Improving Laboratory Monitoring at Initiation of Drug Therapy in Ambulatory Care

A Randomized Trial

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Background: The importance of laboratory monitoring for drugs is reflected in product labeling and published guidelines, but monitoring recommendations are followed inconsistently. Opportunity exists to improve monitoring, with the potential to decrease therapy complications.

Methods: The objective of this randomized trial was to determine whether computerized alerts were effective at increasing the percentage of ambulatory patients with laboratory monitoring at initiation of drug therapy. Physicians and pharmacists teamed up to develop organization-specific guidelines for monitoring selected drugs. In collaboration with physicians, pharmacists were alerted to missing laboratory test results, ordered missing tests, reminded patients to obtain tests, assessed test completion, reviewed test results, and managed abnormal results. Eligible individuals included patients with therapy initiated for any of 15 drugs among 400,000 health plan members.

Results: In the intervention group, 79.1% (n=4076; 95% confidence interval [CI], 78.0%-80.2%) of dispensings were monitored compared with 70.2% (n=3522; 95% CI, 68.9%-71.5%) in the usual-care group (P<.001). For example, 78.6% of amiodarone (95% CI, 73.1%-83.5%) dispensing was monitored in the intervention group vs 51.4% (95% CI, 44.4%-58.4%) in the group receiving usual care (P<.001).

Conclusions: This study demonstrates the effectiveness of a computerized tool plus collaboration among health care professionals at increasing the percentage of patients receiving laboratory monitoring at initiation of therapy. Coupling data available from information systems with the knowledge and skills of physicians and pharmacists can result in improved patient monitoring.

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Drug-specific laboratory monitoring is important for certain drugs that carry a risk of organ system toxic effects or electrolyte imbalance, or that require dosage adjustment in the presence of organ dysfunction. Laboratory monitoring errors occur when there is failure to conduct indicated tests and when there is inadequate follow-up or an avoidable delay in responding to abnormal test results. The importance of laboratory monitoring for drugs such as divalproex sodium, isotretinoin, lithium, metformin hydrochloride, amiodarone, carbamazepine, and allopurinol is reflected in product labeling and in published guidelines. Studies document that laboratory monitoring recommendations for drugs are variably followed that delays in reviewing laboratory test results are common, and that physicians are not satisfied with how they manage laboratory test results.

Opportunity exists to improve laboratory monitoring of patients receiving high-risk drug therapy, with the potential to decrease complications and costs of therapy. We undertook a randomized trial to determine whether a computerized tool that alerts pharmacists to missing laboratory results was effective in increasing the percentage of patients receiving appropriate laboratory monitoring at the initiation of drug therapy, that is, baseline monitoring. The primary outcome was the percentage of drug dispensings with baseline laboratory monitoring. We hypothesized that patients in the intervention group would have an increased percentage of drug dispensings that were monitored compared with the control group receiving usual care (usual-care group).

See also pages 2329 and 2388

METHODS

STUDY SETTING, DESIGN, AND POPULATION

This study was conducted at Kaiser Permanente of Colorado (KPCO), a group model of managed care.
health maintenance organization. In 2003, KPCO provided health care for a diverse population of approximately 375,000 members in the Denver-Boulder-Longmont metropolitan area; about 56,000 of these individuals were Medicare beneficiaries. The Kaiser Permanente institutional review board approved this study and waived the requirement for informed consent.

This prospective randomized trial was conducted in the ambulatory care environment and included all KPCO members 18 years or older. At study initiation, 340,000 individuals were randomized (using the uniform distribution function in the statistical software program SAS [version 8.4; SAS Inc, Cary, NC] to either the intervention or usual-care group). Each month, new health maintenance organization members were randomized. By study completion, 400,000 individuals had been randomized.

For the primary outcome of the percentage of drug dispensings with baseline laboratory monitoring, the time frame for baseline laboratory monitoring was defined as from 180 days (6 months) prior to drug dispensing until 14 days after drug dispensing. This starting time was chosen because, for ambulatory patients, clinicians can consider results of “recently conducted” laboratory tests to be sufficient for baseline monitoring. We defined “recently conducted” as within 180 days. Although baseline laboratory monitoring should be conducted prior to drug dispensing, we considered baseline laboratory monitoring up to 14 days after dispensing because the intervention could not occur until the drug dispensing and missing laboratory monitoring test(s) information had been linked and sent to the pharmacist (and this could only occur after the drug was dispensed). Furthermore, because patients can be provided both the drug prescription and the request for laboratory testing at 1 office visit, the 14-day window accommodated patients who had a 1- or 2-day gap between the drug prescription and the laboratory test. Completion of baseline laboratory monitoring was defined as the presence of a claim for the laboratory test(s). Drug dispensing was defined as the date the prescription was sold to the patient.

When a patient randomized to the intervention group was dispensed a targeted medication, the laboratory test(s) was electronically assessed as completed or not completed. Information about laboratory tests identified as not completed was sent electronically each day to the Clinical Pharmacy Call Center, a centralized team of KPCO clinical pharmacists who work with patients via telephone on medication-related issues. On receipt of the daily report, the call center pharmacists contacted the patients and reminded them to obtain the laboratory tests if their physicians had previously ordered the tests or ordered tests according to the intervention guideline if they had not been previously ordered. Results for laboratory tests ordered by pharmacists were returned to pharmacists for evaluation. These processes were designed to lessen the burden of the intervention on physicians.

Physicians, patients, and pharmacists were blinded as to study group assignment. Pharmacists were alerted to missing laboratory test information only for intervention patients. Pharmacists were not provided information about laboratory monitoring for patients in the usual-care group. Physicians were contacted for intervention patients only.

Patients in the usual-care group received laboratory testing according to each provider’s (clinician’s) usual clinical practice (eg, when patients’ providers ordered tests and patients obtained the tests). When laboratory tests were completed, the results were reported and patients treated according to the prescriber’s usual procedures.

**DEVELOPING AND IMPLEMENTING THE INTERVENTION**

Fifteen drugs and drug classes were included in the intervention (Table 1). Using a sequential process, drugs and laboratory tests were selected based on the presence of US Food and Drug Administration black box warnings, published clinical guidelines, and the potential for adverse clinical consequences related to lack of monitoring. Black box warnings are typically used for drugs that carry the potential for life-threatening adverse events. A draft list of recommended drug-laboratory monitoring pairs was compiled from these sources and circulated to practicing physicians, clinical pharmacists, and pharmacist-leaders in the health plan. Their feedback was incorporated into the final list of drugs requiring laboratory monitoring. The information gleaned from this review was supplemented with information from the Food and Drug Administration Web site. Next, nationally available published guidelines and internal clinical guidelines were searched for other medication-related laboratory monitoring recommendations (eg, American College of Cardiology/American Heart Association Guidelines; Kaiser Permanente National Evidence-Based Guidelines). A draft list of recommended drug-laboratory monitoring pairs was compiled from these sources and circulated to practicing physicians, clinical pharmacists, and clinician-leaders in the health plan. Their feedback was incorporated into the final list of drugs requiring laboratory monitoring. The drugs and laboratory tests ultimately included in the study therefore reflected not only drugs with laboratory testing recommended in product labeling but also clinician-physician, pharmacist, and researcher consensus. For statins and gemfibrozil, the intervention occurred only for patients who were receiving the drugs concomitantly.

An organization-specific guideline for managing abnormal laboratory results was developed (a portion of this guideline is presented in Table 2). Prior to implementation, this guideline was reviewed and agreed on by primary care administration, key clinician-physicians, clinician leaders, the pharmacy department, and researchers. Abnormal laboratory result notifications from pharmacists to prescribing clinicians were communicated in writing or, if urgent action was needed, by telephone (Table 2).

**STATISTICAL ANALYSIS**

The unit of analysis for the primary outcome, that is, the percentage of drug dispensings with baseline laboratory monitoring, was each unique drug dispensing–laboratory test event that occurred between September 9, 2002, and December 31, 2003. Demographic characteristics between groups were compared

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**Table 1. Laboratory Monitoring at Initiation of Therapy**

<table>
<thead>
<tr>
<th>Drug</th>
<th>Laboratory Monitoring Parameter(s)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Allopurinol</td>
<td>Serum creatinine level</td>
</tr>
<tr>
<td>Amiodarone</td>
<td>ALT/AST, TSH</td>
</tr>
<tr>
<td>Azathioprine</td>
<td>ALT/AST, CBC</td>
</tr>
<tr>
<td>Carbamazepine</td>
<td>ALT/AST, CBC</td>
</tr>
<tr>
<td>Divalproex sodium</td>
<td>ALT/AST, CBC</td>
</tr>
<tr>
<td>Felbamate</td>
<td>Reticulocytes, CBC, bilirubin, AST/ALT</td>
</tr>
<tr>
<td>Isotretinoin</td>
<td>Pregnancy test for women, ALT/AST, fasting lipid profile or triglycerides</td>
</tr>
<tr>
<td>Lithium</td>
<td>Serum creatinine level, CBC, TSH</td>
</tr>
<tr>
<td>Methotrexate</td>
<td>Serum creatinine level</td>
</tr>
<tr>
<td>Metformin hydrochloride</td>
<td>Serum creatinine level</td>
</tr>
<tr>
<td>Nefazodone hydrochloride</td>
<td>ALT/AST</td>
</tr>
<tr>
<td>Phenytoin hydrochloride</td>
<td>ALT/AST</td>
</tr>
<tr>
<td>Stalin - gemfibrozil</td>
<td>ALT/AST (only when in combination)</td>
</tr>
<tr>
<td>Ticlopidine hydrochloride</td>
<td>AST/ALT, CBC</td>
</tr>
</tbody>
</table>

Abbreviations: ALT/AST, alanine aminotransferase/aspartate aminotransferase; CBC, complete blood count; TSH, thyroid-stimulating hormone.
using descriptive statistics, \( \chi^2 \) and Wilcoxon signed-rank tests. For each drug or drug class, the percentage of patients who received the recommended laboratory test was compared between groups using the \( \chi^2 \) test. In addition, for the subset of intervention patients between September 16, 2002, and September 12, 2003, the percentage of patients who had the test ordered by the physician but not completed by the patient, the percentage of patients who completed the laboratory test after pharmacist intervention, and the percentage of pharmacist recommendations accepted by the provider when an abnormal laboratory result occurred were tabulated. All analyses were conducted using SAS software.

## RESULTS

During the study, there were 10,169 initial dispensings of study drugs. Characteristics of patients receiving these dispensings are shown in Table 3. No differences existed between the intervention and usual-care groups in the age \( (P = .06) \) or sex \( (P = .92) \) distributions of patients (Table 3). The median age of patients with laboratory monitoring was 55 years, whereas the median age for patients who were not monitored was 49 years \( (P < .001) \).

Recommended laboratory monitoring was completed in 74.7\% \((n = 7598)\) of dispensings at initiation of therapy. In the intervention group, 79.1\% \((n = 4076; 95\% \text{ CI}, 78.0\%-80.2\%)\) of patient drug dispensings received laboratory monitoring, whereas in the usual-care group, 70.2\% \((n = 3522; 95\% \text{ CI}, 68.9\%-71.5\%)\) of patient drug dispensings were monitored \( (P < .001) \). The difference between groups persisted for each age subgroup \( (P < .001) \).

The greatest absolute difference in monitoring between groups was with amiodarone; 78.6\% \((95\% \text{ CI}, 76.9\%-79.9\%)\) of the intervention group but only 53.1\% \((95\% \text{ CI}, 51.3\%-55.0\%)\) of the usual-care group received monitoring \( (P < .001) \). Similarly, 58.6\% \((95\% \text{ CI}, 55.9\%-61.4\%)\) of patients in the intervention group had the laboratory test ordered by the physician but not completed by the patient, whereas only 45.8\% \((95\% \text{ CI}, 43.0\%-48.6\%)\) of patients in the usual-care group had the test ordered \( (P < .001) \). The percentage of pharmacist recommendations accepted by the provider when an abnormal laboratory result occurred was 62.8\% \( (95\% \text{ CI}, 61.3\%-64.4\%)\) in the intervention group and 53.0\% \( (95\% \text{ CI}, 50.6\%-55.5\%)\) in the usual-care group \( (P < .001) \).
73.1%-83.5%) of intervention group patients received laboratory monitoring compared with 51.4% (95% CI, 44.4%-58.4%) of usual-care group patients (P < .001) (Table 4; Figure). Other drugs for which the absolute percentage of intervention group patients monitored was more than 10% greater than the percentage of usual-care group patients monitored include allopurinol, carbamazepine, and lithium (Table 4; Figure). Additional drugs with a statistically significantly higher percentage of patients monitored in the intervention group compared with the usual-care group include metformin, divalproex, and the combination of a statin with gemfibrozil (Table 4; Figure). No statistical difference was observed in monitoring between groups for azathioprine.

### Table 4. Laboratory Monitoring of Patients by Specific Drug

<table>
<thead>
<tr>
<th>Drug</th>
<th>Intervention Group</th>
<th>Usual-Care Group</th>
<th>Absolute Difference in Monitoring Between Groups, %</th>
<th>P Value†</th>
</tr>
</thead>
<tbody>
<tr>
<td>Allopurinol</td>
<td>701</td>
<td>575 (82.0; 79.9-84.8)</td>
<td>12.1</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Amiodarone</td>
<td>257</td>
<td>202 (78.6; 73.1-83.5)</td>
<td>5.4</td>
<td>.20</td>
</tr>
<tr>
<td>Azathioprine</td>
<td>108</td>
<td>97 (89.8; 82.5-94.8)</td>
<td>9.3</td>
<td>.16</td>
</tr>
<tr>
<td>Carbamazepine</td>
<td>499</td>
<td>356 (71.3; 67.2-75.3)</td>
<td>27.2</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Divalproex sodium</td>
<td>517</td>
<td>343 (66.3; 62.1-70.4)</td>
<td>17.4</td>
<td>.02</td>
</tr>
<tr>
<td>Isotretinoin</td>
<td>117</td>
<td>105 (89.7; 82.8-94.8)</td>
<td>12.1</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Lithium</td>
<td>285</td>
<td>152 (53.3; 47.6-59.2)</td>
<td>27.2</td>
<td>.02</td>
</tr>
<tr>
<td>Metformin</td>
<td>1855</td>
<td>1377 (82.9; 81.1-84.5)</td>
<td>7.1</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Methotrexate</td>
<td>259</td>
<td>126 (59.7; 56.5-63.0)</td>
<td>2.1</td>
<td>.43</td>
</tr>
<tr>
<td>Nefazodone hydrochloride</td>
<td>93</td>
<td>54 (56.1; 47.4-68.2)</td>
<td>9.9</td>
<td>.16</td>
</tr>
<tr>
<td>Pioglitazone hydrochloride</td>
<td>131</td>
<td>122 (93.1; 87.4-96.8)</td>
<td>3.6</td>
<td>.32</td>
</tr>
<tr>
<td>Statin + gemfibrozil</td>
<td>326</td>
<td>295 (90.5; 86.8-93.4)</td>
<td>7.0</td>
<td>.01</td>
</tr>
</tbody>
</table>

Abbreviation: CI, confidence interval.

*Data on felbamate and ticlopidine hydrochloride are not presented because of the small number of patients. For felbamate, only 2 patients were newly started on the drug during the study; both were in the usual-care group. For ticlopidine, only 12 patients were newly started on the drug, 5 in the intervention group and 7 in the usual-care group.

†Determined by χ² test.

![Figure](https://archinte.jamanetwork.com/)

**Figure.** Laboratory monitoring at initiation of drug therapy. An asterisk indicates P < .001; dagger, P = .02; double dagger, P = .01.
prine, isotretinoin, methotrexate, nefazodone hydrochloride, pioglitazone hydrochloride, and ticlopidine, although an increase in monitoring occurred in the intervention group vs the usual-care group for all drugs except isotretinoin (Table 4; Figure).

More than 1000 patients (n=1010) in the intervention group had baseline laboratory tests ordered by the pharmacists for intervention drugs between September 16, 2002, and September 12, 2003. For 194 patients, the provider had ordered recommended laboratory tests, and the patient was reminded to have the laboratory test conducted. For 28 patients, the provider had ordered some, but not all, recommended tests. No tests had been ordered for 788 patients. Noncompliance with obtaining the laboratory tests was higher (91 of 194; 47%) for patients for whom the provider had previously ordered the tests than for the group overall (331 of 1010; 32.8%).

Approximately 7% (n=68) of laboratory tests obtained as a result of the intervention yielded abnormal results. Patients started on a regimen of allopurinol had the highest percentage of abnormal test results; serum creatinine levels were elevated in 18 (15.7%) of 115 patients. Eleven (12.8%) of 86 patients started on a regimen of amiodarone also had abnormal results for liver or thyroid tests; another 3% to 7% of patients who had abnormal baseline laboratory test results were taking other drugs, including lithium, carbamazepine, divalproex sodium, metformin, methotrexate, nefazodone, and the combination of a statin with gemfibrozil.

For those patients with abnormal laboratory test results, the prescriber took 91% of the guideline-based recommendations provided by the pharmacist. Recommendations included, among others, repeating the laboratory test within a few weeks (40% of recommendations), notifying the prescriber with no recommended change in therapy or monitoring (33%), changing the drug dosage (11%), and stopping the drug (5%).

The most common intervention was obtaining a serum creatinine level for patients initiating metformin therapy (24.8% of interventions). Obtaining liver enzyme tests or complete blood cell counts for patients started on carbamazepine (16.2%) or valproate (15%) therapy; obtaining serum creatinine levels for patients started on allopurinol therapy (11.4%); obtaining thyroid and/or liver tests for patients started on amiodarone therapy (8.5%); and obtaining serum creatinine, liver, and/or thyroid tests for patients started on lithium therapy (11.1%) were also frequent.

**COMMENT**

Our study demonstrates that a multistage intervention based on physician-pharmacist collaboration and comprising linked laboratory and drug-dispensing information to identify gaps in laboratory monitoring, providing that information to pharmacists, and having them intervene on missing laboratory test results was effective in increasing the percentage of patients receiving recommended laboratory monitoring at initiation of drug therapy. This intervention design minimized the burden on physicians in the busy outpatient office setting.

Nearly 700 (n=679) patients received recommended monitoring as a result of the intervention—monitoring that likely would not have occurred otherwise. A low but potentially clinically important percentage of patients had abnormal laboratory test results (6.7%).

Previous publications6-14 have documented that laboratory monitoring of drugs with potential toxicity related to lack of monitoring is not consistently conducted. This can be true even when multiple educational interventions and/or prescriber notifications are available.6 Little is known about why monitoring is not conducted (eg, the contribution of lack of knowledge, patient nonadherence, and communication gaps). Compounding these issues, specific recommendations for type of laboratory test (eg, the recommendation is to “monitor liver enzymes” rather than to “monitor alanine aminotransferase/aspartate aminotransferase”) and monitoring frequency often do not exist, even when the approved drug labeling indicates that organ system toxic effects can be lessened or avoided with appropriate monitoring and clinical action.24

We developed drug-laboratory monitoring recommendations that were agreed on by researchers, physicians, and pharmacists and applied to patients. The result was improved consistency in patient drug-specific laboratory monitoring. Our intervention was effective at enhancing prescriber and patient adherence to recommended monitoring and in treating patients with abnormal laboratory test results. Obtaining the laboratory test results also served the purpose of establishing patients’ baseline values, thus aiding in interpreting results of future laboratory tests. The overall benefit of this intervention was to enhance patient safety.

One example of improved patient safety is our intervention with amiodarone, an effective cardiac drug that has serious potential for toxic effects in a variety of organs including the liver, lung, heart, and thyroid. Better monitoring of amiodarone increases the drug’s safety.19-24 Stelfox and colleagues14 evaluated the evidence supporting amiodarone monitoring. Although they found numerous monitoring recommendations, they also found that most patients received only minimum testing and that monitoring practices varied. Our intervention was effective in improving the relative rate of amiodarone monitoring by 56%. In contrast, our intervention did not increase alanine aminotransferase/aspartate aminotransferase monitoring for pioglitazone, a thiazolidinedione related to troglitazone (an agent removed from the US market after reported cases of acute liver failure).27,28 At our health plan, pioglitazone use requires prior authorization, with one criterion being to obtain a baseline alanine aminotransferase level, which is likely the explanation for the lack of difference in monitoring between groups.

A challenge of research that documents suboptimal medication use, including laboratory monitoring, is in developing systems that are safe and effective at translating research results into improved practice.20-24 Major focus areas in developing and implementing our drug-laboratory monitoring system were getting institutional support, agreement and stakeholder commitment during project development, solving operational problems between physicians and pharmacists in a cooperative man-


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ner, and seeking feedback throughout the project. We believe that the strengths of this approach are demonstrated by impressions of physicians and pharmacists. Physicians commented that they appreciated the collaboration and assistance in monitoring amiodarone, for example. Pharmacists enjoyed both the patient contact and the opportunity to use their knowledge of laboratory tests. Ongoing communication between providers, pharmacists, and the study team was, we believe, partly responsible for the success of this intervention.

This study indicates the usefulness of merging pharmacy and laboratory data in providing information that can improve the quality and safety of care given to ambulatory patients. A barrier to pharmacists’ involvement in patient safety initiatives is that clinical patient data are not readily available to pharmacists in many care settings. However, the system we developed and implemented overcomes that barrier because it can be developed and implemented in essentially any health care setting where pharmacy dispensing information and laboratory claims data are available and can be linked.

Another strength of our study is that we randomized the entire health plan membership to the intervention group or usual-care group. We included every patient who was initiated on a regimen of 1 of 15 drugs of interest. We addressed patient compliance by reminding patients to obtain laboratory tests and physician adherence by ordering the test according to the intervention guideline. Furthermore, analysis of the administrative data set was enhanced by the additional information we obtained for the intervention group regarding patients who had laboratory tests ordered but not completed and regarding patients with abnormal test results. An additional strength is that no separate “translation step” is necessary to implement this program. The study design ensured that this program was translated into practice from the first day of the intervention. The only translation at study completion was to remove the randomization criterion, therefore providing the intervention to the entire membership. We believe the communication and collaboration efforts throughout the study maximized the likelihood that this intervention could continue for these or other drug-specific laboratory monitoring combinations.

A limitation to our work is the use of health plan prescription and laboratory results reporting data to assess laboratory monitoring and drug dispensing. We could not identify drug dispensing or laboratory testing that occurred outside of our health care system. Although this probably occurred rarely because 98% of KPCO members have a drug benefit, it likely accounted for at least some of the lack of difference we observed between groups for patients who were prescribed isotretinoin. Because isotretinoin prescriptions are not included in the drug benefit, individuals who were prescribed isotretinoin likely obtained some of these prescriptions at pharmacies outside the health plan.

This study was not designed to evaluate the clinical or economic outcomes associated with laboratory monitoring or lack of monitoring. Research is needed to evaluate both the effectiveness and the cost of this type of intervention in reducing adverse outcomes related to drug toxicity.

This study demonstrates that coupling data available from information systems with physician and pharmacist knowledge and skills can result in improved patient medication monitoring. The system developed for this study was already translated into practice and could be fully implemented immediately on demonstration of improved monitoring. In addition, this system can be implemented in any health care environment where laboratory and pharmacy data can be linked.

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Author Contributions: The authors had access to study data, take responsibility for the accuracy of the analysis, and had authority over manuscript preparation and the decision to submit the manuscript for publication. Dr Raebel had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

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