THE EFFECTIVENESS OF INTERIM RESTRICTIONS OF PNEUMOCOCCAL CONJUGATE VACCINE (PCV-7) DURING ITS NATIONWIDE SHORTAGE

BACKGROUND

In February of 2000, a pneumococcal conjugate vaccine (PCV-7) was licensed for infants and children. This vaccine contains the seven serotypes responsible for more than 80% of invasive pneumococcal disease in US children less than 4 years of age. In June of 2000, PCV-7 was added to the National Vaccines for Children Program. The California Department of Health Services (DHS) Immunization Branch made the vaccine available to California local health departments in September of 2000, and by the end of that month, the Los Angeles County DHS Immunization Program (LAC DHS IP) had developed and distributed guidelines and initiated a training program for LAC DHS clinics. By June of 2001, the clinics had integrated PCV-7 into their routine vaccination efforts.

In July of 2001, the manufacturer of PCV-7 first announced delays in the production and shipment of the vaccine. In September of the same year, the CDC first developed interim recommendations on vaccine usage in an attempt to prioritize the vaccine to all children less than 2 years of age, especially infants, and medically high-risk children 2 to 5 years of age [1]. In December of the same year, the CDC promulgated revised interim guidelines which allowed the regular number of vaccine doses to all high risk infants and children up to 5 years of age, but deferred all doses to low risk children 2 to 5 years of age and decreased the number of doses to low risk children under 2 years of age [2]. This revised interim schedule also included a more rigorous dose reduction for the severest shortage situations. As a result of the complexity of both the original and revised interim schedules as well as the routine schedule for this vaccine, there was much concern that vaccine usage would not be limited to the highest priority groups during the shortage of this vaccine.

The following analysis was undertaken to determine the effectiveness of the CDC interim guidelines in restricting vaccine usage to the medically high-risk patients in the LAC DHS community clinics.

METHODS

Monthly usage data for PCV-7 in LAC DHS clinics by age category were analyzed for the period April 2001 through August 2002 to identify differences in utilization of this vaccine before and after implementation of each of the interim guidelines. The Kruskal-Wallis test was used to assess the existence of differences among the different age groups of children, broken down by the period of time during which each of the interim guidelines was implemented. The Dunn test was used to identify the specific groups that differed and the strength of the differences.

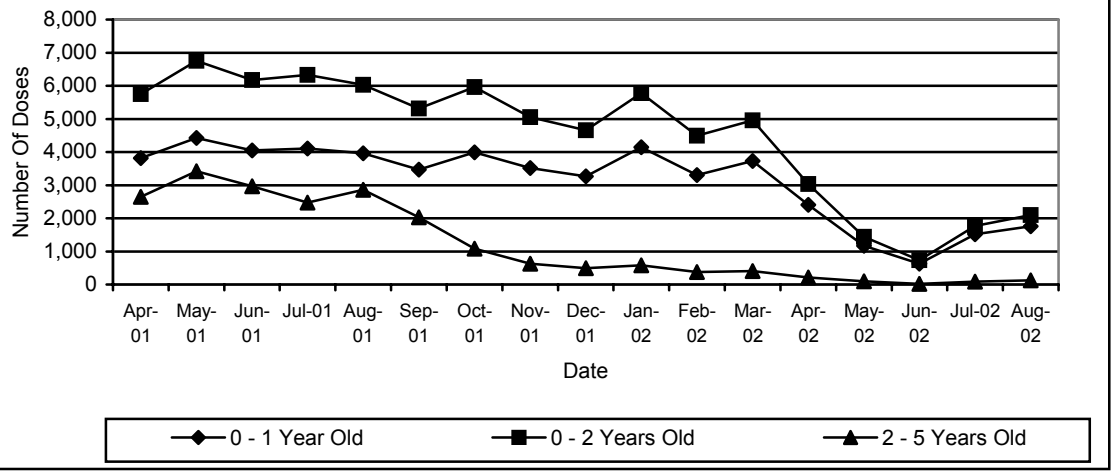
RESULTS

The number of doses rendered to children younger than 2 years of age began to decrease after the first interim guideline (released in September 2001) but decreased more sharply after the second interim guideline which was released in December 2001 (Figure 1). The doses given to infants (children aged under 1 year) did not change appreciably until after the second interim guideline was announced. A marked decrease in doses rendered to children 2–5 years of age was noted and sustained after announcement of the first interim guideline.

In order to rule out the possibility that the decreased doses resulted from either a decrease in availability of vaccine or a decrease in the number of children seen in the clinics during the study period, the proportion of doses administered to the various age groups during the periods covered by each of the guidelines was also determined (Figure 2). Results indicate that the percentage of vaccine rendered to children less

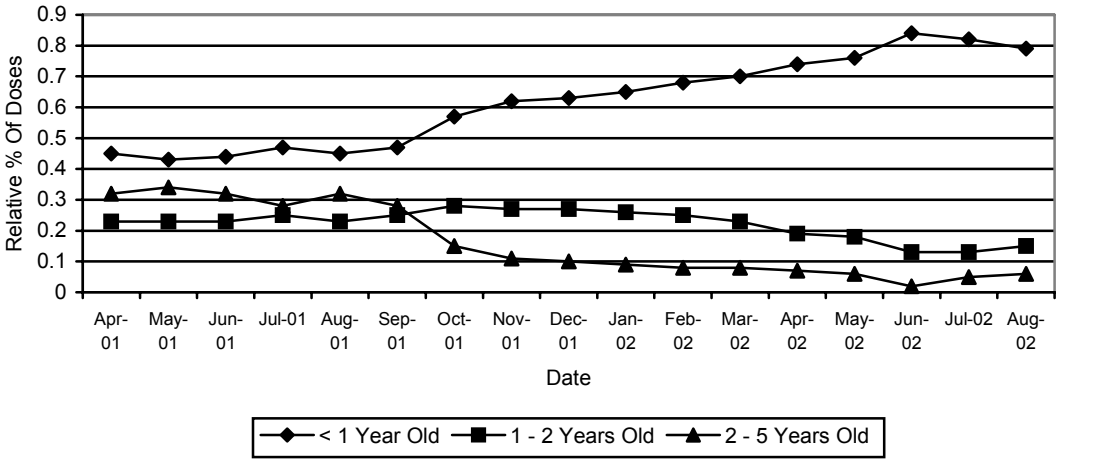
than 1 year of age increased significantly ($p < 0.0001$) after implementation of the first interim guidelines and that this increase was further enhanced after the second interim guidelines ($p = 0.0056$). The percentage of vaccine doses rendered to children 1 and older but less than 2 years of age increased after the first interim guidelines ($p < 0.0003$) but subsequently decreased with implementation of the second interim guidelines ($p = 0.0153$).

Figure 1: Monthly usage data for PCV-7 in LAC DHS clinics, by age category, for the period April 2001 through August 2002



The percentage of doses of PCV-7 rendered to children 2 to 5 years of age decreased significantly after the first interim guidelines ($p = 0.0007$) but did not change significantly after the second interim guidelines.

Figure 2: Monthly usage data for PCV-7 in DHS clinics, by age category as a proportion of total PCV-7 doses administered, LAC, April 2001 - August 2002



DISCUSSION

Freed, Davis, and Clark studied public and private medical practices in 2001 and found that few practices changed their vaccine administration patterns in response to the first interim guidelines for PCV-7 [3]. The analysis of LAC DHS clinic vaccine usage data showed opposite results.

The changes that occurred in the proportion of vaccine doses received by each age group during the time periods studied for LAC DHS clinics appear to be what would have been expected with implementation of each of the interim guidelines for PCV-7. Both the September 2001 and December 2002 guidelines allowed for vaccinating children 2 to 5 years of age only if they had a medical condition which placed them at high risk for invasive pneumococcal disease. This age group accounted for the biggest proportionate decrease in vaccine doses and most of the decrease occurred with implementation of the first interim guideline.

A significant increase in the proportion of vaccine doses given to children under age 1 accompanied the implementation of the first interim guideline and was enhanced further by the second interim guideline. Finally, the slight increase in the proportion of doses rendered to children 1 year of age and up to but not including 2 years of age which accompanied the first interim guideline, and the decrease in proportion of doses to this same age group with implementation of the second interim guideline, are both consistent with the fact that only the “severe shortage” schedule of the second guideline mandated fewer doses for this age group.

Special circumstances that could have led to greater impact of the interim guidelines on LAC DHS clinic vaccine administration practices, compared to other clinics are:

1. LAC DHS IP has a long history of monitoring immunization practices and managing vaccine supply to these clinics. This facilitated the ability of LAC DHS IP to quickly implement the interim guidelines in the LAC DHS clinics.
2. LAC DHS IP took responsibility for removing any discretionary aspects from the guidelines. For example, LAC DHS providers were told to implement the severe shortage schedule of the second interim guidelines, which prevented them from having to decide whether they were in a moderate or severe shortage.

CONCLUSION

For LAC DHS community clinics, both CDC interim guidelines had the desired effect of reducing total vaccine usage and prioritizing vaccine usage to the age groups most at risk for invasive pneumococcal disease. The role of LAC DHS IP in communicating the guidelines to providers in a clear and unequivocal manner that eliminated the need for providers to choose between the different levels of prioritization allowed by CDC, probably contributed to the guidelines’ effectiveness in these clinic settings.

REFERENCES

1. CDC. Notice to readers: Decreased availability of pneumococcal conjugate vaccine. MMWR 2001;50(36):783-4.
2. CDC. Notice to readers: Updated recommendations on the use of pneumococcal conjugate vaccine in a setting of vaccine shortage – Advisory Committee on Immunization Practices. MMWR 2001;50(50):1140-2.
3. Freed GL, Davis MM, and Clark SJ. Variation in public and private supply of pneumococcal conjugate vaccine during a shortage. JAMA. 2003; 289(5):575-578.