

1 **ONLINE SUPPLEMENT:**

2
3 **Factors Associated with Asthma Exacerbations During a Long-term Clinical Trial**
4 **of Controller Medications in Children**

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18
19 **Supported by:**

20 Grants 5U10HL064287, 5U10HL064288, 5U10HL064295, 5U10HL064307, 5U10HL064305,
21 5U10HL064313 from the National Heart, Lung, and Blood Institute; General Clinical Research
22 Centers at Washington University School of Medicine (M01 RR00036) and National Jewish
23 Medical and Research Center (M01 RR00051).

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36 **eFigure legend:**

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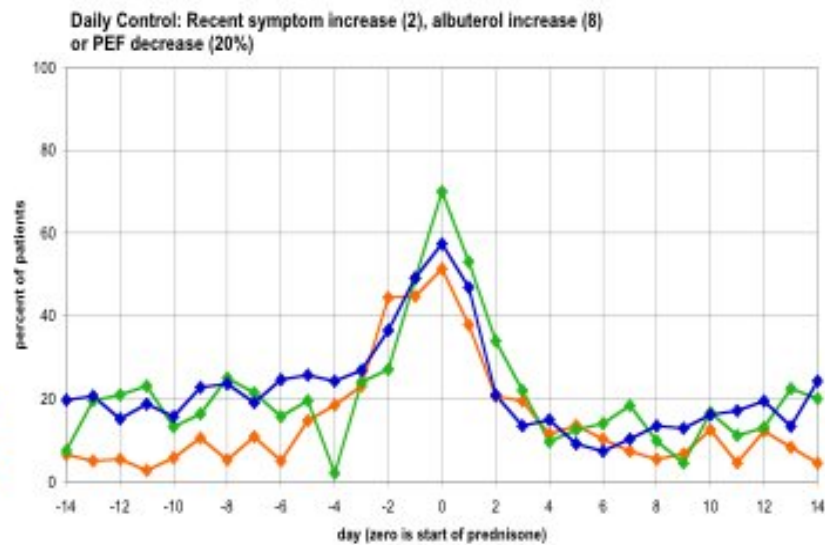
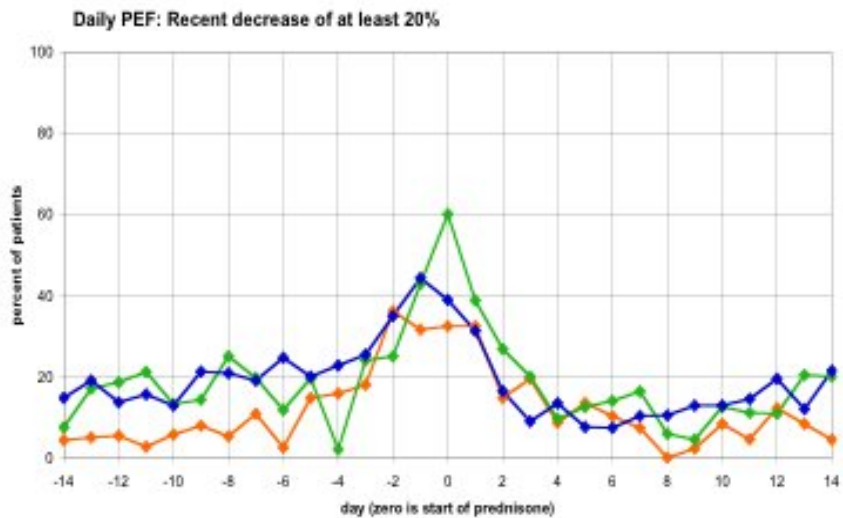
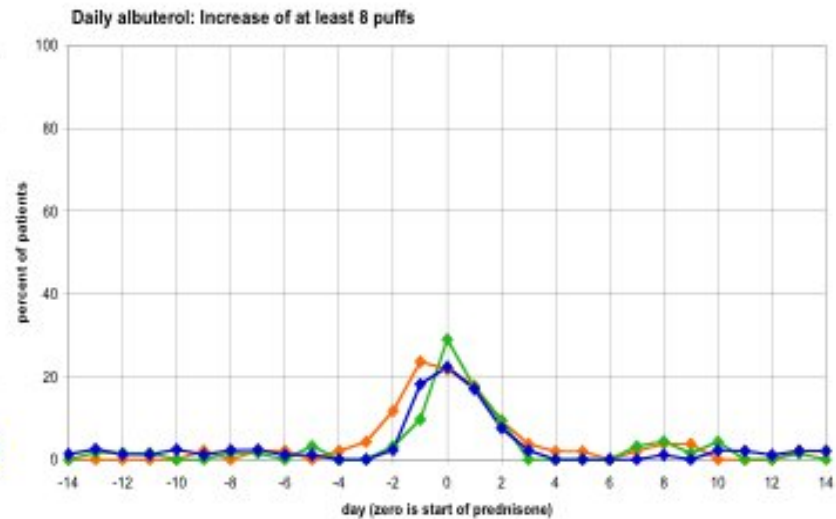
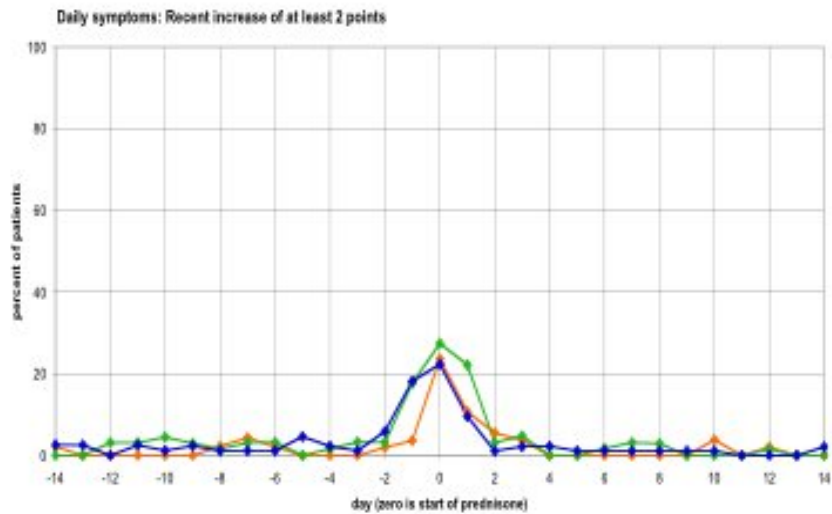
38 eFigure 1: Sensitivity values expressed as percentages of participants in the different treatment

39 groups (— montelukast, — PACT combination, and — FP monotherapy) reporting any of or

40 combination of the following “recent” changes: (a) symptoms (i.e. 2 point increase); (b)

41 albuterol use (at least 8 inhalations per day of the exacerbations; (c) PEF (20% reduction); d)

42 any of the three changes.



44 **eTable 1:** Sensitivity and specificity values of diary card documented changes in the Pediatric Asthma Controller Trial (PACT) indicative of 20%
 45 reduction in peak expiratory flow (PEF) , a 2-level increase in symptom severity score, and albuterol use of 8 inhalations within a 24 hour period

day	Montelukast				PACT combination				FP monotherapy			
	Symptoms	Albuterol rescue use	PEF change	overall	Symptoms	Albuterol rescue use	PEF change	overall	Symptoms	Albuterol rescue use	PEF change	overall
-14	3	1	15	20	0	0	8	8	2	0	4	7
-13	3	3	19	21	0	2	17	20	0	0	5	5
-12	0	1	14	15	3	2	19	21	0	0	5	5
-11	3	1	16	19	3	2	21	23	0	0	3	3
-10	1	2	13	16	4	0	13	13	0	0	6	6
-9	2	1	21	23	3	0	14	16	0	2	8	11
-8	1	2	21	24	2	2	25	25	2	0	5	5
-7	1	2	19	19	3	2	20	21	4	2	11	11
-6	1	1	25	25	3	0	12	16	2	2	3	5
-5	5	1	20	26	0	3	20	20	0	0	15	15
-4	2	0	23	24	2	0	2	2	0	2	16	18
-3	1	0	25	27	3	0	24	24	0	4	18	23
-2	6	2	35	37	3	3	25	27	2	12	36	44
-1	18	18	44	49	18	10	43	49	4	24	32	45
0	22	22	39	57	27	29	60	70	24	22	32	51
1	10	17	31	47	22	17	39	53	11	18	32	38
2	1	8	16	21	3	10	27	34	6	9	15	21
3	2	2	9	13	5	0	20	22	4	4	19	19
4	2	0	13	15	0	0	10	10	0	2	9	11
5	1	0	8	9	0	0	13	13	0	2	14	14
6	1	0	7	7	2	0	14	14	0	0	10	10
7	1	0	10	10	3	3	16	18	0	2	7	7
8	1	1	10	13	3	4	6	10	0	4	0	5
9	1	0	13	13	0	2	4	4	0	4	2	7
10	1	2	13	16	0	4	13	17	4	0	8	13
11	0	2	14	17	0	0	11	11	0	0	5	5
12	0	1	19	19	1	0	11	13	2	0	12	12
13	0	2	12	13	0	1	20	22	0	2	8	8
14	2	2	21	24	0	0	20	20	0	2	4	4
SPECIFICITY*	99	100	88	88	99	100	88	87	99	100	91	91

46 *Using data from participants who did not have an exacerbation in the trial

47 **eTable 2:** Positive predictive values of diary card documented changes in the Pediatric Asthma Controller Trial (PACT) indicative of
 48 20% reduction in peak expiratory flow (PEF), a 2-level increase in symptom severity score, and albuterol use of 8 inhalations within a
 49 24 hour period

day	Montelukast				PACT combination				FP monotherapy			
	Symptoms	Albuterol rescue use	PEF change	overall	Symptoms	Albuterol rescue use	PEF change	overall	Symptoms	Albuterol rescue use	PEF change	overall
-14	2	1	13	17	0	0	7	7	2	0	4	6
-13	2	2	17	18	0	2	15	17	0	0	5	5
-12	0	1	12	14	3	1	16	18	0	0	5	5
-11	2	1	14	17	3	1	18	20	0	0	3	3
-10	1	2	12	14	4	0	12	12	0	0	5	5
-9	2	1	18	19	3	0	13	15	0	2	7	10
-8	1	2	18	20	1	1	21	21	2	0	5	5
-7	1	2	17	17	3	1	17	18	4	2	10	10
-6	1	1	20	21	3	0	11	14	2	2	2	5
-5	4	1	17	21	0	3	17	17	0	0	13	13
-4	2	0	19	20	1	0	2	2	0	2	14	16
-3	1	0	21	22	3	0	20	20	0	4	15	19
-2	5	2	27	28	3	3	21	22	2	10	27	31
-1	14	14	32	34	14	8	31	34	3	18	24	31
0	17	17	29	38	20	21	39	42	18	17	25	34
1	8	14	25	33	17	14	29	36	9	14	25	28
2	1	7	15	18	3	8	22	26	5	8	13	17
3	2	2	9	12	4	0	17	19	3	3	16	17
4	2	0	12	14	0	0	9	9	0	2	8	10
5	1	0	7	9	0	0	12	12	0	2	12	12
6	1	0	7	7	2	0	13	13	0	0	9	9
7	1	0	10	10	3	3	15	16	0	2	7	7
8	1	1	10	12	3	4	6	9	0	3	0	5
9	1	0	12	12	0	1	4	4	0	3	2	6
10	1	2	12	15	0	4	12	15	3	0	8	11
11	0	2	13	15	0	0	10	10	0	0	4	4
12	0	1	17	17	1	0	10	12	2	0	11	11
13	0	2	11	12	0	1	18	19	0	2	8	8
14	2	2	18	20	0	0	17	17	0	2	4	4

52 **eTable 3:** Negative predictive values of diary card documented changes in the Pediatric Asthma Controller Trial (PACT) indicative of
 53 20% reduction in peak expiratory flow (PEF), a 2-level increase in symptom severity score, and albuterol use of 8 inhalations within a
 54 24 hour period

day	Montelukast				PACT combination				FP monotherapy			
	Symptoms	Albuterol rescue use	PEF change	overall	Symptoms	Albuterol rescue use	PEF change	overall	Symptoms	Albuterol rescue use	PEF change	overall
-14	52	52	53	54	52	52	51	51	52	52	51	51
-13	52	53	54	54	52	52	54	54	52	52	51	51
-12	52	52	53	53	53	52	54	55	52	52	51	51
-11	52	52	53	54	53	52	55	55	52	52	50	50
-10	52	52	52	53	53	52	52	52	52	52	51	51
-9	52	52	55	55	53	52	53	53	52	52	52	52
-8	52	52	55	55	52	52	56	56	52	52	51	51
-7	52	52	54	54	53	52	54	55	53	52	53	52
-6	52	52	56	56	53	52	52	53	52	52	50	51
-5	53	52	54	56	52	53	54	54	52	52	54	54
-4	52	52	55	56	52	52	49	49	52	52	54	55
-3	52	52	56	56	53	52	56	55	52	53	55	56
-2	53	52	59	60	53	53	56	57	52	55	61	64
-1	57	57	63	65	57	54	63	65	53	59	59	64
0	58	58	61	69	60	60	70	76	58	58	59	67
1	54	57	58	64	58	57	61	67	55	57	59	61
2	52	54	53	55	53	54	57	59	53	54	54	55
3	52	52	51	52	53	52	54	55	53	53	55	55
4	52	52	52	53	52	52	51	51	52	52	52	53
5	52	52	51	51	52	52	52	52	52	52	53	53
6	52	52	51	51	52	52	53	52	52	52	52	52
7	52	52	52	51	53	53	53	54	52	52	52	51
8	52	52	52	52	53	53	50	51	52	53	50	51
9	52	52	52	52	52	52	50	50	52	53	50	51
10	52	52	52	53	52	53	52	53	53	52	52	53
11	52	52	53	53	52	52	52	52	52	52	51	51
12	52	52	54	54	52	52	52	52	52	52	53	53
13	52	52	52	52	52	52	55	55	52	52	52	52
14	52	52	55	56	52	52	54	54	52	52	51	51