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Improving timely access to food allergy care: a pragmatic controlled trial

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Statement of contribution:

HH, KL, MLKT, participated in the concept and design of the study, analysis and interpretation of data; drafting and reviewing the manuscript; critically reviewing the manuscript for important intellectual content. PP participated in collecting the data; analysis and interpretation of data; drafting and reviewing the manuscript. RP, SS, JM, CS participated in collecting the data; analysis and interpretation of data; reviewing the manuscript. MHD, VS participated in the concept and design of the study, analysis and

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To the editor,

As rates of food allergy rise, specialist allergy services struggle to manage demand,¹ and waiting times to access such services increase.² In many regions, allergy care is primarily delivered by allergists, due to limited allergy training opportunities for general pediatricians and primary care physicians. At The Royal Children's Hospital (RCH), Melbourne, Australia, children referred to the Department of Allergy and Immunology for suspected food allergy wait around 12 months (with the exception of patients with anaphylaxis or aged under one who are seen sooner).³

The diagnosis of food allergy relies on clinical history together with demonstration of allergen specific IgE (sIgE). sIgE may be detected by skin prick test or serum levels of sIgE (ssIgE) and both are applied in the clinical setting, either alone or together.⁴ Recent data have confirmed the reliability of ssIgE testing for the diagnosis of food allergies, paving the way for a decentralized model of care.⁵ In 2011/12, our team developed and piloted a Clinical Decision Support program to upskill community general pediatricians in the diagnosis and management of simple food allergy using ssIgE testing. Pediatricians who completed our training course were able to manage 80% of children independently without referral to an allergist..⁶

We have now conducted a large, pragmatic, controlled trial to determine whether the community-based model of care can reduce time to assessment compared with standard specialist hospital-based care and deliver care that is of comparable safety and quality.

In this pragmatic controlled trial which commenced in 2015, we compared a Control Cohort (CC) with an Intervention Cohort (IC). CC families received standard hospital-based care at the RCH Allergy Clinic and IC families were offered the opportunity to see a community-based general pediatrician who had completed the online Clinical Decision Support training program. IC families who elected not to take up an appointment remained in the IC for analysis and received standard hospital-based care and are still considered as part of the IC. . Children aged 0-12 years newly referred to the RCH Allergy Clinic with suspected food

allergy were eligible. Training included three one-hour webinars, with specific guidance on when to test for simple food allergy using ssIgE testing, management of IgE and non-IgE mediated food allergy and eczema in the context of suspected/known food allergy, and provision of allergy resources and management plans if appropriate. The accompanying online Clinical Decision Support program consisted of two flowcharts (one each for IgE and non-IgE mediated food allergy) which covered nine key practice parameters common to published international guidelines.⁷⁻⁹

Supplementary Table 1 summarizes trial outcome measures. The primary outcome was time to assessment. Secondary outcomes included safety of care as defined by the occurrence of anaphylactic and non-anaphylactic reactions to food, parent satisfaction with care, food allergy-quality of life questionnaire (FAQLQ), quality of care delivered by the clinician (assessed as consistent or inconsistent care based on published guidelines, see Supplementary Table 2 for definitions), and family acceptability of the model as measured by uptake of general pediatrician appointment (IC only). Analyses of primary and secondary outcomes were conducted using an intention-to-treat (ITT). Per protocol (PP) analyses are presented in the Supplementary materials. The study was approved by the RCH Human Research Ethics Committee (HREC 35133). All families provided consent.

115 of 192 IC (60%) indicated they wanted to take-up the community-based model of care with 93 of these (81%) doing so by 12 months. Of the 181 in the CC, 54 (28%) saw a hospital allergist by 12 months, 108 (60%) had not received an appointment at 12 months, and 19 had an appointment scheduled but failed to attend (11%) (Figure 1a). 26 of 47 general pediatricians approached, completed training. Child characteristics were similar in the two cohorts (Supplementary Table 3).

The median time to assessment was 2.4 months in the IC compared to 12 months in the CC (adjusted HR=1.61, 95% CI 1.04-2.49, p=0.03, Figure 1b). There was no difference between the IC and CC in terms of time from triage of referral to trial enrolment.

IC children reported fewer non-anaphylaxis adverse events within 12 months compared to children in the CC (median [IQR] 0 [0, 4] vs 1 [0, 8]; IRR= 0.57 (95% CI 0.42, 0.77); Table 1a). At 6 months, within the CC, five children had one, one child had two and one child had three anaphylaxis reactions. In the IC, six children had one, two children had

two and one child had three anaphylaxis reactions. At 12 months, six children had one in both the CC and IC and one child in the IC had two anaphylaxis reactions. IC families were more satisfied with the overall process compared to CC families at both 6 and 12 months (Table 1a). At 12 months, IC families reported less food allergy-related anxiety but more food related social and dietary limitations compared with CC families (Table 1a).

IC families were more satisfied with “physician communication with parent” than CC families, whilst CC families were more satisfied with the hospital allergist’s “distress relief” (Table 1b). There was little evidence of a difference between cohorts in the proportion of children receiving major and minor inconsistencies in care (Table 1b). Results were similar in PP analyses.

This is the first study to evaluate a community-based model of care for simple childhood food allergy (the IC) compared with hospital-based allergy care (the CC). This pragmatic trial shows that a community-based model of food allergy care, delivered by trained pediatricians, results in faster time to assessment, is acceptable to families, safe and of similar quality. Ensuring the training programme included family education and counselling could have contributed to high parent satisfaction and low accidental anaphylaxis. Some inconsistencies in care may reflect gaps in evidence as to best practice and future research should address these gaps. A study strength is that the majority (63%) of those seen by a general pediatrician were managed in the community, freeing up hospital resources. Implementing such a community-based model could improve access to care for children with less complex food allergy.

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Table 1a: Summary and comparison of secondary outcomes at 6- and 12-months post enrolment by intervention group from the intention to treat analysis

	6 months post-enrolment				12 months post-enrolment			
	Control Cohort	Intervention Cohort			Control Cohort	Intervention Cohort		
No. food related adverse events per child in past 6 months	Median (IQR) [range]	Median (IQR) [range]	Incidence rate ratio (95% CI)	p	Median (IQR) [range]	Median (IQR) [range]	Incidence rate ratio (95% CI)	p
Anaphylaxis	0 (0, 0) [0, 3]	0 (0, 0) [0, 3]	1.03 (0.45, 2.37)	0.95	0 (0, 0) [0, 1]	0 (0, 0) [0, 2]	1.01 (0.35, 2.95)	0.98
Non-anaphylaxis	1 (0, 1) [0, 5]	0 (0, 1) [0, 4]	0.84 (0.63, 1.14)	0.23	1 (0, 1) [0, 8]	0 (0, 1) [0, 4]	0.57 (0.42, 0.77)	<0.001
	Mean difference				Mean difference			
	Mean, SD	Mean, SD	(95% CI)	p	Mean, SD	Mean, SD	(95% CI)	p
Satisfaction with overall process	2.69 (1.75) [†]	3.57 (1.75) [‡]	0.06 (0.02, 0.09)	0.001	2.69 (1.80) [§]	3.60 (1.74) [¶]	0.65 (0.59, 0.71)	<0.001
FAQLQ-PF domains								
Food anxiety	1.57 (1.64) [†]	1.65 (1.73) [‡]	-0.01 (-0.18, 0.16)	0.90	1.80 (1.79) [§]	1.67 (1.84) [¶]	-0.29 (-0.50, -0.08)	0.01

	6 months post-enrolment				12 months post-enrolment			
	Control Cohort	Intervention Cohort			Control Cohort	Intervention Cohort		
No. food related adverse events per child in past 6 months	Median (IQR) [range]	Median (IQR) [range]	Incidence rate ratio (95% CI)	p	Median (IQR) [range]	Median (IQR) [range]	Incidence rate ratio (95% CI)	p
Social & dietary limitations	1.62 (1.40) [†]	1.66 (1.61) [‡]	-0.03 (-0.22, 0.16)	0.75	1.60 (1.45) [§]	1.72 (1.69) [¶]	0.15 (0.12, 0.19)	<0.001

All analyses adjusted for child age in months, family SES (SEIFA), baseline number of foods reacted to, number of atopic conditions and clustering by health professional,.

IQR = inter quartile range, CI = confidence interval. FAQLQ-PF; Food Allergy Quality of Life Questionnaire– Parent form.

[†] Sample size range: n= 129-152; [‡] Sample size range: n= 163-173; [§] Sample size range: n=123-145 [¶] Sample size range: n=148-167

Table 1b: Summary and comparison of consultation outcomes between the intervention groups from the intention to treat analysis

Outcome	Control Cohort	Intervention Cohort		
	Mean (SD)	Mean (SD)	Mean Diff (95% CI)	p
Parent satisfaction with care				
PMISS (n=277[†])				
Physician communication with parent	5.58 (1.18)	5.95 (1.04)	0.39 (0.19, 0.58)	<0.001
Distress relief	5.86 (1.02)	5.65 (1.06)	-0.16 (-0.30, -0.02)	0.03
Adherence intent	5.63 (1.01)	5.81 (1.02)	0.21 (-0.01, 0.43)	0.06
Clinician quality of care[‡]	N (%)	N (%)	OR[§] (95% CI)	p
In children with one or more non-IgE mediated allergy (n=12):	N=5	N=7		
Major inconsistencies	3 (60)	1 (14)	0.21 (0.01, 6.61)	0.37
Minor inconsistencies	5 (100)	3 (43)	1 [¶]	-
In children with one or more IgE				

Outcome	Control Cohort	Intervention Cohort		
mediated allergy (n=222):	N=94	N=128		
Major inconsistencies	31 (33.0)	55 (43.0)	1.06 (0.44, 2.55)	0.90
Minor inconsistencies	40 (42.6)	40 (31.3)	0.66 (0.31, 1.38)	0.27
In children with no allergy (n=20):				
	N=10	N=10		
Major inconsistencies	1 (10)	1 (10)	0.17 (0, 182.9) [#]	0.62
Minor inconsistencies	0 (0)	0 (0)	-	-

[†] Number of patients who had a consultation.

^{*} One child had both an IgE and non-IgE mediated food allergy

[§] Odds ratio for having that type of inconsistency in the intervention compared with the control cohort.

[¶] OR could not be calculated because all the patients in the control cohort had the event.

[#] Analysis conducted without allowing for number of excluded foods due to the sparsity of the data.

Analyses (except where stated) adjusted for child age in months, family SES (SEIFA), baseline number of foods reacted to and number of atopic conditions, and clustering by health professional. For more information on the PMISS scale please see Supplementary Table 1. OR, odds ratio; CI, confidence interval; PMISS, Parent Medical Interview Satisfaction Scale.

Figure 1a: Flowchart of participant

[†] of these 192, 77 chose to remain on the RCH WL and see a RCH allergist. [‡] PP excludes CC families who withdrew, were removed from the waiting list and cancelled or did not attend their appointments and IC families who chose not to see a community pediatrician or did not attend their appointment with the community pediatrician. [§]115 of 192 IC families took up the model. [¶]77 of the 192 IC families chose to remain on the RCH wait list.

Of the 93 children seen by a community pediatrician, 34 (37%) were referred back to the hospital for reasons including oral food challenge (n=19), possible anaphylaxis (n=6), SPT required (n=4) or other (n=5). Of the 19 referred for an oral food challenge, 7 (41%) were thought to need an oral food challenge by an RCH allergist.

The most substantial reasons for “Did not meet inclusion criteria” (n=487) were:

- children referred with more than three suspected allergic foods;
- known or suspected anaphylaxis (based on referral letter or parent report at study intake interview); or
- referred by a paediatrician for specialist allergy opinion

Abbreviations: PP, Per protocol; ITT, Intention to treat; RCH, Royal Children’s Hospital.

Figure 1b: Kaplan Meier curves for time to assessment (primary outcome) for the intention-to-treat (ITT) population[†]

[†]censoring participants who were not seen by 12 months at 12 months

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