Quality Assurance of Data Collection in an Aminoglycoside Dosing Service

Kim H. Lew and Douglas L. Malyuk

ABSTRACT

An aminoglycoside dosing service (ADS) has been in existence at the Hospital since 1984. As part of an overall Quality Assurance (QA) plan for the service, an audit was conducted to ensure that all necessary data were available to allow for proper interpretation of the serum aminoglycoside levels.

The initial audit revealed complete documentation of required data in 75% of PRE-dose levels and 63% of POST-dose levels drawn. Several problems were identified: staff were not aware of procedures on how to complete the serum antibiotic level requisition forms; inaccurate assumptions of infusion times were made by pharmacists; and discrepancies were found to exist in the Hospital's Laboratory Manual and Pharmacy Intravenous Medication Manual. Corrective action was initiated through: education on proper documentation on the serum antibiotic level requisition forms through the hospital-wide distributed Pharmacy Bulletin; revision of the Hospital's Laboratory Manual and Pharmacy Intravenous Medication Manual; communication with head nurses to emphasize the need for documentation of infusion times; and active follow-up with nurses on missing information by the clinical pharmacist.

A re-audit was initiated following implementation of the corrective actions. Complete documentation of required data increased to 93% with PRE-dose levels and 84% with POST-dose levels. This improvement was statistically significant ($p < 0.001$).

Key Words: *aminoglycosides, clinical pharmacy, data collection, pharmacokinetics, quality assurance*

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RÉSUMÉ

Un service de dosage des aminosides (S.A.D.) existe à l'hôpital depuis 1984. À l'intérieur d'un projet d'assurance de la qualité (A.Q.) pour ce service une vérification fut effectuée pour assurer que toutes les données nécessaires étaient disponibles pour une interprétation adéquate des concentrations sériques des aminosides.

La vérification initiale a révélé que pour 75 p.c. des dosages faits prédoses et 63 p.c. des dosages postdoses, toutes les données nécessaires étaient disponibles.

Plusieurs problèmes furent identifiés: le personnel ne savait pas comment remplir les formulaires de demande de dosages sériques des antibiotiques; *les pharmaciens ont émis des hypothèses incorrectes pour les temps d'infusion; et, des contradictions ont été trouvé dans le manuel du laboratoire de l'hôpital par rapport au manuel des médicaments intraveineux de la pharmacie. Les mesures suivantes fut prises: les renseignements pertinents en ce qui concerne* les formulaires de demande de dosages sériques des antibiotiques *furent diffusés par l'intermédiaire du bulletin d'information de la pharmacie de l'hôpital; les manuels de la pharmacie et du laboratoire furent révisés. Les infirmières-chefs furent avisées de l'importance des temps d'infusion; et, un suivi fut effectué chez les infirmières en ce qui concerne les renseignements manquants, par les pharmaciens en clinique.*

Une autre vérification fut effectuée suite à l'implantation des mesures correctives. Dans 93 p.c. des dosages prédoses et 84 p.c. des dosages postdoses toutes les données nécessaires à une interprétation adéquate étaient présentes. Cette amélioration était statistiquement significative ($p < 0.001$).

Mots clés: *aminosides, assurance de la qualité, collection de données, pharmacie clinique, pharmacocinétique*

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INTRODUCTION

At the Hospital, an aminoglycoside dosing service (ADS) has been provided by the pharmacy department since 1984. This pharmacokinetic service involves reviewing the drug history and pathophysiologic information of all patients receiving an intravenous aminoglycoside. The clinical pharmacist also monitors the patient to ensure optimal efficacy and safety of drug therapy. As the disposition of an aminoglycoside will vary in different patients, serum aminoglycoside levels are helpful in optimizing the patient's dosage regimen.[1] The clinical pharmacist is responsible for interpreting these results and making appropriate recommendations to the physician involved.

To ensure a high level of patient care is provided by any pharmacy service at all times, an ongoing quality assurance (QA) program must exist to identify and correct any problems or deficiencies. The goal of the pharmacy department is to complete a QA audit of all components of the aminoglycoside dosing service.

The QA program of the service is divided into five steps (Table I). Although the final objective is to assess the interpretations and recommendations made by the clinical pharmacist, it was realized that the audits for Steps 1 to 4 must be completed first. This will ensure that the information collected is complete and accurate and can be utilized by the clinical pharmacist to provide a dosing recommendation. The American Society of Hospital Pharmacists (ASHP) QA Process Model was used as a guide to conduct the QA assessment.[2] Each of the steps in the overall QA plan for the service can be individually assessed following this model.

This study evaluated the first step: data collection. As a result, the goals of this study were:

1) As part of the QA plan, to develop and conduct the initial audit to ensure that all necessary data were available to allow for the proper interpretation of the serum aminoglycoside levels.
2) To identify and correct any problems found to exist.
3) To make recommendations for the next phase of the QA plan for the aminoglycoside dosing service.

Table I: Quality Assurance Plan for the Aminoglycoside Dosing Service

Assessment of:
Step 1) Data collection.
Step 2) Accuracy of data collected.
Step 3) Accuracy of serum aminoglycoside level assays.
Step 4) Optimization of scheduling and timing of aminoglycoside levels.
Step 5) Clinical pharmacist's interpretation of levels and recommendations.

METHODOLOGY

An audit of the data collection step for the ADS was performed using standard audit methodology.

Criteria were identified for the documentation of pharmacokinetic data onto the serum antibiotic level requisition form. The criteria and standards were derived from the Hospital's Laboratory Manual and reviewed by the assistant-director for clinical pharmacy services (see Appendix I for copy of *Quality Assurance: Aminoglycoside Dosing Service — Documentation of Serum Antibiotic Level Requisition Forms*).

Evaluation of the data collection process was conducted through a retrospective audit. Two months, September, 1988 and February, 1989, were randomly chosen to define the baseline pattern for the documentation of pharmacokinetic data and to confirm that this pattern had not changed. The serum antibiotic level requisition forms from these two months were obtained from the Biochemistry division of the Laboratory. The information on the requisition forms was entered into a database using dBASE III Plus^{R}. Specific information that was audited included: 1) the date and time of the blood collection; 2) the name of the drug (gentamicin or tobramycin); 3) specification of whether PRE or POST-dose level; 4) documentation of time of the last (previous) dose for PRE-dose levels, and 5) infusion start and finish times for the POST-dose levels.

Observations were made on the nursing wards regarding the involvement of physicians, nurses, ward clerks, laboratory personnel, and pharmacists when an aminoglycoside level was requested. Identification of any situation which could lead to a potential problem was documented.

An assessment of the results of the initial audit (September, 1988 and February, 1989) was made. Problems and possible reasons for their cause were determined. Corrective action was taken to resolve each problem identified.

A week following implementation of corrective actions, a re-audit was conducted utilizing the same procedures as the initial QA audit. The serum antibiotic level requisition forms for a one month period (May 8, 1989 to June 8, 1989) were reviewed. This assessed the effectiveness of the corrective actions taken. Both the initial audit and the re-audit were analyzed for differences in documentation of pharmacokinetic data between weekdays (ADS

available) and weekends (ADS not available). The Chi-square test was performed to detect for any statistically significant improvement as a result of the corrective actions taken after the initial QA audit.

RESULTS

The initial audit reviewed 146 PRE-dose levels and 152 POST-dose levels for the months September, 1988 and February, 1989. There were no significant differences between the results obtained from the two individual months ($p < 0.05$ using the Chi-square test) and thus the data were combined to form the results of the initial audit.

This initial audit showed incomplete documentation of pharmacokinetic data (see Tables II and III).

Only 75% of PRE-dose levels and 63% of POST-dose levels had complete documentation of required information. In almost all cases of incompletely documented PRE-dose levels, the administration time of the last dose given to the patient was missing. Other missing data included the name of the antibiotic, and whether it was a PRE or POST-dose level. For the POST-dose levels, an absence of infusion start and finish times accounted for more than 71% of the incompletely documented cases.

Statistical analysis of the initial audit using the Chi-square test showed incomplete documentation (Table IV) which was independent of whether the serum aminoglycoside level was taken on the weekday (ADS available) or on the weekend (ADS not available).

Several problems were identified during this study. There was a lack of understanding by nurses and ward clerks of how to properly complete the serum antibiotic level requisition forms. In addition, the Laboratory Manual contained an outdated version (obsolete requisition form) of instructions regarding the proper documentation on serum antibiotic level requisition forms. There were discrepancies noted between the Laboratory Manual and the Pharmacy Intravenous Medication Manual as to the recommended infusion durations and recommended times to draw levels relative to a dose.

Although infusion start and finish times were documented in 63% of cases, it was found that this information was not being utilized. The clinical pharmacists did not realize that the infusion times, if documented, appeared only in each patient's profile on the laboratory computer and not on the daily printout of the assayed levels received by pharmacy.

Corrective actions were taken in an attempt to resolve the problems identified. Education on the proper documentation of serum antibiotic level requisition forms was accomplished through hospital wide distribution of a pharmacy bulletin. The Laboratory Manual was revised to include instructions on how to properly complete the current serum antibiotic level requisition forms. Infusion duration and sampling times for levels recommended in the Hospital's Laboratory and Pharmacy Intravenous Medication Manuals were updated to eliminate discrepancies. As well, the clinical pharmacists were instructed to check for infusion start and finish times through the patient's individual profile on the laboratory computer. The need for documentation of the infusion

Table II: Pre-Dose Level Documentation (Initial Audit)

	Sep/88	Feb/89	Combined
Pre-dose levels	68	78	146
Missing blood sample time	0	0	0
Missing last dose time	16	16	32
Other	5	0	5
Complete data (%)	47 (69)	62 (79)	109 (75)

Table III: Post-Dose Level Documentation (Initial Audit)

	Sep/88	Feb/89	Combined
Post-dose levels	78	74	152
Missing blood sample time	1	0	1
Missing dosing regimen	9	12	21
Missing infusion time	22	18	40
Complete data (%)	51 (65)	45 (61)	96 (63)

Table IV: Documentation of Levels (Weekdays versus Weekend) on Initial Audit

Documentation	Weekdays	Weekend
Complete (%)	199 (74)	23 (79)
Incomplete (%)	70 (26)	6 (21)
Total	269	29

times (the most often missing data) was re-emphasized with head nurses. Finally, the clinical pharmacists were instructed to actively pursue any missing information with the patient's nurse and to provide this information to the Biochemistry department for inclusion in the patient's laboratory profile.

The re-audit for both documentation of PRE-dose and POST-dose levels, showed a statistically significant improvement ($p < 0.001$ using Chi-square test). Of 106 PRE-dose levels taken during a one month period, 93% had complete documentation compared with 75% on the initial audit (see Table V).

The POST-dose levels were properly documented in 84% of the 110 levels (see Table VI) compared with 63% in the initial audit.

The re-audit revealed a statistically significant higher rate of complete documentation of pharmacokinetic data ($p < 0.05$ using Chi-square test) on the weekdays with the ADS available (Table VII) compared with the weekends when the ADS was not available.

Table V: Pre-Dose Level Documentation (Re-Audit)

	May 8/89 - June 8/89
Pre-dose levels	106
Missing blood sample time	1
Missing last dose time	6
Complete data (%)	99 (93)

Table VI: Post-Dose Level Documentation (Re-Audit)

	May 8/89 - June 8/89
Post-dose levels	110
Missing blood sample time	2
Missing dosing regimen	3
Missing infusion time	15
Complete data (%)	92 (84)

Table VII: Documentation of Levels (Weekdays versus Weekend) on Re-Audit

Documentation	Weekdays	Weekend
Complete (%)	152 (92)	39 (78)
Incomplete (%)	14 (8)	11 (22)
Total	166	50

DISCUSSION

As part of the QA plan for the ADS, audits of the data collection process were performed. The initial audit revealed complete documentation of required pharmacokinetic data for 75% of PRE-dose levels and 63% of POST-dose levels. Several problems were identified. Ward personnel were not aware of how to properly complete the serum antibiotic level requisition form. Information regarding serum aminoglycoside levels required revision in both the Hospital Laboratory Manual and the Pharmacy Intravenous Medication Manual. Finally, pharmacists were not aware that documented infusion times were only available through the patient's profile on the Laboratory computer.

Previous studies have found wide variations in the infusion duration of drugs administered by gravity flow.[3,4] The extrapolated peak and trough concentrations can vary, depending on the duration of the infusion, particularly in patients with rapid elimination rates.[5] Thus actual infusion times must be provided by the nurse administering the medication rather than having them estimated by the clinical pharmacist.

Corrective action was implemented which improved complete documentation to 93% of PRE-dose levels and 84% of POST-dose levels. This improvement was statistically significant ($p < 0.001$) for both the PRE-dose levels and the POST-dose levels. Further improvement may possibly be attained by extending the ADS from a five day to a seven day per week operation so that a clinical pharmacist would be available to monitor aminoglycoside levels ordered on the weekend. Sufficient progress has been made to proceed with the next phase of the overall QA plan for the ADS. This next phase will assure the accuracy of the collected data, eventually leading to QA of interpretations and recommendations made by the clinical pharmacist providing the ADS.

Although the ADS at the Hospital has been operating since 1984, this clinical pharmacy service benefited from having a QA review performed. The results of this study emphasize the valuable role that QA has to play in maintaining and enhancing clinical pharmacy services to provide optimal patient care. The following recommendations were developed as a result of this study.

1) Attempt to extend the ADS to

seven days per week.
2) Proceed with the next phase of the overall QA plan for the ADS (QA of accuracy of collected data).
3) Conduct QA audits of the data collection step at 12 month intervals to assure that standards are maintained.

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Appendix I: Quality Assurance: Documentation of Serum Antibiotic Level Requisition Forms

All ward units at the Hospital will be reviewed periodically to ensure that proper documentation of serum antibiotic level requisition forms are completed for each serum antibiotic level drawn. Proper completion is necessary to allow accurate pharmacokinetic interpretation of the resulting levels.

The criteria and standards have been derived from the Hospital's Laboratory Manual and have been reviewed by the assistant-director for clinical pharmacy services.

The following criteria and their ideal standards are listed below:

Criteria Element	Standard
Documentation of:	
1) Patient's name (addressograph)	100%
2) Date and time that blood was drawn	100%
3) For PRE-dose levels:	
a) marked as PRE-level	100%
b) date and time of last dose	100%
c) name of antibiotic drug	100%
4) For POST-dose levels:	
a) marked as POST-level	100%
b) dosage and frequency	100%
c) infusion times (start and finish)	100%
d) name of antibiotic drug	100%

Audit Procedure:

Conduct a retrospective review of serum antibiotic level requisition forms. These can be obtained with permission from the Biochemistry department of the Laboratory.