In this month’s issue of the Journal of Neurosurgery: Pediatrics, Kestle, Cochrane, and Drake discuss the “July effect” on the safety of common pediatric neurosurgical procedures, reaching a conclusion opposite to that espoused in a paper by Smith, Butler, and Barker, which is also published in this issue.

In the first study, Kestle and colleagues used data obtained from a multicenter hydrocephalus clinical trials database and found that an increased risk of shunt infections and wound problems and a shortened duration of shunt survival were associated with shunt implantation surgery performed in July and August. In the second study, Smith and associates relied on data from the Nationwide Inpatient Sample (NIS) hospital discharge database for the years 1988 to 2000 to examine craniotomy and shunt procedures. Using as end points major adverse indicators, such as mortality rate, adverse discharge disposition, major neurological complications, transfusions, length of hospital stay, and hospital charges, the authors found no such “July effect” when patient data were analyzed.

These confounding outcomes are fairly easy to resolve. In the second study, the authors focused on major complications (except for longer length of stay and hospital charges), which only occur occasionally following typical shunt insertion procedures. The authors of this study commented on the deficiencies of their review due to their use of this type of database, and their comments speak for themselves. I found the more carefully focused study of Kestle and colleagues compelling. Their data were acquired from well-defined, carefully managed studies of shunt design and endoscopic shunt placement, and their data are persuasive. The question that begs an answer is precisely why these investigators noted more complications in July and August. In our institution, there is arguably more supervision of new house officers in July and August than during the rest of the year, and although throughout the year it is the practice for an attending neurosurgeon to scrub for every surgical procedure performed in our operating rooms, instruction and oversight are probably at their height during the summer months. Increased infections might be related to slower surgery under these circumstances, with more wound exposure and manipulation of hardware, but according to the authors’ analysis, the length of surgery was not longer in the summer months. The variables responsible for their findings remain obscure and might even include resistant bacterial flora in the operating room and a greater number of patients presenting with posttraumatic or postinfectious hydrocephalus during the summer months. For example, the authors provide no evidence that causes of hydrocephalus in cases treated in July and August were matched to causes in cases treated in the remainder of the year. Their study does sound a cautionary note, however, and should prompt all of us who practice in academic institutions to look at our own data more precisely to see if these results are more common than we have supposed. I congratulate John Kestle, Douglas Cochrane, and James Drake for a thought-provoking and stimulating article.

RESPONSE: We thank Dr. Scott for his review and comments about our report of shunt surgery complications in the summer. He makes two very good points. Clearly, different databases are suited for different purposes, and the NIS database used in the study by Smith and colleagues is well suited to evaluating the major end points listed by Dr. Scott. Such large databases are probably also useful for evaluating geographic variations and trends over time. To analyze specific outcomes in focused clinical areas, however, clinical trials databases may be appropriate. We were fortunate enough to have data available from several sources for our analysis of shunt implantation surgery.

We agree with Dr. Scott that the reason for our findings is difficult to determine. He lists a number of possibilities, and we are unable to support or refute any of them based on the clinical trials database that we used. Because a “July effect” is among the possible explanations, we believe that increased supervision of new house officers during the summer months is appropriate.
RESPONSE: We enjoyed reading Dr. Scott’s comments on our study and agree with his praise of the study conducted by Dr. Kestle’s group. As Dr. Scott states, we found that mortality and major morbidity rates were not increased for pediatric tumor craniotomies and shunt operations performed in July at teaching hospitals. Although this does not rule out an increase in less severe complications (such as infection rates) during this month, we do believe that our findings can provide reassurance to parents whose children need shunt-related operations or tumor craniotomies in July. Delaying surgery until summer has passed is usually inappropriate for these patients.

Unfortunately, an ideal data source for answering questions such as the ones we asked in our paper does not currently exist. Administrative databases such as the NIS provide substantial statistical power to detect rare events but do not contain the detailed clinical information that is more germane to everyday care. Nor is it immediately clear that the detailed information accrued in randomized clinical trials, with their complicated machinery of informed consent, senior investigator oversight, and government regulation, is the best source to study lapses in the quality of unsupervised routine practice.

At present, health-care payers increasingly place emphasis on measuring the quality of routine, everyday patient care to support pay-for-performance plans and “favored provider” lists. When there are no detailed, comprehensive clinical databases that can be used to measure quality in a way clinicians trust, payers are free to declare that quality is “equal” across the board and to push patients toward lower-cost, “efficient” care instead. Creating better databases now may be one way to prevent such arbitrary restrictions on patient choice in the future.

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