

Adherence to allergy prevention recommendations in children with a family history of asthma

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Allergen avoidance has been a major component of most programs for primary prevention of asthma and allergic diseases in childhood. As a part of the Childhood Asthma Prevention Study, families were provided with written and oral information on measures considered to be helpful in the primary prevention of allergic disease in high-risk infants. Dietary measures included advice to breastfeed for 6 months or longer, to delay the introduction of solid foods until after the infant turned 6 months of age, and to delay giving allergenic foods (egg and peanut butter) until after 12 months of age. In the active group of the randomized controlled trial aimed at reducing house dust mite (HDM) allergen levels, parents were advised to use an HDM-impermeable study mattress cover and an acaricide, to avoid sheep skins, and not to use a pillow before 12 months of age. Families received regular visits from the research nurses at 1, 3, 6, 9 and 12 months and phone calls every 6 wk. Only 43.4% of mothers were breastfeeding by 6 months and less than 20% by 12 months. The introduction of solid foods before 6 months was common, 26% by 3 months and 96% by 6 months. Adherence to infant-feeding recommendations was significantly greater in women over 30 yr of age, women who did not smoke during pregnancy, and women who had a tertiary education. Adherence to HDM reduction measures was greater than to those for infant feeding. The presence of symptoms in the form of an itchy rash by 4 wk did not significantly increase adherence. Complete adherence to infant-feeding recommendations in this intervention study of high-risk infants was low despite the provision of written information and reinforcement at home visits. In considering allergy prevention advice offered during clinical care, the likelihood of adherence is a factor which needs to be evaluated in assessing any potential benefits of allergy prevention regimens.

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Allergen avoidance has been a major component of most asthma and allergy control and prevention programs based on the principle that reducing the allergen levels might reduce the risk of allergic sensitization and hence the risk of allergic disease. Recent position statements regarding allergy prevention in children recom-

mend breastfeeding for 4–6 months and delayed introduction of solid foods, i.e., 6 months of age, while acknowledging the limitations and controversial nature of the supporting evidence (1, 2). The efficacy of house dust mite (HDM) avoidance for primary prevention is also controversial (3, 4).

The available information indicates that adherence to allergy prevention recommendations is often low. Thus, only one-third to one-fourth of the subjects adhered to general recommendations concerning egg and fish avoidance in the first years of life (5). In a trial of primary prevention of asthma even after an intervention involving two pre-natal and one post-natal visit to reinforce adherence, only 51% of the subjects complied with preventative measures, such as keeping pets outside and only 52% avoided maternal smoking (6). In the German Infant Nutritional Intervention (GINI) program, 34% of the subjects had medium to low compliance with recommendations to avoid the introduction of solid foods during the first 6 months of life (7). In many studies of allergy prevention, no information is given about the levels of adherence, and the reasons for non-adherence have not been well studied. Adherence to prevention measures is an important issue in assessing the outcome of clinical trials (7). In addition, the likelihood of adherence under 'real life' conditions should also be considered (8).

The Childhood Asthma Prevention Study (CAPS) is a randomized controlled trial for the primary prevention of asthma and allergy among high-risk infants. It was designed to measure the effectiveness of HDM allergen reduction and supplementation with omega-3 fatty acids, both separately and in combination (4). At the beginning of the trial, all parents received what were considered at the time to be standard allergy prevention recommendations on infant-feeding practices, and families in the active HDM avoidance group received advice on inhaled allergen avoidance, particularly in regard to the infant's bedding. The aim of this report was to investigate the adherence to the recommendations in the first year of the trial and to examine factors that influenced adherence to these recommendations.

Methods

Study design

Pregnant women, whose unborn children were at high risk of developing asthma because of a parent or a sibling with a current diagnosis of asthma or with frequent wheeze, were recruited from the antenatal clinics of six hospitals in Sydney, Australia. A total of 616 women agreed to participate with recruitment beginning in August 1997 and ending in January 2000. Details of the inclusion and exclusion criteria, the interventions used in the trial, and the main

outcomes have been published elsewhere (4, 9, 10).

Interventions

The families received regular visits by the research nurses at 1, 3, 6, 9 and 12 months and phone calls every 6 wk to help maintain motivation between visits. The families were asked to call the research team for extra supplies, if required, between visits. Information from current literature on infant feeding and allergen avoidance was used for the development of messages that nurses could provide to subjects to enhance adherence. The nurses also met regularly with expert consultants in order to provide a responsive approach to parental questions.

HDM avoidance intervention

In the active group, the HDM avoidance intervention involved the use of both physical and chemical methods for the reduction of HDM allergen concentrations. To encourage adherence, HDM-impermeable study mattress covers, playmats and acaricides were provided free of charge. The avoidance procedures were focused on the infant's bed and main play area as the major sites for allergen exposure during infancy. The mattress of the infant's cot or bed was covered in an allergen-impermeable cover. Parents were asked to avoid leaving soft toys in the child's bed and to avoid using sheep-skin underlays. If the child slept for more than 2 h/day in the parents' bed, a zippered impermeable mattress cover and impermeable covers on the pillows were provided for the parents' bed. A washable playmat was provided to reduce the child's contact with carpeted floors. Parents were asked to wash the child's bedding and playmats and their bedding (if the infant slept in their bed) in an acaricidal detergent Acaril® (Allergopharma, Reinbek, Germany) before birth and then every 3 months. Parents were asked to record this in a laundry diary. At each home visit, the study nurses assessed the presence of the study mattress cover and pillows on the child's bed and asked the parents whether they had washed the bedding with the acaricide.

Dietary intervention

Families in the dietary intervention groups were provided with an omega-3-rich tuna fish oil supplement (500 mg; Clover Corporation, Sydney, NSW, Australia), to add to the child's

food or formula (10). The control group received placebo supplements made of Sunola[®] oil (Clover Corporation), and was provided with polyunsaturated oils and margarines for use in food preparation.

All parents in both groups (dietary intervention and control) were asked to breastfeed as long as possible and avoid introducing solid foods before 6 months of age. Written recommendations on infant feeding and HDM allergen avoidance, which were given to the parents, are shown in Table 1. The timing of introduction of allergenic foods was assessed by a set of short questions administered at the quarterly home visits. If issues regarding infant feeding were identified by the nurses, they consulted with experts in nutrition regarding follow-up advice or referrals.

Sociodemographic information

The ages of the child's mother and father, their employment status, educational level, and smoking status during pregnancy and mother's parity were collected using a nurse-administered questionnaire when the women were 36 wk pregnant.

Information about the child, including gender, birth weight, gestational age, and admission to neonatal intensive care unit or special care nursery was obtained from the hospital record after the birth of the child.

Health history and behavior

Other variables that were collected include history of asthma, eczema, hay fever in mother, father, sibling, maternal smoking, history of allergic symptoms in the child, and ethnicity.

Infant feeding

Infant-feeding practices were assessed at each visit using a series of standard questions, which have been used in two Australian National Health Surveys (11, 12). Questions related to 'ever breastfeeding', the age of the child when breastfeeding had stopped, and the age when breast-milk substitutes and/or solid foods were first regularly given. Information on water and juice consumption was not recorded. Therefore, it was not possible to determine the rates of

Table 1. Standard allergy prevention recommendations given to Childhood Asthma Prevention Study families

Recommendation	Adherence measurement
<i>Breastfeeding</i>	
Breastfeeding is the best food for your baby and is recommended by health authorities through the first year of life.	Ever breastfed
Breast milk is the best source of nutrition for your baby and is known to protect your baby against a range of infections. There is also evidence that it may protect babies against early development of allergic diseases like asthma. Your baby needs no other foods, drinks or vitamin and mineral supplements in his/her first 4–6 months, unless prescribed by a doctor.	Breastfed at 6 months
Breastfeeding is the best food for your baby until 6 months and longer. Continuing to breastfeed provides the best nutrition and protects your baby. As your baby gets older he/she will be awake more and be more interested in what is going on around him/her. Crying or being unsettled is not always caused by hunger. If you think your baby is hungry or unsatisfied by feeds, then offer some extra breastfeeds and this will build up your supply.	
<i>Solid food/allergenic food introduction</i>	
Breast milk or formula is the most important food for your baby in the first 6 months of life. There is no need to introduce any other foods until 6 months of age and there is some evidence to suggest that delaying it until that time may reduce the risk of allergies. If you do wish to start your baby on other foods earlier, do not start before 4 months and proceed slowly. Babies should be able to sit with support and hold their head upright and firm before they start solids.	Solid food introduction at 3, 6 months
Starting foods closer to 6 months of age rather than earlier, and keeping to foods like rice, fruits and vegetables, is likely to reduce the chance of allergic reactions. If you do wish to include other foods before 6 months of age, avoid giving cow's milk (as a drink or on cereal), egg, and nuts (e.g., peanut butter).	Egg, milk, nut, cow's milk introduction at 3, 6, 9, 12 months
Delay giving egg, milk (as a drink or on cereal), and nut butters (e.g., peanut butter) until after 12 months of age, as it tends to lead to a higher prevalence of allergies when given before this.	
Cow's milk should not be introduced as a drink until after 12 months of age, as it tends to lead to a higher prevalence of allergies when given before this.	
<i>Bedding recommendations (for active group only)</i>	
Use house dust mite (HDM)-impermeable study mattress cover on child's bed. The cover is impermeable and designed to act as a barrier against dust mite allergens. The cover should be tied firmly underneath the mattress, ensuring that there are no indentations or loose sheeting. The research nurses will assist you to do this on their first visit.	Study cot cover present at 1, 3, 6, 9, 12 months
Avoid sheep skins, because they may cause overheating and can potentially hold large numbers of dust mites.	Sheepskin, pillow present at 3, 6, 9, 12 months
Do not use a pillow for your baby until he/she is at least 1-yr old.	Acaril [®] wash attended at 3, 6, 9, 12 months
Wash both your and your baby's blankets and bedding in Acaril [®] before your baby is born, then every 3 months (after the nurses have visited you).	

exclusive breastfeeding in this study. The following definitions were used, adapted from recommended national breastfeeding definitions and indicators for Australia (13). Ever breastfed infants were defined as children who had ever consumed any breast milk (even once). The duration of any breastfeeding was defined as the age, in weeks or months, that the mother reported the baby to have stopped breastfeeding. Early introduction of solid foods was defined as mother reporting regularly giving solid foods by the 3-month home visit.

Coding and statistical analysis

The prevalence of the adherence to each recommendation at each assessment was determined. To examine the factors which might be related to the adherence to infant-feeding recommendations, women were divided into two groups, those who breastfed for 6 months or more and did not feed solid food for the first 3 months (adherent group) and others who did not adhere to these recommendations (non-adherent group). Similarly, the families were divided into those that complied with specific food-allergen avoidance or HDM-reduction measures and those who did not. Univariate predictors of adherence to recommendations were determined using chi-squared tests. Multivariate predictors were determined using stepwise logistic regression analysis. Each variable was entered into the model and left in the model if it was significant or changed the odds ratio by more than 10%. Univariate and multivariate odds ratios and 95% confidence interval are reported. As a family history of asthma was one of the inclusion criteria to assess the effect of this in the model, we examined each factor separately, i.e., mother's history or father's history or sibling's history, and compared it with the rest of the group who did not have that particular history.

Data management

Microsoft Access Database 97 (database developed by CAPS), Excel 97 and SPSS (version 9.0) were used in this data analysis.

Ethical approval

Ethical approval for this study was obtained from the ethics committees of the Children's Hospital at Westmead, The South Western, Western and Central Sydney Area Health Services and the University of Sydney.

Results

Adherence to recommendations about infant feeding and HDM avoidance over the first 12 months is shown in Tables 2 and 3. Although almost 90% of the women in the study initiated breastfeeding, only 43.4% were breastfeeding by 6 months, and by 12 months, this had dropped to less than 20%. The introduction of solid foods by 3 months was relatively common (26%), and by 6 months, this figure rose to 96%. The feeding of allergenic foods was relatively uncommon in the first 6 months, and most mothers waited until after 9 months to introduce these foods.

To examine the factors which might be related to the adherence to infant-feeding recommendations, women were divided into two groups, those who breastfed for 6 months or more and did not feed solid food for the first 3 months (adherent group $n = 172/566$ or 30.4% and non-adherent group $n = 394$). Significant univariate predictors of adherence to these infant-feeding recommendations included: not smoking during pregnancy, mothers age above 30 yr at the birth of the child, tertiary education (for both parents), no pets, and Caucasian nationality. The only predictors in the final multivariate model were: no maternal smoking in pregnancy, mothers'

Table 2. Adherence to infant-feeding recommendations

Infant-feeding variable	n	N (total)	%
Ever breastfed	539	601	89.7
Duration of breastfeeding*			
1 month	388	523*	74.1
3 months	318	523	60.6
6 months	227	523	43.4
9 months	156	523	29.8
12 months	104	523	19.8
No solid foods†			
By 3 months	384	520	73.8
By 6 months	22	564	3.7
No cow's milk‡			
By 3 months	577	580	99.4
By 6 months	536	574	93.4
By 9 months	443	564	78.5
By 12 months	184	559	32.9
No egg‡			
By 3 months	578	580	98.7
By 6 months	545	574	94.7
By 9 months	448	564	79.4
By 12 months	329	559	58.9
No nuts‡			
By 3 months	579	580	99.4
By 6 months	569	574	99.1
By 9 months	526	564	93.3
By 12 months	437	559	78.2

*Ninety-three missing data on duration of breastfeeding includes those who were never breastfed (62), those who said they had breastfed but do not have data on duration of breastfeeding (16), and those who have withdrawn from the study after the antenatal visit (15).

†May include any solid foods, including fruit, vegetables, and cereals.

‡For allergenic food samples, sizes were reduced because of withdrawals or missing data from the study – at 3 months (36), 6 months (42), 9 months (52), and 12 months (57).

Table 3. Adherence to allergen-avoidance recommendations related to the children's bed (active HDM group only)

Bedding recommendation		n	N (total)	%
No pillow on bed	At 1 month	229	300	76.3
	At 3 months	206	296	69.6
	At 6 months	204	288	70.8
	At 9 months	180	282	63.8
	At 12 months	159	281	56.6
No sheep skin on bed	At 1 month	294	300	98.0
	At 3 months	290	296	98.0
	At 6 months	279	288	96.9
	At 9 months	273	282	96.8
	At 12 months	276	281	98.2
Study mattress cover	At 1 month	109	300	36.3
	At 3 months	165	296	55.7
	At 6 months	236	288	82.0
	At 9 months	255	282	90.4
	At 12 months	243	281	86.5
Acaril® wash completed	At 1 month	18	300	6.0
	At 3 months	214	296	72.3
	At 6 months	224	288	77.8
	At 9 months	241	282	85.5
	At 12 months	237	281	84.3

HDM, house dust mites.

education, and mothers aged over 30 yr. Thus, adherence to these infant-feeding recommendations was seen more often in women over age 30 yr (35.2% cf. 19.5%) than those under 30 yr (chi-squared test, $p < 0.001$), women who did not smoke during pregnancy (35.6% cf. 14.8%) (chi-squared test, $p < 0.001$), and women who had a tertiary education (41.9% cf. those who had primary 17.0% or secondary education 30.2%). Families without pets (38.1% cf. 26.3%) were also more likely (chi-squared test, $p < 0.004$) to comply with infant-feeding recommendations. A history of asthma, hay fever, eczema in mothers, fathers or siblings, the gender of the child, parity, presence of other siblings and birth length, weight, head circumference, or gestational age did not have an effect on adherence to infant-feeding recommendations.

The composite criteria for the examination of adherence included breastfeeding at 6 months or more. As there may be non-voluntary reasons for the cessation of breastfeeding, we also examined the predictors for the introduction of solid food before 3 months of age. The findings (not shown) were similar to the composite criteria; thus, women who smoked during pregnancy, were aged under 30 yr at birth of child, with no tertiary education (for both parents), and with pets, were significantly more likely to have fed solid food by 3 months. A history of asthma, hay fever, eczema in mothers, fathers or siblings did not have an effect on whether the child was fed solid food before 3 months.

Just over half (51.3%) of the parents had introduced allergenic foods (egg and/or peanut) by 12 months of age. There were no significant effects of gender, ethnicity, maternal smoking in pregnancy, mother's or father's education, siblings, pets, childcare, and a history of asthma, eczema, or hay fever in either parent or siblings on the introduction of eggs or peanut by 12 months.

We also examined the influence of an early rash on adherence to the feeding recommendations. Children who had an itchy rash at 4 wk were less likely (20.8% vs. 26.4%) to be fed solids at 3 months, but this difference was not statistically significant – either at 3 or 6 months (not shown).

With regard to the recommendations for reducing HDM in the children's beds (Table 3), adherence was high for avoidance of sheep skins, use of the mattress covers and Acaril® washes. Use of the mattress covers was low in the first month, because most infants were sleeping in bassinets or cots that were irregularly shaped and the cover did not fit. Over 70% of the families completed the Acaril® wash as directed.

A high proportion (over 30%) of infants had a pillow on the bed after 1 month of age. Families, where mothers or fathers smoked in pregnancy, were more likely to have pillows in their children's beds by 12 months. There was no effect of mother's, father's, or sibling's history of asthma, eczema, hay fever, mother's education, father's education, pet ownership, ethnicity, childcare attendance, presence of siblings, or mother's age on the presence of pillows by 12 months.

Discussion

In this study, we found that adherence was low to a number of recommended measures for allergy prevention, in particular, breastfeeding to 6 months of age, the delayed introduction of solids and allergenic foods, and the avoidance of pillows. Adherence is clearly an important issue to be considered both when assessing the possible benefits of allergy prevention measures and in evaluating the results of allergy prevention trials. There are relatively few studies examining adherence to allergy prevention measures, and in most of these, including the present one, the measures have been undertaken as a part of a trial. Some studies have provided control and intervention groups with differing information (6, 14). In the CAPS study, we provided all families in the intervention and control groups with the same dietary information, using the same educational methods and level of contact, given that the

primary aim of our trial was to study the effects of the fatty acid supplements. Thus, we did not aim to investigate the effectiveness of breastfeeding and other infant-feeding practices *per se*, by comparing these practices between groups, or to examine methods of improving adherence to allergy prevention recommendations.

Adherence to the recommendations for the duration of breastfeeding was similar to the overall rates for the state of New South Wales, in which the CAPS subjects reside (15). It is surprising that adherence to breastfeeding recommendations was not higher, given the intensity of effort to promote it. It might be expected that adherence to the aspects of the recommended regimen for allergy avoidance in this study would be higher than that seen in the general population for several reasons: (i) the families were selected on the basis of a history of asthma and for their interest and willingness to comply with the dietary and environmental measures; (ii) the families were presented with oral advice and written material concerning allergy preventative measures and written material has been shown by others to increase compliance (16); and (iii) there was regular contact with the patients by home visits (five occasions in the first year) which can improve adherence (17). This level of family contact during the first year is high as compared with other allergy prevention studies. For example, assessments of patients by physician or nurse occurred four or more times in the first 12 months of two studies (7, 14), once or twice in 12 months in three studies (6, 18, 19), and only collected retrospectively at 12 months of age in another study (5). It might be expected that a greater level of contact by research nurse home visits would lead both to better and a more accurate measure of adherence (20).

Similar to the results of other published studies, we found the adherence to dietary recommendations to be low. This occurred particularly after 6 months of age with respect to highly allergenic foods, such as egg and cow's milk. Nearly all families (96%) had introduced solid foods by 6 months of age. By 3 months of age, 26% of the infants had received solids despite an additional specific recommendation not to start before 4 months. In the prevention of asthma in children (PREVASC) study, 29% of the subjects introduced solid food before 6 months of life (6). In the GINI program, parents received detailed recommendations on the infant's nutrition in a verbal and written form. Mothers were encouraged to breastfeed as long as possible. Potentially allergenic foods,

such as cow's milk and dairy products, eggs, fish, tomatoes, nuts, soya products, and citrus fruits were to be avoided during the first year. At 20 wk, 74% had adhered to solid-food recommendations (7). Adherence to solid-food recommendations was greater in the group which successfully breastfed (21). In the study by Chan-Yeung et al. of high-risk infants, 20% of the intervention group received solids before 6 months despite contrary advice compared with 50% of the control group, which were not given such advice (14). Van Odijk et al. found that only 33% of the parents avoided giving their child fish and 23% avoided egg during the first year even though these measures had been recommended (5). These findings are in contrast with those of the Study on the Prevention of Allergy in Children in Europe (SPACE) study, where 96.3% of the subjects avoided egg and 100% milk in the first year (18). The reasons for the differences are not apparent; however, the SPACE involved children in three different countries with variable modes of contact at 6 months of age and person-to-person contact only at 12 months.

It is of interest that the early appearance of atopic manifestations, such as skin rash, did not produce significantly increased adherence to the dietary recommendations. Similarly, a family history of asthma, hay fever, eczema in mothers, fathers or siblings did not have an effect on whether the child was fed solid food before 3 months. The lack of a significant effect of a family history on adherence may be because a family history of asthma was a criterion for study entry. However, other indicators, such as eczema or hay fever in either the parents or siblings, were also not associated with increased adherence.

In the active HDM avoidance group, adherence to the recommended measures for HDM reduction, apart from the instruction to avoid pillows before 12 months, was higher than that for infant feeding. Our finding that <5% of infants had a sheep skin on their bedding is comparable with 23% in another cohort in a different Australian State, Tasmania, where no specific instructions regarding avoidance were provided (22). This difference may be attributed to the specific instruction to avoid sheep skins in the present study; however, the influence of a different socioeconomic stratification and a cooler climate in the Tasmanian group cannot be discounted. Adherence regarding the use of mattress covers was relatively high (>80% from 6 to 12 months), which is consistent with the finding of Halmerbauer et al. that the average time of mattress cover use was >85% of the

children's sleeping time (18), and that of Chan-Yeung et al., where >90% of the subjects complied with bedding covers and acaricide application over 12 months (14). At 4 yr of age in the prevention and incidence of asthma and mite allergy (PIAMA) study, there was still 87% adherence with mattress cover use (23). The most common reason reported for non-adherence to HDM control measures was the cost of the bedding covers (24). In our study, the covers were provided free of charge, so that adherence is likely to be significantly greater than if the cost were borne by the parents. Our dust mite reduction measures also involved active undertakings, such as the acaricide wash on a three monthly basis, which was completed in about 85% of the cohort at 9 and 12 months. In general, the measures recommended for HDM elimination are less intrusive and onerous than some of the infant-feeding measures, which may have contributed to the generally greater adherence.

Few studies have examined factors associated with non-adherence to recommendations for allergy prevention. Interestingly, the development of early signs of atopy in the form of a rash by 4 wk of age was not associated with significantly greater adherence to the infant-feeding recommendations at 3 or 6 months. In this study and others which have investigated the question, characteristics associated with reduced adherence include younger maternal age, lower educational or social class and maternal smoking (7, 25). Halken in an infant dietary trial observed that those infants who were exclusively breastfed were significantly less exposed to tobacco smoke and pets, had solid foods introduced later, and belonged to higher social classes (26). These observations suggest that if an effective regime were available for preventing allergic disease, families with these characteristics might require increased efforts to promote adherence.

There is a surfeit of advice concerning allergy prevention. In 2004, there were an estimated 424 thousand internet sites offering advice for allergy prevention (27), which had increased in 2007 to 1.38 million (personal observation). There is considerable controversy over the effectiveness of allergy prevention recommendations with questioning of previously accepted measures, such as prolongation of breastfeeding and delayed introduction of allergenic and solid foods (28–30). The CAPS study HDM reduction measures, although successful in reducing the levels, did not result in reduced sensitization or allergic disease (4). The cost of such programs and the apparent lack of a significant clinical

effect have led researchers to question the utility of primary prevention based on a principle of reduction of allergen exposure (27). In considering community-based allergy prevention programs, the likelihood of adherence to the proposed measures is also a factor which needs to be evaluated in assessing any benefits.

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