A cost-effectiveness analysis of the use of a mechanical barrier system to reduce the risk of mistransfusion

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Background: A blood component is transfused to a patient other than the intended recipient because of patient and sample identification problems once in about every 24,000 transfusions. An investigation was performed of the cost-effectiveness of a barrier system to prevent mistransfusion of a unit of red cells through this kind of error.

Study Design and Methods: A decision analysis model was constructed that took into account nonfatal and fatal events, costs of patient care, and legal costs. The model was used to determine the cost-effectiveness of the barrier system in terms of cost per year of life saved and lives saved per million transfusions.

Results: The barrier system is predicted to save 1.5 lives per million transfusions when used as intended. If the cost-effectiveness calculations are based on an average damage award for a fatality of more than $725,000 and a chance of mistransfusion exceeding 1 in 16,700, use of the system results in reduced healthcare expenditures. If no legal costs are included in the cost-effectiveness calculations, use of the system costs $197,000 per year of life saved. Routine use of the system extends patient life by 1 year per 60,000 units transfused.

Conclusion: The application of a barrier system to prevent mistransfusion and related morbidity and mortality can be cost-effective. If legal costs are included in the calculations, the use of a barrier system reduces total costs.

MISTRANSFUSION, THE transfusion of blood to a patient other than the intended recipient, remains a significant cause of transfusion-associated morbidity and mortality. Analyses of cases reported to the Food and Drug Administration have indicated that deaths due to acute hemolytic reactions occur approximately once every 600,000 transfusions.[1,2] A more detailed analysis in New York State hospitals recently documented that 1 in approximately every 12,000 transfusions goes to the wrong patient.[3] The frequency of mistransfusion appears to be unchanged over many years,[1,2] despite the development of complex labeling and identification verification systems.[4,5]

Mistransfusion may occur through a variety of errors, but the most common causes, accounting for about one-half of all mistransfusions, are sample-labeling errors and recipient misidentification.[1,3] The high rates of patient-identification and sample-labeling errors encountered during phlebotomy[6] represent an ongoing potential cause of mistransfusion. Mistransfusion can occur even when the transfusion service has complete control over all aspects of sample acquisition and transfusion.[7] These factors underscore the need for a systems approach to the reduction of mistransfusion.[8,9]

Mechanical barrier systems designed to prevent mistransfusion have been described.[10] Such a system might use a randomly assigned code affixed to the patient's identification band (and not present on the patient's chart). The phlebotomist would transcribe the code onto the tube of blood collected for pretransfusion testing along with all other usual identifiers. When releasing a unit of red cells for transfusion, the laboratory staff member would enter the patient's randomly assigned code into a lock and close that lock to prevent access to the outlet ports of the unit. In addition to comparing the information on the unit label with patient identification, the transfusionist would use the randomly assigned code on the patient's wristband to gain physical access to the unit (open the lock). Access to the unit would be prevented unless the unit were about to be transfused to the patient from whom the pretransfusion testing sample had been collected. Such a system does not require a reduction in human error to reduce mistransfusion.

Such a system could, of course, still fail to prevent a mistransfusion. For example, the phlebotomist and transfusionist could each take actions out of the bounds of common errors, such as the phlebotomist's partially labeling the tube at the side of one patient and completing the process at another patient's bed, or the transfusionist's opening the lock using the randomly assigned code from the first patient's wristband and then moving to the other

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patient's bed to start the transfusion. Alternatively, a specimen might be mislabeled with the identity and randomly assigned code of another patient for whom a transfusion had also been ordered, and intentional circumvention of the system or intentional mistransfusion could still occur. However, outside any of these extraordinary occurrences, this mechanical barrier system would be predicted to prevent the episodes of mistransfusion that are related to sample and patient misidentification.

Whereas the use of a barrier system would appear to provide enhanced patient safety, it also represents a new expenditure. With increasing pressures on the health care system to deliver equivalent or improved care at stable or reduced costs, additional costs may be seen by some as financially unacceptable. Potential benefits also should be assessed according to the expected longevity of transfusion recipients.[11] Therefore, we conducted a decision analysis, using cost-effectiveness measurement tools, to compare benefits and costs associated with the use of a barrier system to reduce the risk of mistransfusion.

Materials and Methods

Model for cost-effectiveness analysis

We constructed a decision tree and performed calculations using standard decision-analysis techniques[12] to estimate the transfusion-related costs for and life expectancy of two cohorts of patients undergoing transfusion; one of these groups received transfusions of red cells to which a barrier system was attached (Fig. 1). The model was constructed on software (Decision Maker, version 7.0, S.G. Pauker, Boston, MA). Calculated costs included those of transfusion, of treating the complications arising from mistransfusion, and of the potential legal ramifications of a mistransfusion and its consequences. We assumed other transfusion-induced sequelae and consequential costs to be the same in both cohorts and excluded them from the analysis. A discount rate of 5 percent was applied to future health benefits; incremental costs (in 1994 dollars) attributable to reactions were not discounted because they were assumed to accrue within 30 days of the mistransfusion. We performed a sensitivity analysis to compare the extent to which the model's estimates of cost-effectiveness were sensitive to uncertainty in the cost and probability data used in the analysis (Table 1). Technical causes of acute hemolytic transfusion reactions, such as mistyping of a patient's sample, were not considered.

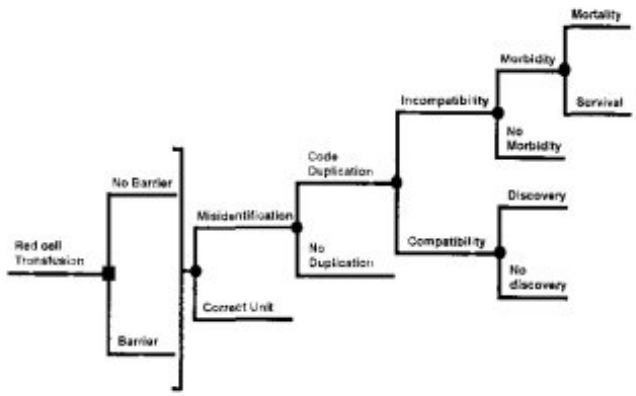

FIG. 1. Decision tree, used as the model for the cost-effectiveness analysis of a barrier system to prevent mistransfusion. Node labeled Code duplication or No duplication applies only to the use of the barrier system and represents the possibility that the barrier system would fail to detect a misidentification because of the presence of duplicate codes.

Probabilities

In the base case (initial calculations using the most likely values), we assumed that, without the barrier system, mistransfusion occurs once every 24,000 transfusions (probability = 0.00004167) (Table 1). In selecting this frequency, we depended primarily on the study of Linden et al.[3] (Other estimates of the risk of mistransfusion due to bedside errors [from studies that did not depend on retrospective reporting systems] are as much

Table 1. *Variables of the model*

	Frequency		Cost		
	Base case	Range	Base case	Range	References
Variable and assumption					
Misidentification	1/24,000	1/1,000-1/100,000			1-3
Barrier system failure	1/12,000	1/1,000-1/100,000			
Incompatibility given that there was mistransfusion	0.36				14-19
Morbidity given that the transfusion was incompatible	0.30	0.1-1			14-19
Mortality given that the transfusion was incompatible	0.33	0.1-1			14-19
Mistransfusion discovery given that the transfusion was compatible	0.50	0-1			
Event					
Barrier system, per use			$3.35	$0-5	
Transfusion, per unit of red cells			200	0-300	20
Transfusion reaction workup			300	0-500	
Care of patient after nonfatal transfusion reaction			20,000	0-100,000	
Care of patient during reaction that ends in death			*		
Legal cost: wrongful death			500,000	0-2,000,000	
Legal cost: nonfatal reaction			†	†	

* Base case cost set at one-half of cost of care of a patient with a non-fatal reaction that caused morbidity.

† Base case cost set equal to legal costs associated with a fatal reaction. In sensitivity analysis, this amount varied from one-half to twice the base case cost.

as 60-fold our estimate.[7,8,13]) However, two studies suggest that, in approximately 25 to 50 percent of incidents in which patients receive a unit of blood of an incorrect blood type, the mistransfusion may be attributed to laboratory errors and probably would not be prevented by a barrier system.[1,3] We thus adjusted the observed frequency of mistransfusion to represent only those cases resulting from misidentification and selected the probability of 1 in 24,000 as a conservative but reasonable estimate of this risk. We further assumed that the use of a barrier system did not alter the rate of misidentification of patients or samples that we found while using a barrier system over a 36-month period.

Use of the barrier system was assumed to interdict potential mistransfusions unless the intended and actual recipients happened to share the same randomly assigned code (probability estimated as 1/12,000). We assumed that the barrier system would function as intended and would not be subject to intentional circumvention.

We calculated the risk of ABO incompatibility from standard tables[4] and based it only on red cell incompatibility. Mistransfusion of an ABO-compatible unit would not be expected to cause symptoms (except perhaps in the unusual case of a recipient with an alloantibody, a possibility not considered in this analysis) but might be detected and investigated later (probability = 0.5). The model assumed that all ABO-incompatible mistransfusions would be detected. We assumed that 30 percent of patients receiving an ABO-incompatible unit would experience some morbidity and that one-third of that group would die. Thus, the probability of death after an incompatible transfusion in the base case became 0.10, which is similar to that reported.[14-19]

Costs

We estimated costs from the perspective of the transfusing hospital on the basis of our hospital's experience and a review of the literature[20] (Table 1). The direct cost of the barrier system to the hospital was set at $3.25 per lock. As we experienced minimal implementation costs and insignificant time requirements for writing codes on labels and for applying and opening locks, we excluded specific additional costs for these factors. However, we did add the cost of recollecting pretransfusion specimens that failed to include the barrier system's code. In 36 months' use of a mechanical barrier system at this institution, approximately 1 percent (0.93-0.98%) of samples were rejected each month for incomplete or missing codes. Under the costliest assumption, that a sample is collected before each unit's transfusion and that phlebotomy costs $10 per collection, the total cost of using the barrier system was increased by $0.10 above the direct cost of the locks. One lock may be used to secure 1 unit or several units, but again the model used the costliest assumption, that each unit was locked individually and that locks were not reused. We assumed that every unit released from the transfusion service laboratory was transfused.

We estimated transfusion reaction work-up costs as one-half of the charges for tests and consultations frequently used in such investigations. The cost of caring for a patient with transfusion reaction-related morbidity was estimated after discussion with clinical intensive care specialists who recommended intensive care for up to 1 week and dialysis support for 2 to 3 weeks. Fatal reactions were assumed to consume only one-half of the resources, because most deaths due to acute hemolysis occur relatively soon after the transfusion.[14-18]

We estimated the legal costs associated with mistransfusions after discussions with hospital risk management experts and defense and plaintiff counsels in active practice and the review of data from the Closed Claims Project of the American Society of Anesthesiologists (Cheney FW Jr, written communication, December 1993). We used an estimate of $500,000 as the average legal cost (including attorneys' fees and a mean, lump-sum damage award) for wrongful death in the base case. The legal costs projected for nonfatal reactions varied from one-half to twice the wrongful-death legal cost. In sensitivity analysis, we varied the average wrongful-death legal cost from $0 to $2 million. Litigation was anticipated only in cases of fatal reactions or nonfatal reactions that caused morbidity.

We estimated longevity after transfusion from a 10-year follow-up study of 810 transfusion recipients.[1] The published data were used to approximate life expectancy using the DEALE formula[21,22] to yield a mean posttransfusion life expectancy of 15.3 years. This was shortened by 0.1 year in patients having morbid but nonfatal reactions, to reflect the reduction in the usual quality of life during recovery from the event. For the purpose of calculating posttransfusion longevity, deaths were assumed to occur immediately after transfusion.

Results

When used as intended, a barrier system is predicted to reduce the risk of a fatal mistransfusion from 1 in 665,000 red cell transfusions to 1 in 7.98 billion, thus preventing 1.5 fatal transfusion reactions per million red cell units transfused. The system extends a patient's life by 1 year for every 60,000 uses of the locking device. Using the model's base-case cost and frequency estimates to determine the cost-effectiveness of the barrier system without including legal costs (Table 1), we found that this barrier system approach saves 1 year of life for an expenditure of $197,000. If legal costs are included in the model, the use of the barrier system results in reduced overall expenditures when mean legal costs in cases of a fatal reaction exceed $725,000 and the chance of misidentification exceeds 1 in 16,700. The barrier system's cost-effectiveness is estimated

FIG. 2. Sensitivity analysis: legal costs associated with fatal and nonfatal reactions. Cost-effectiveness of a barrier system as a function of the average legal costs in the case of a fatal reaction, shown for three different cost levels for a nonfatal reaction. Diagonal lines indicate the multiple of the cost associated with fatal reactions that was anticipated for nonfatal reactions. Multiple of 2.0, ···; multiple of 1.0, – – –; multiple of 0.5, ——. Horizontal line indicates a cost of $50,000 per year of life saved.

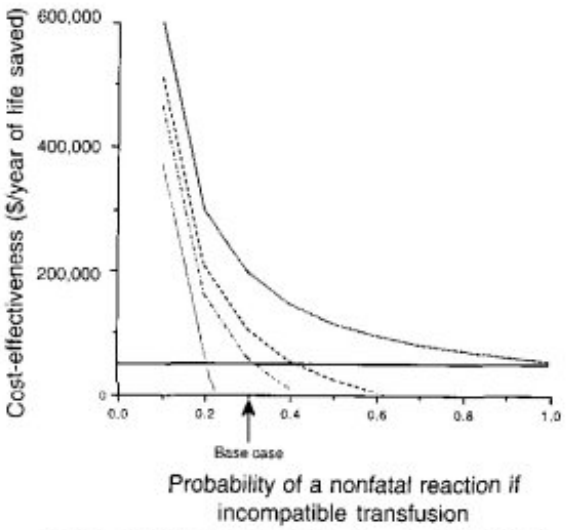

FIG. 3. Sensitivity analysis: probability of reaction. Cost-effectiveness of a barrier system as a function of the probability of a clinically discernible transfusion reaction after transfusion of an incompatible unit with four different estimates of the average damage award in the case of a fatal reaction or nonfatal reaction that causes morbidity. The award (in thousands of dollars) for fatal/nonfatal reactions: 500/1000, ——; 500/500, - • - • -; 500/250, – – –; 0/0, • • •. Solid horizontal line indicates a cost of $50,000 per year of life saved.

as $50,000 per year of life saved if the legal costs exceed $540,000 per death and the chance of misidentification exceeds 1 in 22,650.

We performed a sensitivity analysis to determine the effects on the results of varying the values used for all variables included in the model, including legal costs (Fig. 2), reaction outcomes (Fig. 3), and the probability of mistransfusion (Fig. 4). Increasing the estimated legal costs dramatically decreases the expected cost per year of life saved. The legal experts that we consulted when constructing the model indicated that the liability award in the case of wrongful-death litigation could be expected to approach or exceed $1 million (not including legal defense costs). The model was not sensitive to the costs of treating postreaction complications (data not shown). Increasing the cost of using the barrier system reduces the cost-effectiveness estimate in a linear fashion. A barrier-system cost of $2.33 per use offsets the base-case estimates of complication and legal costs (data not shown). An exponential relationship exists between the cost-effectiveness estimate and the probability of a nonfatal reaction that causes morbidity (in the case of an incompatible transfusion) or of a mistransfusion.

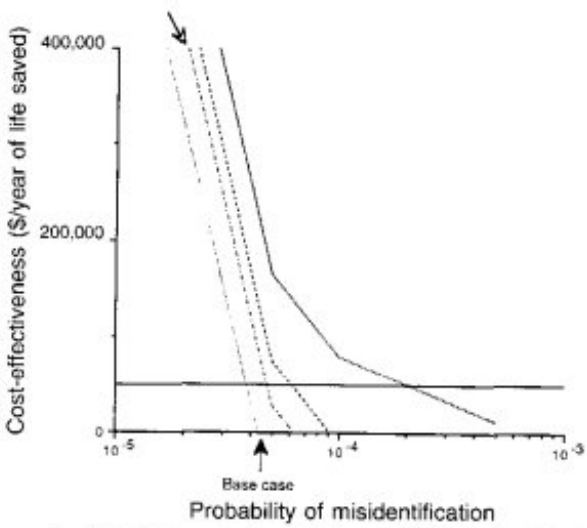

FIG. 4. Sensitivity analysis: probability of misidentification. Cost-effectiveness of a barrier system as a function of the probability of misidentification with four different estimates of the average damage award in a case of fatal or nonfatal reaction. The award (in thousands of dollars) for fatal/nonfatal reactions: 500/1000, ——; 500/500, - • - • -; 500/250, – – –; 0/0, • • •. Solid horizontal line indicates cost of $50,000 per year of life saved.

Discussion

This analysis suggests that the proper use of a barrier system would reduce the risk of a fatal acute hemolytic transfusion reaction due to mistransfusion by more than 99.99 percent (4 $\log_{10}$). At the same time, overall hospital expenses would be decreased by the avoidance of the direct financial consequences of acute hemolytic reactions.

The assumptions of a decision analysis model may influence its accuracy. The model used in this study appears to have accurately captured the salient features of mistransfusion. The risks of an acute hemolytic reaction and death that this model predicts closely approximate those derived from reports of such occurrences to regulatory authorities.[1-3] However, the barrier system must be used properly to achieve the intended benefits, just as intentional circumvention of the safeguard would prevent the realization of its benefits.

Expectations of reduced hospital costs through the use of a barrier system depend on the inclusion of legal costs in the model's calculations. Such costs are often excluded from cost-effectiveness analyses models that use a societal perspective. However, the decision to implement a barrier system to prevent mistransfusion is likely to be that of an individual hospital and to be based on anticipated effectiveness and financial impact. The point at which the legal costs for a wrongful death were estimated to entirely offset the costs of using the barrier system ($725,000/award) was below the amount estimated by legal experts to be likely, and smaller legal costs reduced the cost-effectiveness estimation to a figure within the range of other commonly used medical interventions (<$50,000/year of life saved).[23,24] If a societal perspective were adopted and legal costs were excluded from the calculations, the barrier system approach would appear to be less cost-effective, at $197,000 per year of life saved. This cost-effectiveness estimate is, however, comparable to that for several other transfusion-related interventions, including many applications of solvent-detergent frozen plasma and preoperative autologous blood donation.[23-26] Indeed, the number of transfusion-related deaths that would be prevented by the implementation of a barrier

system would be 50 to 300 percent greater than the number projected by the institution of p24 antigen or RNA polymerase chain reaction testing to reduce human immunodeficiency virus transmission risk—and the cost would be less.[27-29]

The problem of mistransfusion has plagued transfusion medicine for over 50 years. Procedures developed over the years clearly have failed to prevent it. Barrier systems provide a different approach to the avoidance of mistransfusion, one based on a revised system rather than on enhanced expectations of human workers. This study predicts that a barrier device could improve the transfusion system with an expenditure of resources that is at least in line with the cost-effectiveness of many other medical interventions and that may actually reduce overall costs for a hospital.

Note added in proof: Mercuriali et al.[30] recently reported that a barrier system prevented one potentially fatal transfusion error per 2748 red cell transfusions (frequency = 3.6×10^{-4}). This observation indicates that mistransfusion may be much more common than the estimate used in this model (see Fig. 4), which makes a barrier system much more cost-effective.

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