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## To risk prescribing this drug, or not to risk: That is the question

**P**atients and families usually see life in the numerator when they experience unfortunate events, not considering the denominator. The numerator is the child who suffers a reaction to penicillin or the spouse who is killed in a car accident. The denominator is the many patients who are treated successfully with penicillin without incident or the many drivers who arrive safely at their destinations. Clinicians must learn to view life from more than one perspective—both standing with scalpel in hand and lying on the table awaiting surgery.

**PAs have been commended** for our sense of humanity, and when we are considerate of our patients' perspective, we demonstrate a commitment to compassionate care. But when we make health care decisions about an individual, we are also asked to take a population perspective. Although we treat individuals, we gather our perspective of care from a research population, and medical research is performed on populations. Today's PA must be able to analyze population data from research and make an application to the individual. When PAs see life only from the individual's perspective, we forfeit on our promise to deliver evidence-based care.

Over the past decade, medicine has been fascinated with safety. The Institute of Medicine report *To Err is Human* could be a focal point to this discussion.<sup>1</sup> Since this report was published, the FDA, hospitals, professional associations, and other agencies seem more intensely focused on safety. The preface of this report describes humans as the error makers and systems as the way to prevent errors. The problem is, however, that errors are risky but accepting risk is not always an error.

**Our society is largely intolerant** of risk. Health professions seem to have adopted the goals of other industries, such as airlines, where achieving zero risk is the measure of success. But many have suggested that if zero risk were possible, it would be detrimental to medicine. R.J. Rushdoony wrote, "Risk is basic to medical progress ... a society which wants good innovations and no risks is asking for the impossible."<sup>2</sup> If we assume no risk, we deny the possibility of failure, and we limit our learning. But balance is needed because when risk is excessive, we foster fear, limit research, and restrain discovery. Balancing risk and benefit is essential to patient care, innovation and discovery in medical research, and professional advancement.

The balance we seek is greatly affected by how we view the data. When we only look at the numbers in a numerator, we often overestimate the risk. When we see the numbers as

rates, we are left with perspective. We consider rates because there are no absolutes in science. Zero risk truly does not exist, so we must consider what level of risk we are willing to accept. The risk of any treatment must be weighed against its benefits. For medications, adverse event data from the FDA helps inform providers who make decisions about whether to prescribe a treatment. However, the perspective that dominates decision making at the FDA is sometimes questionable. Here is one example.

**Phenylpropanolamine (PPA)**, a decongestant that was also used in some weight control products, was deemed unsafe by the FDA because it increased the risk of stroke. In 2005, the FDA issued a notice of proposed rulemaking for OTC decongestants and weight control products containing PPA, reclassifying PPA as non-monograph not generally recognized as safe and effective.

This decision was based on a case-control study.<sup>3</sup> If we assume a daily incidence of hemorrhagic stroke of 0.6 per million for persons aged 35 to 54 years and accept the odds ratio range of 1.51 to 16.58 from this study, then we could estimate 1 hemorrhagic stroke in 107,000 to 3,268,000 women who use PPA as an appetite suppressant within a 3-day window. This represents an incidence range of 0.00003% to 0.0009%. The *P* value was not significant in those using PPA for cough and cold symptoms.

A person is much more likely to die from any injury (1 in 1,755; 0.06%), die from an automobile accident (1 in 17,625; 0.006%), or die from being struck by lightning (1 in 750,000; 0.00013%) than to die from a hemorrhagic stroke after using PPA.<sup>4</sup> The likelihood of a bad outcome from PPA is about equal to the odds of dying from complications from medical and surgical care (1 in 101,281; 0.0009%).<sup>4</sup> Given this data, was withdrawing PPA from the market justifiable?

Just as medications are not efficacious in every patient, they are not risky in every patient. PAs should know a medication's safety and efficacy data, and we should be able to evaluate its risks and benefits. We should be careful to balance fear of risk with hope of benefit. **JAAPA**

### REFERENCES

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