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Frequency of Laboratory Monitoring of Chronic Medications Administered to Nursing Facility Residents: Results of a National Internet-Based Study

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Abstract

Objective—To determine the minimal frequency of laboratory monitoring of 30 types of chronic medications or classes that are administered to nursing facility residents and are either listed under pharmacy services tag F329 (the tag for unnecessary medications), or have a narrow therapeutic index.

Design and Setting—Cross-sectional, Internet-based survey.

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Participants—National sample of 500 pharmacists, 500 nurse practitioners, and 327 physicians.

Main Outcome Measure—Minimal frequency of monitoring, recorded as an interval of 1, 3, 6, 9, or 12 months, for each of 35 laboratory parameters (e.g., serum drug level, complete blood count, liver function tests) for the 30 types of chronic medications or classes. Agreement was defined as having two or more of the three professional groups select the same minimal monitoring interval.

Results—Overall, 116 professionals (20 pharmacists, 48 physicians, and 48 nurse practitioners) completed the survey. Most respondents were women (58.6% [68/116]), and most had worked in nursing facilities for > 5 years (66.4% [77/116]). Regarding minimal laboratory monitoring intervals, respondents reached agreement concerning 33 of 35 parameters. They selected three or six months as the minimum interval for 30 of 35 parameters (85.7%), one month as the minimum for two parameters, and 12 months as the minimum for one parameter.

Conclusion—The multidisciplinary panel agreed that most medications that were listed under the F329 tag or have a narrow therapeutic index should have laboratory monitoring every three or six months. The results can be used by nursing facility professionals to establish minimal laboratory monitoring parameters for chronic medications, which may potentially reduce the occurrence of adverse drug reactions.

Keywords

Adverse drug reactions; Drug monitoring; Nursing facility

Introduction

The most frequent medication-related adverse events in nursing facilities in the United States are adverse drug reactions (ADRs), defined as unintended or noxious responses to a drug given in a dosage intended for prophylaxis, diagnosis, or therapy.[1] In the nursing facility setting, the incidence of ADRs ranges from 1.19 to 7.26 per 100 resident-months.[2] This rate would likely be significantly higher were it not for the clinical work of consultant pharmacists.[3,4] Data from ADR studies in nursing facilities suggest that about half of these events are preventable, and most (70%-80%) are associated with monitoring errors.[5-7] Therefore, a critical need exists for the development of strategies to detect and prevent monitoring errors and potential ADRs in nursing facilities.

In December 2006, to emphasize the need for enhanced ADR monitoring, the Centers for Medicare and Medicaid Services (CMS) revised the information about the pharmacy services tag F329 (the tag that pertains to unnecessary medications) in the CMS State Operations Manual.[8,9] These changes broaden the medication monitoring responsibilities for all providers, including pharmacists, physicians, and nurse practitioners. Successful medication monitoring serves two main objectives: 1) to track progress toward therapeutic endpoints, and 2) to detect the emergence or presence of ADRs. The revised F329 guidelines state that monitoring for ADRs involves ongoing vigilance and periodic collection of both qualitative and quantitative information, including laboratory data about medications given to patients.[10] Although there is controversy about the utility of routine laboratory screening tests, data suggest that obtaining laboratory data to detect ADRs is useful in the nursing facility setting.[6,11-14]

According to F329 guidelines, medication monitoring involves four distinct steps: 1) identifying the essential information and how it will be obtained and reported, 2) defining the methods for communicating, analyzing, and acting on relevant information, 3) reevaluating and updating monitoring approaches as a nursing facility resident's status or care plan goals change, and 4) determining the frequency of monitoring. The revised F329 guidelines include

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a list of medications that have the potential to cause clinically significant ADRs, as well as a list of specific laboratory-monitoring parameters to assess these medications. However, rather than explicitly stating how frequently laboratory monitoring should occur, they indicate only that laboratory values should be evaluated periodically. The goal of this study was to determine the minimal frequency of laboratory monitoring of chronic medications administered to nursing facility residents that are either listed under pharmacy services tag F329 or have a narrow therapeutic index (NTI) (i.e., medications with little difference between toxic and therapeutic doses) from the perspective of pharmacists, physicians, and nurse practitioners.

Methods

Study Participants

We selected a multidisciplinary group of 1,327 individuals from three professions for participation in our study: pharmacists, physicians, and nurse practitioners. We included members of these three professions because they are all involved in the monitoring phase of the medication use process (i.e., assess resident response to medication and document outcomes) in nursing facilities.[15] Of these individuals, 500 were pharmacists randomly selected from the membership roster of the American Society of Consultant Pharmacists (ASCP), 500 were nurse practitioners randomly selected from the membership roster of the National Conference of Gerontological Nurse Practitioners (NCGNP), and 327 physician members of the American Medical Directors Association (AMDA) Research Network.

Survey Development

To determine what types of medications and laboratory parameters should be included in the survey, two members of our research team (SMH and BHS) began by examining the Centers for Medicare & Medicaid Services' (CMS) State Operations Manual. We compiled a list of 26 types of medications that were included in the “medication issues of particular relevance” section of the F329 guidelines, and were said to require specific laboratory monitoring, but at nonspecified intervals (e.g., lithium treatment requires that the trough serum lithium level be monitored periodically). We did not conduct a literature review for these 26 types of medications, as they were previously agreed upon by a CMS expert panel.[8]

We conducted a literature search to identify additional NTI medications that require periodic laboratory monitoring that were not listed in F329.[16-18] Through the literature search, we identified medications where there was no evidence base or manufacturer recommendations for laboratory monitoring intervals. Based on this literature review, the following four additional medications were added to the list: cyclosporine, disopyramide, procainamide, and quinidine. The final list included 30 types of medications and 35 laboratory parameters to be monitored.

In the survey, we asked respondents to indicate their primary profession (pharmacist, physician, or nurse practitioner), gender, type of facility in which they worked (nonprofit or for-profit), and duration of time working in the nursing facility setting. For each of the 35 parameters, we asked them to select the minimal laboratory-monitoring interval that they felt was most appropriate for a nursing facility resident taking a chronic medication. The interval options were every 1, 3, 6, 9, or 12 months. We intentionally omitted a “don't know” or “not applicable” response option because F329 mandates that all of the medications be monitored if they are prescribed. We instructed the respondents to assume that the nursing facility resident had been taking the medication long enough to achieve steady-state, that baseline laboratory values were normal, and that there were no ADRs or drug-drug interactions present.

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We asked two pharmacists, two physicians, and two nurse practitioners to pilot-test the survey before we administered it to others. The University of Pittsburgh Institutional Review Board approved our study as exempt. Therefore, informed consent was not needed for study participation.

Survey Administration

Potential subjects were contacted between September and October 2007 and invited to participate in the survey; e-mail addresses were provided by the organizations. In our initial e-mail contact with the individuals, we explained the purpose of our study and instructed those who were interested in participating to click on a link that would provide them with access to the survey. Individuals who did not click on the link or complete the survey were sent a follow-up e-mail after two weeks. Individuals who clicked on the link were asked to enter their e-mail address and to select whether they wished to receive a $5.00 gift certificate or donate $5.00 to their professional organization as an incentive to completing the survey.

Survey Analysis

For purposes of calculating response rates, we defined potential respondents as individuals who had a valid e-mail address. If an individual's e-mail address was invalid (i.e., if it did not allow the e-mail to be delivered within a one-week period), the individual was removed from the list of potential respondents. To calculate the overall response rate, we divided the number of actual respondents by the number of potential respondents for the total group. To calculate the response rates for each profession, we used the actual and potential numbers for pharmacists, physicians, and nurse practitioners.

For each laboratory-monitoring parameter, we determined which of the monitoring intervals (1, 3, 6, 9, or 12 months) was most frequently endorsed (i.e., the statistical mode) by each profession. We chose the statistical mode to provide a summary statistic that was originally included in the survey as a possible response option.[19] A professional group was considered to have selected a particular monitoring interval if the largest proportion of responders from the group selected that interval. We operationally defined agreement as having two or more of the three professional groups select the same minimal monitoring interval. We assessed agreement in this manner to ensure that all three professions had equal influence, regardless of the number of respondents in each profession. We used descriptive statistics to summarize sociodemographic information. We used chi-square, Fisher's exact, and Kruskal-Wallis tests to compare results across professions.[19] For all statistical analyses, we used SAS version 9 for Windows (SAS Institute, Inc., Cary, NC).

Results

Of the 1,327 individuals whom we tried to contact, 144 (10.9%) had invalid e-mail addresses and could not be reached. Of the 1,183 with valid addresses, 131 (11.1%) completed part of the survey, and 116 (9.8%) completed the entire survey. Of the 116 respondents, 20 were pharmacists, 48 were physicians, and 48 were nurse practitioners (Table 1). The response rate was lowest among pharmacists 4.7% (20/430) and highest among physicians 15.6% (48/308). In the total group, most respondents were women (58.6% [68/116]), and had worked in the nursing facility setting for > 5 years (66.4% [77/116]).

There were significant differences among groups in terms of gender, employment information, and tenure (Table 1). Although the pharmacist group had approximately equal gender representation, the physician group consisted primarily of men, and the nurse practitioner group consisted primarily of women ($P < 0.001$). Most physicians were from nonprofit or goverment

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facilities, while most pharmacists and nurse practitioners were from for-profit facilities (P = 0.007). The proportion of physicians and nurse practitioners who had spent more than five years in the nursing facility setting was greater than the proportion of pharmacists who had done so ($P < 0.05$).

Regarding minimal monitoring intervals, respondents reached agreement concerning 33 of 35 parameters (Table 2). They selected three or six months as the minimum for 30 parameters (85.7%). They selected one month as the minimum for two parameters (complete blood count for patients receiving erythropoiesis-stimulating agents, and determination of the international normalization ratio for patients receiving warfarin). They selected 12 months as the minimum for one parameter (measurement of the trough serum tricyclic antidepressant [TCA] level for patients receiving TCAs). They did not reach agreement concerning two parameters (use of serum liver-function tests for patients receiving more than 4 grams of acetaminophen daily, and measurement of the trough serum disopyramide level for patients receiving disopyramide).

Discussion

This study provides a multidisciplinary perspective on how often laboratory monitoring should be performed for certain chronic medications or classes that are either listed under pharmacy services tag F329 or have a NTI, and which are administered to nursing facility residents. The study disclosed two important findings: First, the pharmacists, physicians, and nurse practitioners were in general agreement on the monitoring frequency for nearly all medications included in the survey. They failed to reach agreement for only 2 of the 35 laboratory monitoring parameters. In the case of serum liver-function tests for patients receiving more than 4 grams of acetaminophen daily, the intervals recommended by pharmacists, physicians, and nurse practitioners were one month, three months, and six months, respectively. This variability may be attributable to the fact that the literature does not support the routine use of acetaminophen in doses that exceed 4 grams per day, or to the fact that although acetaminophen is the most common cause of acute liver failure among adults, liver function-test results do not always correlate well with acute toxicity.[20-22] In the case of monitoring trough serum disopyramide levels, the intervals recommended by pharmacists, physicians, and nurse practitioners were 12 months, 6 months, and 3 months, respectively. We were somewhat surprised that the groups did not all recommend frequent monitoring of patients receiving disopyramide, since this medication is commonly associated with numerous side effects, and has a NTI.[23,24] The variability among groups may be related to the infrequent use of this drug, since the non-sustained-release formulation of disopyramide is considered a potentially inappropriate medication whose risks outweighs the benefits of its use.[25]

Second, the monitoring interval recommended for the overwhelming majority (30/35) of medications included in this study was either three months or six months. The exceptions were not particularly unexpected. For patients receiving erythropoiesis-stimulating agents (ESAs), respondents recommended a complete blood count every month. This monitoring frequency appropriately reflects safety concerns raised about using these medications. A meta-analysis performed by Phrommintikul et al. suggested that increased mortality rates were associated with high hemoglobin levels occurring in patients being treated for comorbid anemia and chronic kidney disease.[26] The Food and Drug Administration now recommends using the smallest dose of an ESA to maintain the lowest hemoglobin level necessary to avoid the need for transfusions and ensure that the hemoglobin level does not exceed 12 g/dL.[27] For patients receiving warfarin, respondents recommended that the international normalization ratios be measured every month. This is not unanticipated, because warfarin is commonly used in the nursing facility setting, and the quality of anticoagulation care has been demonstrated to be suboptimal and frequently associated with ADRs.[6,28-30] For patients receiving TCAs, respondents selected annual monitoring of trough serum TCA levels. This may be because the

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TCAs are less frequently used and are not recommended as first-line antidepressant agents, or because therapeutic drug monitoring has not consistently been shown to improve the effectiveness of this medication class.[25,31,32]

When we searched the literature, we found guidelines or recommendations about laboratory monitoring intervals for 17 of the 35 parameters that we examined in our study (Table 3).[33-38] For 52.9% (9/17) of the parameters, the intervals recommended in our study were more frequent than the intervals recommended in the literature. These include monitoring of serum potassium while being prescribed angiotensin II receptor blockers; serum blood urea nitrogen and serum creatinine levels while being prescribed digoxin; digoxin levels, phenobarbital levels, phenytoin levels, serum liver function tests while being prescribed a statin; theophylline levels; thyroid-stimulating hormone levels while being prescribed thyroid medications; and valproic acid levels. For 2 of the 17 parameters (monitoring of electrolyte levels in patients receiving diuretics and monitoring of blood-cell counts in patients receiving ticlopidine), the intervals recommended in our study were less frequent than the intervals recommended in other studies. For the remainder of monitoring parameters (6/17), the intervals were either the same or equivalent to at least one of the other studies. For the majority of monitoring parameters, our results suggest that health care workers in the nursing facility setting believe that more frequent monitoring is necessary than the current outpatient guidelines, measures, or indicators suggest. This may be partly because nursing facility residents have multiple comorbid conditions and receive an average of 8.8 medications per day.[39]

Study Strengths and Limitations

Our study had several strengths. First, the study sample consisted of a national panel of individuals representing the three professions involved in the monitoring phase of the medication-use process in nursing facilities (pharmacists, physicians, and nurse practitioners). Second, the methodology ensured that the responses of the three professions had equal influence, regardless of the number of participants in each profession. Third, in an attempt to improve the survey response rate and reduce the possibility of nonrespondent bias, we employed multiple methods, including university sponsorship, monetary incentives, accessibility of the survey on the Internet, and reminders to participants.[40]

The study also had several potential limitations that should be considered. First, because of the small sample size, we were unable to determine whether any of the sociodemographic characteristics of the respondents correlated with the recommendations for short or long laboratory-monitoring intervals. Second, the response rate was low, and this may limit the generalizability of the findings resulting from indeterminable and nonresponse bias. Third, our operational definition of agreement was not designed to establish consensus agreement in the same manner as with the opinion of an expert panel using methodology such as a Delphi survey. Finally, future prospective studies are needed to examine if following the suggested monitoring intervals can result in decreased medication-related adverse events, such as ADRs in the nursing facility setting.

Implications for Future Work

Further research needs to be conducted to: 1) validate the findings of this study with a larger sample size and with a wider range of health care professionals who work in nursing facilities, including geriatric psychiatrists, psychiatric/mental-health nurse practitioners, and physician assistants, 2) determine the characteristics of nursing facility residents who are being monitored at an interval more or less frequently than recommended by this study, 3) determine if computerized decision-support systems in the nursing facility setting can improve the quality of care by increasing adherence to the recommended monitoring intervals, and 4) determine if

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adherence to the monitoring intervals recommended in this study can reduce ADRs in the nursing facility setting.

Conclusions

A multidisciplinary panel of pharmacists, physicians, and nurse practitioners agreed that most medications that were listed under the F329 tag or have a NTI should be monitored every three or six months. The results can be used by nursing facility professionals to establish minimal laboratory monitoring parameters for chronic medications, which may potentially reduce the occurrence of ADRs.

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Abbreviations

ADR
Adverse drug reaction

AMDA
American Medical Directors Association

ASCP
American Society of Consultant Pharmacists

CMS
Centers for Medicare and Medicaid Services

NCGNP
National Conference of Gerontological Nurse Practitioners

NTI
Narrow Therapeutic Index

TCA
Tricyclic antidepressant

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Table 1
Characteristics of Respondents, Stratified by Profession

Characteristic	Pharmacists	Physicians	Nurse Practitioners
Number of potential respondents	430	308	445
Number of actual respondents	20	48	48
Response rate (%)	4.7	15.6	10.8
Gender (female)	45% (9/20)	27.1% (13/48)	95.8% (46/48)
Type of employment facility (working in a nonprofit or goverment facility)	40% (8/20)	60.4% (29/48)	33.3% (16/48)
Number of years spent working in the nursing facility setting (> 5 years)	35% (7/20)	83.3% (40/48)	62.5% (30/48)

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Table 2

Laboratory Monitoring Interval (in Months) Recommended for Chronic Medications

Medication	Laboratory Monitoring Parameter	Interval Recommended by Pharmacists	Interval Recommended by Physicians	Interval Recommended by Nurse Practitioners	Interval Agreement Across Total Sample*
Acetaminophen at a dosage of > 4 grams	Serum liver function tests	1	3	6	No agreement about interval
Angiotensin II receptor blockers (e.g., losartan, valsartan)	Serum potassium level	6	3	6	6
Angiotensin-converting enzyme inhibitors (e.g., captopril, enalapril, lisinopril)	Serum potassium level	6	3	6	6
Amiodarone	Serum liver function tests	6	6	3	6
Amiodarone	Thyroid-stimulating hormone level	6	6	6	6
Antidiabetic medications (e.g., metformin, glyburide, insulin)	Fasting serum glucose or glycated hemoglobin level	6	6	6	6
Antipsychotic medications (e.g., haloperidol, risperidone, quetiapine)	Fasting serum glucose or glycated hemoglobin level	6	6	6	6
Antipsychotic medications (e.g., haloperidol, risperidone, quetiapine)	Serum lipid panel	6	12	6	6
Carbamazepine	Trough serum carbamazepine level	6	6	6	6
Cyclosporine	Trough serum cyclosporine level	3	3	3	3
Digoxin	Serum blood urea nitrogen and serum creatinine level	3	6	6	6
Digoxin	Trough serum digoxin level	6	6	6	6
Disopyramide	Trough serum disopyramide level	12	6	3	No agreement about interval
Diuretics (e.g., furosemide, hydrochlorothiazide, spironolactone)	Serum sodium and potassium level	3	3	3	3
Erythropoiesis-stimulating agents (i.e., epoetin alfa, darbepoetin alfa)	Complete blood count	1	1	1	1
Fibrates (e.g., fenofibrate, clofibrate)	Complete blood count	6	6	6	6
Fibrates (e.g., fenofibrate, clofibrate)	Serum liver function tests	6	6	6	6
Glucocorticoids, oral	Fasting serum glucose or glycated hemoglobin level	6	3	3	3
Lithium	Trough serum lithium level	3	3	3	3
Metformin	Serum blood urea nitrogen and creatinine level	6	6	3	6
Niacin	Fasting serum glucose or glycated hemoglobin level	6	6	6	6
Niacin	Serum liver function tests	6	6	6	6
Phenobarbital	Trough serum phenobarbital level	6	6	6	6
Phenytoin	Trough serum phenytoin level	3	6	3	3
Primidone	Trough serum primidone level	6	6	3	6
Procainamide	Trough serum procainamide or *N*-acetylprocainamide level	6	6	6	6
Quinidine	Trough serum quinidine level	6	6	6	6
Salicylate (e.g., aspirin >1,200 mg/day, salsalate, choline magnesium trisalicylate)	Trough serum salicylate level	6	6	6	6
Statins (e.g., lovastatin, simvastatin)	Serum liver function tests	6	6	6	6
Theophylline	Trough serum theophylline level	3	3	6	3

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Medication	Laboratory Monitoring Parameter	Interval Recommended by Pharmacists	Interval Recommended by Physicians	Interval Recommended by Nurse Practitioners	Interval Agreement Across Total Sample*
Thyroid medications (e.g., levothyroxine, triiodothyronine, propylthiouracil)	Thyroid-stimulating hormone level	12	6	6	6
Ticlopidine	Complete blood count with neutrophil count	6	3	3	3
Tricyclic antidepressants (e.g., amitriptyline, desipramine, imipramine)	Trough serum tricyclic antidepressant level	12	12	6	12
Valproic acid	Trough serum valproic acid level	3	6	3	3
Warfarin	International normalization ratio	1	1	1	1

* Where agreement is defined as having two or more of the three professional groups selecting the same monitoring interval.

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Table 3

Laboratory Monitoring Interval (in Months): Comparison of Current Study with Recommendations in the Literature

Medication	Laboratory Monitoring Parameter	Monitoring Interval in Current Study	Monitoring Interval in ACOVE Study	Monitoring Interval in HEDIS Study	Monitoring Interval in MacKinnon et al. Study	Monitoring Interval in SCRIPT Study
Angiotensin II receptor blockers (e.g., losartan, valsartan)	Serum potassium level	6	12	12	—	—
Angiotensin-converting enzyme inhibitors (e.g., captopril, enalapril, lisinopril)	Serum potassium level	6	12	12	6	12
Antidiabetic medications (e.g., metformin, glyburide, insulin)	Fasting serum glucose or glycated hemoglobin level	6	12	—	6	—
Carbamazepine	Trough serum carbamazepine level	6	—	12	6	—
Digoxin	Serum blood urea nitrogen and serum creatinine level	6	—	12	—	12
Digoxin	Trough serum digoxin level	6	—	—	—	12
Diuretics (e.g., furosemide, hydrochlorothiazide, spironolactone)	Serum sodium and potassium level	3	12	12	2	—
Lithium	Trough serum lithium level	3	—	—	3	—
Phenobarbital	Trough serum phenobarbital level	6	—	12	—	—
Phenytoin	Trough serum phenytoin level	3	—	12	6	—
Primidone	Trough serum primidone level	6	—	—	6	—
Statins (e.g., lovastatin, simvastatin)	Serum liver function tests	6	—	12	—	—
Theophylline	Trough serum theophylline level	3	—	—	6	—
Thyroid medications (e.g., levothyroxine, triiodothyronine, propylthiouracil)	Thyroid-stimulating hormone level	6	—	—	12	—
Ticlopidine	Complete blood count with neutrophil count	3	—	—	2	—
Valproic acid	Trough serum valproic acid level	3	—	12	6	—
Warfarin	International normalization ratio	1	6 weeks	—	1	—

Abbreviations: ACOVE = Assessing the Care of Vulnerable Elders, HEDIS = Healthcare Effectiveness Data and Information Set, SCRIPT = Study of Clinically Relevant Indicators for Pharmacological Therapy.

Source: References [33-38].