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HUMAN FACTORS AND CARDIAC SURGERY: A MULTICENTER STUDY

Marc R. de Leval, MD^a

Jane Carthey, PhD^a

David J. Wright, PhD^b

Vernon T. Farewell, PhD^b

James T. Reason, PhD^c

All United Kingdom pediatric cardiac
centers

Objective: To study the role of human factors on surgical outcomes, with a series of 243 arterial switch operations performed by 21 surgeons taken as a model.

Methods: The following data were collected: patient-specific and procedural variables, self-assessment questionnaires, and a written report from a human factors researcher who observed the operation. The relationship of patient-specific variables to outcomes (death and death and/or near miss) was used to develop a multivariable baseline model to analyze the role of human factors after adjustment for these variables.

Results: The overall mortality was 6.6% with 24.3% of cases resulting in death and death and/or near misses. The self-assessment questionnaires were found to be unhelpful. Major and minor human failures were extracted from the written report. Major negative events were potentially life-threatening failures, whereas minor events were failures that, in isolation, were not expected to have serious consequences. Major events were closely related to death ($P < .001$) and death and/or near misses ($P < .001$). Appropriate compensation, however, sharply reduced the risk of death ($P = .003$). The total number of minor events was also closely related to both death and death and/or near misses ($P < .001$).

Conclusion: The study highlights the role of human factors in negative surgical outcomes. Even in the most eventful circumstances, however, appropriate human factors defense mechanisms can lead to a successful outcome. (J Thorac Cardiovasc Surg 2000;119:661-72)

From the Great Ormond Street Hospital for Children NHS Trust,^a London, the Department of Statistical Science, University College,^b London, Department of Psychology, and The University of Manchester,^c United Kingdom.

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Address for reprints: M. R. de Leval, MD, Great Ormond Street Hospital for Children NHS Trust, Great Ormond Street, London WC1N 3JH, United Kingdom.

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Cardiac surgery shares many properties with high technology systems in which performance and outcomes depend on complex individual, technical, and organizational factors and their interactions. In those systems, often referred to as complex sociotechnical systems, human factors research of the past 2 decades has been a major contributor to safety and reliability enhancement. The present study is an attempt to apply similar research to cardiac surgery with the expectation that this should help physicians to understand adverse events and establish ways to prevent them. The neonatal arterial switch operation (ASO) for transposition of the great arteries (TGA) was taken as a model of high technology surgery. It is a procedure with low error tolerance, requiring a sophisticated organizational structure, the coordinated efforts of multiple persons working as a team, and high levels of cognitive and technical performance. The homogeneity of the patient population and the standardization of the overall management, including the surgical procedures, facilitates the investigation of human factors against a uniform clinical background. To explore the role of situational, organizational, institutional, and individual differences, the study has included multiple surgical teams and institutions.

Methods

Patients and procedures. A total of 243 neonatal (<35 days) ASOs for TGA and TGA plus ventricular septal defect (TGA+VSD) performed by all 21 cardiac surgeons in the United Kingdom in 16 institutions during an 18-month period (January 1996–June 1997) were entered into the study. A questionnaire on perioperative patient-specific and procedural variables was completed immediately after the operation by the surgeon, the anesthetist, and the perfusionist. Appendix A shows all the patient and procedural variables that were included in the study.

Human factors data. Three sets of human factors data were collected.

The Surgical Team Assessment Record (STAR). Self-assessment questionnaires investigating a range of organizational, team, situational, and personal factors were filled in at the completion of the operation by the surgeon, the first and second assistant, the anesthetist, the perfusionist, and the scrub nurse (Appendix B).

Case reports. The ASOs were observed by a human factors researcher who attended the operation from the induction of anesthesia to admission to the intensive care unit. A detailed description of the operation was written down as the procedure was taking place. This included information on individual and team performance, communication within each team and between different teams, as well as situational and organizational data. In addition, errors or failures that occurred during the procedure were carefully recorded and categorized as minor or major negative events. Minor events were failures

that disrupted the “surgical flow” of the procedure but which, in isolation, were not expected to have serious consequences for the safety of the patient. Major events were failures that were likely to have serious consequences for the safety of the patient. Major and minor events were judged by the human factors researcher to be either “compensated for” or “uncompensated.” An event was deemed to have been “compensated for” when the patient recovered or when the consequences of the event were negated by appropriate action.

Because some ASOs took place simultaneously in several institutions, 50 operations were not attended by a human factors researcher. Therefore 193 reports were available for analysis. They were reviewed at the completion of the study by 2 human factors experts (J.C. and J.T.R.) and by a surgeon (M.d.L.). As expected, the accuracy and the depth of these reports increased with experience. So that the consistency and reliability of the data could be ensured, 10 cases considered to be part of this learning curve were discarded from the analysis (5 cases each for 2 human factors researchers). Furthermore, 1 of the 3 human factors observers who attended 10 ASOs never gained sufficient knowledge of the procedure to make informed judgments about problems experienced during the cases. His reports were also rejected in the final analysis. In all, 173 reports were thought to be sufficiently reliable.

Volume of cases. The number of ASOs performed during the course of this study was looked at as a human factor. Surgeons were divided into low (<15 cases) or high (≥ 15 cases) volumes. Six surgeons were accordingly classified as high-volume surgeons and 14 surgeons were classified as low-volume surgeons.

Outcome events. Clinical outcomes (OC) were divided into 4 categories:

- OC1: Extubated and well within 72 hours of the surgical procedure, with no intraoperative or postoperative complications.
- OC2: Prolonged intubation (ie, >72 hours) and/or reversible morbidity; minor infections, paralyzed diaphragm, pneumothorax, pleural effusion, renal failure necessitating nonroutine peritoneal dialysis, minor temporary neurologic complications.
- OC3: Survival with near misses. Near misses included ischemia evidenced on the electrocardiogram and/or hemodynamic problems such as low systemic blood pressure and rising left atrial pressure at the end of the operation, necessitating the reinstitution of cardiopulmonary bypass, support with an extracorporeal membrane oxygenator for poor cardiac performance, profound postoperative low cardiac output, postoperative cardiac arrest, deep-seated infection (mediastinitis and septicemia), and permanent neurologic damage.
- OC4: Hospital death.

All records had a code number unknown to those who analyzed the data to maintain anonymity and to protect confidentiality.

Statistical analysis. The primary analyses were based on logistic regression analyses of 2 binary outcomes. The first modeled the probability of death and the second modeled the probability of death and/or near miss. The results of the logistic

Fig 1. Distribution of ASOs per surgeon.

Fig 2. Frequency of deaths and near misses per surgeon.

regression analyses were summarized in terms of odds ratios. For a continuous variable such as a time measurement, the odds ratio compared the odds of death for 2 individuals whose time measurements differ by 1 unit, typically 1 minute in this study. If individuals' times differed by k minutes, then their odds of death would be related by a factor of $(\text{odds ratio})^k$. For example, if for bypass time an odds ratio was estimated as 1.02 for a difference of 1 minute, the odds ratio comparing 2 patients whose bypass times differed by 60 minutes would be 3.28.

Patient characteristics and procedural variables were first submitted to a univariate analysis. Patient-specific variables were then combined to develop a multivariable baseline

model for death and a similar one for death and/or near miss so as to study the human factors variables after adjustment for patient characteristics.

Because of their close correlation with clinical outcomes, anesthetic time (induction of anesthesia and insertion of lines), crossclamping time, and bypass time were used to define "surrogate outcomes." These surrogate outcomes were defined as the linear combination of the intraoperative timings best related to the probability of negative outcomes after adjustment for patient-specific variables (coronary artery pattern [CAP], VSD, and sex). An indicator of a missing length of anesthesia time was also included to avoid significant data loss.

Table I. CAPs and outcomes

Type	Description of CAP	No. of cases (%)	Deaths (%)	Deaths and near misses (%)
CAP 1	LAD Cx from sinus 1, RCA from sinus 2	157 (63%)	6 (4%)	25 (16%)
CAP 2	LAD from sinus 1, RCA Cx from sinus 2	34 (14%)	0	10 (29%)
CAP 3	Single coronary from either sinus 1 or 2	13 (6%)	2 (15%)	5 (39%)
CAP 4	RCA from sinus 1	14 (6%)	3 (21%)	5 (36%)
CAP 5	Juxtacommissural origin of both coronaries (posterior) and exceptional patterns	9 (4%)	1 (11%)	3 (33%)
CAP 6	Intramural CAP (including both intramural RCA and LCA)	16 (7%)	4 (25%)	11 (69%)

CAP, Coronary arterial pattern; LAD, left anterior descending coronary artery; Cx, circumflex coronary artery; RCA, right coronary artery; LCA, left coronary artery.

Table II. Results of univariate logistic regression analyses of patient and procedural factors in which "death" was the outcome variable

Variable	Coefficient	P value	OR	95% CI for OR
Sex (female vs male)	0.90	.070	2.6	(0.92, 7.08)
CAP 2 vs CAP 1	*	*	*	*
CAP 3 vs CAP 1	1.5	.08	4.6	(0.82, 25)
CAP 4, 5, and 6 vs CAP 1	1.9	.0010	6.5	(2.1, 20)
TGA+VSD vs simple TGA	0.38	.50	1.5	(0.48, 4.38)
BAS (no vs yes)	0.14	.86	0.87	(0.19, 4.0)
Duration of anesthesia (min)	0.030	.010	1.03	(1.01, 1.05)
Length of time on bypass (min)	0.020	<.0010	1.02	(1.01, 1.03)
Duration of total circulatory arrest (min)	0.020	.33	1.02	(0.98, 1.07)
Crossclamping time (min)	0.030	.0010	1.03	(1.01, 1.05)
Epinephrine (no vs yes)	-1.65	.0020	0.19	(0.070, 0.56)
Isoproterenol (no vs yes)	-1.55	.020	0.21	(0.060, 0.74)
Sternum closed (no vs yes)	1.58	.0080	4.9	(1.5, 15.8)

OR, Odds ratio; CI, confidence interval; CAP, Coronary arterial pattern; TGA, transposition of the great arteries; VSD, ventricular septal defect; BAS, balloon atrial septostomy.

*Not estimable (no deaths in CAP 2).

Results

Clinical outcomes. The numbers of cases per surgeon with the frequency of death and near misses are shown in Figs 1 and 2. There were 16 hospital deaths, an overall mortality of 6.6%, with 43 near misses (17.7%). Thus death and/or near misses occurred in 24.3% of the cases. A total of 119 cases (49%) were OC1 and 65 (27%) were OC2.

Logistic regression analysis. The CAP was the patient-specific risk factor most strongly related to both death and death and/or near misses. The CAP was divided into 6 categories. Table I summarizes their frequency and the outcomes for each type.

The results of the single-factor logistic regression analyses of the patient and procedural variables are summarized in Tables II and III with death or death and/or near misses used as the outcome variables. They include only those patient and procedural variables that demonstrated some statistical significance in the univariate analysis. The other patient characteristics that demonstrated some relationship to negative outcomes

other than CAP were balloon atrial septostomy ($P = .040$), the presence of a VSD ($P = .020$), and sex ($P = .07$). The third characteristic was associated with an increased risk of death but not death and/or near miss. TGA+VSD cases were estimated to have an odds of negative outcome 1.5 times (95% confidence interval [CI] 0.80, 2.9) that of simple TGA cases in the death and/or near miss analysis (Table III).

Procedural factors associated with an increased risk of negative outcomes included duration of anesthesia ($P = .01$) in the death analysis, bypass time ($P < .001$), crossclamping time ($P < .001$), and circulatory arrest time ($P = .003$) in the death and/or near miss analysis. Stenting of the sternum and the use of epinephrine and isoproterenol (INN: isoprenaline), which were also related to a high incidence of negative events, were not used in further analyses because they generally reflected intraoperative problems.

On the basis of the results of the univariate analysis and good background knowledge, a multivariable baseline logistic regression model, including CAP,

Table III. Results of univariate logistic regression analyses of patient and procedural factors with “death and/or near miss” used as the outcome variable

Variable	Coefficient	P value	OR	95% CI for OR
Sex (female vs male)	−0.052	.88	0.95	(0.50, 1.8)
CAP 2 vs CAP 1	0.79	.070	2.2	(0.94, 5.2)
CAP 3 vs CAP 1	1.2	.050	3.3	(1.0, 10.9)
CAP 4, 5 and 6 vs CAP 1	1.6	<.0010	5.0	(2.35, 11)
TGA+VSD vs simple TGA	0.43	.020	1.5	(0.80, 2.9)
BAS (no vs yes)	0.88	.040	0.42	(0.18, 0.96)
Duration of anesthesia (min)	0.010	.030	1.01	(1.00, 1.03)
Length of time on bypass (min)	0.020	<.0010	1.02	(1.01, 1.03)
Duration of total circulatory arrest (min)	0.040	.0030	1.04	(1.01, 1.07)
Crossclamping time (min)	0.040	<.0010	1.04	(1.02, 1.05)
Epinephrine (no vs yes)	−1.58	<.0010	0.21	(0.11, 0.39)
Isoproterenol (no vs yes)	−0.90	.070	0.41	(0.16, 1.07)
Sternum closed (no vs yes)	1.1	<.0010	3.0	(1.64, 5.51)

OR, Odds ratio; CI, confidence interval; CAP, coronary arterial pattern; TGA, transposition of the great arteries; VSD, ventricular septal defect; BAS, balloon atrial septostomy.

Table IV. Baseline logistic regression models

Variable	Coefficient	P value	OR	95% CI for OR
Baseline logistic regression model with death used as the response variable				
Sex (female vs male)	0.94	.080	2.6	(0.91, 7.3)
CAP 3 vs CAP 1	1.5	.010	4.4	(0.77, 25)
CAPs 2, 4, 5, and 6 vs 1	1.1	.050	3.0	(1.0, 9.1)
TGA+VSD vs simple TGA	0.36	.54	1.4	(0.46, 4.4)
Baseline logistic regression model with death and/or near miss used as the response variable				
Sex (female vs male)	−0.1	.78	0.91	(0.46, 1.8)
CAP 2 vs CAP 1	0.77	.080	2.2	(0.91, 5.1)
CAP 3 vs CAP 1	1.1	.070	3.1	(0.93, 10.4)
CAP 4, 5, and 6 vs CAP 1	1.6	<.0010	5.2	(2.4, 11)
TGA+VSD vs simple TGA	0.44	.21	1.6	(0.78, 3.1)

OR, Odds ratio; CI, confidence interval; CAP, coronary arterial pattern; TGA, transposition of the great arteries; VSD, ventricular septal defect.

Table V. Multivariable analysis of timings variables

Factor	Death		Death and/or near miss	
	Coefficient	P value	Coefficient	P value
Anesthesia	0.037	.0030	0.014	.070
Bypass	0.040	<.0010	0.021	.0010
Crossclamping	−0.048	.026	0.0030	.82

sex, and an indicator for VSD cases, was then generated (Table IV). Separate models were estimated for death and death and/or near miss. The following points about these models are noteworthy: First, there was no evidence that the balloon atrial septostomy variable added anything to either model; second, there were no deaths among patients with CAP 2, so

these cases were grouped with CAPs 4, 5, and 6 for death and with CAP 1 in another analysis. There was no difference in the results for either grouping of CAP 2. No formal significance level was used in the choice of these models. They are simply used to provide comparable adjustments for CAP, VSD, and sex in subsequent analyses of negative outcomes.

Table VI. Number of major events per case

	No. of major uncompensated events (No. cases with death, death and/or near miss)						Total
	0	1	2	3	4	5	
No. of major events							
0	95 (-, 2)	-	-	-	-	-	95 (-, 2)
1	33 (-, 4)	5 (-, 2)	-	-	-	-	38 (-, 6)
2	5 (-, 2)	6 (-, 5)	5 (3, 5)	-	-	-	16 (3, 12)
3	1 (-, 1)	2 (-, 2)	4 (2, 4)	3 (3, 3)	-	-	10 (5, 10)
4	0	0	2 (1, 2)	0 (-, -)	1 (1, 1)	-	3 (2, 3)
5	1 (-, 1)	0	0	3 (1, 3)	2 (2, 2)	1 (1, 1)	7 (4, 7)
6	0	1 (-, 1)	1 (-, 1)	0	0	2 (1, 2)	4 (1, 4)
Total	135 (0, 10)	14 (0, 10)	12 (6, 12)	6 (4, 6)	3 (3, 3)	3 (2, 3)	173 (15, 44)

Table VII. Number of minor events per case

	No. of minor uncompensated events (No. cases with death, death and/or near miss)											Total
	0	1	2	3	4	5	6	7	8-10	11-14	15-20	
No. of minor events												
0	3	-	-	-	-	-	-	-	-	-	-	3
1	8	4	-	-	-	-	-	-	-	-	-	12
2	1	3	13 (-, 2)	-	-	-	-	-	-	-	-	17 (0, 2)
3	0	1	10 (-, 1)	5	-	-	-	-	-	-	-	16 (0, 1)
4	1	2	5 (-, 1)	7	6 (-, 1)	-	-	-	-	-	-	21 (0, 2)
5	0	1	2	5	9	8 (-, 1)	-	-	-	-	-	25 (0, 1)
6	0	1	0	0	6 (1, 2)	8 (-, 1)	4 (-, 1)	-	-	-	-	19 (1, 4)
7	0	0	0	0	1	6 (-, 1)	1 (-, 1)	4 (0, 1)	-	-	-	12 (0, 3)
8-10	0	0	1	0	0	1	3 (-, 1)	7 (0, 1)	9 (4, 6)	-	-	21 (4, 8)
11-14	0	0	0	1	1 (-, 1)	0	0	0	6 (1, 5)	11 (5, 9)	-	19 (6, 15)
15-20	0	0	0	0	0	0	0	0	0	3 (2, 3)	5 (2, 5)	8 (4, 8)
Total	13	12	31 (0, 4)	18	23 (1, 4)	23 (0, 3)	8 (0, 3)	11 (0, 2)	15 (5, 11)	14 (7, 12)	5 (2, 5)	173 (15, 44)

The linear combinations of timings used to define the surrogate outcomes are defined by the coefficients in Table V.

Human factors data

Surgical Team Assessment Records (STAR). None of the variables from the STAR form was significant at the 1% level on clinical outcomes when added to the baseline multiple regression model. The 1% level was used to make an adjustment for multiple comparisons. Adding the STAR variables to the regression models for surrogate outcomes of death or death and/or near miss, using a semiparametric analysis, also showed no significance at the 1% level.

Surgical volume. The inclusion of the variable high-volume (≥ 15 cases) versus low-volume (< 15 cases) surgeons did not add significantly to the baseline model for death ($P = .376$) or death and/or near miss ($P = .265$). The odds of death for cases of a high-volume surgeon were estimated to be 0.62 (95% CI: 0.22, 1.78) times that for cases of a low-volume surgeon. The odds ratio for death and/or near miss was estimated to be

0.70 (95% CI: 0.38, 1.31). The addition of volume to the model of surrogate outcomes demonstrates a strong relationship with the classification of surgeons as high or low volume ($P = .001$). It must be noted, however, that less than 5% of the variation in the timings variable can be explained by the volume of surgery variable.

Minor and major events. The lists of minor and major events are shown in Appendix C. Tables VI and VII show the frequency of major and minor negative events per case and also the frequency of major and minor uncompensated negative events per case. The number of cases that had negative outcomes (ie, death and/or near miss) is shown in parentheses. For example, 38 cases had 1 major event. In 33 cases the event was compensated for, whereas in 5 cases the major event was left uncompensated. Table VIII summarizes the results of adding information on major and minor events separately to the baseline models. For each type of event, 4 analyses are recorded. The first looks only at the total number of major or minor events (per case) for both the death and death and/or near miss outcomes. The second

Table VIII. Major and minor events examined separately

Type of analysis	Death		Death and/or near miss	
	OR (95% CI)	P value	OR (95% CI)	P value
1. No. of major events per case	2.4 (1.7, 3.5)	<.0010	15 (6.0, 36)	<.0010
2. No. of major events per case + No. of uncompensated major events per case	0.43 (0.12, 1.5) 23 (3.4, 154)	.19 .0030	7.5 (2.7, 21) 5.3 (1.2, 23)	<.0010 .026
3. No. of minor events per case	1.5 (1.3, 1.8)	<.0010	1.6 (1.4, 1.9)	<.0010
4. No. of minor events per case + No. of uncompensated minor events per case	1.1 (0.54, 2.1) 1.5 (0.7, 3.1)	.87 .28	1.2 (0.81, 1.8) 1.4 (0.90, 2.1)	.37 .14

OR, Odds ratio; CI, confidence intervals.

Table IX. Major and minor events examined jointly

Type of analysis	Death		Death and/or near miss	
	OR (95% CI)	P value	OR (95% CI)	P value
No. of major events per case + No. of uncompensated major events per case	0.44 (0.12, 1.6) 13 (2.1, 83)	.21 .0060	6.2 (2.0, 19) 6.4 (0.99, 41)	.0020 .051
No. of minor events per case	1.4 (1.0, 2.0)	.030	1.4 (1.2, 1.8)	.0010

OR, Odds ratio; CI, confidence intervals.

analysis adds the number of major uncompensated events per case to the first model. The third and fourth analyses are the analogous models for the number of minor negative events per case and the number of uncompensated minor negative events.

Table VIII shows that the number of major and minor negative events per case has a strong relationship to both outcomes (ie, death and death and/or near miss). The number of uncompensated major events per case has a major predictive relationship with death (after adjustment for the number of major events per case) ($P = .003$). For deaths and/or near misses, the number of major events remains the dominant predictor ($P < .001$), although there is some evidence for an additional risk associated with the lack of compensation ($P = .026$). The number of uncompensated minor events per case adds little to the information provided by the number of minor events. Hence, whether or not human compensation occurs for a minor event is not the key factor; rather, it is the overall number of minor events per case that is important ($P < .001$).

Table IX presents the results of adding both the number of major events per case, the number of uncompensated major events per case, and the number of minor events per case jointly to the baseline models. The same general patterns found in the separate analyses are seen. The important distinction is that this table provides, after adjusting for the effects of major and major uncompensated events per case, suggestive evidence of a link between the number of minor events per

case and death ($P = .03$), as well as strong evidence of a link between the number of minor events per case and death and/or near miss ($P = .001$).

There was therefore no evidence that a compensated major event influenced the odds of death, whereas the odds of a death and/or near miss were increased by a factor of 6.2 by such an event (see Table IX). For each uncompensated major event, the estimated odds of death are increased by a factor of $13 \times 0.44 = 5.7$ and the estimated odds of a death and/or near miss are increased by a factor of 40. The risk associated with the occurrence of a minor event is less (1.4 and 1.4) per event, but minor events have a multiplicative effect.

Discussion

The prolific human factors research in complex sociotechnical systems of the past 2 decades has created a spirit of *glasnost* within the medical profession concerning the role played by human factors in the causation of medical accidents.¹ This has been particularly apparent in high technology fields such as operating rooms²⁻⁴ or intensive care units.⁵ At the same time, there is an increasing awareness that models and algorithms for risk adjustment based on patient-related and procedural variables investigate only a portion of factors determining outcomes.⁶

The present study is an attempt to carry out a comprehensive and prospective analysis of human factors together with those variables classically included in outcome analysis. It opens the field for novel research

and analytical methods for the study of complex relationships between variables that are not traditionally analyzed together.

Critique of the methodology

Multicenter study and confidentiality issue. The participation of all the surgeons of one country who perform a particular operation in such a sensitive study is a unique feature of this research. It displays openness to failure, which is most commendable in a climate of increasing exposure of the medical profession to litigation and legal proceedings against failure, knowing that in the United Kingdom there is no law that protects confidentiality of human factors research. One of the pitfalls of this multicenter study, however, is that a number of ASOs were performed simultaneously in different institutions. This has accounted for a significant loss of case reports.

Capturing human factors. Although questionnaires are routinely used in human factors research, the implementation of this method in our study was not successful at capturing the wide range of human factors that could have influenced outcomes. Knowledge of the outcome of the case when the STAR forms were filled in may have caused hindsight bias that contributed to their unreliability. Should similar questionnaires be used in the future, they should be filled in before the operations to target features that can potentially influence outcomes.

The case study reports, which were written on-line without knowledge of the outcome by human factors experts who attended the operations, were the most valuable source of human factors data. The training of these researchers and the assessment of their abilities remain an issue to be addressed for future research. The principal human factors researcher had been in post for 6 months before the start of the data collection. This was not possible to achieve with the other 2 researchers, hence the additional waste of data.

Video camera recordings could be a useful adjunct to the observers' reports. Videotaped records of medical treatments were shown to capture performance deficiencies that were not revealed by retrospective self reports.⁷

We believe that human factors should be included in risk factors analysis and that more research is needed to detect them, analyze them, and assess their impact on medical outcomes. To that end, health care organizations could benefit greatly from the training and appointment of human factors researchers who have acquired a specific training in medical fields.

Defining negative events. In a previous study,⁸ we have used the concept of near misses as failure equivalents with the assumption that death and near misses

were the result of the same underlying mechanisms. Near misses, as defined in the present study, are in reality severe temporary or permanent complications. Some recent information would suggest that the risk factors for death and the risk factors for complications are in fact quite different.^{9,10} According to these studies, the risk factors for complications seem to be related more to patient variables than to structural hospital characteristics. The highest quality, lowest risk hospitals do not have a lower incidence of complications but a higher prevalence of "rescue" from complications. In other words, it is the failure to rescue that leads to a negative outcome. This fits with our personal observation. After a period of retraining after a cluster of operative deaths,⁸ one of us (M.dL.) performed 120 consecutive neonatal ASOs with 3 deaths (2.5%). Despite the return of the mortality to low levels, the incidence of near misses has remained unchanged. The apparent difference is that near misses are now less likely to lead to death; in other words, the operating team is better at handling complications.

Major and minor events. The impact of major and minor human failures on outcomes over and above the traditional patient risk factors is the most important finding of this study. Major failures without compensation are likely to lead to death, but appropriate human defense mechanisms can prevent catastrophic consequences.

Uncompensated major events have a multiplicative effect. If each of them is appropriately compensated, however, death can be avoided whatever the number. Minor events are different. They are more subtle and insidious, and many of them are not even noticed by the operators and the team members. No conscious attempt to compensate for them is therefore made in many instances, thus the lack of correlation between compensation and outcomes for minor events. The main feature of minor events is their multiplicative effect. In isolation they have little impact, but their multiplication has a strong relationship to negative outcomes, whereas a single uncompensated major event is likely to lead to death.

Furthermore, after adjustment for the effects of the total number of major uncompensated events in a case, there is still a link between minor events and negative outcomes.

Major and minor events represent various types of human errors. Human error has become an important topic in many areas of applied psychology, particularly in safety research. It is now widely accepted that error tolerance, error detection, and error recovery are as important as error prevention. Error detection is the first step in error handling. A great number of minor events were undetected errors; hence very little was done to enhance error tolerance or error recovery. Compensation

Appendix A. Patient and procedural factors

Type of clinical data	Clinical factor
Patient-specific variables	Age at operation, sex, weight, atrial septostomy Simple TGA, TGA+VSD Relationship of the great arteries (anteroposterior or side by side) Positional cardiac anomalies: isomerism, situs inversus, dextrocardia Coexisting noncardiac anomalies Coronary arterial pattern (see text)
Procedural variables	Anesthetic time (induction of anesthesia and insertion of lines) Cardiopulmonary bypass time Aortic crossclamping time Total circulatory arrest time Lowest temperature (°C) Venous cannulation (bicaval or atrial) Cardioplegia: crystalloid or blood, single or multiple doses Level of aortic transection (proximal, mid-portion or distal) Level of pulmonary artery transection (proximal, mid-portion, distal) Coronary reimplantation into a defect, slit or a trapdoor flap Coronary reimplantation into the same sinus or 2 facing sinuses Single or 2-patch technique to reconstruct the neopulmonary artery Lecompte maneuver VSD closure (transatrial, transventricular, transpulmonary, transaortic) Drugs used: aprotinin, dobutamine, dopamine, epinephrine norepinephrine, enoximone, isoproterenol, sodium nitroprusside (Nipride), glyceryl trinitrate, phenoxybenzamine Mechanical assistance (ECMO or ventricular assistance device) Sternum closed or not Peritoneal catheter inserted or not
Postoperative variables	Postoperative bleeding ($>5 \text{ mL}^{-1} \cdot \text{kg}^{-1} \cdot \text{h}$) Major cardiovascular events (ie, cardiac arrest, profound hypertension, serious arrhythmia, tamponade) Time of extubation Renal failure Neurologic complications Septic complications (wound infection, chest infection, septicemia, or mediastinitis) Paralyzed diaphragm, recurrent nerve palsy, pneumothorax, pleural effusion Time of discharge from ICU Date of discharge from hospital or death 2-D ECHO before discharge

TGA, Transposition of the great arteries; VSD, ventricular septal defect; ECMO, extracorporeal membrane oxygenator; ICU, intensive care unit; 2-D ECHO, 2-dimensional echocardiography.

is a form of error recovery whereby a strategy to remedy the situation is implemented before negative consequences accrue.¹¹ There are parallels between the compensations of negative events by the operating room team and error recovery mechanisms that have been reported in other high technology systems.¹² Our observations suggest, for example, that the surgeon's diagnostic skill, knowledge of the various surgical strategies to correct a problem, and communication with the rest of the team are important prerequisites of compensation. Uncompensated events correspond to the "failure to intervene" errors that have been observed in pilots who do not act promptly to correct their errors.¹³

The present study demonstrates that patients' risk factors and human factors can combine their effects to lead to a negative outcome. It would be a logical step to assume that human compensation actually addresses

both mechanisms of failure. In that context, the words "compensation," "recovery," or "rescue" would take on a wider meaning and include human strategies deployed to prevent negative outcomes in the presence of poor patient risk factors and/or human errors.

Future research. This study has concentrated on human failure at the sharp end of the system. Many minor and major events, however, have their origins beyond the scope of the operating room. They arise from administrative, strategic, and other top-level decisions made by governments, hospital trusts, educational bodies, departmental managers, designers, and the like, which create latent conditions. It is in that context that adverse surgical events would have some similarities with an organizational accident or a system accident in which breakdowns arise from the combined effects of active and latent failures.¹⁴ Investing in the

Appendix B. The STAR questionnaire

Category of factors	Individual STAR factors
Organizational factors	Personnel availability
	Equipment availability
	Bed space in ICU
	Scheduling of the operation
	Substitutions of rostered personnel
Situational factors	Free to concentrate/distractions and interruptions
	Physical conditions in the theater
	"Atmosphere" in the theater
	Equipment design or reliability
	Monitoring of displays or equipment
Team factors	Preoperative team briefings
	Confidence in other team members
	Team's ability to deal with unexpected events
	Communication between theater teams
	Harmony/clashes between teams
Personal factors	Mental readiness/preparedness
	Keeping pace with events
	Technical performance
	Sleep/rest
	Well-being/feeling suboptimal

ICU, Intensive care unit.

understanding of the latent failures that underlie the active failures (major and minor negative events) is probably the most cost-efficient way, long term, to improve safety in health care.

Conclusion

This study highlights the role of human factors on surgical outcomes. It supports the suggestion that human factors should be incorporated in risk factor analysis. It also emphasizes the need for more research in human factors in health care organizations.

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Discussion

Dr John J. Lamberti (*San Diego, Calif*). I would like to compliment the authors on their attempt to analyze human factors that may affect outcomes in cardiac surgery. Although all of us are aware of extraneous factors that may influence both the short- and long-term results in cardiac surgery, few surgeons have attempted to analyze a group of patients in the fashion presented by Dr de Leval and colleagues. Dr de Leval has been interested in this area for a long time, and his previous reports demonstrate his willingness to ask difficult questions in the search for optimal outcomes.

The concept of risk management in complex organizations is widely known in industry and the military. The organization and management of a nuclear power plant or an aircraft carrier requires the complex interaction of many individuals in the performance of precise tasks. One of the limitations of this report is clearly described in the discussion of the paper. The attempt to examine human factors was compromised by the use of a postoperative questionnaire. This type of inquiry permits hindsight bias as described by the authors.

The concept of constant, on-line grading of events is best demonstrated by the evaluation protocols used in the United States Navy during carrier landings. Every landing is graded by the landing signals officer. A videotape is made of every landing. If a pilot disputes his grade, the videotape can be used as a part of the review—instant replay. A pilot who is consistently scoring lower than a B grade or its equivalent may be grounded, and if his scores do not improve with retraining, he may be asked to leave the air corps. Thus a pilot may be dropped from the air wing of a carrier despite the fact that he has always landed on the carrier and never damaged his plane.

Appendix C. Major and minor events

Stage (No.)	Description and examples
Major events	
Preoperative (4)	Serious errors and problems that are experienced before anesthetic induction for surgery, eg, cardiac perforation during BAS
Anesthesia (8)	<ul style="list-style-type: none"> Errors and problems experienced during anesthesia and insertion of lines • Failure to gain sufficient vascular access • Pincushioning during insertion of lines, leading to a serious cardiac event • Delayed diagnosis of a major deterioration in the patient's condition • Lack of monitoring delaying diagnosis of a serious event
Prebypass (27)	<ul style="list-style-type: none"> • Hemodynamic instability of the patient due to rough surgical manipulations • Surgical errors, eg, laceration of the ductus arteriosus before bypass • Serious cannulation problems • Severe unrecognized deterioration in the patient's condition (low ABP and SaO₂) before bypass caused by cognitive tunnel vision on surgical tasks and/or lack of monitoring • Delay in the administration of heparin
Bypass (44)	<ul style="list-style-type: none"> • Decision-making errors in deciding how to reimplant a difficult CAP (inexperienced surgeons) • Technical errors: aortic tear during the administration of cardioplegic solution, accidental injury to a major coronary artery, malrotation of the main pulmonary artery, twisting the pulmonary artery during the Lecompte maneuver, damage to the neo-aortic valve, tear during the closure of the ductus arteriosus, severe laceration of a pulmonary arterial branch requiring patch repair • Major perfusion problems • Anesthetic problems: failure to cool the cardioplegic solution, failure to flush the cardioplegia-infusion set resulting in massive coronary air embolism
Postbypass (84)	<ul style="list-style-type: none"> • Serious ischemic event: delay in diagnosis, incorrect interpretation, inappropriate strategy in the event of a serious ischemic event • Ventilation errors by consultant anesthetist • Surgical omissions; omission of pacing wires in a patient who has severe arrhythmias, omission of securing indwelling catheters such as the left atrial line • Delayed diagnosis; incorrect interpretation of a serious deterioration of the patient during transfer from the operating theater to the ICU
Minor events	
Preoperative (17)	<ul style="list-style-type: none"> • Coordination problems with the blood bank, problems with the availability of ICU beds • Communication problems between the ward and the theater team, scheduling of cases • Poor fasting policy
Anesthesia (67)	<ul style="list-style-type: none"> • Cognitive tunnel vision on insertion of lines to the neglect of monitoring the ECG screen (where no major event results) • Inappropriate delegation of anesthetic tasks to an inexperienced junior • Equipment problems: failed alarm systems, incorrect ECG readings, or unavailability of equipment • Human resource problems, eg, no junior anesthetic assistant available, no technical assistance
Prebypass (144) and bypass (732)	<ul style="list-style-type: none"> • Positioning and tension error(s) by the surgical assistants • Instrument handling errors by the scrub nurse • Distracters: internal and external • Inappropriate task delegation (surgical, anesthetic, perfusion) to an inexperienced assistant • Problems with theater equipment • Communication errors: problems with passing information between theater teams • Absence of a senior team member in theater at safety critical times • Surgical tunnel vision, where the surgeon(s) focuses exclusively on the surgical aspects of the procedure at the expense of monitoring the ECG screen (but no serious problems develop); this usually occurs when closing the sternum • Perfusion problems: air locks, poor visibility because of unsatisfactory blood aspiration
Postbypass (73)	<ul style="list-style-type: none"> • Positioning, tension and instrument handling errors, communication errors, surgical tunnel vision, and equipment problems • Anesthetic problems: eg, adjustment of ventilating parameters, not starting inotropic support and vasodilators at an appropriate time • Communication problems during hand-over to ICU • Lack of seniority during transfer or in the team admitting the patient to ICU • Absence of monitoring for an excessive period of time during transfer to the ICU

BAS, Balloon atrial septostomy; ABP, arterial blood pressure; SaO₂, arterial oxygen saturation; CAP, coronary artery pattern; ICU, intensive care unit; ECG, electrocardiograph.

In contrast, cardiac surgeons do not have a systematic protocol for examining successful outcomes. If we are pursuing perfection, then we ought to review each case, both early after the operation and later in follow-up, to determine which aspects of the management could be improved.

The concept of compensation for a negative event is well defined by Dr de Leval. In both commercial and military aviation, simulators exist for testing the response of a pilot to varying conditions. To my knowledge, there is no formal attempt at this kind of training in cardiac surgery. Landing a plane on a carrier or performing the arterial switch procedure requires a complex interaction between technology, knowledge, and eye-hand coordination. The price of a mistake in either area can be high.

I have several questions for the authors.

There were 243 ASOs, but human factors research was undertaken in only 173. Do you think that the failure to include 30% of the outcomes in the human factors analysis affects the data?

Second, are you planning to repeat the study or expand the study with a preoperative questionnaire and a refined approach to human factors analysis?

Third, would the inclusion of long-term data add to the weight of the conclusion since technical problems occurring

during the surgical procedure might lead to a high incidence of late pulmonary stenosis or left ventricular dysfunction in survivors?

Finally, experienced heart surgeons are inclined to state that any CAP can be switched. Your data suggest that less commonly occurring CAPs are associated with higher risk. Should all low-volume centers be required to clearly define the CAP before performing surgery? If a low-volume center cannot clearly define the CAP as type I or II, should the patient then be referred to a higher-volume center?

Dr de Leval. Thank you, Dr Lamberti. Major and minor events were extracted from only 173 reports because of the learning period required for the human factors researchers to become familiar with the operation. In addition, 1 of the researchers never reached a sufficient level of understanding of the procedure and his reports were discarded.

The answer to the second question is, yes. Human factors questionnaires should be filled in before or during the procedure, but not afterward, to prevent hindsight bias.

The third question relates to long-term data. We are in the process of analyzing the 6-month results.

With regard to the last question, I believe that the ASO should be performed only in institutions capable of dealing with all variants of CAPs.