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Effective Communication of Drug Safety Information to Patients and the Public

A New Look

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Abstract

Recent parallel developments in the fields of medicine and the social sciences are providing us with new insights and resources that have the potential for improving the effectiveness of drug safety communication and decision-making. These developments include medicine's new look at patient safety with its emphasis on complex adaptive systems, education's new appreciation for learning as an internal change process and risk communication's evolving recognition that relevant knowledge may not be the exclusive property of 'experts'.

Eight principles are drawn from this analysis: (i) there cannot be a safer drug until there is a safer system; (ii) all stakeholders are equal partners and have an equal voice in all deliberations; (iii) paternalism must be eliminated; (iv) the expertise for determining acceptable benefit and risk is dispersed throughout society; (v) patients and all stakeholders serve as both teachers and learners; (vi) all stakeholders are involved in the identification of their learning needs, processes and evaluation of outcomes; (vii) in a complex adaptive system all individual actions are interconnected and; (viii) patients must be involved in the continuous feedback and redesign of the evolving drug safety information system. The conclusion is that we are not asking the right questions; 'what information should we communicate?' and 'how do we communicate more effectively?' should be reframed to ask 'how do we provide an equal voice for patients with the other stakeholders in the determination and communication of benefit-risk information?' Some patients are not waiting. The International Alliance of Patient Organizations (IAPO), the Database of Individual Patient Experience (Dipex) and the Self-Help Group Clearinghouse are examples of international patient driven efforts to actively participate in their own care. The author suggests that the emerging discipline of inter-active management can contribute methodologies for creating citizenship models to generate the collective wisdom and translate it into action. A future research agenda calls for creating new models of public accountability that support these evolving systems of engaging the entire community in benefit-risk determination, communication and management.

In a 1996 editorial in the *Lancet*, McNamee concluded that 'Transparency in the dissemination of risk-benefit information is the ultimate goal, to empower consumers to make fully informed choices about what drugs they take'.[1] Edwards and Hugman[2] in a commentary on communication theory and practice observed that not only do we need to apply the best communication practices available but that all of the 'involved groups' – the patient, in specific and society, in general – must be educated.

The premise of the current article is that recent developments in both medicine and the social sciences can provide us with new insights and new resources to improve the transparency of the analysis and decision-making relative to drug safety information. In the practice of medicine, leaders are now taking what has been characterised as a 'new look' at the issue of patient safety and re-examining the factors that can lead to medical error, including the unsafe use of medicines.[3] There are also developments in the social sciences that parallel this effort. Similar 'new looks' are taking place in education and in risk communication. These emerging views and parallel concepts are providing us with valuable insights and a 'new vision' to effectively communicate drug safety and benefit information to patients, health professionals and the general public.

1. The Problem

1.1 Background

One half of patients in Europe, Japan and North America fail to take their medicines properly, according to the 1993 Patient Information Project Report of the International Medical Benefit/Risk Foundation.[4] The same report discloses that the largest gap in patient understanding is a lack of awareness and understanding of the risks of medicines. Edwards[5] traces the emerging recognition of this problem and the attempts to address it, by noting the interest of the Uppsala Monitoring Centre in 1994; the WHO Programme for International Drug Monitoring in Bangkok in 1995, and the Verona Initiative in 1996, that lead to the Erice Declaration in 1997. Participants from 30 countries met in Erice, Sicily to outline principles that support drug safety communications. These principles included, for example, a recognition that benefit-risk education is foremost a public health issue and requires a special commitment and resources; and that all evidence (to access drug benefit and risk) must be openly available.[6] Edwards[5] also notes that we should recognise the work of the Council for International Organisation of Medical Sciences (CIOMS) and in particular, Dr Win Castle, the 'prime mover' of this work, for conducting expert discussion groups relating to drug safety and benefit/risk analysis.[5]

In 1999, The National Patient Safety Foundation (NPSF) in the US sponsored a medication safe use initiative – a deliberation and consensus process – to analyse the problem of unsafe and inappropriate use and to develop an action plan.[7]**1** The 46 participants in this dialogue included patient advocates, pharmacists, nurses, physicians, members of the media, representatives of pharmacy corporations and pharmaceutical manufacturers, academic researchers, and officials form the US Food and Drug Administration (FDA). The 41 step action plan developed by this process identified two influential action steps that the participants perceived as 'deep drivers' to improve safe medication use: (i) recognise that the safe use of medications is a public health issue requiring a partnership among all the stakeholders; and (ii) issue a call for national visible leadership to investigate the safe use of medication and the implementation of far-reaching system change.[8]

These deep driving action steps and the conclusions of this NPSF Medication Safe Use Initiative echo and build on the principles outlined in the

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1 The consensus process used is a product of the scientific revolution in the field of systems analysis. The reader is referred to the pioneer work of Alexander Christakis (see also footnote no. 2). He and his colleagues are applying the rigours of the scientific method to reinvent the dialogue process in order to surface the wisdom of the community. This new scientific model is called demosophia, which in Greek means the 'wisdom of the people'.

Erice Declaration[6] and the Verona Initiative as reported by Edwards and Hugman.[2]

Edwards and Hugman[2] concluded that 'It cannot be taken for granted that experts in pharmacology or drug regulation are naturally also experts in the process and techniques of effectively communicating the content of their expertise'. Making the same observation, the Working Group on Risk Communication of the Danish Board of Technology noted that society faces the practical problem that communication about risk is generally unsatisfactory.[9] 'Experts deliver information and analyses at one end and interested citizens voice their concern and dissatisfaction at the other. (Thus) communication is often characterised by a string of non sequiturs'.[9] The role of the patient-consumer as partner in benefit-risk evaluation or merit analysis, using the Edwards et al.[10] conceptual model, emerges as an underlying theme throughout all of these drug safety discussions.

1.2 Economic Considerations

Treating the complications of preventable drug related problems (as the result of patient noncompliance or inappropriate prescribing or monitoring) in the ambulatory setting costs the US about $US177 billion annually (2001 values).[11] This is reflected in admissions to hospitals (70% of cost) and admissions to long term care facilities and physician visits. Loss of worker productivity as a result of medication related problems has been conservatively estimated in the $US100 billion range (1995 values).[12] The economic consequences of noncompliance and medication misuse can be viewed as partial indicators of the effectiveness of our communication to patients regarding drug benefits and risks. Smith,[13] President of Consumer Health Information Corporation, observed that the data indicate that when patients understand the information they need to take a medication safely, error rates can be cut in half, and patients have fewer adverse effects, fewer physician visits, fewer hospital admissions and a higher quality of life.

2. New Look in Patient Safety

Medicine in the US undertook a new approach to patient safety in 1998 as researchers, academics, healthcare leaders and practitioners acknowledged the problem of medical error in a leadership conference, titled, 'Enhancing Patient Safety and Reducing Errors in Healthcare'.[14] Across medicine, leaders are now calling for rapid application of the growing body of research on human and system performance, to healthcare. This research analyses how complex systems fail and how everyone within the system shares the responsibility for contributing to a 'culture of safety'.[3]

2.1 Faulty People or Faulty Systems?

A key concept of this new approach is a recognition that it is primarily faulty *systems,*not faulty *people*, that create error or poor outcomes. The science of complex adaptive systems (CAS) provide one focus for analysis. A CAS is defined as a collection of individuals that can act in ways that are not always predictable and whose actions are interconnected such that one individual's actions changes the context for the others.[15] Medicine is learning about the nature of this inter-connectedness from other high-performance industries, such as aviation and nuclear power. These industries have learned through experience with serious system breakdowns (that attract considerable media attention), that all stakeholders must be involved in the continuous redesign of their own complex adaptive systems.

For example, the Aviation Safety Reporting System (ASRS) of the US Federal Aviation Administration (FAA) is often cited as a very successful model of system adaptation and improvement. Billings,[16] a lead designer of the ASRS, observed that the people who can tell us the most about the system's problems are the system's everyday users, in this case, pilots and air traffic controllers. There is active community participation by pilots and controllers in the system's implementation, oversight and advocacy. The ASRS has led to numerous improvements for keeping our skies safe.

Obviously pilots have a great incentive to participate in improving the system since they, themselves, 'go down' with the plane. However, when a patient is harmed, everyone involved is also harmed – the manufacturer, the regulator, the administrator and the clinician. Although this may be less apparent to the casual observer, in fact, we also 'go down' with the patient because the system has failed everyone and thus all participants in the system are at risk.

2.2 New Look in Education

The new approach to patient safety calls for the creation of organisations that can learn from their errors, their 'near-misses' as well as their success. Learning, at both the organisational and the individual level, is a change process that results in new understandings and new behaviours. In 1970 Malcolm Knowles[17] revolutionised the field of learning theory. Knowles, characterised as the father of adult learning, called this field of study, andragogy. He described andragogy as an evolving new technology for helping human beings learn as opposed to pedagogy which 'is premised on an archaic conception of the purpose of education, namely, the transmittal of knowledge'. Pedagogy assumes that learners passively absorb knowledge. In contrast, the principles of the new technology of andragogy assume that learning is an internal change process. To facilitate that change process, the principles of andragogy are that learners: (i) recognise the learning goals as their own goals; (ii) share a responsibility for the planning and execution of the learning experience – have a commitment to it; and (iii) participate in the learning process with a sense of progress toward their goals. In addition, the learning experience is related to, and builds upon, the experience of the learners. This 'new look' in education is best summed up as:

'Tell me and I will forget, Show me and I may remember, Involve me and I will understand' (Anon.).

We can conclude that system adaptation, or learning, at the macro-level (organisational) and at the micro- level (individual) is dependent on the degree of involvement of all the system stakeholders and its end users (in this case the patient-consumers). This observation is further enhanced in the following discussion of risk communication.

2.3 New Look in Risk Communication

Canadians Powell and Leiss,[18] described the emergence of good risk communication in three phases: the first phase relies on numbers (or 'body counts'); phase two emphasises empathetic message delivery; and phase three recognises the need for a long term institutional commitment to good communication practices. Based on an analysis of case studies, Powell and Leiss[18] identified lessons for effective risk communication and made the following key observations: (i) there is always more to a risk than what science alone can contribute; (ii) risk messages need to address the context of public opinion; and consequently (iii) the limits of science's contribution in communicating risk and the importance of the consumer's role, is turning out to be a pivotal concept in the analysis of communication and patient safety.

Expanding on this point, the Working Group on Risk Communication of the Danish Board of Technology[9] observed that risk assessment and regulation are carried out in a 'backward manner'. This process needs to be turned around: 'Rather than experts starting by analysing risks, laymen should start by formulating questions to the experts'. Noted risk communication researchers, Fischhoff et al.[19] have suggested there is a growing recognition that the expertise needed for determining acceptable risk is dispersed throughout society. They have further suggested that some of the worst surprises in hazard management have involved events that were not anticipated by the experts. Could people from other disciplines with different frames of reference, have insights that could have prevented the Valdez oil spill in Alaska, the Chernobyl reactor meltdown, the Bhopal chemical explosion? What does 'expert' mean in this context? Fischhoff et al.[19] have suggested that we also invite people who are not normally a part of our policy or decision making circles – 'the poor, the philosophers, the artists'. 'Even when experts may have a near monopoly on technical facts, they need not have a monopoly on alternative perspectives, and may suffer from ingrained disciplinary blinders.'

Arriving at a similar conclusion, Plesner[20] in her analysis of 15 consensus conferences at the Danish Board of Technology, noted that although knowledge is often perceived as an exclusive property of the experts, there is 'scope' for the lay public to also acquire and share knowledge which then becomes a community resource for problem solving. Wisdom, therefore, may arise from the gathered community.**2** Fischhoff[21] pointed out that risk communication research is still in evolution. Describing our current developmental stage, he observed that, 'One of the miracles of democratic life is the ability of lay people, often with little formal education, to master technical material when sufficiently motivated. Unfortunately the motivation for this self-education often comes from a feeling of having been wronged . . . effective communication can fulfil part of the social contract between those who create risks (as a by-product) and those who bear them . . . a complex network of mutually respectful relationships may offer the best hope'.

2.4 A New Look at the Drug Use System

Another indirect measure of the lack of effectiveness of our drug safety and risk benefit communication is the number of recent product withdrawals. In the US, there is a general recognition that many of these products have a legitimate use for some populations but that their safe use in the marketplace cannot be guaranteed as evidenced by the adverse event data. Analyses of these experiences have prompted leaders to observe that there will be no safe drugs until there is a safer system. Currently in the US, the FDA, pharmaceutical companies, healthcare providers and, to some extent, patients' groups, are in dialogue taking a new look at risk communication and risk management models and viewing them as an integral part of the pre-market drug approval process.

2.5 Rethinking the Drug Product

The International Medical Benefit/Risk Foundation[4] has observed that the pharmaceutical industry's investment in patient information and education (the 'software') is substantially less than the high level of investment made in drug development (the 'hardware'). Kuperberg et al.[22] have called for the redesign of the drug product as the 'complete therapeutic product'. This complete therapeutic product contains the medication with prescriber and patient information that is practical and prepared according to patient education guidelines, along with the tools and resources (the 'software') to assist health professionals to effectively involve and communicate with the patient. In the past, pharmaceutical companies considered the prescriber as their primary customer. Today, companies recognise that they need to 'own' their products through product distribution, prescribing, and administration down to the end-user, to influence the patient's appropriate use for increased benefit and reduced risk. Certainly one manifestation of the manufacturers' recognition to have a more direct influence on the patient's behaviour is the escalation of direct-to-consumer (DTC) advertising. US expenditure for DTC advertising has tripled between 1996 and 2000, reaching $US2.5 billion.[23]

3. Reframing the Question of Drug Safety Communication

There is a common thread woven throughout these developments in medicine, education and

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[2] It should be noted that there is an emerging discipline called interactive management (IM) which studies this phenomenon of community and develops tools and processes to expedite the generation of the collective wisdom and translate it into action. The reader is referred to the website of the Institute for the Advance Study in the Integrative Sciences (IASIS) at George Mason University in Virginia (http://www.gmu.edu/departments/t-iasis) for annotated bibliographies encompassing this field; and to http://www.CWAltd.com for illustrations of the applications of this work in a variety of corporate, government and voluntary agency settings across an international spectrum.

communication. It is the recognition that the ultimate end-user of the healthcare system in general, and the drug product in particular, needs to be meaningfully and vitally involved in the development of all decisions in which they are expected to be participants – as the end-users of care. These parallel observations, also point to the need to move beyond an 'expert centered' or 'silo mentality' for future models for drug safety communication as well as for the delivery of all healthcare. The conclusion is inescapable. There cannot be a safer healthcare system until all the stakeholders, including patients in particular and society in general, play an active role in the design and operation of that system.

Therefore, we need to reframe the question. The essential question asks not how, or even what, to communicate but rather, how should we redesign our system to communicate and work effectively with patients to achieve safe drug use? How do we build a structure and a process that moves beyond the self-referential, expert mentality to a more global, system approach in which we are learning together?[19-21] Plsek[15] also raises a similar question in his discussion of complex adaptive systems, 'How can diverse people be brought together, information shared, and forums convened among those to stimulate creative connections who do not normally come together to do so?'

4. New Models

4.1 Beyond Paternalism: a Partnership Model

There are many worthwhile discussions and laudable efforts currently taking place in developing new approaches to benefit-risk models; however, there still is a need for a fundamental shift in the minds – and hearts – of the leaders involved in these efforts.

After analysing research from the Picker Institute in Europe, released in July 2001, Kendall[24] called for an end to the paternalistic attitude of health professionals which, she observed, is a major obstacle to developing partnership models. The prescriptive remedy for the elimination of paternalism, according to Kendall, is the creation of a citizenship model where patients have both rights and responsibilities. This means providing patients with the resources and the motivational support to fulfil their responsibilities as well as exercise their rights. Healthcare professionals and patients both 'must change, sharing responsibility, information and decision-making'.

Kendall further observed that to effect these changes, health professionals 'may have to accept that public perceptions of risk are not necessarily 'wrong' but merely different from their own'. As noted previously, risk communicators are learning that the expertise for determining and communicating acceptable benefit-risk decision making is dispersed throughout society. As with a citizenship model, they similarly propose that society's best hope may lie in creating a complex network of mutually respectful partnerships.[21]

4.2 Examples of Citizenship Models for Decision-Making

Citizenship models for decision-making is not a new idea. Banathy,[25] in his Guided Evolution of Societies, described the agoras or open public spaces of ancient Greece where citizens came together to take part in deliberations and decisions that affected their lives. Banathy observed that this arrangement allowed the everyday citizen to play an active role in serving the common good. 'Athenian democracy thus represented the widest possible diffusion of political power among its citizens, the widest ever practiced in our history'. This coming together of the citizenry to generate community wisdom and serve the common good (in the area of health) is, in fact, beginning to take place on a very large scale today.

To assist in providing the resources and motivational support for patients to meet their partnership or citizenship responsibilities, international communities of patients are emerging. For example, the development of The International Alliance of Patient's Organisations (IAPO)[26] is a strong indicator of the change taking place on an international scale, that illustrates the potential for patient participation in healthcare decision-making and communication. The IAPO mission is to build healthcare services with patients at the centre, and to accomplish this in every country. They intend to fulfil their mission by advocating with a strong international voice and building their organisational capacity. The IAPO journal, *The Patient's Network*, emphasises the patient's role in decision-making, as in, for example, the Medicines Concordance movement in the UK. Concordance emphasises negotiation and agreement. It is currently defined as 'an alliance in which the healthcare professionals recognise the primacy of the patient's decisions about taking the recommended medications'.[27] Recent issues of the IAPO journal have carried articles from patient representatives all over the world discussing patients rights in Latin America, HIV/AIDS treatment activism in Africa, an analysis of British Columbia's target setting for health goals, the US Surgeon General's goals outlined in Healthy People 2010, as well as an update on the struggle for people with autoimmune disease in Italy.

In 2001, July, a new internet database was launched, called Dipex – the Database of Individual Patient Experience.[28] This virtual resource enables people with disease, from around the world, to share and compare their stories. The Dipex creators explain that this is an attempt (the first in the field of healthcare communications, they say) to promote 'a more balanced encounter between patients and healthcare professionals by focusing on the patients' perspective'.[29] Another example of patients coming together to form communities for support and resource sharing is the Self-Help Group Clearinghouse. Initially developed in the United States with a mental health emphasis, their database contains nearly 1000 US and international self-help groups and worldwide clearing houses covering healthcare and social services.[30] This web-based clearinghouse helps patients find local, national, and international member-run mutual aid self-help groups and also provides information on how to start new groups. These three examples of international models for patient participation are a start. They focus on the patient as a equal partner and provide forums for the sharing of information, experience and resources. The next evolutional step is the creation of a structured, deliberative process that brings all stakeholders (all involved groups) together – manufacturers, regulators, practitioners, payers and patient-consumers – for consensus building, decision-making and concordance.

5. Conclusion

The developments in the fields of medicine and the social sciences have surfaced insights that have direct bearing on drug safety communication. The following eight principles emerge as having application for improving benefit-risk communication.

1. There cannot be a safer drug until there is a safer system.
2. There cannot be a safer system until patients and all stakeholders are equal partners, actively involved in the design and communication of benefit-risk information. Everyone has an equal voice in the deliberations and there is a genuine respect for listening to all involved citizens.
3. Paternalism must be eliminated.
4. The expertise needed for determining acceptable benefit and risk is dispersed throughout society (and not confined to 'experts').
5. Patients and all stakeholders serve as both teachers and learners.
6. Patients and all stakeholders need to be involved in the: identification of the learning needs and goals; the educational processes and the evaluation of the outcomes.
7. The action of one stakeholder or group changes the context for all the others. There is a respect and appreciation for the nature of complex adaptive systems in which individual actions are interconnected.
8. Patients, the system's end-users, must be involved in the continuous feedback and redesign of the evolving drug safety information system(s).

In summary, to more effectively communicate and utilise drug safety information, patients and all affected citizens (all involved groups) must play an active role in the design, operation and evaluation of that communication. Christakis, a pioneer researcher in system analysis and inter-active management observes that if people are expected to exercise their power, it is first necessary 'to discover the wisdom of the people'[7] Our challenge is to develop models – participatory systems, modern day agoras – that provide an opportunity for all the stakeholders to come together to dialogue, develop concordance, generate wisdom for the good of the larger community and specifically, to determine together how to more effectively communicate and utilise drug safety information.

6. Future Research Agenda

To complement the developments in medicine and social sciences, our future research agenda will also need a 'new look' at our systems of public accountability to ensure that our organisations move to and stay in a continuous learning mode. Recognising that drug safety communication is a public health issue, that relies less on regulation and more on education, we will build new participatory tools and resources. Whereupon we will also need new models of public accountability that reflect and support these new resources for engaging the patient and the entire community in benefit-risk determination, communication and management. This is the emerging new vision that will shape our next collective challenge.

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