

## ***A Reliable Accounting System for Controlled Substances in the Operating Room***

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**Background:** Drug abuse is a leading occupational hazard for operating room personnel. Easy access to controlled substances allows drug dependence to develop and flourish. A system that accurately audits the distribution of controlled substances used in the operating room may decrease the onset of drug abuse and make it easier to identify drug addicts. A simple, inexpensive, and reliable system that improves accountability of controlled substances is described in detail.

**Methods:** This system involves participation by anesthesiologists, operating room nurses, and pharmacists to accurately record amount and type of drugs dispensed, used, wasted, and returned. Periodic, random, qualitative, and quantitative analyses of drugs returned for wastage are performed.

**Results:** In the first 6 months in which the system was used, 6,336 patients were treated and 7,182 ampules of controlled substances were dispensed. Thirty-seven incident reports describing deviations from the protocol occurred. In each case an explanation for the discrepancy was determined and compliance with the protocol was subsequently improved. No cases of drug diversion were discovered or suspected.

**Conclusions:** The system described is simple and inexpensive to implement and has improved accountability for controlled substance management. (Key words: Analgesics; control system. Anesthesiologists; drug abuse.)

DIFFICULTY in achieving accountability of controlled substances in the operating room is a serious problem. Large quantities of drugs with high abuse potential must be available for the patient and are accessible to many personnel. Stressful working conditions and easy access may tempt any member of the operating room staff to self-administer drugs, easily allowing them to develop tolerance and making their addiction difficult to verify. Substance abuse is more common among anesthesiologists than among any other medical specialty.<sup>1</sup> In one large treatment survey, anesthesia residents comprised 4.6% of the resident physician population but ac-

counted for 33.7% of addicted residents.<sup>2</sup> Unfortunately, partly due to poor accountability, the first sign of drug abuse by anesthesia personnel is often death.<sup>3</sup>

At our medical center, concern with this problem encouraged us to develop a new system of accounting for controlled substances in the operating room. This system was designed to meet all of the goals listed in table 1.

### **Description of New System**

#### *Dispensing*

At the request of an anesthesiologist, an operating room nurse opens the locked controlled substance storage cabinet and removes those drugs required. Each ampule taken is listed on a separate line in the controlled substance log book and assigned a code number (fig. 1). As required by the state of New Jersey, one log book is used for schedule II drugs and one for schedule III, IV, and V drugs. The nurse attaches a label with the code number to the ampule. That ampule is signed out in the name of the nurse dispensing the drug and the anesthesia resident or attending anesthesiologist requesting it. The anesthesia resident and attending anesthesiologist are individually responsible for drugs, so their names are not interchangeable. The nurse then delivers the labeled drug ampule to the requesting doctor.

#### *Accounting*

Each anesthesiologist who receives controlled substances completes an "Operating Room Controlled Substance Administration Form" (fig. 2). The doctor refuses to accept any drug ampule that does not have a code number. The label stays on the ampule and is discarded with it when the ampule is empty. The anesthesiologist records the ampule code numbers and sizes received, along with the patient name and the drugs administered. The form has three columns listing the most commonly administered controlled substances

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**Table 1. Goals of Operating Room Controlled Substance Accounting System**

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Patient care not adversely affected
Easy access to prescribed drugs
Functions at all times
Minimal paperwork
Inexpensive
Simple for many staff to learn and follow
Accounts for outcome of all controlled substances dispensed, including unopened ampules and portions to be wasted
Anesthesia records accurately document drug administration
Identifies individuals not accounting for controlled substances
Identifies source of drugs found in operating room suite
Reliable quality assurance mechanism to compare controlled substance dispensing against the actual drug administration record <sup>5</sup>
Compliance with federal, state and JCAH regulations

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(fentanyl, thiopental, and midazolam) and three blank columns for other drugs. If the doctor forgets to write the ampule number on the administration form before discarding the ampule, then the number can be found in the controlled substance log book at the central control desk.

When the anesthesiologist finishes work for the day, he or she signs the administration form and takes all leftover drugs to the operating room central control desk. Noted on this form for each drug is the total received, total administered, waste in syringes, and unopened ampules to be returned. With a nurse as witness, the anesthesiologist puts the syringes containing drugs to be wasted and unopened drug ampules to be returned into a sealable plastic bag. The nurse signs the administration form to confirm any waste and returns, and places the form in the outside pocket of the plastic bag. Thus the form can later be removed without touching the syringes. With the nurse as witness, the doctor then deposits the plastic bag in the controlled substance collection box. This locked box is mounted on the wall next to the operating room central control desk. It has a lid for deposits but cannot be accessed without a key. If there is no waste or return, the anesthesiologist completes, signs, and deposits the administration form into the controlled substance collection box without a witness or counter signature.

If an anesthesiologist wants to discard a syringe containing drug to be wasted or to return an unopened drug ampule before the work day is over, then the administration form is completed, witnessed, and deposited in the controlled substance collection box with

the waste and returns, and a new administration form with new drugs is started. An anesthesiologist may file as many administration forms per day as is necessary to account for all drug ampules, but each must be completed and deposited appropriately.

All controlled substances dispensed to a doctor must be reconciled before he or she leaves the hospital. The administration form must be completed and deposited with any waste or returns in the controlled substance collection box before the anesthesiologist leaves, even if the last case is in progress. If more controlled substances are needed for that case, then the relieving anesthesiologist uses drugs dispensed earlier to the relieving anesthesiologist or gets new drugs. All controlled substances used by the relieving anesthesiologist are reported on an administration form completed when that anesthesiologist is ready to leave the hospital.

At the end of each nursing shift, one nurse from each shift takes an inventory of ampules in the locked controlled substance storage cabinet. Together they verify that the controlled substance log book inventory matches the shift starting numbers, minus dispensed ampules, plus pharmacy deliveries.

If any breakage occurs before an ampule is given to a doctor, then the nurse, and a witness if there is one, document this in the controlled substance log book. If the ampule was already given to a physician, then he or she documents this breakage on the administration form.

### *Pharmacy*

Every weekday morning, a pharmacist delivers a new supply of controlled substances to the operating room. These drugs are added to the locked controlled substance storage cabinet and recorded in the controlled substance log book by the nurse at the operating room central control desk. The nurse then opens the controlled substance collection box and gives the contents, and a copy of the controlled substance log book pages from the previous day(s), to the pharmacist. Together with an operating room nurse or anesthesiologist, the pharmacist verifies all waste and discards of the syringes properly. They verify all return drug ampules, remove the code number label, and add them to pharmacy stock. They verify that each drug ampule, dispensed according to the controlled substance log book, is listed on one of the administration forms. If a drug ampule is not accounted for, then the nurse and doctor noted in the controlled substance log book are contacted.

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**HACKENSACK MEDICAL CENTER**  
SCHEDULE II — OPERATING ROOM

NURSING UNIT \_\_\_\_\_ DATE 5/7-5/92  
(BEGINS AT 11 P.M.)

HANDLE AND REPORT DISCREPANCIES IMMEDIATELY

#	DOCTOR	NURSE	3rd	2nd	1st	3rd	2nd	1st	3rd	2nd	1st	3rd	2nd	1st
			ALPENTA	DIETILOR	FENTANYL	FENTANYL	FENTANYL	HYDRO	PROPINE	SUFENTA	SUFENTA	SUFENTA		
			<b>ON HAND AT 11 P.M.</b>	34	45	38	30	18	0	22	45	43		
			<b>RECEIVED FROM PHARMACY</b>			20	20	5						
			<b>BALANCE ON HAND</b>			58	50	23						
324	Pan	Soalfrank												
325	Pan	Soalfrank												
326	Pan	Soalfrank												
327	Saladini	Chiang												
328	Horan	Ciancella												
329	Molaco	Schilling												
330	Hummel	Goldson												
331	Koch	Henkel												
332	Gentile	Conroy												
333	Kaumen	Felten												
334	Kaumen	Felten												
335	Giuffne	Chiang												
336	Giuffne	Chiang												
337	Giuffne	Chiang												
338	Giuffne	Chiang												
339	Saladini	Vicente												
340	Pan	Santora												
341	Pan	Santora												
342	Pan	Santora												
343	Higgins	Fionella												
344	Kay	Alvarez												
345	Reddy	Ricci												
346	Stone	Connico												
347	Stone	Connado												
348	Stone	Connaco												
349	Banatta	Wagner												
350	Olson	Quinn												
351	Kay	Quinn												
352	Thurston	Guzay												
353	Ginnar	Egan												
354	Horan	Caumey												
355	Hummel	Weitz												
356	Wagoo	Hahn												
			<b>TOTAL DISPENED</b>	31	0	4	12	10	0	0	4	0		
			<b>BALANCE</b>	31	45	54	38	13	0	22	47	43		
<b>Nurse Signature Out</b>			<b>Nurse Signature In</b>			<b>Count</b>			<b>ON HAND 7 A.M.</b>			<b>ON HAND 7 A.M.</b>		
7 A.M. <u>Renee Ives RN</u>			7 A.M. <u>Maurice Candella RN</u>			34			45			38		
3 P.M. <u>Maureen Ciancella RN</u>			3 P.M. <u>Laura Lando RN</u>			31			45			38		
11 P.M. <u>Laura Lando RN</u>			11 P.M. <u>Lana Schilling RN</u>			31			45			38		
						<b>ON HAND 3 P.M.</b>			<b>ON HAND 3 P.M.</b>			<b>ON HAND 11 P.M.</b>		
						31			45			38		

Fig. 1. Sample page from controlled substance log book.

The controlled substance log book pages and completed administration forms are stored in a secured manner by date. Together they account for the administration of all controlled substances in the operating room.

*Quality Assurance*

Any deviation from protocol is reported on the form "Operating Room Controlled Substance Incident Report," which is completed by the person who discovered the discrepancy. This incident report describes the problem, the individual(s) involved, and whatever

facts are available. This incident report is given in sequence to the Director of the Operating Room if a nurse was involved, the Director of Anesthesiology if a doctor was involved, and then to the Anesthesia Quality Assurance Committee.

Once a month, 12 cases from the previous month are randomly selected for review by an attending anesthesiologist. The anesthesia records are compared to the administration forms of that month. If a discrepancy is noted, then four additional cases of that anesthesiologist from that month are randomly selected for review, and an incident report is completed. Results of this audit

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	cc Fentanyl	mg Pentothal	mg Versed	mg MS		
Ampule # 104		500				
Ampule # 382	5					
Ampule # 112			10			
Ampule # 394	5					
Ampule # 401	2					
Ampule # 410				15		
Ampule #						
<b>TOTAL RECEIVED</b>	12	500	10	15		
Patient: Jones Charles	5	300				
Patient: Horn, Marie	6					
Patient: Brown, Katherine				15		
Patient:						
Patient:						
Patient:						
Patient:						
<b>TOTAL ADMINISTERED</b>	11	300	0	15		
<b>BALANCE</b>	1	200	10	0		
<b>WASTE COUNTERSIGNATURE:</b> Maureen Cardell RN	1	200	0	0		
<b>RETURN COUNTERSIGNATURE:</b> Maureen Cardell RN	0	0	10	0		

Date: 5/19/92 Doctor Name Printed: A. Elummet Signature: *A. Elummet*

Fig. 2. Administration form with fictional patient names.

are reported in sequence to the Director of Anesthesiology and the Anesthesia Quality Assurance Committee.

On a random schedule, some of the wasted controlled substances in syringes are placed in coded test tubes, and sent without the anesthesiologist's name to a laboratory for chemical analysis. Any discrepancy is reported immediately to the Director of Anesthesiology, and an incident report is completed. A written report of the waste verification results is forwarded to the Anesthesia Quality Assurance Committee.

All incident, audit, and waste verification reports are reviewed by the Anesthesia Quality Assurance Committee, which submits a semiannual report to our medical center's Quality Assurance Committee.

## Results

In the first 6 months after the new accounting system was implemented, 6,336 patients were treated in the operating room and 7,182 ampules of controlled substances were dispensed. The outcome of every microgram of drug was noted on the administration forms, except for one day shortly after the system was implemented when the pharmacist checked the contents of the collection box without supervision. The protocol was subsequently changed to have the pharmacist review the contents of the collection box with a nurse or doctor. The log book count did not balance twice, but was corrected when contents of the collection box were reviewed. Thirty-seven incident reports have been filed. Fifteen incidents involved the anesthesiologist forgetting to deposit an administration form and nine involved improperly completed forms. Six times, mostly in the early months, ampules or syringes containing controlled substances were found in the operating room and traced to the anesthesiologist responsible. On two occasions anesthesiologists reported depositing syringes containing waste fentanyl in the sharps disposal box accidentally. The monthly anesthesia record audit revealed four cardiac anesthesiologists whose anesthesia records did not correspond to their administration forms. Random chemical analysis of waste syringes did not reveal any discrepancies.

## Discussion

Our previous controlled substance accounting system was that used throughout the hospital. A log book was kept at the operating room central control desk. Each time an anesthesiologist requested a controlled substance, the nurse at the desk or circulating in the operating room opened the cabinet containing the drugs and removed the requested ampule(s). The nurse then recorded the name of the drug, patient, nurse, and doctor in the log book, and delivered the drug to the doctor. In most of the hospital, the nurse who signs out the drug is also the person who administers it. In the operating room, the nurse is only a transporter for the drug. This third-person carrier system was responsible for much of the inaccuracy of the old system. The simple process of assigning a number to each ampule, allows the origin of each ampule to be traced. If a nurse signs out a drug that the doctor never receives, then that nurse will be identified. Even if a doctor has several

ampules signed out by different nurses, the origin and outcome of each ampule is easily accounted for.

With the old system, there were frequent and serious problems with drug accountability in our operating room. The controlled substance log book count at the end of each nursing shift was often incorrect. The name of the patient or doctor listed often did not match how the drug was actually administered. All drugs given to a patient were not always listed on the anesthesia record. There was no record for unused portions of drug. Syringes containing drugs were frequently found in the operating rooms, lounge, and locker room. Unopened ampules were sometimes found in the anesthesia machines, and some staff even saved them in their lockers until the next day. When these drugs were found, there was no way to trace their origin. When anesthesiologists relieved each other on a case, the drugs stayed with the case so that actually no one was responsible. Poor accountability allowed all of the staff in the operating room to have easy access to drugs. When an individual was suspected of being addicted to opioids, it was difficult to closely monitor how drugs were administered. Easy access probably encouraged at least one nurse to become addicted and delayed her discovery for a long time. One resident with highly suspicious behavior could not be caught taking drugs for himself. These problems in our operating room were similar to those found in many hospitals.<sup>4</sup>

One of the reasons that it took so long to correct the accountability problem was that a simple and accurate system could not be found. As a trauma center, our operating room is very busy even on weekends, holidays, and nights. Last year more than 14,000 controlled drugs were distributed to more than 12,000 patients by 175 nurses, 22 attending anesthesiologists, and 12 residents. As a teaching hospital with long complex cases, one patient may be cared for by as many as 6 anesthesiologists, with as many as 12 other individuals present during surgery.

An alternative system is to have a pharmacist present to dispense controlled substances in the operating room.<sup>5</sup> Since most of our anesthesiologists work into the evening and our operating room is very busy on nights and weekends, five pharmacists would be needed for full-time staffing. Otherwise, a separate system would be needed when the pharmacist was not present.

In some hospitals each anesthesiologist is dispensed a box containing controlled substances.<sup>6</sup> Problems with this system include the fact that each doctor prefers to use different drugs, so each box must be counted and

stocked individually. This requires several hours of work each day by the pharmacist. Security for these boxes, which would contain large quantities of potent drugs, would be a problem between cases and after hours. A different system would be needed to account for controlled substances in the emergency backup drug supply, kept by the nurses at the central control desk for when the pharmacist was not immediately available.

Another system involves a machine that dispenses drugs and keeps a record of the patient, doctor, waste, and returns. This equipment is expensive, requires the patient name or identification number, and involves stocking and inventory by a pharmacist. To avoid requiring the anesthesiologist to leave the patient, a separate machine would be needed near each anesthetizing location. If the doctor allowed the circulating nurse to obtain the drugs with the doctor's access code, then accountability would be lost.

The benefits of our new system are many. Due to its simplicity, it was easily learned and enthusiastically practiced by more than 200 operating room staff who are involved in administering drugs. Each doctor can obtain the drugs that he or she prefers to use. Drugs can be requested before the name of the patient is known. If ampules are not used for one case, the doctor does not need to return them if the same drug is planned for the next case. One administration form can be used for all patients treated by the anesthesiologist. This new system functions at all times, with drugs quickly available whenever needed.

One reason that this system works so efficiently is that the staff received proper in-service education. For the first time a joint staff meeting was held for all nursing and anesthesia personnel. This stressed the importance of drug accountability and cooperation. The in-service training included a discussion of drug abuse among operating room personnel, a review of problems with drug administration during the previous year, a description of the new system, and an opportunity for asking questions. Before participating in the new procedure for drug administration, each staff member was required to sign a statement that the written protocol had been read.

The doctor who developed this system monitored it closely in the beginning. All administration forms were reviewed and discrepancies discussed with the individuals involved. On the first day of the new system, 97% of ampules were accounted for on the administration forms, with the missing 3% easily traced. After

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the first month, mistakes were relatively rare. The most common problem was that anesthesiologists would forget to account for drugs at the end of the day. This has been corrected since a sign was posted on the locker room exits, and it is known that the anesthesiologist will be called at any hour to complete the administration form. When syringes containing drugs were found in the operating room, they were easily traced to the individuals involved since their administration form was missing or showed waste that was not deposited in the collection box. The persons involved were disciplined and their compliance with the protocol improved. When the log book count was incorrect, review of the administration forms showed which types and doses of drugs had been dispensed, so that the reason for the incorrect count could be discovered. Comparison of anesthesia records with the administration forms stressed to the anesthesiologists the importance of maintaining accurate anesthesia records.

Cost analysis of this system is positive considering the large quantity of controlled substances dispensed and importance of proper accounting. Only minimal paper printing and a few hours per month in administration time are needed. The nurses find it easier and quicker to record ampule numbers than patient names in the log book. The ability to request drugs for several cases at once also decreases operating room turnover time between cases. The doctors find the administration form easy to complete, and it requires just a minute at the end of the day to get a counter signature for unused ampules and waste deposits. Review of the contents of the controlled substance collection box each weekday usually takes less than 10 min time of the pharmacist and operating room nurse or doctor. This compares favorably with the cost of five full-time pharmacists or \$18,000 per dispensing machine needed for alternative systems. When a discrepancy is noted, investigation and completion of the incident report usually takes less than 20 min. The monthly chart review takes the anesthesiologist approximately 1 h to complete.

The most expensive aspect of this system is chemical analysis of waste syringe content by an off-campus laboratory. This costs \$135 for qualitative and \$273 for quantitative analysis per specimen. Due to high cost, this analysis is conducted on only a small percentage of waste syringes, but could be done more often if a problem is suspected. Statistically, this aspect of quality assurance serves more as a means of verifying a problem rather than discovering one.

Since controlled substance availability plays a role in

the onset of addiction,<sup>7</sup> this system, which audits the distribution of drugs within the operating room, should serve a preventative function. Illegal access to drugs by nurses who transport drugs from the controlled substances cabinet to the anesthesiologist is greatly reduced by the ampule number labeling system. All personnel in the operating room are now more careful not to leave controlled substance ampules and syringes unprotected. Waste material is now discarded by the supervised pharmacist, rather than left on anesthesia machines or placed in syringe disposal containers throughout the operating room suite.

Although on paper this system accounts for all controlled substances dispensed, there is no guarantee that this record corresponds to the way the drugs were administered. With any system the amount of drug administered will never be known unless two people observe the drug being administered. Any practitioner can divert small to moderate amounts of drugs for his or her own use, while recording on the anesthesia record and administration form that the drugs were administered to patients. Although a resourceful addict will usually find a method to obtain drugs,<sup>8</sup> this becomes more difficult with time when tolerance increases the amount of drug needed to avoid symptoms related to withdrawal. Anesthesiologists dependent on fentanyl, which is one of the most commonly abused drugs, often within a few months require more than 50 ml per day of 50 µg/ml fentanyl.<sup>9</sup> Although one incident with this new controlled substance accounting system would not convict someone, repeat incidents or high-volume drug requests would identify an individual with a dependence problem earlier than when drugs are not audited thoroughly.<sup>6</sup> If an individual is showing signs of drug abuse,<sup>1</sup> that person's controlled substance administration practice and patient response can be closely monitored. The collection of waste syringes and occasional verification of their contents does not completely remove waste as a source of abuse, but warns anesthesiologists that they will be held accountable for how waste is handled.

In conclusion, this simple and inexpensive system has improved accountability of controlled substances in our operating room.

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