REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 0704-0188

1. REPORT DATE *(DD-MM-YYYY)*	2. REPORT TYPE	3. DATES COVERED *(From - To)*
01-04-2005	Annual	15 Mar 2004 – 14 Mar 2005

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, WA 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

The purpose of this study is to examine a population-based intervention using preventive measures of a remote call-based asthma disease management program utilizing proactive education and monitoring. This intervention will be compared to a control population of pediatric asthma patients receiving printed education materials and usual care at three DoD military treatment facilities in a similar geographic region. Comparison will be made to examine differences in patient and caregiver quality of life (QOL), disease severity (as measured by reduced inhaled short acting beta agonist use), pulmonary function as measured by peak flow and spirometry (FEV1), and Emergency Department visits and hospital admissions.
To date the study has obtained IRB approval, established and utilized the contracting organization to hire study staff and reimburse the selected disease management (DM) firm. Needed supplies and equipment were purchased. A research database was created. Rollout procedures visits to the sites and DM firm were completed as were subsequent quality assurance visits. The study population was identified, recruited and enrollment was completed with 451 patients. 398 patients completed the study and final data acquisition and analysis are underway.

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			19b. TELEPHONE NUMBER *(include area code)*
U	U	U	UU	11	

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, WA 98405

REPORT DATE: April 2005

TYPE OF REPORT: Annual

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

DISTRIBUTION STATEMENT: Approved for Public Release;
Distribution Unlimited

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 will conduct a benefit analysis of an alternative disease management (DM) process.

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 Peak Expiratory Flow
- 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, patient peak flow values, 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 health 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 has been obtained. The Geneva Foundation established the trust and has been disbursing funds as requested. The study coordinators all have 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 have been hired. The DM statement of work was put out for bid. Asthmatics in the three study locations have been identified. Electronic peak flow meters have been purchased. Patient education materials and informed consent documents have been 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 is 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 has been identified via military and Foundation Health databases. Tricare Southwest has 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 have been contacted and enrolled. Informed consents have been signed and collected. Enrollment began in January 2003 and closed in December 2003 with 451 total patients enrolled. Educational materials have been 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 has been obtained. Patients have been randomized and the DM firm has been implimenting 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 will 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 have made it largely unusable. With the disappearance of TRICARE region VI we lost the personnel in that office supporting our grant. We have been working over the recent months to attempt to resurrect usable data from the final pull as well as to first find the source and get permission to access the claims and central pharmacy data that used to reside with region VI. This has been incompletely successful to date and we are attempting to merge the request with the possibility of using remaining personnel monies to contract the data acquisition but the legality and/or acceptability regarding policy are under review. We have 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 is complete and we have 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) have been accomplished.

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, the look at closeout regarding healthcare utilization has been problematic. The QOL, PEF, and FEV1 data have been converted to computerized format and are ready for analysis on the 398 patients completing the study

Months 28-29: Final data analysis

We are awaiting the cost and central pharmacy data prior to analysis..

Months 29-30: Findings and conclusion write up.

Pending above.

Key Resesarch Accomplishments

From first annual review:

- IRB approval obtained at both Wilford Hall Medical Center and Brooke Army Medical Center
- The Geneva Foundation established as contracting organization
- Study staff hired at each of the three sites
- Bids received and DM firm selected – National Jewish Medical and Research Center
- Study population identified via military and Foundation Health databases
- Electronic peak flow meters purchased
- Patient education materials and informed consent documents reproduced
- Research database established by Tricare Southwest
- Traveled to the DM firm to review and establish rollout procedures
- Traveled to three sites to review rollout and provide education/overview to primary care providers
- Study participants contacted and enrolled beginning January 2003 - 115 patients to date
- Patients randomized and DM firm performing call-based disease management
- Study participants contacted and enrolled with enrollment closed in December 2003 after enrolling 451 patients
- Seventy one participants have completed the study
- Electronic database has been modified and updated to capture all outcomes data for 6 month and 1 year/closeout visits
- Quality assurance visits have been undertaken to the DM firm (one to date) and to the sites (two to date)
- TRICARE lead agent has provided pharmacy data for participants that have completed the study and data is being entered
- TRICARE is engaged with the medical informatics staff to accumulate utilization and cost data on patients and to manipulate the format for most efficient analysis

New for this second annual review

- Patient enrollment, follow-up, and all patient driven data completed and closed out
- Drop-out and lost-to-follow-up rates remained low with 398 subjects completing the trial for a >88% retention
- Three clinical sites have closed and data collected with records centralized at lead site
- Adequate funds remained to allow for no-cost extention to finish data acquisition and analysis

Reportable Outcomes

Enrollment Data

SITE	Number intervention group/Number enrolled	Number completed[2]	Number withdrawn[2]	Number lost to follow-up[2]
	71/142	114	0	28
Tinker AFB				
Ft Sill	77/154	146	3	5
Sheppard AFB	77/155	138	2	15
Totals	**225/451**	**398**	**5**	**48**

Site	Mild Intermittent (%)	Mild Persistent (%)	Moderate Persistent (%)	Severe Persistent (%)	Mean Age (yr)	Male (%)	Mean FEV1 (L)	Mean FEV1 (% Predicted)
Tinker AFB	32	60	8	3	12.53	68	2.32	101
Ft Sill	27	39	29	5	13.45	62	2.02	94.3
Sheppard AFB	26	32	38	4	11.58	53	2.01	94.5
Totals	28	43	25	4	12.52	59	2.11	96.4

Conclusions

None

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.