

Conference Synthesis

Research Agenda for Ambulatory Patient Safety (continued)

Introduction

On November 30 and December 1, 2000, the MGMA Center for Research, with support from the Agency for Healthcare Research and Quality (AHRQ) and the Health Care Financing Administration (HCFA, now the Centers for Medicare and Medicaid Support or CMS) and assistance from the Partnership for Patient Safety (p4ps), held a multidisciplinary conference to develop an agenda for research in ambulatory patient safety.¹ This report is a synthesis of the presentations and discussions of conference participants, who included researchers, clinicians, ambulatory care administrators, purchasers, and policymakers.² Conference participants first reviewed the available evidence on the epidemiology of safety, risks, errors, and adverse events in ambulatory care and interventions to improve safety. They then posed and discussed directions for research to better understand the epidemiology and determinants of safety and injury in ambulatory care, and potential experiments and demonstrations to test approaches to reducing risks, errors, and injuries.

The conference was held after the publication of the Institute of Medicine's report on patient safety in the United States (Institute of Medicine 1999). In introductory remarks to the participants, Dr. John Eisenberg, Director of AHRQ, reviewed the increasing attention to patient safety by Congress and by AHRQ and other Federal agencies,³ and described AHRQ's plans for a substantial increase in support for research and demonstrations in patient safety. Dr. Eisenberg also noted the commitment to initiatives to improve patient safety by health care purchasers including CMS and larger employers such as those in the Leapfrog Group (Milstein et al. 2000, <http://www.leapfroggroup.org/>).

Though the conference focused on patient safety in ambulatory care, this must be considered within the larger context. Much ambulatory care is provided within episodes of care that include several sites and several providers. Unfortunately, the events that comprise an episode of care are seldom "seamless," and transitions between inpatient and ambulatory care are points of increased risk of adverse events. Also, the consequences of ambulatory care events may become apparent in the emergency department or the hospital, and consequences of inpatient care may become evident in the ambulatory setting.

The scope of the conference discussions ranged from "micro" topics, such as the value of automated physician order entry, to "macro" topics such as the infrastructure required to support highly reliable information and communication in physician practices. The range of topics reflected assumptions, shared by all or most of the conference participants, that understanding the determinants of patient safety and identifying ways to reduce adverse events and injuries requires understanding both how errors are made by individual physicians and other clinicians, but also understanding how risks are determined by processes and systems (Leape 1994, Leape et al. 1995, Institute of Medicine

1999, 2001, Berwick and Leape 1999, Leape et al. 2000, Nolan 2000). Discussions focused as much on larger "systems" issues such as improving the infrastructure to support ambulatory care, as on particular interventions that could improve safety.⁴

Because the determinants of patient safety are many, as are the opportunities for improving safety, the conference was designed to examine patient safety from many points of view. Participants in the conference were drawn from a number of perspectives to provide a wide range of knowledge and experience, and an opportunity for interactions among persons with those perspectives.

This synthesis begins with a description of the conference and the methods used to organize the discussion of ambulatory patient safety. We describe the importance of the ambulatory sector, provide a review of the available literature on patient safety in ambulatory care, and summarize the main points from discussions among the conference participants. Recommendations from those discussions address what information should be sought and how to obtain it, what interventions to improve safety should be tested and how effective interventions could be implemented. Because research and demonstrations will proceed within the context of law and regulation related to injury, error, and fault, and of culture and beliefs as well as scientific knowledge about the determinants of safety, the conference included a discussion of the environment for patient safety and its implications for research.

A summary conclusion from this conference, consistent with other reports on patient safety in ambulatory care, is that there is inadequate knowledge and understanding of the ambulatory care sector of the health care system. The lack of in-depth knowledge severely limits our ability to understand the risks to patients, and to design and predict the effects of changes in ambulatory health care to improve care and outcomes, including medical error and patient safety. Nevertheless, considerable agreement on a number of points emerged from discussions among conference participants. The research agenda presented in this report, including the specific recommendations made, was extracted from these discussions, and the recommendations represent points of consensus as perceived by the authors of this synthesis, and confirmed by subsequent survey of participants' degree of agreement with each recommendation.

Many of the references cited in this synthesis have been published since the conference was held. They are included to provide a more comprehensive set of references for those who will use this synthesis, but conclusions and recommendations from the conference participants' discussions are not based on them except insofar as participants, many of whom are investigators in patient safety, had advance knowledge of work described in subsequent publications.

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Methods

The conference posed three sets of questions to the participants, with intent to derive a research agenda from the discussions and recommendations of the fifty experts participating in the conference. For each of the three topics, we asked participants to focus on:

- **What do we know, and what are our assertions?**

- **What do we need to know, what are our hypotheses?**
- **How will we find out/where can we get this information and test these hypotheses?**

The three topics were:

- What do we know and what do we need to know about the **epidemiology of patient safety in ambulatory care**? What are the nature and scope of the risks to patient safety, and of adverse events? How will we get the data/knowledge we need?
- What do we know and what do we need to know about **strategies and methods to improve/ensure patient safety** and to reduce adverse events? How will we get the data/knowledge we need?
- What do we know and what do we need to know about **effects of cultural, legislative, and regulatory environments on patient safety and efforts to improve** and ensure patient safety? How will we get the data/knowledge we need?

Presentations and Group Discussions

Each of the three topics was introduced by a presentation designed to review much of what we know from the existing literature, and to set the stage for discussion. For each of the first two topics, six small groups of eight-nine persons then spent four hours in facilitated discussions. For the third topic, the entire group remained together for discussion.

We provided a facilitator for each of the small and large discussion groups, and asked that each group search for consensus on what we know, and recommend research that would enable us to learn what we need to know. Each group was provided a number of specific questions that could be used to focus the discussions, but was encouraged to redefine the questions or focus on additional questions they considered to be equally relevant. These questions, many of which were raised in the presentations preceding the group discussions, are provided in Appendix Two.

From Discussions to Synthesis and Recommendations

The research agenda presented in this report, including the specific recommendations made, was extracted from these discussions by the authors of this synthesis. The recommendations represent points of consensus as perceived by the authors.

Confirming Consensus Support for the Recommendations

About 9 months after the conference, each participant was provided a draft of this synthesis and asked to indicate his or her degree of agreement with each of the 11 recommendations. The results are consistent with representing the recommendations as reflecting a consensus of the participants. The table following shows the responses from 46 (92 percent) of the 50 eligible participants. Recommendation 1 received the weakest support, while recommendations 6 and 9 the strongest. Because some participants did not indicate a response for one or more questions, the number of responses for individual recommendations ranges from 43 to 46.

Select for Text Version.

Recommendation	1	2	3	4	5	6	7	8	9	10	11
Strongly agree	18	19	20	17	28	31	19	24	27	26	24
Agree	15	17	20	17	11	10	13	8	12	12	16
Neutral	6	6	2	10	3	4	5	11	5	3	4
Disagree	7	3	0	1	4	0	6	2	0	2	1
Strongly disagree	0	1	1	0	0	0	0	0	0	0	0

The recommendations have not been formally endorsed by any individual participant.

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Definitions and Assumptions

Discussions of patient safety and how to improve it are influenced by differences in assumptions about the nature of safety and risk, and the language used may reflect those assumptions. For example, the term "medical error" suggests that someone is at fault, and that patient safety can be improved by affixing fault, blame, and liability to a particular individual physician or nurse and taking action against that individual. While the participants in this conference generally used traditional terms like adverse event and medical error, most shared an assumption that the principal path to patient safety is to understand all the factors that lead to or result in injuries and suboptimal outcomes for patients, and to focus on what can we do to improve patient care. Most participants shared a belief that while some injuries in health care are the result of physicians, nurses, or other clinicians who are irresponsible, incompetent, impaired, or corrupt, most injuries and errors occur through more complex mechanisms that involve the processes and systems of care. And while patients should be protected from impaired and incompetent providers, improving processes and systems—which in turn will improve the performance of individual clinicians—is a far more powerful approach to improving patient safety.

People, Processes, Systems, and Outcomes

Errors and adverse events may occur because of individual actions or inaction due to deficiencies in an individual's knowledge, information, skills, judgment, and commitment. Where individuals err because of deficient knowledge, skill, judgment, or commitment, the individual should accept responsibility for the error and for its consequences. There are mechanisms that address individual performance in medicine: credentialing, State licensing and disciplinary boards, professional liability system, and peer review and other peer influences.

Responsibility for most errors and adverse outcomes is shared by the organizations, processes, and systems within which individuals provide care (Institute of Medicine 1999, 2001, Becher and Chassin 2001, Nolan 2000, Berwick and Leape 1999, Berwick 2001, Reason 2001). A person's knowledge, skill, judgment, and experience are factors that influence the person's performance and patients' outcomes. The processes and systems within which that person works are factors as well, and people and systems are interdependent.⁵

For example, if a physician practices in a group that provides immediate access to guidelines for choosing antibiotics and information to apply the guideline—available when the physician is making that decision—then the practice infrastructure (the clinical support system) reduces the risk of a suboptimal or inappropriate choice. Another physician who must care for patients with little support may have to cope with missing patient records and missing laboratory results, leaving the patient (and physician) exposed to greater risk (Kravitz et al. 1997). Actions to reduce risks and errors will involve improvements on the part of the individual, in the processes that support the individual, and the systems within which the individual provides care. Responsibility for improving patient safety is widely shared.

In ambulatory care, a substantial fraction of care depends on the patient and family as well as clinicians and organizations. In this context, it is appropriate to consider not only the knowledge, skill, judgment, and commitment of clinicians, but of patients and families as well—and processes and systems that do or could support them.

Patient care in hospitals is clinically and technologically complex. It often requires the management of multiple physiologic abnormalities, the coordination of the work of multiple clinicians, and the management of complex equipment and technologies. Complexity is generally balanced by systems to cope with it. An inpatient's care usually occurs in a single hospital with relatively well-developed communication, coordination, and information support for clinicians involved in a patient's care. Clinicians also are generally able to control what the patient does, and control the patient's environment. In short, hospitals provide the resources and infrastructure needed to manage patients' care.

In ambulatory care, a substantial proportion of care depends not only on general and specialty physicians, but also on other health professionals, patients, and family members. Communications and coordination among these caregivers therefore may substantially influence outcomes of care.

While most ambulatory care is less technologically complex than inpatient care, it is often more complex logistically, and the infrastructure frequently provides far less than optimal support for managing care. An episode of ambulatory care often requires communication and coordination among a number of clinicians, the patient, and family, and among several different sites. An episode of care occurs in bits and pieces over a period of time, and involves handoffs and transitions. Laboratories, imaging facilities and other diagnostic services are often located in disparate sites, and communication of results may be subject to a variety of sources of failure. A multi-component episode of care that includes a number of ambulatory events such as filling a prescription and taking it as directed, finding a particular imaging facility or laboratory, and so forth, may seem particularly complex to a patient who, in contrast to the physician, has little familiarity with how the health care "system" is supposed to work.⁶ Complexity is increased by insurers' requirements that force clinicians—and patients—to use particular laboratories, imaging facilities, and consulting physicians with which they are often unfamiliar and with whom they do not have working relationships.

The coordination and management of all these events is difficult for patients, and for physicians and their practices. It is complicated by physicians' acceptance of inadequate support systems. The organization of ambulatory health care—particularly of physician practices—reflects health care of a far simpler time, and has not kept up with the rapid development of medical science and of diagnostic and therapeutic capability, and the increase in the clinical, technological, and logistical complexity of ambulatory care.⁷

Finally, patient and social factors are more prominent in ambulatory care. The patient has "many degrees of freedom" so clinicians have less influence and much less control than in the hospital over the patient's decisions and actions (e.g., whether the patient gets a test or receives a medication), and the patient's environment (e.g., whether a smoker is present). We rely on the patient, influenced by his social environment, to seek care and to carry out much of the clinical management in ambulatory care (e.g., using point of care testing to manage therapy). Patients are increasingly active in making decisions about and managing their care (Wagner 2000, Holman and Lorig 2000, Nesse et al. 2000, Deyo 2001). In ambulatory care, everything happens in context of the patient's entire life and work and family; in hospital, the patient is temporarily removed or distanced from many of these influences.

Safety and Quality, Errors of Omission

Should "safety" be considered part of "quality," or are they fundamentally different? Most of the conference participants consider safety to be a part of quality, and believe that understanding risk and improving safety should take advantage of the conceptual framework and tools of "quality" (Institute of Medicine 1999). However, participants suggested that there are differences, at least in emphasis, and that these differences should influence where effort is focused. For example, risks and injuries from errors of commission would seem to offer "low hanging fruit" for improving patient safety. Also, a focus on safety occurs within a different cultural environment, and is subject to stronger external influences such as tort liability.

Consistent with the assumption that safety is best viewed in conjunction with quality, most conference participants include errors of omission within the rubric of patient safety, both at the level of individual decisions (e.g., failure to order an indicated drug) and at the system level (e.g., failure to establish a reliable mechanism to ensure follow-up of test results).

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Dimensions Of Ambulatory Patient Safety

The Institute of Medicine's (IOM) Report estimated 44,000 to 98,000 hospital patients die each year from avoidable medical error (Institute of Medicine 1999, Chassin 1998). While there is some disagreement about the accuracy of these estimates and the assumptions upon which they are based (McDonald 2000, Leape 2000, Sox and Woloshin 2000, Hofer et al. 2000, Hayward and Hofer 2001), it could also be argued that they underestimate the extent of medical error throughout health care since they are based almost entirely on hospital data.

Relatively little information has been collected on risks, errors, and their consequences in ambulatory care (Institute of Medicine 1999,

Healthcare Business Roundtable 2000, Wilson et al. 2001, Gandhi et al. 2000a). Yet much of the health care in the United States is delivered in ambulatory settings. The scope of ambulatory practice has steadily increased over the past several decades due to rapid changes in technology, and changes in financing and organization of health services. Most medical and surgical procedures that were once provided only in hospitals, are now routinely performed in ambulatory settings. The IOM Report (1999) establishes the substantial level of patient risk in inpatient care, and it implies an urgent need to develop a clear understanding of patient safety issues in ambulatory care, including the transitions and handoffs between inpatient and outpatient care.

Increasing Volume, Scope, and Complexity of Ambulatory Care

Ambulatory services are those provided without admission to an acute or long-term care facility.⁸ Ambulatory services are performed by a variety of health care providers and support personnel in a dizzying array of practice settings: physician offices, hospital emergency and outpatient departments, home health agencies, community health centers, urgent care centers, chemotherapy and radiation therapy centers, dialysis centers, diagnostic imaging centers, mobile imaging centers, outpatient surgery centers, occupational health centers, mental health centers, rehabilitation centers, sports medicine clinics, women's health clinics, wound care centers, hand injury rehabilitation clinics, wellness and fitness centers and increasingly alternative and complementary health care settings. Ambulatory care is provided in both relatively simple and in more complex ambulatory settings. Physician office care, for example, is provided in small physician offices and in large group practices and medical centers. Most primary care, provided mainly by family practice, general internist, pediatric, and obstetric/gynecology specialties, usually takes place in ambulatory care settings (Barr et al. 1999, Woodwell 2000).

The last twenty years have seen rapid growth in the volume and complexity of procedures provided in ambulatory settings, driven by improvements and innovation in technology, linked with changes in financing and reimbursement. Over 77 percent of all medical procedures are now performed in ambulatory settings.⁹ Improved anesthesia and pain management have expanded the scope of surgical procedures performed outside the hospital (Davis 1993, Duffy and Farley 1995). For example, a study of surgical patterns from 1980 through 1995 revealed that the number of inpatient operations remained relatively constant at about 17 million per year, while outpatient surgeries increased dramatically from 3 to 27 million operations (Kozak et al. 1999). Between 1980 and 1997 ambulatory surgeries as a proportion of all surgeries increased from 16.3 percent to 60.7 percent (NCHS 1999b).¹⁰ The increase in ambulatory surgery is driven by both substitution of outpatient for inpatient care, and growth of surgical procedures usually provided in ambulatory settings. The demand for ambulatory procedures has increased independently of the demand for inpatient surgery due to lower time costs, better management of pain and the increasing breadth of procedures that are performed in ambulatory settings. This trend is likely to continue.

Ambulatory care occurs in a variety of settings, and is provided by an array of clinicians. The physician office practice is usually considered to be the "hub" of ambulatory care. The National Center for Health Statistics reports that 787.4 million visits were made to office based physicians in 1997. Over half (55.7 percent) of these visits took place in physician offices while 12.3 percent, 15.6 percent, 3.3 percent, and 13.1 percent took place in hospital outpatient, clinic, home settings and by telephone (NCHS 1999b), and nearly 69 percent of these visits were to primary care providers (NCHS 1999b). Requirements and influences of managed care have made the job of the primary care provider increasingly demanding and complex. A recent study of 12,107 (58 percent primary care) physicians revealed that nearly one fourth of them

felt that the scope of care expected of them was greater than it should be (St. Peter et al. 1999), with the potential for increased risk to patients.

There are many types of health care personnel that are responsible or involved in providing ambulatory patient care. In addition to the nearly 720,000 non-federal physicians, a large array of non-physician personnel provide a substantial proportion of patient care in ambulatory settings. Nurses are important providers of patient care. Advanced practice nurses, especially Nurse Practitioners and Certified Nurse Midwives, have substantial autonomy including the authority to prescribe medication. Physician Assistants (PAs) are also important in the provision of primary care, and in most States the PA has the authority to order prescriptions and operates with considerable autonomy. These "mid-level practitioners and physician-extenders" are an increasingly important part of the health care delivery system, particularly in primary care. In 1997, there were over 29,000 Physician Assistants, 60,000 Nurse Practitioners and over 6,000 Certified Nurse Midwives practicing in the United States (Fitzgerald 1996, Cooper et al. 1998).

The large numbers and variety of health care personnel, sites, and organizations imply a large number of transitions in patient care or "hand-offs" of responsibility for care, which are known to be points of increased risk for occurrence of error (Leape 1994).

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Ambulatory Patient Safety: What Do We Know?

Though there is little doubt that medical error and injury are substantial in ambulatory care, there has been little systematic research specifically aimed at patient safety questions in ambulatory care. The rapid increase in size, scope, and complexity of ambulatory health services sector has outpaced our knowledge of how and how well it works. A system this large and complex, with so many loosely linked components, makes it difficult to adequately frame the discussion of patient safety and identify the key questions that need to be addressed. The increasing size and complexity of ambulatory health care makes it reasonable to infer that the same types of errors that occur in inpatient care are also common in ambulatory care. In their discussion of the epidemiology of medical error, Weingart et al. (2000) conclude that most estimates of error in outpatient settings underestimate the magnitude of the problem. They note that in both the Harvard (Brennan et al. 1991) and Australian (Wilson et al. 1995) studies of inpatient injury and error, between 8 percent and 9 percent of adverse events took place in doctor's offices and 2-3 percent at home.¹¹

The principal sources of our knowledge of the epidemiology of patient safety in hospital care include the Harvard Medical Practice Study and several additional studies with similar methodology: the California study in the 1970s, and similar studies in Utah and Colorado (Brennan et al. 1991, Thomas et al. 2000). A comprehensive study of risk and adverse events and their consequences in ambulatory care could be quite valuable, though a study of that magnitude would be challenging.¹² There was consensus of participants that an analogous "Harvard study" for ambulatory health care would be very difficult to do well because of the variability and fragmentation of care,¹³ and the paucity or incompleteness of data sources such as the ambulatory medical record.¹⁴ A study would also be more difficult than in hospitals due to fear of liability and litigation. It was generally agreed that if such a study could be demonstrated to be feasible (through pilot studies, for example), it

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would be useful and valuable, but would not be essential to improving ambulatory patient safety.

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