Letters

THE PEDIATRIC COSTS OF STRATEGIES FOR MINIMIZING THE RISK OF EARLY-ONSET GROUP B STREPTOCOCCAL DISEASE

To the Editor:

The analysis of costs associated with prevention of early-onset group B streptococcal disease by Fargason et al (Obstet Gynecol 1997;90:347–52) includes incorrect information regarding the Centers for Disease Control and Prevention’s (CDC’s) suggested management algorithm for newborns after intrapartum prophylaxis.1,2 The correct algorithm should indicate that asymptomatic infants born before 35 weeks’ gestation should receive a limited evaluation, with 48 hours’ observation, rather than a full diagnostic evaluation with empiric therapy. Use of the incorrect algorithm does not affect the study’s results but does perpetuate the original printing error.

The authors stated that the CDC prevention strategies “are an extension of guidelines previously published by ACOG and the American Academy of Pediatrics.” The CDC guidelines, however, have some important differences from earlier approaches, although they were developed with and endorsed by ACOG and the American Academy of Pediatrics. The authors estimated that 58% of culture-positive gravidas would receive more than 4 hours of antibiotics before delivery. The source of this figure is not found readily in the reference cited. The proportion of women who receive more than 4 hours of therapy may be higher for the culture-based approach than for the risk-factor–based approach, because intrapartum prophylaxis can be started without waiting for recognition of obstetric risk factors. This difference would reduce the cost difference between the two strategies.

Enhanced evaluation and observation of infants after intrapartum prophylaxis add to the costs ($11–$14 per case), but this cost is probably acceptable to ensure early detection of sepsis in those few infants for whom maternal prophylaxis was ineffective. We endorse the authors’ view that efforts should be made to evaluate the actual impact of pediatric management algorithms for prevention of group B streptococcal disease.

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References


In reply:

We had referenced the algorithm contained in the original CDC publication which, as O’Brien et al point out, was revised subsequently. However, changing the portion of the algorithm addressing premature infants does not affect the results of our study, which focuses on term infants.

We acknowledge the differences between the CDC, ACOG, and American Academy of Pediatrics approaches to group B streptococcal risk management. The genealogy of the various guidelines was presented to assist readers attempting to relate our work to previously published decision analyses focusing on the cost-effectiveness of obstetric approaches for reducing the risk of early-onset group B streptococcal sepsis in newborns.

Our estimate of the number of mothers receiving therapy for more than 4 hours was obtained from reference 23 in the manuscript.1 During the editing and revision process, references were inserted and the accompanying citation in Table 1 was not renumbered appropriately. We apologize for this error. O’Brien and colleagues suggest that this study may underestimate the number of mothers who will receive antibiotics for more than 4 hours before delivery. Even in the unlikely event that the proportion of women receiving therapy for more than 4 hours is 100%, our estimate of the costs associated with the pediatric algorithm proposed by the CDC would decrease by no more than 15% for term infants.

While the marginal cost of a pediatric intervention is relatively small, these are costs generated in the care of term infants whose risk of group B streptococcal disease has decreased as a result of obstetric approaches for preventing perinatal group B streptococcal sepsis. Professional assessments of parents’ willingness to have their children endure medical interventions are not
always accurate, as Kramer and colleagues demonstrated. In addition, the pediatric costs associated with strategies for minimizing the risk of early-onset group B streptococcal disease affect a large number of children on an annual, recurring basis. The additional benefit that pediatric approaches provide to the health of children whose mothers have received intrapartum antimicrobial prophylaxis has not been demonstrated convincingly. Therefore, pediatric costs associated with strategies for prevention of group B streptococcal disease warrant attention from a public health perspective.

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References

RESEARCH DESIGN AND METHODS
OF QUANTITATIVE SYNTHESIS OF
MEDICAL EVIDENCE

To the Editor:

Peipert et al (Obstet Gynecol 1997;90:473–8) concluded that the randomized controlled trial (RCT) is the “gold standard” of research designs. However, they did not mention a major weakness that underlines all “properly designed” RCTs, which is that they are conducted under strict experimental protocols and, therefore, may not represent real-life scenarios. The so-called Hawthorne effect already is known and it represents a side effect of conducting the RCT under (ideal) circumstances that do not represent real-life scenarios.

There were several problems with the classification criteria recommended by the Preventive Services Task Force (Table 1 of the article) for judging quality of evidence. Under this classification, the highest quality of evidence (I) is that evidence obtained from at least one properly designed RCT; however, RCTs do not represent real-life scenarios. It is unclear by whom and on the basis of what objective criteria it is determined that an RCT is properly designed (quality of evidence I) or whether a nonrandomized trial or an observational study is “well designed” (qualities of evidence II and III, respectively). Also, it is very subjective to cite “dramatic results” as quality of evidence II-3 without defining what “dramatic” means. In addition, we can hardly agree that “opinions of respected authorities” or “reports of expert committees” should be classified under “quality of evidence” (III). In our view, opinions or reports, no matter where they emanate from, do not constitute evidence. Judging quality of evidence, based on the classification proposed by the Prevention Services Task Force, therefore remains subjective, a fact that cannot be overlooked.

Finally, the choice of correct terminology is crucial in our understanding of research designs. The authors refer to the “unexposed” group, in cohort studies, as “control group of unexposed patients”; however, the term “control” solely applies to case-control and not cohort studies. The appropriate term for cohort studies would be “comparison group of unexposed patients.” Also, a cohort study can be used to evaluate several “outcomes,” which the authors did not mention.

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In reply:

We agree that the randomized controlled trial (RCT) may not always represent real-life scenarios, but we do not consider this a “major weakness” in the methodology. Although it is true that properly designed RCTs are performed using specific protocols, not all RCTs are “strict” experiments that are not representative or generalizable. There are many reports of observational studies and case series that some might call real-life scenarios, but these studies are more prone to bias and, in the case of descriptive studies, have extremely limited scientific value.

The Hawthorne effect mentioned by Vintzileos and colleagues does not apply to RCTs conducted “under (ideal) circumstances” but rather is an effect (usually positive or beneficial) noted in any study in which the subjects perform “better” simply because they are being studied. In fact, in the original description at the electric plant in Hawthorne, IL, reported by Elton Mayo,
employee productivity improved with minor adjustments in the working environment; the workers were not “randomized.”

With regard to the Preventive Services Task Force’s classification of evidence, Vintzileos et al expressed the opinion that the criteria for determining which RCTs are “properly designed” and which observational study is “well designed” are unclear. However, there are numerous reports in the medical literature outlining guidelines for “properly designed” RCTs and for “well-designed” observational studies. We do agree that interpretation and scoring of these quality criteria can be somewhat subjective.

In many clinical circumstances, clinical decisions need to be made when there are no controlled trials or observational reports in the literature. In such circumstances, the “opinions of respected authorities” and “reports of expert opinions” are the only “evidence” by default. We agree that correct terminology is crucial to our understanding of research designs. According to a popular dictionary of epidemiology, control groups or controls are “subjects with whom comparison is made in a case control study, randomized trial, or other variety of epidemiologic study.”

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References

FAMILY VIOLENCE ISSUES IN OBSTETRICS AND GYNECOLOGY, PRIMARY CARE, AND NURSING TEXTS

To the Editor:

Parsons and Moore (Obstet Gynecol 1997;90:596–9) evaluated major texts in obstetrics, gynecology, primary care, and nursing for inclusion of domestic violence material and found the texts lacking this content. An important group of primary women’s health care providers is missing from this evaluation—certified nurse-midwives. There are more than 5000 certified nurse-midwives in the United States offering primary care to women of all ages and social strata, in a variety of clinic and private, urban and rural settings. Nurse-midwives’ approach to care acknowledges the psychosocial aspects of a woman’s life and their potential impact on her health and well-being. Domestic violence is one such issue.

The American College of Nurse-Midwives has addressed the issue of domestic violence in a comprehensive manner. A 3-year education project funded by the Maternal and Child Health Bureau of the Department of Health and Human Services, functioning since October 1994, has succeeded in providing content on domestic violence to all members through a variety of mechanisms including full-day training sessions, a home-study journal, training of trainers sessions specifically for educators, public service announcements, and a video training package. Further, in the fall of 1996, the college published a position statement and clinical guidelines on the issue of violence against women espousing zero tolerance and universal screening. The core competencies specifically include assessment for domestic abuse, which ensures that all future nurse-midwives will receive domestic violence education as part of their basic training.

Finally, in the November 1996, third edition of the classic text Varney’s Midwifery are specific information and case studies regarding assessment for domestic violence.

We are disappointed that nurse-midwives were not included in this evaluation, particularly because they have responded to the issue of domestic violence in such a comprehensive manner. Including them may have altered the authors’ conclusions to some extent. Additional information regarding the domestic violence project may be obtained by contacting Pat Paluzzi, CNM, MPH, at (202) 728-9863, ppaluzzi@acnm.org, or the address below.

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In reply:

We recognize the contribution of nurse-midwives to the health care of women. The American College of Nurse-Midwives has been a leader in education and care of women in the area of domestic violence. Our study was designed to examine the texts readily available to practicing physicians and nurses, students, and physicians in residency. Unfortunately, in the libraries, bookstores, and book vendors surveyed, Varney’s ex-
Excellent text on nurse-midwifery was not available. We must still conclude that the textbooks accessible to the majority of physicians and nurses (both in practice and as students) are deficient in the spectrum of family violence information.

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WHERE HAVE ALL THE YOUNG MEN GONE? KEEPING MEN IN OBSTETRICS AND GYNECOLOGY

To the Editor:

The commentary by Lyon (OBSTET GYNECOL 1997;90:634–6) is a first step in a dialogue about gender discrimination, an issue that has the ability to splinter obstetrics-gynecology. In many cities, women obstetrician-gynecologists are forming large gender-specific groups, and I fear this can become an us-against-them situation. Twenty years ago if a female physician was not considered for a job based on her gender, there would have been an out-pouring of angry sentiment against her treatment, and the anger would have been justified. But today, when male residents are not even interviewed by female groups or recruiters because of their gender, nothing is said—no angry outbursts, no demonstrations, nothing.

Women and men have spent years working toward equality and the elimination of barriers related to gender, race, and disability, so it seems ironic that some use the same arguments today that were used against them in the past. Dr. Lyon says that this is consumer-driven and based on market forces and therefore justified. It was not too long ago that there were many white-only businesses and services that also were driven by market forces and personal preferences. But the courts stated that, even though it upset many belief systems and caused much emotional discomfort, such discrimination should not be allowed. We now have clinics advertising that they are staffed only by women. How would the medical community respond to a group of doctors advertising that they were staffed only by whites?

At some point this issue will find itself in the courts. I predict that one day, a well-trained male resident will want a job in some town that is advertising for a female physician, and when the job opportunity is denied based on gender, he will engage an equal opportunity attorney to take his case.

Some of the finest physicians I know are in exclusive groups. When a patient has to change doctors due to insurance needs, I refer to these physicians, not because they are women, but because they are excellent doctors. The point I am trying to make is that discrimination is discrimination whether it is based on race, gender, or any other grouping. To promote it for any reason, I believe, is morally and ethically wrong.

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In reply:

Kincheloe misunderstands me when he equates “based on market forces” with “justified.” Indeed, it is my very dissatisfaction with this state of affairs that prompted me to write the clinical commentary.

Sadly, most of the responses I received (now referred to as my “hate mail”) from fully trained male colleagues deny the very existence of a hiring bigotry. This represents an ostrich-in-the-sand denial of a problem that prevents creative contemplation of a solution. I fully acknowledge that my proposed solutions of better communication training and higher residency emphasis on expressed empathy are not likely to reverse completely the trend in consumer preference. There is an element of blind bigotry that no amount of politically correct retooling can overcome. I don’t believe it can even be overcome in the courts. My life in the southeastern United States is replete with examples of persistent and legally untouchable bigotry based in race, gender, or religious preference. I suspect the problem isn’t unique to this patch of real estate, either.

I can offer only the sincere conviction of one who has been on the receiving end of blind bigotry: bitterness is a one-way street to self-destruction. If one cannot find a place in this specialty that brings satisfaction worth the effort, then one should do something else rather than be consumed by the unfairness of it all. And if one does find satisfaction, in spite of the odds, then he (or she) will ultimately succeed in this specialty. There is no realm of human endeavor that can afford to waste committed, compassionate competence. I have a marvelous set of male mentors within the specialty to attest to that.

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