

## Effects of Information Feedback and Pulse Oximetry on the Incidence of Anesthesia Complications

Jeffrey B. Cooper, Ph.D.,\* David J. Cullen, M.D.,† Roberta Nemeskal, R.N.,‡ David C. Hoaglin, Ph.D.,§  
Clifford C. Gevirtz, M.D.,¶ Marie Csete, M.D.,\*\* Claudia Venable, M.D.††

No standard outcome measures exist to evaluate the effect of interventions intended to improve the quality of anesthesia care. The authors established a clinically practical definition of outcome, and used it to assess the effect of feedback of information about complications and the effect of pulse oximetry on the rate and severity of important anesthesia-related problems encountered in the operating room (OR) and recovery room (RR). On admission to the RR, the patient's anesthesiologist documented *Recovery-Room-Impact Events* (RRIE), defined as an "unanticipated, undesirable, possibly anesthesia-related effect that required intervention, was pertinent to recovery-room care, and did or could cause at least moderate morbidity." Following a control period with no feedback of data, intense feedback of grouped (anonymous) RRIE rates was provided. Later, pulse oximeters were introduced to all anesthetizing locations. Among 12,088 patients (71% of all RR admissions), 18% had at least one RRIE in the OR or RR. The most common RRIEs were hypotension (4.4%), arrhythmia (3.9%), hypertension (1.5%), intubation difficulties (0.8%), hypoventilation (0.8%), and hypovolemia (0.6%). Feedback of information produced no demonstrable change in the rate of RRIEs. Although significantly fewer patients experienced RRIEs (15.6% vs. 12.4%,  $P < 0.0001$ ), hypotensive RRIEs (5.2% vs. 3.8%,  $P = 0.0003$ ), and hypovolemic RRIEs (0.88% vs. 0.42%,  $P = 0.0017$ ) following the introduction of pulse oximetry in the OR, confounding factors prevent establishment of a cause-and-effect relationship. Quality assurance may require more direct intervention and individual feedback to be effective. Still, the RRIE measure requires minimal effort at low cost and encourages improved transmission of information at the time of admission to recovery-room care. (Key words: Complications. Adverse outcomes. Pulse oximetry. Recovery room. Hypotension.

RECENT EVIDENCE suggests that there are many non-lethal anesthesia complications<sup>1</sup> in addition to the relatively rare anesthesia-related deaths.<sup>2,3</sup> Quality assurance activities, especially the documentation of fatal and morbid events, are mandated to reduce risk and improve outcome. Yet, there is no standard measure for the quality of anesthesia care or for assessing the effectiveness of modifications in practice intended to im-

prove outcome. We designed a simple, inexpensive, self-reporting form to: 1) establish a baseline rate of important, anesthesia-related problems encountered in the Operating Room (OR) and Recovery Room (RR); 2) implement a simple, ongoing, quality assurance measure; 3) assess the effect of feedback of information about anesthetic complications; and 4) assess the effect of pulse oximetry on the rate and severity of complications. Our working hypotheses were: 1) the feedback of summary information about numbers and types of undesirable anesthesia events would decrease the combined rate of all such events, and the rate of some, but not all events; and 2) the introduction of pulse oximetry would further decrease some events and increase the identification of hypoxemic episodes.

### Materials and Methods

A *Recovery-Room-Impact Event* (RRIE) was defined as "an unanticipated, undesirable, possibly anesthesia-related effect that required intervention, was pertinent to recovery room care, and did or could cause mortality or at least moderate morbidity." A one-page form (fig. 1) listed eighty specific RRIEs under nine headings. The above definition of an RRIE was printed on each form. Patient data and RRIEs that occurred in the OR were entered by the patient's anesthesiologist or nurse anesthetist (CRNA) when he/she reported the patient for admission to the recovery room staff (post-hoc reporting was not permitted). Patients admitted directly to an intensive care unit (all those having cardiac procedures or requiring postoperative monitoring *via* a PA catheter, almost all patients having thoracic, vascular, and neurologic procedures, and some patients having a serious complication who would otherwise have been admitted to the RR) were not included. RR nurses encouraged participation (which was voluntary) at the time of recovery room admission, but did not document RRIEs occurring in the OR. A RR nurse or RR anesthesiologist documented any event that occurred during the recovery room stay. At the time the patient was discharged from the RR, the discharging anesthesiologist assessed the cumulative postoperative outcome (severity) of each patient's RRIEs according to a five-point scale defined on the back of the form (table 1). Forms were deposited in a locked box located in the recovery room.

\* Associate Professor of Anaesthesia.

† Professor of Anaesthesia.

‡ Research Nurse.

§ Research Associate in Statistics, Harvard University.

¶ Quality Assurance Fellow.

\*\* Critical Care Fellow.

†† Resident in Anesthesia.

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Address reprint requests to Dr. Cooper: Department of Anesthesia, Massachusetts General Hospital, Boston, Massachusetts 02114.

# ANESTHESIA RECOVERY-ROOM IMPACT EVENTS

PATIENT UNIT# \_\_\_\_\_ ASA \_\_\_\_\_ AGE \_\_\_\_\_ DATE \_\_\_\_/\_\_\_\_/ 86

Were there any impact events in the OR? ☐ Yes ☐ No  
 Were there any impact events in the RR? ☐ Yes ☐ No

If you answered YES, check event in proper column below.

## INSTRUCTIONS

Record only unanticipated, undesirable possibly anesthesia-related effects which:

required intervention and, are pertinent to RR care and, did or could cause mortality or at least moderate morbidity.

Please CHECK the proper columns below.

## SEVERITY (assess only at RR discharge for sum of impact events. CHECK only one.)

☐ none  
☐ minor  
☐ moderate  
☐ serious  
☐ catastrophic  
☐ catastrophe just avoided  
☐ unknown

## NEUROLOGIC SYSTEM

OR RR  
☐ air embolism  
☐ coma  
☐ emergence delirium  
☐ neurologic dysfunction from local anesthetic  
☐ stroke  
☐ unexpected block after regional anesthetic  
☐ other \_\_\_\_\_

## AIRWAY

OR RR  
☐ accidental extubation  
☐ dental injury  
☐ esophageal intubation  
☐ endobronchial intubation  
☐ epistaxis  
☐ obstruction (trach. tube)  
☐ obstruction (airway)  
☐ premature extubation (intentional)  
☐ reintubation (unplanned)  
☐ traumatic injury to airway  
☐ unanticipated difficulty with intubation  
☐ other \_\_\_\_\_

## CIRCULATION/CARDIAC

OR RR  
☐ arrhythmia:  
☐ sinus tachy req. Rx  
☐ sinus brady. req. Rx  
☐ atrial  
☐ ventricular  
☐ cardiac arrest  
☐ hypervolemia  
☐ hypovolemia  
☐ hypotension  
☐ hypertension  
☐ myocardial ischemia  
☐ non-specific ST changes  
☐ \*IF cardiovascular comprise:  
☐ error with drug container  
☐ error in drug selection  
☐ drug overdose  
☐ drug underdose  
☐ undesired synergy of drugs  
☐ other \_\_\_\_\_

## TRAUMATIC INJURY

OR RR  
☐ blood vessel injury from vascular catheter  
☐ burn:  
☐ electrosurgical  
☐ chemical  
☐ esophageal injury  
☐ eye injury  
☐ musculoskeletal injury:  
☐ drug induced  
☐ positioning injury  
☐ other \_\_\_\_\_

## VENTILATION

OR RR  
☐ aspiration  
☐ bronchospasm  
☐ hypercapnia  
☐ hyperventilation  
☐ hypoventilation due to:  
☐ drug error  
☐ equipment error  
☐ prolonged NM blockade  
☐ clinical misjudgement  
☐ other  
☐ hypoxia/hypoxemia  
☐ pneumothorax  
☐ prolonged intubation  
☐ pulmonary embolus  
☐ pulmonary edema  
☐ other \_\_\_\_\_

## ADVERSE REACTIONS (DRUGS, ETC.)

OR RR  
☐ anaphylactic/allergic rxn.  
☐ seizure  
☐ severe shivering  
☐ transfusion rxn. - febrile  
☐ transfusion rxn. - allergic  
☐ transfusion rxn. - other  
☐ vasovagal  
☐ other \_\_\_\_\_

## RENAL SYSTEM

OR RR  
☐ hematuria (unanticipated)  
☐ anuria  
☐ oliguria  
☐ urinary retention

## OTHER SYSTEM EFFECTS OR INJURIES

OR RR  
☐ anemia  
☐ acute coagulopathy  
☐ hyponatremia  
☐ hyponatremia (H<sub>2</sub>O intox.)  
☐ hypokalemia  
☐ hyperkalemia  
☐ hypothermia <94°  
☐ hyperthermia >102°  
☐ malignant hyperthermia  
☐ nausea/vomiting (severe)  
☐ other electrolyte  
☐ wet tap  
☐ other \_\_\_\_\_

## EQUIPMENT PROBLEMS

OR RR  
☐ anesthesia machine  
☐ breathing system  
☐ ventilator  
☐ monitor  
☐ other \_\_\_\_\_

RETURN TO WHITE RECOVERY ROOM

FIG. 1. Recovery-Room-Impact Event form.

TABLE 1. Definitions of Severity Scores

Severity rating of the <i>total impact</i> of all events and occurrences on the postoperative course:
None: no clinically significant sequelae upon recovery room admission and no special observation in recovery room required.
Minor: clinically significant sequelae requiring continued observation in the recovery room, but resolved by discharge to floor.
Moderate: sequelae requiring unanticipated, additional care beyond discharge from the recovery room.
Serious: sequelae not resolved upon recovery room discharge and care in a critical care unit required.
Catastrophic: died (unexpectedly) in recovery room.

The objectives and basic methods of the study were described to the Anesthesia Department verbally and in writing. Strong assurances of confidentiality and anonymity were given (the anesthetist was not identified on the form). The study received administrative approval from the hospital's Committee on Human Studies.

During a 3-week trial period, which began on June 10, 1985, adjustments were made to the form and to the logistics of data gathering. Official data collection began on July 1, 1985. Data were managed on an IBM PC-XT® computer using an applications program (R:Base 5000®; trademark Microrim). After initial entry, each data item was verified against the form.

The duration of the study was 65 weeks. For the first 17 weeks of data collection, data on complications were *not* reported to the department staff (66 attendings, 65 residents and fellows, 17 CRNAs). At meetings and through mailings, the staff were periodically encouraged to cooperate with the study. Intensive feedback of information on complications began at week 18. Summaries of data were reported to the staff regularly *via* verbal reports, and written data summaries were distributed to every staff member (note: anesthetists did

not receive reports of their own complications). However, we did not attempt to interpret the data nor to influence the rate of complications. At the beginning of week 29, pulse oximeters were placed in all (51) anesthetizing locations; during the previous year, only seven had been shared for use primarily with sicker patients. Two weeks before this intervention, a training seminar was conducted at the regular staff meeting, and carefully written operating information about the oximeters was distributed. The frequency of feedback was decreased after the introduction of oximeters; only three summary reports were issued during the 37 weeks of oximetry *versus* six during the 11-week feedback period.

### VALIDATION

The accuracy of information entered on forms was compared to information on anesthesia records. During the seventh and eighth months, one anesthesiologist investigator, blinded to the scoring of the admitting anesthetist, independently scored 601 patients at RR discharge, using the anesthesia and recovery room records as the sole sources of information. This blinded investigator was guided by specific operational definitions for the most frequent individual events (table 2). Two other blinded anesthesiologist investigators repeated this comparison process for 422 patients near the end of data acquisition.

At the completion of the study, an eight-item questionnaire was distributed to all anesthesia staff to evaluate perceived changes in: 1) each individual's "threshold" for scoring an RRIE, *i.e.*, interpretation of the RRIE definition, 2) the impact of data collection alone, and 3) the impact of feedback on practice habits and quality of care.

The experimental design was based on the following estimates: 4% rate of RRIEs in both the OR and the RR; 60 patients/week admitted to the RR; 20% decrease in total event rate; null hypothesis tested at  $\alpha = 0.05$  and power = 0.8. These estimates suggested a requirement of 26 weeks each for the control (no feedback) and feedback periods. Clinical considerations (unrelated to this study) led to the introduction of pulse oximeters earlier than planned for this study alone, forcing us to shorten the control and feedback intervals.

The proportions of patients having at least one event in the OR, in the RR, and in the OR or RR during the three study periods were compared by using the z-test for proportions. If the admitting anesthesiologist/CRNA or discharging anesthesiologist did not place a check in the box indicating that no RRIEs had occurred in the OR or RR, respectively (fig. 1), the patient was excluded from that portion of the data. That is, we did

TABLE 2. Sample Operational Definitions Used by Blinded Investigators

Unanticipated difficulty with intubation: documentation of more than three attempts and difficulty visualizing the cords or arytenoids, or more than one laryngoscopist.
Sinus tachycardia: sinus rate of greater than 120; documentation of drug for reducing rate.
Hypovolemia: documented by insufficient fluid replacement, low CVP or PCWP (<5 mmHg), not detected as soon as would be expected with accompanying signs of tachycardia, narrowed pulse pressure, repeated fluid bolus, oliguria, or anuria.
Hypotension: blood pressure <70/40 mmHg (MAP = 50) or <70% of baseline in a patient >50 yr or with hypertension.
Hypertension: diastolic blood pressure >120 mmHg or systolic >180 in previously normal patient.
Ischemia: ST segment depression or elevation.
Oliguria: <0.3 cc/kg/h urine produced.
Hypernatremia: Na >150 mEq/L.

TABLE 3. Summary of Database

	Control	Feedback	Oximetry	Total
# Weeks	17	11	37	65
# Patients	4339	2854	9929	17,122
Forms returned (%)	3227 (74%)	2022 (71%)	6839 (69%)	12,088 (71%)
% With OR RRIEs*	16.4%	14.3%	12.4%	13.8%
% With RR RRIEs*	8.6%	7.3%	6.2%	7.1%
% With 1 or more†	21.1%	18.9%	16.2%	18.0%
# of RRIEs in OR	684	364	1093	2141
OR RRIEs/100 patients	21.2	18.0	16.0	17.7
% ASA PS I	35.2	33.0	32.3	33.2
% ASA PS II	50.8	53.4	52.6	52.2
% ASA PS III & IV	14.0	13.7	15.0	14.6
Age $\pm$ s.d.	55.7 $\pm$ 21	54.5 $\pm$ 20	54.0 $\pm$ 21	54.7 $\pm$ 21

\* Denominator = number of patients for whom form completed.

† Denominator = number of patients for whom OR and RR information documented.

not assume that the absence of a response indicated an absence of events. Similarly, if no severity score was given, we did not assign a severity.

The effect of feedback was tested by comparing the feedback period to the control period. The effects of oximetry (with reduced feedback) were tested by comparing the oximetry period to the feedback period. In addition, because feedback had no statistically significant effect, the oximetry period was compared to the entire pre-oximetry period. To maintain the overall significance level in the face of simultaneous testing, significance of these comparisons was judged according to Bonferroni's inequality with a (simultaneous) level of 0.05.<sup>4</sup> That is, the individual *P* values had to be less than 0.05 divided by the number of comparisons, 0.05/3 = 0.0167, to achieve significance. The same approach was applied to compare rates of specific events occurring in the OR and the RR. To avoid dividing the overall significance level among many rare events, the experimental design limited the comparisons only to proportions of hypoxia/hypoxemia plus the nine events that occurred most frequently in the OR during the full 65 weeks of the study. All arrhythmias were combined to form a single RRIE classification. Because the resulting 30 comparisons (ten events, three periods) involve the same outcome measure, it is appropriate to regard them as simultaneous and to require that their individual *P* values be less than 0.05/30 = 0.00167 for significance.

Comparisons of age, ASA physical status, and severity distributions among the three study periods used the chi-squared test (for independence—the first two in a 3  $\times$  3 table, *df* = 4, and the third in a 4  $\times$  3 table, *df* = 6). Correlations between event rates and form-return rates were measured by the customary product-moment correlation coefficient. To summarize graphically the time trend of event rates, smoothed curves were produced

by the LOWESS technique for robust locally weighted regression (see Appendix).<sup>5</sup>

### Results

From 7/1/85 through 9/27/86, 12,088 patients, ranging in age from less than 1 yr to 95 yr, were assessed (71% of the 17,122 RR admissions). Thirteen point eight per cent had at least one RRIE in the OR, 7.1% had at least one RRIE in the RR, and 18.0% had at least one RRIE in either the OR or the RR (table 3). The ten most common events were hypotension, arrhythmia, hypertension, unanticipated difficulty with tracheal intubation, hypoventilation, hypovolemia, bronchospasm, laryngospasm, hypoxemia, and prolonged intubation (table 4). Table 5 shows the event rates by three age groups and ASA physical status. Severity scores for the three periods are given in table 6.

In both the OR and RR, after a few weeks of higher compliance, the rate of completion of forms declined

TABLE 4. Rates of Ten Most Frequent Intraoperative RRIEs:  
% of Patients with OR Event\*

	Control	Feedback	Oximetry	Total
Hypotension	5.4	4.8	3.8†	4.4
Arrhythmia	4.4	3.7	3.7	3.9
Hypertension	1.6	1.5	1.4	1.5
Unanticipated difficulty with intubation	0.99	0.89	0.72	0.82
Hypoventilation	0.68	0.99	0.73	0.76
Hypovolemia	1.0	0.59	0.42†	0.62
Bronchospasm	0.65	0.54	0.56	0.58
Laryngospasm	0.22	0.54	0.45	0.41
Hypoxia/hypoxemia	0.34	0.25	0.47	0.40
Prolonged intubation	0.28	0.54	0.26	0.31

\* Denominator = number of forms completed.

† Significantly different from pre-oximetry, *P* < 0.05/30 = 0.0017.

TABLE 5. RRIE Rate by ASA Physical Status and Age: % of Patients in Each Cell with One or More RRIEs

Age (yr)	ASA Physical Status			
	I	II	III + IV	All ASA
≤40	9% (264/2866)	13% (216/1626)	16% (31/197)	11%
41-64	12% (119/1011)	19% (504/2673)	24% (147/601)	18%
≥65	19% (27/139)	23% (464/2020)	33.5% (324/967)	26%
all ages	10%	19%	28%	

slowly and then stabilized. At week 46, an effort to improve cooperation resulted in an upward trend. The average rate of completion of OR information was 74%, 71%, and 69%, respectively, during the three periods. There was only a weak association between the return-rate of forms and the rate of events in both the OR ( $r = 0.280$ ,  $P = 0.024$ ) and the RR ( $r = 0.266$ ,  $P = 0.032$ ).

#### VALIDATION

Of the 1023 patients scored by the blinded investigators, 724 (71%) had also been scored by the admitting anesthesiologist/CRNA. One hundred five of these patients (14.5%) were assessed as having an event by both the AA and the blinded investigators. The admitting anesthesiologist/CRNA and the blinded investigator agreed on the absence or presence of an RRIE in 94% of patients (table 7). The blinded investigators identified 22 of 33 patients with hypotension as reported by the admitting anesthesiologist/CRNA. Of the 299 unmatched patients (admitting anesthesiologist/CRNA failed to complete a form), 47 (15.7%) had an RRIE

TABLE 6. Severity of RRIEs (Sum of Effect of all Events): % of RR Patients for Whom Form was Completed\*

Severity	Control	Feedback	Oximetry
No RRIE	79.2%	82.3%	84.7%
Yes, RRIE resulted in the following severity:			
no sequelae	5.6%	3.3%	3.7%
minor sequelae	12.5	10.8	8.8
moderate sequelae	2.3	3.2	2.2
serious sequelae	0.4	0.4	0.5
catastrophic sequelae	0	0	0
% of forms with RRIE scored for severity	45%	44%	41%

\* Assumes unscored severity group had same distribution of severities as group scored for severity, i.e., the percentages are normalized to account for non-respondents.

assessed by the blinded investigators. Although this rate of RRIEs is not significantly different from the 14.5% in the matched group of patients ( $P = 0.62$ ), the sample size permits detection only of a true difference larger than about eight percentage points (power = 0.9;  $\alpha = 0.05$ ).

#### FEEDBACK EFFECT

The percentage of patients having at least one RRIE in the OR was *not* significantly lower for the 11-week feedback period (14.3%) compared to the 17-week control period (16.4%) ( $P = 0.108$ ; table 3). The actual sample sizes provide a power of 0.78 at  $\alpha = 0.05/3$  for detecting a 20% lower rate of RRIEs during the feedback period. Similarly, the percentage of patients having at least one event in either the OR or the RR was not significantly lower (18.9% *vs.* 21.1%;  $P = 0.078$ ). The gradually declining rate of RRIEs and the absence of a step decrease in RRIE rate distinctly associated with the start of feedback (figs. 2, 3) also suggest that feedback was not an important influence. No single RRIE was identified as significantly different for the feedback *versus* the control period in either the OR or the RR.

#### OXIMETRY EFFECT

The percentage of patients having at least one RRIE in the OR was *not* significantly lower for the oximetry period (12.4%) compared to the feedback period alone (14.3%) ( $P = 0.023$ ; table 3). But the percentage of patients having at least one event in either the OR or the RR was significantly lower (16.2% *vs.* 18.9%;  $P = 0.011$ ). No single RRIE was identified as significantly different for the oximetry period *versus* the feedback period in either the OR or the RR. There was a significant decrease in the percentage of patients having at least one OR RRIE during the *oximetry* period compared to the pre-oximetry (control plus feedback) period (12.4% *vs.* 15.6%;  $P \leq 0.0001$ ). Also, compared to pre-oximetry, the oximetry period had a significantly lower rate of OR hypotensive RRIEs (3.8% *vs.* 5.2%;  $P = 0.0003$ ), OR hypovolemic RRIEs (0.42% *vs.* 0.88%;  $P = 0.0017$ ), RR arrhythmias (0.9% *vs.* 1.6%;  $P = 0.001$ ), and RR hypovolemic RRIEs (0.7% *vs.* 1.5%;  $P = 0.0004$ ). The rate of detection of hypoxemic events was higher (0.47% *vs.* 0.30%), but not to a significant degree.

The distribution of patient ages and ASA physical status was equivalent during the three time periods (table 3). To measure resident experience in terms of duration of training, we calculated the number of

TABLE 7. Validation of Event Scoring (N = 724)

		≥1 Impact Event in OR: Blinded Anesthesiologist		Hypotension in OR: Blinded Anesthesiologist		
		Yes	No	Yes	No	
Admitting anesthesiologist/CRNA	yes	84	21	22	11	
Percent agreement	no	21	598	7	684	
		94%		98%		

months since start of residency (excluding the first four weeks of tutorial, which involves continuous direct staff supervision) for all anesthesia teams admitting to the recovery room. The average level of resident experience declined during the first 3 months of the study, owing to the 27-month character of the residency program and the phased introduction (every 2 weeks) of small groups of new residents starting each July, *i.e.*, new residents enter before senior residents leave. There was no association between the degree of resident experience and the declining rate of RRIEs.

#### QUESTIONNAIRE

One hundred one questionnaires were returned. Participants reported that their definitions of an RRIE and, in particular, a "hypotensive" RRIE had not changed substantially during the course of the study (table 8). But there was also a strong perception that neither the documentation of events itself nor the feedback of information had any influence on individual practice habits or improved patient care.

#### Discussion

RRIEs indicate the rate of adverse anesthesia events for routine recovery room patients. Does the rate of

complications decrease as a result of feedback of information to anesthesia staff? Does routine monitoring of oxygen saturation alter the rate of complications? Does the documentation of complications, by itself, reduce the rate of those complications?

A major aim of this study was to introduce a simple, inexpensive measure of anesthesia outcome that could be used continuously to monitor the work product of an anesthesia group. The comparison of data between anesthesia records and RRIE forms suggests that the RRIE reports reasonably represent the true rate of anesthesia-related complications. The patients not scored by admitting anesthesiologists/CRNAs had very similar rates of RRIEs (as judged by the blinded investigators) as those who were scored suggests that anesthesiologists were forthright in their documentation of events.

The total rates of events scored by admitting anesthesiologists and blinded investigators are the same, although differences clearly exist in how anesthesiologists used the RRIE definition compared to how blinded investigators used more rigorous operational definitions. It is difficult to say, however, which should be the "gold standard." Clinically realistic operational definitions for complications such as hypotension or hypovolemia are not easily created. The RRIE definition was created

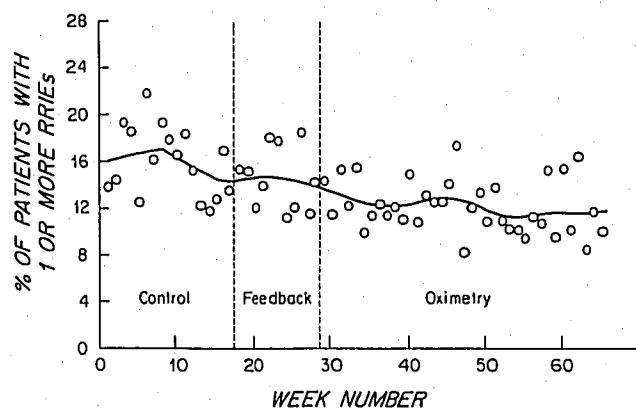


FIG. 2. Percentage of patients experiencing at least one intraoperative RRIE each week.

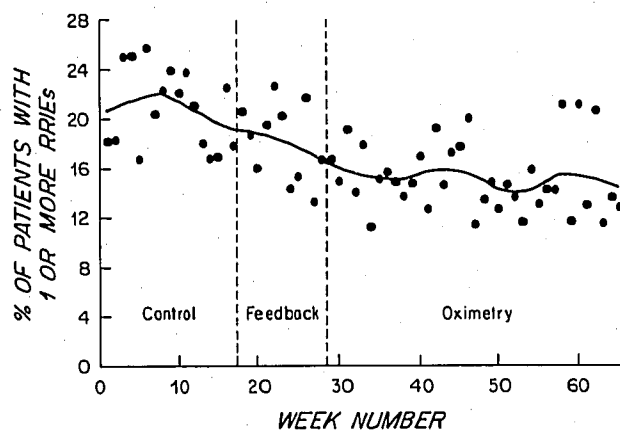


FIG. 3. Percentage of patients experiencing at least one OR or RR RRIE each week.

TABLE 8. Survey of Anesthetists' Perceptions, N = 101  
(1 = Strongly Agree; 5 = Strongly Disagree)

Question	Average Score
1. I understand what is meant by a Recovery Room Impact Event.	1.8
2. My definition of an RRIE changed since I started documenting events.	3.9
3. My definition of a "hypotensive" RRIE changed since I started documenting events.	4.5
4. Documenting events for every patient has, by itself, influenced my anesthesia management.	4.5
5. Receiving information about events has increased my awareness of actual or potential complications.	3.5
6. This study has improved patient care.	3.9

deliberately to give the anesthetist latitude to make judgements based on the clinical situation. But, despite the overall perception that their definitions had not changed markedly, participating anesthetists felt that more specific definitions of at least some events would help maintain consistency between and within the individual scorers.

Although the total rate of RRIEs and the rates of some specific RRIEs showed statistically significant decreases between pre-oximetry and oximetry, there was no change in the severity of events, *i.e.*, outcome, of patients admitted to the RR. We did not, however, document events for patients admitted directly to an intensive care unit, because it is so difficult to differentiate what is and what is not "unanticipated" in such cases. We do know that a few patients were admitted directly to an ICU because of an RRIE. A retrospective review of an independent record-keeping system for the ICUs suggests that there were few such patients, and that their inclusion would not have altered our overall findings.

To what can we attribute the decline in the overall rate and some specific rates of RRIEs? The weak correlation between return rate and RRIE rate suggests that compliance with the study had little influence. The average resident experience level actually decreased during the first 3 months, so the lower rate of RRIEs cannot be attributed to greater resident experience. Most importantly, the lower rate of events by June, 1986, continued through the second summer of reporting, confirming that resident experience and/or summer changeover were not implicated in the progressive reduction of RRIE rates seen during the summer of 1985.

Because this study was designed and implemented quickly, in anticipation of the introduction of pulse oximeters, there was not adequate time to plan a randomized, controlled trial of these hypotheses. The lack of a concurrent control, *e.g.*, a matched group without feedback or without pulse oximetry, prevents us from distinguishing among the effects of several possible causes of the decline in the overall rate of events. It is possible that each anesthetist modified his/her threshold for documenting an RRIE as the study progressed. But the responses to the questionnaire indicate that anesthetists thought that their definitions had not changed substantially since the start of the study. This suggests that the approximately 25% reduction in RRIEs is real. Overall, there was also a strong subjective impression that documenting RRIEs did not affect the practices of individuals nor improve care. Among the attending staff, however, a substantial minority (25/67) felt that the study had improved patient care to some degree (score of 3 or less). We cannot say definitively whether the process of documenting quality assurance data in this way improves patient care or reduces the number of complications. The feedback and "Hawthorne" effects could be better examined in a repeat study by having a concurrent control, stricter definition of key events, and concurrent record review just before the start of event documentation.

The feedback of grouped (anonymous) complications information, by itself, did not reduce RRIEs. This was consistent with the perception of the entire staff of anesthetists. We believe a more aggressive, targeted approach to risk reduction is necessary; *e.g.*, individual feedback of each anesthetist's own complications, prewarming of ORs to reduce hypothermia, and fluid loading to reduce hypotension.

Routine monitoring of pulse oximetry did not produce the hypothesized increase in reporting of episodes of hypoxia or hypoxemia. Pulse oximetry may be providing sufficiently early detection and correction of clinical problems to rule out the need to report the event to the RR staff. This is an example of where the experimental design would have been improved by a more sensitive operational definition.

There is only weak evidence to support the conclusion that pulse oximetry was related to a lower rate of hypotensive and hypovolemic events. Because the survey respondents felt strongly that their criteria for "hypotension" had not changed (table 8), we do believe that the decrease is real. And, because the frequency of feedback was diminished after the introduction of oximetry, we do not attribute the decrease in hypotensive and hypovolemic events to the continuing effects of

feedback. That the rate of arrhythmias, hypertension, and bronchospasm (events unlikely to be linked to pulse oximetry) remained fairly constant suggests that reporting habits did not change markedly. There is a possible link between pulse oximetry and reduced incidence of hypotension and hypovolemia; a small decrease in oxygen saturation or peripheral pulse volume may precede hypotension or hypovolemia, leading to earlier diagnosis and treatment. Neither the decrease in oxygen saturation nor the degree of hypotension or hypovolemia treated would necessarily exceed the threshold for reporting an RRIE.

How does our rate of RRIEs compare with rates of similar events reported in other studies of anesthesia complications? An equivalent comparison is not possible because of differences in definitions, patient mix, patient acuity, and difficulty of procedures. But two studies are similar enough to provide some basis for comparison. Cohen *et al.* described the complications of all patients self-reported by anesthesiologists at a large teaching hospital in Canada.<sup>1</sup> The acuity of those patients was similar to that in our recovery room alone (ASA I & II, 79% *vs.* 86%; ASA III & IV, 21% *vs.* 14%). Although we have no accurate quantitative data on the surgical procedures that our patients underwent, there appear to be differences in the degree of difficulty of procedures between our two patient populations. Their definition of "complications" appears similar to our definition of RRIEs. Their overall rate of OR "complications" was 10.6% (60,500 patients; 1979–83) *vs.* our 13.6%; in the RR, the rate was 5.6% *vs.* 7.1%. Hypotensive episodes were also similar (3.2% *vs.* 4.4%). Certainly, no conclusions can be drawn about institutional differences, but the similarities support an important conclusion drawn from the Canadian study—although the rate of anesthesia mortality may be very low, a substantial number of patients are exposed to anesthesia complications.

Vaughan *et al.*<sup>‡‡</sup> documented "anesthesia related complications" (ARCs—any "pivotal occurrence" that required intervention and could have led to an undesirable outcome), which include a much greater range of problems than RRIEs. One investigator, using some specific operational definitions, assessed 451 patients (>18 yr, no OB or cardiac surgery). Forty-six point six per cent had at least one OR ARC, and 38.6% had an RR ARC. The large difference between this and our

RRIE rate indicates the effects of widely varying definitions. RRIEs are a subset of ARCs. The RRIE represents an event of greater morbidity, lower frequency, and, perhaps, more direct correlation with more serious adverse outcomes. The higher frequency of the ARC offers the advantage of requiring a lower sample size for identifying associations with interventions. Still, the quality of care represented by our rate of RRIEs cannot be judged until other data are collected in a similar fashion.

It is difficult to document an improvement in care from quality assurance studies, even under the best of conditions. A 5-yr study involving 16 clinical ambulatory care groups evaluated eight medical care processes, *e.g.*, follow-up of a test of low hematocrit, cancer screening in women 25–65.<sup>6</sup> Despite a careful study design with evaluation controls and great expense (\$47/case evaluated), only the slightest improvement in the care process resulted from feedback of QA audit data (only two of the eight processes showed a statistically significant improvement over the control, and the best was by 9.8%). In a randomized, controlled trial, prescribing habits of internists improved by 14% with face-to-face education, but not with mailed instruction alone.<sup>7</sup> Yet, in a smaller study, feedback of written instructional material alone, based on feedback from analysis of individuals' prescriptions, improved prescribing habits by 30% *versus* 3% for a control group.<sup>8</sup> These and our results suggest that feedback to individuals of their own complications is necessary for quality assurance to be effective.

The rate of serious anesthetic mishaps, although already small, is believed to be reducible. Because these are relatively rare events, very large samples are required to evaluate anesthetic performance and the effects of interventions when final outcome is the sole measure. RRIEs fall on a continuum of adverse anesthesia-related events ranging from minor errors to preventable brain death. Collecting RRIEs in the manner described measures an important component of outcome anonymously, requires minimal effort from clinicians and minimal additional resources (no substantive increase in operating cost), and encourages improved transmission of pertinent information at a critical time in perioperative care. The information can be used to identify abrupt changes in overall quality of care and specific problem areas. Incorporation of the form into the anesthesia record is certainly appropriate.

‡‡ Vaughan RW, Vaughan MS, Hagan RM, Cork RC: Predicting adverse outcomes during anesthesia and surgery by prospective risk assessment (abstract). ANESTHESIOLOGY 59:A132, 1983

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### Appendix

LOWESS is a technique for producing a smoothed curve to represent a set of  $(x, y)$  data. For each  $x_i$ , a smoothed value of  $y_i$  is computed. The method is quite involved. Briefly, around each  $x_i$ , a window is arbitrarily set to include some fraction of the data closest to  $x_i$  (we set the fraction at 25% to produce less smoothing). A robust regression line is fitted to the  $x$ -values in the window, yielding a predicted value of  $y$  at  $x_i$ . In computing the regression, each of the  $x$ -values included in the window is weighted according to its distance from  $x_i$ . The further away from  $x_i$ , the less the weight the  $x$ -value has in the regression. The robustness refers to the down-weighting of outlying  $y$ -values. A line connecting the predicted  $y$ -values usually yields a good approximation to a smooth curve. For more information, the reader is referred to Cleveland WS: *The Elements of Graphing Data*, Monterey, CA, Wadsworth Advanced Books and Software, 1985, pp 174-178.