access to study results through study registration (e.g., by medical journal editors; DeAngelis et al. 2004), clinical trials still remain inadequately registered (Mathieu et al. 2009). The use of ghost writers and guest authors is an additional problem associated with industry-initiated randomized trials (Gøtzsche et al. 2007; Ross et al. 2008).

It must be noted, however, that this research only demonstrates an association; causation is open to interpretation. Given the high quality of most trials funded by the pharmaceutical industry, there are alternative explanations, such as the careful selection of experimental treatments before phase III trial is conducted.
In the Dissemination of Information

The process of disseminating information causes bias in many ways. The financial power of manufacturers often creates an imbalance in the information landscape. The industry is in a position to provide excellent information, but often this is not done. Search engines can be manipulated so that search results emphasize certain products and approaches at the expense of others. Financial dependency creates self-censorship situations in the media. For example, glossy journals produced for continuing medical education (throwaway journals), which are read by most physicians, depend on advertisements for their production; this, in turn, can and does impact, or bias, the journals’ content (Becker et al., submitted).

Industry, researchers, and medical professional societies are often criticized for transforming life or lifestyle difficulties into diseases to create markets for drugs or devices (“disease-mongering”). They are also criticized for lowering the thresholds for conditions to be treated medically, such as hypertension (Hopkins Tanne 2003) and hyperlipidemia (Moynihan and Cassels 2005). Although in some cases, this may be justified by improving the quality of life through the use of a particular drug, it creates a bias toward drug treatments. Non-pharmacological interventions are no longer an option, and the choices presented to the public diminish. This situation leads to what we term the “disempowerment of citizens.”

Coverage in the general media can influence the acceptance of treatments. A particular form of this is found in disease awareness campaigns in countries where direct-to-consumer advertising is not permitted (see Ludwig and Schott, this volume). Examples are campaigns by different manufacturers for fungal toenail infections in the Netherlands (’t Jong et al. 2004) or erectile dysfunction.

Delivery of Evidence: Pipeline versus Crowded Marketplace

When the implementation of evidence is being discussed, the process is often understood as a simple, unidirectional pipeline (Figure 13.1): Results from clinical studies are fed into a linear process eventually producing easy to understand messages aimed at changing provider behavior. The target group is often assumed to be waiting eagerly for the message so that successful implementation is simply a matter of money and effort. Proponents of this model often assume that some clearly definable clinical policy does emerge from clinical studies so that deviations from this can easily be defined as irrational or aberrant.

The model has several limitations. First, insight that emerges from clinical studies is often cloudy, conflicting, and/or patchy. Apart from the biological, psychosocial, and system complexity, bias arises from the research process.
itself and thus limits the usability of the evidence. Health providers, educators, and scientists further down the line are well aware of these limitations. As a result, they are selective in receiving information from this continuum.

Second, health professionals and patients do not operate within a vacuum or based on a tabula rasa. They receive a range of messages, all aimed at changing their behavior. In addition, professional traditions and individual experience play influential roles. We suggest that research evidence, like any other information, enters a crowded marketplace where multiple vendors hawk their wares. This metaphor helps us understand how individuals, as well as collectives, must process multiple pieces of information as well as interact with players (“vendors”) who promote their interests in a pluralistic environment.

Although most industrialized countries can be regarded as pluralistic, this does not mean that each person has the same chance to make their message heard and heeded. Consider a small town market, where there are rich and powerful vendors with large stands (big manufacturers, pharmaceuticals and manufacturers of medical devices). Such vendors may not only be more successful at selling their goods than their smaller competitors, they may be able to shape the perception of their products and to manipulate related values and attitudes. As in a municipality which sets conditions, governments influence markets through regulations. For information dissemination, the type of media is as important as the government regulation in terms of technical level, ownership, and the degree to which it is dependent on commercial interests.

Figure 13.1  Schematic depiction of how evidence is delivered.

Individual customers (clinicians, patients) wield much less influence than groups or institutions (health service organizations).

The message received, and eventually adopted, depends only to a small degree on the scientific quality of the evidence base. Patients’ and professionals’ emotions and related expectations, payment systems, commercial interests, and cultural influences can be much more influential than the scientific validity of the message.

In this complex environment, critical awareness is required of patients, health professionals, and also those who process and disseminate information. Our recommendations in this chapter focus on improving the evidence base and message design.

Reducing Bias

Public Funding of Clinical Trials

The pharmaceutical industry invests up to 20% of its annual income in research and development (the sum invested worldwide in 2008 exceeded 65 billion US$). These funds are invested in the projects designed to elucidate the etiology and pathophysiology of disease, both within industry and in the research and clinical communities, as well as in clinical evaluations of the safety and efficacy of its products.

The quality of trials funded by industry is high. However, as discussed above, favorable outcomes may arise through the biased choice of a research question or selective publication of positive results. A more extensive mandatory registration of trials may resolve selective publication, but it will not address problems that arise from the other types of bias mentioned above.

Patients and doctors want head-to-head trials that compare all possible treatments of a condition, including nondrug treatments. Understandably, drug companies are not willing to fund such trials and, even if they were, there would be anxieties among competitors, patients, and doctors about bias in the results. Thus a strong case can be made for public funding of clinical trials.

Research funding bodies have been reluctant to fund drug trials because of multiple demands placed on their budgets. In addition, there is an unspoken belief that drug trial funding can be left to the wealthy pharmaceutical industry. An increasing recognition of the substantial scale of bias in industry-funded studies, the absence of head-to-head trials, and the bias toward drug rather than nondrug treatments has caused a shift toward greater public funding of clinical trials (Lewis et al. 2007; ’t Jong et al. 2004).

The main benefit from publicly funded trials would be an evidence base, accessible by doctors and patients, containing research evidence unrelated to immediate commercial interest (e.g., head-to-head comparisons of established treatments). However, there might also be economic benefit. For example,
the publicly funded ALLHAT trial showed that off-patent anti-hypertensives were just as effective as newer, more expensive drugs (ALLHAT Collaborative Research Group 2002). Given that hundreds of millions of patients are treated globally every day for hypertension, the financial savings could be substantial. Similarly, a study of acne treatments revealed that most treatments were not very effective and that cheaper treatments were just as effective as more expensive ones (Ozolins et al. 2004). The CATIE study showed similar results for recently marketed antipsychotic drugs (Lieberman et al. 2005). These examples demonstrate the potential to inform clinical and policy decisions.

The cost of conducting such studies will, of course, be high. However, Italy provides an example of how they can be funded: To finance independent drug research, a 5% tax was levied on the marketing costs of drugs (Agenzia Italiana del Farmaco 2003). Proposals were required to cover three areas: (a) orphan drugs for rare diseases and drugs for non-responders, (b) comparison among drugs and therapeutic strategies, and (b) strategies to improve the appropriateness of drug use and pharmacoepidemiology studies (Garattini 2007).

One can expect resistance to such a tax and perhaps any move to increase the number of publicly funded trials, based on the argument that the results would be slowed innovation and reduced profitability to an industry that is important to the economy of many developed nations. Governments cannot always be expected to be on the side of an improved evidence base. Recent debates about drug regulation (e.g., direct-to-consumer advertising) reveal the presence of a competing objective in support of the pharmaceutical and medical device industry. Similarly, the evidence gap is unlikely to be filled by regulatory authorities demanding comparative studies.

**Message Design**

From an industry point of view, imbalance in the information landscape is normal; from a public point of view, this constitutes a problem. Just as regulatory authorities require manufacturers to submit studies on the efficacy and safety of commercial products, public institutions can help establish balance in the “crowded marketplace.” Publicly funded institutions and voluntary groups could process evidence from clinical trials and present them to the public. Examples of the former include NICE and NHS Choices (United Kingdom) and IQWiG and Unabhängige Patientenberatung (Germany), and independent drug bulletins for the latter.

One approach developed in a number of countries has been to encourage the evaluation of health information materials against a standardized set of criteria. Large numbers of rating instruments have been developed. One study found 98 examples of Internet rating tools (Gagliardi and Jadad 2002); however, many of these have not had sufficient institutional support to encourage and sustain their adoption and continued use.
Health on the Net (HoN 2010) is an exception to this rule. Established in 1995 to promote quality standards in web-based health information and to help users find reliable information, its voluntary certification scheme has been used by nearly 7,000 websites worldwide. It has been effective in sensitizing users to the factors affecting information quality.

Despite the plethora of different rating instruments, there is a broad, general consensus on the key factors to look for in assessing health information. Gute Praxis Gesundheitsinformation [good practice health information] is a recent example that describes a standard for the content and presentation of health information (Klemperer et al. 2010). This standard (see Table 13.1) was developed by the Fachbereich Patienteninformation und Patientenbeteiligung [division of patient information and patient involvement] of the German Network for Evidence Based Medicine in cooperation with a group of scientists,

**Table 13.1** Quality criteria for health information, based on *Gute Praxis Gesundheitsinformation* (Klemperer et al. 2010).

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Description</th>
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<tbody>
<tr>
<td>Clear purpose</td>
<td>The information product clearly explains its aims and purpose.</td>
</tr>
<tr>
<td>Relevance</td>
<td>The material meets a clearly defined need and has been tested with representatives of the target audience; where possible, links to sources of further information and support are provided.</td>
</tr>
<tr>
<td>Evidence-based</td>
<td>The information is consistent with up-to-date clinical evidence, medical and social research; personal opinion is clearly distinguished from evidence-based information.</td>
</tr>
<tr>
<td>Authoritative</td>
<td>Sources of evidence are clearly indicated; names and credentials of authors, funders and sponsors are clearly stated; any conflict of interest is disclosed; any advertising is clearly identified.</td>
</tr>
<tr>
<td>Complete</td>
<td>Where relevant, all alternative treatment, management or care options are clearly stated and all possible outcomes are clearly presented.</td>
</tr>
<tr>
<td>Secure</td>
<td>Where users’ personal details are requested, there is a clear policy for safeguarding privacy and confidentiality.</td>
</tr>
<tr>
<td>Accurate</td>
<td>The product has been checked for accuracy; in the case of user-generated content there is a clear procedure for moderation.</td>
</tr>
<tr>
<td>Well-designed</td>
<td>The layout is clear and easy to read; if necessary, the product contains specific navigation aids such as content lists, indexing and search facilities.</td>
</tr>
<tr>
<td>Readable</td>
<td>The language is clear, where possible conforming to plain language standards.</td>
</tr>
<tr>
<td>Accessible</td>
<td>There is a clear dissemination plan for the product; the material conforms to accepted standards for accessibility, where possible including versions for use by people with sensory and learning difficulties.</td>
</tr>
<tr>
<td>Up-to-date</td>
<td>The date of issue or latest update is clearly indicated along with the planned review date.</td>
</tr>
</tbody>
</table>
representatives of patient organizations, and service providers. Already it has garnered the support of many influential groups.

*The Information Standard*

The Information Standard (2010) is an initiative of the U.K. Department of Health to develop a certification scheme for producers of health and social care information for the public. Launched in November 2009, the scheme covers multiple types of information, including print as well as electronic materials. Any information producer (e.g., NHS organizations, local authorities, voluntary organizations, patient groups, commercial publishers, or industries) can apply for certification. The Information Standard evaluates development processes rather than individual pieces of information and, in that respect, is similar to other producer accreditation schemes, such as Fairtrade. Organizations that apply for certification must produce clear documentation of the procedures that were used to develop the health information, together with a sample of their information materials. These are independently assessed by an accredited certification agency. Certification entitles the organization to include the scheme logo on all materials that meet the criteria.

*Patient Decision Aid Standards*

Not being properly told about their illness and potential treatment options is the most common cause of patient dissatisfaction (Coulter and Cleary 2001; Grol et al. 2000). The desire for more information and participation in treatment decisions (i.e., shared decision making) has been expressed by many patients. In shared decision making, patients work together with the clinician to identify acceptable medical options and choose a preferred course of clinical care (Sheridan et al. 2004). The availability of reliable evidence-based information is an essential component in the shared decision-making process.

Patient decision aids have been developed to support shared decision making. These aids take a variety of forms including web applications, videos or DVDs, computer programs, leaflets or brochures, and structured counseling. Most share the following characteristics (O’Connor, Wennberg et al. 2007):

1. They provide facts about the condition, options, outcomes, and probabilities.
2. They clarify patients’ evaluations of the outcomes that matter most to them.
3. They guide patients through a process of deliberation so that a choice can be made that matches their informed preferences.

A large number of decision aids are now available, the majority of which were developed in North America. The Cochrane Register (OHRI 2010) lists decision aids that meet certain criteria. Table 13.2 lists the principal developers of these decision aids and the number of tools they have developed.
The International Patient Decision Aids Standard (IPDAS) was established to help ensure that aids conform to high-quality standards. A Delphi process involving a group of researchers, practitioners, policy makers, and patients from 14 countries was used to develop the standards and assessment criteria (Elwyn, O’Connor et al. 2006, 2009). IPDAS is still being tested and further refinements are likely. In the meantime, however, discussion is underway about the possibility of developing a certification scheme for decision aids, potentially under the auspices of an organization with experience of running such schemes.

### Continuing Medical Education

Although difficult to prove, it is reasonable to assume that at least a portion of the overuse of commercially marketed drugs and devices can be traced to continuing medical education (CME). Used for credit, and generally formatted as lectures or workshops, the CME enterprise in the developed world has been largely supported by commercial interests. For example, in the multi-billion dollar industry of CME in the United States, over half is paid for by

### Table 13.2  Decision aids, developers, and number of tools.

<table>
<thead>
<tr>
<th>Developer</th>
<th>Country</th>
<th>Decision aids</th>
<th>No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Healthwise</td>
<td>U.S.A.</td>
<td>Decision points</td>
<td>137</td>
</tr>
<tr>
<td><a href="http://www.healthwise.org">www.healthwise.org</a></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>FIMDM/Health Dialog</td>
<td>U.S.A.</td>
<td>Shared decision-making programs</td>
<td>26</td>
</tr>
<tr>
<td><a href="http://www.informedmedicaldecisions.org">www.informedmedicaldecisions.org</a></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><a href="http://www.healthdialog.com">www.healthdialog.com</a></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mayo Clinic</td>
<td>U.S.A.</td>
<td>Treatment decisions</td>
<td>16</td>
</tr>
<tr>
<td><a href="http://www.mayoclinic.com">www.mayoclinic.com</a></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Midwives Information and Resource Service</td>
<td>U.K.</td>
<td>Informed choice</td>
<td>7</td>
</tr>
<tr>
<td><a href="http://www.infochoice.org">www.infochoice.org</a></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>University of Sydney</td>
<td>Australia</td>
<td>Decision aids</td>
<td>6</td>
</tr>
<tr>
<td>National Cancer Institute</td>
<td>U.S.A.</td>
<td></td>
<td>5</td>
</tr>
<tr>
<td><a href="http://www.cancercontrol.cancer.gov">www.cancercontrol.cancer.gov</a></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ottawa Health Decision Center</td>
<td>Canada</td>
<td>Patient decision aids</td>
<td>3</td>
</tr>
<tr>
<td><a href="http://www.ohri.ca/decisionaid">www.ohri.ca/decisionaid</a></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Agency for Healthcare Research and Quality</td>
<td>U.S.A.</td>
<td>Consumer summary guide</td>
<td>2</td>
</tr>
<tr>
<td><a href="http://www.ahrq.gov">www.ahrq.gov</a></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Centers for Disease Control and Prevention</td>
<td>U.S.A.</td>
<td>Decision guide</td>
<td>2</td>
</tr>
<tr>
<td><a href="http://www.cdc.gov">www.cdc.gov</a></td>
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<td></td>
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</tr>
<tr>
<td>Cardiff University</td>
<td>U.K.</td>
<td>Decision explorer</td>
<td>1</td>
</tr>
<tr>
<td><a href="http://www.informedhealthchoice.com">http://www.informedhealthchoice.com</a></td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>

The International Patient Decision Aids Standard (IPDAS) was established to help ensure that aids conform to high-quality standards. A Delphi process involving a group of researchers, practitioners, policy makers, and patients from 14 countries was used to develop the standards and assessment criteria (Elwyn, O’Connor et al. 2006, 2009). IPDAS is still being tested and further refinements are likely. In the meantime, however, discussion is underway about the possibility of developing a certification scheme for decision aids, potentially under the auspices of an organization with experience of running such schemes.
industry, particularly the pharmaceutical industry. Health systems, medical schools, governments—and physicians themselves—contribute much less. Furthermore, most physicians are directly affected by CME: the majority must attend hours (generally on the order of 50 hours) of lectures or workshops on an annual basis, as required by state and other regulatory bodies. The support of this large enterprise by interests not always aligned with quality of care or patient-centered care, leads to questions of bias and decision making based on less-than-ideal evidence.

In recognition of the potential bias, authorities responsible for the delivery and accreditation of CME increasingly require conflict-of-interest disclosures for faculty within the CME setting. This disclosure, regulated in the North American setting to occur at the beginning of a lecture or educational activity, includes a listing of grants, monetary rewards, speakers’ fees and other sources of income which might produce bias in presentations on the part of the faculty member.

Despite its wide adoption and enforcement, problems still occur. For example, new information on side effects, risks and benefits, numbers-needed-to-treat (NNT), and other aspects is often not presented or fully explored. This stands in sharp contrast to a wider movement of transparency falling under the rubric of patient-centered, evidence-based decision making.

Two proposals are suggested to remedy this situation on a programmatic or institutional level: The first concerns the presentation or activity itself: by using a standardized form, which would include absolute risk, NNT, and other factors, clinical options could be made clearer. A structured abstract format is recommended for use whenever a clinical intervention, screening procedure, medication, or other therapeutic option is presented. This should be accompanied by a checklist for use by program planners, teachers, and participants in the CME setting. The checklist could be based on the IPDAS framework or other instruments designed to measure qualities related to active patient participation in decision making.

The second proposal includes the establishment of a CME review board. This board would be made up of educators, clinical teachers, bioethicists, and perhaps patients and charged to oversee the institutional or programmatic acceptance of commercial expenditures in support of educational activities. The board would review the general content of CME, the flow of funding, and its impact on educational programming. In addition, it would oversee the micro process involved in the first suggestion. Again, an evaluative tool is needed and should be in line with the above checklist. Apart from intervening in cases where bias from funding is shown, a preventive effect can be expected as well as raised consciousness within the professions.

We believe these two approaches would broaden the ethical approach to conflict-of-interest bias and CME—doing no harm, doing good, providing balance, equity and full disclosure. In addition, we believe that, regardless of commercial support, a structured risk assessment format is useful at the level of the participating physicians, the faculty member, and perhaps the health
care system itself. In both proposals, a deeper commitment is advocated to the Kirkpatrick model of assessment (Kirkpatrick 1979)—one that stresses evaluation of CME activities beyond the perception of an activity and includes competency, performance, and health care outcomes. This advocacy would ensure, in our opinion, a concurrent commitment to shared, evidence-based decision making.

A similar process has been established in France, where any promotional material, including advertisements in professional journals, must be presented to the Haute Autorité de la Santé for approval.

Continuing Medical Education: A Dissenting Opinion

This proposal highlights a number of situations where bias and conflict of interest are inherent or have been allowed to develop. Prime reasons for this can easily be found in the profit orientation of industry, as information provider and sponsor, and the reliance of the CME system on such sponsorship.

Our group discussion did not yield consensus. A few wanted to stress the positive roles that industrial sponsorship has played in providing information on the latest scientific developments and/or novel principles for disease treatment, diagnosis, or control. In addition, industry contributes substantial financial support to the CME system—annually US$1.1 billion alone in the United States—which offsets the costs of many programs; costs that would otherwise fall onto institutions and/or health care providers themselves.

As to the criticism that industry uses CME unduly as an advertising platform, one must also weigh the role that others bear. Take, for example, the expectations of many health care professionals, who have come to view the luxury aspects of CME offerings as their right. There may also be a certain reliance on the current level, if not mode, of funding.

To address the first example, conflict of interest can be minimized by requiring full disclosure from all who participate: key opinion leaders, contributors, lecturers, instructors, participants, etc. An effective remedy, and perhaps deterrent, may be to make this mandatory disclosure the subject of review, with the results publicly available.

To address the issue of funding (i.e., its flow and impact on educational programming) the establishment of a CME review board has been suggested. In the interest of achieving balance among the various players as well as to optimize the responsible usage of funds and secure access to the large amount of useful data generated by the pharmaceutical industry, particularly in the science of disease, it seems counterproductive, if not naïve, to exclude industry from this board. Of course, efforts can be made to minimize reliance on industrial funding through the procurement of alternate funding sources. For example, funds could be raised by levying a tax on the sales of drugs, through voluntary contributions, as well as by charging higher fees for participation from health professionals who receive CME credits. It seems unlikely,
however, that a cost-neutral solution will be possible, and that one could expect for these costs to be passed on to the health care system in one form or another.

A final note to the harmonization of curricula and presentation formats: It appears that there is a working framework upon which this can be achieved. However, any form of harmonized curriculum should most certainly contain the teaching of critical awareness.

**Drug Bulletins**

Drug bulletins are periodicals that report on issues related to drug therapy, but they are produced independently of the pharmaceutical industry. They aim to provide balance to the large number of journals that depend more or less on advertising by manufacturers.

Their circulation and their impact on prescribing vary widely from country to country. Their influence not only depends on their quality and the willingness of the profession to subscribe, but also on financial incentives. Where clinicians are made responsible for their prescribing cost there is an increased demand for independent information.

This is illustrated by the ambulatory care sector in Germany. Here, physicians are required to prescribe economically. There are strict rules in place to reduce their income if prescribing targets are not met. The demoralizing effect of this is frequently expressed. However, this requirement has fostered a culture of quality and provides practitioners with critical feedback on their prescribing practices. A number of independent periodicals help counterbalance the hundreds of CME journals dependent on advertising.

**Learning to Express Uncertainty: Creating a Safe Space**

At the level of the individual clinician as well as at a system level, uncertainty is rarely discussed. Despite the presence of evidence-based medicine and statistics in medical curricula, physicians are “determinists by training” (Tanenbaum 1994). When asked to provide a prognosis (e.g., after cancer has been discovered), physicians are prepared to express uncertainty. However, this happens much less frequently when diagnosis or treatments are discussed.

Patients, citizens, and often even decision makers are not usually aware of the uncertainties inherent in the clinical process. One of the most basic misconceptions holds that anything expressed in numbers must be certain. Clinicians often feel that admitting uncertainty will undermine patients’ trust.

How can a space be created that will enable both clinicians and patients to recognize the role that uncertainty plays in most medical decisions? The measures we suggest relate to the structure of health care and information systems, with education playing a key role.
In terms of a physician’s training, proficiency in the concept of uncertainty should be a prerequisite for entry into medical school. During basic science training, “facts” (e.g., the Krebs cycle) are presented as givens, although they are only theoretical approximations for very complex realities (Fleck 1980). Later, as residents/registrars or clinicians, “decision points” must be able to be identified. As new clinicians, trust and uncertainty are not contradictions, and the communication of uncertainty is complex: Excellent communication and people skills are necessary, as is the cultivation of a good doctor–patient relationship.

Viewed from a different perspective, patients must be capable and prepared to acknowledge and live with uncertainty. Equipping patients with this knowledge can be best achieved through educational efforts, either in a formal setting or through other means (Spiegelhalter 2010). In addition, preparing patients to discuss relevant questions before a consultation is important.

Decision support tools exist to aid the understanding of uncertainty (Spiegelhalter 2010; Arriba 2010). As discussed by Schwartz and Woloshin and Ludwig and Schott (this volume) drug labeling should express information to clinicians and patients in a transparent and understandable manner (see also Schwartz and Woloshin 2009). This information could also be collected and made available by independent bodies (e.g., UK Database of Uncertainties about the Effects of Treatments) to help the public learn about knowledge limitation (NHS 2010).

Clinicians could be more aware of stochastic and collective professional uncertainty if guidelines relied less on algorithmic prescriptions and more on honest presentations of effectiveness measures and study quality. This is a difficult issue because, in general, clinicians need a certain level of confidence in order to function properly. However, they also need to reflect on professional uncertainty in an honest way.

Likewise, the willingness of the patient to confront uncertainty is shaped by the general public’s understanding of science. Numerous examples can be found where scientists emphasize “certainty,” when addressing the public, rather than that which has not been fully resolved.

The primary care sector is a privileged place in which to address the uncertainty of treatments, since hospital structures often do not allow for discussion and reflection of options and their respective benefits and harms. However, primary care can assume this role for only common conditions. Primary and secondary care need to clarify their respective roles and flow of information at the regional level so that the information needs of patients are adequately addressed.

In the early 19th century, it was not clear which way medicine would develop. The scientific determinist, the artist, and the statistician were the options available at the time (Gigerenzer et al. 1989, Chap. 4). While the deterministic scientist has prevailed, at least in the academic field, the statistician–clinician has gained ground over the last twenty years and will hopefully continue to do so.
Patient Feedback for Monitoring Information Delivery

The systematic measurement of patients’ experience is a good way to monitor performance in terms of information provision and shared decision making. In the United Kingdom, the NHS survey program has been implemented in all NHS trusts and primary care units since 2002. It includes surveys of inpatient, outpatient, and local health services as well as mental health, maternity, and long-term conditions (NHS Surveys 2010).

These surveys measure most aspects of patient-centered care, including access and waiting time, communications with staff, privacy and dignity, information provision, involvement in treatment decisions, physical comfort and pain relief, support for self-care, coordination and continuity, environment and facilities, involvement of family and friends, and an overall evaluation of care. Relevant questions could be adapted for use in other health systems to monitor performance of evidence-based information (see Table 13.3). In addition, in the United States, the Consumer Assessment of Healthcare Providers and Systems (CAHPS surveys) includes questions about receipt of information to inform treatment decisions (CAHPS 2010).

Media Literacy

Inappropriate use of statistics is sometimes part of a deliberate, albeit often well-meaning attempt to influence beliefs and actions. However, it is far from being the only way societal knowledge and emotions are biased. If we want the least biased evidence to compete effectively in the battle for people’s hearts and minds on health-related matters, then society needs to become more statistically literate.

The mass media is a major source of bias in society’s perceptions of disease (M. E. Young et al. 2008), and more. Whether it is the impact of disease-mongering (Doran and Henry 2008) or other forms of awareness creation, we, as citizens, need to ensure that we are resilient to manipulation in this era of sophisticated media and advertising.

One key area that has emerged to increase media literacy is intervention programs in schools (Bergsma and Carney 2008), including the call to action of a group convened by the World Health Organization (Tang et al. 2009). A small body of evidence is growing that even brief encounters with media literacy interventions can have a positive effect, for example, on adolescents’ body image and may be able to contribute to the prevention of eating disorders (Pratt and Woolfenden 2002; Ridolfi and Vander Wal 2008; Wilksch and Wade 2009). These initial experiences show that the study and development of effective interventions to increase media literacy warrants increased attention and investment.

Media literacy is an essential skill for a healthy citizenry in an information age. However, media literacy is also an important issue for health professionals.
The appraisal skills typically described in textbooks of evidence-based medicine are not always suitable for finding quick answers to clinical questions. Since evidence-based medicine has been suggested as the preferred approach to professional decision making in health care, learning and reflection, the media and related customer behaviors have changed considerably. In response, a simple three-step heuristic has been suggested to help primary care practitioners judge the validity of a claim regarding treatment, diagnosis, and screening (Donner-Banzhoff et al. 2003; Eberbach et al., submitted). This heuristic makes explicit use of the bias of a particular source and is therefore adapted to our information landscape.

### Conclusion

The dissemination of evidence is not a single process that can be carefully planned and implemented. No single actor exists whom everyone would trust.
as being objective or competent. Instead, we must accept that ours is a pluralis-
tic environment where information from many sources is transferred between
multiple audiences. The message from valid clinical trials addressing relevant
questions must compete with numerous ideas of obscure origin as well as with
manipulation on many levels.

An all-knowing information demon that disseminates comprehensive and
unbiased information to all is not a realistic response. The recommendations
we have made aim at correcting and/or avoiding imbalances. Powerful play-
ers, above all commercial interests, can influence the production of evidence
(research) as well as its dissemination. In most countries, this poses a greater
threat to pluralism than government suppression or the threat to free thought.
The solution will be found in a balanced interplay between private sources (in-
dustry), voluntary and academic organizations, a broad range of media, as well
as government regulation; under this, a balanced expression and promotion of
information will be more likely.

As in other areas of society, public regulation as well as public interven-
tion may be needed for this to happen. For initiatives that are neither linked to
commercial interests nor government initiated, lessons should be drawn from
industry, for they have to create trusted brands, use persuasion methods, and
support tools (Hastings 2007).