Patient safety strategies targeted at diagnostic errors: a systematic review
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CRD summary
The authors concluded that there was a growing amount of research on diagnostic errors, with promising interventions that should be evaluated, in large studies and various settings. The review focused on the results of randomised controlled trials and was largely well conducted. The authors’ conclusion reliably reflects the limited evidence from trials, and their research recommendations seem justified.

Authors’ objectives
To evaluate patient safety strategies aimed at the prevention of diagnostic errors.

Searching
MEDLINE (1996 to 2012) and the Agency for Healthcare Research and Quality (AHRQ) Patient Safety Network were searched. Search terms were reported. Bibliographies and previous systematic reviews were screened to identify further studies.

Study selection
Eligible for inclusion was any design of study that evaluated any intervention to decrease diagnostic errors, or the time to a correct diagnosis or clinical action, in any clinical setting. Studies had to measure patient-related outcomes, such as correct diagnosis – confirmed by patient follow-up tests, surgery, autopsy, or other method, or a proxy measure. Simulation studies were excluded.

The included studies evaluated medical techniques, personnel changes, educational interventions, structured process changes, technology-based systems, or (most studies) additional review methods, such as redundancy in interpreting test results. Control groups, in the included randomised controlled trials (RCTs), largely received usual care. The patient-related outcomes included diagnostic accuracy, such as false-positive and false-negative results; management outcomes, such as the use of further diagnostic tests or therapy; and (less often) direct patient-level clinical outcomes, such as death, disease progression, or deterioration. Some studies assessed composites of these outcomes. Few details were given on those delivering or receiving the intervention; some were presented in the full report (Shekelle, et al. 2013, see Other Publications of Related Interest).

Two independent reviewers selected the studies for inclusion. Discrepancies were resolved by discussion with the research team.

Assessment of study quality
The quality of the RCTs was assessed using Cochrane criteria for sequence generation, allocation concealment, blinding, completeness of outcome data, selective outcome reporting, and other sources of bias. The risk of bias was assessed as low, medium, high, or unclear. It was unclear how other study designs were assessed.

Two independent reviewers assessed study quality.

Data extraction
For RCTs, the data were extracted to present effect sizes and 95% confidence intervals. Other extracted data included the proportions and directions of effect for a variety of measures, and the diagnostic accuracy or time to diagnosis.

Two independent reviewers extracted the data.

Methods of synthesis
A narrative synthesis was conducted. The authors grouped the results according to the type of intervention.

Results of the review
One hundred and nine studies were included in the review. There were 14 RCTs. The number of participants was
neither reported in the paper, nor in the full report. Nine trials had a moderate risk of bias, and five trials had a low risk of bias. The areas of high risk or uncertainty were sequence generation, allocation concealment, blinding, and selective outcome reporting.

In 11 of the 14 RCTs, statistically significant improvements were seen for at least one outcome.

**Medical technique**: Most of the 23 studies (including the three RCTs) showed that diagnosis could be improved (or not made worse) following interventions, such as ultrasonography-guided biopsy, changes to the number of biopsy cores, cap-fitted colonoscopy, and relief for abdominal pain.

**Personnel changes**: There were six studies, one of which was a RCT. The RCT favoured the performance of emergency nurse practitioners over junior physicians, in reducing unplanned follow-up visits.

**Educational interventions**: There were 11 studies, and two were RCTs. The RCTs showed that parent education improved their identification of serious symptoms necessitating physician intervention, and patient education improved the performance of screening for breast cancer.

**Structured process changes**: Of the 27 studies, three were RCTs and these provided mixed evidence on diagnosis-related outcomes, for mental illness and radiography ordering for injured patients. Two of the three trials did not demonstrate a significant effect.

**Technology-based systems**: There were 32 studies, and four were RCTs. All four RCTs reported beneficial effects in reducing diagnostic error following computer-based diagnosis and decision-making interventions.

**Additional review methods**: Of the 38 studies, one was a RCT and this trial showed a statistically significant effect following an audit and feedback approach, in cancer screening, but the evidence was weak.

There were no studies that evaluated direct patient harm, and no conclusions could be drawn on the effects of complex interventions (24 studies). The full results were reported in the paper.

**Authors’ conclusions**
There was a growing amount of research on diagnostic errors, with promising interventions that should be evaluated, in large studies and various settings.

**CRD commentary**
The review question was clear. The inclusion criteria were broad, and found a wide variety of studies. Two major data sources were searched, but no sources of unpublished material were accessed, meaning that relevant studies might have been overlooked. The review process was conducted with sufficient attempts to minimise error and bias, and the quality assessment of the included trials showed that they were generally of a sufficient standard on set criteria. The study details were presented, but the participants and those delivering the intervention were not described, making the generalisability of the findings unclear. In most cases it was not possible to determine the trial sample size, which limits interpretation of their ability to detect significant effects. Clinical variation between the studies suggests that the chosen method of synthesis was appropriate.

The review focused on the results of RCTs and was largely well conducted. The authors’ conclusion reliably reflects the limited evidence from trials, and their research recommendations seem justified.

**Implications of the review for practice and research**
**Practice**: The authors did not state any implications for practice, but they noted that further evidence was required before any patient safety strategy targeting diagnostic errors was scaled up.

**Research**: The authors stated that further research should use appropriate measurements of diagnostic errors and consequential delays in diagnosis. Evaluations of the costs of the interventions and their implementation were needed.

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