Serum Drug Level Utilization Review in a Family Medicine Residency Program

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A total of 161 tests, comprising six of the most commonly ordered serum drug levels (SDLs) in a family medicine residency program, were audited retrospectively by a review panel. Audit criteria assessed the appropriateness of three factors associated with this laboratory test ordering procedure: (1) indication for the level, (2) procedure and documentation, and (3) physician utilization of the results. There were no statistically significant differences ($P < .05$) when comparing the percentage of appropriate indications and uses with the individual drug levels ordered or with the number of years in practice. However, this audit indicated that a large number of therapeutic decisions were based upon information obtained from improperly ordered SDLs. Also, lack of proper documentation and charting of SDLs appeared to hamper optimal continuity of care in a clinic where patients were seen by several physicians. It is suggested that educational and administrative strategies may be effective in promoting better ordering and use of laboratory tests by family physicians in the future.

Laboratory tests, which account for approximately 10 percent of the patient care costs in the United States, have continued to grow by greater than 10 percent a year for the last 20 years.[1] Utilization studies of laboratory tests suggest that, based upon either perceived need or clinical income, physicians order more tests than necessary.[2-6] This problem is a greater concern in teaching hospitals, where laboratory test ordering is higher than in community hospitals.[7] It is also in these institutions that medical students and residents learn patient care habits that may ultimately follow them into practice.

Six different strategies (education, peer review, administrative changes, participation, penalties, and rewards) have been suggested in an effort to change physician use of laboratory tests and to develop new behavioral patterns.[8] Although no strategy has been shown to alter ordering habits, and therefore to reduce costs when used alone, administrative changes (eg, properly designing order forms) have been advocated as the simplest, fastest, and surest method to alter physicians' laboratory test ordering.[9]

With respect to the ordering of serum drug levels (SDLs), a review of the medical literature disclosed many audits of SDL use, primarily in community[10,11] or university-affiliated hospitals.[12-18] In addition, several authors[19-21] have reported on the utility of an institution-based, clinical pharmacokinetic (ie, drug assay-based therapeutic monitoring and consultation) service. Only one report evaluates such a service in a family practice medical group,[22] but no baseline assessment of SDL use by family physicians prior to initiation of the

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service was noted, nor are there any similar reports in the family medicine literature.

Whereas appropriate SDL use can enhance and individualize drug therapy, indiscriminate use can lead to costly and even dangerous therapeutic decisions.[18] The economic implication of inappropriate SDL use may be most significant to those with chronic diseases who are seen on an outpatient basis, where medical care costs may be uninsured by third-party payment policies. By evaluation and utilization of the results of a SDL-use audit, improved patient care may be provided at a lower cost. Also, deficiencies in physicians' knowledge base and practice skills may be corrected by strategies designed to provide instruction in and use of pharmacokinetic principles and through consultation with clinical pharmacists for selected drug therapy problems.

Since a review of SDL use among family physicians has not been documented in the medical literature, it was decided to evaluate the extent of SDL utilization in a family medicine residency program. The major objectives of this SDL utilization review were to evaluate (1) SDL ordering by family physicians, (2) the appropriateness of the SDL ordering process (blood drawing, laboratory reporting, and chart entry), and (3) physician utilization of the reported SDL results.

Methods

This study was conducted at the Family Practice Center, a division of the Department of Family Medicine, University of North Carolina at Chapel Hill. The Family Practice Center has 18 residents and 11 faculty physicians.

The time interval selected for the audit of SDL use was a one-year period (July 1, 1981, to June 30, 1982) prior to the initiation of clinical pharmacy services. During that time, only the six most commonly ordered SDLs (digoxin, theophylline, phenytoin, phenobarbital, carbamazepine, and lithium; n = 161) at the Family Practice Center were audited. The audit was conducted by a Doctor of Pharmacy candidate (JLP), the clinical pharmacist at the center, and a family physician who serves as the center's director.

Audit criteria were designed to assess the appropriateness of each SDL with respect to three factors: (1) rational indication for SDL ordering, (2) laboratory procedure and chart documentation, and (3) physician utilization of the results. Specific criteria for each drug (example in Appendix) were developed with elements and exceptions following the Joint Commission on Accreditation of Hospitals format.[23] After all laboratory SDL order forms were examined, each patient's chart was reviewed to determine proper indications for the ordering and subsequent physician use of the SDL. Uncharted SDL indications and uses were considered inappropriate. If all three criteria (indication, process, and use) were met, the SDL order was considered appropriate.

Comparisons of the appropriateness of SDL ordering were made for each of the above-mentioned factors. Comparison variables were the type of SDL ordered and the length of physician experience, as determined by years in training (residents) or in practice (faculty). Data were analyzed for statistical significance using the F test.[24]

Results

The 161 SDLs were ordered by 21 physicians (15 residents and 6 faculty), ranging from 1 to 20 requests each (mean, 7.67). Sixty-nine patients (range, 2 to 91 years; mean age, 45.9 years) received SDL determinations.

The most frequently ordered SDL was digoxin (34.2 percent) followed by theophylline, phenytoin, phenobarbital, lithium, and carbamazepine (Table 1). The indication for obtaining a SDL was considered appropriate in 133 (82.1 percent) of 161 cases (range, 76.6 percent for theophylline to 90.5 percent for phenobarbital). The current laboratory order form requires only the date and time of phlebotomy, requesting physician, patient name, and drug ordered. With respect to the time of phlebotomy, 27 (16.8 percent) SDL order forms did not meet the process criteria. However, none of the 161 SDLs were considered appropriate because other vital information (eg, time of last dose) was not recorded on the form or in the chart. All other normally required information (as noted above) was present. As the time of the last dose was available for only two SDLs, criteria for steady-state and peak-trough levels were unmet for all other orders. Appropriate utilization of the test re-

Table 1. Serum Drug Levels (SDLs) Meeting the Audit Criteria

	Digoxin	Theophylline	Phenytoin	Phenobarbital	Lithium	Carbamazepine	Total
Number of patients	20	26	9	9	5	4	69
Number of SDLs ordered (%)	55 (34.2)	45 (27.9)	22 (13.7)	21 (13.0)	13 (8.1)	5 (3.1)	161 (100)
Appropriate indications (%)	47 (83.9)	34 (76.6)	18 (81.8)	19 (90.5)	11 (84.6)	4 (80.0)	133 (82.1)
Appropriate process (%)	—	—	—	—	—	—	None
Appropriate use (%)	32 (58.2)	21 (46.7)	11 (50.0)	15 (71.4)	4 (30.8)	1 (20.0)	84 (52.2)
Cost to patient per SDL	$32	$20	$20	$20	$9	$20	—
Cumulative cost of SDLs	$1,760	$900	$440	$420	$117	$100	$3,737

Note: Four patients had SDLs drawn for two different drugs; none of the SDLs met process criteria (see text)

sults was noted in only 84 (52.2 percent) cases (range, 20.0 percent for carbamazepine to 71.4 percent for phenobarbital).

Although the number of SDLs ordered during the year was relatively small for some individual physicians, no statistically significant difference ($P < .05$) was demonstrated when comparing the percentage of appropriate indications and uses to the individual SDLs ordered. A comparison of physician experience, as measured by years in residency program or practice, and appropriateness of SDL indication or use showed no statistical difference ($P < .05$) between physician groups. The percentages for each group (three resident and one faculty) could be attributable to chance variation rather than physician experience.

Discussion

The primary problem determined from the audit was making therapeutic decisions based upon information obtained from improperly ordered SDLs. In several cases, patients with potentially toxic SDLs had dosage changes without prior determination of the individual patient and pharmacokinetic parameters necessary for proper therapeutic decision making. Cumulative patient costs for the SDLs were also considerable. During the one-year study period, charges totaled $3,697, and it can be argued that the SDLs were of little to no therapeutic value.

Another problem was a lack of documentation. In a setting in which different family physicians utilize the same clinic chart for various patient visits, a thorough charting procedure is essential for optimal continuity of care. Of the 77 SDLs found to have inappropriate use, 76 (98.7 percent) were due to a lack of charting rather than improper decision making based upon erroneous SDLs. Therapeutic decisions can be hampered by a lack of clinical information resulting in potentially deleterious consequences or unnecessary medication use. For example, included in this group were eight subtherapeutic digoxin SDLs with neither

chart documentation nor subsequent dosage adjustments.

Family medicine residents in North Carolina were surveyed recently as to their perceptions of the most important areas of their curriculum.[25] Three of the top four identified areas (clinical therapeutics, management of chronic diseases, and management of common acute problems of adults) have potential for laboratory test utilization and pharmacokinetic consultation. It has been suggested that pragmatic instruction for physicians, especially family physicians, in laboratory test interpretation is both necessary and welcomed.[26-28] Although there has been only mixed success with educational interventions, individualized instruction has been shown to be effective,[8,29] albeit temporary. A recent report, however, demonstrated improvement in pharmacokinetic knowledge after completion of a self-instructional pharmacokinetic education curriculum for family medicine physicians.[30] With this in mind and specifically on the basis of the adult data, an educational program has been planned for the family medicine residents and faculty emphasizing basic pharmacokinetic principles and their utilization with the most commonly monitored drugs. In addition to educational strategies, consultation with the clinical pharmacist or laboratory technician prior to SDL ordering will allow for a determination of SDL indications, appropriately timed blood sampling, and plans for utilization of the drug level. Also, implementation of a new laboratory form specifically for SDL ordering, requiring specific information including drug dosage, dosing regimen, time of last administration, and time of phlebotomy, may be an effective strategy[31] to help the laboratory improve the use of the SDL ordering process by family physicians.

The results of this study are similar to other reports in which a clinical pharmacist was not involved in pharmacokinetic consultations.[11,12,32-34] Reports demonstrate that pharmacy involvement consistently improves appropriate SDL ordering.[17-19,35-38] Clinical pharmacists, making pharmacokinetic recommendations, have been shown to move SDLs into the therapeutic ranges 94 percent of the time.[19] This audit methodology can be implemented in other family medicine residency programs, private practice centers, and ambulatory care practice sites to evaluate SDL use and to improve upon the use of laboratory tests. It is hoped that this utilization review will encourage other family physicians, clinical pharmacists, and laboratory technicians to include this activity in their expanding roles in ambulatory health care settings.

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Appendix: Audit Criteria: Digoxin Serum Drug Levels

Elements	Screening Standards (%)	Exceptions
Indication for Serum Levels		
Base-line assessment	100	Patient shows signs of efficacy and is not toxic
During maintenance therapy		
At dose changes		
Subtherapeutic response	100	None
Suspicion of noncompliance		
Continuance of signs and symptoms requiring digoxin therapy		
Suspected intoxication (nausea, vomiting, anorexia, confusion, visual disturbances, arrhythmias)	100	None
Disease or physiologic states that alter digoxin pharmacokinetics:	100	None
Unstable renal function with rapidly changing serum creatinine		
Severe renal impairment (creatinine clearance less than 10 mL/min/1.73 m^2)		
Change in renal function during maintenance therapy		
Initiation of therapy with interacting drugs (quinidine, verapamil, nifedipine, spironolactone)	100	Patient is not clinically toxic

Appendix: Audit Criteria: Digoxin Serum Drug Levels (Continued)

Elements	Screening Standards (%)	Exceptions
Process Elements		
Blood sample timing	100	Suspicion of toxicity
During maintenance, at least 8 hours after oral dose		None
After achievement of steady-state		Unless patient has been on chronic digoxin therapy
(1) At least 5 half-lives without a loading dose (7 to 10 days), or		(1) If patient has creatinine clearance less than 50 mL/min, after 2 weeks
(2) 8 hours after first maintenance dose, if loading dose was given		
Information on the Laboratory Report	100	None
Time of last dose		
Dosage and schedule		
Time blood sample was drawn		
Concomitant drugs and dosages, especially those that might interfere with radioimmunoassay (progesterone, spironolactone)		
Conditions that may interfere with radioimmunoassay (hyperbilirubinemia, renal failure)		
Screening by laboratory for radioactive contamination before assaying (from previous radiolabel studies, eg, gated blood scans, intravenous pyelograms)		
Follow-up Indicators		
Therapeutic range is maintained	100	Level is 0.8-1.4 ng/mL, and clinical response is not adequate, dosage can be increased
For congestive heart failure, 0.8 to 2.0 ng/mL		
For atrial fibrillation, up to 2.5 ng/mL		
Level is less than 0.8 ng/mL, dose is increased	100	Patient is elderly and shows therapeutic response
		Patient is not elderly—consider discontinuing digoxin
Level is greater than 2.0 ng/mL, dose is decreased	100	Patient is not toxic, and has stable renal function
		Diagnosis is atrial fibrillation