Published in final edited form as:

Clin Trials. 2008 ; 5(1): 31–37. doi:10.1177/1740774507086647.

Internet-based monitoring of asthma symptoms, peak flow meter readings, and absence data in a school-based clinical trial

Leslie A McClure^a, Kathy F Harrington^b, Holli Graham^c, and Lynn B Gerald^b

^aDepartment of Biostatistics, School of Public Health, University of Alabama at Birmingham, Birmingham, Alabama, USA

^bLung Health Center, Division of Pulmonary, Allergy and Critical Care Medicine, Department of Medicine, School of Medicine, University of Alabama at Birmingham, Birmingham, Alabama, USA

^cBlue Cross and Blue Shield of Alabama, Birmingham, Alabama, USA

Abstract

Background—Asthma is the most common chronic childhood disease and has significant impact on morbidity and mortality in children. Proper adherence to asthma medication has been shown to reduce morbidity among those with asthma; however, adherence to medications is known to be low, especially among low-income urban populations. We conducted a randomized clinical trial to examine the effectiveness of an intervention designed to increase adherence to asthma medication among children with asthma that required daily collection of data.

Purpose and Methods—A specifically designed web-based data collection system, the *Asthma Agents System*, was used to collect daily data from participant children at school. These data were utilized to examine the intervention's effectiveness in reducing the frequency of asthma exacerbations. This study examines the *Asthma Agents System's* effect on the frequency of missing data. Data collection methods are discussed in detail, as well as the processes for retrieving missing data.

Results—For the 290 children randomized, 97% of the daily data expected were available. Of the outcome data retrieved via the *Asthma Agents System*, 5% of those expected were missing during the period examined.

Limitations—Challenges encountered in this study include issues regarding the use of technology in urban school settings, transfer of data between study sites, and availability of data during school breaks.

Conclusions—Use of the *Asthma Agents System* resulted in lower rates of missing data than rates reported elsewhere in the literature.

Introduction

Asthma is the most common chronic childhood disease and has significant impact on morbidity and mortality in children [1]. Inhaled cortico-steroids, when properly used, can offer considerable protection against asthma-related morbidity [2]. However, adherence to prescribed inhaled steroids among children is low; rates reported from various studies range from 22–77% [3–9] and differ markedly among populations with the lowest rates found among

inner-city and low income populations [7,10–13]. Recently, we conducted a randomized clinical trial to examine the effectiveness of an adherence intervention in children with asthma. The primary goal of this trial was to assess whether daily supervision of inhaled steroids at school could decrease asthma exacerbations among a population of children known to have low adherence rates. To accomplish the aims of the study, it was necessary to collect daily data on outcome measures such as peak flow monitor readings, asthma symptoms, and school absences. Previous experience with data collection in the schools indicated that such daily data collection is difficult to achieve without interrupting school schedules. Therefore, the investigators developed and pilot tested a system which would allow collection of such data with minimal interruption to the school day [14].

Data collection via internet

Increasing adherence to prescribed medications is an important step in reducing asthma-related morbidity. Identifying efficacious ways to increase adherence requires valid and complete data. Collecting data via the internet has been shown to result in more complete data and children have indicated a preference for this mode of data collection [15,16]. A study among fifth graders found a significant difference for missing responses for paper versus web-based surveys with seven times more missing responses for the paper format [16]. Additionally, internet direct data entry eliminates possible transcription errors, reduces staff work-load, and can force response selection, thereby reducing missing data [16]. This system, often referred to as computer-assisted survey interviewing (CASI) eliminates the potential of interviewer bias and allows engaging graphics to guide children's attention [17]. As well, this method can automate referral of participants for appropriate medical intervention [18]. Another advantage of web-based data entry is the ability to mechanize highlighting of missing or unclear data, facilitating correction or completion [19].

Asthma and absenteeism

School children with asthma have been found to miss 1.3 days [20] to 2+ days [21,22] more of school than their non-asthma peers. However, determining if asthma is responsible for these increased absences can be difficult. Moonie and colleagues [21] examined asthma severity and missed school days among a population of students in a predominantly African-American low income school district. Absences were determined by school records and documenting reasons for absences by a school nurse was a labor-intensive endeavor requiring interviewing absent students within two weeks of the missed school day(s). Of the 3408 absences tracked, 9% had missing or unclear data for absence reason. More frequently, reasons for missing school have been collected from school records [22–24], which often provide incomplete or inconclusive data. Others have noted problems in accessing asthma-related absence rates from schools [25]. Another source of absence reports, parental retrospective reports, was found to have poor correspondence with school records [20].

Asthma symptoms and peak flow meter monitoring

Symptom monitoring provides one mechanism with which to assess the severity of asthma exacerbations. However, among 110 adult asthmatic patients studied in South Africa, self-report of asthma symptoms tended to underestimate severity of disease [26]. Monitoring peak flow with a meter is a relatively simple and accurate way to assess children's airway obstruction, which provides an alternative to symptom monitoring. Peak flow meters provide a reading of the air flow from the lungs, resulting in a value in liters per minute. Asthma interventions frequently train children to monitor their asthma through daily use of a peak flow meter. These data often are collected through daily diaries as part of the study outcomes or to monitor the child's health. However, when studied, children have been found to be poor record keepers of peak flow meter readings. In a study of the accuracy and completeness of peak flow

diaries among 6–16-year-old asthmatic white children, Kamps and colleagues [27] found that peak flow diaries were unreliable, in that children did not actually utilize their peak flow meter as frequently as reported. A study among African-American and Hispanic asthmatic children aged 5–9 years similarly found that the children involved had difficulty maintaining peak flow records, so that data recorded in diaries did not reflect data recorded electronically [28]. Tinkelman and Schwartz [29] provided educational sessions to children with asthma and their parents that included daily peak flow meter use. Despite assistance by a staff person and use of a school computer, peak flow meter readings were recorded only 50% of the time (excluding holidays) into the internet monitoring system. In a randomized clinical trial exploring adherence to peak flow meter monitoring, Burkhart *et al.* [30] found at baseline that only 43% of children were adhering as prescribed to their peak flow meter monitoring. Poor compliance with adherence to monitoring translates to an inability to collect serial data of peak flow meter readings. To assess adherence with peak flow meter monitoring, Burkhart and colleagues utilized microchip technology, which is built in to the peak flow meter, and automatically tracks much of the data of interest. However, devices such as these do not include assessment of symptoms, another aspect of the data of interest in the current study.

Study purpose

This manuscript describes successful data collection using a web-based data collection system (the *Asthma Agents System*) specifically designed to collect daily data from children with asthma at school. The *Asthma Agents System* is instrumental in providing both daily monitoring of a child's asthma, as well as in collecting primary outcome measures that examine the efficacy of interventions to reduce asthma exacerbations. Two of the required outcome data, peak flow meter readings and school absences, were captured using the web-based data collection system.

Methods

Study design

After a one-semester baseline period during which all children were monitored using the *Asthma Agents System*, children were randomized to receive either the supervised therapy intervention or usual care. Randomization occurred at an individual student level within school system, in order to account for factors that may be similar within school systems. For those randomized to the supervised therapy intervention, study personnel monitored asthma medication use daily, while for those randomized to usual care, asthma medication use was assumed to be parentally supervised. Therapy was supervised by the same study staff member each school day at approximately the same time during the day. Study staff were responsible for supervising an average of 30 children (range: 21–39) in four schools (range: 3–7). Study staff assignment to schools was done on a geographical basis, in order to minimize travel time between schools. Peak flow meter monitoring was incorporated into the daily routine for the children and was done at the same time each day to avoid diurnal variation. However, if children forgot to do their monitoring, school staff prompted them to do so. School staff reports verified the peak flow meter reading when the child was present, or indicated that the child was absent. The primary outcome measure was asthma exacerbations, which were defined as one or more of the following each month: (1) red or yellow peak flow meter reading; (2) rescue medication use more than two times per week (not including pre-exercise treatment); or (3) absence from school coded as respiratory illness/asthma. Red and yellow peak flow meter readings were based on the values representing the child's 'best' peak flow rates during healthy periods at the beginning of each school year. Red readings indicated peak flow rates less than or equal to 50% of the 'best' value, while yellow readings indicated peak flow rates between 50–80% of the 'best' value. The primary study hypothesis was that those children randomized to the supervised therapy group would experience fewer exacerbations during the follow-up period than those randomized to usual care. Determining exacerbations required daily data collection

of peak flow monitor readings, school absences, and rescue medication use. The University of Alabama at Birmingham's (UAB) Institutional Review Board for Human Use approved and monitored the study. Details of the study design have been published elsewhere [31].

Population

Two hundred and ninety children in 37 inner-city schools were randomized. All children had persistent asthma and the need for daily controller medication. Parents provided consent for the child's participation and children gave assent. The average age of the students was 10.0 years (standard deviation = 2.1), 91% were African-American, and 57% were male.

Data collection

An interactive web-based system for collection of data from children with asthma and school staff was developed by Blue Cross and Blue Shield of Alabama in conjunction with UAB. The resulting *Asthma Agents System* allowed real-time monitoring of data and notification of health status while providing a fun way for children to provide data. Details of this system's development are provided elsewhere [14].

After enrollment into the study, data regarding peak flow meter readings and asthma symptoms, as well as absence data, were collected from students at school via an internet connection. Both children and school staff were trained to use the web-based system correctly. Each school day, participating students logged into the *Asthma Agents System* through a school computer terminal. With each log-in, the student was asked, 'How is your breathing today?' Response choices included: fine, coughing, wheezing, or tightness in chest. The program allowed children to report more than one symptom. Children were then prompted to blow into their peak flow meter and record the reading. When a child reported a green zone reading, the system replied with the message, 'Great! Go and play today.' When a child reported a reading falling into either the yellow or red zone, the system instructed the child to 'Stop and talk to an adult.' Yellow and red zone results generated automatic e-mails to the school nurse and study coordinator containing peak flow meter results and symptoms. Per the design of the study, a designated school staff member also logged into the *Asthma Agent System* daily to verify the child's reported peak flow meter reading. The school nurse logged on weekly to report whether any action resulted from the student's reported symptoms or readings. On any given day, if a student did not enter a report, the designated school staff member was prompted to enter a reason with response choices of: absent, did not report (indicating that the child simply did not complete the report that day), or other. When 'absent' was entered as the reason for no daily report being entered, upon the student's return, the staff was prompted to enter the reason for the absence. This information was obtained from a brief interview with the child. Response choices for reason absent included: asthma or respiratory illness, other illness, and other. Each school staff person had a designated back-up to perform these duties upon their absence. School staff were responsible for four children, on average. Based on anecdotal feedback from the teachers involved, school staff spent ≈ 10 min daily fulfilling their responsibilities for this protocol. There was no indication from school staff that the study interfered with day-to-day responsibilities in the classroom.

Daily reports were generated each day at 1:00 p.m. by the study statistician for student and teacher log-ins. At this time, study personnel reviewed the missing data and contacted school staff to encourage completion. Monthly reports were produced for reasons for school absences, highlighting any missing data, which the study personnel then attempted to retrieve.

As the outcome also included an increased frequency of rescue medication use, study staff also monitored this on a regular basis. In particular, rescue medication use was measured through the use of a DoserTM attached to the top of the inhaler, and activated automatically to record

use when an inhalation was taken. Study staff read the children's Doser™ at approximately two-week intervals. Since these data were collected off-line by study staff, missing data were not an issue, and thus will not be discussed herein.

Incentives

Both children and designated school staff were offered incentives to complete the daily *Asthma Agent System* log-in. Points were awarded to children for the completeness of their reports which could be redeemed for prizes. Staff also received points based on the frequency of their reports; their points could be redeemed for a national discount chain's gift cards.

Results

Between October 3, 2005 and May 30, 2006 a total of 40,044 daily *Asthma Agent* reports were expected from participating students and the school staff. During this time 35,296 (88%) reports from children were received, while 39,032 (97%) reports were received from the school staff. Figure 1 shows the proportion of expected reports missing by both the children and the school staff for each month and year of the data collection period. Of note in the figure is that the proportion of missing reports from the school staff improved after the intervention began on January 1, 2006. In fact, during the period prior to the intervention, 5% of the expected reports were missing, while only 1% was missing post-intervention ($p < 0.0001$). The last month of the school year has traditionally introduced additional challenges in data collection in this population due to increased absences and end of the year school activities. Therefore, it is not surprising that the proportion of data missing is higher among both the children and school staff for this time period.

Of the 4748 reports not obtained from a child, 540 (11%) of these were not obtained from the school staff either. Further, there were 472 reports for which peak flow meter readings were provided by the child, but were not verified by a staff report; however, for these instances we have sufficient data to indicate that the child was in school that day and to determine whether an exacerbation occurred. Among those reports obtained from the school staff but not from the child, an additional 304 did not include a reason for the child not completing the report. Thus, a total of 844 reports out of the expected 40,044 (2.1%) were missing, in that they did not provide adequate data regarding an exacerbation or a potential absence due to respiratory illness. Among the child reports that were not obtained, for which a report was completed by the school staff, 230 (6%) were missing for reasons other than the child was absent from school. Reasons for reports not being completed included that the student simply did not report ($n = 132$), the student was on a field trip ($n = 79$), the student was involved in standardized testing ($n = 4$), or the student was on vacation ($n = 15$). Thus, there were 3674 instances for which a child did not complete a report due to absence; 3490 (95%) had the reason for absence documented. One-hundred and eighty-four reports were missing the reason for absence (5%) overall and, thus, did not provide any information regarding the primary outcome. Figure 2 shows a flow chart indicating the completeness of the data. Since randomization (January 1, 2006), 123 reports were missing the reason for the absence. Of the children absences, those randomized to the supervised intervention were missing significantly fewer reasons than those randomized to usual care (38 vs. 63%, $p = 0.0007$), suggesting that the increased interaction between the study staff and school staff for the supervised group may be responsible for more complete data for this outcome. However, the proportion of the total number of reports that were missing did not differ between the usual care and supervised intervention groups (11%).

Overall, we were able to collect data 98% of the time that reports were expected; that is, only 2% of the time were expected reports missing. However, in order to determine the study outcome, it was not only important to have daily data collected, but when a student was absent the reason for the absence needed to be captured. Among the absence data collected, we are

missing the reason for the absence in 184 instances, representing 5% of the absence data. If we include these 184 missing reasons for absence in our overall missing data rate, the proportion of data missing is increased to 2.6% (1028 out of the expected 40,044 reports).

Limitations

While utilization of the *Asthma Agents System* provided many benefits, there were also challenges involved in the implementation and maintenance of the system. Initially, there was great difficulty in getting the system running on the computers in all of the schools. Problems encountered include: technical support problems in the individual schools and districts, as well as issues pertaining to firewall allowances given that the system involves flash video. The utilization of the school system technical staff required costs incurred by the school system beyond what was anticipated for this study. Further, the technical group at Blue Cross and Blue Shield of Alabama, who initially developed the system, also maintained the database. This required data transfers between the database manager and the study staff; however, a system for doing so was developed early in the study and was successful at reducing the amount of data that were missing overall and the number of absences that were missing the reason for absence. Given that the intervention was school-based, we were necessarily limited by when school was in session. That is, we were unable to collect data, especially data regarding asthma exacerbations, when the children were out of school: weekends, holidays, and during the summer. Additionally, the use of a system that allows all children to regularly monitor their asthma symptoms may introduce bias to the overall study in that, as children are more aware of the severity of their illness, they are more likely to treat it. In fact, this bias was observed as we saw improvement in all children enrolled in the study, regardless of the group to which they were randomized. Similarly, there is a potential ethical dilemma in providing a system by which the children monitored their asthma daily during the study period, but then eliminating their access to daily monitoring at the conclusion of the study. However, since the *Asthma Agents System* included educational and skills training components, it is the hope of the study team that during the study period the children developed the habit of assessing their lung function based on the presence and absence of symptoms and use of the peak flow meter. Finally, the system did not allow serious adverse events to be monitored. A separate database was developed to track these events.

Conclusions

Overall, the *Asthma Agents System* has been shown to be a successful means for tracking absences and peak flow meter data from inner-city school children and school staff. It provided a fun environment for the children to learn about and monitor their asthma, while providing a research tool that resulted in a small proportion of missing data, both outcome and explanatory data. This proportion was smaller than other studies have reported previously in the literature. For example, the Moonie *et al.* [21] study reports 9% of their reasons for absence as either missing or reason unclear compared to only 2.6% in our data. Further, Tinkelman and Schwarz [29] report that students in their study, with a similar design, entered asthma-related data into an electronic diary $\approx 50\%$ of time. In our study, we captured 87% of the daily asthma-related data; however, this estimate does not account for the fact that we were also able to capture the reasons that a child did not enter their data 95% of the time it was missing. As Tinkelman and Schwarz utilized an internet data collection tool in school similar to ours, it is interesting that their rate of missing data is much higher than what we observed. It is possible that since our system allowed for real-time data monitoring, which provided study staff the opportunity to actively retrieve missing data in a timely fashion, we were able to obtain reports that may have otherwise been missing. This, in turn, permitted more complete data for analysis. Further, it is also possible that the use of incentives motivated both children and school staff to enter data more completely. As the primary goal of the Tinkelman and Schwarz study was to examine

the effect of a school-based educational intervention on absences, which were not collected via the students' internet-based diaries, few details regarding the processes utilized to obtain these data are provided, making direct comparisons between the two studies difficult. Finally, the system allowed children to take an active role in their asthma management and care, in a population for whom this is not the norm.

The *Asthma Agents System* has been effective in reducing the amount of missing data for research purposes. However, a similar system providing asthma education and symptom and peak flow meter monitoring could be effective in day-to-day asthma management for children having daily computer access. Further, utilization of a system such as this may offer interesting opportunities for studies not only assessing medical outcomes, but also behavioral outcomes, such as adherence and medical care use, as well as quality of life outcomes. While a system such as *Asthma Agents* may not be the best means for reducing missing data in other settings, the results described herein highlight the need for data collection tools that are well-suited to the study at hand, as well as the population being studied.

Acknowledgments

Support provided by: NHLBI 5 R01 HL075043, Blue Cross and Blue Shield of Alabama, AstraZeneca Pharmaceuticals

References

1. Akinbami LJ, Schoendorf KC. Trends in childhood asthma: prevalence, health care utilization, and mortality. *Pediatrics* 2002 August;110:315–322. [PubMed: 12165584]
2. McAllister J. An overview of the current asthma disease management guidance. *British Journal of Nursing* 2004;13:512–517. [PubMed: 15215726]
3. Bender BG, Rand C. Medication non-adherence and asthma treatment cost. *Curr Opin Allergy Clin Immunol* 2004;4:191–195. [PubMed: 15126940]
4. Conn KM, Halterman JS, Fisher SG, et al. Parental beliefs about medications and medication adherence among urban children with asthma. *Ambul Pediatr* 2005;5:306–310. [PubMed: 16167856]
5. Farber HJ, Capra AM, Finkelstein JA, et al. Misunderstanding of asthma controller medications: Association with nonadherence. *Journal of Asthma* 2003;40:17–25. [PubMed: 12699208]
6. Fiese BH, Wamboldt FS. Tales of pediatric asthma management: Family-based strategies related to medical adherence and health care utilization. *J Pediatr* 2003;143:457–462. [PubMed: 14571219]
7. McQuaid EL, Kopel SJ, Klein RB, Fritz GK. Medication adherence in pediatric asthma: reasoning, responsibility, and behavior. *Journal of Pediatric Psychology* 2003;28:323–333. [PubMed: 12808009]
8. Milgrom H, Bender B, Ackerson L, et al. Noncompliance and treatment failure in children with asthma. *Journal of Allergy and Clinical Immunology* 1996;98:1051–1017. [PubMed: 8977504]
9. Walders N, Kopel SJ, Koinis-Mitchell D, McQuaid EL. Patterns of quick-relief and long-term controller medication use in pediatric asthma. *J Pediatr* 2005;146:177–182. [PubMed: 15689902]
10. Apter AJ, Reisine ST, Affleck G, et al. Adherence with twice-daily dosing of inhaled steroids: socioeconomic and health-belief differences. *Am J Respir Crit Care Med* 1998;157:1810–1817. [PubMed: 9620910]
11. Bender B, Wamboldt FS, O'Connor SL, et al. Measurement of children's asthma medication adherence by self report, mother report, canister weight, and doser CT. *Ann Allergy Asthma Immunol* 2000;85:416–421. [PubMed: 11101187]
12. Celano M, Geller RJ, Phillips KM, Ziman R. Treatment adherence among low-income children with asthma. *Journal of Pediatric Psychology* 1998;23:345–349. [PubMed: 9824922]
13. Zoratti EM, Havstad S, Rodriguez J, et al. Health service use by African Americans and Caucasians with asthma in a managed care setting. *American Journal of Respiratory & Critical Care Medicine* 1998;158:371–377. [PubMed: 9700109]
14. Mangan JM, Gerald LB. Asthma agents: monitoring asthma in school. *Journal of School Health* 2006;76:300–302. [PubMed: 16918859]

15. Caro Sr JJ, Caro I, Caro J, Wouters F, Juniper EF. Does electronic implementation of questionnaires used in asthma alter responses compared to paper implementation? *Qual Life Res* 2001;10:683–691. [PubMed: 11871589]
16. Mangunkusumo RT, Duisterhout JS, de Graaff N, et al. Internet versus paper mode of health and health behavior questionnaires in elementary schools: asthma and fruit as examples. *J Sch Health* 2006;76:80–86. [PubMed: 16466471]
17. Rew L, Horner SD, Riesch L, Cauvin R. Computer-assisted survey interviewing of school-age children. *Ans* 2004;27:129–137.
18. Kable S, Henry R, Sanson-Fisher R, et al. Childhood asthma: can computers aid detection in general practice? *Br J Gen Pract* 2001;51:112–116. [PubMed: 11217622]
19. Barnes J, Chambers I, Piper I, et al. Accurate data collection for head injury monitoring studies: a data validation methodology. *Acta Neurochirurgica* 2005;95:39–41. [PubMed: 16463817]
20. Bonilla S, Kehl S, Kwong KYC, et al. School absenteeism in children with asthma in a Los Angeles inner city school. *J Pediatr* 2005;147:802–806. [PubMed: 16356435]
21. Moonie SA, Sterling DA, Figgs L, Castro M. Asthma status and severity affects missed school days. *J Sch Health* 2006;76:18–24. [PubMed: 16457681]
22. Silverstein MD, Mair JE, Katusic SK, et al. School attendance and school performance: A population-based study of children with asthma. *J Pediatr* 2001;139:278–283. [PubMed: 11487757]
23. Bener A, Abdulrazzaq YM, Debuse P, Abdin AH. Asthma and wheezing as the cause of school absence. *J Asthma* 1994;31:93–98. [PubMed: 8175636]
24. McCowan C, Bryce FP, Neville RG, et al. School absence-a valid morbidity marker for asthma? *Health Bulletin* 1996;54:307–313. [PubMed: 8783484]
25. Meng A. A school-based asthma clinic: a partnership model for managing childhood asthma. *Nurse Practitioner Forum* 2000;11:38–47. [PubMed: 11219894]
26. Bheekie A, Syce JA, Weinberg EG. Peak expiratory flow rate and symptom self-monitoring of asthma initiated from community pharmacies. *Journal of Clinical Pharmacy and Therapeutics* 2001;26:287–296. [PubMed: 11493372]
27. Kamps AWA, Roorda RJ, Brand PLP. Peak flow diaries in childhood asthma are unreliable. *Thorax* 2001;56:180–182. [PubMed: 11182008]
28. Redline S, Wright EC, Kattan M, et al. Short-term compliance with peak flow monitoring: results from a study of inner city children with asthma. *Pediatr Pulmonol* 1996;21:203–210. [PubMed: 9121848]
29. Tinkelman D, Schwartz A. School-based asthma disease management. *J Asthma* 2004;41:455–462. [PubMed: 15281331]
30. Burkhart PV, Rayens MK, Oakley MG, et al. Testing an intervention to promote children's adherence to asthma self-management. *J Nurs Scholarsh* 2007;39:133–140. [PubMed: 17535313]
31. Gerald LB, McClure LA, Harrington KF, et al. Design of the supervised asthma therapy study: Implementing an adherence intervention in urban elementary schools. *Contemp Clin Trials*. 2007 (doi: 10.1016/j.cct.2007.07.010)

Figure 1.
Proportion of expected reports missing

Figure 2.
Status of the 40,044 child and staff reports expected