AD_____

Award Number: DAMD17-02-1-0182

TITLE: Call-Center Based Disease Management of Pediatric Asthmatics

PRINCIPAL INVESTIGATOR: James M. Quinn, M.D.

CONTRACTING ORGANIZATION: The Geneva Foundation
Tacoma, Washington 98405

REPORT DATE: April 2006

TYPE OF REPORT: Final

PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

DISTRIBUTION STATEMENT: Approved for Public Release;
Distribution Unlimited

REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 0704-0188

1. REPORT DATE *(DD-MM-YYYY)*	**2. REPORT TYPE**	**3. DATES COVERED** *(From - To)*
01-04-2006	Final	15 Mar 2002 – 14 Mar 2006

4. TITLE AND SUBTITLE

Call-Center Based Disease Management of Pediatric Asthmatics

5a. CONTRACT NUMBER

5b. GRANT NUMBER
DAMD17-02-1-0182

5c. PROGRAM ELEMENT NUMBER

6. AUTHOR(S)

James M. Quinn, M.D.

E-Mail: james.quinn@lackland.af.mil

5d. PROJECT NUMBER

5e. TASK NUMBER

5f. WORK UNIT NUMBER

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)

The Geneva Foundation
Tacoma, Washington 98405

8. PERFORMING ORGANIZATION REPORT NUMBER

9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)
U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

10. SPONSOR/MONITOR'S ACRONYM(S)

11. SPONSOR/MONITOR'S REPORT NUMBER(S)

12. DISTRIBUTION / AVAILABILITY STATEMENT
Approved for Public Release; Distribution Unlimited

13. SUPPLEMENTARY NOTES

14. ABSTRACT

There are no population based prospective randomized controlled trials comparing exclusive telephonic disease management in pediatric asthma. Objective: Determine the effectiveness of exclusively telephonic disease management on a population of pediatric military family members. Primary endpoints were patient and caregiver quality of life (QOL), inhaled short acting beta agonist use, pulmonary function (FEV1), and healthcare utilization and costs. Methods: Patients were enrolled at three DoD military treatment facilities in a similar geographic region. There control group received usual care compared with an intervention group that received a remote call-based asthma disease management program utilizing proactive education and monitoring in a series of pre-determined calls in conjunction with a 24/7 help/advice line. Comparisons were made for time 0, 6, and 12 months for QOL and FEV1 while medication use, healthcare utilization and costs were compared for the 12 month period pre-enrollment vs the 12 month of the study period. Data was analyzed as intention to treat via a three-factor ANOVA (treatment, entry severity, time). Results: A total of 452 patients were enrolled, 222 control and 230 intervention. While there were significant differences among the variables with regard to severity and over time, there were no significant effects between the intervention and control groups. Conclusions: There is no evidence that exclusively telephonic disease management improved outcomes in pediatric military family members over usual care.

15. SUBJECT TERMS
Pediatric asthma, disease management, military health services

16. SECURITY CLASSIFICATION OF:			**17. LIMITATION OF ABSTRACT**	**18. NUMBER OF PAGES**	**19a. NAME OF RESPONSIBLE PERSON**
a. REPORT	**b. ABSTRACT**	**c. THIS PAGE**			USAMRMC
U	U	U	UU	23	**19b. TELEPHONE NUMBER** *(include area code)*

Table of Contents

Introduction

Background: Call-center based disease management programs (CBDMP) are used in the commercial healthcare industry, however, they have not been utilized in the Military Health System (MHS). They provide population based proactive education and monitoring for specific disease states. Patients are educated and empowered to seek treatment according to nationally accepted guidelines for their particular condition. Asthma is the number one reason for childhood hospitalizations in the MHS, has a significant impact on missed school days, and impacts duty restrictions for asthmatic child caregivers. This study conducted a benefit analysis of an alternative disease management (DM) process that could be easily adapted and applied for wide distribution throughout the DoD without need of added personnel and on-site resources at Military Medical Treatment Facilities.

Objective/Hypothesis: That a CBDMP, applied to asthma, will:

- Improve patient and caregiver quality of life (QOL)
- Reduce disease severity, as measured by reduced inhaled short acting beta agonist use
- Improve patient condition as measured by spirometry (FEV1)
- Reduce Emergency Department (ED) visits and hospital admissions

Specific Aims: This study will measure the impact of CBDMP, which promotes patient education and empowerment, on multiple factors to include; patient/caregiver quality of life, FEV1, and utilization of MHS and MCSC healthcare resources. The study will assess the impact on an asthmatic population randomly selected from three military TRICARE Prime communities, to see if CBDMP improves patient outcomes compared to a control group selected from the same three communities. It will also quantify cost savings/avoidance as a result of such programs.

Body

THE ORIGINAL APPROVED STATEMENT OF WORK APPEARS IN BLACK. TEXT IN *ITALICS* DESCRIBES THE ACCOMPLISHMENTS ASSOCIATED WITH EACH TASK.

STATEMENT OF WORK

All dates are from the time of grant acceptance. Assuming grant funds are not delayed.

Months 1-3: **IRB review and approval, coordinate with Geneva Foundation for establishment of trust fund and trust fund disbursements processes. (Geneva has already agreed to be the trust agent). Purchase PC for study coordinator, prepare statement of work for DM firm bids.**

IRB approval was obtained. The Geneva Foundation established the trust and distributed funds as requested. The study coordinators received computers. The statement of work for the Disease Management (DM) firm was completed

Month 3: **Geneva to hire program administrator, offer DM statement of work for DM for bid, identify asthmatics in three study locations. Purchase peak flow meters. Prepare and reproduce patient education materials, and informed consent work sheets. Contract Oracle data base administrator to establish database for research data collection. Contract peak flow meter data collection web site support**.

The program administrator and site coordinators were hired. The DM statement of work was put out for bid. Asthmatics in the three study locations were identified. Electronic peak flow meters were purchased. Patient education materials and informed consent documents were reproduced. A web-based Oracle data-base was determined to be both prohibitively expensive and in peril of violating at the time existing standards of privacy and systems security within the DoD computer systems and would with near certainty violate the evolving HIPPA and DoD systems security as identified at the time. An in-house security/privacy compliant Microsoft Access Database was created for research data collection. The company utilizing web based site support for peak flow meters went out of business. The peak flow company contracted was able to support electronic data transmission but not web based support.

Months 2 – 4: **Receive bids, select DM firm. Geneva to arrange for 1 additional study assistant to help with initiation of study, material distribution, and study participant recruitment and education. Coordinate data exchanges with DM firm and research group. Potential study population identified from available military and Foundation Health databases. Establish research database at Tricare Southwest. Travel to DM firm to make arrangement for rollout and data integration. Travel to study location to educate providers about the program that their patients may be randomly selected to enter.**

Bids were received and a DM firm was selected – National Jewish Medical and Research Center. The Geneva Foundation hired a coordinator at each site after approval and additional funding from PRMRP. Data exchange was coordinated with the DM firm. The potential study population was identified via military and Foundation Health databases. Tricare Southwest established a research database. Travel to the DM firm, arrangement for rollout and data integration was accomplished. Travel to the study sites with rollout education was accomplished.

Months 1 - 12: **PI visit to Texoma for brief provider education. Contact study participants, describe study and consent documents. Collect informed consents. Basic educational material and spirometer to all study participants. Collect baseline information and QOL. Randomized subjects to control or intervention group. Begin CBDMP support**

Principle Investigator (PI) visit to Texoma for provider education and rollout was accomplished. Study participants were contacted and enrolled. Informed consents were signed and collected. Enrollment began in January 2003 and closed in December 2003 with 452 total patients enrolled. Educational materials were given to all participants. In order comply with national guidelines; the protocol was amended with IRB approval to distribute peak flow meters only to patients with persistent asthma (mild persistent, moderate persistent, severe persistent) and to defer peak flow distribution to mild intermittent asthmatics unless requested by any patient's healthcare provider. Anticipated savings and an IRB approved amendment allowed the purchase of a spirometer for each site to measure FEV1. Baseline QOL information was obtained. Patients were randomized and the DM firm iplimented call-based disease management.

Months 1 – 24: **Collect retrospective MCSC claims, CHCS encounter and medication on all study participants in both the intervention and control groups as they enter and continue with the program. DM intervention and prospective data collection begins. Data collection/enrollment will be for 12 consecutive months. Data transferred from DM firm and entered into research database. Research assistants to contact control groups and collect data every 6 months (QOL). Conduct patient satisfaction surveys for the intervention group when they complete the study. Make quality assurance visit to DM firm and study office in Texoma**

To standardize the process of analysis and improve efficiency, claims, pharmacy, and provider visit analysis were decided to be done at completion of the study for individual patients looking back two years (with separation of year one vs year two) rather than analysis at enrollment looking back one year and at completion looking back one year. Our study staff at the TRICARE lead agent pulled interim data and to test the quality and format of the data in the fall of 2004. Formatting and availability of some of the data were incomplete but much of the data pulled was adequate and accurate and entered into the database. In late 2004, the TRICARE leadagent for region VI ceased to exist in the rollover to the new TRICARE central region organizational structure. Another data pull was accomplished but its formatting and content made it largely unusable. With the disappearance of TRICARE region VI we lost the personnel in that office supporting our grant. We worked over the ensuing months to attempt to resurrect usable data from the final pull as well as to find the source and get permission to access the claims and central pharmacy data that used to reside with region VI. Initialyl our efforts were not productive as access was limited and prioritized, while we were acknowledged permission we were initially prioritized very low on a long list. We had monies remaining to support contracting help with final data acquisition and analysis and were granted a one-year no-cost extension for that purpose. DM intervention was completed and we closed all three sites and brought the original CRF records and data to our central location. Interim quality assurance visits to DM firm (June 2003) and to sites in Texoma (June 2003, October 2003, June 2004, November 2004, June 2005) were accomplished. Finally in the February and March of 2006, TRICARE was able to support our request for data pull for drug utilization, healthcare utilization, and healthcare cost for the period of 1 year prior enroll and the period of the study for each of the patients.

Months 15-27: Collection of last 12 months of healthcare resource utilization, QOL and PEF data (must wait 3 months post intervention for reliable claims data to be recorded)

As above, we obtained the closeout regarding healthcare utilization and cost and medication and were finally able to complete those in the spring of 2006. The healthcare utilization cost and medication data and the QOL, PEF, and FEV1 data were converted to computerized format by our research coordinator until the end of her contract in April 2006. Our local active duty study staff then finished conversion and formatting and sought statistical analysis. The malfunctioning of the peak flow meters, the low adherence rate and malfunction of the software in labeling the data made the peak flow data un-usable.

Months 28-29: Final data analysis

In the spring of 2006 the healthcare utilization cost and medication data and the QOL, PEF, and FEV1 data were converted to computerized format by our research coordinator until the end of her contract in April 2006. During this period, we discovered a duplicate record based on identical internal database identifier was actually two patients bringing our enrollment to 452. After initial difficulties accessing statistical support, we were finally and with good fortune able to access statistical support through the Brooke Army Medical Center Clinical Research Facility. Final statistical analysis was completed in December 2006.

Findings are described below, statistical analysis and support was provided by Dr John Ward, PhD, Department of Clinical Investigation, BAMC.

In this study, the independent variables are treatment (control, intervention), entry level severity (1, 2, 3, 4) and time (0, 6, 12 months). The dependent variables are FEV1, combined ED visits and hospitalizations, use of beta-agonist, PAQLQ and PACQOLQ scores. The null hypothesis is that there will be no difference in the dependent variables relative to treatment, entry level severity or time. The alternative hypothesis is that there will be a difference in the dependent variables relative to treatment, entry level severity or time. The appropriate statistical test is a two-tailed, three-factor ANOVA (treatment, entry level severity, time) with repeated measures on one factor (time), followed by two-tailed post hoc tests corrected for multiple comparisons. Data was present on 452 subjects. This decreased by 77/452 = 17.0% by 12 months for FEV1 scores and 66/452 = 14.6% for QOL scores. The investigator decided that this study should be analyzed as an intention to treat study, i.e., subjects who were lost to follow up will be considered to be treatment failures. Missing values for FEV1 and QOL were replaced with numeric values for analysis. The investigator carried forward the last recorded value to replace missing values. Other variables missing data from patients lost to follow up/withdrawl were analysed with only available data points.

Descriptive statistics on demographic and dependent variable by treatment group. Descriptive statistics on demographic and dependent variables by treatment group are shown in Table 1.

Table 1. Descriptive statistics on demographic and dependent variables by treatment group.

Group Statistics						95%CI	95% CI
	Intervention 1 = yes 0=No	N	Mean	Std. Deviation	Std. Error Mean	Low	High
age at enroll	0	222	11.08	2.57	0.17	6.05	16.11
	1	230	11.20	2.85	0.19	5.61	16.79
Severity Clasification at Enroll 1=Mild Int 2=Mild Pers 3=Mod Pers 4=Severe Pers	0	222	2.18	0.98	0.07	0.25	4.11
	1	230	2.47	0.97	0.06	0.57	4.37
Tobacco in home 1 = yes	0	222	0.26	0.44	0.03	-0.60	1.11

0 = no							
	1	230	0.29	0.46	0.03	-0.60	1.18
FEV1 at Enroll	0	222	2.10	0.75	0.05	0.63	3.58
	1	230	2.12	0.79	0.05	0.57	3.66
FEV1 Percent Expected at Enroll:	0	222	94.95	15.69	1.05	64.19	125.71
	1	230	94.86	18.26	1.20	59.07	130.65
FEV1 6 mos	0	222	2.23	0.77	0.05	0.71	3.74
	1	230	2.24	0.81	0.05	0.65	3.84
FEV1 Percent Expected 6 mos	0	222	95.96	15.74	1.06	65.12	126.80
	1	230	96.02	16.94	1.12	62.82	129.21
FEV1 12 mos	0	222	2.35	0.80	0.05	0.78	3.91
	1	230	2.34	0.83	0.05	0.71	3.97
FEV1Percent Expected 12 mos	0	222	96.08	15.62	1.05	65.47	126.69
	1	230	95.20	15.89	1.05	64.04	126.35
Patient QOL Score at Enroll	0	222	126.76	27.45	1.84	72.96	180.56
	1	230	123.20	29.08	1.92	66.21	180.20
Patient QOLscore at 6 month	0	222	138.79	22.88	1.54	93.95	183.63
	1	230	136.67	23.83	1.57	89.96	183.38
Patient QOLscore at 12 month	0	222	143.78	19.05	1.28	106.44	181.12
	1	230	138.57	23.69	1.56	92.14	185.00
Caregiver QOL Score at Enroll	0	222	76.21	14.66	0.98	47.47	104.95
	1	230	72.59	16.00	1.06	41.22	103.96
Total CarGiv QOLscore at 6 month	0	222	80.89	12.05	0.81	57.27	104.51
	1	230	79.62	13.32	0.88	53.51	105.73
Total CarGiv QOLscore at 12 month	0	222	82.40	10.22	0.69	62.36	102.43
	1	230	81.43	12.15	0.80	57.62	105.24
Enrollment Symptom Score	0	222	5.52	2.18	0.15	1.25	9.79
	1	230	6.35	2.75	0.18	0.95	11.74
6 Month Symptom Score	0	187	5.10	1.93	0.14	1.30	8.89
	1	198	5.46	2.36	0.17	0.85	10.08
12 Month Symptom Score	0	187	5.05	1.79	0.13	1.54	8.57
	1	199	5.41	2.49	0.18	0.53	10.30
Short acting beta agonist 1 yr pre-study	0	222	1.60	2.85	0.19	-3.97	7.18
	1	230	1.87	2.31	0.15	-2.65	6.40
Short acting beta agonis 1 yr during study	0	222	1.72	2.77	0.19	-3.71	7.15
	1	230	2.23	2.51	0.17	-2.69	7.15
Systemic steroid 1 yr pre-study	0	222	0.46	1.05	0.07	-1.59	2.52
	1	230	0.60	1.12	0.07	-1.60	2.80
Systemic steroid 1 yr during study	0	222	0.30	0.71	0.05	-1.09	1.68
	1	230	0.59	1.09	0.07	-1.54	2.73
Inhaled steroid 1 yr pre-study	0	222	1.46	2.72	0.18	-3.88	6.79
	1	230	1.66	2.49	0.16	-3.22	6.53
Inhaled steroid 1 yr during study	0	222	1.40	2.61	0.18	-3.71	6.52
	1	230	2.18	2.82	0.19	-3.36	7.71
Number ER Visits Year Prior	0	222	0.25	0.64	0.04	-1.00	1.50
	1	230	0.32	0.67	0.04	-0.99	1.62
Sum Of ER Cost Year Prior	0	222	74.00	261.75	17.57	-439.03	587.03
	1	230	90.04	289.80	19.11	-477.97	658.04
Number ER Visits Year Enrolled	0	222	0.23	0.60	0.04	-0.96	1.41
	1	230	0.31	0.68	0.04	-1.02	1.64
Sum Of ER Cost Year Enrolled	0	222	71.27	234.92	15.77	-389.16	531.71
	1	230	85.78	245.02	16.16	-394.47	566.02
Number of Admissions Year Pre Enrollment	0	222	0.02	0.13	0.01	-0.24	0.28
	1	230	0.05	0.22	0.01	-0.38	0.49
Number of Bed Days Year Pre Enrollment	0	222	0.03	0.26	0.02	-0.48	0.54
	1	230	0.10	0.44	0.03	-0.76	0.95
Inpatient Cost Year Pre Enrollment	0	222	98.38	1032.25	69.28	-1924.83	2121.59
	1	230	242.01	1312.52	86.55	-2330.54	2814.56
Number of Admissions Year of Study	0	222	0.00	0.07	0.00	-0.13	0.14
	1	230	0.03	0.18	0.01	-0.33	0.39
Number of Bed Days Year of Study	0	222	0.01	0.13	0.01	-0.25	0.27

	1	230	0.08	0.48	0.03	-0.86	1.03
Inpatient Cost Year of Study	0	222	11.38	169.60	11.38	-321.03	343.80
	1	230	203.28	1144.45	75.46	-2039.84	2446.41
Patient School Days Missed Year Prior to Enroll	0	222	2.40	3.74	0.25	-4.94	9.73
	1	230	4.26	6.14	0.40	-7.78	16.29
Patient School Days Missed Year of Study	0	190	1.43	2.49	0.18	-3.45	6.31
	1	203	2.05	3.56	0.25	-4.92	9.02
Caregiver Missed duty year prior to enroll	0	202	0.46	1.29	0.09	-2.07	2.99
	1	210	0.70	2.69	0.19	-4.57	5.97
Caregiver Missed duty year of study	0	189	0.12	0.56	0.04	-0.99	1.22
	1	202	0.26	0.93	0.07	-1.56	2.07
Female	0	222	0.40	0.49	0.03	-0.56	1.36
	1	230	0.42	0.49	0.03	-0.55	1.39

Spearman rank correlation on demographic and dependent variable by treatment group and severity. Spearman rank correlation was used because it is a non-parametric test that allows us to examine relationships between interval, ordinal and binomial type variables. The results are shown in Table 2. Results shown in bold face type with a gray background are statistically significant ($p < 0.05$). With large sample sizes, such as in this study, results can be statistically significant without being clinically significant. We are primarily interested in the coefficient of determination, which is the square of the correlation coefficient. A correlation coefficient of 0.70 has a coefficient of determination of $0.70^2 = 0.49$, which tells us that 49% of the variation in the dependent variable is determined by the independent variable. Correlations of 0.7 or greater are considered strong correlations. The highest correlation is between severity and enrollment symptom score ($r = 0.677$, $r^2 = 0.458$, $p < 0.001$, $n = 452$).

Table 2. Spearman rank correlation on demographic and dependent variables by treatment group.

Correlations								
	Spearman's rho	Intervention	**Severity**	Age	**Tobacco**	FEV1 Enroll	**FEV1% Enroll**	FEV1 6 mo
Intervention	Correlation Coefficient	1.000	**0.151**	0.013	0.039	0.017	0.014	0.010
	Sig. (2-tailed)	.	**0.001**	0.786	0.412	0.725	0.763	0.835
	N	452	**452**	452	452	452	452	452
Severity	Correlation Coefficient	**0.151**	1.000	0.022	**0.098**	-0.091	**-0.238**	-0.043
	Sig. (2-tailed)	**0.001**	.	0.644	**0.038**	0.054	**0.000**	0.358
	N	**452**	452	452	**452**	452	**452**	452

Correlations								
	Spearman's rho	FEV1% 6 mo	FEV1 12 mo	FEV1% 12 mo	PatQOL Enroll	PatQOL 6mo	**PatQOL 12mo**	**CGQOL Enroll**
Intervention	Correlation Coefficient	0.004	0.005	-0.027	-0.057	-0.053	**-0.097**	**-0.114**
	Sig. (2-tailed)	0.937	0.908	0.563	0.224	0.265	**0.038**	**0.016**
	N	452	452	452	452	452	**452**	**452**
Severity	Correlation Coefficient	**-0.133**	-0.024	**-0.103**	**-0.327**	**-0.218**	**-0.251**	**-0.298**
	Sig. (2-tailed)	**0.005**	0.607	**0.028**	**0.000**	**0.000**	**0.000**	**0.000**
	N	**452**	452	**452**	**452**	**452**	**452**	**452**

Correlations								
	Spearman's rho	CGQOL 6mo	CGQOL 12mo	**Enr Sympt**	6M Sympt	12M Sympt	**Betag 1yrpre**	**Betag 1yrdur**
Intervention	Correlation Coefficient	-0.054	-0.010	**0.155**	0.078	0.027	**0.094**	**0.132**
	Sig. (2-tailed)	0.253	0.826	**0.001**	0.127	0.602	**0.045**	**0.005**
	N	452	452	**452**	385	386	**452**	**452**
Severity	Correlation Coefficient	**-0.161**	**-0.236**	**0.677**	**0.327**	**0.307**	**0.160**	**0.203**
	Sig. (2-tailed)	**0.001**	**0.000**	**0.000**	**0.000**	**0.000**	**0.001**	**0.000**
	N	**452**	**452**	**452**	**385**	**386**	**452**	**452**

Correlations								
	Spearman's rho	Syster 1yrpre	**Syst 1yrdur**	**Inster 1yrpre**	**Inster 1yrdur**	ERVisit Prior	ERCost Prior	ERVisit Enrol
Intervention	Correlation Coefficient	0.088	**0.159**	**0.104**	**0.178**	0.067	0.064	0.086
	Sig. (2-tailed)	0.063	**0.001**	**0.027**	**0.000**	0.156	0.176	0.069
	N	452	**452**	**452**	**452**	452	452	452
Severity	Correlation Coefficient	**0.145**	**0.169**	**0.261**	**0.278**	**0.169**	**0.165**	**0.156**
	Sig. (2-tailed)	**0.002**	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**	**0.001**
	N	**452**	**452**	**452**	**452**	**452**	**452**	**452**

Correlations								
	Spearman's rho	ERCost Enrol	**Adm Pre**	**BedDay Pre**	**InpatCost Pre**	**Adm Study**	**BedDay Study**	**InpatCost Study**
Intervention	Correlation Coefficient	0.078	**0.092**	**0.093**	**0.093**	**0.108**	**0.108**	**0.109**
	Sig. (2-tailed)	0.099	**0.050**	**0.049**	**0.049**	**0.021**	**0.021**	**0.021**
	N	452	**452**	**452**	**452**	**452**	**452**	**452**
Severity	Correlation Coefficient	**0.154**	0.067	0.067	0.068	0.089	0.089	0.089
	Sig. (2-tailed)	**0.001**	0.155	0.154	0.151	0.059	0.057	0.058
	N	**452**	452	452	452	452	452	452

Correlations						
	Spearman's rho	**PatSchool MisPri**	PatSchool MissStudy	CGMiss dutypri	CGMiss dutystudy	FEMALE
Intervention	Correlation Coefficient	**0.187**	0.093	0.017	0.068	0.021
	Sig. (2-tailed)	**0.000**	0.065	0.733	0.178	0.651
	N	**452**	393	412	391	452
Severity	Correlation Coefficient	**0.308**	**0.182**	**0.140**	0.084	-0.038
	Sig. (2-tailed)	**0.000**	**0.000**	**0.004**	0.096	0.422
	N	**452**	**393**	**412**	391	452

As Table 2 indicates there were variables that were statistically different between treatment groups at varied time points including at enrollment. As a result

The results of ANOVAs are summarized in Table 3. Significant effects are indicated in bold face type on a gray background. All of the dependent variables were significantly different with respect to severity. All but combined ED and hospital visits were significantly different with respect to time. None were significantly different with respect to treatment. On the Spearman rank correlation, there were significant relationships between treatment and several pretreatment variables, including severity classification at enrollment, caregiver QOL, enrollment symptoms, beta-agonist use 1 year pre study, inhaled steroid use 1 year pre study, admissions pre enrollment, bed days per enrollment, inpatient costs pre enrollment and patient school days missed prior to enrollment. All of these variables are related to the severity classification at enrollment, which is one of the independent variables. The critical question is whether treatment groups were mismatched relative to severity classification at enrollment. The appropriate test is a Mann-Whitney rank sum test, the results of which are shown in Table 4. The distributions are graphed in Figure 1.

Table 3. Summary of ANOVA results.

	Significance		
	Between		Within
Variable	Treatment	Severity	Time
FEV1 %	0.851	**0.000**	**0.015**
ED&Hosp	0.219	**0.000**	0.171
B-agonist	0.501	**0.000**	**0.006**
PatQOL	0.529	**0.000**	**0.000**
CGQoL	0.227	**0.000**	**0.000**

Table 4. Mann-Whitney rank sum test, severity by treatment.

Group Statistics

	Intervention 1 = yes 0=No	N	Mean	Std. Deviation	Std. Error Mean
Severity Clasification at Enroll 1=Mild Int 2=Mild Pers 3=Mod Pers 4=Severe Pers	0	222	2.18	.984	.066
	1	230	2.47	.970	.064

Ranks

	Intervention 1 = yes 0=No	N	Mean Rank	Sum of Ranks
Severity Clasification at Enroll 1=Mild Int 2=Mild Pers 3=Mod Pers 4=Severe Pers	0	222	207.19	45996.00
	1	230	245.14	56382.00
	Total	452		

Test Statistics(a)

	Severity Clasification at Enroll 1=Mild Int 2=Mild Pers 3=Mod Pers 4=Severe Pers
Mann-Whitney U	21243.000
Wilcoxon W	45996.000
Z	-3.217
Asymp. Sig. (2-tailed)	.001

a Grouping Variable: Intervention
1 = yes
0=No

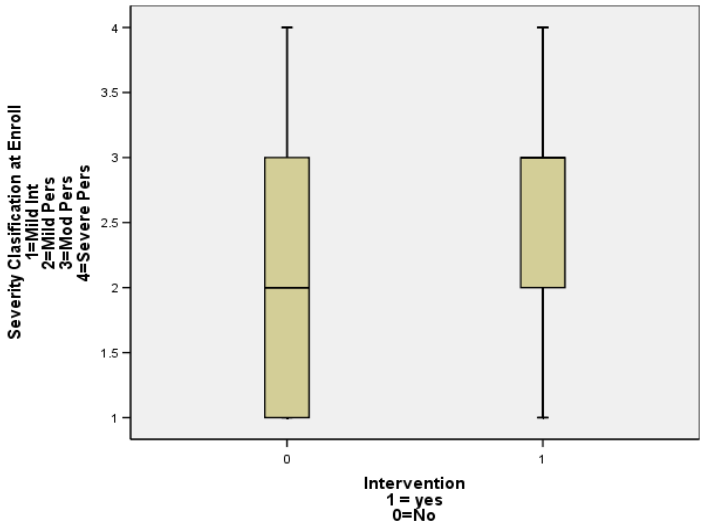


Figure 1. Distribution of severity by treatment. In the box plots, the median is the dark line within the box. The box is defined by the 25th and 75th percentiles so 50% of the cases have values within the box. The error flags represent the largest and smallest observed values that are not outliers. Outliers are values more than 1.5 box-lengths from the quartile. Extremes are values more than 3 box-lengths from the quartiles.

The severity classification at enrollment was significantly greater by an average of 0.3 in the treatment group ($p < 0.001$). This is important,

because severity is a covariate and the relationship between the dependent variables and severity could be masking a treatment effect. To examine this, we repeated the ANOVAs with severity as a covariate. The results are summarized in Table 5. Significant effects are indicated in bold face type on a gray background. None of the dependent variables were significantly different with respect to treatment.

Table 5. Summary of ANOVA results with severity as a covariate.

	Significance	
	Between	Within
Variable	Treatment	Time
FEV1 %	0.666	**0.000**
ED&Hosp	0.148	0.882
B-agonist	0.331	0.547
PatQOL	0.326	0.085
CGQoL	0.262	**0.035**

It can be argued that treating severity as a covariate in ANOVA is not sufficient to test for a treatment effect because severity is an ordinal, not an interval type variable. Alternatively, we can stratify by severity categories and repeat the ANOVA with only treatment and time as independent variables. The results of stratification are shown in Table 6. There are significant differences in FEV1 % and beta-agonist use between study groups, but they are not consistent across all levels of severity. Before we draw any conclusions, we have to look at the distributions.

Table 6. Summary of ANOVA results stratified by severity.

	Significance			
	Treatment Effect			
Variable	Severity = 1	Severity = 2	Severity = 3	Severity = 4
FEV1 %	**0.039**	**0.000**	0.893	0.524
ED&Hosp	0.558	0.333	0.209	0.880
B-agonist	0.725	**0.006**	0.703	0.881
PatQOL	0.877	0.117	0.512	0.777
CGQoL	0.763	0.432	0.691	0.390

ANOVA FEV1 % by treatment and time, severity = 1. The results are shown in Table 7 and graphed in Figure 2. There was no significant difference with respect to time ($p > 0.05$). There was no significant interaction between treatment and time ($p > 0.05$). The lack of a significant interaction means the trends are parallel. There was a significant difference between treatment groups ($p = 0.039$). The groups were mismatched on FEV1 % at enrollment. Group 0 (control) decreased from 102.0% to 101.1% in 12 months. Group 1 (intervention) decreased from 97.3% to 94.0 % in 12 months. The deterioration was greater in group 1.

Table 7. ANOVA FEV1 % by treatment and time, severity = 1.

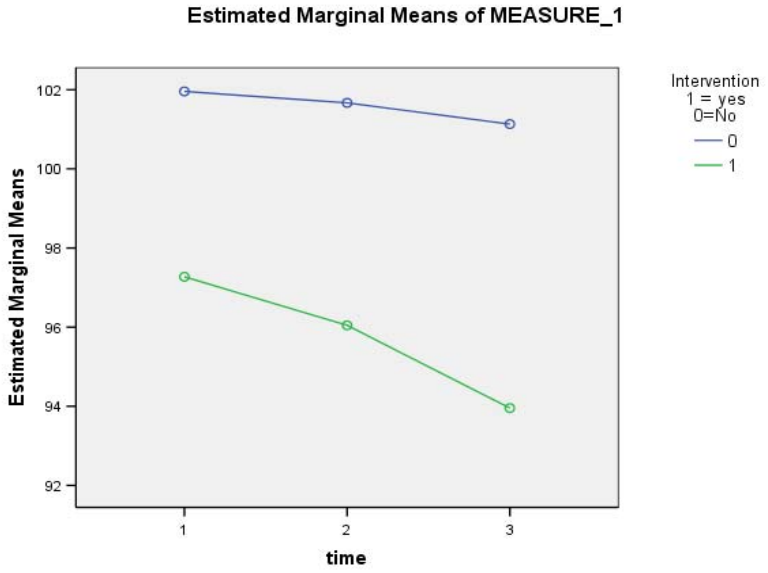
Descriptive Statistics				
	Intervention	Mean	Std. Deviation	N
FEV1 Percent Expected at Enroll:	0	102.0	15.4	69
	1	97.3	12.0	44
	Total	100.1	14.3	113
FEV1 Percent Expected 6 mos	0	101.7	17.7	69
	1	96.0	12.6	44
	Total	99.5	16.1	113
FEV1Percent Expected 12 mos	0	101.1	17.1	69
	1	94.0	14.1	44

	Total	98.3	16.3	113

Tests of Within-Subjects Effects						
Measure: MEASURE_1						
Source		Type III Sum of Squares	df	Mean Square	F	Sig.
time	Sphericity Assumed	236.2	2.0	118.1	2.866	0.059
time * Intervention1yes0No	Sphericity Assumed	85.1	2.0	42.6	1.033	0.358
Error(time)	Sphericity Assumed	9148.7	222.0	41.2		

Tests of Between-Subjects Effects					
Measure: MEASURE_1					
Transformed Variable: Average					
Source	Type III Sum of Squares	df	Mean Square	F	Sig.
Intercept	3138948.2	1	3138948.2	4988.318	0.000
Intervention	2736.7	1	2736.7	4.349	**0.039**
Error	69847.8	111	629.3		

Figure 2. FEV1 % by treatment and time, severity = 1.



ANOVA FEV1 % by treatment and time, severity = 2. The results are shown in Table 8 and graphed in Figure 3. There was no significant difference with respect to time ($p > 0.05$). There was no significant interaction between treatment and time ($p > 0.05$). The lack of a significant interaction means the trends are parallel. There was a significant difference between treatment groups ($p < 0.001$). The groups were mismatched on FEV1 % at enrollment. Group 0 (control) decreased from 94.7% to 93.4% in 12 months. Group 1 (intervention) decreased from 102.0% to 100.1% in 12 months. The changes were similar.

Table 8. ANOVA FEV1 % by treatment and time, severity = 2.

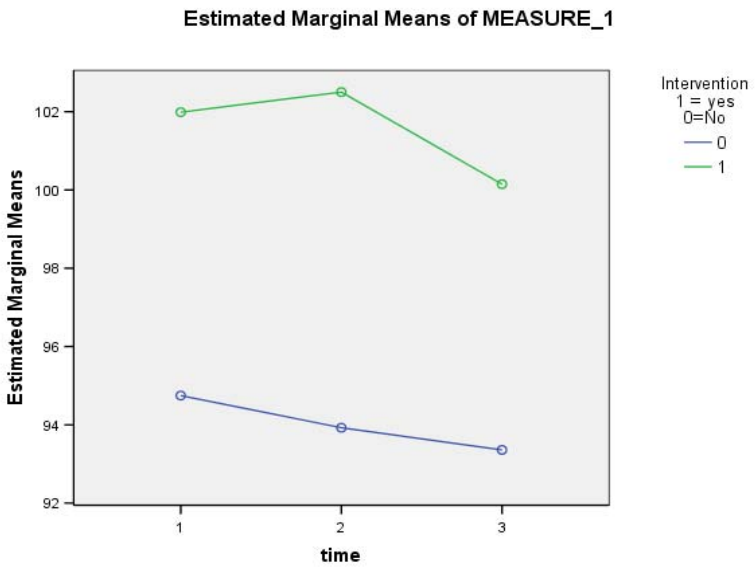
Descriptive Statistics				
	Intervention 1 = yes 0=No	Mean	Std. Deviation	N
FEV1 Percent Expected at Enroll:	0	94.7	11.0	67

	1	102.0	15.5	68
	Total	98.4	13.9	135
FEV1 Percent Expected 6 mos	0	93.9	10.8	67
	1	102.5	15.6	68
	Total	98.2	14.1	135
FEV1Percent Expected 12 mos	0	93.4	10.8	67
	1	100.1	14.9	68
	Total	96.8	13.4	135

Tests of Within-Subjects Effects						
Measure: MEASURE_1						
Source		Type III Sum of Squares	df	Mean Square	F	Sig.
time	Sphericity Assumed	214.1	2.0	107.0	2.219	0.111
time * Intervention1yes0No	Sphericity Assumed	58.2	2.0	29.1	0.603	0.548
Error(time)	Sphericity Assumed	12833.3	266.0	48.2		

Tests of Between-Subjects Effects					
Measure: MEASURE_1					
Transformed Variable: Average					
Source	Type III Sum of Squares	df	Mean Square	F	Sig.
Intercept	3871728.6	1	3871728.6	8940.252	0.000
Intervention	5747.0	1	5747.0	13.270	**0.000**
Error	57597.9	133	433.1		

Figure 3. FEV1 % by treatment and time, severity = 2.



ANOVA beta-agonist use by treatment and time, severity = 2. The results are shown in Table 9 and graphed in Figure 4. There was no significant difference with respect to time ($p > 0.05$). There was no significant interaction between treatment and time ($p > 0.05$). The lack of a significant interaction means the trends are parallel. There was a significant difference between treatment groups ($p = 0.006$). The groups were mismatched on beta agonist use 1 year pre study. Group 0 (control) increased from 1.3 to 1.4 in 12 months. Group 1 (intervention) increased from 2.1 to 2.4 in 12 months. The increase was greater in group 1.

Table 9. ANOVA beta-agonist use by treatment and time, severity = 2.

Descriptive Statistics				
	Intervention 1 = yes 0=No	Mean	Std. Deviation	N
Short acting beta agonist 1 yr pre-study	0	1.3	1.5	67
	1	2.1	2.3	68
	Total	1.7	2.0	135
Short acting beta agonis 1 yr during study	0	1.4	1.6	67
	1	2.4	2.5	68
	Total	1.9	2.2	135

Tests of Within-Subjects Effects						
Measure: MEASURE_1						
Source		Type III Sum of Squares	df	Mean Square	F	Sig.
time	Sphericity Assumed	2.1	1.0	2.1	1.588	0.210
time * Intervention1yes0No	Sphericity Assumed	0.7	1.0	0.7	0.531	0.467
Error(time)	Sphericity Assumed	177.2	133.0	1.3		

Tests of Between-Subjects Effects					
Measure: MEASURE_1					
Transformed Variable: Average					
Source	Type III Sum of Squares	df	Mean Square	F	Sig.
Intercept	900.5	1	900.5	130.965	0.000
Intervention	53.6	1	53.6	7.801	**0.006**
Error	914.5	133	6.9		

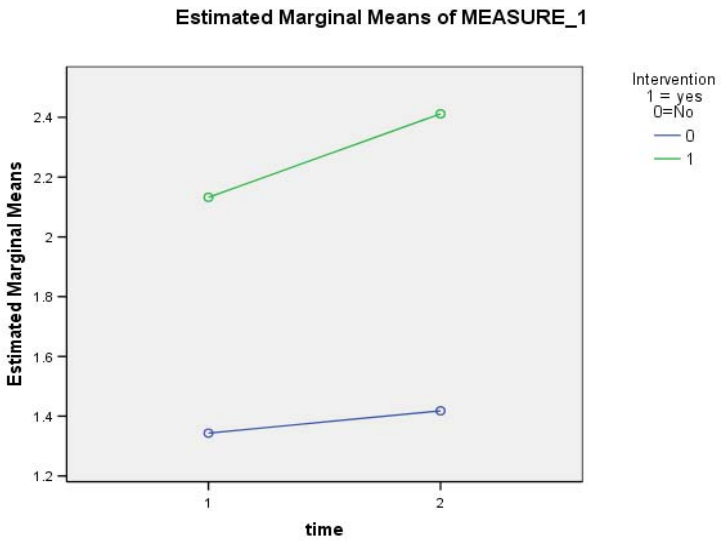


Figure 4. Beta agonist use by treatment and time, severity = 2.

Data Analysis Summary. There was no evidence that intervention improved outcome.

Months 29-30: Findings and conclusion write up.

Final conclusions and final report were completed. Consideration of submission for publication is underway.

Key Research Accomplishments

- Our research demonstrated that when compared with usual care at three separate DoD Military Treatment Facilities, remote call-based (telephonic) disease management in pediatric asthma patients does not improve:
    - Quality of life
    - Healthcare cost or utilization
    - Disease severity

- Despite randomization, our treatment group and control group were statistically different in several of the demographic enrollment data and enrollment outcome measures when compared via the Sprearman rank correlation. Despite the statistically significant differences in the identified parameters, the coefficients of determination were small. More importantly, changes in measured outcomes between the control and intervention group over the study period were not significantly different as mentioned above

Reportable Outcomes

Presentations:

1. Presentation of research study design and goals, not data: Exploring the Effect of Pediatric Asthma Disease Management: US Department of Defense and national Jewish Medical & Research Center. Annual Meeting of The Disease Management Conference, Boston, Massachusetts, August 2003. No abstract submitted or required.

2. Poster presentation of research study design and goals with some enrollment demographics but no data: Call Center-Based Disease Management of Pediatric Asthma. Department of Defense Peer Reviewed Medical Research Program Military Health Research Forum, San Juan, Puerto Rico, April 2004. Non-published but abstract below.

   CALL CENTER-BASED DISEASE MANAGEMENT (CBDMP) OF PEDIATRIC ASTHMATICS Quinn JM, Rathkopf M, Edwards HF, Terry RM, Blamire G, Napoli DC, Stritmatter F, Grissom J 59th Medical Group, Wilford Hall Medical Center, Lackland Air Force Base, Texas

   BACKGROUND/PURPOSE: The goal of CBDMP is motivating patients to take charge of their condition rather than relying on the MHS to control acute episodes of care. The CBDMP will be a population-based intervention using preventive measures to control asthmatics through the use of proactive education and monitoring. This study will attempt to determine if CBDMP, applied to asthma will: improve patient and caregiver quality of life (QOL); reduce disease severity, as measured by reduced inhaled short acting beta agonist use; improve patient condition as measured by Peak Expiratory Flow and/or FEV1; reduce Emergency Department (ED) visits and hospital admissions, and/or reduced costs.

   METHODS: Subjects 7 to 16 years of age with the diagnosis of asthma are eligible to enroll. Subjects are being recruited from three TRICARE Prime Military Treatment Facility (MTF) communities with similar resources - Fort Sill, Oklahoma; Tinker Air Force Base, Oklahoma; and Sheppard Air Force Base, Texas. Patients are randomly assigned to either and intervention group or a control group at each site. All subjects receive an electronic peak flow meter along with written instructions for self-monitoring of peak expiratory flow. All subjects are assessed for their appropriate National Heart Lung and Blood Institute (NHLBI) classification and all will receive the DoD/VA standardized asthma education materials.

   The intervention group is entered into a CBDMP for 12 months. Only the intervention group is contacted by the CBDMP. The intervention is predetermined and timed education calls that assess, monitor and educate asthmatics on a variety of health and environmental factors related to asthma control as developed and applied by the CBDMP contractor - National Jewish Medical and Research Center. The CBDMP allows unlimited patient initiated contact through 24 hour telephone access.

   All control and intervention subjects have retrospective and prospective Emergency Department visits, hospital admissions, and beta-agonist utilization collected. Specific retrospective utilization, cost and compliance data are collected from all subjects. Prospective ED and hospital admissions, peak flow values, short acting rescue medication, FEV1, and QOL data are collected at baseline, 6 months and at 12 months. QOL data is also be collected from caregivers. Junipers Quality of Life instruments is used for the study. The asthmatic subjects are randomized into control and intervention groups. Utilization data will be collected from Managed Care Support Contract (MCSC) claims, MHS encounter, and self reported data. Analysis of variance (ANOVA) and Chi-Square analysis will be used to test for changes over the course of the study, to compare the intervention and control groups, and to compare the four asthma severity level groups. All statistical testing will be performed at the 0.05 alpha level.

   RESULTS: To date 420 patients have been enrolled and enrollment continues through Dec 2003.

   CONCLUSION: Subjects are continuing to enroll. No outcome data has been finalized or analyzed at this time.

   Funding by U.S. Army Medical Research Materiel Command under DAMD17-02-1-0182

3. Poster presentation of research study design and goals with some enrollment demographics but no final data: Call Center-Based Disease Management of Pediatric Asthma. Wilford Hall 59th Medical Wing "In-house" Research Symposium, June 2004. Non-published abstract below.

   CALL CENTER-BASED DISEASE MANAGEMENT (CBDMP) OF PEDIATRIC ASTHMATICS. Quinn JM, Rathkopf M, Edwards HF, Terry RM, Blamire G, Napoli DC, Stritmatter F, Grissom J.

   BACKGROUND/PURPOSE: The goal of CBDMP is motivating patients to take charge of their condition rather than relying on the MHS to control acute episodes of care. The CBDMP will be a population-based intervention using preventive measures to control asthmatics through the use of proactive education and monitoring. This study will attempt to determine if CBDMP, applied to asthma will: improve patient and caregiver quality of life (QOL); reduce disease severity, as measured by reduced inhaled short acting beta agonist use; improve patient condition as measured by Peak Expiratory Flow and/or FEV1; reduce Emergency Department (ED) visits and hospital admissions, and/or reduced costs.

   METHODS: Subjects 7 to 16 years of age with the diagnosis of asthma are eligible to enroll. Subjects are being recruited from three TRICARE Prime Military Treatment Facility (MTF) communities with similar resources - Fort Sill, Oklahoma;

Tinker Air Force Base, Oklahoma; and Sheppard Air Force Base, Texas. Patients are randomly assigned to either and intervention group or a control group at each site. All subjects receive an electronic peak flow meter and instructions for self-monitoring of peak expiratory flow. All subjects will be assigned the appropriate athma severity classification and all will receive the DoD/VA standardized asthma education materials. The intervention group is entered into a CBDMP for 12 months. The intervention is predetermined and timed calls that assess, monitor and educate asthmatics on a variety of health and environmental factors as developed and applied by the CBDMP contractor. The CBDMP allows unlimited patient initiated contact through 24 hour telephone access. All subjects will have retrospective and prospective ED visits, hospital admissions, and beta-agonist utilization collected. Retrospective utilization, cost and compliance data are collected from all subjects. Prospective ED and hospital admissions, peak flow values, rescue medication, FEV1, and QOL data are collected at baseline, 6 months and at 12 months. Juniper QOL data is also be collected from caregivers. The asthmatic subjects are randomized into control and intervention groups. Utilization data will be collected from Managed Care Support Contract (MCSC) claims, MHS encounter, and self reported data. Analysis of variance (ANOVA) and Chi-Square analysis will test for changes over the course of the study, to compare intervention and control groups, and to compare asthma severity level groups. All statistical testing will be performed at the 0.05 alpha level.

RESULTS: 451 patients were enrolled through Dec 2003 and 71 patients have completed the study through March 2004 with 5 withdrawls and 7 lost to follow-up. Patient follow-up will continue through December 2004. Demographic data for the enrolled population revealed a mean age of 12.52 years, mean FEV1 of 2.11 liters, mean FEV1 % expected of 96. 4%, and 59% males. Sbugroup severity distribution revealed 28% mild intermittent, 43% mild persistent, 25% moderate persistent, and 4% severe persistent.

CONCLUSION: Subjects are continuing with follow-up and data collection. No outcome data has been finalized or analysed at this time. (Funding by U.S. Army Medical Research Materiel Command under DAMD17-02-1-0182)

4. Presentation of research study design and goals with some enrollment demographics but no final data: Call Center-Based Disease Management of Pediatric Asthma. Society of Air Force Physicians Annual Meeting, Dayton, Ohio, March 2005. Non-published abstract below.

CALL CENTER-BASED DISEASE MANAGEMENT (CBDMP) OF PEDIATRIC ASTHMATICS. Quinn JM, Rathkopf M, Edwards HF, Terry RM, Blamire G, Napoli DC, Stritmatter F, Grissom J.

PURPOSE: This study will attempt to determine if CBDMP, applied to asthma will: improve patient and caregiver quality of life (QOL); reduce disease severity, as measured by reduced inhaled short acting beta agonist use; improve patient condition as measured by Peak Expiratory Flow and/or FEV1; reduce Emergency Department (ED) visits and hospital admissions, and/or reduced costs.

METHODS: Subjects 7 to 16 years of age with the diagnosis of asthma are eligible to enroll. Subjects are being recruited from three TRICARE Prime Military Treatment Facility (MTF) communities with similar resources - Fort Sill, Oklahoma; Tinker Air Force Base, Oklahoma; and Sheppard Air Force Base, Texas. Patients are randomly assigned to either an intervention group or a control group at each site. All subjects receive a peak flow meter and self-monitoring instructions. All subjects will be assigned an asthma severity classification and will receive DoD/VA standardized asthma education materials. The intervention will be for 12 months and will consist of predetermined to assess, monitor and educate asthmatics as developed and applied by the contractor. Patients also have unlimited initiated contact through 24-hour telephone access. All subjects will have retrospective and prospective ED visits, utilization, cost and compliance data, hospital admissions, and beta-agonist utilization collected. Prospective ED and hospital admission, peak flow, rescue medication, FEV1, and QOL data are collected at baseline, 6 and 12 months. QOL data is also be collected from caregivers. Analysis of variance (ANOVA) and Chi-Square analysis will test for changes over the course of the study, to compare intervention and control groups, and to compare asthma severity level groups.

RESULTS: 451 patients were enrolled through Dec 2003 and 71 patients have completed the study with 12 withdrawls/lost to follow-up. Patient follow-up will continue through December 2004. Demographic data for the enrolled population revealed a mean age of 12.52 years, mean FEV1 of 2.11 liters, mean FEV1 % expected of 96. 4%, and 59% males. Subgroup severity distribution revealed 28% mild intermittent, 43% mild persistent, 25% moderate persistent, and 4% severe persistent.

CONCLUSION: Subjects are continuing with follow-up and data collection. No outcome data has been finalized or analysed at this time. (Funding by U.S. Army Medical Research Materiel Command under DAMD17-02-1-0182)

Conclusions

While there are various trials in the literature that have demonstrated efficacy of disease management, these trials were in discrete localized populations and/or were managed by individual subspecialty clinics with on-site face to face interactions/connections with local providers. These trials have used differing disease management programs of varied intensity and complexity and differing endpoints of success. There have not been any published trials of remote call-based (telephonic) disease management

Our data suggests that exclusively remote call-based (telephonic) disease management in pediatric asthma patients does not improve outcomes with regard to quality of life, healthcare cost or utilization, or disease severity. The results of our study may not be applicable to the general populations. Our patients were enrolled from a well supported diverse managed care organization in the form of patients receiving their Primary Care at Military Treatment facilities supported with TRICARE prime managed care insurance and provider networks. Patients all had opportunities for no-cost primary care and no-cost basic asthma medications supported by either no-cost or low-copay access to emergency care, specialty care, and a full formulary. Additionally, during the period of the study, the DoD and VA had identified Pediatric Asthma as an important disease and had supplied resources and education (although not uniformly utilized or applied) including the DoD/VA algorhythm and toolkit for healthcare providers. The institutions where this study took place had all created ad-hoc voluntary programs of varied intensity/complexity with varied penetration/adherence by providers and patients in an effort to improve outcomes for pediatric asthma patients. In this setting, our attempt to provide a uniform, easily implemented, remote call-based (telephonic) disease management program did not offer improved outcomes over usual care.

References

1. Mannino, D.M.; Homa, D.M.; Pertowski, C.A.; Ashizawa, A.; Nixon, L.L.; Johnson, C.A.; et al. Surveillance for asthma—United States, 1960-1995. *Morbidity and Mortality Weekly Report CDC Surveillance Summaries* 47:1-27, 1998.
2. National Center for Health Statistics (NCHS). Current estimates from the National Health Interview Survey, 1995. National Center for Health Statistics. *Vital and Health Statistics,* Series 10(199), 1998.
3. National Heart, Lung, and Blood Institute. *Data Fact Sheet. Asthma Statistics.* Bethesda, MD: National Institutes of Health, Public Health Service, January 1999.
4. Mannino, D.M.; Homa, D.M.; Pertowski, C.A.; et al. Surveillance for asthma—United States, 1960-1995. *Morbidity and Mortality Weekly Report CDC Surveillance Summaries* 47(1):1-27, April 24, 1998.
5. NCHS. Current estimates from the National Health Interview Survey, 1990-92. National Center for Health Statistics. *Vital and Health Statistics*, Series 10(194), 1997.
6. National Asthma Education and Prevention Program. *Expert Panel Report 2: Guidelines for the Diagnosis and Management of Asthma*. NIH Pub. No. 97-4051. Bethesda, MD: National Institutes of Health, 1997.
7. Panhuysen, C.I., Vonk, J.M., Koeter, G.H., Schouten, J.P.; van Altena, R.; Bleecker, E.R.; et al. Adult patients may outgrow their asthma: A 25-year follow-up study [published erratum appears in *American Journal of Respiratory and Critical Care Medicine* 156(2, Pt 1):674]. *American Journal of Respiratory and Critical Care Medicine* 155:1267-1272, 1997.
8. NCHS. Ambulatory care visits to physicians' offices, hospital outpatient departments, and emergency departments: United States, 1996. National Center for Health Statistics. *Vital and Health Statistics*, Series 13(134), 1998.
9. NCHS. *Healthy People 2000 Review, 1998-99.* Hyattsville, MD: Public Health Service, 1999.
10. Weiss, K.B., Gergen, P.J.; and Hodgson, T.A. An economic evaluation of asthma in the United States. *New England Journal of Medicine* 326:862-866, 1992.
11. Sullivan, S., Elixhauser, S., Buist, A.S., Luce, B.R., Eisenberg, J., and Weiss, K.B. National Asthma Education and Prevention Program working group report on the cost effectiveness of asthma care. *American Journal of Respiratory and Critical Care Medicine* 154(3, Pt. 2):584-595, September 1996.
12. Glaxo Canada. *The Costs of Asthma in Canada.* Princeton, NJ: Communications Media for Education, 1993.
13. Koren, H.S. Environmental risk factors in atopic asthma. *International Archives of Allergy and Immunology* 113:65-68, 1997.
14. Becklake, M.R., and Ernst, P. Environmental factors. *Lancet* 350(suppl. 2):10-13, 1997.
15. Office of Air Quality Planning and Standards, Environmental Protection Agency. *National Air Quality and Emissions Report*, 1997. CPA Pub. No. EPA 454/R-98-016. Research Triangle Park, NC: Environmental Protection Agency, 1998.
16. Schwartz, D.A., and Peterson, M.W. Occupational lung disease. *Advances in Internal Medicine* 42:269-312, 1997.
17. Busse, W.W., Gern, J.E., and Dick, E.C. The role of respiratory viruses in asthma. *Ciba Foundation Symposium* 206:208-213, 1997.
18. U.S. Department of Health and Human Services. *Action Against Asthma: A strategic plan for the Department of Health and Human Services*. Washington, DC, draft March 22, 1999.
19. Wade, S., Weil, C., Holden, G.; Mitchell, H.; Evans, R.; Kruszon-Moran, D.; et al. Psycho social characteristics of inner-city children with asthma: A description of the NCICAS psychosocial protocol. National Cooperative Inner-City Asthma Study. *Pediatric Pulmonology* 24:263-276, 1997.
20. Evans, D., Mellins, R.; Lobach, K.; Ramos-Bonoan, C.; Pinkett-Heller, M., Wiesemann, S., et al. Improving care for minority children with asthma: Professional education in public health clinics. *Pediatrics* 99:157-164, 1997.
21. To, T., Dick, P., et. al. A cohort study on childhood asthma admissions and readmissions. *Pediatrics* 98: 191-195, 1996.
22. O'Brien, K. Managed care and the treatment of asthma. *Journal of Asthma* 32: 325-334, 1995.
23. Fowler, M.G., Davenport, M.G., Gorg, R. School functioning of US children with asthma. *Pediatrics* 90: 939-944, 1992.
24. Taylor, W.R., Newacheck, P.W. Impact of childhood asthma on health. *Pediatrics* 90: 657-662, 1992.
25. Meyer, L.C., Rohl, B.J. An innovative approach to treating chronic, disabling asthma. *Case Manager*, July/Aug/Sep, p. 55, 1993.
26. Bone, R.C. The bottom line in asthma management is patient education. *American Journal of Medicine* 94: 561-563, 1993.
27. Creer, TL., Backial, MA, Burns KL., et. al. Living with asthma. I. Genesis and development of a self-management program for childhood asthma. *Journal of Asthma* 25: 335 – 362, 1988.
28. Fireman, P., Friday, GA., et. al. Teaching self-management skills to asthmatic children and their parents in an ambulatory care setting. Pediatrics 68: 341-348, 1981.
29. McNabb, WL., Wilson-Pesano, SR., et. al. Self-management education of children with asthma: AIR WISE. American Journal of Public Health 75: 1219-1220, 1985.
30. Clark, NM., Feldman, CH., et.al. The impact of health education on frequency and cost of health care use by low income children with asthma. Journal of Allergy Clinical Immunology 78: 108-115, 1986.
31. Whitman, N., West, D. et. al. A study of self-care rehabilitation program in pediatric asthma. Health Education Quality 12: 333-342, 1985.
32. O'Brien, KP. Establishment of an asthma program in a large health maintenance organization. Conference Program, First National Conference on Asthma Management. Arlington, VA. 1992, p. 64.
33. Neir, et al. Economic analysis of two structured treatment and teaching programs on asthma. Allergy 51:313-319, 1996.
34. NCHS. Healthy People 2010 Review. Hyattsville, MD. Public Health Service, 2000.

35. Forsee, et al. The effectiveness of one-on-one nurse education on the outcomes of high-risk adult and pediatric patients with asthma. Managed Care Interface 11(12):82-92, 1998.
36. Jowers JR, Schwartz AL, Tinkelman DG, et al. Disease management program improves asthma outcomes. American Journal of Managed Care 6:585-92, 2000.
37. Kelly SC, Morrow AL, Shults J, et al. Outcomes evaluation of a comprehensive intervention program for asthmatic children enrolled in Medicaid. Pediatrics 105:1029-35, 2000.
38. Fireman P, Friday G, Gira C, et al. Teaching self-management skills to asthmatic children and their parents in an ambulatory care setting. Pediatrics 68:341-8, 1998.
39. Greineder DK, Loane KC, Parks P. Reduction in resource utilization by an asthma outreach program. Archives of Pediatric and Adolescent Medicine 149:415-20, 1995
40. MacKinnon, Neil, MS, RPH. A systems approach to the evaluation of a disease management program. Formulary 33:769-788, 1998.
41. Coons, Stephen, PhD. Disease Management: Definitions and Exploration of Issues. Clinical Therapeutics 18:16, 1996.
42. 1998 Disease Management Directory and Guidebook. National Health Information 4-5, 1998.
43. First Consulting Group, National MHS Optimization Implementation Plan, March 2000 ON LINE (Aug 2000): http://www.tricare.osd.mil/mhsoptplan/download/pdf/MHSOPTFINAL.pdf
44. DoD/VA Asthma Clinical Practice Guidelines. ON LINE (Aug 2000): http://www.cs.amedd.army.mil/qmo/asthmfr.htm
45. MHS Optimization Plan. ON LINE (Aug 2000): http://www.tricare.osd.mil/mhsoptplan/plan_summary.html.
46. Bartter T, Pratter MR, Asthma: Better Outcomes at Lower Cost?, Chest, 110/6, 1589-1596, 1996.
47. Lieu TA, Quesenberry CP, Sorel ME, Mendoza GR, Leong AB, Computer-based Models to identify High-risk Children with asthma, American Journal of Respiratory Critical Care Medicinew, 157, 1173-1180, 1998.
48. National Institutes of Health, National Heart, Lung, and Blood Institute. Practical Guide for the Diagnosis and Management of Asthma, NIH Publication 97-4053. Oct 1997.
49. O'Connell et al. Results of a telephone-based asthma management pilot program. JCOM 6(4):22-30, 1999.
50. Juniper E.F., Guyatt G.H., et al. Measuring Quality of Life in the parents of children with asthma. Quality of Life Research 5:27-33, 1996
51. First Consulting Group, National MHS Optimization Implementation Plan, March 2000 Available on line (22 Aug 00) http://www.tricare.osd.mil/mhsoptplan/download/pdf/MHSOPTFINAL.pdf
52. CDC; MMW report; / 47(SS-1);1-28, April 24, 1998.
53. Juniper, E.F., et al. How important is quality of life in pediatric asthma? Pediatric Pulmonology Supplement, 15:17-21, 1997.
54. Guyatt, G. H., Juniper, E. F., et al. Children and adult perceptions of childhood asthma. Pediatrics, 99(2):165-168, 1997.
55. Juniper, E. F., Guyatt, G. H., et. Al. Minimum skills required by children to complete health-related quality of life instruments for asthma: comparison of measurement properties. European Respiratory Journal, 10:2285-2294, 1997.
56. Asthma in America™ A Landmark Survey, Executive Summary December 1998, www.asthmainamerica.com
57. Baena-Cagnani CE. Allergic rhinitis and asthma in children: disease management and outcomes. Current Allergy & Asthma Reports. 1(6):515-22, 2001.
58. Chan DS. Callahan CW. Moreno C. Multidisciplinary education and management program for children with asthma. American Journal of Health-System Pharmacy. 58(15):1413-7, 2001.
59. Buchner DA. Butt LT. De Stefano A. Edgren B. Suarez A. Evans RM. Effects of an asthma management program on the asthmatic member: patient-centered results of a 2-year study in a managed care organization. American Journal of Managed Care. 4(9):1288-97, 1998.
60. Gendo K. Sullivan SD. Lozano P. Finkelstein JA. Fuhlbrigge A. Weiss KB. Resource costs for asthma-related care among pediatric patients in managed care. Annals of Allergy, Asthma, & Immunology. 91(3):251-7, 2003.
61. Wyrwich KW. Nelson HS. Tierney WM. Babu AN. Kroenke K. Wolinsky FD. Clinically important differences in health-related quality of life for patients with asthma: an expert consensus panel report.[see comment]. Annals of Allergy, Asthma, & Immunology. 91(2):148-53, 2003.
62. Georgiou A. Buchner DA. Ershoff DH. Blasko KM. Goodman LV. Feigin J. The impact of a large-scale population-based asthma management program on pediatric asthma patients and their caregivers. Annals of Allergy, Asthma, & Immunology. 90(3):308-15, 2003.
63. Kercsmar CM. Current trends in management of pediatric asthma. Respiratory Care. 48(3):194-205; discussion 205-8, 2003.
64. Lukacs SL. France EK. Baron AE. Crane LA. Effectiveness of an asthma management program for pediatric members of a large health maintenance organization. Archives of Pediatrics & Adolescent Medicine. 156(9):872-6, 2002.
65. Battleman DS. Callahan MA. Silber S, et al. Dedicated asthma center improves the quality of care and resource utilization for pediatric asthma: a multicenter study. Acad Emer Med. 2001 Jul;8(7):709-15.
66. Sin DD. Fell NR. Man SF. Effects of increased primary care access on process of care and health outcomes among patients with a sthma who frequent emergency departments. Am J Med. 2004 Oct 1;117(7):479-83.

Appendix

Informed Consent (Not applicable, enrollment completed in Dec 2003 and patient follow-up completed Dec 2004)