

## Palivizumab (Synagis): Counting "Costs" and Values

To the Editor.—

The continuing reports, letters, and pharmacoeconomic analyses concerning the use of expensive respiratory syncytial virus (RSV) prophylaxis regimens for neonatal intensive care unit (NICU) graduates mark what appears to be a shift in decisional processes for clinicians.<sup>1-3</sup> The consideration of cost, although not new in medical or pediatric decision-making, must be approached with care as decisions to provide or withhold therapies or prophylactic interventions for certain patient populations are made. In attempting to assess the *costs* of a proposed therapy or prophylactic regimen, and make decisions accordingly, one must recognize the attendant implied *values* of all parties affected by such decisions toward either the intervention or the outcome. Values are inherently subjective and will be perceived differently by different groups . . . eg, patients, families of patients, the general public in a public health sense, taxpayers, physicians, hospital administrators, private insurance and payer groups, and industry. "Cost" analyses must be inclusive of more than simple pharmacoeconomic constructs that are currently available.

"Value" analyses should include considerations for:

1. Medical-physiologic aspects of the regimen; eg, "Does it work?"
2. Pharmacoeconomic perceptions of institutions, hospitals, and payer groups.
3. Personal or parental/family values both individually and more corporately; eg, a social utility perspective that should include the voices of parents of at-risk infants. This includes consideration of time and expenses borne by parents, employers, and daycare providers for physician office visits, emergency department visits, hospitalization, and treatments, as well as residual concerns about the infant's health.
4. A broader and somewhat more long-term societal view that might consider:
  - a) years of life saved/lost
  - b) productive versus debilitated life (eg, residual pulmonary morbidity, either acute or long-term)
5. The societal value assumed already in treating premature infants and preserving their health (eg, the societal expectation for the availability and optimal outcome from NICUs, and the investment society makes in this broadly as well as the costs already borne by families, payers, and society to get a premature infant to the point of discharge).
6. The relative value of RSV prophylaxis as a fraction of total NICU economic and resource costs (realizing that for many premature infants hospitalization charges have been in the hundreds of thousands of dollars).

Furthermore, pharmacoeconomic analyses should be projected forward from the point of NICU discharge and consideration for RSV prophylaxis to include the continued post-NICU discharge investment in infants during the first 12 months of life such as: a) percent of rehospitalization; b) number/costs of visits to pediatrician's offices or emergency departments in the first year of life (bronchopulmonary dysplasia-related, and otherwise); c) relative costs of RSV prophylaxis to continued investment in post-NICU care, such as any effect on a reduction in office/emergency department visits, ward/ICU hospitalization, and oxygen or ventilator days; reduced post-RSV infection care (such as office/emergency department visits for wheezing and reactive airways disease and consequent therapies)<sup>4</sup>; reduced numbers of sick days and their effect on parents' and siblings' emotional state, employment, daycare arrangements, and costs.

Recent history attests to the consideration of social utility in a number of decisions for providing or withholding certain therapies. Blood products are often withheld from Jehovah's Witnesses and recombinant erythropoietin has been suggested as a preferred alternative therapy for some infants of Jehovah's Witness parents who might only require a small transfusion. In the AAP recommendations for the use of varicella vaccine, deference is given to the social impact of infection; recommendations for vaccination to avoid these social "costs" has resulted in an essentially universal vaccination program in the United States.<sup>5</sup> No published data exist, however, to substantiate that there has been either a reduc-

tion in the total numbers of varicella cases, hospitalizations, or deaths in the 5 years since the vaccine was approved. The economic costs of this vaccination program have not been inconsiderable, given an estimated charge of \$30 to \$40 per vaccine when applied to the more than 4 million infants born in the United States each year.

In attempting to arrive at consistency in clinical decision-making, issues of strict economic cost cannot overshadow a more thorough evaluation of value. In the recent RSV prophylaxis literature, the only costs being considered are those of the hospital or payer groups (private and public). Although a recent report by Joffe et al<sup>2</sup> gives some consideration to a hypothetical cohort of premature patients, no published trials have tabulated actual costs to families for RSV disease-related care or considered the costs to parents of potential recipients of RSV prophylaxis who were either not informed about the availability of the regimen or denied the drug. Such costs might be considered emotional or perceptual (because parents know about RSV and dread it), or very real (because they visit the physician's office with every cough and runny nose their formerly premature infant gets; or worse, have lost a child to RSV). Simple pharmacoeconomic commentaries are not enough. It is people that pediatricians treat, and very human values become much more significant in the decisional process (remember "shared decision-making"). It should not be the place of physicians or payer groups alone to assume the prerogative to deny some babies RSV prophylaxis because of available pharmacoeconomic cost data. Unilateral decisions of such a nature amount to rationing, which is not uncommonly practiced in somewhat inconsistent manners . . . such that someone, or some group of patients from some payer groups, will not be justly represented.

In the issue of RSV prophylaxis for NICU graduates, pediatricians might be better off wearing the hat of a child advocate than a gatekeeper.

BRIAN S. CARTER, MD, FAAP  
Clarksville, TN 37043

### REFERENCES

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2. Joffe S, Ray GT, Escobar GJ, Black SB, Lieu TA. Cost-effectiveness of respiratory syncytial virus prophylaxis among preterm infants. *Pediatrics*. 1999;104:419-427
3. Moler FW. RSV immune globulin prophylaxis: is an ounce of prevention worth a pound of cure? *Pediatrics*. 1999;104:559-560
4. Stein RT, Sherrill D, Morgan WJ, et al. Respiratory syncytial virus in early life and risk of wheeze and allergy by age 13 years. *Lancet*. 1999;354:541-528
5. American Academy of Pediatrics, Committee on Infectious Diseases. Policy statement Recommendations for the use of live attenuated varicella vaccine. *Pediatrics*. 1995;95:791-796

In Reply.—

The letter by Dr Carter lists several emotional issues pediatricians must face when they decide whether to recommend immune globulin prophylaxis for RSV in high-risk infants. Recent publications related to RSV-IGIV and palivizumab have suggested that the costs of these products may not be justified based on the hospital outcomes prevented.<sup>1-3</sup> At this time, immune globulin prophylaxis for RSV has not yet been established to affect severe outcomes like need for mechanical ventilation or mortality. Beneficial effects of development of future chronic lung disease are also not known. What is known at this time is simply that immune globulin products for RSV do not decrease the number of hospital admissions for uncomplicated RSV disease. Unfortunately, the additional costs to avoid a single uncomplicated hospitalization for RSV may be in the range of an order of magnitude greater than the costs of hospitalization avoided.<sup>4</sup> (We previously estimated it would cost over \$75,000 to prevent an uncomplicated RSV hospitalization. This was based on an assumption that just over 17 patients would require treatment to avoid 1 hospitalization (number needed to treat [NNT] = 17) and cost for 5 monthly intramuscular (IM) injections of palivizumab would be \$4,500 per season. The cost to avoid a single day of hospitalization was estimated to be just over \$17,000, and would additionally require 19 IM injections and up to 19 clinic visits). Because there exist limited and