drives these decisions—we are so appreciative that this spirit of collaboration and partnership between a journal and its contributors has continued to flourish.

As I do each year, I want to remind everyone that *JAMA Neurology* is your journal, not ours, and we would appreciate any suggestions you have as we continue to evolve to better serve your needs. From all of us at *JAMA Neurology*, thank you for a great 12 months, and we are so looking forward to continuing our work together during the coming year.

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How Safe Is Safe Enough for Space and Health Care?
Communication and Acceptance of Risk in the Real World

James P. Bagian, MD

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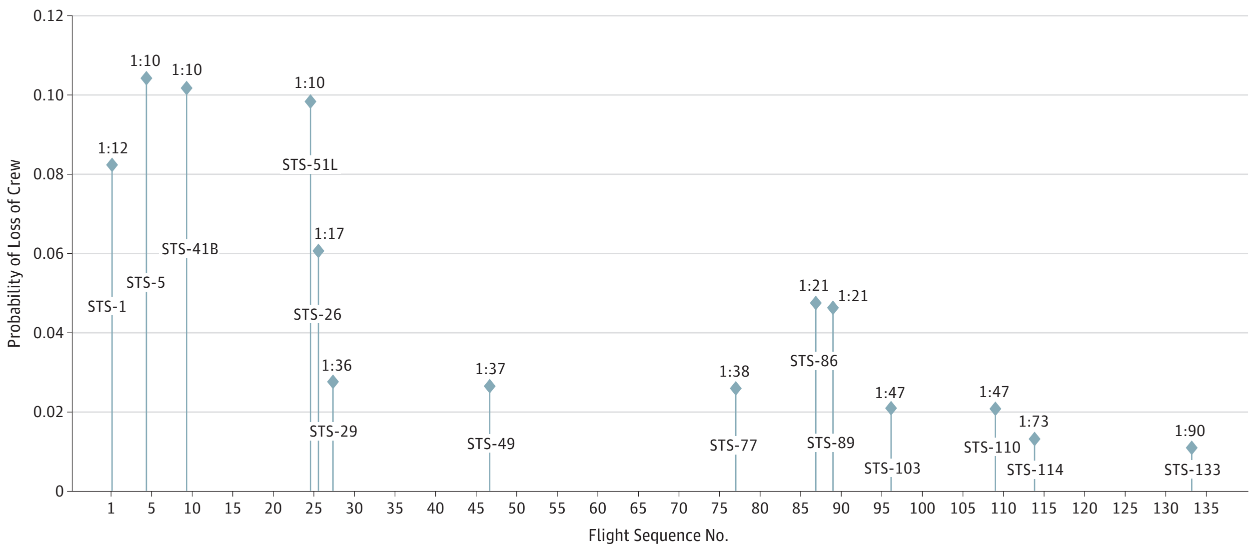
Patient safety has become an important topic over the last 20 years both for patients and those that provide health care on a worldwide basis. Despite the attention, there is often confusion regarding what the goal of patient safety is. Since 1999, I have posed this question regarding the goal of patient safety during hundreds of presentations to audiences around the world and observed the following responses. Twenty years ago, when given the hypothetical choice between defining the goal of patient safety as ensuring (1) that no individual would ever make an error or (2) that no patient would be inadvertently harmed while under the care of their institution, more than 95% of health care workers selected that the goal was for no one to ever make an error. However, as the health care field has become more sophisticated in how it views safety (which is by selecting the desired outcome rather than the method of achieving it), the latter choice of no patient being inadvertently harmed is now selected in more than 95% of the audience responses. Said another way, safety is nothing more or less than a description of the level of risk that an entity chooses to accept under a given set of circumstances.

In this issue of *JAMA Neurology*, Lee et al[1] describe a retrospective study of astronauts where changes in brain white matter as well as changes in free water distribution were observed and associated with spaceflight inferred from preflight and postflight magnetic resonance imaging. The availability of information from the population of astronauts was of a very limited nature owing to a number of constraints, not the least of which was the small number of participants (n = 15) available for study. As with many studies, especially those faced with such limited retrospective information, the authors indicate the need for further study to better understand if there is any operational or clinical significance to their early observations.[1] The suggestion for further study is a familiar lament and must have a sufficiently high priority to be satisfied when compared with other alternative demands for resources. In the final analysis, knowledge must not be pursued for knowledge's sake alone; the knowledge to be gained must have some hypothetical greater value compared with other opportunities. Put another way, the value of further future study has to outweigh the value that might be realized

Figure. Results on Retrospective Analysis on Shuttle Risk



STS-1 estimate includes crew escape with ejection seats (risk is 1:9 ratio without ejection seats). STS-1 risk may have been higher because of unquantified risks. The vertical lines indicate individual flights. Adapted from the National Aeronautics and Space Administration Aerospace Safety Advisory Panel.[4]

were the resources applied elsewhere. In the case of the benefit to the astronauts, the risk reduction and the additional safety the astronauts would gain have to be weighed against other hazards and attendant risks to which the crews are already subjected as well as any impacts the risks would pose to mission accomplishment.

To intelligently and productively discuss safety, it is first imperative to identify the hazards that could cause unintended harm, determine what level of risk—that is the probability—that the hazard-caused harm would occur, determine the magnitude of the harm that could occur, define an acceptable level of harm, outline the cost in terms of resources needed to be expended (eg, financial, time, goodwill, and reputation) to reduce the risk of harm to an acceptable level, and identify the relative value—and to what entities—of mitigating the risk compared with application of resources to other activities. These considerations are in play in virtually any decision-making process, although they are not always addressed in a thorough, transparent, and explicit manner combined with a clearly communicated rationale underlying any decision together with accountability for the results. The more complex the process under consideration and the more personnel involved, the more imperative it becomes that the decision-making process not be ad hoc. It is especially interesting that this case involves 2 endeavors—spaceflight and medicine—that involve hazards that can result in serious or fatal outcomes to the involved personnel. However, the traditional approach to decision making and managing risk are substantially different on a day-to-day basis in these 2 fields.

During my own time as an astronaut and as a member of the mishap investigation teams for space shuttles *Challenger* and *Columbia* as well as a member on the National Aeronautics and Space Administration Congressionally mandated Aerospace Safety Advisory Panel, our discussions were grounded around 2 basic concerns: loss of crew (LOC) and loss of mission (LOM). Our first priority was preventing LOC; after that was adequately dealt with, we considered reducing the risk of LOM. Both are safety-related discussions, and they were the foundational bedrock on which all decisions were based. As with medicine, when there is seldom a zero-risk choice, the question is: what is the prudent risk?

Determining the prudent risk required thorough analysis and description of the various hazards that were present, the probability of their occurrence, and the resulting decision to either eliminate, control, or accept the risks. This would all have to be weighed against the costs of risk mitigation and the net value to be realized compared with the other opportunities available and their impact on the system as a whole. This process, by its very nature, promoted better communication throughout the organization and encouraged more open discussion of the problems and their solutions, resulting in better-informed decisions that were based much more on the merit of the arguments than the status of the person making the arguments. These are some of the characteristics that have been become popularized as components of a high-reliability organization.[2] Additionally, it was clearly recognized and articulated that decisions must be made by individuals, not committees. When the clarity for accountability of decisions is lost, the outcomes can be catastrophic, as was reinforced by the loss of the *Challenger* in 1986.[3] Even with well-thought-out and well-executed processes, there can still be significant risk.

For example, a probabilistic risk assessment performed in 2013[4] retrospectively examined the entire Space Shuttle Program and showed the risk of LOC was as high as 1:10 in the early 1980s and improved to 1:90 by 2010 (**Figure**). While this is a big improvement over a 30-year period, it is still a far cry from the 1:12 million chance of LOC on a large commercial airline flight.[5] The fact that the chance of loss of life in spaceflight is higher than in commercial aviation doesn't mean that the there is something wrong with spaceflight but that those involved, including astronauts like me, felt that the benefits to flying the space shuttle outweighed the potential for LOC. Here too, it should be clear what risks have not been eliminated, and these residual risks must be accepted by a specific individual, not a group, so that clarity of responsibility is maintained. The changes to free water and white matter discussed by Lee et al,[1] its contribution to the risk of LOC or LOM, the resources needed to both better understand the hazards and resultant risk, and the cost of doing so will have to be weighed against the impact and costs to mitigate other risks to crews, such as space radiation, behavioral health and performance, and extravehicular exercise performance.

This consideration of risk is not unlike the same discussions that are familiar in health care when a patient has a meaningful conversation with their health care professional regarding informed consent. When done well, the patient is the ultimate individual who accepts the risk and can only do so if the risks and alternatives have been clearly explained, which involves much more than merely securing a signature on an informed consent form. Interestingly, in health care, decisions among personnel during decision-making processes often lack this thorough consideration of alternatives, opportunity cost, residual risk, responsibility for acceptance of residual risk, and transparency. The frequently expressed dissatisfaction by physicians with the electronic health record and its impact on patient care is but one symptom of this failure to effectively communicate, identify, and deliberately and transparently accept residual risks and has many underlying causes, such as a lack of clear goals, their relative priorities, and individual responsibilities. It is only after identifying the various hazards, their probability of occurrence, the acceptable level of harm, and the opportunity cost that influences the resources available for risk mitigation that one can establish the definition of the acceptable residual risk. This accepted residual risk is really what an organization deems as safe (enough) and is only rarely done in an explicit and transparent manner.[6,7] The transparent, explicit decision-making process also has the additional advantage of facilitating teamwork by creating a shared mental model among members and stakeholders of the organization that can enhance its credibility, efficiency, and effectiveness.[8]

What is deemed as safe or unsafe is within the control of the organization, and it is dependent on what the organization's top individual specifies as an appropriate level of residual risk after weighing it against the opportunity costs to mitigate the risk, ie, the acceptable risk. Determining this certainly takes input from many entities both inside and outside the organization, but the decision and responsibility resides with the boss, since the buck ultimately stops there. There are many influences, such as regulatory, public opinion, and fiscal constraints, that must be considered, but ultimately, the individual in charge must clearly own the decision and communicate the decision and the underlying rationale to all stakeholders. Without a highly functioning, transparent, well-defined, explicit, risk-acceptance process that defines what is considered to be safe (enough), the dream that the health care industry will become recognized as a shining example of a high-reliability organization will remain simply that—a dream.

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