

DEVELOPING A CONSENSUS ON THE ACCOUNTABILITY AND RESPONSIBILITY FOR THE SAFE USE OF PHARMACEUTICALS

A Preliminary White Paper

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I. OVERVIEW

A. Objective of the Pharmaceutical Safety Project

Develop a consensus on the accountability and responsibility of the community of stakeholders for pharmaceutical safety and design a collaborative action plan.

B. The Purpose and Scope of this Document

The primary purpose of this preliminary white paper is to orient participants in the NPSF Collaborative Action Planning Workshop on June 10-11, 1999. It is focused on problem framing and context for the Pharmaceutical Safety Project as suggested by interviews with a subset of participants. The format for this workshop is provided in a scenario in *Appendix G*.

The secondary purpose is to begin the collective cultivation of a white paper, on the Collaborative Action Plan, to be published in July, 1999. The white paper will be based predominantly on contributions of participants before, during, and after the workshop.

The content of this present document depicts the emergence of the discourse on issues and critical problems in Pharmaceutical Safety. This draft is intended to provide a context for the level of discourse during the workshop by summarizing topics of discussion identified by the interviewees. The content draws on a first round of interviews of a subset of workshop participants and thought leaders, which elicited 145 statements of perspectives on framing issues in pharmaceutical safety. The collection and inductive classification of these issues is included as *Appendix A*.

As we began delving more deeply into this subject of pharmaceutical safety, reviewed the relevant literature, listened to thought leaders and major stakeholder representatives, certain key events served to help define the most useful context for our work. They were: the discussion within the NPSF community in response to the meta-analysis of studies on the incidence of adverse drug events in hospitalized patients by Lazarou et al. published in JAMA (April, 1998), the GAO stakeholder panels (February, 1999) and the AEI (American Enterprise Institute for Public Policy) program (April, 1999) - both programs are referenced later in this paper. The choice of this preliminary framework was further confirmed by explicit feedback from several NPSF Board members and content experts upon reviewing NPSF's original proposal on pharmaceutical safety. The workshop context we are proposing as a useful framework for our discussion is that of *pharmaceutical use – safe and appropriate use*. The choice of this context is not to infer that industry and academic research should not continue to strive to develop less inherently toxic therapies, or that regulators should not improve their approval processes. It is, in fact, to bring these and related issues into sharper focus as they affect prescribers, clinicians, and the patients' abilities to use these products safely – to maximize therapeutic benefit, reduce risk and eliminate

harm. The workshop participants will be challenged to identify and bring forward all the factors they think impact pharmaceutical safety, and the collective wisdom of the community will play out in the ensuing dialogue and the collaborative design of the action plan. Our framework is a recommended place to start that discussion.

A second round of more focused interviews on the topics for discussion will continue in the week preceding the workshop. The results of the second round of interviews will be made available at the start of the workshop.

This preliminary white paper opens inquiry on collaborative challenges in improving safe medication use through the Pharmaceutical Safety Project. It begins the cultivation of the scope of the resulting white paper. As such we request and will include contributions from reviewers and participants in subsequent versions.

This white paper will be supported by citations of the literature as they pertain to the emerging focus of the participant's deliberations. An annotated bibliography, assembled in parallel, can be found in *Appendix L*.

There are many more organizations with an interest in this topic than can be accommodated in the June workshop, i.e. prospective organizations are listed in *Appendix C*. A communication plan is in development and will consider the journal venues indicated in *Appendix J*. It is intended that the white paper to be published after the workshop will be deployed on the World Wide Web.

C. The Role of the National Patient Safety Foundation

The National Patient Safety Foundation's role is as a catalyst to focus resources, by persuasive invitation, to highly leverage the collective action identified by the representatives of the Pharmaceutical Safety Chain. Background information is found in *Appendix D*. The NPSF expects that its role in this important aspect of patient safety will emerge more explicitly during the workshop. To ensure the integrity of NPSF's position it has established an *Advisory and Oversight Board*, (*Appendix E*), has retained a neutral third-party *Inquiry Design and Facilitation Team* (*Appendix F*), and is conducting the workshop and the development of the white paper in an open and transparent fashion.

II. PHARMACEUTICAL SAFETY

A. Stakeholders in the Pharmaceutical Safety Chain

1. The Pharmaceutical Safety Chain

A key design question for the collective development of this initiative is “Who are the stakeholders?” At present this question is open. For the purpose of convening the workshop, the identification of participants follows a proxy stakeholder identification heuristic – that is the notion of the “Pharmaceutical Safety Chain.” For the purpose of this workshop, this is defined loosely as the primary regimes of influence on safe medication use. For practical matters of timeliness, productivity, and scale of the event we can not include all stakeholders, but rather must rely on “representatives” of key stakeholder groups. The workshop will include representatives of stakeholders in the Pharmaceutical Industry, FDA & Government, Medicine & Healthcare Practitioners, Pharmacists, and Patient and Public Interest groups. These groups represent the functions of: pharmaceutical research and development, product approval and regulation, prescribing, dispensing and administration, and ultimate end use of the therapy/product. The reader will note an orientation to engaging a diversity of perspectives rather than towards an in-depth investigation of a particular sub-field. A comparison of the *Participant List*, (*Appendix B*), and preliminary prospective identification of *Stakeholder Organizations*, (*Appendix C*), indicates that while there will be a diverse profile of perspectives in the June event, it is extremely modest with respect to “representation” in its proper sense. An important goal of the event, and its white paper, is to call for the collaboration of a broader set of stakeholders that will be directly represented in this event. In this sense, the event is a staging arena to build a consensus for focused collaboration and action.

2. Stakeholder Representation in the NPSF Workshop

The names, affiliations and contact information for participants in the workshop are provided in the *Participant List*, (*Appendix B*). A summary of the types of organizations affiliated with the invitees of the NPSF Workshop on the Pharmaceutical Safety project is presented in Table 1. These organizations are positioned, left to right, according to their primary orientation in the Pharmaceutical Safety Chain. Naturally, these demarcations and assignments do not represent the network of relationships across the safety chain which are present within many of these organizations. This table simply provides a snapshot of the cross-cutting assemblage of participants in the June event. It is intended that this particular collection of individuals will represent the community of stakeholders as well as provide advice regarding resources.

The reader should note that all participants will have an opportunity to contribute their views, request clarification, deliberate, and assess the saliency of stated challenges in the project.

Table 1: Stakeholders of the “Pharmaceutical Safety Chain” in the NPSF Pharmaceutical Safety Project Workshop

Industry	Government	Medicine, Nursing & Healthcare	Pharmacy	Consumers
Manufacturers, Industry Associations, and Consultants	FDA, GAO, HHS, IOM and Consultants	Professional Associations, Hospitals, Academia, and Consultants	Industry Associations, Professional Associations, Hospitals, Pharmacies and Consultants	Consumer & Public Interest Organizations, Patient Special Interest Groups, Information Service Companies and the Media

The objective of the workshop is to “Develop a consensus on the accountability and responsibility of the community of stakeholders for pharmaceutical safety and design a collaborative action plan.” One of the participants’ products at the workshop will be a Figure indicating potential stakeholder collaborations for high leverage action options. The Figure can be envisioned as a matrix with columns representing individuals and organizations in the Pharmaceutical Safety Chain, with rows identifying collaborative actions, and the cells indicating commitment.

Following the workshop, this matrix will be extended through a broader call for collaborative action.

B. Issues in Pharmaceutical Safety

1. Context and Themes

1.1 The Emerging Field

Increased activity regarding Pharmaceutical Safety is occurring in the context of major transitions. In the first round of open-ended interviews, phrases indicating a shift in thinking, or a desired shift in thinking, were found throughout the contributions. It is interesting to note that there were no pre-formed questions directed at such transitions or shifts. During the course of preparation for the workshop, an unordered list of these observations were collected and complemented by statements in literature cited by participants. They appear in Table 2. They reflect a broad diversity of opinion.

A review of the literature confirms that source materials, pertaining to the intended themes of the Pharmaceutical Safety Project, are characteristic of a “field in emergence”. The literature is extremely fragmented, spans disciplines not traditionally part of the healthcare arena, and is not yet well indexed as to its pertinence. This is reflected in a growing rate of authors’ invocation of disciplinary practice largely considered remote by the healthcare community. There also seems to be a small but increasing rate of new entry of researchers and authors into this arena over the last several years. Important new work on taxonomies for reporting has been completed only for a few years, while broadly accepted and endorsed glossaries of the field are only currently in development.

From an innovation standpoint, across all the interests in the Pharmaceutical Safety Chain there is a higher rate of growth of publication on process innovation as compared to product innovation as it pertains to safety. It is also observed that this process innovation, while intended to minimize variation in the long run, is also increasing the diversity of approaches. The increasing publication rate on the topic is unintentionally amplifying this effect. Furthermore, there has emerged a morass of erratic, uncoordinated, and sometimes conflicting process oriented initiatives (i.e. regulatory, legislative, quality, and professional organization initiatives) which are adding a burden of coordinating what should be done at the point of care. Much of the language in the most recent literature calls for the integration of various process perspectives, such as, the quality movement, regulatory reform towards risk management vs. enforcement, in combination with approaches in human factors, safety engineering, systems practitioners, complexity analysts, and semioticians having evolved, in large part outside the healthcare arena. These observations, collectively, indicate that the field is in a transitional regime of process innovation , process adoption and process adaptation from remote domains.

There are perhaps less than a dozen books which could be considered seminal within the intended focus of the Pharmaceutical Safety Project, half of which have only been published in the last five years. The “most comprehensive” book to date is being published in June of this year. In a “snowball” search of

relevant articles,¹ one-hundred-fifty -five journals with one or more relevant articles were identified. Yet, there is a lack of concentration of relevant articles in any one of these journals, especially as a percentage of their “main stream” of material. The most commonly cited works are several articles written within the last five years, indicating just how recently there is a heightened focus on this problem.

In a review of 300 website sections, found through a combination of key phrases, and snowball search, very few provided substantial indication of their relationship to the “network” of organizations and interests on the topic of safety (safe use) of pharmaceuticals. Those that provided an indication, typically did so in text-only form, very, very few in hypertext form. In other words, in a media that highlights the networking nature of relationship building and partnerships, on an issue which is calling for the emergence of partnering, few are employing this media in a highly leveraging fashion, though many clearly have invested heavily in their websites.

In the literature and website reviews, at least 168 organizations (primarily national organizations in large part already associated with the healthcare community) can be identified with a prospective stake in involvement in safe medication use (pharmaceutical safety). But no one source exists that identifies them all.

We reviewed publishing activity in newspapers, magazines, and the lay press only as they may have been cited in journals, websites, testimonies before congress, or speeches. The concentration of media activity seems to have emerged around 1995, a year cited in the professional literature as when this issue of medication safe use really began to come to public attention. This was due to an increased focus in this genre on “celebrated cases.” Not surprisingly, with a fairly short delay, or in parallel, there was increasing pressure on and the development of related legislative initiatives.

The literature and website reviews identified 50 legislative Acts and legislative initiatives cited for their influence with respect to Pharmaceutical Safety. The literature on related legislation and jurisprudence is better coordinated, as one would expect. Still, a succinct delineation of their precedents and encapsulated values, from the standpoint of researchers and healthcare practitioners, with respect to safe medication use would be a valuable contribution.

Although this review has focused on the evidence of the transition in focus on safe medication use, especially over the last half dozen years, 130 cited Marshaling Events in the History of Discourse Related to Pharmaceutical Safety were identified (*see Appendix I*). This indicates that a profound task of the Pharmaceutical Safety project will be the encompassing of the current discourse while wrestling with the ethical balance of value systems which have a longstanding history.

For the purpose of demarcating the transitional nature of this field, a collection of statements on

¹ A snowball search means tracing citations of relevant literature, through a base set, then reviewing the citations in those, and so on until there is convergence.

the nature of these transitions has been tabulated, and reported anonymously, in Table 2.

Table 2: Contextual Shifts in Thinking Identified by Interviewees & Cited Literature

From	A culture of blame, shame, and punishment	To	Creating a culture of safety, blame-free reporting methods safe harbors, safe havens non-judgmental forums, safe places to talk about error, and continuous improvement
From	Focus on toxicity	To	Focus on appropriate & safe use
From	Reliance on the FDA	To	Pharmaceutical Safety Chain, understanding partnerships in public health, enabling healthcare, pharmacy and patients
From	Study of celebrated cases	To	Systemic inquiry, systems orientation, systems approach, “Moving beyond the parables”
From	Quality measures	To	Quality care
From	Counting error	To	Developing an action plan
From	Reporting error	To	Talking about what works
From	Biomedical analysis	To	Clinical and social
From	Conducting the project in an enterprise-based paradigm	To	Anticipatory consideration of broader educational and culture challenges
From	Science and legal foundation	To	Community and a model grounded in the communication and educational sciences
From	Medicine as art	To	Medicine as science, emergence of a new science
From	Patient-centered ethics	To	Population-based ethics with one-to-one obligations for the physician
From	Concentration on verifying efficacy	To	Consideration and assessment of effectiveness in clinical use
From	Risk assessment by experts	To	Public participation in risk confrontation, risk management
From	Orientation to minimizing risk	To	Balanced consideration of benefit
From	Medical specialists orientation	To	Adoption of practices, science, and research from remote domains
From	Pharmacy as dispensary	To	Comprehensive pharmacy care
From	Specialist orientation in FDA	To	Integrated review of safety
From	Regulation as traditional enforcement or control	To	Regulation as risk management
From	Regulator as independent	To	Partnerships with stakeholders
From	Regulatory compliance	To	Responsive regulation coordinated to the structure of relationships in the Safety Chain
From	Data as corporate assets	To	Social assets
From	Localized best practices	To	National initiative
From	Technical deliberations	To	An inquiry into our value system

1.2 Preliminary Suggestions of Themes for the Workshop

The following is an unordered list of themes suggested to be a basis for the workshop, prior to the first round of in-depth interviews. These should not be taken as firm recommendations but rather as an illustration of the diversity of perspectives represented by the community of stakeholders. These are:

- Follow up to the regional awareness raising by NPSF.
- Follow-up to the Tale of Two Stories.
- Follow-up to Human Error in Medicine.
- Lead-in to Solutions Conference & Annenberg 2000 planned by the NPSF.
- Coincide with GAO Report due in September, 1999.
- A covenant to speak the truth (from NPSF Vision workshop).
- Moving beyond counting error to action (Classen).
- From celebrated cases to systemic inquiry (Wood).
- Moving beyond the parables.
- Moving beyond blame.
- The need for Safe Harbors – safe place to talk about error (Regional NPSF meetings).
- Non-judgmental forums (FDA).
- Talking about what works vs. reporting error
- Safety as the “sweet spot” of the healthcare quality movement.
- Emergence of a new science.
- Barriers to Creating a Culture of Safety (VA).
- Maximizing Benefit, Minimizing Risk, Eliminating Harm (NPSF Theme).
- The need for an action plan.
- Public Participation in Risk Confrontation (FDA, NIH).
- Many analogies to other domains but few cross over people.
- Pervasive call for a systems approach, but few systemic publications or studies.
- Many straightforward statements of what is wrong (see Table 3 in Appendix A).
- Transforming from finger-pointing to collaboration.
- Address the gap between what we know and what we do (AHCPR).
- Pursue the perceived problem in getting information out.
- From Science and Legal foundation to community.
- Safety taken to be a matter of discipline but rarely eliminating people.
- Pervasive call for a systemic approach.
- Few or no seminal works.
- The source of key literature is not in the traditional healthcare literature.
- Case and anecdote oriented.
- Most case reports don’t get to the deeper story.
- An existing culture of blame at both the societal and institutional levels.
- The paradigm of the health professions that teaches professionals to work as individuals rather than as members of teams.
- Existing reporting methods that promote blame-placing.
- Problems in hierarchical structure of the health care.

2. Stakeholder Perspectives on the Issues

2.1 First Round Interviews with Stakeholders

The views presented in this section were generated through a series of interviews conducted with key thought leaders in the field, representing a diversity of stakeholder viewpoints. In the search for enough variety, we solicited comments from industry, academia, medicine, the pharmacy profession, and consumer groups. In addition, we sought the opinions of nursing and physician assistant groups, and members of the GAO panel, conducted February 24, 1999. For more complete coverage, we analyzed the American Enterprise Institute's presentation on the Safety of Pharmaceuticals on March 26, 1999.

Panelists during that discussion included: Mr. Michael Cohen, Institute for Safe Medical Practices; Dr. Lucien Leape, Harvard School of Public Health; Dr. Richard Platt, Harvard School of Medicine; Dr. Hugh Tilson, University of North Carolina School of Public Health; and Dr. Janet Woodcock, Dr. Susan Ellenberg of the US Food and Drug Administration, and Dr. Eleanor Vogt of the NPSF.

The interview questions were directed towards an understanding of the barriers to safe use of pharmaceuticals as perceived by respondents. They were unstructured in format, and respondents were encouraged to allow their perspectives to carry the discussion toward those topics which they felt were most significant in addressing the issue of drug safety.

2.2 Content Analysis

Content analysis of the data gathered through the interviews suggested thirteen clusters of concern, or dimensions defining the drug safety situation. As new data came in from respondents, these dimensions were clarified and enhanced. These clusters were named:

1. Science Policy for Safe Use of Pharmaceuticals
2. Pre-Market Risk Assessment
3. Partnership Building
4. Safety Chain Distinctions
5. Safety Chain Transparency
6. Information Technology Systems
7. Post-Marketing Surveillance
8. Post-Marketing Assessment
9. Post-Marketing Reporting
10. Human Factors
11. Product Design
12. Risk Perception
13. Special Populations

A summary narrative description of each of these thirteen clusters of concern is provided here. For a more complete rendering of the content analysis and classification of the interview data, please refer to Appendix A. Opinions here are those expressed by one or more respondents during the information gathering phase of this project.

Cluster #1: Science Policy for Safe Use of Pharmaceuticals

Is it possible to provide a healthcare system that serves all the people, from the public health advocate, who wants no risk at all, to the patient with a critical illness, who is willing to sustain a high level of risk? While the above question may go unanswered, we do need a public health system that provides surveillance and policy development to maximize benefit, reduce risk and eliminate harm. If we couch the issue of drug safety within the context of quality assurance, we can begin to think proactively about safety, and to offer incentives about best practice. We can begin to understand current approval standards and to think about improving them and the implications for improving them. Perhaps most important, we can begin the dialogue in order to better understand the complexities and interdependencies of the system.

As medicine moves from an art to a science, we cannot address new needs with old mechanisms. New paradigms for the care-giving professions can increase safety. We need to develop policy that finds a balance between the necessary privacy for confidentiality and the public's need for informed decisions about drug safety, or useful research. We need to prioritize high leverage actions that can be addressed soon.. We have enough knowledge to begin the solution of problems, and enough authority within regulatory agencies to speak out for safety. On a cautionary note, a respondent suggested the need for an oversight body to consider the long-term effects of recommendations on changes to the current system. A new agency on drug safety, for example, may be a premature solution to a problem that needs clearer definition.

Cluster #2: Pre-Market Risk Assessment

Although more drugs are currently approved under PDUFA, outcomes from the pre-market review process have improved, when measured by the decreased rate of drug withdrawal. Evaluation standards have gone up, and more patients in heterogeneous groups are studied. Questions still remain as to how effective a drug should be, how many patients, how well and long should they be studied. Should the FDA approval bar be raised? More definitive risk/benefit data with controls should be available. Perhaps most important, the pre-market approval process creates a group of drug experts.

Cluster #3: Partnership Building

We need an increased understanding of partnerships in public health. The quality in pharmaceutical use is dealt with by a collaboration of partners. This issue is an international one. Groups involved with medical safety often exist in isolation: civic community, health industry, physicians, pharmacists, community health professionals, public agencies should have access to reporting information. Knowledge currently gets lost in the system. The solution to patient safety lies in non-traditional thinking about roles; for example, the FDA should not be driven by its traditional role as a regulator. The Agency and private partners should join to create a solution to the problem of safe drug use. In addition, new needs rising from recent healthcare system changes have no traditional "owners," and are filled by entrepreneurial businesses, e.g., demand management capability. Safety is a series of dynamic relationships, with clear understanding of mutual capabilities and limitations. Each groups' role in this relationship needs clarification for modifying practice patterns. We need to apply the knowledge we already have to the solution of this problem, and we need to prioritize high leverage actions that need to be addressed soon.

Participation from attorneys in resolving the problem of drug use error is critical. Medical, nursing, and pharmaceutical students need to learn that healing is a partnership between patient and provider. 98% of the public believes they have a role in public safety, but they don't know what it is. Patient understanding and buy-in to an intervention protocol, delivered in a culturally competent and sensitive manner, is the only way to assure adherence to that protocol.

Cluster #4: Safety Chain Distinctions

Healthcare risks should be evaluated in a systems context. How we manage risk can be better managed. The diagnostic process should be applied to public health problems as well as decisions about what problems to address. We need to be able to distinguish between the intrinsic safety of a drug and medication errors. Better analysis of failure can assess benefit and risk two ways: by testing efficacy (how well the drug works under ideal circumstances), and efficiency (how well the drug works when a clinician uses it). This distinction can be clearer with physician participation overlooking reports as they come in. Better reporting can establish causality: whether an event is caused by a drug, by the disease itself, or by something else altogether. Confusion arises from duplicate reporting, and reporting about reactions that aren't unique to these drugs, but can manifest as increased frequencies of reactions that occur normally. The important thing is to make drug use safe, with the understanding that most errors are not due to reckless behavior, but by good people trying to do a good job.

Cluster #5: Safety Chain Transparency

We need to focus on public health and safety. This is not a competitive issue, e.g., antitrust laws, or a blame issue, e.g., the threat of malpractice, although we need a process to deal with competing interests in this system. A forum, a safe place to talk about mistakes can help to eliminate the fear and shame about talking that prevent learning. We need to establish the influence of organizational and professional roles on medical safety. We need to work with the legal system, instead of allowing it to hinder us. The train and blame strategy for use safety is outmoded; we need to recognize blame as a social artifact that we assign after the fact. We need to move away from the punishment mentality to a continuous process improvement mentality. Error reporting should be voluntary (Charles Billings, speaking of the aviation industry, claims that all reporting is voluntary anyway). Reporting individuals should have the choice to identify themselves or not. Practitioners should have standards for correct and complete information, and notification about problems through press releases. The Internet and continuing education courses are vehicles for information dissemination. At the patient level, practitioners and pharmacists should have a clear idea as to how much patients can realistically be expected to know. Patients should have access to package inserts with understandable medication information. Patient responsibilities for self-care could be spelled out in, for example, a Patient Bill of Rights.

Cluster #6: Information Technology (IT) Systems

Information turns over so quickly, with a half-life of three years now, instead of seven just ten years ago. Large automated multipurpose population based databases can greatly help pharmaco-epidemiologists. While these systems currently exist in medical record automated systems, healthcare systems, the FDA, and insurance systems, there remain problems of limited resources and confidentiality measures. The Institute for Safe Medical Practices has been collecting information on post-market surveillance using a volunteer practitioner reporting program for over 15 years. The new FDA IT system, if properly funded, will allow for electronic submissions and will be able to provide data to interested parties. Hospitals spend limited resources competing with each other over diagnostic equipment instead of upgrading their internal IT systems.

Cluster #7: Post-Marketing Surveillance

While post-marketing surveillance for rare, serious adverse events functions well, even at the international level, there is a call for improved surveillance in post-market programs involving larger and more heterogeneous populations. Long-term follow-up studies can clarify expected risks. Label

changes reflect contraindications and warnings. Mandatory field reports that are protected by attorneys and risk managers may not contain the information that can prevent future errors of the same type. Some respondents claim that the blinded data already exists for surveillance, and that inaction during the collection of additional data leads to more harm.

Cluster #8: Post-Marketing Assessment

The post-market assessment of benefit and risk depends upon good data and access to confidential data systems, and a calculation of where the drug fits into the armamentarium of the individual practitioner. It is based on three principles: objectivity (we know more than we use in making decisions), equity (we need to be sure we learn from prior experience), and accountability (we need to be explicit about biases and assumptions and externalize them). The information retrieved from practitioners should be properly utilized, for example the MedWatch data is only presented in summaries. The FDA's management actions on risky pharmaceuticals is well mapped: restricted distribution to a group of practitioners, mandated testing by pharmaceutical firms, and registration of drug use. Continuing education credits on adverse drug event issues could be mandated for license to practice. The Agency's role in drug use issues is less clear. Use of the Internet for dissemination of information as well as for promotion and sale is a possibility for reducing medication error. Providers could recognize that every interaction with a patient is a teachable moment, and alternatives to medicating patients, who may need a different form of intervention, should be explored.

Cluster #9: Post-Marketing Reporting

Post-marketing adverse reaction reporting has improved, bringing rare events to light more rapidly, as can be measured by the decreased rate of label changes. Yet while the community of stakeholders is aware that there is still consistent underreporting, there is no way to measure the extent of the problem. We need a clearer understanding of the reasons for the lack of reliable and accurate data. Some of these include an unfamiliarity with the forms used for reporting, an attitude that "everyone knows it happens," that a patient may seek different care for a therapy problem than for the original therapy, and a physician may simply not recognize an adverse event.

Drug dispensers should be educated to understand that immediate error reporting can save lives that may be at risk but are not yet harmed. Acting to prevent a greater mistake should be rewarded, not punished. A strong orientation toward patient concerns is the strongest antidote to the threat of malpractice. Reporting can be a way of learning, a way of improving systems to avoid future problems. Voluntary reporting can be enhanced with more funding and a system that responds with investigation and change to avoid the same problem in the future.

Cluster #10: Human Factors

Even when human beings function at their highest efficiency levels, there is an unacceptable 0.05% error rate. Healthcare could emulate the example of other high reliability organizations, such as the nuclear industry and airlines, in designing systems with human factor principles in mind. A careful review of the extant literature may begin establishing the prevalence of drug use error. The cooperation of human factor experts and the institutionalization of medical errors programs, with more sophisticated tools to measure error, can minimize risk. Specific examples include external review of labels by practitioners before products go to market and restricted access to dangerous drugs, e.g. potassium.

Cluster #11: Product Design

Improved product design could rapidly reduce error without high costs. Sound alike names, look alike labels, non-standard labeling are all potential accidents. Derivative drugs, multiple pill design, dosage, and labels per drug add to possible confusion. Electronic barcodes for dosage, expiration dates and drug/drug interactions could provide a solution.

Cluster #12: Risk Perception

Pharmaceutical safety is a lens through which we perceive the quality of healthcare. If 42% of the US population believes that they or a member of their family has been exposed to medical error, we need to more clearly understand this perception and develop a more realistic view of risk. While other high risk industries, for example the airlines, create awareness among their consumers that there is risk, healthcare patients need to be educated that medication is a continuous calculation of benefit to risk. Therapies that come from other cultures, moreover, may carry different values about risk.

Cluster #13: Special Populations

In order to meet the increasing demands of an aging segment of the population, we need more information about drug reactions in these groups, as well as such other special groups as children and pregnant women. In addition, culturally competent and sensitive care can assure patient buy-in for greater compliance.

2.3 Influence Pattern amongst the Clusters of Issues

The inquiry design team explored the influence relationship amongst the thirteen clusters of issues identified from the content analysis of the interviews, by focusing on the generic question:

**“Suppose the stakeholders were able to make progress in resolving the issues in:
(Cluster - X)
will this help significantly the community in resolving issues in
(Cluster - Y)?”**

The product of this inquiry is shown in Figure 1 as a pattern with the influence relationship propagating along the pathways. Those clusters that are located deeply in the pattern, such as Levels IV, V, and VI are the most influential. The three most influential clusters, as shown graphically in Figure 1, are:

Cluster #1: Science policy for safe use of pharmaceuticals (Level VI);

Cluster #3: Partnership building (Level V); and

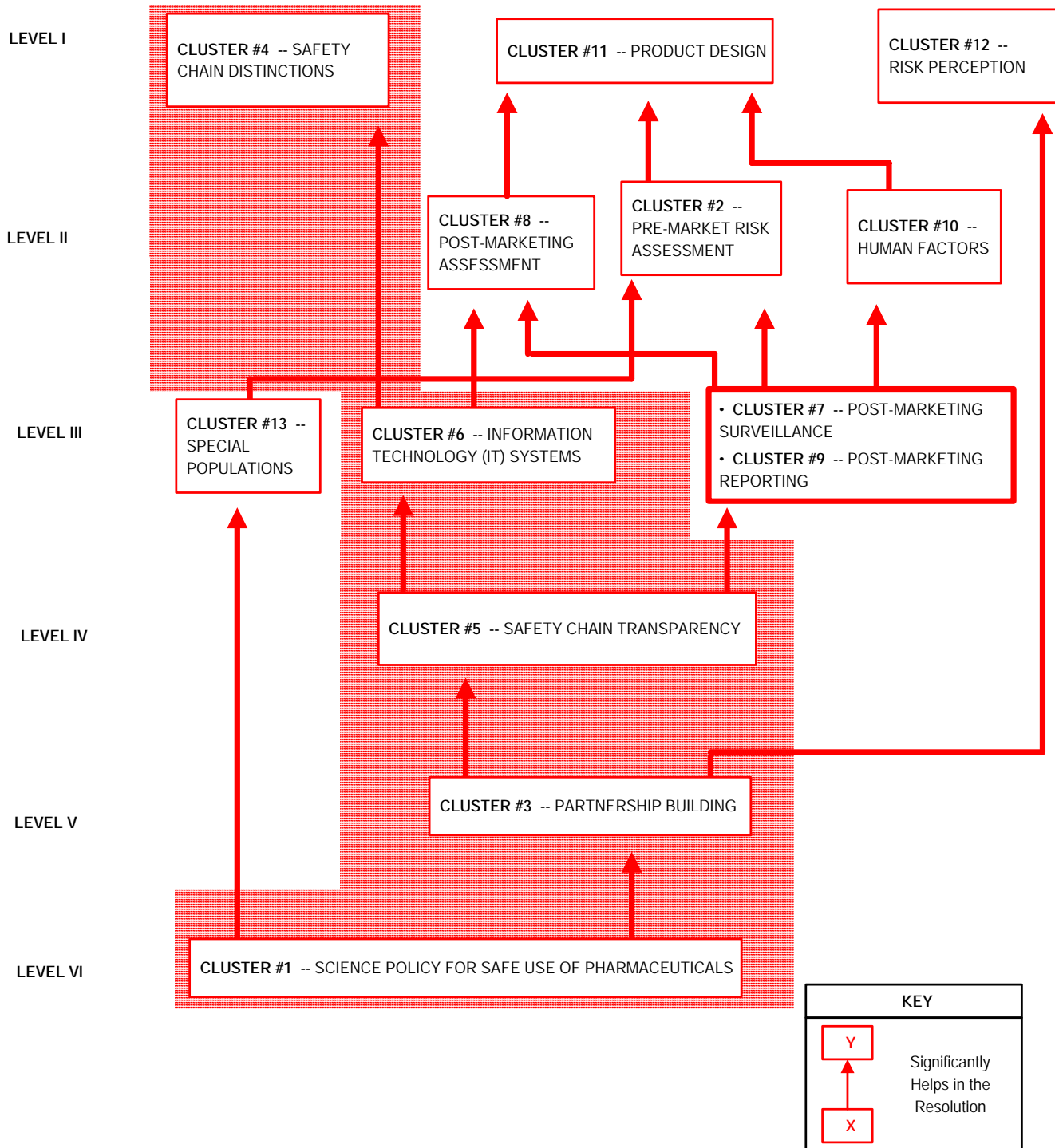
Cluster #5: Safety chain transparency (Level IV)

Enabling the community of stakeholders to resolve issues in the above three clusters will exert strong influence in resolving, or even dissolving, some of the issues appearing in Levels I, II, and III of the influence pattern in Figure 1.

For example, the interpretation for one interesting pathway in Figure 1 reads: Resolving issues in the “science policy” cluster at Level VI will help significantly the community in the resolution of issues in the “partnership building”, “safety chain transparency”, “IT systems”, and “safety chain distinctions” clusters, as shown graphically by the shaded area in Figure 1. Cluster #1 at Level VI influences every single one of the clusters at the higher levels of Figure 1, so it can be thought as a “root source” in terms of the strong leverage it exerts for resolving the safety chain issues.

By drawing distinctions in terms of the systemic leverage among the clusters of issues, the community of stakeholders is better informed in designing a strategy and an action plan for addressing the complex situation of improving pharmaceutical safety.

Figure 1: Influence Pattern among the Cluster of Issues Identified from the Content Analysis



C. Topics for Discussion

1. A Summary of Critical Problems

Critical Problems were distilled from the stakeholder statements with support from literature cited by participants. Following admonitions by interviewees to focus on problem framing, problem definition, and appropriate “diagnosis”, these statements are made in the form of directives for systemic investigation of critical problem areas. These are summarized below. The detailed list appears in Table 4 found in *Appendix K*. The categories and order of Table 4 follow the schema developed in previous sections. Table 4 can be viewed as an abridgement of Table 3 (*see Appendix A*) representing statements which concern critical problems. It condenses the 145 statements of issues generated through the interviews to 52 statements of critical problems. The purpose of this analysis is to help focus on highly leveraging topics of discussion. This is described in the next section.

- **Science Policy for Safe Use of Pharmaceuticals**
Balanced Risk Management & Accountability,
Qualitative Systems Modeling for Policy
Information Privacy vs. Social Assets
- **Partnership Building**
Model the Evolution, Relational Dynamics, Roles and Diffusion Paths
Redefine “Accountability and Ownership” in a Systems Context
Design an Ideal Role for the FDA
Improve support for enhancing the Patient-Provider Partnership
- **Safety Chain Distinctions**
Focus on Problem-Framing for Safe Drug Use
Consider the Broad Systemic Context of Risk Management
Identify Systemic Problems in Measurement & Determining Causality
- **Safety Chain Transparency**
The Problem of Broadly Establishing Safe Forums and Safe Reporting
Practical Concerns in Access to the Right Information throughout the Drug’s Lifecycle
Needs for Enhanced Pedagogy, CE & Licensing Requirements
- **Human Factors and Product Design**
Problems in Adoption and Diffusion of Design Principles from Remote Domains
Assigning Responsibility for Design for Safe Use
Issues in Institutionalizing Medication Error Programs
Design Standardization Influences on Electronic Standards

- Pre-Market Risk Assessment, Risk Perception and Special Populations**
 Problems in Aligning Risk-Benefit Perceptions for Productive Public Discourse
 Effects and Unintended Side Effects of “Raising the Bar” on the FDA & Industry
 Distinguishing the Public’s Perspective and the Unique Individual’s Patient Risk Management
- Post-Marketing Reporting, Surveillance & Assessment, and Information Technology Systems**
 Investigate incentives on current inadequacies in reporting and effect of changing incentives.
 Engage the problems of ‘anticipatory reporting.’
 Identify the problems in earlier diffusion of information of known reactions and interactions.
 Depict the problems of accessibility of existing data, basis for decision making to physicians.
 Consider the barriers and resource constraints in IT system enhancements and innovation constraints.

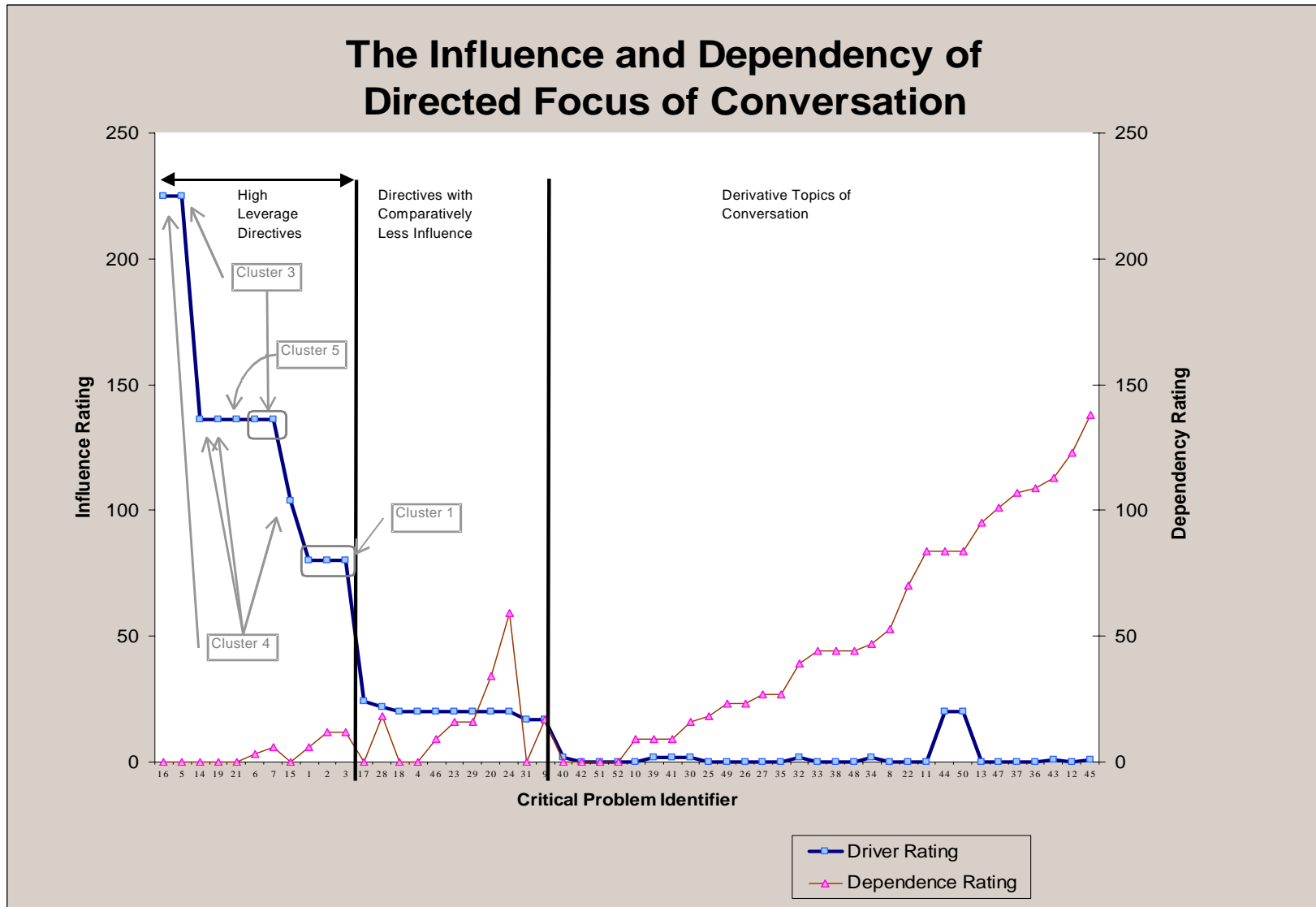
2. Influence Pattern of Making Progress on Critical Problems

The inquiry design team explored the influence relationship amongst the fifty-two critical problems listed in Table 4 (*see Appendix K*), by focusing on the generic question:

**“Suppose there is an increased rate of progress on resolving:
 (Critical Problem - X)
 would this significantly increase the rate of progress on resolving:
 (Critical Problem - Y)?”**

The first product of this inquiry is the Structure Levels Report which appears at the end of *Appendix K*. This is a contextual representation of an influence pattern that is similar to the Figure 1 presented earlier in this document. A cross-impact analysis of this pattern was conducted to determine the comparative influence of making progress on one problem vs. another. A graphical summary of the comparative strength of influence is illustrated in Figure 2 displayed in the following page. The X-Axis indicates the label of the items listed in Table 4 (*see Appendix K*).

Figure 2:



3. High Leverage Topics for Discussion

Based on the cross-impact analysis, the most highly leveraging critical problems to make progress on are found to the left of Figure 2 above. They are:

16. Address the challenge of considering risk management in the overall healthcare systems context.
5. Develop a conceptual model of the evolution of partnerships, and the dynamic nature of relationships in public health and healthcare at national and international levels, with respect to Pharmaceutical Safety.
14. Depict the overall challenge of making medication use safe in a compelling way.
19. Focus on reporting problems such increasing reporting rates, eliminating redundancy, and the coordination challenge of more parties involved in reporting and reviewing reports.
21. Delve deeply into the problems in transforming the culture of blame and punishment.
6. Evolve the notion of individual and organizational accountability in the context of the systems perspective, quality, process, partnering, collaboration, and teaming which seems to blur the assignment or acceptance of “ownership” in pharmaceutical safety.
7. Assess the “ownership” associated with emerging needs and recent changes in the healthcare system with respect to Pharmaceutical Safety.
15. Avoid jumping to a solutions orientation prematurely. Work first to ask the right questions, properly “diagnose” the problem(s,) and decide which problems we want to address
 1. Investigate how to foster a greater balance of a concern with benefits, along with eliminating harm, for a more robust approach to risk management.
 2. Develop the accountability of health care systems with respect to public advocacy for “no-risk” in medication use and the risk affinity of patients with critical illness.
 3. Review the systemic nature of current approval standards, the mixed actions of evaluators and approvers, the changing nature of the healthcare system, incentives promoting best practice, and consider the overall systemic effects and implications of recommended changes to the system.

III. CHALLENGES IN IMPROVING PHARMACEUTICAL SAFETY

Studying the interactions among the suggested themes, observed or desired transitions, the breadth of issues and diversity of critical problems represents a major systemic challenge to the participants of the June workshop on improving pharmaceutical safety. In light of the considerations presented in this document, it was decided that the design inquiry for the representatives of the community of stakeholders participating in the workshop should focus on the following theme:

**WORKSHOP THEME:
DESIGNING THE DEVELOPMENT OF AN INITIATIVE FOR IMPROVING
PHARMACEUTICAL SAFETY.**

We offer below some explanatory comments for the choice of the theme to focus the deliberations. These are:

- The word “development” has been introduced in the proposed theme to indicate that we are talking about a “developmental continuum of stakeholder engagement” and not a “one-shot event” that will begin and end with the June workshop in Washington. In other words, the June workshop is the beginning of a process;
- The participants in the Washington workshop will be asked to design the process for the development of an initiative for improving pharmaceutical safety as defined by the NPSF, namely (a) maximize benefits, (b) reduce risk, and (c) eliminate harm;
- The relevant domain for deliberations among the workshop participants will be identified as being the appropriate (including safe) use of medications;
- By asking the workshop participants to anticipate challenges facing the “community of stakeholders” in improving pharmaceutical safety, we will enable them to transcend their current focus with issues centered primarily in their own domain of experience and expertise, i.e., we will elevate the level of the discourse;
- The proposed theme encompasses all the questions that have been identified in the March 24, 1999, proposal of the NPSF project prepared by Dr. Eleanor Vogt, such as: Where are the strengths and the vulnerabilities in our system? Can we maximize what we already do well and more effectively manage and reduce the associated risks? Are we managing risks appropriately? Etc.

The goals for the two-day workshop are:

- **To create a shared understanding of the “anticipated challenges” that the community of stakeholders will face in improving pharmaceutical safety (first day);**
- **To build commitment to an action plan for collaboratively addressing the “system of challenges” (second day); and**
- **To begin forging a “chain of partnerships” which will embrace the variety of actors in implementing a program for improving pharmaceutical safety (second day and DELPHI study).**

The workshop is based on structured, collaborative design dialogue. Collectively, the representatives of the community of stakeholders will initiate the design of an initiative for the resolution of the complex set of issues relevant to improving pharmaceutical safety. On the first day of the workshop the dialogue will be focused on the triggering question:

“What challenges do we anticipate the community of stakeholders will face in improving pharmaceutical safety?”

After generating and clarifying the meaning of the proposed challenges, the participants will be engaged in constructing a pattern that displays the influences among the challenges. By exploring methodically the influences among the proposed challenges, they will discover those challenges that exert the maximum leverage on other challenges, and construct a “system of challenges” displayed by a pattern similar to what was presented as Figure 1 earlier in this document.

On the second day of the workshop the focus of the dialogue will be on the triggering question:

“What are action options which, if adopted and implemented by the community of stakeholders, will maximize the plausibility of addressing the system of challenges?”

Details of how the deliberations will be conducted during the two-day workshop are included in *Appendix G* titled “Scenario for the National Patient Safety Foundation Workshop on an Initiative for Improving Pharmaceutical Safety”.

IV. WORKSHOP RESULTS

To be inserted after June 10 & 11 workshop.

APPENDICES

- A. Classification of Issues Generated through Content Analysis of the Interviews Conducted with Selected Representatives of the Community of Stakeholders**
- B. Participant List**
- C. Prospective Stakeholder Organizations**
- D. The NPSF**
- E. Advisory and Oversight Boards for the Initiative**
- F. Inquiry Design and Facilitation Team**
- G. Scenario for the NPSF Workshop**
- H. Glossary of Terms**
- I. Marshaling Events**
- J. Journal Venues**
- K. Critical Problems for Investigation from First Round Interviews**
- L. Bibliography**

APPENDIX A

Table 3: Classification of Issues Generated through Content Analysis of the Interviews Conducted with Selected Representatives of the Community of Stakeholders

CLUSTER #1 -- SCIENCE POLICY FOR SAFE USE OF PHARMACEUTICALS

- (Issue - 18) Set policy to find balance between necessary privacy and public's need for informed decisions about drug safety
- (Issue - 19) Assure necessary public health services: surveillance, policy development
- (Issue - 36) Distinguish between totally open access to information and useful research
- (Issue - 76) Ask the right question: can our healthcare system serve ALL the people?
- (Issue - 77) Provide a healthcare system that is accountable, serve the public advocate who wants no risk, and serve the patient with critical illness who is willing to sustain a high level of risk
- (Issue - 78) Maximize benefit while reducing risk and eliminating harm: research, gather data, make judgements based on our experience and values, use decision making skills, communicate, educate
- (Issue - 85) Ask the right questions, think proactively about safety, incentives about best practice, begin to understand current approval standards, to think about improving them and the implications of improving them
- (Issue - 100) Create new agency on drug safety to avoid FDA's mixed role as approvers and evaluators
- (Issue - 102) Prioritize high leverage actions that can be addressed soon
- (Issue - 103) Apply knowledge we already have to solution of problems
- (Issue - 105) Transition of medicine from an art to a science, a system not a cottage industry
- (Issue - 124) New needs should not be addressed with old mechanisms
- (Issue - 131) Provide an oversight body to consider the effects of recommendations on changes to the system
- (Issue - 138) Dialogue to begin to understand the complexities and interdependencies of this system, so that we can all push in the same direction
- (Issue - 139) Couch the issue of drug safety within the context of quality assurance. How much do we spend for healthcare and what do we get for it?
- (Issue - 140) The FDA needs to use the authority of its capable scientists and policy makers to be more outspoken in the marketplace
- (Issue - 141) Need for new paradigms within each profession for the cause of safety

CLUSTER #2 -- PRE-MARKET RISK ASSESSMENT

- (Issue - 24) Acknowledge improved pre-market, pre-approval risk management
- (Issue - 26) Acknowledge improved outcomes from pre-market review process
- (Issue - 28) Emphasize standards for FDA approval: how effective should drug be? How many patients, for how long, and how well should patients be studied before release?
- (Issue - 34) Raise the bar for FDA approval in pre-market phase.
- (Issue - 60) Better pre-market phase oversight, with more information on older patients
- (Issue - 61) Provide definitive risk/benefit w/ control data. Consider safety not just during product application, but pre-market phase
- (Issue - 99) Raise the bar on FDA approval standards, get more data, define FDA's role in managing medical errors, risk management actions in future
- (Issue - 101) Pre-marketing approval process creates a group of drug experts
- (Issue - 137) Develop a realistic view of risk

Table 3: Classification of Issues Generated through Content Analysis of the Interviews Conducted with Selected Representatives of the Community of Stakeholders (cont.)

CLUSTER #3 -- PARTNERSHIP BUILDING

- (Issue - 20) Increase understanding of partnerships in public health
- (Issue - 23) Acknowledge that safety issue is an international one
- (Issue - 31) Improve quality control: US market is well controlled, though global market is not
- (Issue - 52) Provide reporting information to Joint Commission of Healthcare Orgs., State Boards, Pharma boards, Depts. of Health, Med Boards
- (Issue - 83) Bring together groups involved with med safety - civic community, health industry: all blaming themselves for lack of communication among systems. Silo formations. MD, community health pro, pharma all exist in isolation. even church battles
- (Issue - 84) Knowledge gets lost in the holes in system
- (Issue - 90) 98% public believes they have a role in public safety, but they don't know what it is
- (Issue - 95) Boards of Meds, pharma, professional societies, HMOs are set up to deal with misprescribing, off label use, costs issues, as well as harm to patients
- (Issue - 96) Quality in med use is dealt with by a collaboration of partners, no one can say who's in charge
- (Issue - 97) Clarify everyone's role: analyzing data, modifying practice pattern. Med errors, e.g.: FDA has a leading role with packaging problem
- (Issue - 102) Prioritize high leverage actions that can be addressed soon
- (Issue - 103) Apply knowledge we already have to solution of problems
- (Issue - 118) Educate in medical, nursing, and pharmacy schools that healing is a partnership between patient and provider
- (Issue - 119) Teach culturally competent and sensitive care for greater patient buy-in
- (Issue - 122) FDA's role in solution of patient safety issues should not be driven by its historical framework as a regulator
- (Issue - 123) FDA and private partners should join to create a solution to problem of safe drug use
- (Issue - 125) Patient understanding and buy-in to intervention protocol is only way to assure adherence
- (Issue - 126) No "ownership" of new needs rising from recent healthcare system changes: e.g., demand management capability
- (Issue - 127) Educate the patient and patient's family to ask the right questions
- (Issue - 130) Understand the safety is a series of dynamic relationships, with mutual understanding of limitations
- (Issue - 135) Greater attorney participation in resolving problem of error reporting

Table 3: Classification of Issues Generated through Content Analysis of the Interviews Conducted with Selected Representatives of the Community of Stakeholders (cont.)

CLUSTER #4 --SAFETY CHAIN DISTINCTIONS

- (Issue - 1) Distinguish between intrinsic safety of drug and medication errors
- (Issue - 15) Need for clearer information about reactions that aren't unique to these drugs, but manifest as increased frequencies of reactions that might occur normally
- (Issue - 33) Apply diagnosis to public health problems as well: decide what problems we want to address.
- (Issue - 35) Evaluate risks in a systems context. Healthcare system, and how we manage risk, can be better managed.
- (Issue - 38) Post-market assessment of benefit and risk tests two things: efficacy, and effectiveness
- (Issue - 56) Utilize physician participation to overlook reports as they come in
- (Issue - 57) Better failure analysis
- (Issue - 67) Duplicate reporting to FDA and company, multiple reporting from different people confuses events, impossibility of accurate risk estimate
- (Issue - 68) Establish causality with better reporting
- (Issue - 69) Establish whether event is caused by drug, by disease itself or something else entirely
- (Issue - 111) Not require reporting, but focus on making drug use safe

CLUSTER #5 --SAFETY CHAIN TRANSPARENCY

- (Issue - 2) Improve on train & blame strategy for use safety
- (Issue - 21) Move to continuous process improvement mentality rather than punishment mentality
- (Issue - 42) Threat of malpractice can hinder error admissions from physicians
- (Issue - 43) Focus on public health and safety, it's not a competitive issue, e.g. antitrust laws
- (Issue - 46) Allow reporting individuals the choice to be identified or not
- (Issue - 47) Use voluntary reporting in practitioner program for medical errors
- (Issue - 75) Notify physicians actively about problems through press releases
- (Issue - 79) Provide a forum, a safe place to talk about mistakes
- (Issue - 80) Recognize blame as a social artifact that we assign after the fact - lesson from risk industries, nuclear industry, aerospace industry. Often used to close the books, but we need to learn
- (Issue - 81) Identify how to do all the things in Issue 79 better
- (Issue - 82) Work with the legal system instead of allowing it to hinder us
- (Issue - 104) Eliminate fear of talking in cultural sense, the notion of shame
- (Issue - 106) Build in continuing education credits on adverse drug event issues, medication errors, test individuals on adverse drug events
- (Issue - 107) Internet promotion & sale as well as information. FDA should provide accurate info to consumers ASAP
- (Issue - 110) All reporting is actually voluntary, whatever the FDA mandates (Charles Billings, from aviation control)
- (Issue - 128) Provide correct and complete information
- (Issue - 129) Educate providers as to what patients can realistically be expected to know
- (Issue - 133) Create a list of patient responsibilities, e.g., Patient Bill of Rights
- (Issue - 134) Provide patient package inserts with medication information
- (Issue - 142) Need for a process to deal with competing interests in this system
- (Issue - 144) Need to establish safe standards for informing prescribers about medicinal chemicals: common dosages, side effects, etc.
- (Issue - 145) Need to establish the influence of professional and organizational roles on safety of medicine use

Table 3: Classification of Issues Generated through Content Analysis of the Interviews Conducted with Selected Representatives of the Community of Stakeholders (cont.)

CLUSTER #6 -- INFORMATION TECHNOLOGY (IT) SYSTEMS

- (Issue - 16) More access to new resources: medical record automated systems, healthcare systems, insurance systems
- (Issue - 17) Improve flawed database systems; FDA, HMO systems are not set up to provide efficient use of data
- (Issue - 22) Use of large automated multipurpose population based databases to help pharmacoepidemiologists
- (Issue - 44) Utilize data from Institute for Safe Medical Practices' (ISMP) volunteer practitioner reporting program
- (Issue - 45) Utilize ISMP volunteer practitioner reporting program, separate from FDA MedWatch program
- (Issue - 70) Facilitate new FDA database system for electronic submissions
- (Issue - 71) Use large healthcare databases: HMOs w/ information on vaccinations and outcomes already have data
- (Issue - 72) Register product use, so that those who receive drugs can be directly followed, esp. during pregnancy
- (Issue - 92) Increase funding for FDA IT system, (almost in place) that will be able to provide data to interested parties
- (Issue - 109) Need for a better way to process too much information
- (Issue - 117) Hospitals spend dollars competing with each other over large diagnostic equipment rather than upgrading internal IT systems

CLUSTER #7 -- POST-MARKETING SURVEILLANCE

- (Issue - 50) Inaction during collection of data on errors can slow down reaction time - lead to more deaths. Blinded data already exists
- (Issue - 51) Field reports that are mandatory do not identify potential errors - BEFORE they happen. These reports require facility reports.
- (Issue - 62) Better surveillance in post-marketing programs, looking for new problems w/ wider use, more heterogeneous populations
- (Issue - 73) Clarify expected risks w/ long-term follow-up studies.
- (Issue - 74) Post-market surveillance includes label changes to include observed risks, e.g. contraindications, warnings
- (Issue - 91) Post-marketing surveillance, for rare, serious adverse events, functions well, even internationally

Table 3: Classification of Issues Generated through Content Analysis of the Interviews Conducted with Selected Representatives of the Community of Stakeholders (cont.)

CLUSTER #8 -- POST-MARKETING ASSESSMENT

- (Issue - 14) Need for increased availability of information about reactions to drugs that aren't identified before drugs are marketed
- (Issue - 30) Improve calculation of risk: how many of known side effects are preventable, with, e.g., chemotherapeutics?
- (Issue - 39) Post-market assessment of benefit and risk depends on good data and use of large data systems, when they are safe and confidential
- (Issue - 40) Post-market assessment of benefit and risk calculates where drug fits into the armamentarium left to individual practitioner
- (Issue - 41) Post-market assessment of benefit and risk based on three principles: objectivity; equity; and accountability
- (Issue - 48) Properly utilize information retrieved from practitioners
- (Issue - 59) Unusability of MedWatch data by practitioners, only summaries available. Need more access to FDA data for reports on medical errors
- (Issue - 94) FDA system not intended or designed to deal with drug use or issues of misprescribing drugs
- (Issue - 98) FDA management actions on risky pharmaceuticals: mandate testing by pharma firm, restricted distribution to group of practitioners, registries
- (Issue - 106) Build in continuing education credits on adverse drug event issues, medication errors, test individuals on adverse drug events
- (Issue - 107) Internet promotion & sale as well as information. FDA should provide accurate info to consumers ASAP
- (Issue - 120) Emphasize alternatives to medicating patients, who may need a different form of intervention
- (Issue - 121) Teach that every interaction with a patient is a teachable moment

CLUSTER #9 -- POST-MARKETING REPORTING

- (Issue - 12) Identify reasons for inadequate adverse drug reaction reporting to FDA
- (Issue - 25) Acknowledge pre- and post-market surveillance improvement in science of drug/drug interaction
- (Issue - 27) Decrease in rate of label changes with post-market adverse reaction reporting
- (Issue - 32) Improve lack of adequate and reliable data, e.g. bleeding from heparin not reported because "everyone knows it happens."
- (Issue - 54) Provide proper funding to enhance voluntary reporting
- (Issue - 63) Improve frontline spontaneous reporting system. Reports to companies who then report to FDA slows process down
- (Issue - 64) Spontaneous reporting gets wide coverage at little cost, rare events can come to light rapidly
- (Issue - 65) Identify reasons for underreporting when there is no way to know how serious the problem is
- (Issue - 66) Improve inaccurate reporting: forms filled out by people who are not used to them
- (Issue - 113) Educate drug dispensers to understand that immediate error reporting can save lives that may be at risk but are not yet harmed
- (Issue - 114) Create a system where reporting, i.e., acting to prevent a greater mistake, is rewarded
- (Issue - 115) Use reporting as a way of learning, to improve systems to avoid future problems
- (Issue - 116) Reduce risk with a strong orientation toward patient concerns as an antidote against malpractice suits
- (Issue - 132) Voluntary reporting depends on a system that responds with investigation and change to avoid the same problem in the future

Table 3: Classification of Issues Generated through Content Analysis of the Interviews Conducted with Selected Representatives of the Community of Stakeholders (cont.)

CLUSTER #10 -- HUMAN FACTORS

- (Issue - 3) Lower high performance 99.95% error rate
- (Issue - 4) Design systems for the application of human factor principles: safety by design
- (Issue - 6) Improve product design: packaging products should be tested by human factors experts for all new drugs
- (Issue - 49) Require pharma to undertake systematic analysis of potential for error with external review by practitioners
- (Issue - 55) Ensure cooperation of human factors experts
- (Issue - 93) Institutionalize medical errors programs, more sophisticated tools to measure error, avoid name mix-ups
- (Issue - 112) Restrict access to dangerous drugs, e.g. potassium
- (Issue - 143) Need to establish prevalence of errors from current literature

CLUSTER #11 --PRODUCT DESIGN

- (Issue - 5) Acknowledge danger of sound alike names, lookalike pills, packaging variations
- (Issue - 6) Improve product design: packaging products should be tested by human factors experts for all new drugs
- (Issue - 7) Get rid of derivative drugs; one name for each drug
- (Issue - 8) Ensure one pill design per drug
- (Issue - 10) Bar-code products
- (Issue - 11) Produce identical labels for any given drug
- (Issue - 37) Overprescribing, underprescribing, misprescribing are all problems, esp. off-label use, when the label is a guidance document for practice
- (Issue - 53) Packaging, labels, product information, samples of MDs handwriting
- (Issue - 58) Electronic standardization of labels, prescriptions, bar-coding
- (Issue - 108) Standardize bar codes for dosage, expiration dates, drug/drug interactions

CLUSTER #12 -- RISK PERCEPTION

- (Issue - 29) Consumer has no access to risk/benefit information written in patient's language, despite FDA mandate
- (Issue - 86) Improve understanding of therapies that come from other cultures and how we evaluate them. May carry different values about risk
- (Issue - 87) See safety as a perception, a lens through which we look at the quality of healthcare we get
- (Issue - 88) Awareness created in airline industry that there is risk. Oxygen mask, exit aisle, etc. We need to create same sense in healthcare
- (Issue - 89) Understand perceptions of public about error: 42% public believes they or member of family has been exposed to wrong diagnosis or inappropriate treatment
- (Issue - 136) Educate patients to perceive medication as a continuous calculation of benefit to risk
- (Issue - 137) Develop a realistic view of risk

CLUSTER #13 -- SPECIAL POPULATIONS

- (Issue - 9) Growing segment of aging population
- (Issue - 13) Need for increased information about drug reactions in special populations: e.g. elderly, & children
- (Issue - 60) Better pre-market phase oversight, with more information on older patients
- (Issue - 119) Teach culturally competent and sensitive care for greater patient buy-in

APPENDIX B

List of Participants

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APPENDIX B

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Linda T. Kohn, PhD
Senior Program Officer
Institute of Medicine

Jill Pierce, PhD
Senior Vice President
PAX Family Health Television

Bert Spilker MD, PhD
Senior Vice President, Scientific and Regulatory Affairs
PhRMA

Ben St. John (Invited)
Inspector General Office, HHS

Laurene West
Patient Consultant
Year 2000

NATIONAL PATIENT SAFETY FOUNDATION

Louis H. Diamond, MBChB
Chair, Applications & Learning Program
National Patient Safety Foundation
Vice President and Medical Director
The MEDSTAT Group

Martin J. Hatlie, JD
Executive Director
National Patient Safety Foundation

Carol A. Ley, MD, MPH
Vice Chair, Board of Directors
National Patient Safety Foundation
Associate Medical Director
3M

Eleanor M. Vogt, RPh, PhD
Senior Fellow
National Patient Safety Foundation

APPENDIX C

Prospective Stakeholder Organizations

PRELIMINARY IDENTIFICATION OF NATIONAL ORGANIZATIONS HIGHLIGHTED IN THE LITERATURE WITH A ROLE RELATED TO THE INITIATIVE

The following list is an unevaluated collection of national, (and some international,) organizations cited in documents reviewed in our initial content analysis of the literature related to Pharmaceutical Safety, especially focused on safe use. Note that some of these organizations are transient, have been renamed, or no longer exist. At some time they either produced cited material, were deemed relevant by active authors, or may be organizations which influenced current authors or in which they were members. Some, for example, the informatics groups, are indirectly influential via standards and so forth. This list will now be extended based on review of the NHC Index and confirmation of an interest or role in this focus of this project. The purpose of this list is to:

1. Provide a baseline list of acronyms and names which are in the related literature and may be employed by participants during the deliberations. For this purpose, this list is an aid to the facilitation team, recorders, reporters, authors, and reviewers. A subset or superset of this list may form an appendix or index for the final report.
2. Identify “agents for change” in a diffusion model of the initiative. A key stated purpose of the initiative is to identify “the players and their roles.” This list extends the consideration of organizations beyond those attending the event. It can be employed to look at the network of relationships.
3. Extend the review of websites, policy documents, guidelines, educational materials, research, collaborative initiatives, and literature.
4. Identify specific individuals with an interest in joining “the community.”
5. Employ 2,3, and 4 in the formation of a communication strategy.
6. Document the multiple associations of individuals in the workshop and “the community.”

The current list does not yet identify corporations, such as GM or Xerox, which have taken an active role in healthcare quality, nor does it identify specific hospitals, medical centers, pharmaceutical companies, or health care technology companies. It is also weak on special conditions, both medical and patient special interest groups.

Prospective Stakeholder Organizations (cont.)

AAAS	American Association for the Advancement of Science
AACP	American Association of Colleges of Pharmacy
AAHP	American Association of Health Plans
AAMC	Association of American Medical Colleges
AAPR	American Academy of Pharmaceutical Physicians
AAPS	Association of American Physicians and Surgeons
AARP	American Association of Retired Persons
ACMQ	American College of Medical Quality
ACP	American College of Physicians
ACP	American College of Physicians - Health and Public Policy Committee
ACPE	American Council on Pharmaceutical Education
ACS	American College of Surgeons
ADA	American Diabetic Association
AEI	American Enterprise Institute
AHA	American Hospital Association
AHCA	American Health Care Association
AHCPR	Agency for Health Care Policy Research part of DHHS
AHSR	Association for Health Services Research
	Alliance for Aging Research
	Alliance for Health Reform
AMA	AMA Council on Medication Education
AMA SSS	AMA Specialties and Services Section
AMA	American Medical Association
AMAP	American Medical Accreditation Program
AMIA	American Medical Informatics Association
ANA	American Nurses Association
ANA	Nursing's Safety and Quality Initiative
ANSI HISB	American National Standards Institute Healthcare Informatics Standards Board
APhA	American Pharmaceutical Association
ASA	American Society of Anesthesiologists
ASC	American Standards Committee (X12, X12N and Z80)
ASCP	American Society of Consultant Pharmacists
ASHP	American Society of Health-System Pharmacists
ASHRM	American Society for Healthcare Risk Management
ASHRM	American Society for Healthcare Risk Management
ASLME	American Society of Law, Medicine & Ethics
ASQ	American Society for Quality
ASSE	American Society of Safety Engineers / Healthcare Division
ASTM	American Society for Testing & Materials E31 Committee
	Best Practice Network
BHCAG	Buyers Health Care Action Group (Minnesota)
	Boston Collaborative Drug Surveillance Program
	Bureau of Quality Assurance at HEW
	Cato Institute
CCMUE	Canadian Coalition Medication Use & Elderly
CE	The Council of Europe
CEN	European Committee for Standardization Technical Committee 251
	Center for Health Policy Research
CePOR	Center for Pharmaceutical Outcomes Research at the University of North Carolina at Chapel Hill School of Pharmacy
CIOM	The Council for International Organizations of Medical Sciences
CIOM	Working Group IV on Benefit-Risk Balance for Marketed Drugs: Evaluating Safety Signals
	Coalition for Quality in Medication Use
	Committee on the Cost of Medical Care
	Committee on the Safety of Medicines

Prospective Stakeholder Organizations (cont.)

	CON Certificate of Need programs
	Consumer Coalition for Quality Health Care
DHHS	Department of Health and Human Services
EMCRO	Experimental Medical Care Review Organizations (a leading reform effort to integrate quality regulation into the Medicare Program)
EU	European Union
FAA	Federal Aviation Administration
FACCT	Foundation for Accountability
	Federal Employee Health Benefits Program
FIMDM	Foundation for Informed Medical Decision Making
	Forum for Health Quality Measurement and Reporting in the private sector.
GPIA	Generic Pharmaceutical Industry Association
	Harvard Risk Management Foundation
HAS	Health System Agencies
HCFA	Health Care Financing Administration
HCSI	Health Care Safety Institute
HELIX	Healthcare Education Learning and Information Exchange
HEW	Department of Health Education & Welfare (DHHS)
HL7	Health Level 7
HMO	Health Maintenance Organization
	Hospital Standardization Program of the American College of Surgeons (Predecessor to the JCAHO)
HRG	Health Research Group of Public Citizen
HRSA	Health Resources & Services Administration, Sharing Innovations in Quality
HSP	Health System Plans
IAHHS	International Association for Healthcare Security & Safety
ICH	International Conference on Harmonization
IEEE	Institute of Electrical and Electronic Engineers P1157 & P1073 Committees
IHI	Institute for Health Care Improvement
	Information Industry Association
	Institute for Ethics and Policy Studies
IOM	Institute of Medicine
ISMP	Institute for Safe Medication Practices
ISTAHC	International Society of Technology Assessment in Health Care
JCAHO	Joint Commission on Accreditation of Healthcare Organizations
	The Keystone Committee
	Medic Alert Foundation
	Medical Outcomes Trust
MHQP	Massachusetts Health Quality Partnership
NABP	National Association of Boards of Pharmacy
NAHQ	National Association for Healthcare Quality
NAS	National Academy of Sciences
	National Coalition on Health Care
	National Council of State Boards of Nursing
	National Forum on Health (Canada)
	National Forum on Quality Improvement in Health Care
	National Prescribing Service Advisory Group (Australia)
	National Roundtable on Health Care Quality
NCCMERP	National Coordinating Council for Medication Error Reporting and Prevention - Taxonomy of Medication Errors
NCHC	National Coalition on Health Care
NCHSR	National Center for Health Services Research
NCL	National Consumers League
NCPIE	National Council on Patient Information & Education
NCQA	National Committee for Quality Assurance
NCSBN	National Council of State Boards of Nursing
NCVHS	National Committee on Vital and Health Statistics

Prospective Stakeholder Organizations (cont.)

NGC	National Guideline Clearinghouse www.guideline.gov a repository for evidence-based clinical practice guidelines with AMA and the AAHP
NHC	National Health Council
NHCSC	National Health Care Safety Council
NICHSR	National Information Center on Health Services Research and Health Care Technology
NIH	National Institute of Health
NIST	National Institute of Standards and Technology
NLN	National League for Nursing
NPAGE	National Program of All-Inclusive Care for the Elderly
NPC	National Pharmaceutical Council
NPSF	National Patient Safety Foundation
NPSF	National Patient Safety Partnership
NPSRC	National Professional Standards Review Council (see also SPSRC)
NQC	National Quality Council – VA
NRC	National Research Council
NTSB	National Transportation Safety Board
	Nursing Safety and Quality Initiative
NVAC	National VA Council
OECD	The Organization for Economic Cooperation & Development
OSHA	Occupational Safety & Health Administration
OTA	Office of Technology Assessment
PBGH	Pacific Business Group on Health
	Pharmacoinformatics Network
	Pharmacy Quality Council
PhRMA	Pharmaceutical Research and Manufacturers of America
PHS	Public Health Service
	Physician Insurers Association of America
	Picker Institute
PNHP	Physicians for a National Health Program
PNHP	Physicians for a National Health Program
PQC	Pharmacy Quality Council
	President’s Advisory Commission on Consumer Protection and Quality in the Health Care Industry
PROs	Peer Review Organizations – Professional Standards Review Organizations
PRSA	Public Relation Society of American / Health Academy
PSO	Provider Service Organization
PSRO	Professional Standards Review Organizations
PSRO	Professional Standards Review Organizations
	Public Citizen Research Group
	Quality Council (VA)
	Rand Corporation’s Health Insurance Experiment
RWJ	Robert Wood Johnson Foundation
SHEA	Society for Healthcare Epidemiology of America Inc.
SIQ	Sharing Innovations in Quality, non-regulatory collaborative project including HRSA – State Agencies, Consumer, Professional and Industry Representatives
SPSRC	State Professional Standards Review Councils
	State Boards of Medical Examiners
	State Medical Society
	State Pharmacy Boards
	Task Force on Prescription Drugs
	The Medical Review and Accrediting Council, subsidiary of the state medical society
USP	Advisory Panel on Medication Errors
USP	United States Pharmacopoeia
VA	Department of Veterans Affairs
	W. K. Kellogg Foundation
WHO	World Health Organization
	Workgroup for Electronic Data Interchange

APPENDIX D

The National Patient Safety Foundation

APPENDIX E

Advisory and Oversight Boards

NATIONAL PATIENT SAFETY FOUNDATION Rx SAFETY PROJECT: LIST OF CRITICAL EVENTS FOR REVIEW AND FEEDBACK

by the NPSF Board Project Oversight and Technical Advisory Committees and the NPSF Program Chairs

1. Review and comment on list of stakeholders a) to be interviewed for the preparation of the “White Paper and b) to be invited as participants for the two day consensus building workshop – due May 3.
2. Review and comment on draft of “White paper” – due May 23.
3. Review and comment on Workshop Report – due July 11

Roles and Responsibilities

National Patient Safety Foundation Board Oversight Committee: Mary Woolley, David Lansky & Carson Porter

This committee represents the generalized, at-large stakeholder community that is not directly participating in the project. This unique perspective will ensure the integrity of the project by 1) emphasizing the qualities of neutrality and inclusiveness and 2) assuring the alignment of the project with the NPSF Vision and Mission to measurably improve patient safety.

Project Technical Advisory Committee: Henri Manasse (C. Myers), Janet Woodcock and Andrew Smith

This committee represents three of the major stakeholders who are directly participating in the project. This unique perspective will provide expert review and analysis of both the content and the process.

NPSF Program Chairs: Bill Hendee, Jeff Cooper, Dawn McGinley & Lou Diamond

The Program Chairs are functionally responsible for the specific program activities of the Foundation. In that capacity they will receive the reviews of the Board Oversight and Technical Advisory Committees and make recommendations, as appropriate, to the Foundation’s Executive Committee and Board of Directors.

criticalevents.doc

April 25, 1999

APPENDIX F

Inquiry Design and Facilitation Team

Alexander N. Christakis, Ph.D. & CEO

Dr. Christakis is responsible for all the technical aspects in implementing the Interactive Management approach for a variety of businesses, including the pharmaceutical, chemical, and insurance industries. His career experience includes a wide range of noteworthy achievements in the academic, business, and industrial arenas, both in the United States and internationally. Christakis has served on the faculties of Yale University, the University of Athens (Greece), and as Professor of Systems Management at the University of Virginia. He also spent five years at George Mason University, where he was Director of the Center for Interactive Management. In this latter role, he was responsible for the development and implementation of the *CogniScope*[™] system approach to “focused and open dialogue” which is used in the resolution of complex issues. Christakis holds an undergraduate degree in Physics from Princeton University and a Ph.D. in Theoretical Physics from Yale University. A keynote speaker at several international symposia, he is also the co-author of two books on Technology Assessment, and the co-founder of the Club of Rome. Numerous scientific papers written by Dr. Christakis on the management of complexity have been published. He is a member of the Editorial Boards of Systems Research and Behavioral Sciences, Systems: Journal of Transdisciplinary Systems Science, and the Journal of Applied Systems Studies.

Dimitri A. Christakis, MD, MPH

Dr. Christakis is an assistant professor of pediatrics in the department of pediatrics and the department of health services at the University of Washington. He completed undergraduate work at Yale University and Medical school at the university of Pennsylvania. He did his residency at the University of Washington and completed a Robert Wood Johnson Clinical scholarship in 1998. In 1999, he was awarded a Robert Wood Johnson Generalist Faculty Scholar grant. He has over 20 peer-reviewed publications. His present research interests include clinical practice guideline development and implementation and health services delivery to children with chronic health problems. He has worked at the National Institute of Neurological Communications Disorders and Stroke, the Department of Emergency Services at Children’s Hospital in Boston, and as a research associate in the Division of Oncology at the Children’s Hospital of Philadelphia. Dr. Christakis has participated in many CWA projects primarily offering his expertise in the development of pharmaceutical products and medical diagnostics.

Diane S. Conaway, Vice President

Diane is currently serving as Vice President of Operations for CWA, Ltd. As a member of the CWA facilitation team, Ms. Conaway is responsible for the overall flow in the application of the *CogniScope*[™] system approach during workshops. Her project coordination skills allow the facilitation team to perform smoothly when dealing with complex issues. She has trained others in the use of the *CogniSystem*© software, which is an integral component in the application of the *CogniScope*[™] process. As Vice President of CWA, Diane is responsible for the quality of services and products delivered by the company to its clients. Diane joined CWA Ltd. in 1992 and has been responsible for major process and product improvements in the practice Interactive Management.

Inquiry Design and Facilitation Team (cont.)

Kevin M.C. Dye, Chief Process Scientist

Kevin complements the CWA team with fifteen years experience in process redesign, cycle-time reduction, cost restructuring, and quality metrication. This spans roles in Fortune 20 aerospace & building systems and launch of two Decision Support Systems companies in finance and health care. His background is particularly apropos to CWA engagements in product development and strategic information technology acquisition & implementation. Kevin's "attention to method" was formed early in life through the arts especially through Japanese training in gymnastics and Tea Ceremony. The Thermodynamics faculty at Northeastern University introduced Kevin to systems thinking where he was conferred with the Outstanding Senior Award in Mechanical Engineering. Continuing his pursuit of method in a professional realm he mastered a broad collection of techniques through apprenticeships with practitioners of Systems Engineering, Total Quality Management, Business Process Reengineering, and Design Theory & Methodology. In 1994, he became a Sloan Visiting Fellow at MIT, where he began research on the Coordination Science of Interactive Management and its applications to Process Architectures and Product Platforms. Kevin provides CWA clients a unique combination of change-agent experience and deep insight into methodological foundations.

J.Christopher Feudtner. MD, Ph.D.

Dr. Feudtner is presently a Robert Wood Johnson Clinical Scholar at the University of Washington in Seattle. Chris received his M.D. and Ph.D. from the University of Pennsylvania School of Medicine and Department of the History and Sociology of Science. He is a reviewer for the Journal of the American Medical Association, Journal of General Internal Medicine and the Bulletin of the History of Medicine. In addition, he has authored and co-authored numerous articles, many of which have been peer reviewed. He has collaborated with Dimitri A. Christakis in a series of Articles focusing on the "Ethical Dilemmas" that Medical Students confront, some of which have been published in *Academic Medicine*. Chris has extensive experience with the application of the *CogniScope*TM system approach, and has been involved in a number of applications with the FDA as a member of the CWA Ltd. team.

Diana Post, Technical Specialist

Diana received her MA in Genetics from the University of Pennsylvania and her undergraduate degree in Comparative Literature and Biology from the same institution. Diana spans the humanities and science to translate complex technical subjects, particularly the scientific world, and make them more accessible. At McGraw-Hill Publishing, she worked as a science writer/editor specializing in new biotechnology business ventures. She researched and built a library of information on workplace toxins and risk management for one of Philadelphia's top law firms. The Philadelphia Department of Streets hired her to integrate and educate the public and private sectors about solid waste management. As a part of the CWA team, Diana is responsible for stakeholder preparation, team education, and both recording and facilitating organizational change and learning, especially during the application of the *CogniScope*TM system.

APPENDIX G

SCENARIO FOR THE NATIONAL PATIENT SAFETY FOUNDATION WORKSHOP ON AN INITIATIVE FOR IMPROVING PHARMACEUTICAL SAFETY

PREFACE

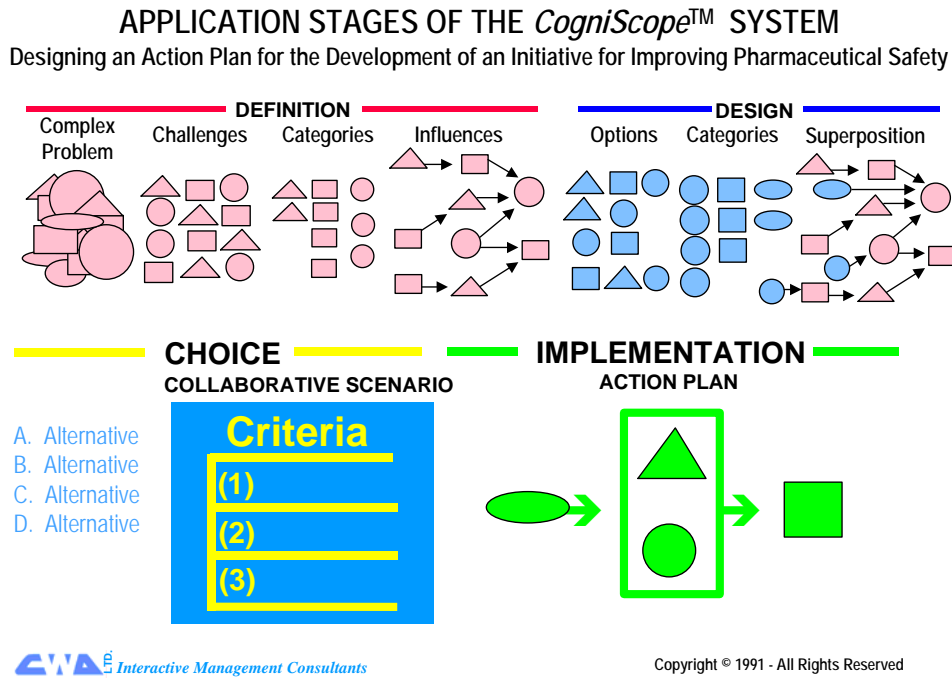
Participants representing the community of stakeholders interested in the safe use of pharmaceuticals are convened. This group has been carefully selected to cover the diversity of experiences and knowledge needed for the success of an initiative for improving pharmaceutical safety.

Before the workshop, participants will have received a Preliminary White Paper summarizing the thinking of key leaders within the community of stakeholders including, the National Patient Safety Foundation/AMA, the pharmaceutical industry, oversight and regulatory agencies, patients, consumers, and others. This paper provides the context for the workshop deliberations about responsibly serving the public's interest and the nation's health. The participants' sole responsibility in preparation for the workshop is a careful reading of this White Paper.

As the participants arrive in the large and pleasant Collaborative Facility (see Attachment 1), they note the layout, with a large table and comfortable chairs for the participants. At each seat, there is a name card and a prepared workbook enabling the participants to track the progress of the deliberations. As the workshop proceeds, participants receive in real time written products of the group's work.

On a wall near the table is a projection screen in view of the entire room. The screen exhibits the groups' ideas as they are proposed and supports the group in exploring relationships among ideas, which helps focus the dialogue and build patterns of ideas. During the two-day workshop the participants co-create a series of idea patterns, gradually converging to the design of a Collaborative Action Scenario identifying actions and roles for the various actors along the pharmaceutical safety chain. The four stages of the process to be employed by the representatives of the community of stakeholders are shown below:

Figure 1:



DAY 1: DEFINITION STAGE

The workshop begins with a short welcome from a representative from the NPSF. Participants then briefly introduce themselves.

Aleco Christakis, the Lead Facilitator, assures participants that a climate of equity, authenticity and humility will prevail during their deliberations at the workshop. The facilitator reviews the agenda, and introduces the **triggering question**. This question which represents the entry point to the group dialogue has been framed after careful review of the relevant literature and content analysis of the responses to the interviews conducted during the preparation of the White Paper by the project team. The triggering question reads:

“What challenges do we anticipate the community of stakeholders will face in improving pharmaceutical safety?”

Participants silently think and write their responses to the triggering question. Their contributions are then voiced and recorded. The language of the participants appears on the projection screen. The facilitation team prints each contribution in large font, color coded in red to identify the **definition of the situation** stage of the process. The printouts are posted on the wall, so that the participants can see at a glance all the “challenges” they have identified.

After all challenges are recorded, each participant clarifies his/her statements through focused and open dialogue, and the facilitation team captures the meaning of each contribution for inclusion in the workbook. Through listening to each other, the group creates a common language for addressing the situation.

The participants vote, individually and subjectively, on the five challenges that each participant believes are the most important. As the participants draw away from the wall, the distribution of votes reveals the diversity of viewpoints.

Starting with those challenges that received the most votes, the participants methodically explore the influences among them two at a time. The participants are intrigued, as they are invited to focus on the generic question:

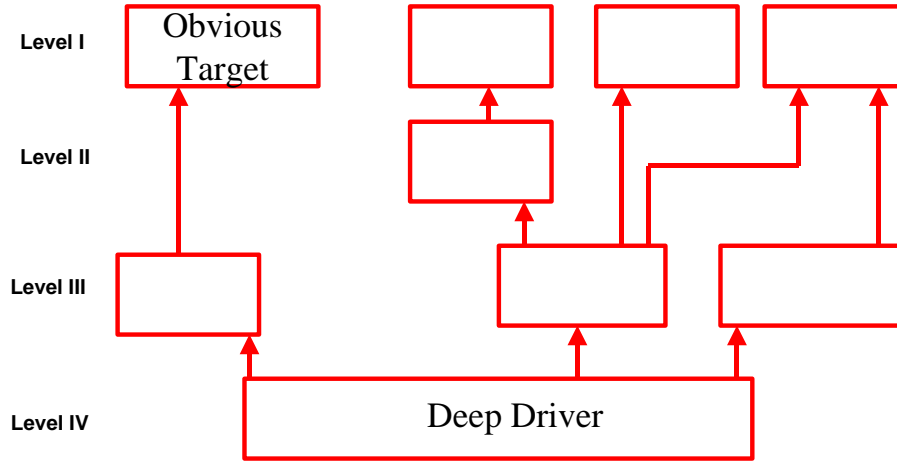
“Suppose the community of stakeholders is able to make progress in meeting (Challenge X), Will this help significantly in meeting (Challenge Y)?”

The representatives vote yea or nay on each question as it appears on the screen and explain the rationale for their votes.

When all of the questions have been considered, the screen shows a map of the influences as generated by the participants. This map represents the “system of challenges” that the participants must address through collaborative action. The group arrives at a systemic understanding of the situation. Exploring influence relationships among challenges enables the participants to draw distinctions between strongly influential challenges and those challenges that, although they appeared to be important during the individual and subjective voting, are not exerting strong influences on other challenges (see Figure 2).

Figure 2:

Seeing a Leverage Map of the System of Challenges Facing the Community of Stakeholders



The example shown above is an INFLUENCE structure.
↑ demonstrates the direction of influence.

The participants break for dinner and informal conversation in small teams of six participants per table with diverse perspectives. During the dinner they are offered the opportunity to reflect upon the enlarged perspective and the convergence of views about what challenges are strongly leveraged and what action options they would like to propose the next day for meeting the most influential challenges. Although there is some sense of being overwhelmed by the diversity of views, in light of what they have already witnessed during the course of the day, there is also high expectancy of the possibility of the community meeting the system of challenges.

DAY 2: DESIGN STAGE

The design stage of the process begins. The challenges from the previous day are on the wall in red paper, as is the influence map, and these products are delivered to the participants for inclusion in the workbooks. The prior day's work is revisited for discussion and interpretation of the meaning of the products. The configuration of the Facility has been changed so that participants are seated in round tables of six per table (see Attachment 2).

Participants are asked to make contributions and clarify the meaning of action options for meeting the system of challenges, employing a process for generating and explaining their ideas similar to that used on Day 1. The triggering question for the second day is:

“What are action options which, if adopted and implemented by the community of stakeholders, will maximize the plausibility of meeting the system of challenges?”

The proposed action options are posted on the wall on blue paper.

During the lunch break the Facilitation Team organizes the proposed action options into similar categories by focusing on the question:

“In the context of designing an Action Plan for improving pharmaceutical safety, does:

(Option-X)

Have significant characteristics in common with (is similar to):

(Option-Y)?”

After the clustering of the action options is completed with input from the participants, they will vote, individually and subjectively, on the five options that each participant believes are the most important. Again, as the participants draw away from the wall, the distribution of votes reveals the diversity of viewpoints in terms of action options.

Studying the proposed action options, the participants begin to discover the interdependencies amongst their roles in the pharmaceutical safety chain. A clear understanding of how the group could act collaboratively to have a powerful impact on patient safety can ignite the motivation to work together to maximize benefit, reduce risk, and eliminate harm in the use of drugs. Participants leave the Collaborative Facility in small groups, enthusiastically engaged in dialogue on how stakeholders can work together.

FOLLOW-UP DELPHI: CHOICE STAGE

Shortly after the workshop, participants respond to a DELPHI study, a proven consensus method for generating, clarifying, and amending ideas. The Facilitation Team will organize the information from the workshop and provide some interpretive comments, primarily to make the ideas and patterns produced by the participants more transparent. DELPHI respondents will first review the products of the workshop to suggest possible amendments.

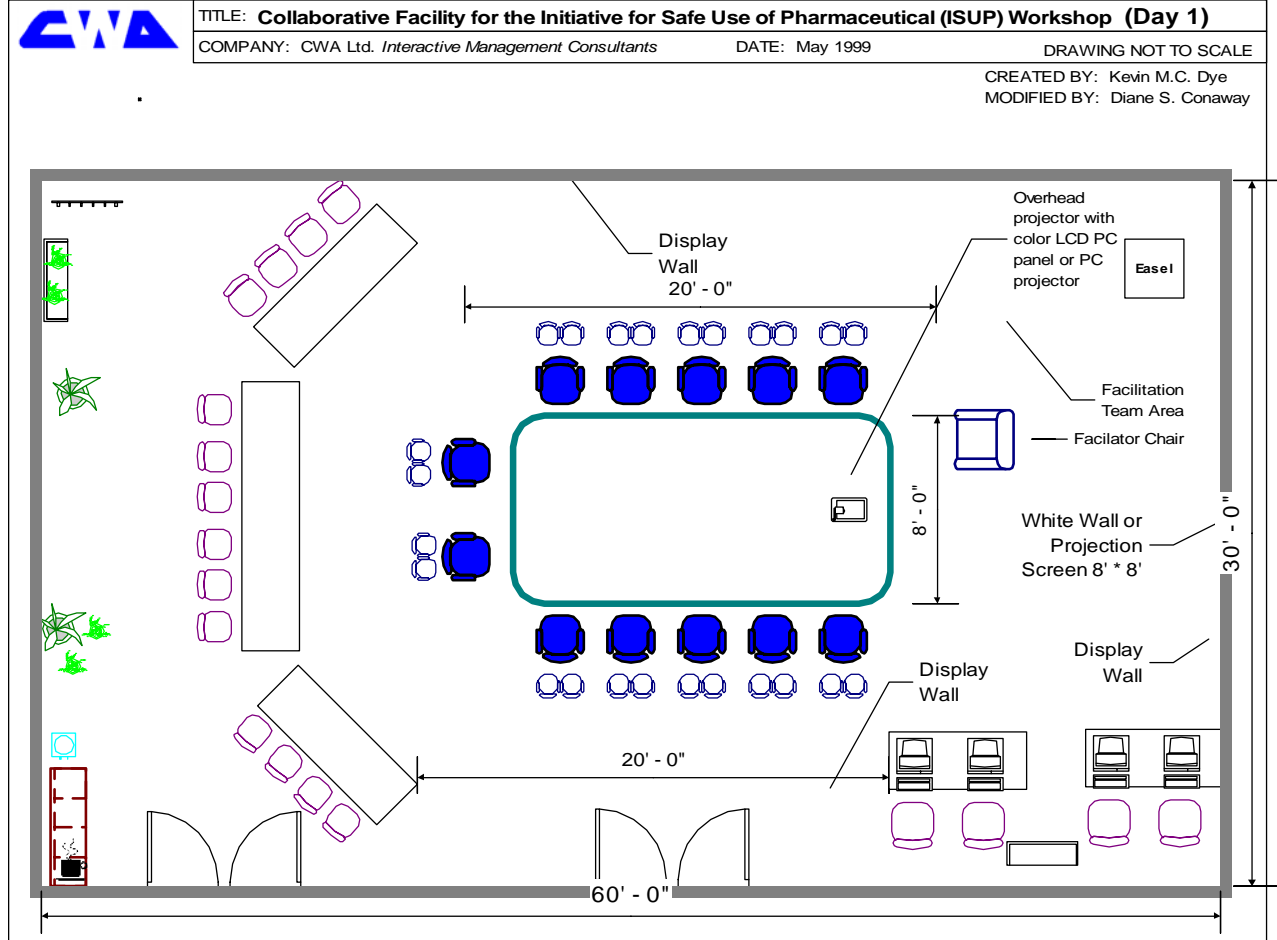
They will then be asked to make **choices** among the action options for meeting the system of challenges in order to design a Collaborative Action Scenario. An action scenario is defined as a subset of options (blue ideas), selected from the set of all participant contributions, that offers the highest desirability and plausibility of attaining the objective, i.e., identifying roles and actions for meeting the challenges for pharmaceutical safety for all actors in the safety chain. The choices of options will be informed by the shared understanding of the high leverage challenges that was reached during the workshop (See Figure 2). With the understanding and language developed over the two-day workshop, the scenarios are usually profound, rich, highly focused, and easily communicated.

CONCLUSION

The risk that unanticipated challenges and uncoordinated actions will be encountered during the implementation of the action scenario by the community of stakeholders has been greatly reduced through the collaborative design process applied during the two-day workshop. The value that this approach offers is framed in terms of the risk, time, and costs savings associated with reaching a commitment to a plan of action from a broad range of stakeholders. By leveling the playing field in the Collaborative Facility, each participant has had an equal share in designing the action scenario, and by extension, equal ownership in the implementation.

The climate of equity, authenticity, and humility has allowed the participants to accomplish a great deal of work, while carrying none of the responsibility for the management of the process itself. By co-designing a scenario for identification of the roles and responsibilities along the pharmaceutical safety chain, participants can leave with a clear vision of the interdependencies needed to build the partnership, and the ownership of individual roles within the common vision of working together for improving pharmaceutical safety.

ATTACHMENT 1 - DAY ONE FLOORPLAN



ATTACHMENT 2 - DAY TWO FLOORPLAN



TITLE: **Collaborative Facility for the Initiative for Safe Use of Pharmaceutical (ISUP) Workshop (Day 2)**

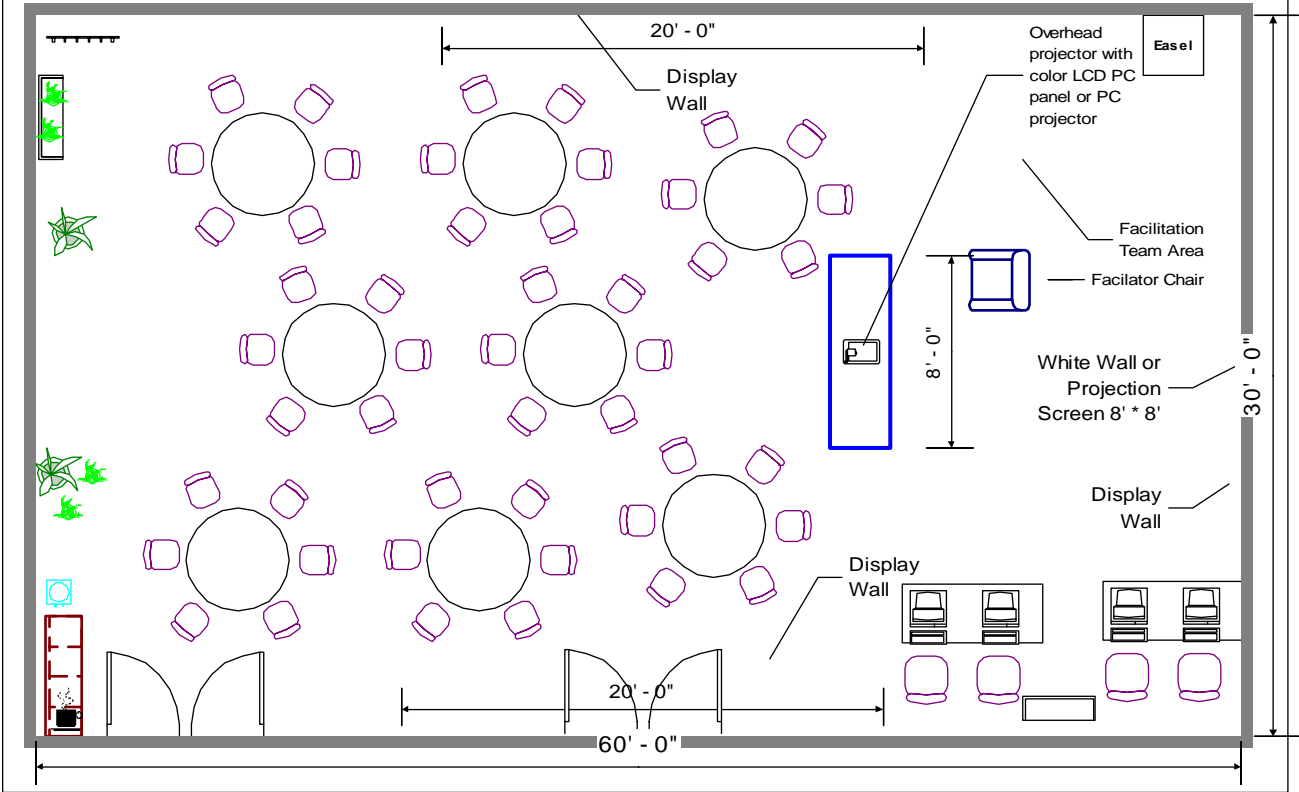
COMPANY: CWA Ltd. *Interactive Management Consultants*

DATE: May 1999

DRAWING NOT TO SCALE

CREATED BY: Kevin M.C. Dye

MODIFIED BY: Diane S. Conaway



APPENDIX H
Glossary of Terms

APPENDIX I

Marshaling Events in Pharmaceutical Safety & Appropriate Use

This section is a collection of influential events cited in the literature review. We intend to develop it more fully as a touchstone regarding the long history on the topic. We have not yet turned to books on the histories of the related fields. It serves only as an indication of the historical formation of our culture of safety as it currently stands. It does not reference many important conferences and publications as yet, nor founding dates for related organizations. Events highlighted in the NPSF newsletters are also absent. In general, it is also unbalanced with respect to highlighting the “benefits” side of the issue.

Markers in the discussion

- 1817 Dr. Lyman Spalding submits a plan to create a National Pharmacopoeia
- 1820 First U.S. Pharmacopeial Convention
- 1847 Founding of the AMA
- 1848 Congress forbids Drug Adulteration
- 1856 Elisha Graves Otis Safety Brake
- 1879 Squib prepares a rough draft for a proposed law.
- 1892 58th Congress passes an Omnibus Bill on Pharmacopeial Standards and Names
- 1898 National Pure Food & Drug Congresses
- 1898 AHA Founded
- 1902 At least 37% of Drugs proven to be adulterated, 315/345 suspected
- 1903 Samuel Hopkins Adams calls the patent medicine business “The Great American Fraud” and the industry is condemned by journalists.
Omnibus Laws move to include “proprietarys”
- 1904 The beginning of the “Progressive Period”
- 1906 Pure Food & Drug Act (The Wiley Act)
Upton Sinclair Publishes “The Jungle” although focused on the problem of labor in the food processing industry it spurs legislative action on drugs as well.
- 1912 Cited as the first year “a random patient, with a random doctor...” stands a 50-50 chance.
- 1914 Codman, in conjunction with industrial engineers forms a view of the hospital as a production system and “discovers” the Product of Health Care and calls for a focus on systematic data analysis and research, along with teaching and professional learning.
- 1917 American College of Surgeons’ for Hospital Standardization Survey
- 1920s Werner Schultz in Germany observe agranulocytosis, an Adverse Reaction to an analgesic.
- 1933 Lee-Jones Report of the Committee on the Cost of Medical Care a Policy Model focused on the prevention, adequacy, availability & compensation and emphasized preventive medicine and public health practice. A comprehensive bottom-up analysis, driven by an expert-consensus approach to develop a model of the total demand for health care services based not on existing patterns of care but ideal images of care given the best available scientific evidence. (Berwick 102)
- 1937 Diethyleneglycol introduced as a solvent for sulfanilamide – 105 people killed.
- 1938 FDA&C Act
Creation of the Food & Drug Administration

APPENDIX I

Marshaling Events in Pharmaceutical Safety & Appropriate Use (cont.)

- 1940s Human Factors Field begins as a partnership between psychologists and engineers
Hospital Standardization Program of the American College of Surgeons (Predecessor to the JCAHO)
- 1942 ASHP Founded
- 1946 Hill-Burton Act focuses on access
The disconnection of quality regulation from clinical activity.
Passing of the Progressive era and with it a progressive phase in professional medical self-regulation. (Berwick 104)
Professional Societies consolidate their hegemony over the right to judge the quality of work of medicine, a right exercised mostly in secret. (Berwick 104)
Biomedical science begins its rapid ascent drawing away intellectual resources from the less crystalline challenges of policy, systems, and day to day work. Whatever the cause, a wide chasm began to open between the real workings of health care – its management, financing, and provision – and the concerns of those few and scattered academicians who continued to make the quality of health care an object of their investigations. (Berwick 104)
- 1951 JCAHO incorporated
- 1956 AMA Registry of Reports of Blood Dysrasias initiated
- 1958 Assistant Commissioner of Patents address the 46th American Drug Manufacturers Association admonishing that a key provision for Trademarks, to eliminate confusion and mistakes for the public was already a very serious problem in pharmaceuticals. She cites the threat of legislation such as the Dispensing Chemists Act of Denmark to severely restrict or prohibit trademarks and indicates the conflict with the International Convention on Protection of Industrial Property.
- 1962 Drug Industry Act
- 1962 Kefauver Committee Amendments for the evaluation of Efficacy
- 1962 Report to the Council on Drugs of findings in the AMA Registry
- 1960s Interest in an EPA initiated
Mine Safety and Health Administration
“Unsafe at any speed” published by Nader
Consumer Product Safety Commission
- 1964 Medicaid & Medicare
- 1964 Report of the Commission on Drug Safety
- 1966 Health Planning and Public Health Services Amendments funds state and local health planning
The call for a Systems Approach in Health Care
- 1969 Cyclamate Ban
- 1970 OSHA Act
- 1970s Three Mile Island
- 1972 Social Security Act Amendments create PSROs
- 1974 Health Maintenance Organization Act
- 1974 National Health Planning and Resources Development Act

APPENDIX I

Marshaling Events in Pharmaceutical Safety & Appropriate Use (cont.)

- 1974 NAS “How Safe is Safe”: The Design of Policy on Drugs and Food Additives Conference.
- 1974 The Privacy Act of 1974
- 1975 ASRS
- 1977 Safe Medication Act
Medicare Preventive Benefit Improvement Act
- 1978 Cooper Anesthesiology Systemic Incidence Reporting
Alfred Kahn’s work on the economics of regulation stimulates advocacy for deregulation and use of market incentives.
- 1982 Capsizing of the Herald of Free Enterprise
Programs in OSHA, EPA, and Consumer Product Safety Commission reduced, spending on regulation reduced 3% and regulatory personnel at the Federal level declined by 20%.
Richard J. Ward, M.D. Professor of Anesthesiology, University of Washington & Richard Solazzi study closed malpractice claims against anesthesiologists in Washington State.
ASA’s general goal is to find ways to promote and improve the safety of anesthesia (Caplan ASA) The Anesthesia patient safety movement.
- 1984 “ASA adopts a simple but far-reaching philosophy: the best method for controlling the cost of professional liability is the prevention of injuries.” Robert Caplan, ASA
Ward convinces Pierce, then president of the ASA that a nationwide effort would be the best way to realize the potential benefits of closed claims analysis. (Caplan, ASA Newsletter)
The Computer Matching & Privacy Protection Act 1984
- 1985 Anesthesia Patient Safety Foundation
US Pharmacopoeia Convention establishes the National Coordination Council for Medication Reporting and Prevention
Institute for Healthcare Improvement begins project to reduce Adverse Drug Events
Blood safety incidents due to Aids
- 1986 The Challenger Disaster
- 1987 Prescription Drug Marketing Act
- 1988 International Society for Pharmacoepidemiology founded
- 1988 Catastrophic Coverage Act
- 1989 AHCPR Founded
- 1990 Safe Medical Devices Act
- 1991 Healthy People 2000
- 1991 IHI Founded
- 1992 Federally Supported Health Centers Assistance Act
- 1993 FTCA Federal Tort Claims Act
- 1993 Harvard University Study
June 23 ASHP Guidelines on Preventing Medication Errors in Hospitals
Health Security Act

APPENDIX I

Marshaling Events in Pharmaceutical Safety & Appropriate Use (cont.)

- 1993 Government Performance & Results Act
- 1994 Leape, L. Error in medicine JAMA 1994, 2272, 1851-1857
- 1995 “Mayhem” and Amplification in the Media
Betsy Lehman at Dana Farber
University of Chicago Hospital Overdose
Ben Kolb at Martin Memorial
Libby Zion – Drug-Drug Interaction Case
Bates, D., Cullen, D., Laird, N. et al. Incidence of adverse drug events and potential adverse drug events: implications for Prevention, JAMA 1995; 274: 29-34A study of two tertiary care hospitals find that among nonobstetrical patients that suffered an adverse reaction to a prescribed drug, an estimated 28% were deemed preventable.
- 1996 Jose Martinez at Herman Hospital
- 1996 AMA launches the NPSF
October: Examining Errors in Health Care Conference: Developing a Prevention, Education and Research Agenda at the Annenberg Center for Health Sciences – “emphasis on Patient Safety galvanized” and marked the inception of the NPSF
VA Launches Public-Private Partnership
JCAHO Requiring Why creates accreditation watch replacing the punishment of probation with a more collaborative problem-solving approach
Health Insurance Portability and Accountability Act provides an excellent opportunity to rethink the nature of clinical and clinically relevant data and how new approaches to recording it could overcome current problems with incomplete and inaccurate data (aapsonline.org/aaps/newsletter/nov98.htm)
Reports of Quality Suffering Under Managed Care
JCAHO Sentinel Events Policy
David Bates Studies of Error
104th Congress Tort Reform Movement in Congress
AMA Begins partnering with Lucien Leape
PDUFA
FDAMA
FDA External Stakeholder Meetings
FDA Review
ASHP Council on Professional Affairs, Council on Legal & Public Affairs issue ASHP 9707 on Reporting Medication Errors and Adverse Drug Reactions
- 1996 HIPAA – Health Insurance Portability and Accountability Act
ASHP Research & Education Foundation to convene a group to discuss the development of fail-safe medication use systems
- 1995-96 Whistleblower Protection Amendment for Health Care Workers 1995-96
- 1997 FDA pulls 150 drug ads for false or misleading advertising (New York Times, Zuger, 8/5/97)
Bates, D., Spell, N., Cullen D., et al. The costs of adverse drug events in hospitalized patients. JAMA

APPENDIX I

Marshaling Events in Pharmaceutical Safety & Appropriate Use (cont.)

- 1997 Estimate that preventable adverse drug events cost an additional \$2.8 million for a 700-bed teaching hospital. \$2B a year nationally estimated.
- 1997 Medicare Medication Evaluation & Dispensing Act (The Stark Bill)
- 3/13/97 Health Care Quality Act passed in NJ
Massachusetts Model Database on physicians
- 8/28/97 As of 1997 only 16 states have comprehensive laws regarding health privacy. HHS calls for a new privacy law.
Legislation announced that would permit off-label information sharing with physicians.
- 8/22/97 Health Care Quality Act NJ
- 11/97 Patient Bill of Rights recommended by the President's Advisory Commission on Consumer Protection and Quality in the Health Care Industry
- 1997 December "Assembling the Scientific Basis for Progress on Patient Safety", Chicago
- 10/97 National Coalition on Health Care releases study on Quality of Care in America
National Health Care Safety Council
VA launches the National Patient Safety Partnership
- 1997 Medicare Preventive Benefit Improvement Act (The Thomas Bill)
- 1997 Safe Medication Act
- 1998 Measuring preventable medication misadventures - ASHP
- 1998 January 15, AJHP ASHP Definitions of Terms
NCCMERP – Taxonomy of Medication Errors
Presidential Commission on Health Care includes Patient Safety as a high national priority
Major journals recognize the topic
Leape L, Kabacoff A., Berwick, D., and Roessner, J., Breakthrough Series Guide: Reducing Adverse Drug Events. Boston Institute for Healthcare Improvement 1998
March 1998 President's Advisory Commission on Consumer Protection and Quality in the Health Care Industry, Quality First: Better Health Care for All Americans – Final Report to the President of the United States.
March 1998 President's Advisory Commission on Consumer Protection and Quality in the Health Care Industry proposes that the Forum for Health Quality Measurement and Reporting in the private sector and Advisory Council on Health Care Quality in the public sector serve as a vehicle to develop a comprehensive national plan for quality measurement, data collection and reporting standards. It would periodically endorse core sets of measures for standardized reporting of health care quality.
The Challenge and Potential for Assuring Quality Health Care for the 21st Century. Pub. No. OM 98-0009. Prepared by the Department of Health and Human Services for the Domestic Policy Council, Washington D.C., June 17, 1998 <http://www.ahcpr.gov/qual/21stcena.htm>
Chassin, Galvin and the National Roundtable on Health Care Quality: "The Urgent Need to Improve Health Care Quality," JAMA 280:1000-1005, 1998
June 17, Vice President Al Gore launched the planning committee that will create the Forum for Health Quality Measurement and Reporting in the private sector.
- 1998 U.S. district Court rolls back limits on off-label drug promotions. AMNews Summaries, September 7, 1998 based on pharmaceutical companies' rights to free speech.

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Marshaling Events in Pharmaceutical Safety & Appropriate Use (cont.)

3/31/98 JCAHO Sentinel Event Policy – voluntary reporting

QUEST Health Care Quality, Education, Security and Trust Act under consideration

4/1/98 PARCA Patient Access to Responsible Care Act under consideration

11/23/98 Web Based Healthcare Report Cards Stir Interest and Concern

Drug Companies expected to spend \$1Billion in Advertising in 1998

Department of Veterans Affairs – designs an error reduction system in healthcare for use throughout its delivery system taking lessons from the Aviation Safety Reporting System.

AAPS – Association of American Physicians and Surgeons, “Quality” =Compliance, Vol. 54, No. 11 November 1998, indicating a perceived increased pressure on independent physicians due to Chassin’s (urgent need) argument that quality requires a more group and systems oriented focus

Starfield, “Quality-of-Care Research: Internal Elegance and External Relevance,” JAMA 280:1006-9, 1998

NJHA annual Leadership Conference – Pervasive message of national experts is that consumerism and information technology will be the driving forces behind future changes in healthcare delivery. 11/98

1/14/99 HHS launches the NGC National Guideline Clearinghouse

1999 GAO Study of Drug Safety

1999 Congress to Enact Health Care Privacy Legislation

1/15/99 NJ Assembly approves measure A1581 permitting Advanced Practice Nurses to Prescribe Life-Sustaining Medications (Controlled Dangerous Substances)

3/15/99 JCAHO announces a toll-free hotline to encourage patients, their families and caregivers to share concerns regarding quality of care issues at accredited healthcare organizations.

2000 DHHS promulgate Privacy Regulations by February

APPENDIX J

Journal Venues

PRELIMINARY IDENTIFICATION OF JOURNALS CITED IN RELATED LITERATURE

The following list of journals were identified in the literature review. This provides a basis for a more comprehensive review by journal. The current list is predominated by publications in the healthcare domain. It is not yet representative of journals from fields, traditionally remote from healthcare but increasingly pointed to in the literature.

Aerospace Medicine	Consumer Reports
Alternative Law Journal	Controlled Clinical Trials
American Behavioral Scientist	Critical Care Medicine
American Family Physician	Diabetes Care
American Journal of Dis Child	Dig Dis Sci
American Journal of Health-System Pharmacy	Dimensions in Health Service
American Journal of Hospital Pharmacy	Drake Law Review
American Journal of Law & Medicine	Drug Information Journal
American Journal of Medicine	Drug Intelligence and Clinical Pharmacy
American Journal of Nursing	Drug News and Perspectives
American Journal of Preventive Medicine	Drug Safety (Adis)
American Journal of Psychiatry	Drug Topics
American Journal of Public Health	Drugs & Aging
American Professional Pharmacists	Drugs in Health Care
American Psychologists	Duke Law Journal
Anesthesiology	Epidemiology
Annals of Pharmacotherapy	European Journal of Clinical Pharmacology
Annual Review of Public Health	Gastroenterology
Applied Nursing Research	Geriatric Nursing Association
Archives of Family Medicine	Gerontologist
Archives of Internal Medicine	Gerontology
Archives of Pediatric and Adolescent Medicine	Gut
ASA Newsletter	Health Affairs
Australian NZ J Med	Health Care Supervisor
Baylor Law Review	Health Community
Biometrics	Health Data Management
British Journal of Medical Pharmacology	Health Policy
British Journal of Surgeons	Health Psychology
British Medical Journal	Health Services Research
Canadian Journal of Hospital Pharmacy	Heart and Lung
Canadian Medical Association Journal	Holistic Nursing Practice
Chest	Home Healthcare Nurse
Clinical Epidemiology	Hospital Case Management
Clinical Pharmacological Therapy	Hospital Formulary
Clinical Radiology and Nuclear Medicine	Hospital Pharmacy
Clinical Therapy	Hospitals
Computers in Nursing	Image

Journal Citations (cont.)

Inquiry
International Journal for Quality in Health Care
International Journal of Technology Assessment
in Health Care
JAGS
JAMA – Journal of the American Medical
Association
JAMIA – Journal of the American Medical
Informatics Association
Joint Commission Journal of Quality
Improvement
JONA
Journal for Healthcare Quality
Journal of Allergy & Clinical Immunology
Journal of Chronic Disease
Journal of Clinical Epidemiology
Journal of Community Health
Journal of Continuing Education in Nursing
Journal of Economics and Political Science
Journal of Family Practice
Journal of General Internal Medicine
Journal of Gerontology
Journal of Health Politics, Policy and Law
Journal of Healthcare Risk Management
Journal of Intravenous Nursing
Journal of Law, Medicine & Ethics
Journal of Nursing Care Quality
Journal of Nursing Quality Assurance
Journal of Occ Therapy)
Journal of Pharmaceutical Care
Journal of Professional Nursing
Journal of Public Health Medicine
Journal of the American Geriatrics Society
Journal of the Maine Medical Association
Journal of Trauma
Journal on Quality Improvement
Journal on Radiation Oncology, Biology and
Physics
Lancet
MD Computing
Medical Bulletin - FDA
Medical Care
Medical Decisionmaking
Medical Economics
Medical Letter
Medical Toxicology
Millbank Quarterly – A Journal of Public Health
and Health Care Policy
Modern Healthcare
Monographs in Epidemiology and Biostatistics
Mt. Sinai Journal of Medicine
NC Med J
NEJM – New England Journal of Medicine
New Republic
NITA
Nurse Educator
Nurse Practitioner
Nursing Clinics of North America
Nursing Management
Nursing Research
P&T
Patient Care
Pediatrics
Pharm World Sci
Pharmacoepidemiology and Drug Safety
Pharmacotherapy
Philosophical Transactions of the Royal Society
of London
Postgraduate Medical Journal
Proceedings of the Royal Society of Medicine
Public Health Review
Quality Assurance in Health Care
Quality of Life Research
Quality Review Bulletin
Risk Reducers
RN
Science
SCRIP Magazine
Society of Science in Medicine
Statistics in Medicine
Topics in Hospital Pharmacy Management
Trained Nurse
Transactions of the Association of American
Physicians
Western Journal of Medicine
Western Journal of Nursing Research

APPENDIX K

Table 4: Critical Problems for Investigation from the First Round of Interviews

Science Policy for Safe Use of Pharmaceuticals

1. Investigate how to foster a greater balance of a concern with benefits, along with eliminating harm for a more robust approach to risk management.
2. Develop the accountability of health care systems with respect to public advocacy for “no-risk” in medication use and the risk affinity of patients with critical illness.
3. Review the systemic nature of current approval standards, the mixed actions of evaluators and approvers, the changing nature of the healthcare system, incentives promoting best practice, and consider the overall systemic effects and implications of recommended changes to the system.
4. Focus on policy development regarding individual privacy and confidentiality laws vs. public interest in information that will improve decision making regarding drug safety.

Partnership Building

5. Develop a conceptual model of the evolution of partnerships, and the dynamic nature of relationships in public health and healthcare at national and international levels, with respect to Pharmaceutical Safety. Include, for example the roles of: Healthcare Organizations and Professional Societies; the Healthcare & Pharmaceutical Industry; Regulators and Legislators; State Boards, Medical Boards, and Pharmacy Boards; Departments of Health and Community Healthcare Professionals; Schools of Medicine, Nursing and Pharmacy; Legal Professionals; Civic Community and Religious Groups.
6. Evolve the notion of individual and organizational accountability in the context of the systems perspective, quality, process, partnering, collaboration, and teaming which seems to blur the assignment or acceptance of “ownership” in pharmaceutical safety.
7. Assess the “ownership” associated with emerging needs and recent changes in the healthcare system with respect to Pharmaceutical Safety.
8. Clarify the roles of particular organizations and individuals in pharmaceutical safety within the network of partnerships.
9. Consider a thought experiment defining FDA’s ideal and leadership roles as well as a new type of relationship with the private sector unencumbered by FDA’s historical role as a regulator.
10. Develop a systemic view of knowledge sources, information flow, technology and practice diffusion, reporting targets amongst the partnerships.
11. Develop the conceptual model of the Public’s Role in Pharmaceutical Safety
12. Develop an agenda to leverage a Patient’s Role in Pharmaceutical Safety including improving the patient’s, patient’s advocate’s, and patient’s family’s “asking the right questions,” and developing their understanding of the patient’s rights and responsibilities in forming an agreement on an intervention protocol.
13. Develop and or promote pedagogy on the healthcare practitioner – patient partnership, cultural competence and sensitivity, patient rights, patient buy-in to an intervention protocol.

Table 4: Research Directives on Critical Problems (cont.)

Safety Chain Distinctions

14. Depict the overall challenge of making medication use safe in a compelling way.
15. Avoid jumping to a solutions orientation prematurely. Work first to ask the right questions, properly “diagnose” the problem(s,) and decide which problems we want to address.
16. Address the challenge of considering risk management in the overall healthcare systems context.
17. For the purpose of the workshop and the project, focus on medication errors and “effectiveness-in-use” rather than intrinsic drug safety and “efficacy-in-ideal-use.”
18. Identify systemic problems in the determination of causality in adverse events and adverse reactions including: the challenge of improving failure analysis, its use and deploying more sophisticated tools to measure error such as the manifestation of increased frequency of reactions which are not unique to particular drugs.
19. Focus on reporting problems such increasing reporting rates, eliminating redundancy, and the coordination challenge of more parties involved in reporting and reviewing reports.

Safety Chain Transparency

20. Focus on the challenge of establishing forums for the safe discussion of mistakes.
21. Delve deeply into the problems in transforming of the culture of blame and punishment.
22. Identify problems in ameliorating the threat of malpractice as it hinders error admission, reporting, dialogue and experience sharing. Consider problems in directly engaging the legal system.
23. Depict the problem of benefits and tradeoffs of alternative reporting policies - voluntary vs. mandatory, individual choice for anonymity.
24. Delineate the pathways of notification of drug problems and highlight focus areas and challenges with them.
25. Consider the problems web-based drug information, including sales and promotional material and the challenge of ensuring its accuracy, correctness, and completeness.
26. Develop licensing requirements and continuing education credits on adverse drug event issues and medication errors.
27. Educate healthcare providers as to what patients can realistically expect to know.

Human Factors

28. Address problems in promoting pharmaceutical “safety by design” through the application of human factors principles throughout the safety system. For example, identify the challenges in deploying the principles of simplification, standardization, decreased reliance on vigilance, improved information access, reducing handoffs, decreasing multiple entries, distinguishing things that look too much alike.
29. Identify problems in increasing the involvement of human factors experts in pharmaceutical safety.
30. Consider the problems of institutionalizing medication error programs.
31. Identify the problems in greater restrictions on the access to dangerous drugs, e.g. potassium.

Product Design

32. Identify problems in cultivating user-centered drug design and design review, testing and evaluation to eliminate the potential for practitioner error, i.e., labeling and the use of the same label for any given drug, names and derivative names, potential confusion of names via the informality of handwriting and verbal exchange, packaging distinctions, variations in strengths, and pill design.
33. Consider issues in the label as a guidance document for practice in off-label use.
34. Consider the problems in electronic standardization of labels, prescriptions and bar-coding especially with respect to dosage, expiration dates and drug/drug interactions.

Table 4: Research Directives on Critical Problems (cont.)

Pre-Market Risk Assessment

35. Address the public's awareness that higher standards are being employed for evaluation, that more patients and special groups are now being studied, that pre-market approval outcomes have improved, and drug withdrawal has decreased.
36. Depict the sources of confusion of the public perception that reduced cycle-time for approval, which benefits more patients in the large, has led to lesser standards and higher risk.
37. Consider the problems of imposing increased pre-market oversight, higher standards, and more intense data requirements and risk/benefit control data throughout the approval system.

Risk Perception

38. Identify the problems in evolving the public's understanding of the balance of risk and benefit in drug approval decision making, and the distinction of balancing risk and benefit as a continuous calculation as a patient.
39. Identify the barriers to following the mandate to providing risk/benefit information in easy to understand language for patients.

Special Populations

40. Summarize the difficulties in increasing the gathering and distribution of information about drug reactions in special populations, including the elderly and children in a way which forms the basis for a national / international agenda.
41. Promote research into advanced methods for assessing the effect and interactions of multi-drug treatment of the elderly (which can number between six to ten different drugs,) for which little data exists, and controlled trials precluded.
42. Engage the consideration of multiple cultures value systems with respect to pharmaceutical care as a basis for forming a healthcare practitioner pedagogy.

Post-Marketing Reporting

43. Call attention to current inadequacies in the reporting systems especially the influences in underreporting, inaccurate reporting, lack of immediacy.
44. Review the incentives and rewards systems for: reporting; the investigation, learning and change enabled by reporting; the effect of reporting incentives on risk and cost reduction to the reporting party and organization, and the potential influence of increased funding towards these ends.
45. Seek to understand the problems in improving and acknowledging improvements in the determination of drug/drug interactions.

Surveillance & Assessment

46. Investigate problems in resolving the conflict of risk managers and legal concerns in making facility reports and other reports concerning potential errors, expected errors, observed risks, contraindications, and warnings.
47. Address shortfalls in the information diffusion of known reactions.
48. The problem in "objectifying" risk and benefit decision making through externalization of assumptions, biases, basis in prior experience and making this available to practitioners.

Information Technology Systems

49. Determine the barriers to improving flawed database systems in HMOs and the FDA.
50. Consider the need for independence of reporting systems as contrasted with the need for integration.
51. Consider the competition for resources with respect to IT system enhancements.
52. Look at the issues in promoting innovative IT solutions such as registries and adapting related IT systems from other domains.

APPENDIX L

Bibliography

An annotated bibliography is in preparation for the final report. The following list is an annotated bibliography is from one of the best annotated bibliographies on the web, provided by Bridge at www.mederrors.com. This list has not yet been merged with the NPSF list, nor the extended literature review conducted in this project. Yet, it represents the best annotated bibliography currently available on the web that we know of for this arena.

Incidence of Medication Errors

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