SAFE USE OF PHARMACEUTICALS AS A NATIONAL HEALTH PRIORITY:

DEVELOPING A LEADERSHIP AGENDA

Summary from Report

July 1999
(August Version)

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June 1999, Washington, D.C.

This project was made possible by a public/private partnership reflected in a major grant from Pfizer, Inc. with additional support from Bristol-Myers Squibb Research Institute, CVS, DuPont Pharmaceuticals Company, Janssen Pharmaceutica, the US Food and Drug Administration, and Warner-Lambert Company.

ACKNOWLEDGEMENTS

For their assistance in the preparation of this document, the authors would like to thank the individuals who generously offered their time and expertise. The paper presents a collaborative action plan relying on the voice of sixty people representing fifty organizations. The project to date includes a broad diversity of stakeholder representatives from industry, government, academia, medicine, physician assistants, nursing, the pharmacy profession, pharmacies, patient & special population organizations, consumer groups, information technology companies, and the media. The collaborators in the workshop are listed on the following page. Thought leaders, not in the workshop, contributing via interview included Lucian Leape MD, Harvard University School of Public Health; David Lansky PhD, Foundation for Accountability; Beverly Malone RN, PhD American Nurses Association; Henri Manasse Jr. PhD, ScD, RPh, American Society of Health System Pharmacists; Donald Palmisano MD, JD, American Medical Association Board of Trustees;. Diane Pinakiewicz, Schering-Plough; Larry Sasich, PharmD, Public Citizen; Richard Cook MD, University of Chicago; David Classen MD, Dept. of Clinical Epidemiology, Latter Day Saints Hospital, Karen Williams, National Pharmaceutical Council; David Woods PhD, Ohio State University.

We sought the opinions of members of the GAO panel, conducted February 24, 1999. We also drew on 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; Drs. Janet Woodcock and Susan Ellenberg of the US Food and Drug Administration, and Dr. Eleanor Vogt of the NPSF.

Individuals contributing in a review and oversight role for the National Patient Safety Foundation, include: Mary Woolley, David Lansky PhD, and Carson Porter JD, of the NPSF Board Oversight Committee; Henri Manasse Jr. PhD, ScD, RPh, Janet Woodcock MD, Andrew Smith JD of the Technical Review Committee and William Hendee PhD, Jeff Cooper PhD, Dawn McGinley, and Lou Diamond M.B.Ch.B. as NPSF Program Chairs.

Special recognition is accorded to Melissa Stegun for her responsiveness and coordination skills, which facilitated the identification and contact of the workshop participants, the communication among the many committees, as well as the arrangement of the workshop logistics on an aggressive schedule. The participation of all these individuals, committed to a health system that maximizes benefit, reduces risk and eliminates harm, infuses this paper -and this work- with the authenticity of their own expertise and life experience.

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I. SUMMARY

INTRODUCTION

As America prepares to enter the twenty-first century, pharmaceutical safety has become a major national public health priority. As the amount of medication use rises steadily each year (with approximately 2.6 billion prescriptions filled in 1997[1] for an estimated total cost of $79 billion[2]), more Americans are exposed daily to an ever-widening array of pharmaceuticals. How can we maximize the benefits of medications while reducing the associated risks? Answering this question with sound policy and effective action will require broad cooperation across diverse segments of our health care system. Redesigning our medication practices – from bench to bedside and into the home – so that every patient receives the optimal pharmaceutical in the proper amount, with adequate precautions against drug interactions, efficient monitoring, and prompt recognition and treatment of adverse reactions, will necessitate strong national leadership and collaborative effort: health care workers and pharmaceutical manufacturers, researchers and regulators, hospitals and ambulatory care clinics, lawyers and legislators all will need to work together – along with patients and consumers – to accomplish this goal.

THE PHARMACEUTICAL SAFETY INITIATIVE

To advance this common cause of pharmaceutical safety, the National Patient Safety Foundation (NPSF) initiated a multi-disciplinary collaborative process. After extensive preparatory work, the NPSF convened in June of 1999 a workshop that brought together a wide variety of stakeholders, including patient advocates, pharmacists, nurses, physicians, members of the media, representatives of the pharmaceutical industry, researchers on pharmaceutical safety from academic medical centers, and officials from the Food and Drug Administration. During the course of two days, the group used several consensus methods for problem analysis and action prioritization. Through this systematic and scientific process, the participants defined the anticipated challenges to improving pharmaceutical safety, examined how these challenges related to each other, then identified means to address these challenges, and ultimately composed a prioritized agenda for strategic action. Subsequently, all participants identified specific actions for which they would assume a collaborative leadership role. This report summarizes the current findings and conclusions of this ongoing process, considering first the challenges and then an agenda for action.

[1] IMS America & NACDS
[2] HCFA National Health Expenditures

SYSTEM OF INTERCONNECTED CHALLENGES

Absence of National Leadership

The most deep-seated obstacle to advancing the cause of medication safety in America is the absence of national leadership to investigate the issues, make recommendations, and instigate far-reaching change. Such leadership, operating from a prominent public forum and within a collaborative infrastructure across sectors of the health care system, could best address a cascade of interrelated challenges.

Fundamental Perceptions

Americans hold widely divergent concepts of medication risk and benefits, views of how these features ought to be weighed, and perceptions of how much risk they are willing to take – or in fact are taking – when being treated with pharmaceuticals. There also seems to be general confusion about the distinction between adverse drug reactions and prescription or usage errors. A subsequent overemphasis of the dangers posed by the innate side effects of medication, and relative underemphasis on the harm caused by preventable human mistakes, has led our society to conceive of medication safety as a problem to be solved by regulatory oversight as opposed to wide-spread public health and safety measures. A preventive approach is further compromised by, broadly speaking, the prevailing adversarial environment of blame with regard to pharmaceutical mishaps and adverse events.

Difficulties in Collaborating Across Segments of the Health Care Community

Collaboration across most segments of the health care community – vitally important to the long-term success of efforts to improve safe pharmaceutical use – poses its own distinct challenges. Systematic changes to enhance safety may require certain stakeholders to relinquish some control and thereby feel threatened. Unclear roles and responsibilities among the stakeholder groups to enhance safe use, along with differing degrees of economic and political power, compound difficulties arising from a lack of trust between many potential partners. Building bridges is further hampered by poor communication (due to unclear language, jargon, and secrecy) and by the substantial challenge of maintaining the confidentiality of shared information. Finally, collaborative efforts may be especially hamstrung by the stifling threat of legal liability if adverse reactions and human mistakes – effectively documented to promote analysis and systemic safety improvements – are considered discoverable evidence.

Conflicting goals and perspectives

People who take medications – as patients and consumers – are the major stakeholders in advancing pharmaceutical safety. A deep conflict, however, exists between an economically-driven free-enterprise health care system that tends to focus on short-term profits and our broader, long-term societal need to make pharmaceutical use as safe as possible. Indeed, there may be an unexamined but critical mismatch between the outlay of health care dollars to purchase drugs versus the allocation of resources to manage and enhance their safe and appropriate use.

Insufficient Knowledge and Inadequate Adoption of 'Best Practices'

We currently do not have a sufficient understanding of the problems involving safe medication use. While good research has been done on the range of human factors that led to a variety of medication errors, and on redesigning our pharmaceutical products, delivery methods, medical records, and computer systems to cut down on this error, this research needs to be performed in the wide variety of health care settings used in America. To this end of broadening our knowledge-base, we do not yet have a compendium of well-defined, measurable steps in the administration of pharmaceuticals and the monitoring of patients for untoward effects that would enable a continuous quality improvement process. In light of these areas of ignorance – and despite our sense of urgency – we must resist embracing ill-conceived solutions too quickly, but rather define the problems thoroughly and thoughtfully, and identify solutions that already have been proven effective or try new solutions to critically evaluate their impact. As important, we must assure that once we have rigorously identified effective means to promote safe pharmaceutical use, these 'best practices' are adopted widely as part of an ongoing quality of care assessment and improvement process.

Point-of-Care Constraints

Physicians typically make prescription decisions within the time constraints imposed by brief office visits, limiting their ability to obtain all pertinent information about a medicinal compound, analyze this information in the context of a particular patient's medical conditions and perhaps numerous other medications, reach a well-considered conclusion, and institute an adequate follow-up plan for monitoring. Physicians and pharmacists are further hindered, often dangerously so, by fragmented or unavailable patient records that might have revealed previous drug reactions, forgotten conditions, abnormal laboratory results, or other current medications that failed to be mentioned. Any new safety-enhancing systems or regimens will need to prove themselves feasible within these and other fairly intractable work constraints, requiring all innovative approaches to be assessed comprehensively with well-designed field trials.

Patient Education and Empowerment

Finally, current efforts and methods to create a well-educated and empowered patient population are proving to be inadequate. Too many patients have an insufficient understanding of the information they need to know in order to take their medications safely. Too frequently patients do not know when they have experienced either an adverse drug reaction or a medication error. Too often patients and providers can not obtain, in a timely manner, accurate and culturally-appropriate information about pharmaceuticals and their safe use. And too many health care providers appear unaware of the extent of illiteracy in general and health illiteracy in particular, which grievously impairs patients' comprehension of medical discussions and their ability to meaningfully provide informed consent.

AN AGENDA FOR ACTION

Considering the network of challenges outlined above, the members of the workshop compiled an extensive list of possible solutions, analyzed the relations between these proposals, and finally prioritized the following actions as especially crucial to confronting the challenges successfully.

Leadership with a Broad Agenda

Our national dialogue about pharmaceutical safety needs to be re-framed, shifting away from a focus purely on regulatory oversight and towards a comprehensive public health plan to improve the well-being of citizens who take medications. To advocate effectively for this broader vision of pharmaceutical safety, we need to foster open communication between all stakeholders in the health care system about the safe and appropriate use of medications and secure their earnest collaboration in this long-term collective effort. Some national organization – and the workshop participants strongly suggested the NPSF, although other possibilities exist, such as creating an new office under the Secretary of Health and Human Services, or a national pharmaceutical safety board (modeled after the National Transportation Safety Board) – must assume the initiative to promote this agenda, mobilizing widespread political support and spearheading the development of a national pharmaceutical safety plan.

Building Public Awareness

One of the principal tasks of a leadership organization would be to build public awareness regarding pharmaceutical safety, communicating clearly the balanced concepts of desired therapeutic benefit and ongoing risk management. Conducting national forums that involved stakeholders at all levels of the medication use process to deliberate safety issues, convening a congressional caucus of representatives on safe medication use for patients and consumers, or supporting a national medication safety awareness campaign on network television are examples of possible actions.

Education and Information

As a society, we need to educate both health care providers and consumers in safe pharmaceutical use, including giving them a better understanding of what is and is not known about each particular medication. In addition to incorporating a curriculum component focusing specifically on contemporary medication safety concepts into the training of medical providers and all other stakeholders involved in health care, we should ensure that current and clear information about pharmaceuticals and their side effects is readily available (via the Internet World Wide Web and other venues) for both professional and lay use.

Legislation

In order to re-frame pharmaceutical safety more fundamentally as proactive injury prevention than reactive injury identification and compensation, as well as to promote voluntary reporting and collaborative efforts, several legislative steps should be taken. First, legislation should be passed that recognizes the innate potential harm from medications and establishes a public/private fund to compensate injured patients. Second, legislative protection should be granted for information submitted to national error reporting programs. Finally, new legislation should allow direct competitors to freely share information regarding safety initiatives without concern for legal discovery or anti-trust litigation. These steps would be facilitated by a formal ongoing collaborative process (modeled perhaps on the format used by the International Conference on Harmonization) to consider and recommend legal reforms needed to facilitate development of patient safety programs.

Research and Development

Several avenues of research need to be pursued to supply the necessary knowledge to enhance safe pharmaceutical use practices. Chief among these is to conduct research on medication use in multiple settings, delineating in detail the step-wise processes used by various health care systems when providing medications, so as to identify steps prone to error and then enact continuous quality improvement. Another research approach is the systematic critical review of already-implemented medication use protocols and standards, so as to select and promote best practices. These and other projects would benefit by increasing the number of and funding for Centers for Education and Research in Therapeutics (CERTS) programs, as sponsored by the Agency for Health Care Policy and Research (AHCPR). Finally, the development of a national collaborative multi-disciplinary research and policy center (bringing together, for example, workers from the Food and Drug Administration, the National Institutes of Health, the Institute of Medicine, the AHCPR,PhRMA, and – of fundamental importance – patient advocates and consumers) to conduct research on safe medication use and generate effective policy.

Innovation and Diffusion

Successfully meeting the challenges of enhancing safe pharmaceutical use will require not only research and development but also the innovation of new patient and medication information systems, as well as effective new drug prescription, delivery, and monitoring processes, and their subsequent diffusion into myriad health care settings. The first step in such innovation might be to develop uniform, legally-acceptable guidelines for communicating patient-specific information among health care providers, while maintaining privacy and confidentiality. Once such standards were in place, a computer-based network system must be designed and implemented so as to enable information in all health care settings to be collected specifically for identifying pharmaceutical safety issues and analyzing patient outcomes. As a parallel effort – with the same degree of vigor and commitment as was shown by the Apollo program in working to place a man on the moon – a consortium of private and public organizations (with backing from the federal government) must push to develop, implement, and then require computer-based medical records and eventual order entry of prescriptions (with appropriate encryption and signature validation) in all health care settings within the next five years.

Further basic research into the causes of adverse drug reactions is warranted, so as to enable the identification of individuals at greater risk through screening tests. For patients unfortunate enough to experience adverse drug reactions and medication errors, we should create new mechanisms to enhance reporting to the US Pharmacopeia and to MEDWATCH from all health care settings (particularly targeting newly marketed pharmaceuticals). We must also – and this is imperative – improve our response to such events, developing a plan for quick and accurate diagnosis of adverse drug reactions, and providing these patients with timely and effective treatment.

CONCLUSION

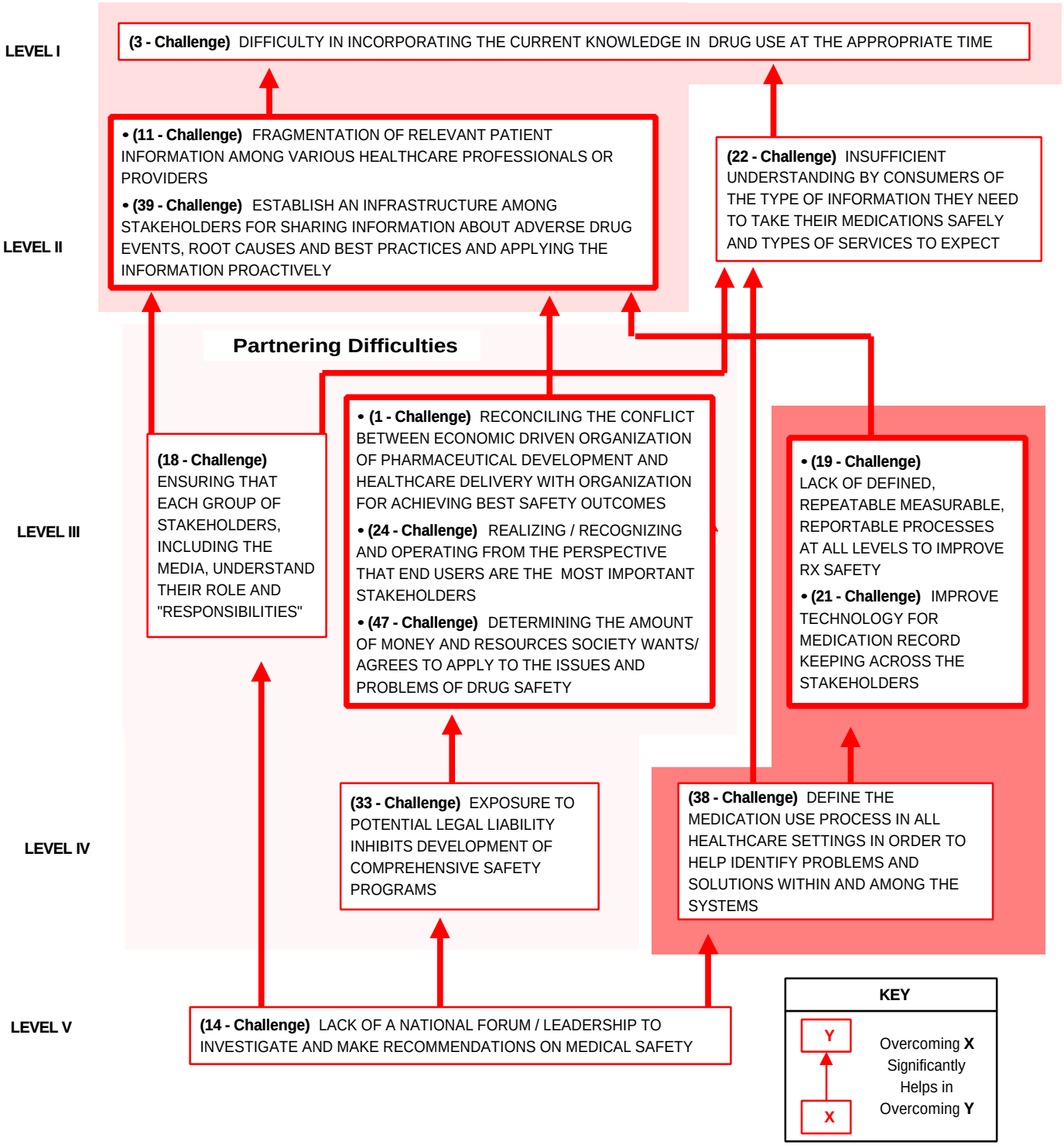
Improving pharmaceutical safety will require ongoing collaboration across all sectors of our multifaceted health care system. The strategic assessment and planning process initiated by the NPSF has thus far identified a host of challenges and potential actions that, broadly speaking, fall into 'global' and 'local' action categories.

In the global category are several problems and actions located at the highest levels of cross-institutional cooperation, collaboration, and leadership. We need to create a common framework for action, focusing our national attention on safe medication use as a major public health priority. Groups such as the NPSF and patient advocacy organizations can serve as catalytic forums to mobilize widespread support, educate the public about pharmaceutical safety, and heighten our society's awareness. Simultaneously, ongoing working groups – including representatives of all stakeholders at

every level of pharmaceutical use – need to continue the assessment and planning process to improve medication safety, thereby deepening our understanding of critical problems and facilitating collaborative responses. Of note, for these broad initiatives, the participants at this workshop expressed nearly unanimous commitment.

Local actions are also called for, as outlined previously, and these must not be overlooked as they will provide a sound information base and ultimately the capacity to 'get the job done.' At the same time, unless we tackle the larger challenges of securing a shared agenda for change through better organization and collaboration, the strong consensus opinion is that we will find our local efforts to prove insufficient to improve the safety of medications for all Americans. And that is a collective failure that we can no longer tolerate.

Figure 1: Influence Pattern among Most Important Challenges



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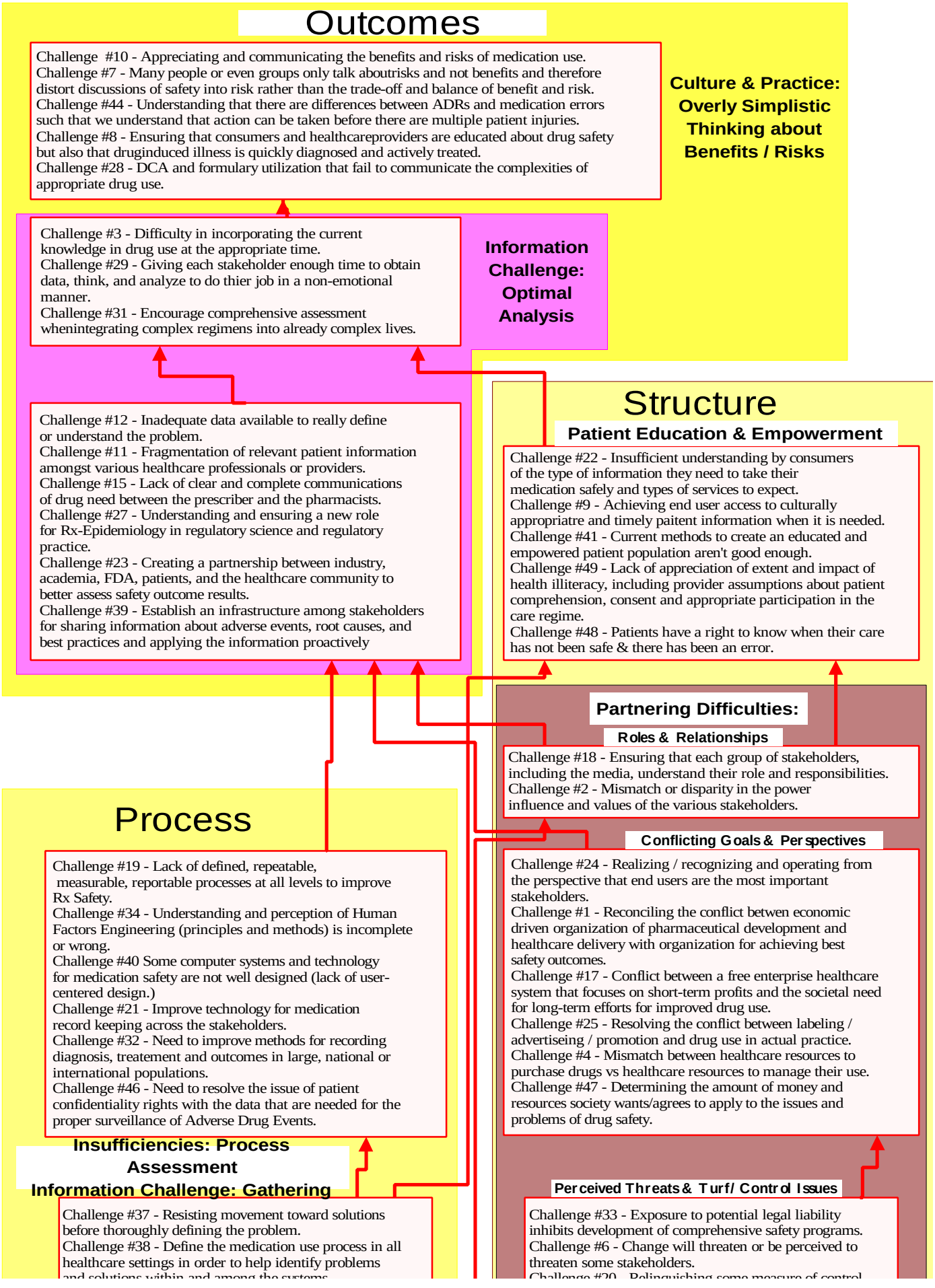
Produced by the participants at the National Patient Safety Foundation Workshop -- June 10, 1999

In-Depth Analysis for Figure 1



Influence Pattern of the Action Options