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The outcome index and system outcome score: a method of quality assurance through outcome analysis in the special care area

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Abstract

A scoring system intended to assess mortality risk and permit surveillance, evaluation and comparison of medical care was developed in our Surgical Intensive Care Unit. Five simple clinical components were identified and assigned scores according to their statistically validated relationship to mortality and the summation of the component scores resulted in a daily System Outcome Score (SOS). Cluster analysis was used to divide the creation data set of 2,777 patients into suitable groupings of scores to predict mortality and the clustering was confirmed for reproducibility with a validation set of an additional 2,860 patients.

Two patient care surveillance techniques were then developed. The first involved the definition of three unfavourable SOS patterns evolving during the course of a patient's admission and detection of one or more of these patterns permits identification of specific patients for whom review of care delivered may be appropriate. The second involves a global assessment of care utilizing the Outcome Index (OI) which relates overall mortality risk in the unit to the actual mortality rate over a given time period. The effectiveness of care can then be compared between different time periods within the one unit or between different units with similar patient mix. A simple menu driven program has been developed for the IBM^{R} personal computer and clones that facilitates data storage and retrieval, production of outcome reports and customization of the scoring ranges to meet local standards of performance.

Introduction

In recent years the amount of health care resources diverted to the provision of intensive care has steadily increased. Although attempts have been made to analyze the results of such care in some university affiliated hospitals [9, 15] there is little reliable information available about the overall performance of the majority of intensive care units (ICU), most of which are outside university centers. Even in such centers episodes as extreme as malicious interference with patient management by disturbed individuals has occurred and passed unnoticed for months to years [1, 4, 8, 16, 17].

Our purpose was to develop a system of outcome analysis for intensive care patients that would meet the goals outlined in Table 1 by generating a daily System Outcome Score (SOS) for each patient that would reflect mortality risk. The development of this scoring system was based upon the premise that a relationship exists between the degree of disturbance of vital function and the mortality rate [14, 18]. The SOS was then used to create two objective systems for evaluating the quality of care

delivered. Since early expectations for survival or non-survival are not always fulfilled [3, 5, 13], we attempted to define and detect unfavorable SOS patterns emerging during a patient's admission as a method of identifying specific patients in whom all aspects of care delivery might be profitably examined. Three such patterns were identified and referred to by the acronym SDL, where S refers to *sudden* clinical deterioration, L represents a non-survivor with an inappropriately *low* peak SOS score and D is a non-survivor whose SOS pattern in the first 72 hours indicated survival but then exhibited *delayed* deterioration.

Finally, an index designed to reflect the level of care delivered to all patients as it affected their mortality rate was created from the SOS data and termed the Outcome Index (OI). The rationale for development of the OI was based upon the premise that if the quality of care delivered as it affected outcome was constant, then the average SOS of all patients should rise and fall with the mortality rate provided SOS is both aetiology independent and does accurately measure mortality risk. Assuming that the latter reservations are satisfied, then an index created by dividing the mean SOS for all patients over a given time span by the mortality rate for the same time span should be constant unless the quality of care changed.

Table 1. Aims of outcome analysis scoring system.

a	permit evaluation of the competence of ICU care as it affects both specific patients and the general ICU patient population
b	possibly detect malicious interference with patient care
c	facilitate quality assurance studies
d	incorporate a limited number of simple items, the assessment of which is not dependent upon the knowledge, skill, experience or judgement of observer
e	involve a simple and rapid data entry and retrieval format
f	be implemented on economical and widely available computer hardware
g	include a menu driven system for producing reports
h	permit development of a hospital specific database from which a local performance standard baseline can be established
i	develop a universal measure of outcome performance against which local performance can be evaluated in comparison with other ICU's of similar patient mix and level of medical sophistication

Method

2,777 consecutive patients (creation data set) admitted to our surgical intensive care unit were evaluated upon admission and at 8.00 a.m. each subsequent day for the presence or absence of scoring system components outlined in Table 2. 146 of these patients died while in the unit. Forty-six were classified as brain dead secondary to head injury (defined as head injured patients admitted with a Glascow Coma Scale of less than 5 and either meeting the criteria for brain death on admission or within 36 hours of admission). The components evaluated include a mixture of simple clinical signs of organ system failure and therapeutic interventions, with the latter being taken to indicate related organ system failure the majority of times that they occur. The patients were evaluated in two stages (Stage I and II) with 60% of patients included in the second phase.

Patient biographical data and the daily presence or absence of the components being evaluated were entered by one of the authors (J.G.) into a VAX Datatrieve data management system implemented on a VAX 11-750 minicomputer (Digital Equipment Corp., Maynard, MA). At the end of Stage I customized subroutines written within the SPSS statistical package (Statistical Package for the Social Sciences, Inc., 444 North Michigan Ave., Chicago, IL) were run to check for errors in data entry.

Once errors were eliminated, BMDP stepwise logistical regression (BMDP Statistical Software, Inc., 1964 Westward Blvd., Los Angeles, CA, USA) was utilized to determine which of the components were most commonly associated with non-survival. BMDP default values were used to enter and remove components. The results for Stage I patients were incorporated into the choice of components monitored in Stage II. At the end of Stage II the stepwise logistical regression was repeated and the components entered were as shown in Table 3.

Stepwise discriminate analysis (BMDP7M) was then applied to the five scoring system components accepted by the logistical regression equation. Scores were assigned to these components as shown in Table 3 by expressing each component's discriminate index as a percent of the sum of all indices and then normalizing to a total summation maximum of ten. The sum of the scores was referred to as the SOS. A further error detecting subroutine was then written to identify an invalid SOS.

Using SAS cluster analysis (SAS Institute, Inc., SAS Circle Box 8000, Cary, NC, USA) the maximum SOS during each patients admission were grouped into clusters and verified for their discreteness by Chi-square analysis. From April 1, 1985 to March 31, 1988 a further 2,860 consecutive patients admissions were evaluated using the SOS (validation data set). Of these 166 patients died including 40 patients who were brain dead secondary to head injury. The accuracy of the SOS for predicting outcome was examined for five different time periods, each one utilizing the maximum SOS within that time period, and receiver operating characteristic (ROC) curves [7] prepared for both the creation and validation data sets. Areas under the curves were calculated and standard errors obtained.

In reviewing summaries of daily scores arranged chronologically, three unfavorable SOS patterns were identified and referred to by the acronym SDL. S stands for patients whose SOS declined in any 24 hours period by an amount $\geq$ the mean difference between survivors and non-survivors. D represents patients who exhibited a delayed deterioration in the early SOS trend. Chang [5] and Bion [3] showed Apache II to improve in accuracy by following trends over the first 3–4 admission days, so we defined a D patient as one whose maximum SOS during the first 3 admission days predicted survival but who subsequently died. L category patients were defined as patients who died with an inappropriately low SOS, the value of which was to be defined later on the basis of the results obtained.

The OI was created for any given time period according to the following formula.

Table 2. Components evaluated in SOS development stages.

Stage I (1982–83)	Stage II (1983–85)
Glascow Coma Scale (GCS) > 9	Glascow Coma Scale (GCS) 5–9
Glascow Coma Scale (GCS) 5–9	Glascow Coma Scale (GCS) < 5
Glascow Coma Scale (GCS) < 5	
Ventilator support	Ventilator support < 12 hrs duration
	Ventilator support > 12 hrs duration
Effective FiO_2 > 0.5	Effective FiO_2 > 0.5
Administration of sympathomimetic amine	Administration of sympathomimetic amine > 12 hrs duration (excluding low dose dopamine at < 4 μg/kg/min)
BUN/Creatinine ratio < 10	BUN/Creatinine ratio < 10
Urine output < 0.5 cc/kg/hr for previous 8 hours	Urine output < 0.5 cc/kg/hr for previous 8 hours
Temperature > 102° F in previous 24 hours	Temperature > 103° F in previous 24 hours
WCC > 20,000 in previous 24 hrs	WCC > 25,000 in previous 24 hours
	WCC < 4,000 in previous 24 hours
Admin. of immunosuppressive drugs	Barotrauma
Coagulopathy (any abnormal test of clotting function present after the first day)	Coagulopathy present after first admission day
Age (years)	
14–40	
41–60	
61–80	
> 80	

Table 3. SOS components and values.

GCS < 5	3.75
FiO_2 > 0.5	0.75
Administration of sympathomimetic amine > 12 hrs duration (excluding renal perfusion dopamine)	1.75
Oliguria < 0.5 cc/kg/hr for previous 8 hours	2.50
Coagulopathy present after first admission day	1.25
	10.00

$$\text{O.I.} = \frac{\text{Mean daily SOS for all patients} \times \text{No. of admissions}}{\text{No. of deaths}}$$

Results

Although not included in the list of scoring components accepted by the stepwise logistic regression equation (Table 3), ventilator support greater than 12 hours had the same p value for entry as $FiO_2 > 0.5$. While it had good sensitivity, its specificity was poor and accuracy of this component was markedly inferior to $FiO_2 > 0.5$. For this reason and also because true positives substantially overlapped between these two components, it was decided to continue to collect data on ventilator support for quality assurance reasons but as a non-scoring component in the SOS system.

Patients brain dead secondary to head injury often had only one organ system failure (CNS). Their median SOS on the day of death was 3.75 compared to 6.25 for the other deceased patients. Since nothing therapeutically can be done for these patients and because a clustering of such patients in any given time period could bias the SDL incidence and OI, it was decided to identify and exclude these patients from further evaluation. Brain dead patients who did not fall within our definition (see first paragraph, Methods section), were included in the analyses along with all other deceased patients.

Unless stated to the contrary, the following results apply to the validation data set. When the mean SOS values are broken down by calendar quarter (Table 4) the difference between survivors and non-survivors is statistically significant at a p value of < 0.001 (two-tailed t test). The differences between the individual component scores for survivors vs non-survivors (Table 5) is also statistically significant at a p value < 0.001 for all components except $FiO_2 > 0.5$ when $p = 0.001$ (two-tailed t test). The component occurrence and mortality rates are shown in Table 6.

Utilizing cluster analysis and the creation data set, patients were grouped by maximum SOS during the entire admission and associated mortality rate determined (Table 7). The discreteness of each group was confirmed by Chi-square analysis with a p value of < 0.05.

The accuracy and reproducibility between the two data sets for the SOS system in predicting outcome is represented by the area under receiver

Table 4. Mean SOS by calendar quarter including brain dead: survivors vs. non-survivors.

Quarter/year		Mean survivor SOS	No. of patients	Mean non-survivor SOS	No. of patients
II	1985	0.16	239	3.65	21
III	1985	0.12	250	3.57	17
IV	1985	0.07	238	4.52	15
I	1986	0.08	189	5.20	9
II	1986	0.09	202	5.18	11
III	1986	0.11	243	4.98	15
IV	1986	0.09	243	4.41	17
I	1987	0.14	200	3.21	9
II	1987	0.09	253	4.88	8
III	1987	0.04	208	2.37	12
IV	1987	0.04	223	3.62	13
I	1988	0.13	207	4.34	19

Table 5. Mean SOS component scores: survivors vs. non-survivors.

	Survivor	Non-survivor	p
GCS > 5	0.064	2.733	< 0.001
F_IO_2 > 0.5	0.034	0.502	0.001
Vasopressor	0.072	1.139	< 0.001
Oliguria	0.053	1.506	< 0.001
Coagulopathy	0.038	0.663	< 0.001

Table 6. Occurrence and mortality rates for SOS components.

	Occurrence rate (% of admissions)	Mortality rate (% of occurrences)
GCS < 5 not inc. brain dead	4.8	65.9
FiO_2 > 0.5	7.7	43.5
Sympathomimetic amine	7.3	46.4
Oliguria	5.3	61.7
Coagulopathy	5.6	48.7
Ventilator Support (Non-scoring component)	28.2	15.7

operating characteristic (ROC) curves (Fig. 1). The consistency of performance is evident (Table 8).

Based upon the data acquired to this point, the definitions for the three unfavorable SOS scoring patterns (SDL) were completed. The difference in mean SOS between survivors and non-survivors for the entire admission to be 3.6. Thus sudden clinical deterioration (S) is defined as an increase in the SOS of 3.6 or more from one day to the next. 49 patients fell in this category and the mortality rate was 85.7%. The records of these patients can be reviewed regarding the acceptability of the cause of the sudden deterioration.

Delayed clinical deterioration (D) was defined as a non-surviving patient whose maximum SOS during the first three admission days was in the survivor category. The ROC curve areas (Table 8) confirm the appropriateness of choosing day three as a decision point given the statistically significant and progressive improvement in accuracy of outcome prediction which extended over the first three admission days only. The admission day 1–3 mean maximum SOS for survivors is 0.21 (SD 0.77). Thus any non-survivor whose day 1–3 maximum SOS is ≤ 1.75 (mean maximum + 2 standard deviations) is classed as a D. The total number of D patients was 40 representing a 1.53% misclassification rate for the 2,568 patients expected to survive (sensitivity = 98.5%). By identifying these misclassified patients review of their care can be undertaken to determine if any deficiencies are present in the medical care they received.

Patients dying with an inappropriately low maximum SOS for the entire admission were classed as L. Based on the data presented in Table 7 this inappropriately low level was determined to be < 4.0, since patients with maximum scores less than this have a mortality rate predicted to fall in the 0–6% range. 43 patients fell in this category. The average number of SDL's was 2.9 per month and each patient was represented in 1.3 SDL categories.

As part of a quality assurance review it is possible to evaluate specific aspects of care by presenting the component SOS data as illustrated in Table 9. Ventilator support or any other item of interest can be evaluated by incorporation into the data set as a non-scoring component.

Table 7. Mortality within groups based upon peak SOS.

	0		0.75–2.0		2.5–3.75		4.0–7.0		> 7	
	N	%	N	%	N	%	N	%	N	%
No. of patients and (%) of admissions	2333	(84.9)	165	(6.3)	117	(4.4)	67	(2.5)	49	(1.9)
Mortality in group	0	(0)	2	(1.2)	7	(6.0)	44	(65.7)	47	(95.9)

The OI was calculated according to the previously specified formula. When calculated on a monthly basis wide fluctuations occurred that were difficult to interpret. Extension of the time interval with inclusion of approximately 250 patients and 10 non-survivors reduced the volatility of the results and this was not enhanced by enlarging the groups further. The overall OI was 6.03 (SD1.54). A fall in the OI to a value more than two standard deviations below the mean (OI < 2.95) would suggest the probability of a changed and less effective level of care. The mean OI for 1985 was 6.34, rising to 6.77 in 1986 and falling 5.64 in 1987. The value of the OI fell to 2.72 in the third quarter of 1987 mandating a review of clinical care and its delivery (Fig. 2). Although outside the range of the validation data set, OI results for 1988 and 1989 have been added to Fig. 2.

It is reasonable to expect the total number of SDL's in any one calendar quarter to also reflect the quality of care delivered, particularly if review of these SDL's revealed instances of deficiency in care delivered. The incidence and type of SDL's with the associated OI is shown in Table 10. The total of patients represented by these SDL's correlated negatively with the OI at a p value of 0.03 and a r of -0.55 (Pearson Correlation Coefficient).

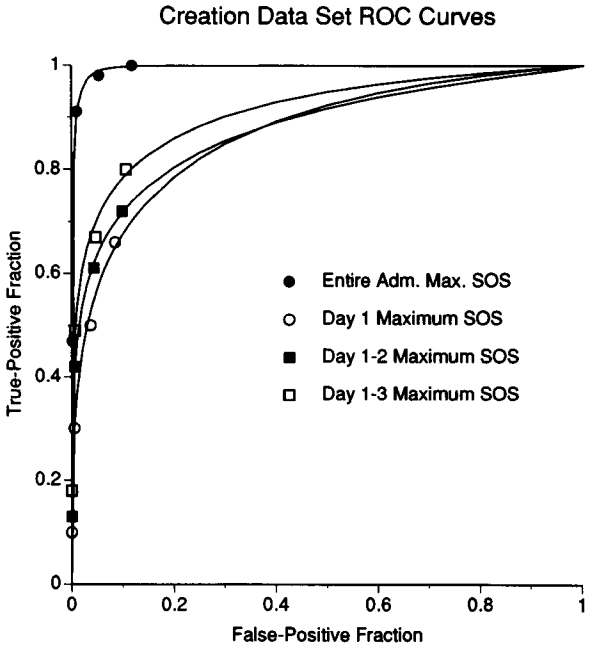

Fig. 1. ROC curves from creation data set.

Discussion

The purpose of this study was to develop a practical system of medical care surveillance in the ICU, principally by indicating specific cases where thorough review of the medical care delivered to specific individuals would be indicated. In addition a measure of overall care that could permit assessment of care across different time periods and between different intensive care areas was sought. Specifications were chosen to permit implementation of the scoring system in smaller community hospitals.

The SOS has permitted a consistent clustering of patients (Table 7) with a highly reproducible mortality rate (Table 8). The SOS is a measure of mortality risk and not of degree of illness, and it is

Table 8. ROC curve area (%) and S.E. and patient populations.

	Creation data		Validation data		Validation data patient population			
	ROC area		ROC area		Survivors		Non-survivors	
	%	SE	%	SE	Number	(%)	Number	(%)
DAY 1 Maximum SOS	80.1	2.9	80.0	2.6	2694	(95.5)	126	(4.5)
DAY 1–2 Maximum SOS	83.3	2.8	83.9	2.4	2433	(95.3)	119	(4.7)
DAY 1–3 Maximum SOS	87.4	2.4	86.8	2.2	1298	(92.9)	99	(7.1)
DAY 1–4 Maximum SOS	87.9	2.4	88.0	2.1	791	(90.1)	87	(9.9)
Entire Adm. Max. SOS	99.3	0.2	98.9	0.5				

possible for a patient who is quite ill (e.g. a septic patient on a ventilator with a $FiO_2 < 0.5$ and achieving adequate cardiovascular stability and urine output with just fluid administration) to score 0. The accuracy of such an assessment is confirmed by the fact that of the 2,233 patients whose maximum SOS was 0, none died (Table 7). As we anticipated, there is a statistically significant increase in accuracy in predicting outcome with increasing duration of admission up to day 3 (Table 8). The highest accuracy is achieved by the entire admission maximum SOS which is to be expected from the system design.

While the maximum SOS score is important to permit clustering of patients for mortality risk, it has little other function except at its highest level where it may lend support to a clinical decision to limit care because of a hopeless prognosis. What does appear to be important is the emerging pattern of SOS and the recognition of unfavorable SOS patterns referred to as SDL's. Peer review activities can be focused on specific patients identified by the SDL characterization, recurring patterns of management problems identified and remedial action undertaken. A preponderance of SDL's being associated with any one particular care giver would also be cause for evaluation, counseling and monitoring of the performance of the individual. In reviewing our own SDL's we have found that the majority have a satisfactory explanation. We have, however, identified situations that required changes in our Unit Policies and Procedures resulting in restrictions on physician privilges to modify some aspects of therapy and have identified individuals for whom counseling about patient management was deemed appropriate.

It has been suggested that using scoring systems to predict outcome may become a self fulfilling prophesy once the prognosis appears hopeless. [2] We share that concern and for this reason our data collection cards no longer contain the component scores and the patients maximum score does not enter into daily management decisions, although we are aware of the components present in each patient. Rather than the SOS inhibiting treatment, we have more often found it to be a source of encouragement when looked at from the point of view of how many or how few components have been scored as present in any specific patient. If a patient appears critically ill and the overall impression is of a poor prognosis but the patient has a low SOS component count, then the enthusiasm of both medical and nursing staff for continuation of aggressive care can often be fostered by pointing out the failure of the objective SOS component count to confirm the poor prognosis derived from clinical impression.

We have not been able to validate our OI as a measure of the competence of clinical care except by circumstantial association. It does correlate negatively with the number of SDL's, which would be expected if it does in fact measure quality of care. A review of the third quarter of 1987 when the OI dropped to 2.72 found that effective July 1, 1987

Table 9. Comparison of component occurrence and mortality rates in different time periods.

	1984		1985		1986		1987	
	0%	(M)%	0%	(M)%	0%	(M)%	0%	(M)%
GCS < 5	–	–	5.1	(62.7)	5.5	(62.0)	3.3	(73.3)
$FiO_2 > 0.5$	16.6	(41.1)	8.3	(36.1)	7.5	(40.6)	7.4	(41.2)
Sympathomimetic - amine > 12 hrs	11.5	(63.6)	7.4	(50.0)	7.4	(33.8)	8.3	(38.2)
Oliguria > 8 hrs	11.5	(57.6)	5.5	(52.7)	4.9	(64.4)	4.4	(70.0)
Coagulopathy after first day	5.2	(66.7)	5.3	(56.6)	5.8	(59.5)	4.8	(47.7)
Overall mortality (%)		(6.7)		(4.5)		(4.0)		(3.8)
Ventilator support	29.1	(32.3)	21.4	(21.0)	27.9	(14.5)	31.1	(11.9)

0 = Occurrence as a % of admissions.
(M) = Mortality as a % of occurrence.

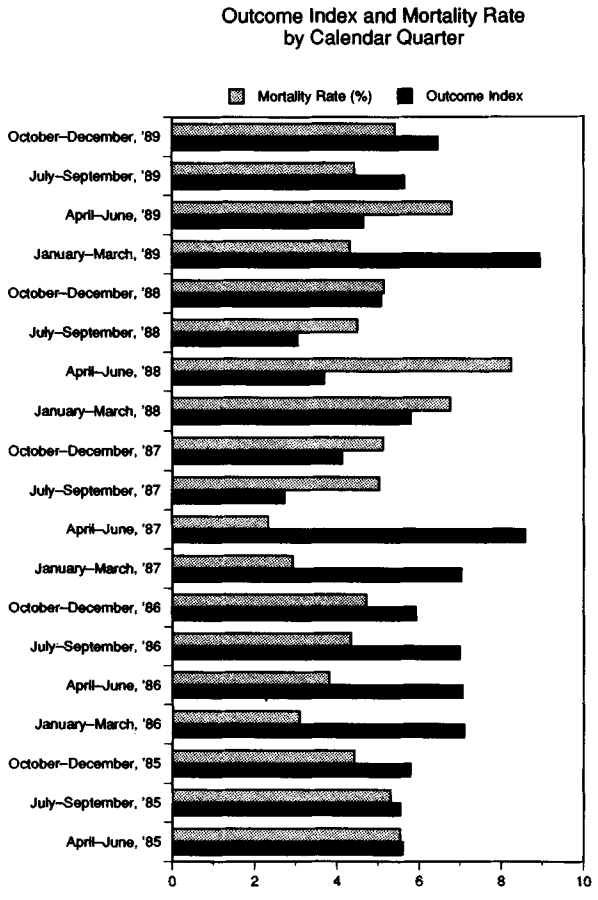

Fig. 2. Outcome index and mortality rate by calendar quarter.

there had been a significant change in the organization and areas of responsibility of the house staff servicing the unit, giving more responsibility to junior resident staff and reducing oversight by more experienced residents. In addition, there were repeated failures of communication with a major consulting service. This finding reinforces that of Knause [10] who found that variations in outcome in high risk patients depended to some extent upon unit staff interaction and coordination. Changes intended to correct these deficiencies led to a gradual overall rise in the OI (Fig. 2). Finally the component occurrence and mortality data as presented in Table 9 does appear to improve or deteriorate in parallel with rises and falls in the OI. The decline in mortality rate for the sympathomimetic amine group, reduction in incidence of oliguria and improved survival for ventilated patients

Table 10. The outcome index and occurrence of unfavorable SOS patterns (SDLs) by quarters.

	S	D	L	Number of patients represented	OI
Quarter 2 1985	10	7	2	14	5.60
Quarter 3 1985	4	5	4	9	5.54
Quarter 4 1985	4	3	1	7	5.79
Quarter 1 1986	3	1	3	4	7.10
Quarter 2 1986	1	2	0	3	7.06
Quarter 3 1986	3	3	0	6	6.99
Quarter 4 1986	3	4	1	5	5.92
Quarter 1 1987	3	2	0	4	7.17
Quarter 2 1987	5	1	0	5	8.57
Quarter 3 1987	4	6	1	8	2.72
Quarter 4 1987	3	2	3	7	4.12
Quarter 1 1988	6	4	2	9	5.80

S = Sudden clinical deterioration.
D = Death with delayed deterioration.
L = Death with low maximum SOS.

appear to have resulted from an educational emphasis stimulated by the 1984 results (Table 9). This emphasis involved the use of metabolic end-points of therapy, alteration in the balance of crystalloids versus colloids utilized in resuscitation and acute therapy with an overall reduction in total fluids administered, and less use of vasopressor agents together with an expanded use of dobutamine. Ventilator management techniques were altered to emphasize uniform lung expansion, stability of lung volumes in the expiratory phase and limitation of pulmonary excursion and airway pressure.

One of the principle reasons for undertaking this study was to be better able to detect malicious interference. This subject is repugnant to many physicians, yet it can from time to time be a serious

Table 11. Outcome analysis reports generated by the DOS program.

a	SDL, mortality rate and OI
b	Specific patient information for each SDL
c	SDL patient review and report forms
d	Scoring and non-scoring component reports
e	Mortality by SOS grouping
f	Patient biographical data summaries

problem with appalling consequences. The event that took place in our own institution [8, 16] where a nurse was believed to have been the cause of multipe deaths in a pediatric intensive care unit, served as a stimulus for this project. We do not know if our system can detect malicious interference. We believe that it has the potential to do so utilizing the mechanism of the SDL's. A sudden increase in the number of SDL's, an association between the presence of a particular care giver and the occurrence of SDL's or a new and recurring pattern of occurrence of any one of the three SDL patterns should alert those responsible for reviewing the results of this surveillance system to a potential problem. Similarly a reduction in the OI below the previously established threshold would have a similar warning effect.

In discussing this scoring system we are often asked to compare it to The APACHE System [11, 12] There is, however, no comparison. APACHE is based upon the input and opinions of a panel of experts and was initially developed in a medical unit to measure the degree of illness of patients and help ensure equality between randomized patient groups in clinical studies. Its application has subsequently been expanded into the area of prognostication of outcome and quality assurance, although its role in these remains unclear. APACHE is a mature system that has been widely validated for its original purpose. SOS is, on the other hand, a simplistic and inflexible system created by statistical methods utilizing an approach that should be applicable in a wide variety of intensive care units, even those that are community based and without a full-time medical direction. It aims to measure mortality risk and not degree of illness and it seeks patterns of evolution of that mortality risk as an indication of possible deficiency in quality of care. The results of individual patients can be pooled to produce an index that may allow the quality of care to be assessed across time within the one unit or between different units.

In order to provide for widespread application of this system we have developed a version that can be implemented on any basic IBM^R personal computer or compatible for recording and examination of SOS and OI data. This system can produce a series of reports as outlined in Table 11.

The SOS system has succeeded with regard to some of its goals. It is a simple and highly objective system with limited potential for error in data collection and entry. It gives a measure of clinical performance that appears to correlate with other measures of outcome in the unit in which it was devised. It highlights patients where peer review may be appropriate and it gives limited information that may assist in some quality assurance evaluation. A variety of reports are generated without need for or knowledge of any query language. It can be used on a wide range of IBM compatible computers although report generation is slow on a basic XT personal computer. Despite these successes, the system remains unproven outside the unit in which it was created leaving performance transportability as a major unanswered question. This can only be addressed by widespread implementation of the SOS system.

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