

# A Model-based Approach to Prioritizing Medical Safety Practices

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## Abstract

This report shows how a model of skilled human performance can be used to evaluate safety practices aimed at reducing medical error when randomized trials evidence regarding the effectiveness of such practices is not available. In the modeling approach, safety practices are described by a collection of variables, and the impact of these practices is estimated in terms of the effect of changes in these variables on the behavior of the model. The usefulness of this approach depends on having a model that is validated in terms of the available data. The report describes evidence for the validity of the human performance model and illustrates the use of the model to prioritize safety practices.

## Background

In response to the Institute of Medicine (IOM) report, *To Err Is Human*,<sup>1</sup> the Agency for Healthcare Research and Quality (AHRQ) commissioned the Stanford University–University of California, San Francisco Evidence-based Practice Center to develop a compendium of evidence-supported medical safety practices as a resource for health care safety professionals. The result was an AHRQ report containing recommendations for a number of patient safety practices for which there is clear evidence of effectiveness.<sup>2</sup> Notably absent from these recommendations were many well-accepted safety practices that are aimed at reducing the incidence of medical errors.<sup>3</sup> These error-reduction practices were not mentioned in the report because they did not meet rigorous evidence-based standards for proof of demonstrated effectiveness.<sup>4</sup>

## Evidence and error reduction

Leape, et al<sup>5</sup> argue that the implementation of error-reduction practices is too urgent to await rigorous proof of efficacy in randomized trials tests that may never be done. But Shojania, et al<sup>4</sup> note that the implementation of unproven error-reduction practices could be a costly mistake. They point to several examples of practices that common sense says should be effective, but that research shows are not. For example, requiring handwritten (as opposed to verbal) medication orders is thought to reduce medication error. The only study comparing error rates for handwritten versus verbal orders, however, found a fourfold decrease in error rate with verbal orders.<sup>6</sup> So a practice that should “obviously” reduce errors (e.g., requiring handwritten medication orders) may actually increase them. Shojania, et al<sup>4</sup> further notes that the costs of implementing unproven error-reduction practices could exceed the benefits. For

example, the expense involved in obtaining evidence through randomized trials of the true effectiveness of a proposed error reduction practice such as the use of Computerized Physician Order Entry (CPOE), an automated approach for entering medication orders, would be costly. Still, such research would be far less costly in terms of dollars (tens of billions) and person hours (tens of millions) than the price of implementing the practice in every U.S. hospital, were it found to be actually ineffective.

The best evidence of the effectiveness of error-reduction practices comes from properly conducted randomized trials testing, but such tests have been rare.<sup>7</sup> One reason for the lack of testing is the actual rate at which medical errors occur, which is rather low. Prescribing errors, for example, occur in 0.4 percent to 1.9 percent of all medication orders, and only a fraction of these errors cause harm to patients in the form of adverse drug events (ADEs).<sup>8-10</sup> Leape, et al<sup>5</sup> point out that it would be “incredibly difficult to mount a controlled study of sufficient power...to prove that the ADE rate was decreased” by a proposed error reduction intervention. Such a study would require the observation of many thousands of orders—half written with the proposed intervention in effect and half without it—in order to be able to conclude with confidence that the intervention was or was not effective.

Despite their emphasis on the urgency of the medical errors problem, Leape, et al<sup>3</sup> recognize that it is not practical to implement error-reduction practices without some evidence of their effectiveness. For this reason, they recommend development of evidence-based methods for prioritizing error-reduction practices, in lieu of randomized trials testing for the effectiveness of such practices. Indeed, Leape, et al<sup>5</sup> suggest that evidence-based “methods for prioritizing medical safety practices be a key area for health policy research.” Such methods would provide a basis for determining the most effective means by which to tackle patient safety issues, as called for by the IOM and more recent findings recognizing threats to patient safety from medical errors.<sup>11, 12, 13</sup>

## **Modeling and policy analysis**

One approach to the problem of prioritizing safety practices in the absence of randomized trial evidence is through the use of modeling. Modeling is a standard means of evaluating policies in areas such as bioterrorism, where there has been little randomized trials research regarding the effect of the proposed policies.<sup>14</sup> In the health safety area, the policies being evaluated are medical safety practices aimed at reducing harm to patients that can result from medical error. The models used in policy analysis are simulations of the system to which the policies are applied. Since medical safety practices are applied to the problem of eliminating the errors that occur when people implement health care practices, the relevant system consists of people working in various health care environments. A model that can be used to evaluate the effectiveness of medical safety practices will, therefore, simulate the behavior of people carrying out health care activities in appropriate clinical environments. Such a model must be informed by an

understanding of how health care practices are carried out, as well as by psychological theories regarding human errors and why they occur.<sup>15–17</sup>

## Psychology of error

Psychology has a long history of interest in the causes of human error. The analysis of everyday errors—slips of the tongue and memory lapses—was a central feature of Freud’s approach to understanding the “psychopathology of everyday life.”<sup>18</sup> More recently, human error has been of particular interest to psychologists known as “human factors engineers,” who are interested in understanding the causes of workplace errors.<sup>19–21</sup> Their work is motivated by the need to improve the “usability” of systems, such as personal computers, by designing them to prevent errors such as those that immediately destroy hours of work.<sup>22</sup> It is further motivated by the fact that human error is a main contributor to many industrial incidents, such as the near-meltdown occurrence at the Three Mile Island nuclear power plant.<sup>23</sup>

Human factors engineering has contributed several theories of human error.<sup>24–26</sup> These theories describe possible causes of human error, but they do not say why these causes operate at certain times and not others. Theories of human error attribute errors to factors such as poor system design, but these theories do not offer explanations for why these factors come into play only occasionally.<sup>27</sup> In order to use modeling to analyze error reduction policies, the model must be based on a theory that identifies not only the causes of human error, but also the reasons behind the rate of error occurrence. Such a model was developed as part of a project aimed at evaluating the appropriate role of electronic prescribing (e-prescribing) technology in health care.<sup>28, 29</sup> The model describes the psychological processes involved in writing prescriptions and was used to estimate the potential error reduction benefits of e-prescribing technology.<sup>30</sup>

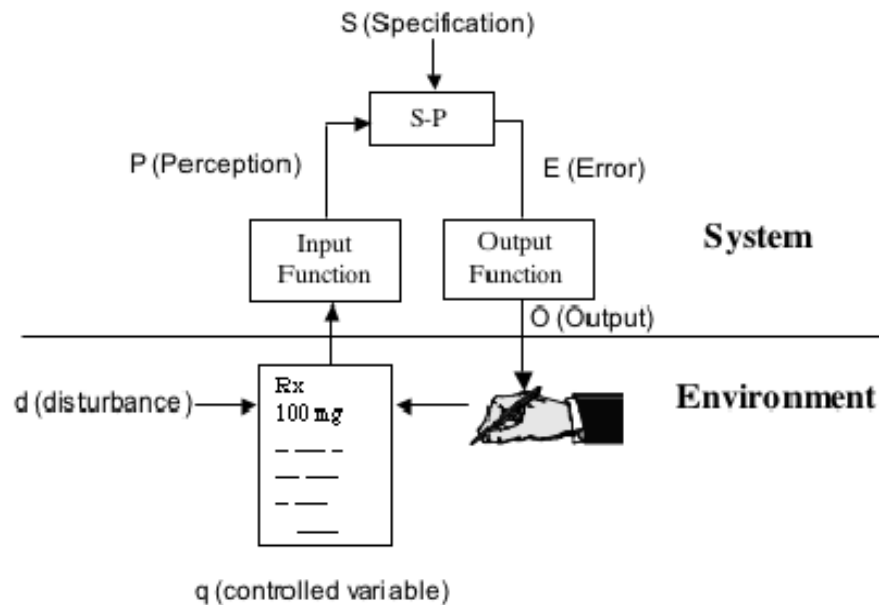
## Methods

### A model of medical error

The prescribing error model is a computer simulation of a skilled human activity—writing prescriptions. The model is based on control theory, a psychological theory of human performance that has been used successfully to explain several different kinds of skilled human behavior.<sup>31, 32</sup> Control theory assumes that behavior is a purposeful process aimed at producing consistent results in an unpredictably changing environment.<sup>33</sup> Writing prescriptions is a control process because it involves the production of consistent results (e.g., a prescription that is always appropriate for the patient) in an unpredictably changing environment and one in which the patients’ symptoms and indications, drug allergies, and medication histories vary unpredictably.

A functional flow diagram of the prescribing control model is shown in Figure 1. The model acts to bring a perceptual representation of a prescription (P), to a specified or intended state of a prescription (S). The prescription that is being

Figure 1. Control model of prescribing



produced ( $q$ ) is a *controlled variable*. The model compares the current state of the prescription ( $P$ ), to the specified (intended) state ( $S$ ). Any difference between  $S$  and  $P$  is an *error* ( $E$ ), causing the output ( $O$ ), that brings the prescription to the intended state. The output is complex cognitive and motor activity. Cognitive activities include consideration of the patient's condition and history, as well as possible drug side effects and interactions. Motor activities include the writing or typing movements that produce the prescription.

The prescription that is being produced ( $q$ ) is dependent upon system output, as well as the effects of unpredictable *disturbances* ( $d$ ). These disturbances correspond to variable characteristics of the environment, such as patient symptoms and indications, drug allergies, similar sounding drug names, and even leaky pens. The model acts to produce the intended prescription, while compensating for disturbances that can sometimes interfere with the successful production of the prescription. The production of the intended prescription is a dynamic process that occurs over time. The model introduces errors (which represent a failure of control), when the process of producing the intended prescription stops before the prescription is sufficiently close to the intended state.

The prescribing control model provides a general framework for understanding human error. The model can be generalized to many health care behaviors that are performed by individuals, such as filling prescription orders or administering medications. It is called a “working model” to distinguish it from the more common “descriptive models” of behavior seen in the behavioral sciences. A descriptive model is an equation such as the “general linear model” of statistics that represents a guess about the mathematical relationship between environmental and behavioral variables.<sup>34</sup> A working model, on the other hand, is

organized to produce an analog of the behavior under study. Such models are most common in the study of human motor skills, and less common in the study of human error.<sup>35</sup>

## “Wind tunnel” tests

The advantage of working models over descriptive models is that they allow researchers to predict the effects of variables that have not yet been determined through experimental testing. In the analysis of safety policies, we make these predictions by seeing how variables that correspond to dimensions of error reduction interventions affect the error rate produced by the model. The process is similar to testing a new aircraft design by placing a model in a wind tunnel.<sup>36</sup> The wind tunnel sets up a flow of air that simulates flight through the atmosphere under the desired conditions. Engineers use instruments attached to the model to measure the lift forces and air resistance of the aircraft. Changing the model's angle of attack and orientation in the tunnel allows the engineers to better assess the proposed aircraft's stability and controllability.

The control model of error is used to test the effectiveness of safety practices in the same way that the aircraft model is used in a wind tunnel to test the flying characteristics of the real plane. We use the error model by placing it in a “wind tunnel” that corresponds to the relevant health care environment. We can then measure the error rate produced by the model as we vary its “angle of attack” by varying parameters of the model and the environment that correspond to generalized aspects of the health care process under study. The parameters that can be varied include skill level, system design characteristics, the time available to carry out the health care process, and the range of different results that can be produced.

The usefulness of the model-based approach to evaluating error-reduction practices depends on having a model that has been validated. We can validate the control model of error by testing its ability to account for existing medical error data. The validated model's reaction to changes in variables representing different error-reduction practices then should provide a good idea of the kind of error reduction that could be expected, if these practices were to be implemented.

## Validating the model

We validated the prescribing model shown in Figure 1 by testing its ability to account for existing data on the rate of occurrence for different types of prescribing errors. Studies by Leape, et al<sup>37</sup> and Lesar, et al<sup>8</sup> determined the rate of occurrence for several different types of prescription errors, including wrong drug name, dosage, route, and other prescription aspects. The results of these two studies were combined and the overall rates for the different types of prescribing errors are shown in the top row of Table 1. The error rates produced by the prescribing model are shown in the lower row of the table. Clearly, the distribution of the different types of errors produced by the model corresponds almost exactly to the empirical distribution of error rates.

**Table 1. Distribution of different types of prescription error**

	<b>Drug</b>	<b>Dose</b>	<b>Route</b>	<b>Other</b>
<b>Leape/Lesar data</b>	39%	57%	3%	1%
<b>Model data</b>	39%	57%	4%	0%

The results in Table 1 provide some evidence that the control model is a valid representation of the prescription-writing process and of the causes of error inherent to this process. Further quantitative validation of the model comes from the fact that the distribution of model error rates shown in Table 1 was produced when the model’s overall error rate was 1 percent, which is close to the overall error rate found in the prescription error studies. Of the 1 percent of prescriptions that are written in error, the model (like those individuals writing prescriptions) attributes the majority of the errors to incorrectly written drug doses. The next largest cause of errors was incorrectly written drug names.

### **Prescription fulfillment errors**

Other tests of the model were done using prescription-fulfillment error data collected by Flynn and Barker.<sup>38</sup> This data showed error rate as a function of workload, where the number of prescriptions filled per half hour was the measure of workload. The data provided a nice opportunity to test the model’s ability to account for a different kind of medical error—prescription fulfillment rather than prescription-writing error. It further enabled testing of the model’s ability to predict the effect of an environmental variable (workload) on error rate.

Prescription-fulfillment error rates are shown as a function of workload in Figure 2. The observed error rate (filled squares) actually declined as the workload increased, at least up to the levels of workload observed in the study. The fulfillment-error rates produced by the model (open triangles) also are shown as a function of workload in Figure 2. Workload was measured in terms of the number of prescriptions filled per hour. As the workload increased, the average time available to produce the intended result (a properly filled prescription) decreased. Increased workload allows less average time available to fill each prescription. Having the model simulate the actions required to fill thousands of prescriptions at each workload level and counting the proportion of erroneous fulfillments resulted in the model predictions.

Figure 2 shows that the behavior of the error model can be made to match the behavior of pharmacists filling prescription orders fairly closely. Like the pharmacists, the model’s error rate goes from about 3 errors per 100 opportunities (3 percent) when only 2 prescriptions are filled per hour to about 1 error per 200 opportunities (0.5 percent) when 40 prescriptions are filled per hour.

The control model had to be extended in order to account for the error data shown in Figure 2. The extended model’s error rate goes down as workload increases, because it is designed to act more carefully in order to successfully fill the prescriptions at a higher rate. The model’s error rate does not continue to

Figure 2. Error rate versus workload



decrease with increasing workload, however, because there is a limit to how careful the model can become. The “predicted” results in Figure 2 (filled diamonds) show the model error rate starting to increase again as workload goes above the maximum level observed (42 prescriptions per hour). The model, therefore, makes the rather sensible prediction that error rate will not continue to decrease as workload increases, and suggests that there is an optimal workload. Below that optimal level, errors decrease with the increasing workload; above it, however, errors increase precipitously as a result of the reduced time allowed for the completion of the task.

More tests against existing data are needed before the model can be considered properly validated. The testing that has been done to date, however, suggests that the model provides a reasonably accurate framework for understanding the factors that influence the rate at which errors occur in highly skilled activities such as writing and fulfilling prescription orders.

## Results

### Model excursions

The validated error control model can be used to determine how proposed error-reduction practices might affect error rate. The first step in this process is to look at how variations in safety-related parameters of the model affect error rate. These “model excursions” are the initial wind tunnel tests, designed to determine how the behavior of a health care provider might be affected by these same factors. The parameters that were tested in the model excursions were skill level, system design, workload, range of results, and external checks.

### Skill level

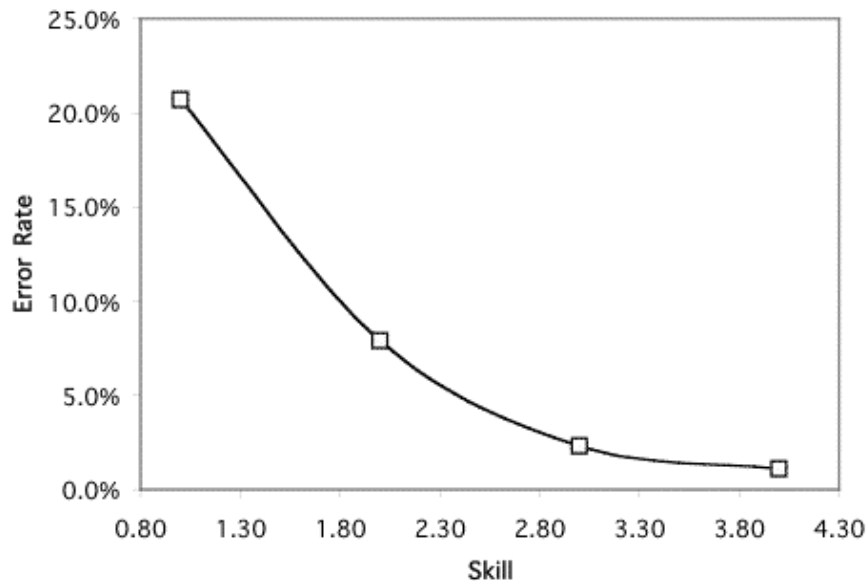
The skill level of the control model has a large effect on the produced error rate while carrying out health care tasks. With all other factors held constant, increases in skill are associated with decreases in error rate. This result, which is consistent with the common sense notion that highly skilled health care providers make fewer errors, is shown in Figure 3.

While the results in Figure 3 show that error rate decreases as skill level increases, the size of the decrease is negligible when error rate is already low (around 2 percent). Since health care error rates are already quite low—about 1 percent for prescription writing errors—the model suggests that very large increases in skill would be necessary to significantly reduce error rate from its current level. It takes several years of training for health care providers to reach the skill level associated with a 1 percent error rate. The model suggests that several more years of training would be needed to get the provider’s skill level up to a point where error rate is cut in half, to 0.5 percent. Health safety practices aimed at reducing error by increasing skill level are, therefore, likely to be an inefficient way to reduce error when the error rate already is quite low.

### System design

System design characteristics, such as system interfaces and drug name similarities, are associated with environmental disturbances that can interfere with the health care provider’s ability to produce correct results. The magnitude of these disturbances corresponds to the impact of system design on the correctness of the prescription components that are being produced. The model excursions suggest that these system design factors have surprisingly little effect on error

Figure 3. Error rate as a function of skill level



Error rate approaches, but never actually equals zero.



rate, when the error rate is already quite low. Doubling the magnitude of environmental disturbances did result in a five-fold increase in the error rate (from 1 percent to about 5 percent.) However, halving the magnitude of these disturbances (which translates to an improvement in the system design) brought about no decrease in the error rate.

The model shows that improvements in external system design characteristics bring about only small error-rate reductions when those rates are already relatively low. This finding is most surprising, since human factors experts have suggested that external system design characteristics such as human-computer interface designs and confusing drug names, are one of the main causes of human error.<sup>39</sup>

## **Workload**

The effect of workload on error rate can be seen in the “model” curve shown in Figure 2. The curve identifies an optimal workload in terms of error reduction. When the workload is very low, the error rate is actually higher than when the workload is at an optimal level (about 45 filled prescriptions per hour, in this case). Increasing the workload above the optimal level results in a steep error-rate increase. What constitutes the optimal workload depends on the task being performed. The faster a task can be performed (on average), the higher the optimal workload for that task.

## **Range of results**

The range of results parameter is associated with the range of different results that might have to be produced to successfully complete a health care task. In prescription writing, for example, the range of results parameter is associated with the number of different kinds of prescriptions that a physician might produce in a practice. This model parameter has a large effect on the error rate, even when the error rate is already low. Halving the value of this parameter cuts the error rate in half. This result suggests that error-reduction practices that make use of standardization (such as “unit dosing,” where a standard prepackaged medication dosage is delivered to the patient), which effectively reduce the range of results that must be produced, could make a significant contribution to error reduction.

## **External checks**

External checks for errors are carried out by technologies such as electronic decision-support systems. Such a system was added to the model by having a simulated decision-support system detect error with some probability. The results of running the model with this decision support error-reduction scheme were not surprising: error rate was reduced in proportion to the probability that the decision support system detects errors. The model, therefore, shows that prescribing error can be reduced to the extent that a system can detect errors. Indeed, there is evidence that decision-support systems, such as CPOE, will reduce errors to the extent that incorrect results can be recognized and flagged by the system.<sup>40, 41</sup>

## Parameters of error-reduction practice

Many different strategies aimed at reducing medical errors have been proposed, including: (1) using distinct drug names; (2) standardization; (3) encouraging the development of a culture of safety; (4) implementing an error-reporting system; (5) using e-prescribing systems for ordering medications; (6) using human factors principles in the design of medical information systems; (7) improving working conditions; and (8) increasing the amount of training given to medical practitioners.<sup>42-44</sup> Each of these strategies can be related to parameters of the prescribing error model. For example, the use of distinct drug names relates to the magnitude of environmental disturbances that affect the behavior of the model; distinctly different drug names are less of a disturbance to prescription writing than are drug names that could be easily confused.

In order to evaluate error-reduction practices, it is necessary to map these practices to the parameters of the model examined in the model excursions. One possible mapping of model parameters to safety practices is shown in Table 2. The columns of the table describe the model parameters affecting the rate at which errors are generated. The value of the weight under each model parameter is proportional to the effect size of variations in that parameter on the error rate, when the error rate is already in the 1 percent range. The result range and workload parameters, for example, have relatively large weights. This is because changes in these parameters have a large effect on the error rate, even when the error rate is already low.

The rows of Table 2 represent various error-reduction practices that have been proposed as a means of reducing the occurrence of human error. “Working conditions,” for example, refers to practices aimed at optimizing workload and reducing interruptions, thereby improving the working environment. The entries in the matrix indicate whether or not a particular safety practice (row) affects a condition in the real world that is associated with a model parameter (column). A “1” in a cell means that the practice does affect a condition corresponding to a model parameter; a blank cell means that the practice does not affect a condition that corresponds to a model parameter.

## Prioritization

The “weighted value” numbers in the rightmost column of Table 2 are error reduction scores. They are assigned to each safety practice, according to their ability to reduce error from the perspective of the prescribing error model. These “weighted value” scores are just the sum of the error reduction weights of parameters that are associated with the safety practice. Safety practices that are associated with model parameters having a large effect on error rate are the practices that score high in likely effectiveness. Human factors (HF) principles, for example, are associated with the result range, system design, and workload parameters of the model, and have a weighted value score of 1.60, the second highest score.

Table 2. A mapping of model parameters to safety practices

Model Parameters							
		Result Range	Skill	System Design	Workload	External Checks	Weighted value
Safety Practice	Weight	0.7	0.1	0.1	0.8	0.9	
	Culture of safety	1	1	1	1	1	2.60
	HF principles	1		1	1		1.60
	Alarm devices			1		1	1.00
	Redundancy					1	0.90
	Interception					1	0.90
	Consequence mitigation					1	0.90
	Working conditions				1		0.80
	Standardization	1		1			0.80
	Training		1				0.10
	Sanctions		1				0.10
	Distinct drug names			1			0.10
	Leading zeros			1			0.10
	Interface design			1			0.10
	Improved communications			1			0.10
Error reporting			1			0.10	

The error-reduction practices in Table 2 are ordered from highest to lowest in terms of their composite scores. This ordering is a preliminary prioritization of error reduction practice classes, based on “wind tunnel” simulation tests of the human error control model. The two most prioritized error-reduction practices, culture of safety and human factors (HF) principles, are associated with the largest number of model parameters. The next four error-reduction practices (alarm devices, redundancy, interception, and consequence mitigation) have been given a high priority because they are associated with external checks (such as second looks in the case of redundancy), that are assumed to be very effective (resulting in a parameter weight of 0.9). The next two error-reduction practices (working conditions and standardization) are effective because each is associated with a single parameter of the model (workload and result range, respectively) that has a very pronounced effect on the error rate.

Several error-reduction practices had surprisingly low error-reduction scores. Distinct drug names and leading zeros, for example, had very low error-reduction scores despite having been touted as important error-reduction practices.<sup>45, 46</sup> These practices score low because they are associated with skill and system design—model parameters that have only a small effect on error reduction, when error rate is already low. Error reporting also receives a low score when it is treated as an error reduction practice. Error reporting can be used as the basis for

training, so it is associated with the skill parameter of the error model, which has very little effect on error reduction when error rates are already low. Although error reporting gets a low priority as an error-reduction practice, it is still very important to the process of monitoring and maintaining the quality of health care services.

## Conclusion

A control model of human error can be used as the basis for evaluating the likely effectiveness of error-reduction practices in the absence of randomized trial evidence of their effectiveness. The model also shows that to err is, indeed, human in the sense that human performance never can be completely error-free. No matter how skillfully created, the error model will never produce an error rate of zero (Figure 3). The model shows that the most effective error-reduction practices are those involving standardization, workload optimization, and automated information systems that prevent error. However, while error-reduction practices can sometimes reduce errors significantly, they cannot eliminate them completely. Therefore, the most effective way to deal with the problem of human error in health care may ultimately be to combine effective error-reduction practices with systems designed to protect patients from error by placing barriers, such as double checks, between providers and patients.

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