Allergy rescue medication in schools: Modeling a new approach

To the Editor:

Over 95% of epinephrine autoinjectors (EAIs) prescribed for children are for a food allergy.¹ Ninety percent of schools have at least 1 child with allergy among their students.² Physicians and families are aware that most prescribed EAIs are never used.^{1,3,4}

We used a questionnaire to explore with families attending a regional allergy clinic, and their schools, how acceptable to them it would be to switch from a prescription for a named patient only to a more generic provision, to reduce the number of EAIs prescribed each year.

Ethical permission was obtained for this study, and written informed consent was given by each family that participated.

The current practice is E = 2n: each child (n) has 2 of their named EAIs at school (E = EAIs). Used EAIs are replaced from the children's prescriptions before they next attend school. During a school trip, the 2 named EAIs are taken out of school to go with the child.

In this hypothetical model, called E = n + 2, each child prescribed EAIs would have only 1 named EAI in school, and the school would have 2 spare, unnamed EAIs (with appropriate additional provision of EAIs for children above and below 30 kg). Under E = n + 2, children would first use the named EAI, and only if a second dose of epinephrine were needed would 1 of the school's 2 unnamed, weight-appropriate EAIs be used. For school trips, the unnamed, weight-appropriate EAIs would remain in the school as potential second EAIs for other children. Therefore, a child going on a field trip would need to bring in a second named EAI from home.

Families whose child had been prescribed EAIs completed questionnaires at routine allergy clinic visits and gave written permission to contact the child's school. Schools were contacted in writing with follow-up telephone contact.

All 30 parents approached took part in the study. Twenty-four children (80%) had 2 EAIs available at school. Three children who had more than 2 EAIs at school were all at primary schools outside the Southampton area. Six (20%) children had ever used their EAI (none needed to use a second EAI), and only 2 (6.7%) had ever used an EAI at school.

Twelve of 30 contacted schools replied. Eleven schools had a total student population of 7248 pupils, and 59 of these had EAIs (representing 1 in 123 children, 0.8%).

Fifteen (50%) parents were happy with the current system E = 2n, and 10 (33.3%) were not happy with it. Twenty-six (86%) parents and 6 (50%) schools gave positive feedback on the E = n + 2 system (P = .02), although slightly fewer parents, 15 (50%) parents and 4 (36%) schools, would prefer to have the proposed system in place at their school.

Parents were more positive about the proposed system (E = n + 2) compared with the current system (E = 2n; $\chi^2 = 10.1$; df = 1; P < .003) and significantly more positive than negative with regard to the proposed system ($\chi^2 = 2.1$; df = 1; P < .05). Parents felt that the proposed system would be more easily manageable, sensible, and cost-effective than the current system. Several parents were unsure of the new system's safety in a large secondary school or in schools with more than 1 building. (In a secondary school, pupils could carry their own single EAI, and the second unnamed EAI could be brought to them).

Schools were generally more equivocal about change than parents. There were no differences in school satisfaction with the current or proposed system reported by school personnel. The main reason given for lack of support was concern about a school's additional responsibility for maintenance of un-named EAI's. "[It] sounds like...taking on extra responsibility, which we would want to avoid (school respondent number 4)."

According to the most recent school population data available at the time, changing to E = n + 2 system would save £128,000 per annum in Hampshire (Table I). This calculation was made using a very conservative estimate of the number of children for whom an EAI kit might be prescribed, limiting it mainly to those with peanut allergy, for which there are local prevalence data,⁵ and allowing only a small fraction of that for all other potentially serious allergies.

Our examination of a hypothetical change in EAI provision from E = 2n to E = n + 2 was generally well received by both groups of stakeholders, with most negative comments reflecting a general anxiety about how effective any plan can be for rare medical emergencies.

Families appeared dissatisfied with the current system of E = 2n, and most parents were happy to try E = n + 2, because it meant change. Parents noted the cost of EAIs to society, whether used or unused. This parental awareness contrasts with the

TABLE I. Estimate of savings generated by switching to $E = n + 2$ mo	del of EAI provision
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	Primary/junior school	Secondary school
Total population of school children (2001)	76,996	70,616
No. of schools in Hampshire	305	77
Average no. of pupils/school	252	995
Number of children suitable for EAIs, assuming 2% prevalence of food allergy*	5	20
Average no. of EAIs needed, using $E = 2n/school$	10	40
Average no. of EAIs needed, using $E = n + 2/school$	7	22
Average no. of EAIs saved, using $E = n + 2/school$	3	18
EAI 6-month shelf-life, so number of EAIs saved/school/y	6	36
EAIs @ £28, number saved/school/y (× £28)	£168	£1008
Cost of EAIs saved/school /y \times no. of schools	£51,240	£77,616
Total savings by using $E = n + 2$ in Hampshire schools for 1 y	£128,856	

*Local prevalence of peanut allergy 1.8%⁵, and conservatively allowing 0.2% for all other food allergies and allergies to stings and so forth.

stereotyped view of these families as extremely anxious and overfocused on the medical needs of their own children rather than the nutritional and social needs of the children and their classmates. In contrast, schools were less positive, relating to training needs, institutional and personal liability, and responsibility, although some schools were positive about the option.

Even with an overall broadly positive response from parents and schools (although the proportion of schools responding was disappointing), the proposed system could not currently be put into action. This is because epinephrine is a prescription medication. However, legislation can be changed, and precedents have been set in related areas such as external automatic defibrillation.

Our study has limitations because of sampling bias. The families recruited had a high rate of having 2 EAIs available at home and at school and a lower rate of having used of EAIs to treat anaphylaxis in schools, compared with the available literature.² A lower number of schools reported experience of anaphylaxis in a student. A lower than average number of severe reactions may reflect the local availability of specialized allergy care. These findings may suggest that the life experience of children with food allergy who receive their care from a regional allergy unit⁶ is different from the life experience where such expertise is not so available.⁷

The proposed system has the potential to save the United Kingdom National Health Service a significant amount of money. Parents of children with food allergy are more sensitive to the societal cost of their children's food allergies than many people give them credit for, whereas schools mostly identified major needs for staff retraining and liability coverage if the system were to be introduced. The projected cost savings from the new model of provision could meet some of these costs.

> Laura Norton, MB^a Audrey Dunn Galvin, MA^b Jonathan O'Brien Hourihane, MD^{a,b}

From ^aChild Health, University of Southampton, United Kingdom; and ^bPediatrics and Child Health, University College Cork, Cork, Ireland, E-mail: J.Hourihane@ucc.ie.

Disclosure of potential conflict of interest: J. O. Hourihane has received speaker fees from Novartis, Numico, and Menarini; has received research funding from the European Commission; has received a project grant from the Irish Lung Foundation; has received research support from Numico plc; has served as an expert witness in an opinion case of immunodeficiency; has served as a Paediatric section board member for the European Academy of Allergology and Clinical Immunology; has served as a board member for the Clemens von Pirquet Foundation; and has received travel support from Menarini, DPC, Merck, Sharp, and Dohme. The rest of the authors have declared that they have no conflict of interest.

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Available online June 6, 2008. doi:10.1016/j.jaci.2008.04.020

Biologic IgG level in primary immunodeficiency disease: The IgG level that protects against recurrent infection

To the Editor:

The serum IgG level that protects patients with primary immunodeficiency disease (PID) against recurrent bacterial infection and bronchiectasis remains unknown, despite several decades of debate.¹⁻⁴ Existing studies are limited by small sample size, retrospective study design, and dissimilar outcome variables. Despite these laudable efforts, the serum IgG level that protects patients with PID from infection has not been determined, primarily because the optimal IgG level that prevents bronchiectasis/infection is not likely to be uniform in all patients. However, Medicare/Medicaid generated local coverage determinations for IgG replacement reimbursement in PID based on maintaining a fixed IgG trough, hereafter called level, within a narrow range (400-600 mg/dL).⁵ Thus reimbursement is allocated as if one size fits all. Although they allow for "rare" exceptions to this rule, a description of these exceptions and the documentation required to prove that higher IgG levels are needed are not provided. Thus they do not take into account the wide quantitative and qualitative serum IgG variations that are a hallmark of PID.

The 2006 review by members of the Primary Immunodeficiency Committee⁶ suggests that IgG levels should be at least more than 500 mg/dL for agammaglobulinemic patients and 300 mg/kg greater than the initial IgG level for patients with common variable immunodeficiency (CVID). Furthermore, IgG levels of greater than 500 mg/dL might reduce infection and improve clinical outcomes, and IgG levels of greater than 800 mg/ dL might "improve pulmonary outcome." These guidelines infer that different requirements for IgG exist between and within a given PID group. Thus individualizing the amount of IgG given should be the goal to improve clinical outcome, unlike what is dictated by restricted insurance reimbursement. Thus documenting clinical symptoms and serum IgG levels over time, on a caseby-case basis, should improve care and resolve reimbursement dilemmas.

Some patients with PID, such as those with CVID, can present with relatively high IgG levels (400-600 mg/dL), yet show poor qualitative function by failing to mount primary/anamnestic responses to protein or carbohydrate vaccine or both. These patients often require higher quantitative IgG levels than mandated by insurance coverage determinations⁵ to provide adequate protection. As a result, higher IgG serum levels might be required to protect these patients from recurrent sinopulmonary infections and bronchiectasis compared with those who present with lower IgG levels. Thus the goal of IgG replacement, administered intravenously or subcutaneously,' should be to identify and maintain the biologic IgG level of an individual patient with PID within the age-matched control range. We coin the term biologic IgG level to represent the minimal serum IgG level that renders a patient as disease free as possible. Because there is a wide (peak trough) variation in serum IgG levels with intravenous IgG replacement versus subcutaneous IgG infusions, it might be easier and more cost-effective to identify and maintain the IgG level at, or just above, the biologic IgG level. We recommend that physicians plot their patients' IgG levels over time against documented infections to identify the biologic IgG level, help optimize care, and address IgG reimbursement queries, should they arise (see patients A and B in Fig 1 below).