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Patient Safety Strategies Targeted at Diagnostic Errors

A Systematic Review

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Missed, delayed, or incorrect diagnosis can lead to inappropriate patient care, poor patient outcomes, and increased cost. This systematic review analyzed evaluations of interventions to prevent diagnostic errors. Searches used MEDLINE (1966 to October 2012), the Agency for Healthcare Research and Quality's Patient Safety Network, bibliographies, and prior systematic reviews. Studies that evaluated any intervention to decrease diagnostic errors in any clinical setting and with any study design were eligible, provided that they addressed a patient-related outcome. Two independent reviewers extracted study data and rated study quality.

There were 109 studies that addressed 1 or more intervention categories: personnel changes ($n = 6$), educational interventions ($n = 11$), technique ($n = 23$), structured process changes ($n = 27$), technology-based systems interventions ($n = 32$), and review methods ($n = 38$). Of 14 randomized trials, which were rated as having mostly low to moderate risk of bias, 11 reported interventions that reduced diagnostic errors. Evidence seemed strongest for technology-based systems (for example, text message alerting) and specific techniques (for example, testing equipment adaptations). Studies provided no information on harms, cost, or contextual application of interventions. Overall, the review showed a growing field of diagnostic error research and categorized and identified promising interventions that warrant evaluation in large studies across diverse settings.

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The Problem

The family of patient safety targets that includes diagnostic errors has unclear boundaries. An operational definition includes diagnoses that are "unintentionally delayed (sufficient information was available earlier), wrong (another diagnosis was made before the correct one), or missed (no diagnosis was ever made), as judged from the eventual appreciation of more definitive information" (1, 2).

Although the definition is a bit fluid, there is no doubt that the scope of the problem is large. A systematic review of 53 series of autopsies reported a median antemortem error rate of 23.5% (range, 4.1% to 49.8%) for major errors (clinically missed diagnoses involving a principal underlying disease or primary cause of death) and 9.0% (range, 0% to 20.7%) for incorrect diagnoses that are likely to have affected patient outcomes (3). Disease-specific studies show that 2% to 61% of patients experience missed or delayed diagnoses (4). In a survey of pediatricians, 54% admitted making a diagnostic error at least once per month, and 45% noted making diagnostic errors that harmed patients at least once per year (5). Lack of pertinent historical or clinical information and team processes (for example, inadequate care coordination) contributed to errors (5).

Furthermore, research on variation in patient outcomes related to diagnosis timing suggests that there is room for improvement for some high-risk conditions. For example, early identification of sepsis may decrease mortality in surgical intensive care (6).

Problems in care related to diagnosis are particularly prevalent among precipitating causes for lawsuits; 25% to 59% of malpractice claims are attributable to diagnostic errors (4, 7, 8). A recent study of 91 082 diagnosis-related malpractice claims from 1986 to 2005 estimated payments summing to $34.5 billion (inflation-adjusted to 2010 U.S. dollars) (9). Among 10 739 malpractice claims from the 2005–2009 National Practitioner Data Bank, diagnosis-related problems accounted for 45.9% of paid claims from outpatient settings and 21.1% of paid claims from inpatient settings (10).

Some authors have asserted that diagnostic errors are both more likely to result in patient harms and more preventable than treatment-related errors (such as wrong-site surgery or incorrect medication dose), making the problem particularly important to address (11). Given this potential, the purpose of this review is to assess the multitude of interventions to prevent diagnostic errors and better understand their effectiveness.

Patient Safety Strategies

There is a broad array of patient safety strategies (PSSs) that could affect diagnostic errors. Approaches might involve technical, cognitive, and systems-oriented strategies, usually tailored to specific conditions or settings.

Strategies might address specific types of diagnostic error, root causes of the error, or particular technologies that are available. Strategies might target clinician errors related to assessment (for example, failure or delay in considering an important diagnosis) or laboratory and radiology testing (including failure to order needed tests, techni-

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Key Summary Points

Missed, delayed, or incorrect diagnosis can lead to inappropriate patient care, poor patient outcomes, and increased cost.

Patient safety strategies targeting diagnostic errors have only recently been studied.

Approaches to reduce errors may involve technical, cognitive, and systems-oriented strategies tailored to specific conditions or settings.

A framework that organizations might use to classify intervention strategies aimed at reducing diagnostic errors includes technique, personnel, education, structured process, technology-based systems, and review methods.

Limited evidence from randomized, controlled trials shows that some interventions, such as text messaging—a technology-based systems strategy—can reduce diagnostic errors in certain situations.

Very few studies of interventions to reduce diagnostic errors have examined clinical outcomes (for example, morbidity, mortality) or evaluated the utility of engaging patients and families in prevention of diagnostic errors.

cal errors in processing specimens or tests, or erroneous reading of tests) (2). Interventions that target such failure areas might include tools that generate differential diagnosis lists based on algorithms and checklists; electronic monitoring of test result follow-up; and redesigned documentation systems that efficiently aggregate relevant evidence and aid cognitive interpretation (2). Broad-based strategies might target changes in residency training, board certification, and even patient and family engagement in diagnostic problem solving.

Finally, many strategies could incorporate advances in medical problem solving (including heuristics and metacognition), decision analytic or normative decision making, and clinical diagnostic decision support (12–14). Strategies in this area—computerized diagnosis management—could include computerized physician order entry with clinical decision support.

Review Processes

We captured relevant literature for review through 2 main mechanisms. First, we identified 2 key systematic reviews that summarized data on system-related interventions addressing organizational vulnerabilities to diagnostic errors (15) and cognitively related interventions that could affect diagnosis (16). Then, we used broad search strategies to identify additional literature. We searched MEDLINE (1966 to October 2012), the Agency for Healthcare Research and Quality (AHRQ) Patient Safety Network (www.psnet.ahrq.gov/), and bibliographies of background articles and previous systematic reviews to identify literature on effects of interventions targeting diagnostic errors and/or diagnostic delays. The major Medical Subject Heading terms were "diagnostic errors" and "delayed diagnosis."

Eligible studies were those that evaluated any intervention to decrease diagnostic errors (incorrect diagnoses or missed diagnoses) in any clinical setting and with any study design, provided that they addressed patient-related outcomes (that is, the correct diagnosis was eventually confirmed through patient follow-up testing, surgery, autopsy, or other means) or proxy measures of patient-related outcomes. We also considered studies that evaluated interventions intended to affect the time to correct diagnosis or appropriate clinical action. We excluded studies in which there was no intervention or no real patients (for example, simulations), the intervention was not aimed to reduce diagnostic errors, or there were no patient outcomes or proxies thereof.

Two independent investigators screened articles for eligibility at the title and abstract level, and any discrepancies about selection were resolved through discussion with the entire research team. We also screened all of the studies included in the reviews by Singh and colleagues (15) and Graber and associates (16) and identified 23 studies that were evaluations of interventions.

In total, we identified 109 articles that met inclusion criteria. The **Supplement** (available at www.annals.org) provides a complete description of the search strategies, article flow diagram, and evidence tables.

We used AMSTAR, a tool that addresses such items as the comprehensiveness of the search, the assessment of the quality of included studies, and the methods for synthesizing the results, to assess the methodological quality of the 2 key systematic reviews (17). We used a standard risk of bias assessment to evaluate quality of the randomized trials (**Table 3** of the **Supplement**) (18). We developed and used a categorization scheme to classify, from an organizational perspective, interventions that target diagnostic errors (**Table**). Categories included changes that an organization might consider generically to reduce errors. Such changes include techniques investment; personnel configurations; additional review steps for higher reliability; structured processes; education of professionals, patients, and families; and information and communications technology–based enhancements.

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Benefits and Harms

Benefits

Prior Systematic Reviews

Singh and colleagues (15) considered 43 diagnostic error studies of systems interventions related to provider–patient encounters, diagnostic test performance and inter-

pretation, follow-up and tracking, referral-related issues, and patient-related issues. Their high-quality review (score of 9 out of 9 relevant AMSTAR criteria) identified only 6 evaluations of interventions that met eligibility criteria for our review. Three of the 6 reported diagnostic outcomes, such as incidence of delayed diagnosis of injury, incidence of missed injuries, or misdiagnosis rates. None provided information on patients' downstream clinical course.

Graber and colleagues (16) summarized 141 articles on improving cognition and human factors affecting diagnosis. Their high-quality review (score of 9 out of 9 relevant AMSTAR criteria) included 42 evaluations of interventions. These investigators classified interventions in 3 dimensions. For interventions to increase knowledge and expertise, only 1 (19) of 7 studies provided information on diagnostic outcomes and clinical course for actual patients. For interventions to improve intuitive and deliberate considerations, none of the 5 identified studies reported effects on documented diagnoses with actual patients during clinical course of care. In the largest group of studies—interventions on getting help from colleagues, consultants, and tools—16 of the 28 identified studies evaluated diagnostic outcomes in actual patients (20–35).

Graber and colleagues noted the current scarcity of evidence for any single intervention targeting cognitive and human factors in reducing diagnostic error. They highlighted potential for interventions that target content-focused training, feedback on performance, simulation-based training, metacognitive training, second opinion or group decision making, and the use of decision support tools and computer-aided technologies.

Table. **Categories of Organizational Interventions to Decrease Diagnostic Errors**

Category	Example
Technique	Changes in equipment, procedures, and clinical approaches that target diagnostic performance in clinical practice
Personnel changes	Introduction of additional health care members and replacing certain professionals with others
Educational interventions	Implementation of educational strategies, residency training curricula, and maintenance of certification changes
Structured process changes	Implementation of feedback loops or additional stages in the diagnostic pathway
Technology-based system interventions	Implementation at the system level of technology-based tools, such as computer assistive diagnostic aids, decision-support algorithms, text message alerting, and pager alerts
Additional review methods	Introduction of additional independent reviews of test results, from reporting through interpretation

Studies of PSS Evaluations

We identified 109 studies, including 14 randomized trials, of interventions that targeted diagnostic errors and addressed patient-related outcomes (see **Tables 1** to **4** of the **Supplement**). Of the 6 categories of interventions, most studies pertained to interventions in the categories of technology-based systems and additional review methods (**Figure 1**). **Figure 2** shows increases over time in available evidence related to the categories of additional review methods, structured process changes, technique, and technology-based systems interventions.

Patient-related outcomes and their proxies can be categorized as diagnostic accuracy outcomes (for example, false-positive and false-negative results), management outcomes (for example, use of further diagnostic tests or therapeutic interventions), and direct patient outcomes (for example, death, disease progression, or deterioration). An intervention that leads to better diagnosis does not automatically change management or improve patient outcomes. Management change depends on treatment options and the feasibility of implementing those options. Improvements in direct patient outcomes depend also on effectiveness of treatment or management. Outcomes that were assessed in the 109 studies varied markedly, but few studies (5 randomized, controlled trials and 8 other designs) evaluated direct patient-level clinical outcomes (6, 31, 36–46).

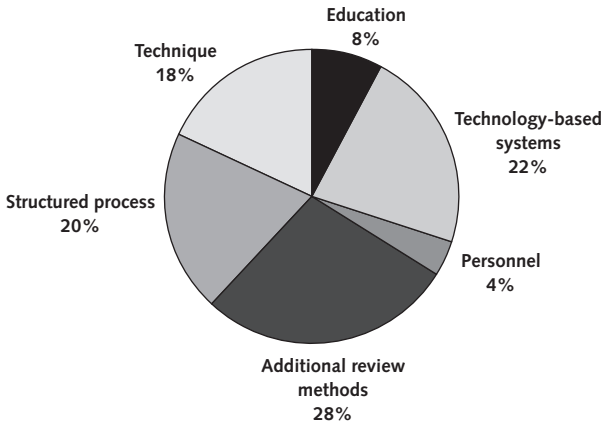
Results of Randomized, Controlled Trials

Primary and secondary outcomes that were assessed in the 14 randomized trials are summarized in **Table 2** of the **Supplement**. Eight trials (9 comparisons) addressed diagnostic accuracy outcomes, and 3 trials (5 comparisons) addressed outcomes related to further diagnostic test use. Six trials (8 comparisons) addressed outcomes related to further therapeutic management. Five trials (7 comparisons) addressed direct patient-related outcomes. Three trials addressed composite outcomes (diagnostic accuracy and therapeutic management, and therapeutic management and patient outcome). One trial addressed time to correct therapeutic management, and another trial addressed time to diagnosis.

Trials evaluated various interventions. The control group used most often was usual care. No trials had high risk of bias, whereas 9 and 5 trials had moderate and low risk of bias, respectively.

Statistically significant improvements were seen for at least 1 outcome in all but 3 trials. Of the 3 trials with non–statistically significant improvements, 1 was a noninferiority trial that showed no more diagnostic errors occurred during work-up of abdominal pain among patients given morphine and those not given morphine (47). Two trials that involved patients with mental conditions (46, 48) reported no beneficial diagnostic error effects from computerized decision-support systems. Only 1 trial (42) reported improvements in direct patient outcomes; whether improvements were related to the comparison

Figure 1. **Interventions, by type.**



The percentage of studies as categorized by the 6 types of interventions.

against the randomized concurrent control group or a preintervention period was unclear.

Technique

There were 23 studies of interventions related to medical techniques (39, 47, 49–69). Most of these studies, including 3 randomized trials (47, 49, 55), found that these interventions can enhance diagnosis (for example, visual enhancements via ultrasonography-guided biopsy, changes to number of biopsy cores, and cap-fitted colonoscopy) or not make it worse (for example, medical interventions for pain relief in patients with abdominal pain).

Personnel Changes

Six studies (44, 45, 70–73) compared the effect on diagnosis of substituting 1 type of professional for another, or adding another professional to the care team. The 3 studies (71–73) in which a specialist was added to examine the interpretation of a test result reported an increase in case detection, although the studies were quite small and targeted narrow patient populations. There was only 1 randomized trial, showing that emergency nurse practitioners perform better than junior physicians (45).

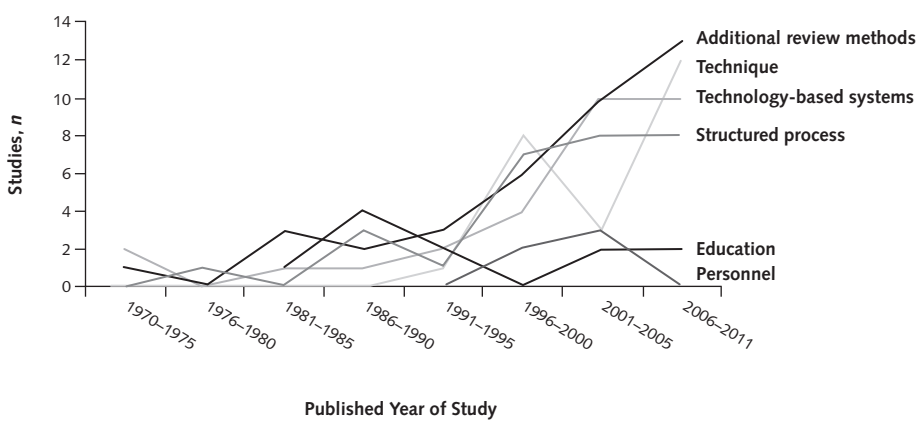
Educational Interventions

Eleven studies (19, 43, 74–82) used educational interventions for various targets: patients, parents, community doctors, and intensive care unit doctors and nurses. Strategies targeted at professionals produced improvements, but the studies were nonrandomized. Two randomized trials that targeted consumers found that parent education improved discrimination of serious symptoms necessitating physician diagnosis and patient education improved the performance of breast cancer screening (74, 78).

Structured Process Changes

Twenty-seven studies (43, 44, 46, 48, 56–59, 73, 77, 79, 83–98) examined interventions that added structure to the diagnostic process. Structure included, among other things, triage protocols, feedback steps, and quality improvement processes. Most interventions included the addition of a tool, often a checklist or a form (for example, to guide and standardize physical examination of a patient). Some of the studies centered on laboratory processes, whereas others occurred during clinical management, often in situations related to trauma patients. Beneficial effects on diagnosis-related outcomes were seen in most nonrandomized studies, but of the 3 randomized trials, 2 did not show benefit for improving diagnosis of mental illness (46, 48) and 1 had mixed results for a protocol for ordering radiography in injured patients (84).

Figure 2. **Intervention studies, by year.**



Timeline of the included studies categorized by the 6 types of interventions.

Technology-Based Systems Interventions

Thirty-two studies (6, 29–36, 40–42, 44, 46, 60, 71, 78, 80, 97, 99–111) included computerized decision support systems and alerting systems (for example, for abnormal laboratory results), most of which were associated with improvements to processes on the diagnostic pathway (for example, relaying a critical laboratory value to the clinician in a more timely manner). Some interventions related to specific symptoms (for example, a computer-aided diagnostic tool for abdominal pain interpretation), whereas others intervened at the level of a particular test (for example, an electronic medical record alert for a positive result on a fecal occult blood screen for cancer). All 4 randomized trials (31, 36, 42, 100) reported beneficial diagnostic error effects (see **Table 2** of the **Supplement**).

Additional Review Methods

The most common type of intervention that was evaluated was the introduction of redundancy in interpreting test results (6, 20–28, 34, 37–39, 72, 73, 76, 78, 79, 81, 95, 96, 109, 112–126). Most studies showed that an additional review step (usually by a separate reader, from the same specialty or from another specialty) had a positive effect on diagnostic performance. However, in some cases, false-positive results also increased. Tradeoffs between sensitivity and specificity were reported erratically. Some studies targeted higher-risk patients for enriched review. However, the systems to support such targeting were neither described nor evaluated. Randomized evidence was weak, based on 1 group of 1 trial showing statistically significant benefit (no effect size reported) for an audit and feedback approach (78).

Studies With Interventions That Corresponded to Multiple Categories

Twenty-four studies (6, 34, 39, 43, 44, 46, 56–60, 71–73, 76–80, 95–97, 109, 127) combined approaches in a variety of ways and covered diverse clinical areas, with mixed results. These studies are also included in the categories covered above. Twenty of the 24 studies combined 2 categories of intervention in almost every permutation possible (11 of 15 combinations). With only 1 to 4 studies for any combination set, it is not possible to draw conclusions about whether benefits are enhanced with more complex interventions. Moreover, complex approaches may be more costly, but this information was not reported.

Notifying Patients of Test Results

Another potential grouping of PSSs focuses on the interface between the system and the patient, such as strategies that involve patient notification of test results (128). No studies with comparative designs evaluated this intervention. The review by Singh and colleagues (15) identified 7 studies of patient preferences or satisfaction with different options for receipt of test results. They also found no studies that tested ways to reduce error using an intervention that affected test notification.

Casalino and colleagues (129) found a 7.1% rate of apparent failures to inform patients of an abnormal test result and identified a positive association between use of simple processes by physician practices for managing results and lower failure rates. A systematic review that examined failures to follow up test results with ambulatory care patients reported that failed follow-up ranged from 1.0% to 62.0%, depending on the type of test result, including failures associated with missed cancer diagnoses (130). None of the studies included in that systematic review evaluated patient-oriented interventions.

Harms

No studies in our review evaluated direct patient harm. Studies generally did not assess unintended adverse effects, although some reported false-positive rates.

Implementation Considerations and Costs

The context in which a safety strategy is implemented depends on the specific type of diagnostic error and practice being examined. The studies that we reviewed covered a range of subspecialties, settings, patient populations, and interventions. Context varied greatly. Most interventions were not tested in more than 1 site. Many studies were small, early proof-of-concept evaluations. No information was reported on the cost of implementing the reviewed PSSs; costs would probably vary greatly, depending on the particular strategy or practice.

Discussion

This review identified over 100 evaluations of interventions to reduce diagnostic errors, many of which had a reported positive effect on at least 1 end point, including statistically significant improvements in at least 1 end point in 11 of the 14 randomized trials. Mortality and morbidity end points were seldom reported.

We also identified 2 previous systematic reviews of cognitive and systems-oriented approaches to improve diagnostic accuracy that mostly found proof-of-concept strategies not yet tested in practice. Our review built on the previous systematic reviews by grouping PSSs targeting diagnostic errors from an organizational perspective into changes that an organization might consider more generically (techniques investment; personnel configurations; additional review steps for higher reliability; structured processes; education of professionals, patients, families; and information and communications technology–based enhancements), as opposed to individual clinicians looking for ways to improve their own cognitive processing in specific diagnostic contexts. Although many of the PSSs tested thus far target diagnostic pathways for specific symptoms or conditions, grouping interventions into common leverage points will support future development in this field by

the various stakeholders who seek to reduce diagnostic problems. Involvement of patients and families has received minimal attention, with only 2 studies addressing education of consumers.

Data synthesis is difficult because few studies have used randomized designs, comparable outcomes, or similar interventions packages. The existing literature may be susceptible to reporting biases favoring "positive" results for different interventions. It is expected that with heightened awareness of the problem, the number of studies in this field will increase further in the future, including more randomized trials and studies testing different approaches: for example, policy-level efforts. However, the range of outcomes assessed in the studies that we reviewed highlights the known lack of tools to routinely measure the effect of interventions to decrease diagnostic errors. Additional work is needed on appropriate measurements of diagnostic errors and consequential delays in diagnosis. A final limitation, especially for synthesis, is the diversity of interventions that are reverse-engineered on the basis of the many diagnostic targets; the diverse tailored needs for each clinical situation (for example, protocols designed for specific work-up pathways); and the variety of specialized personnel, and even patients, receiving educational or cognitive-support approaches.

Evidence is also lacking on the costs of interventions and implementation, particularly how to reduce diagnostic errors without producing other diagnostic problems, such as overuse of tests. Eventually reaching the correct diagnosis with inefficient testing strategies (for example, some sequences of multiple test ordering) is not the appropriate pathway to improved diagnostic safety. Our review found a paucity of studies that assessed both sensitivity and specificity of interventions addressing diagnostic performance in the context of mitigating diagnostic errors. Thus, although we found several promising interventions, evaluations need to be strengthened before any specific PSSs are scaled up in this domain.

In conclusion, our review demonstrates that the nascent field of diagnostic error research is growing, with new interventions being tested that involve technical, cognitive, and systems-oriented strategies. The framework of intervention types developed in the review provides a basis for categorizing and designing new studies, especially randomized, controlled trials, in these areas.

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