Chapter 16. Prevention—Safety and Quality

Carol Loveland-Cherry

Background

To date, the preponderance of research on patient safety and the transformation of the work environment has focused on inpatient, acute care settings. Institute of Medicine (IOM) reports[1, 2] clearly recommend that work be done on "studies and development of methods to better describe, both qualitatively and quantitatively, the work nurses perform in different care settings"[2] (p. 325). Specifically, the recommendation is that research on patient safety needs to be addressed across care settings. Preventive services, primary care, and ambulatory care settings are areas in which there is a more limited body of work related to patient safety. Yet, these nonacute care settings constitute growing loci of health care services. This chapter will review the extant research on patient safety in preventive services, primary care, and ambulatory care settings. Preventive services, broadly defined, include screening, counseling, and chemoprophylaxis. This chapter will not focus on prevention of adverse events in ambulatory care or inpatient settings.

The Surgeon General's report[3] and subsequent plans for ensuring the health of the nation[4, 5] emphasize the role of prevention in addressing the leading causes of morbidity and mortality. Clinicians play important roles in both primary and secondary prevention.[6] Primary prevention is directed at measures to avoid or prevent the onset of disease or adverse condition. Secondary prevention focuses on the identification and treatment of asymptomatic individuals who have identified risk factors to prevent the development of active disease and/or reduce morbidity and mortality. Preventive services encompass health care provided in primary care settings, such as office-based practices and clinics, and in community-based settings. Preventive services are less regulated and controlled than health care services provided in institutions such as hospitals, long-term care facilities, and nursing homes. Not only have preventive services increased and become a central component of primary health care, these services also have become a focus of scrutiny in terms of quality and safety[6] (p. 13). Screening, counseling, preventive medications, skill building, and behavioral change strategies comprise the major foci of preventive services.

Two national task forces have been charged with the evaluation of preventive services. The Agency for Healthcare Research and Quality (AHRQ) convened the United States Preventive Services Task Force (USPSTF), an independent body of experts, to evaluate and make recommendations for clinical preventive services. The Centers for Disease Control and Prevention (CDC) established the Community Task Force to evaluate public health prevention programs.[7] Both task forces focus on establishing the efficacy of prevention strategies and also consider the relative harms and benefits of preventive services. The recommendations of these two task forces are available in print and online (http://www.ahrq.gov/clinic/prevenix.htm; http://www.thecommunityguide.org/) and will not be reviewed in this chapter.

Several IOM reports have emphasized the need to address not only the efficacy and effectiveness of health care strategies, but also patient safety.[8] The report *To Err is Human: Building a Safer Health System*[8] defines important terms. Safety is defined as "freedom from accidental injury" (p. 4) and error as "failure of a planned action to be completed as intended or the use of a wrong plan to achieve an aim" (p. 28). Error can occur in either the planning or

execution of health care services. In preventive services, the challenges are defining and tracking safety issues or adverse events. Thus, identification of literature related to patient safety and quality of care in preventive services is difficult. Further, with few exceptions, the studies are of medical errors. The studies of medical errors and adverse events cover doctors and other primary health care providers, such as nurse practitioners.

The research evidence for patient safety in preventive services falls into five distinct groups: identification and classification of errors in primary care, harms of screening, harms of information technology, errors arising from language in preventive services, and potential interventions to prevent errors and adverse events. The evidence in each of the first four groups will be summarized and assessed in this chapter; the potential interventions will be included within each of the relevant categories.

Research Evidence

Errors in Preventive Services/Primary Care

In the United States, the literature on patient safety has focused primarily on the inpatient, acute care setting. In contrast, a growing literature in the United Kingdom focuses on identifying, tracking, and assessing errors in primary care. Seven manuscripts describe some aspect of errors in preventive services, primary care, or ambulatory services. The first priority for promoting patient safety in primary care was to identify the most common errors that occur in primary care.[9]

Researchers have used several different methodologies to identify errors in primary care. The approaches include observational prospective studies,[10, 11] review of malpractice claims,[12] reports from physicians,[13, 14] and interviews with adult patients.[15] One systematic review has summarized literature in this area published between 1965 and 2001.[16] The different methodologies, including study length and modes of data collection, make it difficult to compare rates of errors or adverse events. The number of events reported were

- 117 errors for 15 physicians in 83 visits across 7 offices over 3 half-day sessions[11]
- 221 incidents from interviews with 38 patients asking them to recall events that occurred at any time in the past[15]
- 344 incidents from 42 physicians over 20 weeks[13]
- 940 incidents over 2 weeks across 10 practices[14]
- 805 incidents occurring between October 1993 and June 1995 from 324 physicians[10]
- 5,921 incidents from claims data for over a 15-year period[12]
- 1,223 incidents from 4 articles published 1995-2002[16]

Regardless of the methodology, similar categories of errors and events were identified and patterns emerged that provided the basis for development of classification systems. Dovey and colleagues[13] developed a taxonomy based on the identified types of errors and sources of errors. The most general groupings of errors resulted in two major categories: process errors, and knowledge and skills errors. Each of the two categories had three additional levels of specificity. For example, a process error in investigating a patient's condition, specifically in the process of laboratory investigations, might involve a wrong test being ordered or a test not ordered when appropriate. Bhasale and colleagues[10] classified incidents as pharmacological (e.g., inappropriate drug), nonpharmacological (e.g., treatment omitted/delayed), diagnostic (e.g., missed), or equipment (e.g., malfunction/ineffective). Preventable harms identified by patients were

classified as psychological (e.g., personal worth), physical (e.g., pain) or economic/other (e.g., avoidable personal medical expense).[15] Elder and colleagues[11] described office administration errors (i.e., charting, general office administration), physician-related errors, patient communication errors, and preventable adverse events. Rubin and colleagues[14] noted six categories of errors: prescriptions, communication, equipment, appointments, clinical, and others. Elder and Dovey[16] identified three categories: diagnosis—related to symptoms or prevention with either missed or delayed diagnosis; treatment—either drug or nondrug as incorrect/inappropriate, delayed or omitted; and preventive services—inappropriate, delayed, omitted, or procedural complication. In addition to classifying types of errors, Elder and Dovey identified related factors, such as clinician factors (clinical judgment and procedural skills error), communication factors (clinician–patient, clinician–clinician/health care system personnel), administration factors (clinician, pharmacy, ancillary providers, office setting), and blunt-end factors (personal and family issues of clinicians and staff, insurance company regulations, government regulations, funding and employers, physical size and location of practice, general health care system).[16] Kuzel and colleagues[15] offered a similar list of access breakdown, communication breakdown, relationship breakdown, technical error, and inefficiency of care.

Bhasale and colleagues[10] also identified differences in individuals involved in preventable incidents. The incidents involved slightly more females (58 percent) than males and more older individuals 25 years and older (around 85 percent) than younger ones. Overall, infants and females older than 75 years were overrepresented in the incidents. The same study described factors that mitigated the outcomes of adverse events: early intervention by reporting physician, patients, patient's relative, another provider; plain good fortune; patient's good physical or psychological condition; prior experience or training; reliability of professional backup; skilled assistant; high awareness via quality assurance activities; and reliability of equipment.

The data from this group of studies, regardless of the methodology, provide both identification of errors or adverse events in preventive services or primary or ambulatory care and direction for interventions. Dovey and colleagues'[13] major classifications of process and knowledge and skills errors provide major conceptual groupings within which to examine the specific error identified in the schema. Combined with Bhasale and colleagues'[10] identification of mitigating factors, this group of studies provides direction for both identifying errors and adverse events and for proposing interventions to address them. The findings specific to preventive services imply that errors or adverse events result from screening, counseling, or chemoprophylaxis being inappropriate, delayed, or omitted, or involve procedural complications. These errors or adverse events may arise from either process errors or knowledge and skill errors. Process errors are defined as resulting from some aspect of care delivery systems.[13] Examples of process errors include care that was provided but not documented in the patient's chart (e.g., a mammogram performed but not recorded) or a medication not being dispensed as ordered. Knowledge and skill errors are related to providers' clinical skills and knowledge (e.g., a wrong or missed diagnosis or a wrong treatment based on lack of clinician knowledge).

The next section examines two groups of studies that represent specific instances of areas with potential harms: medication errors and screening activities.

Adverse Drug Events in Preventive Services/ Primary Care/Ambulatory Care

Twelve studies[17–28] examined adverse drug events in primary or ambulatory care. None of these studies were specific to chemoprophylaxis. Rather, the foci were similar to those in acute care or inpatient care, but occurred in ambulatory or primary care settings. Thus, this group of studies was not included in this review as adverse drug events are covered in other chapters in this book.

Potential Harms Related to Screening in Preventive Services

Screening is a major intervention in preventive services. Although a number of benefits have been associated with screening activities in preventive services, risks have also been identified. Potential risks of screening include misunderstanding test results, misdiagnosis, mislabeling, stigmatization, and decreased psychological well-being.[28] Three major reviews[30–32] and 10 studies[33–42] examined the benefits, risks, and harms associated with screening activities. The most common screening tests reported were for breast, cervical, prostate, and colorectal cancers.

Screening mammography is recommended for women ages 40 years and older, but there is limited evidence for the upper age for screening. There are potential harms associated with mammography. The incidence of ductal carcinoma in situ (DCIS) increases in elderly women. The risk of death from DCIS progressing to invasive breast cancer is very low; therefore, the risks of surgery to treat DCIS outweigh the benefits. Three studies found that approximately 8 percent of women ages 70 years and older had an abnormal result from mammography, and 85 percent to 92 percent of those with an abnormal result did not have cancer.[31, 33, 35] A slightly lower percentage of clinical breast examinations (3.9 percent) resulted in abnormal results, but a higher percentage of these women (97 percent) did not have cancer on followup.[33] Thus, potential harms of screening mammography or clinical breast examination include unnecessary biopsy and the stress and worry related to the possibility have having cancer.[20]

Similarly, overdiagnosis and overtreatment in 40 percent of women[34] are potential harms of cervical cancer screening. Results of a cohort study of Pap smear results in postmenopausal women 44–79 years of age[37, 31] demonstrated a high incidence of false positive results (all but 1 of 110 abnormal Pap smears). Other harms of Pap smear screening include identification and treatment of inconsequential disease, high anxiety, low self-esteem, and disrupted partner relationships.[31]

In addition to the potential harms of psychological distress and false-positive results, perforation, bleeding, stroke, myocardial infarctions, Fournier gangrene and thrombophlebitis, and treatment of inconsequential disease are harms associated with colonoscopy in 3 of 1,000 screenings.[31] Woolf [36] identified potential harms of PSA testing for men without disease and for those with prostate cancer. False-positive results cause unnecessary followup procedures and anxiety. Treatment of inconsequential disease results in unnecessary procedures and potential complications.

These potential harms of cancer screening are especially important in decisionmaking for elderly individuals, as there are fewer studies and evidence for this segment of the population. Based on analysis of all-cause and cancer-specific mortality from the National Center for Health Statistics and Surveillance Epidemiology and End Results Survey (SEER), Rich and Black[38] concluded that potential harms may outweigh the small benefit of screening for breast cancer,

colon cancer, and cervical cancer in elderly individuals. Volk and colleagues[39] evaluated a patient-educational approach to shared decisionmaking for prostate cancer screening that included both potential benefits and harms of screening. The results of the randomized clinical trial indicated positive outcomes in terms of increased knowledge and more informed decisions regarding prostate cancer screening. Walter and Covinsky[40] advocated including potential harms in their framework for individual decisionmaking in cancer screening in elderly individuals.

In summary, harms of various cancer screening procedures have been identified. However, it is important to evaluate the potential harms for each procedure relative to the benefits for specific age groups and other individual considerations. Thus, the USPSTF recommends routine screening mammography for women ages 40 years and older; routine screening for cervical cancer in women who have been sexually active and have a cervix, but against routine screening for women older than 65; and routine colorectal cancer screening for men and women 50 years and older. However, the USPSTF is currently updating recommendations for screening for colorectal, cervical, and breast cancer. The USPSTF currently recommends against routine screening for pancreatic cancer or ovarian cancer. The task force concluded that there was insufficient evidence to recommend for or against routine screening for prostate cancer, skin cancer, oral cancer, or lung cancer.

Errors and Adverse Events Related to Language in Preventive Services

A small but interesting group of studies[41, 42] and one review[43] examined the role of language either as a barrier to receiving care or as a factor in adverse events. This area of study is particularly relevant given the growth of ethnic populations in the United States. Nearly 20 percent of U.S. citizens over the age of 5 years speak a language other than English at home.[41] However, it is estimated that "more than 50 percent of adults over the age of 18 who speak a language other than English at home speak English 'very well'"[41] (p. 254). Lack of proficiency in English may result in communication problems with health care providers and decreased utilization of care, and it may reflect cultural values and beliefs.[42] Results of two studies supported the potential for harm resulting from women not receiving preventive services[42] and infants of parents whose primary language is not English not receiving recommended preventive care.[41] Using data from a cross-sectional survey of 22,448 women completing the 1990 Ontario Health Survey, logistic regression calculated odds ratios for receiving breast examinations, mammograms, and Pap tests for women who reported a language other than English as spoken at home versus those who reported English as the primary language, adjusting for socioeconomic factors, contact with the health care system, and cultural measures.[42] Results indicated that women who reported a language other than English spoken at home were less likely to receive important preventive services than those who spoke English at home. These findings persisted after adjusting for the confounding variables. French-speaking women were less likely to receive breast examinations or mammograms, and women speaking other languages were less likely to receive Pap tests.

In a retrospective cohort study of 38,793 year-old infants enrolled in Medicaid, relative risk of receiving appropriate and timely preventive care was estimated using multivariate regression.[41] Primary language of parents, race and ethnicity, rural residence, and managed-care plan were independent variables. Results indicated that "fewer than one in six infants enrolled in Medicaid in their first year of life received recommended preventive care as defined by the

[American Academy of Pediatrics]"[41] (p. 257). Further, infants whose parents reported that English was not their primary language were half as likely to receive recommended preventive care. When confounding factors were considered, results indicated that Asian-American infants were less likely to experience disparities in preventive care associated with primary language than White, Hispanic, and African-American infants.

While the evidence is limited, the results of these two studies support the potential for adverse events resulting from language barriers. An obvious strategy would be to reduce the language barriers. A systematic review of the impact of medical interpreter services on the quality of health care[43] indicated that health care was compromised for patients not proficient in English; they were less likely to receive preventive screening, more likely to have a greater number of tests done at higher costs; and were less satisfied with care. Additionally, the quality of care is further compromised when untrained or ad hoc interpreters, especially children, are used. However, availability of trained interpreters was positively associated with obtaining preventive screening, such as mammograms. In light of the changing demographics and diversity of the U.S. population, this small but growing body of literature on language as a barrier or factor in adverse events in preventive services provides another challenge for the health care systems.

Errors and Adverse Events Related to Information Technology in Preventive Services

A final group of studies explored the impact of the growing use of information technology (IT) in health care. IT in health care has been examined from several perspectives. There is a literature on the use of e-mail and the Internet by consumers, another on the adoption of IT by health care systems, and a third on the unintended consequences of the use of IT in health care.

Although reports of the extent of use of the Internet and e-mail for health care vary from 35 percent to 80 percent of adults in the United States,[44] the actual and potential impact of IT in health care is significant. A survey of a nationally representative sample of 8,935 (69.4 percent of a random sample of 12,878) adults age 21 years and over, individuals age 50 and older, and veterans identified four frequent uses of the Internet and e-mail.[44] The most common use of the Internet (reported by 40 percent of respondents) was for information or advice about health or health care. This was followed by use of e-mail or the Internet to communicate with family or friends about health, use of e-mail or the Internet to communicate with a health care professional, and use of these technologies to communicate with other people with similar health conditions. However, use of the Internet for health care was a relatively infrequent activity (every 2 to 3 months or less frequently). Individuals younger than 75 years old and women were more likely to use the Internet and e-mail for health. Results also indicated that e-mail and the Internet were used most often to gain health-related information and had little effect on the number of contacts with health care providers or to obtain a prescription drug.

IT has been more developed and adopted for financial management than for quality and safety purposes.[45] Results from a study of IT use in a variety of health care settings in the Boston and Denver areas indicate that physician practices (the most common site of preventive services), which are generally run as "small independent practices"[46] (p. 6), use IT primarily to manage billing and schedule patients. Poon and colleagues[46] propose that the limited use of electronic health records in these practices is related to the perception of limited proven benefits relative to the required financial and time commitments needed.

Based on results from separate qualitative studies, Ash, Berg, and Coiera[47] presented evidence that implementation of electronic patient care information systems (PCISs) in many instances appears to promote rather than limit errors. They argued that factors, including the complexity of PCISs and the physical space and other system characteristics, contributed to the occurrence of "unintended consequences"[47] (p. 104). The authors identified errors in two general areas: process of entering and retrieving information, and communication and coordination processes. They attributed errors in entry and retrieval of information to the high level of interruption and "cognitive overload" related to practice environments. Further, the authors proposed that errors in communication and coordination were related to the assumptions of a linear workflow and communication as information transfer. They advocated for educating health care providers to have a critical approach to PCISs, that developers and vendors of PCISs be clearer about the limitations of the systems, and that clinicians be supported in continuing interactions that are part of monitoring the safety of clinical systems.

Research that evaluates the ability of IT systems to promote patient safety and reduce errors is limited but growing,[45] especially in preventive services. Five studies[48–52] examined the use of an electronic health record system to generate physician, telephone, and letter reminders for patients to obtain preventive services. Results indicated that all three types of reminders were effective. There is evidence supporting the reduction of medication errors and adverse events through the use of computerized physician order entry and online decision support.[53] Bakken and colleagues[54] advocated the use of informatics to address errors associated with impaired access to information through the use of personal digital assistants, to address communication failures associated with adverse events, to promote the use of standardized practice patterns, and to provide automated surveillance to detect and prevent real-time errors. The proposed approaches have direct application in preventive care settings.

Evidence-Based Practice Implications

The evidence on errors and adverse events in preventive care provides preliminary direction for practice. Few if any studies proposed or evaluated approaches to avoid or reduce errors and adverse events in prevention. However, a growing number of studies have evaluated strategies to reduce errors and adverse events in acute, inpatient, ambulatory, primary, and home care, and they provide potential direction for prevention as the field matures. Leape's[55] directives—identify what works, ensure that the patient receives it, and deliver it flawlessly—are relevant for ensuring safety in prevention. At this point, perhaps the most viable approach to assure patient safety in prevention practice is use of the guidelines of the USPSTF, AHRQ, the Community Task Force, and CDC.

Research Implications

The greatest challenge in patient safety and quality in preventive care is the lack of a strong body of evidence on which to base our understanding of errors and adverse events in prevention and, more broadly, in ambulatory and primary care settings. Research in preventive care is limited relative to that in acute care, inpatient settings, and home care. The focus has been on research evaluating the efficacy of preventive services, which includes an evaluation of the potential and actual harms of the services in order to determine the net benefit. While there is a growing body of evidence for safety and quality in health care in primary and ambulatory

settings, there is very limited literature on harms or adverse events in preventive care and how to avoid them. Additionally, much of the research is observational and descriptive, with few interventions being tested. The research on identifying and describing errors in primary and ambulatory care has relevance for preventive care. However, there is a need for research directed at explicating errors and adverse events in preventive care.

Once the types of errors and adverse events have been identified and described, then research describing the factors associated with these events is needed. Further, there is limited evidence on basic questions, such as when to begin or discontinue screening, chemoprophylaxis, or counseling and implications for adverse events or potential harms. Only then can nurses and other health care professionals develop and test strategies to reduce risk related to preventive services. For example, the evaluation of the use of IT to decrease risks and adverse events is a major focus in acute care, ambulatory care, and primary care settings. Would the use of IT approaches be appropriate in preventive services? How can the human factor principles of standardization, simplification, and use of protocols and checklists[55] be facilitated by the use of IT in prevention? Finally, the difficulties inherent in research on preventive services present significant challenges, including timing of services and consideration of contextual factors (age, culture, race/ethnicity, gender, setting, etc.).

Thus far, the evidence presented attempts to answer the following: (1) How do errors and adverse events in prevention differ from those for other types of health care services? (2) How do contextual factors contribute to potential errors and adverse events in prevention? and (3) What are potential areas of research for nursing that would contribute to addressing patient safety in prevention? The following areas are the critical research gaps:

- Descriptive data on errors and adverse events in preventive services
- Data on factors related to errors and adverse events in preventive services
- Evaluation of interventions to reduce errors and adverse events in preventive services.

Conclusion

The limited body of evidence on errors and adverse events in preventive services, especially from a nursing perspective, supports the need for additional research to move ahead in the area of patient safety. It is likely that some of the evidence from studies in ambulatory and primary care will provide direction for research and subsequent evidence-based practice in preventive care. However, there may be unique errors and adverse events associated with preventive services. It is clear that there is potential for errors and adverse events in preventive services, but additional evidence is needed to explicate what they are. The evidence that is available is largely from either descriptive studies or from randomized controlled trials (RCTs) examining the efficacy of preventive services, specifically in cancer screening. There is less systematic evaluation of counseling interventions for prevention. The nature of preventive services and their outcomes and where they are delivered increase the complexity of both establishing an evidence base and implications for practice. The continued evaluation of using information technology to address risks and adverse events is a promising area for study and practice.

The focus in safety and quality research in health care has been on preventable events rather than on preventive services. Screening, counseling, and chemoprophylaxis are the key elements of preventive services. The evidence base on errors and adverse events in preventive services is limited and needs to be developed to provide direction for practice.

Search Strategy

A search of the CINAHL®, Ovid MEDLINE®, Cochrane Database of Systematic Reviews electronic databases, and the AHRQ Web site from 1990 to 2006 was conducted using the following search terms: patient safety, safety, quality, preventive services. The search was further limited to research studies and reviews. A total of 115 references were identified and the abstracts reviewed. The criteria for inclusion in the review for this chapter were (1) systematic review of published research; (2) nonsystematic review of published research; and (3) published research that used randomized control, comparison, and pretest–post-test no control designs. Based on the review of the abstracts using these criteria, 6 reviews, 10 commentary or background articles, and 32 studies were selected for inclusion in the review.

Author Affiliation

Carol J. Loveland-Cherry, Ph.D., R.N., F.A.A.N., professor and executive associate dean, University of Michigan School of Nursing. E-mail: Loveland@umich.edu.

References

1. Institute of Medicine. Crossing the quality chasm. Washington, DC: National Academy Press; 2001.

2. Institute of Medicine. Keeping patients safe: transforming the work environment of nurses. Washington, DC: National Academy Press; 2004.

3. U.S. Department of Health, Education, and Welfare. Healthy people: the Surgeon General's report on health promotion and disease prevention. Washington, DC: DHEW (PHS); 1979.

4. U.S. Department of Health, Education, and Welfare. Healthy People 2000: National health promotion and disease prevention objectives. Washington, DC: DHEW (PHS); 1991.

5. U.S. Department of Health, Education, and Welfare. Healthy People 2010 (2nd ed.). Washington, DC: DHEW (PHS); 2000.

6. Woolf SH, Atkins D. The evolving role of prevention in health care: contributions of the U.S. Preventive Services Task Force. Am J Prev Med 2001; 20(3S):13-20.

7. Briss PA, Brownson RC, Fielding JE, et al. Developing and using the guide to community preventive services: lessons learned about evidence-based public health. Annu Rev Public Health 2004; 25:281-302.

8. Institute of Medicine. To err is human: building a safer health system. Washington, DC: National Academy Press; 2000.

9. Wilson T, Pringle M, Sheikh A. Promoting patient safety in primary care. BMJ 2001; 323:583-4.

10. Bhasale AL, Miller GC, Reid SE, et al. Analysing potential harm in Australian general practice: an incident-monitoring study. MJA 1998;169:73-6.

11. Elder NC, Vonder Meulen MB, Cassedy A. The identification of medical errors by family physicians during outpatient visits. Ann Fam Med 2004;2(2):125-9.

12. Phillips RL, Bartholomew LA, Dovey SM, et al. Learning from malpractice claims about negligent, adverse events in primary care in the United States. Qual Saf Health Care 2004;13:121-6.

13. Dovey SM, Meyers DS, Phillips RL, et al. A preliminary taxonomy of medical errors in family practice. Qual Saf Health Care 2002;11:233-8.

14. Rubin G, George A, Chinn DJ, et al. Errors in general practice: development of an error classification and pilot study of a method for detecting errors. Qual Saf Health Care 2003;12:443-7.

15. Kuzel AJ, Woolf SH, Gilchrist VJ, et al. Patient reports of preventable problems and harms in primary health care. Ann Fam Med 2004;2(4):333-40.

16. Elder NC, Dovey SM. Classification of medical errors and preventable adverse events in primary care: a synthesis of the literature. J Fam Pract 2002;51(11):927-32.

17. Gurwitz JH, Field TS, Rothschild J, et al. Incidence and preventability of adverse drug events among older persons in the ambulatory setting. JAMA 2003;289(9):1107-16.

18. Mayo AM, Duncan D. Nurse perceptions of medication errors: what we need to know for patient safety. J Nurs Care Qual 2004:19(3):209-17.

19. Gandhi TK, Weingart SN, Borus J, et al. Patient safety: adverse drug events in ambulatory care. N Engl J Med 2003;348(16):1556-64.

20. Brown CA, Bailey JH, Lee J, et al. The pharmacist-physician relationship in the detection of ambulatory medication errors. Amer J Med Sci 2006; 331:22-4.

21. Triller DM, Clause SL, Hamilton RA. Risk of adverse drug events by patient destination after hospital discharge. Am J Health-Syst Pharm 2005;62(Sept 15):1883-9.

22. Kralewski JE, Dowd BE, Heaton A, et al. The influence of the structure and culture of medical group practices on prescription drug errors. Med Care 2005;43(8):817-25.

23. Metlay JP, Cohen AJ, Polsky D, et al. Medication safety in older adults: home-based practice patterns. J Am Geriatr Soc 2005;53:976-82.

24. Field TS, Gurwitz JH, Harbold LR, et al. Strategies for detecting adverse drug events among older persons in the ambulatory setting. J Am Med Inform Assoc 2004;11:492-8.

25. Hicks RW, Becker SC, Cousins DD. Harmful medication errors in children: a 5-year analysis of data from the USP's MEDMARX® program. J Ped Nurs, 2006;21(4): 290-8.

26. Gandhi TK, Weingart SN, Seger AC, et al. Outpatient prescribing errors and the impact of computerized prescribing. J Gen Intern Med 2005;20:837-941.

27. Glassman PA, Belperio P, Simon B, et al. Exposure to automated drug alerts over time: effects on clinicians' knowledge and perceptions. Med Care 2006;44:250-6.

28. De Smet PA, Dautzenberg M. Repeat prescribing: scale, problems and quality management in ambulatory care patients. Drugs 2004; 64(16): 1779-1800.

29. Quaid KA. Psychological and ethical considerations in screening for disease. Am J Cardiol 1993;72:64D-7D.

30. Brawley OW. Kramer BS. Cancer screening in theory and in practice. J Clin Oncol 2005;23:293-300.

31. Walter LC, Lewis CL, Barton MB. Screening for colorectal, breast, and cervical cancer in the elderly: a review of the evidence. Am J Med 2005;118(10):1078-86.

32. Mandelblatt J, Saha S, Teutsch S, et al. The cost-effectiveness of screening mammography beyond age 65 years: a systematic review for the U.S. Preventive Services Task Force. Ann Inter Med 2003;139(10):835-42.

33. Tabar L, Vitak B, Chen HH, et al. The Swedish Two-County Trial twenty years later. Radiol Clin N Am 2004;11:126-9.

34. Bonneux L, Raffle AE, Quinn M, et al. Harms and benefits of screening to prevent cervical cancer. Lancet 2004;364:1483-6.

35. Kerlikowske K, Salzmann P, Phillips KA, et al. Continuing screening mammography in women aged 70 to 79 years: impact on life expectancy and cost-effectiveness. JAMA 1999;282(22):2156-63.

36. Woolf SH. Public health perspective: the health policy implications of screening for prostate cancer. J Urolog 1994;152:1685-8.

37. Sawaya GF, Grady D, Kerlikowske K, et al. The positive predictive value of cervical smears in previously screened postmenopausal women: the heart and estrogen/progestin replacement study (HERS). Ann Intern Med 2000;133(12):942-50.

38. Rich JS, Black WC. When should we stop screening? Eff Clin Pract 2000;3(2):78-84.

39. Volk, RJ, Cass AR, Spann SJ. A randomized controlled trial of shared decision making for prostate cancer screening. Arch Fam Med 1999;8:333-40.

40. Walter LC, Covinsky KE. Cancer screening in elderly patients: a framework for individualized decision making. JAMA 2001;285(21):2750-6.

41. Cohen AL, Christakis DA. Primary language of parent is associated with disparities in pediatric preventive care. J Pediatr, 2006;148:254-25.

42. Woloshin S, Schwartz L, Katz SJ, et al. Is language a barrier to the use of preventive services? J Gen Intern Med 1997;12:472-7.

43. Flores G. The impact of medical interpreter services on the quality of health care: a systematic review. Med Care Res Rev 2005;62:255-99.

44. Baker L, Wagner TH, Singer S, et al. Use of Internet and e-mail for health care information. JAMA, 2003;289(18):2400-6.

45. Poon EG, Jha AK, Christino M, et al. Assessing the level of healthcare information technology adoption in the United States: a snapshot. BMC Medical Informatics and Decision Making 2006;6:1.

46. Ash JS, Berg M, Coiera E. Some unintended consequences of information technology in health care: the nature of patient care information system-related errors. J Am Med Inform Assoc 2004;11(2):104-12.

47. Shekelle PG, Morton SC, Keeler EB. Costs and benefits of health information technology. Evidence Report/Technology Assessment No. 132. (Prepared by the Southern California Evidence-based Practice Center under Contract No. 290-02-0003.) Rockville, MD: Agency for Healthcare Research and Quality; April 2006. AHRQ Publication No. 06-E006.

48. McDowell I, Newell C, Rosser W. A randomized trial of computerized reminders for blood pressure screening in primary care. Med Care 189;27(3): 297-305.

49. McDowell I, Newell C, Rosser W. Computerized reminders to encourage cervical screening in family practice. J Fam Pract 1989;28(4):420-4.

50. Rosser WW, Hutchinson BG, McDowell I, et al. Use of reminders to increase compliance with tetanus booster vaccination. CMAJ 1992;146(6): 911- 7.

51. McDowell I, Newell C, Rosser W. Comparison of three methods of recalling patients for influenza vaccination. CMAJ 1986;135(9):991-7.

52. Rosser WW, McDowell I, Newell C. Use of reminders for preventive procedures in family medicine. CMAJ 1991;145:807-14.

53. Koshy R. Navigating the information technology highway: computer solutions to reduce errors and enhance patient safety. Transfusion 2005;45:189S-205S.

54. Bakken S, Cimino JJ, Hripcsak G. Promoting patient safety and enabling evidence-based practice through informatics. Med Care 2004;42(2): II-49-56.

55. Leape LL, Berwick DM, Bates DW. What practices will most improve safety? Evidence-based medicine meets patient safety. JAMA 2002;288(4):501-7.

56. Barratt AL, Irwig LM, Glasziou PP, Salkeld GP, Houssami N. Benefits, harms and costs of screening mammography in women 70 years and over: a systematic review. MJA. 2002; 176: 266-272.

57. Barton MB. Breast cancer screening: benefits, risks, and current controversies. Postgrad Med. 2005; 118(2): 27-36.

58. Hibbard JH, Stockard J, Tusler M. It isn't just about choice: the potential of a public performance report to affect the public image of hospitals. Med Care Res Rev. 2005; 62(3):358-71.

Evidence Table. Prevention—safety and quality

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design, Study Outcome Measure(s)	Study Setting and Study Population	Study Intervention	Key Finding(s)
Ash 2004[46]	Patient care information system-related (PCISs) errors	Literature review, nonsystematic, and series of qualitative studies	Qualitative studies (5) impact of PCISs in health care and unintended outcomes (2).	Health care delivery settings and interviews with professionals in the United States, Netherlands, and Australia	None	Types of errors: Process of entering and retrieving information – juxtaposition error, orders entered for or on behalf of the wrong person, cognitive overload, communication and coordination process – inflexibility, urgency, work-arounds, transfers, loss of communication, loss of feedback, decisions support overload, catching errors, multidisciplinary qualitative research.
Baker 2003[44]	Use of Internet and e-mail for health care information	Cross-sectional study	National survey of Internet use for health care and prevalence of e-mail use for health care (5). Use of Internet and e-mail for health care and effects on knowledge of health care and use of health care system (3).	4,764 individuals ages 21 years and older who were self-reported Internet users drawn from a research panel of more than 60,000 U.S. households	Internet and e-mail use	~40 percent of respondents with Internet access used Internet to look for advice or information about health or health care; 6 percent used e-mail to contact a health care professional; ~1/3 using Internet for health reported it affected a health or health care decision; little effect on health care utilization – 94 percent reported no effect on number of visits and 93 percent no effect on number of telephone contacts; 5 percent reported use of Internet to obtain prescriptions or pharmaceutical products.

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design, Study Outcome Measure(s)	Study Setting and Study Population	Study Intervention	Key Finding(s)
Bakken 2004[54]	Use of informatics to promote patient safety and enable evidence-based practice	Literature review, nonsystematic	Literature review, nonsystematic (6). Patient safety and evidence-based practice (3).	Review of literature on informatics infrastructure for patient safety and evidence-based practice	None	Examples of how components of informatics infrastructure can be integrated to achieve evidence-based practice and patient safety objectives in four areas: improving information access, automated surveillance for real-time error detection and prevention, facilitating communication among members of the health care team, and standardization of practice patterns.
Barratt 2002[56]	Harms of screening mammography	Systematic literature review	Decision-analytic, cost-effectiveness models; quality of life and life expectancy	Australian women 70 years and older	None	Five models met inclusion criteria; two included quality of life. Life-expectancy benefit of screening mammography diminishes with increasing age: 70–79 years, 40–72 percent without quality of life adjustment, 18–62 percent with it. 9,600 of 10,000 will be told they do not have breast cancer, ~400 will have further tests; ~70–112 will undergo breast biopsy and 19–80 cancers detected; ~ 15–20 percent will be DCIS; quality-adjusted life-year = $8,119–$27,751. Relatively cost-effective. Not studied: anxiety, mortality from mastectomy, post-op morbidity.
Barton 2005[57]	Risk factors for breast cancer	Literature review, nonsystematic/ narrative	Accepted screening methods and new technologies	Women in the United States	None	False-positive approach 50 percent after 10 screens; discovery of DCIS with transformation 14–60 percent; MRI more sensitive but led to >three times the number of biopsies with no cancer; high costs.

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design, Study Outcome Measure(s)	Study Setting and Study Population	Study Intervention	Key Finding(s)
Bhasale 1998[10]	Incident monitoring of potential harm in general practice	Noncomparative study	Observational study (5). Reports of number and type of incidents, contributing factors, mitigating factors, additional resource use (Level 1).	324 general practitioners (GPs) from nonrandom sample of Australian GPs 10/93–6/95	None	805 incidents reported: 76 percent preventable, 27 percent potential for severe harm, no long-term harm for 66 percent, related to pharmacological management, nonpharmacological management, diagnosis, or equipment; most common contributory factors poor communication between patients and health care professionals, actions of others, and errors in judgment.
Brawley 2005[30]	Biases, harms, accuracy of cancer screening	Literature review, nonsystematic/ narrative	Nonsystematic literature review (6). Harms of screening (2).	Review of screening modalities for specific cancers, including potential harms and accuracy of screening	None	Biases – selection, lead-time, length; harms – complications of treating true-positives and false-positives, labeling, mental anguish; accuracy – sensitivity, specificity positive predictive value, negative predictive value; breast cancer false-positives – repeat mammogram, ultrasound, biopsy; ovarian – additional, invasive evaluation; prostate – missed cases, clinically insignificant cases.
Brown 2006[20]	Pharmacist-physician relationship in detecting ambulatory medication errors	Noncomparative study	Observational study without controls (5). Data pharmacist's role, responsibilities, and expectations to inform physicians about medication errors (3).	Focus groups with 30 pharmacists and 31 patients in community pharmacies in Mississippi	None	Ambulatory pharmacist is common link between physician and patient, multiple physicians; pharmacist is patient educator, pharmacist is interceptor in detecting medication errors; hesitancy to contact physicians, physician accessibility barriers.

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design, Study Outcome Measure(s)	Study Setting and Study Population	Study Intervention	Key Finding(s)
Cohen 2006[41]	Disparities in pediatric preventive care associated with primary language of parent	Retrospective cohort study	Review of Medicaid data (5). Appropriate and timely receipt of six preventive care visits in first year of life (2).	Review of records for 38,793 Medicaid - enrolled 1-year-old infants in Washington State	Primary language of parent	Infants of parents whose primary language was not English were half as likely to receive recommended preventive care; disparity evident for white, Hispanic, and African-American but not Asian-American infants.
De Smet 2004[28]	Repeat prescribing	Systematic literature review	Repeat prescribing in ambulatory care patients: definition and scale of repeat prescribing; problems with repeat prescribing and areas for improvement; characteristics and results of intervention studies; conclusions and recommendations for future research (3).	Ambulatory care patients	Review of medications by pharmacist; feedback to patient and physician; home inventory of medications; monthly dispensing with protocol led to check on drug-related problems; chart review; written feedback by physician	Repeat prescriptions range from 29 percent to 75 percent; much by GPs without direct doctor-patient contact; overall interventions helped resolve pharmaceutical care issues – compliance; effects on health-related quality-of-life, death rate, health care consumption or total health care cost not observed; real clinical improvements – adverse effects score, lipid values, reduced inappropriate prescribing in elderly outpatients receiving polypharmacy; some showed positive effect on number of medications, medication units, and medication cost.

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design, Study Outcome Measure(s)	Study Setting and Study Population	Study Intervention	Key Finding(s)
Dovey 2002[13]	Medical errors in family practice	Noncomparative study	Observational study without controls (5); "error is defined as the failure of a planned action to be completed as intended or the use of a wrong plan to achieve an aim"; "safety is defined as freedom from accidental injury"; "anything that happened in your own practice that should not have happened, that was not anticipated, and that makes you say 'that should not happen in my practice and I don't want it to happen again'" (1).	42 family physicians from the National Network for Family Practice and Primary Care Research	Preliminary taxonomy of medical errors in family practice	330 error reports resulting in four-layered taxonomy: Process errors and knowledge and skills errors; knowledge and skills – receptionist failing to make urgent appointment, physicians decided to discharge patients before able to function well at home; process – treatment delivery problems, miscommunication; consequences – none, care delayed/extended, financial and time costs to patients, physicians, system, patient upset or lost trust in physician, became ill, did not regain health, admitted to hospital, or died.

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design, Study Outcome Measure(s)	Study Setting and Study Population	Study Intervention	Key Finding(s)
Elder 2002[16]	Errors and preventable adverse event from medical care in outpatient primary care settings	Systematic literature review	Systematic review of original research (7 studies); process errors and preventable adverse events (1).	Seven studies from family practice, ambulatory care, primary health care	Classification of preventable adverse events (PAE) and process errors in primary care	Limited number of small studies; classification of three main categories of PAEs – diagnosis (misdiagnosis related to symptoms or prevention) treatment (drug or nondrug), and preventive services (inappropriate, delayed, omitted, procedural complications); attributable to four groups of process errors: clinician factors (clinical judgment, procedural skills error), communication factors (clinician-patient, clinician-clinician, or health care system personnel), administration factors (clinician, pharmacy, ancillary providers, office setting), blunt-end factors (personal and family issues of clinicians and staff, insurance company regulations, government regulations, funding and employers, physical size and location of practice, general health care system).
Elder 2004[11]	Errors and preventable adverse events by family physicians in outpatient visits	Noncomparative study	Observational study without controls (5). Errors and preventable adverse events, patient harm (1).	15 family physicians in 7 practices in Cincinnati area	None	117 errors or preventable adverse events; most common were administration errors (charting, general office administration); physician-related errors; patient communication errors. Harms: actual minor physical discomfort, mild adverse drug reaction, moderate physical injury from a procedure, progression of disease; most common emotional distress and wasted time for the patient; potential harms development of preventable disease, pain or physical distress, progression of disease, drug-drug interactions, infection, and poor outcomes from procedure.

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design, Study Outcome Measure(s)	Study Setting and Study Population	Study Intervention	Key Finding(s)
Field 2004[24]	Strategies for identifying adverse drug events (ADEs)	Prospective cohort study	Observational study without controls (5); drug/drug-related incidents (1).	31,757 Medicare enrollees in large multispecialty group practice in New England over 12 months	None	1,523 ADEs, 28 percent considered preventable; positive predictive values for sources – 54 percent, highest provider reports but accounted for only 11 percent of ADEs and 6 percent of preventable ADEs, hospital discharge summaries very low PPV, computer-generated signals accounted for 31 percent of ADEs and 37 percent of preventable ADEs, electronic notes accounted for 35 percent of ADEs and 29 percent of preventable ADEs; little overlap in ADES identified across all sources; electronic strategies identify more ADEs than other sources; use multiple sources.

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design, Study Outcome Measure(s)	Study Setting and Study Population	Study Intervention	Key Finding(s)
Flores 2005[43]	Effect of medical interpreter services on health care quality	Systematic review	Systematic review of 36 studies (RCT, descriptive, qualitative, survey) on LEP (limited in English proficiency) (1). Quality of health care and errors related to use of interpreters; communication issues; patient satisfaction with care; and processes, outcomes, complications, and use of health services (2).	Urban emergency department, hospitals, physician offices	None	Lack of interpreters results in poor self-reported understanding of diagnosis and treatment plan. Ad hoc interpreters misinterpret or omit up to half of all physicians' questions, are more likely to commit errors with potential clinical consequences, have a higher risk of not mentioning medication side effects, and ignore embarrassing issues when children are ad hoc interpreters. Lack of interpreters affects communication and quality of psychiatric encounters, including positive effects of bilingual providers and an adverse impact of ad hoc and no interpreters. Bilingual providers and telephone interpreters yield highest levels for satisfaction. Interpreters resulted in increase of preventive screening and reduced disparities in LEP and EP patients: with interpreters, greater increase in office visits, number of prescriptions written and filled, but none in number of phone contacts, urgent care phone calls, or urgent care visits. Controversy on duration of visits. LEP with no or ad hoc interpreter have more medical tests, higher test costs, more frequent intravenous hydration, and higher risk of hospitalization.

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design, Study Outcome Measure(s)	Study Setting and Study Population	Study Intervention	Key Finding(s)
Gandhi 2003[19]	Adverse drug events in primary care	Prospective cohort study	Observational study without controls (5). Adverse drug events (1).	Survey of 661patients who received at least one prescription during a 4-week period (55 percent response rate) and chart review at four adult primary care practices in Boston (two hospital based and two community based)	None	25 percent (n = 162) had a total of 181 adverse drug events;13 percent (24) serious, 28 percent (51) ameliorable, 11 percent (20) preventable. Of 51 ameliorable 63 percent attributed to physician's failure to respond to medication-related symptoms, and 37 percent to patient's failure to inform physician of symptoms; most frequent medication classes – selective serontonin-reuptake inhibitors (10 percent), beta-blockers (9 percent), angiotensin-convertying-enzyme inhibitors (8 percent), nonsteroidal anti-inflammatory agents (8 percent). Multivariate analysis – only number of medications taken significantly associated with adverse events.
Gandhi 2005[26]	Outpatient prescribing errors	Prospective cohort study	Observational study without controls (5). Adverse drug events (1).	Outpatients over age 18 who received a prescription from 24 participating physicians in 4 adult primary care practices in Boston using prescription review, patient survey, and chart review	None	Screened 1,879 prescriptions from 1,202 patients and 661 surveys (55 percent response rate); 143 prescriptions contained a prescribing error, 3 errors led to preventable ADEs, and 62 had potential for patient injury. 1 (2 percent) was potentially life threatening and 15 (24 percent) were serious. Rates of medication errors and potential ADEs not significantly different at basic computerized prescribing sites vs. handwritten sites; advanced checks could have prevented 95 percent of potential ADEs; prescribing errors in 7.6 percent of outpatient prescriptions.

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design, Study Outcome Measure(s)	Study Setting and Study Population	Study Intervention	Key Finding(s)
Glassman 2006[27]	Effects of automated drug alerts on clinicians' knowledge and perceptions	Pretest and post-test study	Observational study with controls (4). Increased recognition of selected interacting dug pairs and perceptions of computerized order entry (3).	97 clinicians (82 physicians and 15 nurse practitioners/physician asst) in ambulatory settings in Southern California Veterans Affairs Healthcare System	Interval (~2 years) exposure to automated drug alerts via computerized patient record system (CPRS)	Clinicians recognize seven interacting and/or contraindicated drug-drug pairs at both time periods; recognition of three contraindicated drug-drug pairs moderately improved; more clinicians preferred order entry at followup vs. baseline (63 percent vs. 45 percent); most common barrier to use of order entry system was "poor signal to noise" ratio or too may nonrelevant alerts.
Gurwitz 2003[17]	Adverse drug events among older person in ambulatory setting	Retrospective cohort study	Observational study without controls (5). Adverse drug events (1).	Medicare enrollees cared for by multispecialty group practice during a 12-month period	None	1,523 adverse drug events – 27.6 percent (421) considered avoidable; 578 (38 percent) categorized as serious, life threatening, or fatal; overall rate of 50.1 adverse drug events/1,000 person-years; rate of 13.8 preventable adverse drug events/1,000person-years. Errors occurred most often at stages of prescribing (58.4 percent) and monitoring (60.8 percent); 21.1 percent of errors involved patient adherence. Most common medication categories were cardiovascular (24.5 percent), diuretics (22.1 percent), nonopioid analgesics (15.4 percent), hypoglycemics (10.9 percent), anticoagulants (10.2 percent).

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design, Study Outcome Measure(s)	Study Setting and Study Population	Study Intervention	Key Finding(s)
Hibbard 2005[58]	Medical errors	Cross-sectional	Assess the effectiveness of 12 recommendation actions form AHRQ's 20 tips; respond to scenarios of 29 different possible medical errors; response to terms patient safety and medical errors; how effected are recommended actions; how likely are consumers to engage in actions.	195 consumers of medical care recruited from University of Oregon classified staff, mean age 42, 71 percent female, 81.5 percent Caucasian, 12 percent high school graduates, 55.4 percent college graduates, 14 percent listed health as fair or poor, 44 percent reported they or family member had experienced a medical error.	None	Patient safety (27 percent not a serious problem) perceived as less of a problem than medical errors (23 percent not a serious problem); more likely to engage in older established recommended actions (4.6) than newer recommended ones (2.9) or those actions requiring questioning (2.6). Self-efficacy and effectiveness of action related to likelihood to engage in recommended actions.
Hicks 2006[25]	Medication errors in children	Retrospective cohort study	Observational study without controls (5). Harmful medication errors in children (1).	Data from voluntary medication error reporting system (MEDMARX®) over 5 years for individuals <17 years old	None	816 harmful outcomes involving 242 medications; 11 medications accounted for 34.5 percent of errors; wrong dosing and omission errors common; associated with opioid analgesics (11 percent), antimicrobials (7.5 percent), antidiabetic agents (4.5 percent), fluids and electrolytes (4.4 percent).

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design, Study Outcome Measure(s)	Study Setting and Study Population	Study Intervention	Key Finding(s)
Kerlikowske 1999[35]	Cost effectiveness and impact on life expectancy of mammography screening in women 70–79 years	Noncomparative study	Decision analysis and cost-effectiveness analysis using a Markov model (4). Deaths due to breast cancer averted, life expectancy, cost effectiveness (2).	General population of women 65 and older	Outcomes of screening mammography based on three screening strategies	Continuing screening to age 79 with bone mineral density in top 3 quartiles prevent 9.4 deaths and add ~2.1 days to life expectancy with incremental cost of $66,773 /year of life saved; continuing screening in all women to age 79 prevents 1.4 additional breast cancer deaths and adds 7.2 hours to life expectancy with incremental cost of $117,689/year of life saved. Goal is to prevent deaths from breast cancer at reasonable cost and minimize harms of screening healthy women. Incidence of DCIS increases with age with 25 percent of cancer being DCIS in elderly women; increases rate of surgical treatment of insignificant lesions; 8 percent of women ages 70 and older will have abnormal result; 85 percent–92 percent with abnormal result do not have cancer; worry and anxiety.
Koshy 2005[53]	Medical errors and patient safety	Literature review, nonsystematic/ narrative	Review of literature (5). Computer solutions to medical errors and patient safety (2).	Biometrics data base; biometrics – fingerprints, CPOE (computerized physician order entry), DSSs (decision support systems)	None	Proposed Patient Care Information System – integrated, seamless, with access to real-time patient information (biometrics, CPOE. electronic medical records, etc.). Recommendations: existing error-prevention strategies are not adequate to reduce errors and assure safe health-care deliver; proposes layout of linked data systems from hospital medical information system to regional database to central database

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design, Study Outcome Measure(s)	Study Setting and Study Population	Study Intervention	Key Finding(s)
Kralewski 2005[22]	Influence of structure and culture of medical group practices on prescription drug errors	Retrospective cohort study	Observational study without controls (5). Influence of structure and culture of medical group practices (3).	Care Plus claims data, prescription drug error rates at enrollee level aggregated for 78 group practices in upper Midwest, ambulatory care	None	30 percent of 250,024 prescriptions written flagged as potential errors; ~half of errors were for over- or underdoses; predictors of drug errors – physician workload, use of outpatient case managers related to lower error rates; coordinating care in rural areas related to higher error rates; urban group practices lower error rates; value of physician autonomy lower error rates; financial incentive use of electronic information systems not associated with lower error rates; structure and culture variable explain 52 percent of variance.
Kuzel 2004[15]	Medical errors in primary care	Noncomparative study	Observational study without controls (5). Stories of preventable problems with primary care that led to physical or psychological harm (1).	38 in-depth anonymous interviews with adults from rural, suburban, and urban locales in Virginia and Ohio	None	221 problematic incidents reported; 37 percent (n = 82) involved breakdowns in clinician-patient relationship; 29 percent (n = 63) involved breakdown in access to clinicians; several reports of perceived racism; incidents linked to 170 reported harms (psychological – 70 percent, physical – 23 percent).
Mandelblatt 2003[32]	Cost effectiveness of screening mammography beyond age 65 and potential harms	Systematic literature review	Systematic review (1). Cost-benefit analysis, cost effectiveness, life-years gained, and costs per person of biennial screening after age 65 (2).	Women 65 years and older; cost-effectiveness articles published between January 1989 and March 2002	None	115 studies – 10 met inclusion criteria; Incremental costs of ~$34,00 to $88,000 per life-year saved after age 65; cost effective to screen if had not been regularly screened before age 65; potential harms not fully captured in any study; potential harms include anxiety associated with false-positive results, misdiagnosis, and previous knowledge of cancer or living longer with consequences of treatment, quality of life, operative mortality.

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design, Study Outcome Measure(s)	Study Setting and Study Population	Study Intervention	Key Finding(s)
Mayo 2004[18]	Nurses' perceptions of medication errors made by nurses	Noncomparative study	Observational study without controls (5). Perceptions of medication errors (1).	Random sample of 983 acute care nurses in Southern California; self-report survey	None	Causes of drug errors – physician's writing is difficult to read or illegible, nurses are distracted on the unit, nurses are tired and exhausted, confusion between two drugs with similar names, nurse miscalculates the dose, physician prescribes the wrong dose, nurse fails to check patient's name band with the medication administration record, nurse sets up or adjusts an infusion device incorrectly, medication labels/packaging are of poor quality or damaged, nurses are confused by different types and functions of infusion devices. 45.6 percent of nurse believed all drug errors are reported; reasons for not reporting include fear of manager and peer reactions.
McDowell 1986[51]	Comparison of methods for recalling patients for influenza	Randomized clinical trial	Randomized clinical trial comparing three methods of reminding patient to receive influenza vaccination (2). Influenza vaccination rates (3).	939 patients ages 65 years and older in four family practices in Canada	Personal reminder by physician vs. telephone reminder by nurse vs. reminder by letter vs. no reminder	Vaccination rates – 22.9 percent for physician reminder, 37 percent for nurse reminder, 35.1 percent for letter reminder, 9.8 percent for no reminder; reminders automatically generated from a computerized medical record system.
McDowell 1989[49]	Computerized reminders for cervical screening	Randomized clinical trial	Randomized clinical trial (2). Cervical screening rates (3).	1,587 women ages 18–35 overdue for a screening test in family medicine center in Canada	Personal reminder by physician vs. telephone reminder by nurse vs. reminder by letter vs. no reminder	Screening rates – 16.1 percent for physician reminder, 25.9 percent for letter reminder, 20 percent for nurse reminder, 13.7 percent for no reminder; reminders automatically generated from a computerized medical record.

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design, Study Outcome Measure(s)	Study Setting and Study Population	Study Intervention	Key Finding(s)
McDowell 1989[48]	Computerized reminders of blood pressure screening in primary care	Randomized clinical trial	Randomized clinical trial (2). Blood pressure screening rates (3).	8,298 patients ages 18 and older who had not had a blood pressure measurement during the previous year, from large family practice in Canada	Computer-generated reminder to physician to check blood pressure during visit vs. telephone reminder by nurse vs. reminder by letter vs. normal care control	Screening rates – 30.7 percent for physician reminder, 35.7 percent for letter reminder, 24.1 percent for nurse reminder, 21.1 percent for no reminder; reminders automatically generated from a computerized medical record.
Metlay 2005[23]	Medication-taking practices on high-risk medications in home-based older adults	Noncomparative study	Observational study without controls (Level 4).	Telephone survey of 4,955 community-dwelling older adults in Pennsylvania in PACE (a State insurance program) program	None	32 percent had not received any specific instructions about medications; 35 percent received instructions from primary care provider and 46 percent from pharmacist; 54 percent used pillbox to organize meds; those prescribed warfarin more likely to report receiving instructions than those with digoxin or phenytoin.

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design, Study Outcome Measure(s)	Study Setting and Study Population	Study Intervention	Key Finding(s)
Phillips 2004[12]	Malpractice claims in primary care	Retrospective cohort	Observational study without controls (4). Review of malpractice claims data 1985–2000 from Physician Insurers Association of America (4).	49,345 primary care claims; 26,126 peer reviewed, 5,921 assessed as negligent	None	No single condition accounted for >5 percent, internists and family practice/general practitioners more common than general pediatricians. Diagnostic error, failure to supervise or monitor case, improper performance, medication errors, failure/delay in referral, not performed, performed when not indicated, no medical misadventure, delay in performance, failure/delay in admission to hospital, failure to recognize a complication of treatment. Causes – problems with records, content issue; premature discharge from institution, x-ray error, vicarious liability, communication between providers, others; similar to the United Kingdom.

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design, Study Outcome Measure(s)	Study Setting and Study Population	Study Intervention	Key Finding(s)
Poon 2006[46]	Health care information technology (HIT) adoption	Multisite qualitative study	Multisite qualitative study; survey of electronic results review, CPOE, EHR (electronic health record), claims and eligibility checking, patient-doctor electronic communication, provider to provider electronic communication. Modified Delphi approach to obtain national estimates (5), adoption of HIT in two markets: Boston and Denver (4).	Key informants from stakeholder groups in each city	None	52 of 119 potential informants (44 percent) agreed to interview; functionalities to support financial reimbursement were better developed than those to support safety and quality clinical care; national estimate similar to those from Boston and Denver; major barriers; HIT adoption is limited.
Quaid 1993[29]	Psychological and ethical considerations in screening for disease	Literature review, nonsystematic	Nonsystematic review (6). Potential harms of screening (2).	Nonsystematic literature review of potential risks of screening for disease	None	Risks include misunderstanding of test results, misdiagnosis, labeling, stigmatization, and decreased psychological well-being; results may be misused by industry or insurance companies; screening should not be implemented until certain safeguards in place; clinicians and public should be educated about potential risks and benefits; use accurate, reliable, valid, and sensitive screening tests; obtain informed consent; followup surveillance; procedures to protect right to privacy should be implemented.

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design, Study Outcome Measure(s)	Study Setting and Study Population	Study Intervention	Key Finding(s)
Rich 2000[38]	Screening for breast, cervical, and colon cancer	Cross-sectional study	Model days of life lost by stopping screening at various ages using SEER data (5). Days of life lost by stopping screening at various ages (1).	Randomized trial data, model using life tables to calculate life expectancy at various ages for stopping screen and for continuing until death for breast, cervical, and colon cancer	Stopping screening at various ages	Start age of 50 years, maximum potential life expectancy benefit of 43 days for breast cancer, 28 days for colon cancer. Start at age 20, maximum potential benefit of 47 days; 80 percent of benefit is achieved before age 75 for breast cancer, 80 years for colon cancer, and 65 years for cervical cancer. Small benefit may be outweighed by harms of anxiety, additional testing, and unnecessary treatment.
Rosser 1991[52]	Reminders for preventive procedures	Prospective randomized controlled study	Prospective randomized controlled study (2). Completion of preventive procedures (2).	8,502 patients 15 years or older not in a hospital or institution; 5,883 randomly assigned by family to a control, physician reminder, or telephone or letter reminder group; 2,619 not assigned to group but monitored	During 1 year patients in active reminder groups received a telephone or letter reminder of any overdue preventive procedures,and those in passive groups received a physician reminder vs. no reminder	All three reminder systems improved delivery of preventive services completion rates – 42 percent for letter reminder, 33.7 percent for physician reminder, 14.1 percent in control group; reminders were computer generated.
Rosser 1992[50]	Reminders of tetanus booster vaccination	Prospective randomized controlled study	Prospective randomized controlled study (2). Proportion of patients receiving tetanus toxoid during study year or had claim of vaccination in previous 10 years (2).	8,069 patients 20 years or older not in a hospital or institution – 5,589 randomly assigned to control, physician reminder, telephone reminder, or letter reminder group; 2,480 patients not randomized but monitored	No reminder vs. physician reminder at office visit vs. telephone reminder vs. letter reminder	Rates of recorded tetanus vaccination – 3.2 percent for control no reminder, 19.6 percent for physician reminder, 20.8 percent for telephone reminder, 27.4 percent for letter reminder; all three reminder systems were computer generated and increased the rate of tetanus vaccination, but all fell sort of achieving complete population coverage.

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design, Study Outcome Measure(s)	Study Setting and Study Population	Study Intervention	Key Finding(s)
Rubin 2003[14]	Errors in general practice	Noncomparative study	Observational study without controls (5). Staff reported errors – classification and frequency (1).	5 physicians, 1 nurse, 1 pharmacist, and 11 administrative staff from 19 practices in UK general practice, North East of England	Error classification	940 errors in prescriptions, communication, equipment, appointment, clinical, other; 75.6/1,000 appointments; most were administrative relating to prescriptions or communication; 13 percent related to computers.
Shekelle 2006[47]	Costs and benefits of health information technology (HIT)	Systematic review of studies related to HIT systems in all care settings	Systematic review of studies (meta-analysis, systematic review, original research) (1). Costs and benefits of HIT for pediatric care; ability of one aspect of HIT – the electronic health record (EHR); costs and cost effectiveness of implementing EHR; effect of HIT on making care more patient centered (2).	256 articles of 855 screened from electronic search of articles published 1995 to January 2004	None	156 studies about decision support, 84 assessed EHR, and 30 on computerized physician order entry (CPOE); 124 in outpatient or ambulatory setting, 82 in the hospital or inpatient setting; 97 used a randomized design; 11 controlled clinical trials, 33 pre/post-test design, 20 time series, 17 case studies with concurrent control; 211 hypothesis-testing studies, 81 had at least some cost data. Clinical decision support systems (CDSS) reduce medication dosing error; CPOE plus CDSS reduce incidence of harmful medication errors in inpatient pediatric and neonatal intensive care settings; evidence for HIT cost savings in pediatrics is limited but promising; current use of EHR systems is limited. Added guidelines show decrease in orders for overused tests and increase in orders for underused tests; costly – 3–13 years to break even. Limited evidence on patient-centered care. Barriers to HIT implementation – situational, cognitive and/or physical, liability, and knowledge and attitude. Potential to dramatically alter health care, but limited experimental evidence.

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design, Study Outcome Measure(s)	Study Setting and Study Population	Study Intervention	Key Finding(s)
Sawaya 2000[37]	Positive predictive value of cervical smears in previously screened women	Randomized controlled study	Prospective cohort study and randomized double-blind, placebo-controlled trial (2). Positive predictive value of cervical smears and the effect of oral estrogen plus progestin on incident cervical cytologic abnormalities (1).	2,561 women with a uterus and normal cytologic characteristics at baseline in 20 U.S. outpatient and community clinical centers	Annual smear; oral conjugated equine estrogens, 0.625 mg/d, plus medroxyprogesterone acetate, 2.5 mg/d, or identical placebo	Incidence of new cytologic abnormalities 2 years after a normal smear was 110/person-years. In 103 women with known histologic diagnoses, 1 had mild to moderate dysplasia; positive predictive value of any smear abnormality 1 year after normal smear was 0 percent, 2 years was 0.9 percent. Conclusion – cervical smear should not be warranted within 2 years of normal cytologic results in postmenopausal women.
Tabar 2004[33]	Efficacy of breast cancer screening by age	Randomized controlled trial	Clinical trial of breast cancer screening (2). Mortality (1).	133,065 Swedish women ages 40–74 with 13-year followup of 2,467 cancers	Breast cancer screening	30 percent reduction in mortality associated with screening in women 40–74 after 13 years, 34 percent in women 50–74, and 13 percent for women 40–49; reduced effect on mortality in women 40–49 due to prognostic factors of tumor size, lymph node status, and histologic type.
Triller 2005[21]	Prevalence of risk factors for adverse drug events (ADEs)	Retrospective cohort study	Observational study without controls (5). Risk factors for ADEs (2).	Data on 10 risk characteristics of patients at point of discharge discharged in 2000 to home health care, self-care, long-term care	None	Data on 4,250 discharges; risk characteristics varied across three groups: home health care – highest prevalence of heart failure, cardiovascular medication use, and poly pharmacy; long-term care – highest prevalence of hypoalbuminemia, cognitive impairment, and psychiatric drug use.

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design, Study Outcome Measure(s)	Study Setting and Study Population	Study Intervention	Key Finding(s)
Volk 1999[39]	Shared decisionmaking for prostate cancer screening	Randomized controlled trial	RCT with pre-office visit assessment and 2-week followup (2). Patients' core knowledge of prostate cancer, reported preferences for PSA testing, and ratings of videotape (3).	160 men ages 45–70 with no history of prostate cancer or treatment, from university-based family practice center	Patient-educational approach to shared decisionmaking for prostate cancer – PSA videotape	Significant change in knowledge about prostate cancer knowledge – mortality, performance of PSA testing, treatment complications and disadvantages of PSA testing; significant decrease in patient preferences for PSA.
Walter 2005[31]	Extrapolation to older person of efficacious screening tests for cancer, harms	Literature review, nonsystematic	Nonsystematic literature review (6). Surrogate outcomes (2).	Review of evidence-based literature	None	Few screening trials include person >70; questions to ask when deciding to extrapolate results of cancer screening trials to older individuals: Are there differences in the behavior of cancers in older people that reduce the benefit of early detection/treatment? Are there differences in the accuracy of screening tests in older people that make tests more likely to miss cancer? Are there differences in individual characteristics of older people that: Reduce the likelihood of benefit from screening? Increase the likelihood of benefit from screening? Potential complications of screening identified (e.g., physical complications, psychological distress, followup procedures, high anxiety). Screening in older persons is individual and requires weighing potential benefits and harms.

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design, Study Outcome Measure(s)	Study Setting and Study Population	Study Intervention	Key Finding(s)
Walter 2001[40]	Framework for individualized decisionmaking for cancer screening	Cross-sectional study	Description of development of framework (6). Potential benefits and harms of screening (1).	Elderly individuals (50–90 years old); use of life expectancy tables and published data	Development of framework for individualized decisionmaking	Potential benefits presented as number needed to screen to prevent one cancer-specific death; variability in potential benefit for patients of similar ages with varying life expectancies; with <5 years unlikely to derive a survival benefit. Potential harms – greatest occur by detecting cancers that would never be clinically significant; burdens due to screening; individualized decisionmaking with consideration of patient's values and preferences.
Woloshin 1997[42]	Main spoken language as barrier to preventive services	Cross-sectional survey	Self-report of breast examination, mammogram, and Pap test (20).	22,448 women completing 1990 Ontario Health Survey, population-based random sample of households	Language spoken	French-speaking women or those who spoke a language other than English were less likely to receive important preventive services.