# J. Roger Maltby MB FRCA FRCPC,\* Douglas A. Levy MSc,† Chris J. Eagle MD FRCPC\*

Operating rooms require a storage, dispensing and accounting system for restricted drugs which satisfies narcotics control authorities and is compatible with efficient care of patients. We describe narcotic kits containing fentanyl-morphine-midazolam, alfentanil-midazolam and sufentanil-midazolam, for general operating rooms, and two kits with larger quantities of fentanyl and sufentanil for cardiac operating rooms. The container for each kit is a video cassette holder which has a foam-rubber liner with sculpted depressions for each ampoule. Sealed kits are delivered each morning from pharmacy to the locked narcotics cupboard in the recovery room. On request, the recovery room nurse unlocks the cupboard and the anaesthetist signs out the required kit(s) for the day. A drug utilization form is enclosed with each kit, on which the anaesthetist records the amount of drug administered to each patient, and before returning the kit to the locked narcotics cupboard, the total amount of each drug used, discarded, and returned. Used kits are collected the following morning by a pharmacy technician who reconciles the contents and drug form of each kit. More than 40 staff anaesthetists and a similar number of residents have used the system for seven years, during which time 130,000 patients have passed through the operating rooms. Detection of one case of drug diversion by a staff anaesthetist was made partly by the control system, but mainly by behavioural changes. The system is simple, inexpensive, and effective and has been well

# Key words

ANALGESICS: abuse, alfentanil, fentanyl, morphine, sufentanil; DRUGS: control; HYPNOTICS: benzodiazepines, midazolam.

From the Departments of Anaesthesia\* and Pharmacy<sup>†</sup>, Foothills Hospital and the University of Calgary, 1403 - 29 Street N.W., Calgary, Alberta, Canada.

Address correspondence to: Dr. J.R. Maltby, Department of Anaesthesia, 1403 – 29 Street N.W., Calgary, Alberta, Canada T2N 2T9

Accepted for publication 10th November, 1993.

# **Special Article**

Simple narcotic kits for controlled-substance dispensing and accountability

received by the departments of pharmacy, anaesthesia, and nursing.

En salle d'opération, nous avons besoin d'un système de réserve, de distribution et de contrôle des produits d'usage spécialisé qui satisfait aux exigences des autorités civiles et qui est compatible avec l'efficacité des soins. Nous décrivons des trousses contenant les associations fentanyl-morphine-midazolam, alfentanil-midazolam et sufentanil-midazolam pour la chirurgie en général et une trousse spéciale avec des quantités plus importantes de sufentanil-midazolam pour la chirurgie cardiaque. Le contenant est une boîte de cassette vidéo rembourrée avec une mousse de caoutchouc avec moulage en haut-relief destiné à recevoir chacune des ampoules. Ces trousses sont scellées et livrées le matin par la pharmacie, et déposées dans le cabinet à verrou de la salle de réveil. Sur demande, l'infirmière de la salle de réveil ouvre le cabinet et l'anesthésiste signe pour l'obtention de la trousse nécessaire à son usage quotidien. Est insérée dans la boîte, une formule sur laquelle l'anesthésiste enregistre la quantité totale de drogue administrée à chaque patient. Avant de remettre la trousse dans cabinet de médicaments qui est mis sous clé, il enregistre la quantité totale de chaque produit utilisé, jeté ou retourné. Le lendemain matin, les trousses entamées sont recueillies par un aide-pharmacien qui compare les contenants avec les formules d'utilisation. Plus de 40 anesthésistes et le même nombre de résidents utilisent ce système depuis les sept dernières années au cours desquelles 130,000 patients sont passés en salle d'opération. Un cas de détournement de morphinique par un des membres du département d'anesthésie a été, en partie, détecté par ce système de contrôle, mais il le fut surtout à cause de son comportement. Ce système est simple, coûte peu, et est efficace. Il a été accepté facilement par les départements de pharmacie, d'anesthésie et des soins infirmiers.

Substantial quantities of narcotics and other controlled drugs with high abuse potential are used in operating rooms, labour and delivery suites, intensive care units,

# and emergency departments.<sup>1</sup> Control over their distribution and use in the operating room presents unique problems because many individuals have potentially easy access to them. Whatever system is used, it must be compatible with efficient care of surgical patients in a busy operating room and in the post-anaesthetic recovery room (PARR). Because there is little or no relationship between accountability and drug dependence,<sup>2</sup> it is more appropriate to have a simple system that meets the requirements of narcotics control authorities and safeguards the integrity of physicians' accountability than a more complex and costly system which is incompatible with efficient patient care and cannot prevent deliberate diversion and misuse of drugs.

A variety of dispensing methods is used in American hospitals.<sup>3</sup> The most common is that in which a registered nurse dispenses the drug from the narcotics cupboard to the anaesthetist. Other methods include dispensing machines from which anaesthetists obtain required drugs,<sup>4</sup> a satellite pharmacy located adjacent to or in the main operating room suite,<sup>46</sup> a box that is restocked and drug usage tabulated by a central pharmacy,<sup>7</sup> and the "fanny pack."<sup>8</sup>

We describe a narcotics kit method of dispensing and accounting that was developed in 1985-6 as a research project by a pharmacy fellow. This was a joint project of the departments of pharmacy, anaesthesia and nursing that has met with widespread acceptance by all three departments. Since then, modifications have been made so that we now have three kits for the general operating rooms and two for cardiac operating rooms.

# Methods

## Pharmacy

Each sealed kit consists of a used video cassette holder (Figure 1) with a sculpted foam-rubber liner to hold and protect the ampoules listed in the Table. A pharmacy technician requires about two hours each weekday to stock the kits. When this has been done, the contents of each is checked by a pharmacist and sealed with three plastic tabs. The kits cannot be opened without destroying the tabs. Each kit contains a form on which pharmacy records the contents of the kit, the date on which it is filled, the lot number of the ampoules, and the initials of the responsible technician and the pharmacist (Figure 2).

In our hospital there is a nine-theatre suite on the seventh floor, a four-theatre suite on the first floor and two cardiac theatres on the ninth floor. Every weekday morning, a pharmacy technician delivers a new supply of general kits (22 each of fentanyl, sufentanil and alfentanil) and cardiac kits (two fentanyl, three sufentanil) to the

#### CANADIAN JOURNAL OF ANAESTHESIA



FIGURE 1 Sealed narcotic kit.

seventh floor PARR. Sufficient kits are delivered on Friday to cover the weekend. The registered nurse (RN) in charge of PARR opens the locked narcotics cupboard and gives the previous day's kits, both used and unused, to the technician. The technician and RN check the numbers of old kits against their respective day sheet, and the technician verifies the amounts of drugs recorded as used, discarded and returned on the form in each kit. If there is any discrepancy, the form is returned to the anaesthetist for correction or explanation. The new kits are checked against the new day sheet and locked in the narcotics cupboard.

# Dispensing

At the request of the anaesthetist, a PARR nurse unlocks the narcotic storage cupboard and the anaesthetist removes the required kit or kits. The anaesthetist prints his or her name on the day sheet (Figure 3) and signs opposite the code numbers for the kits taken. A nurse checks the accuracy of the identification of the kits and cosigns the day sheet. Each staff anaesthetist or resident is individually responsible for the kits signed out and their contents. At the end of the working shift, the anaesthetist returns the kit(s) to the PARR, where the anaesthetist signs and an RN cosigns the day sheet to record their return to the narcotics cupboard.

#### Accounting

The anaesthetist who signs out the kit is responsible for writing his or her name legibly on the enclosed form, the date on which it was signed out and the amount of narcotic administered to each patient. Before returning the kit, the inventory must be completed so that the amounts used, discarded and returned, are equal to the amount supplied in the sealed kit. Unopened ampoules are returned in the kit, wasted drug in a syringe is discarded in the presence of a nurse or physician who cosigns the form. If accidental breakage of an ampoule is witnessed, the same procedure is followed, otherwise the anaesthetist makes a notation on the form.

# Maltby et al.: NARCOTIC KITS

TARLE		ntente	ofn	arcot	ic i	li te
INDLE	s uu	ments	01.11	arcou	10	KIIC

General			Cardiac			
Fentanyl			Fentanyl			
Fentanyl	5 ×250 μg	(5 ml ampoules)	Fentanyl	6 × 1000 μg	(20 ml ampoules)	
Morphine	2 × 10 mg	(1 ml ampoules)	Midazelam	6 × 5 mg	(1 ml ampoules)	
Midazolam	$2 \times 5 mg$	(1 ml ampoules)				
Sufentanil			Sufentanil			
Sufentanil	7×50 μg	(1 ml ampoules)	Sufentanil	10 × 250 µg	(5 ml ampoules)	
Midazolam	$2 \times 5 \text{ mg}$	(1 ml ampoules)	Midazolam	6  imes 5 mg	(1ml ampoules)	
Alfentanil						
Alfentanil	$10  imes 1000 \ \mu g$	(2 ml ampoules)				
Midazolam	$2 \times 5 \text{ mg}$	(1 ml ampoules)				



FIGURE 2 Opened kit showing recording sheet and contents.

Quality a	ssurance
-----------	----------

Incomplete or inaccurately completed forms are returned to the anaesthetist who signed out the kit. Reference to the anaesthetic records of the day should allow the anaesthetist to complete the form correctly. Unreasonable delays in returning the corrected form to pharmacy are brought to the attention of the Chief Pharmacist who refers the matter to the Director of Anaesthesia. Except in the case of suspected misuse of drugs, random comparison of drug administration on the anaesthetic records with that recorded on form is not performed, nor is there random chemical analysis of syringe or opened ampoule contents.

FoothUla Hospital				DAILY KIT USAGE RECORD						
PRAFMAG T DEPARTMENT					PARE 7 DATE 93:05:04					
8/1.4	101 04	Annual Science	DT CUT	2	Public Spanse	(Pres)	5	RIT	DATE SIGNED OUT	
+2	6	Derallas	WWW/	Qz	2-62 M	(hear)	FF-		13. 05.04	
A 4	17	ONC1	topesto	0	are		a	1	13.05.01	
A 13	1				10	0	1	1		
A 15	1				11			1		
A 19		Mann	Steven	Ŷ.	Swin		$\geq$	$\leq$	4105.04	
A 20	1	Felkysten			12m		m	1	Y01201EP	
8 21	1	INP	ritse		m	PRH.	m	1	43 cs 64	
\$ 26	1						⊢	1		
1 31	1							$\leq$		
A 38	1		-				1	~		
A 39	-						⊢	1		
R 44	×	A					6	<u> </u>		
4 8	1	1 Alaw	441674	-6	All orn	Yemer-	þd.	1		
PA	3	2 Char	Loven	k)	and the	Loken	1	1	93.06.04	
1 04	Z	price	ARNER	₽∩.	one	Atura	Ęυ	1	33. 06.04	
1 30	~	NV -		L	101		۴.	~		
1 22	4	2Vm res	Christ	r.	ANA		₽	<u>۲</u>	93 05.041	
E 22	~	pullabar	MALTRY	5	pointer	MALTOY	<u><u>e</u></u>	14	S.05.01	
1 22	1	-10 11	Nagi	Ľ.	LAL/	rala	192	1	S 36.144	
1 92	4	BUHUAN	ratel	22	- HALL	Harder	⊢	14		
E 41	1			H			⊢	14		
1 2	Ľ.			H			⊢	1×	1	
1. 51	1			H			⊢	1×		
5	Ľ,	Clb Li		t	m_		t.,	15	0	
61	Ľ	Alal	D.D.	5	Pab	P de	6	E	State and	
53	Ľ,	SANIL A	Ukar	í.	SAVA	the start	K	5	42 aC. m/	
51	۲.	Cherry-	Todatico	6	3201	many -	6	1		
55	5	Sement V.	,	100	alima	VENER	Кĭ	12	Rhof att	
224	Ľ	Quin.	VEINA	唜	Balan	10.110	157	t	9305.04	
33	1	- Of	The second	K	11		f <sup>a</sup> '	1-		
536	17			t,			t	ビ		
540	V			Г			t	V		
1342	1							17		
TTA TO PARE CONSISTOR A										
8 5 0 6										
None Technican None Technican							decian			

FIGURE 3 Daily recording sheet from the Post-Anaesthesia Recovery Room.

#### Results

The kits were introduced in the general surgical operating room suites in 1986. In the seven years from April 1986 through March 1993, 130,000 patients have undergone surgical procedures. There has been no reported theft of a kit, or of individual ampoules from a kit. There were initial problems in persuading anaesthetists of the importance of signing out the kit on the day sheet and of accurate recording of narcotic usage on the kit form as well as on the anaesthetic record. Gentle persuasion by the Director of Anaesthesia and visits from the Chief Pharmacist to anaesthesia rounds convinced staff anaesthetists and residents that compliance with alternative systems might be much more onerous! Discrepancies still appear on 5-10% of kit forms, usually arithmetical slips which are easily corrected by the responsible anaesthetist. Unless there has been suspicion of misuse, such errors have always been assumed to be innocent and the contents of partially used ampoules and syringes have not been analyzed. The number of reportedly broken ampoules has, with the exception of one episode (see Discussion), been so small and randomly distributed that follow-up has not been required. One case of drug dependence by a staff anaesthetist was suspected from a combination of "breakage" of four 5 ml fentanyl ampoules on two occasions, an excessive desire to take extra night and week-end calls, and a reluctance to be relieved for breaks. A one month retrospective comparison of this individual's anaesthetic records and narcotic forms showed no discrepancy in drug accountability: the documentation was the most careful and complete of any member of the department.

# Discussion

The objective in designing our narcotic kits was to satisfy the legal requirements for documentation of narcotic use in a system that is flexible enough to satisfy the practical requirements of the large number of anaesthetists and their patients in a tertiary care centre. Before the kit system was introduced, anaesthetists signed out as many individual ampoules of their preferred narcotics as they expected to use in the day. It was difficult to keep track of usage and unused ampoules were frequently left unattended on the anaesthetic carts for several hours at the end of the day's work. Despite the laxity of this system, no case of narcotic abuse was detected in staff anaesthetists, anaesthesia residents, or other operating room personnel in the 20 yr before introduction of the narcotic kits.

Our concern is not so much who receives the unopened ampoules but what happens to the contents. All of the systems in common use identify the anaesthetist to whom ampoules or kits are dispensed and all use the honour system for recording usage. A stricter but impractical system would require that a second person witnesses the opening of each ampoule, the drawing up of its contents into a syringe, administration of the required dose to the patient and the immediate discard of any unused portion of the drug. Not only would this require wastage of large quantities of drug, it would frequently involve theatre staff, commonly the circulating nurse, who may be busy with other duties. For example, at the beginning of a case drugs could not be drawn up by the anaesthetist until the scrub and circulating nurse finished counting instruments.

Any narcotic dispensing system must be available 24 hr per day, seven days per week throughout the year to satisfy the requirements of emergency as well as elective surgery. Anaesthetists and administrative bodies must recognize that, however strict the dispensing system may be, it is unlikely to prevent or detect the deliberate misuse of these drugs by operating room personnel. Misuse among anaesthetists is usually recognized by changes in personal and professional behaviour, mood swings, withdrawal from colleagues, friends and family, and denial, 2,9 There may also be requests for relief during surgical cases to self-administer narcotics and eagerness to take extra night and week-end call to gain access to them.\* The PARR nurses may suspect that patients of a particular anaesthetist have undue amounts of postoperative pain when consideration is given to the amount of narcotic recorded on the anaesthetic record although the issue may be clouded by the administration of benzodiazepines.

A satellite operating room pharmacy in our hospital would require 4.5 full-time equivalent pharmacists to provide continuous 24 hr cover at a cost of \$270,000 per year. The pharmacist's time would be well used during the day shift when all theatres are in use. During evenings, nights, and week-ends, the volume of surgery is unpredictable and, although the individual anaesthetist requires the same service during the day, the employment of a full-time pharmacist for the variable work load of only one or two anaesthetists cannot be financially justified. We have one cardiac and two general operating room suites which would each need its own satellite. Furthermore, unit dose dispensing from the satellite pharmacy may not be entirely satisfactory because of the difficulty in predicting the individual patient's requirements and the necessity of further supplies when the anaesthetist is unable to leave the theatre.

Drug dispensers are available to which anaesthetists have access by means of a personalized plastic card (Lionville Systems Inc., Lionville, PA) at a cost of US \$33,000 per unit. If there is only one unit for the entire operating room suite, anaesthetists may take more than they require for the individual case rather than risk not having enough. The alternative of having a dispenser in each theatre in our hospital would mean a capital cost of \$600,000 and daily re-stocking and reconciliation of

\*American Society of Anesthesiologists "Patient Safety Program" videotape series #6; 1990: Patient Safety and Risk Management.

## Maltby et al.: NARCOTIC KITS

the dispensers would still take the same amount of a pharmacy technician's time as for the narcotic kits.

We believe there are several advantages to our system. The total cost of approximately C \$10,000 per year is comprised mainly of the pharmacy technician's time to stock and reconcile the kit contents, and the pharmacist's time to verify this work. The capital outlay is minimal, as is the involvement of PARR nurses in the system. The anaesthetist remains responsible for maintaining an accurate record of narcotics administered to each patient on the form in each kit and on the anaesthetic record, but is not subjected to a highly structured or complicated process. With cooperation of the anaesthetists, accountability for narcotics is easily achieved.

There is no guarantee, with this or any other dispensing system, that the actual administration of drugs corresponds with what the anaesthetist records on the anaesthesia record and on the form in each kit. Nevertheless, routine analysis of all unused portions of opened ampoules is prohibitively expensive. An off-campus laboratory at one American centre charges US \$135 for qualitative and US \$273 for quantitative analysis per specimen.<sup>1</sup> Our hospital is fortunate in having its own toxicology laboratory, but the costs would still be C \$100 and C \$150 respectively.\* Quantitative analysis of all syringe contents would not only cost C \$60,000 per year if one-third of our returned kits contained syringes with unused drug in them, but would also involve personnel in the Department of Laboratory Medicine in the accounting process.

An alternative qualitative technique may be provided by the refractometer which has been claimed to offer a simple, cost-effective method of screening for tampering with the unused drug. This instrument can distinguish undiluted fentanyl citrate from fentanyl citrate diluted with 0.9% sodium chloride. Using this device, two such admixtures from 1100 random samples were identified because of their unexpected refractive indices.<sup>10</sup> Since a batch of 30 samples can be screened in approximately five minutes, an audit programme using this technique can easily be incorporated into the daily activities of the pharmacy technician. However, although refractometry appears to be a worthwhile first screen and deterrent. it has considerable limitations because refraction of fentanyl citrate, sufentanil and sterile water are indistinguishable, and refraction of alfentanil and morphine is largely unaffected by dilution with Ringer's lactate or normal saline.11

The major advantages of the narcotics kit system are its flexibility and simplicity that satisfy both health care

\*Personal communication: Dr. Keith Todd, Director of Laboratories, Foothills Hospital. personnel and narcotics control officers. The cooperation required for completion of the forms by anaesthetists requires constant encouragement. The absence of chemical analysis of wastage and returned ampoules, and lack of frequent correlation or spot check of anaesthetic records compared to narcotic forms, means the system is without tight controls. Nevertheless, it is likely that any system can be abused, until behavioural changes appear in an individual who becomes addicted to narcotics.

## Acknowledgments

The narcotic kits were developed in 1985-86 as a pharmacy resident research project by Nermen Suleman BSc under the supervision of Dale Wright MSc. The authors of this paper acknowledge the comments, suggestions and cooperation of staff at Foothills Hospital, Calgary in the development and improvement of the kits.

# References

- Schmidt KA, Schlesinger MD. A reliable accounting system for controlled substances in the operating room. Anesthesiology 1993; 78: 184–90.
- 2 Ward CF. Substance abuse. Now, and for sometime to come (Editorial). Anesthesiology 1992; 77: 619-22.
- 3 Klein RL, Stevens WC, Kingston HGG. Controlled substance dispensing and accountability in United States anesthesiology residency programs. Anesthesiology 1992; 77: 806-11.
- 4 Moleski RJ, Easley S, Barash PG, Primer G, Shier NQ, Shrier RI. Control and accountability of controlled substance administration in the operating room. Anesth Analg 1985; 64: 989-95.
- 5 Shafer AL, Lisman SR, Rosenberg MB. Development of a comprehensive operating room pharmacy. J Clin Anesth 1991; 3: 156-66.
- 6 Powell PJ, Maland L, Bair JN, McCall JD, Wong KC. Implementing an operating room pharmacy satellite. Am J Hosp Phar 1983; 40: 1192–8.
- 7 Adler GR. Potts FE III, Kirby RR, LoPalo S, Hilyard GR. Narcotics control in anesthesia training. JAMA 1985; 253: 3133-6.
- 8 Partridge BL, Weinger MB, Sanford TJ. Preventing unauthorized access to narcotics in the operating room (Letter). Anesth Analg 1990; 71: 566-7.
- 9 Arnold WP. Substance abuse and chemical dependence in anesthesiology. American Society of Anesthesiologists Newsletter, February 1991; 55: 4-8.
- 10 Gill DL Jr., Goodwin SR, Knudsen AK, Wade C. Refractometer screening of controlled substances in an operating room satellite pharmacy. Am J Hosp Pharm 1990; 47: 817-8.
- 11 Eagle CJ, Maltby JR, Kryski S, Hardy D. Use of refractometry to identify opioid-containing solutions. Can J Anaesth 1994; 41: 248-52.