

The Validity and Acceptability of a Text-Based Monitoring System for Pediatric Asthma Studies

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Summary. A meaningful analysis in research requires robust, valid data. Paper diaries allow the collection of data from individuals over time but are notorious for poor compliance and validity. SMS-technology is a novel method for data collection in medical research. Time-tagged SMS are transferred directly to an electronic file. We used SMS to collect symptoms and peak flow rate (PEFR) meter readings from 32 children with asthma. Parents responded first to five SMS daily for 7 days during an asymptomatic period and then for 14 days during a cold. Compliance with use of PEFR meter and SMS system were assessed. Digital PEFR meters enabled data download at the end of the study to confirm validity of transmitted data. Parents of 24 participants provided feedback about this data collection tool. Mean ($\pm$ SD) "SMS-diary and PEFR-meter compliance" were 96% ($\pm$ 8) and 84% ($\pm$ 21) during baseline and 91% ($\pm$ 12) and 82% ($\pm$ 20) during cold respectively. Correctly reported PEFR values were found in 65.5% of all cases, in 8.3% PEFR values sent were "self-invented" and 2.4% of values were missing. All of the 22 parents completing the baseline questionnaire were happy to use SMS for this study. Of the 20 parents completing the follow up questionnaire, 95% (19/20) found the system user-friendly, 55% (11/20) would be more likely to participate in studies if they were using SMS data collection and 25% (5/20) were "sometimes unhappy" about receiving messages. This real-time capture of data is well accepted and could avoid some of the pitfalls of backfilled paper diaries. **Pediatr Pulmonol.**

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INTRODUCTION

A crucial aspect of a clinical trial is the instrument used to acquire the data for analysis. The quality of the data collected is dependent on the quality of that instrument. A meaningful analysis is only possible if the collected data is valid. Traditionally face-to-face or telephone interviews, observation, paper questionnaires, or diaries completed by participants have been used. Questionnaires allow the respondent to reflect on the response, and answer more intimate or embarrassing questions. Written questionnaires assume the participant has sufficient literacy skills to understand and respond. Interviews allow personal contact between researcher and participant but the respondent may choose to please rather than be entirely honest and accurate. Paper diaries allow the collection of carefully selected data from an individual over time but they are renowned for low compliance and low reliability.¹ Web-based systems are limited by the need for participants to have access to a computer and the internet.

Short Message Service (SMS) is a text messaging service component of phone, web, or mobile communication systems. It is very commonly used in everyday life as a way of communication, especially among younger generations. SMS has recently been used as a novel way

of collecting data in research.^{2–4} This system is either free or relatively cheap and is user-friendly with messages delivered instantaneously to individuals at any time or

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place. Messages can be stored and retrieved and be answered at the recipient's convenience. The same message can be sent to multiple recipients simultaneously. In combination with the appropriate software, SMS data can be transferred automatically and directly to an electronic data file accessible by the researcher. This real-time capture of data also avoids the pitfalls of backfilled and/or falsified paper diaries as responses are time-tagged.

In our study the parents of children aged 5–11 years were asked to respond to regular text messages sent by the study team. These text messages related to symptom reporting and to expiratory peak flow values recorded by digital peak flow meters. The aim was to first capture baseline measurements during an asymptomatic period of 7 days and then obtain measurements during 14 days of cold symptoms $\pm$ cold induced exacerbation. Before these data were used for calculation of a continuous variable reflecting asthma control/exacerbations ("asthma index"⁵), compliance, validity of collected data, and acceptability of the method were evaluated.

METHODS

Study Design

We conducted an observational study to assess the feasibility of using a SMS data recording system in children with asthma. Children were recruited and assessed during a baseline visit (history, examination, lung function, nasal washings and saliva sampling, blood test, skin prick testing). Children monitored their peak expiratory flow rate (PEFR) at home using a peak flow meter (Mini-Wright; Clement Clarke International, UK) that digitally stored results. Participants measured their PEFR twice a day at home during a baseline week. Parents received a daily text message asking about cold symptoms. The maximum period of monitoring for colds was 10 months. Home visits were conducted by the study team when children developed an upper respiratory tract infection and examinations and tests were repeated. During a cold episode, PEFR was again measured twice daily over a 2 week monitoring period. The information from the digital PEFR was sent via SMS to the study team together with further information about cold and asthma symptoms. The study was approved by the Southampton & South West Hampshire Research Ethics Committee B (Ref. 10/H0504/52). Written informed consent from parents and assent from children were obtained. Figure 2 gives an overview of the study.

Participants

Children aged 5–11 years with doctor diagnosed asthma, treatment with inhaled corticosteroids, and a history of interval symptoms and exacerbations with

upper respiratory tract infections (at least two such exacerbations in the previous year) were recruited from pediatric outpatient clinics, the pediatric assessment unit or the emergency department at Southampton Children's Hospital and via community asthma nurses. Children who were unable to perform lung function measurements, who were known for poor compliance with medication, who were treated with more than 1,000 mcg beclomethasone equivalent a day or who had a history of other lung diseases were excluded.

Text Message System

The researchers sent SMS messages to parents of participating children and received their responses via a third party SMS provider called *ClinicalSMS Ltd* (Bournemouth, UK). This is a two-way SMS messaging server that sent, received and stored time-tagged messages. No identifiers other than mobile phone numbers were stored. The schedule of SMS messages used in this study is shown in table 1. All parents of children participating in the study received as a standard six text messages a day (four in the morning, two in the evening) for seven days during the baseline week (total number: 42 SMS) and five text messages a day (three in the morning, two in the evening) for fourteen days during a cold episode (total number: 70 SMS) (see table 1). Parents chose a time in the morning (7:00–10:00) and in the evening (17:00–20:00) when they wanted to receive the text messages. They received a reminder after one and after two hours if they had not responded to the messages.

Assessment of Compliance

Compliance with the SMS data collection system was assessed using the proportion of sent text messages (SMS 3; table 1) to the number expected ("SMS-diary-compliance"). The proportion of digitally stored PEFRs to the number expected was calculated to determine the compliance to the PEFR-monitoring ("PEFR-meter-compliance"). Results are reported as percentage (standard deviation).

Assessment of Validity

Participating children and their parents were informed that the digital peak flow meters stored the measurements of peak flows and these would be downloaded at a later stage. Parents were asked to score asthma related symptoms and to send these together with the PEFR (measured by the digital peak flow meter) by text message system (SMS 3; table 1) twice daily during the baseline period and cold episode (most severe episode where more than one was monitored). The PEFR data sent by SMS ("sent") were compared with the PEFR data stored and then downloaded from the digital peak flow meter

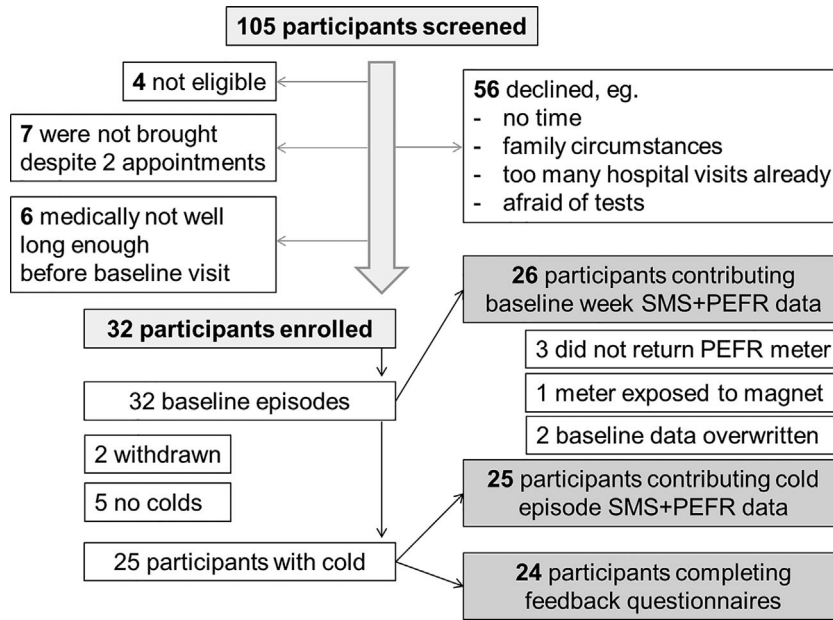


Fig. 1. Flow sheet of all participants screened for participation in study and numbers contributing to final analysis sets.

(“measured”) at the end of the study (both types of data were time-tagged). Data points were split into the following 5 categories: (1) PEFR sent/PEFR measured/corresponding (“correct”); (2) PEFR sent/PEFR measured/not corresponding (“incorrect”); (3) PEFR sent/PEFR not measured (“self-invented”); (4) PEFR not sent/PEFR measured (“not sent”); (5) PEFR not sent/PEFR not measured (“missing”). Median percentages (25th and 75th percentile) are presented. Additionally, the median

difference between paired SMS and digital peak flow meter PEFR measurements were calculated for individual participants and representative Bland–Altman plots generated.

Assessment of Acceptability

A total of 24 parents received a baseline questionnaire focused on their everyday use of mobile phones, SMS

TABLE 1—Data Collected Via SMS System

Text message	Name	Time of day	Text message sent	Example of response	Baseline 7 days	Daily monitoring	Cold 14 days
SMS 1	Daily Cold question	am	Does your child have a sore throat, more nasal symptoms than usual (not hayfever/allergy related), or a cold or flu? (Y/N)	‘Y’ e.g., in parent’s view child has cold symptoms	✓	✓	
SMS 2	Cold symptoms	am & pm	Sore throat? Runny nose? Sneezes? Nasal congestion? Tired? Fever? Headache? Hoarseness? Earache? Cough? (Score each 0–3)	“1012200112” e.g., mild sore throat no runny nose etc.	✓		✓
SMS 3	Asthma symptoms I	am & pm	Chest tightness? (0–3) Wheeze? (0–3) Cough? (0–3) Short of breath? (0–3) PEFR value? (030–999)	“1220420” e.g., mild chest tightness, moderate wheeze and cough, no SOB, PEF 420	✓		✓
SMS 4	Asthma symptoms II	am	No of times woken during the night to use inhaler? (0–9) No of extra puffs used in 24 hr for acute symptoms? (0–99)	“212” e.g., used inhaler twice over night and used 12 extra puffs in previous 24 hr	✓		✓

messaging, and their feeling about using text messages in the context of a research study. All parents received a text message information sheet explaining the use of SMS in this research study. This also included a troubleshooting guide and contact details for the research team. A follow up questionnaire at the end of the study more specifically asked about the parents' experience with the text message system, the reason why they might not have replied, and whether they would be happy if this was used in a future study where they (or their child) might take part. Both questionnaires allowed for free comments in addition to either yes–no or Likert scale questions.

RESULTS

A total of 32 children were recruited into the study and baseline visits were performed. Participating children had a mean (range) age of 7.7 (5.3–11.7) and 56% (18/32) were male. Their daily inhaled corticosteroid dose was 100–200 µg, 250–400 µg, 500–800 µg, and 1000 µg in 40.6%, 28.2%, 21.9%, and 6.3%, respectively. 12/32 (37.5%) were using a long acting β-agonist and 15/32 (47%) leukotriene receptor antagonists. Pre- bronchodilator lung function using the Global Lungs Initiative (GLI) equations showed a mean (SD) forced expiratory volume in first second (FEV1) of 94.8% (15.9) of predicted and a full vital capacity (FVC) of 106% (12.3) of predicted. Two children withdrew from the study and five children did not develop a cold episode during the study period. This left 25 children who were monitored by regular PEFR measurements and 2 home visits during each cold episode (Fig. 1). Nine of these children developed a second cold episode. The average number of days ($\pm$ standard deviation) between baseline and cold

episode was 70 ($\pm$ 64) days with a range of 6–286 days.

Three participants (V007, V008, V013), who did not develop a cold and did not return their digital peak flow meter at the end of the study, were excluded from this analysis as their peak flow meter data were missing. One participant (V004), who withdrew from the study before developing a cold, reported exposure of the peak flow meter to strong magnetic field and no data could be downloaded and they were therefore also excluded. Two participants (V009 and V010) continued to use their peak flow meter on a daily basis beyond the recommended monitoring as part of the study involvement and their data exceeded the data storage limit of the digital peak flow meter leading to the initial baseline data to be overwritten. V010 developed a cold and the SMS and peak flow meter data during the cold episode were available for analysis (see fig. 1).

Compliance

The overall “SMS-diary- compliance” during baseline (32 participants) and during a cold episode (25 participants) was 96% ($\pm$ 8) and 91% ($\pm$ 12), respectively. The overall “PEFR-meter compliance” during baseline (26 participants) and during a cold episode (25 participants) was 84% ($\pm$ 21) and 82% ($\pm$ 20) respectively. Illustrative examples of participants with different levels of compliance are given in Figure 3.

Validity

The median percentage of correctly reported PEFR values for all the participants (baseline and cold weeks combined) was 65.5% (32.7, 82.1) with the lowest value being 7.1% in one participant and up to 100% in others (Table 3). There was a statistically non-significant

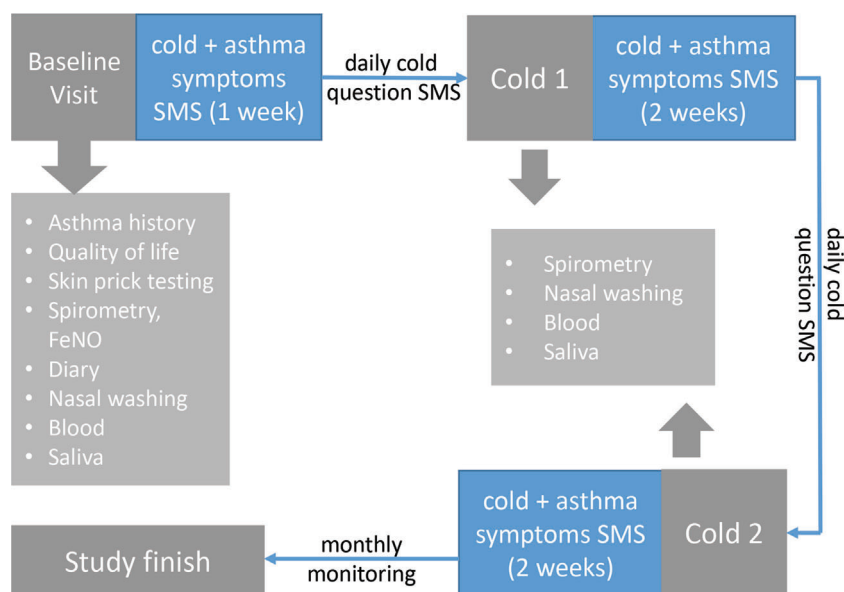


Fig. 2. Study overview.

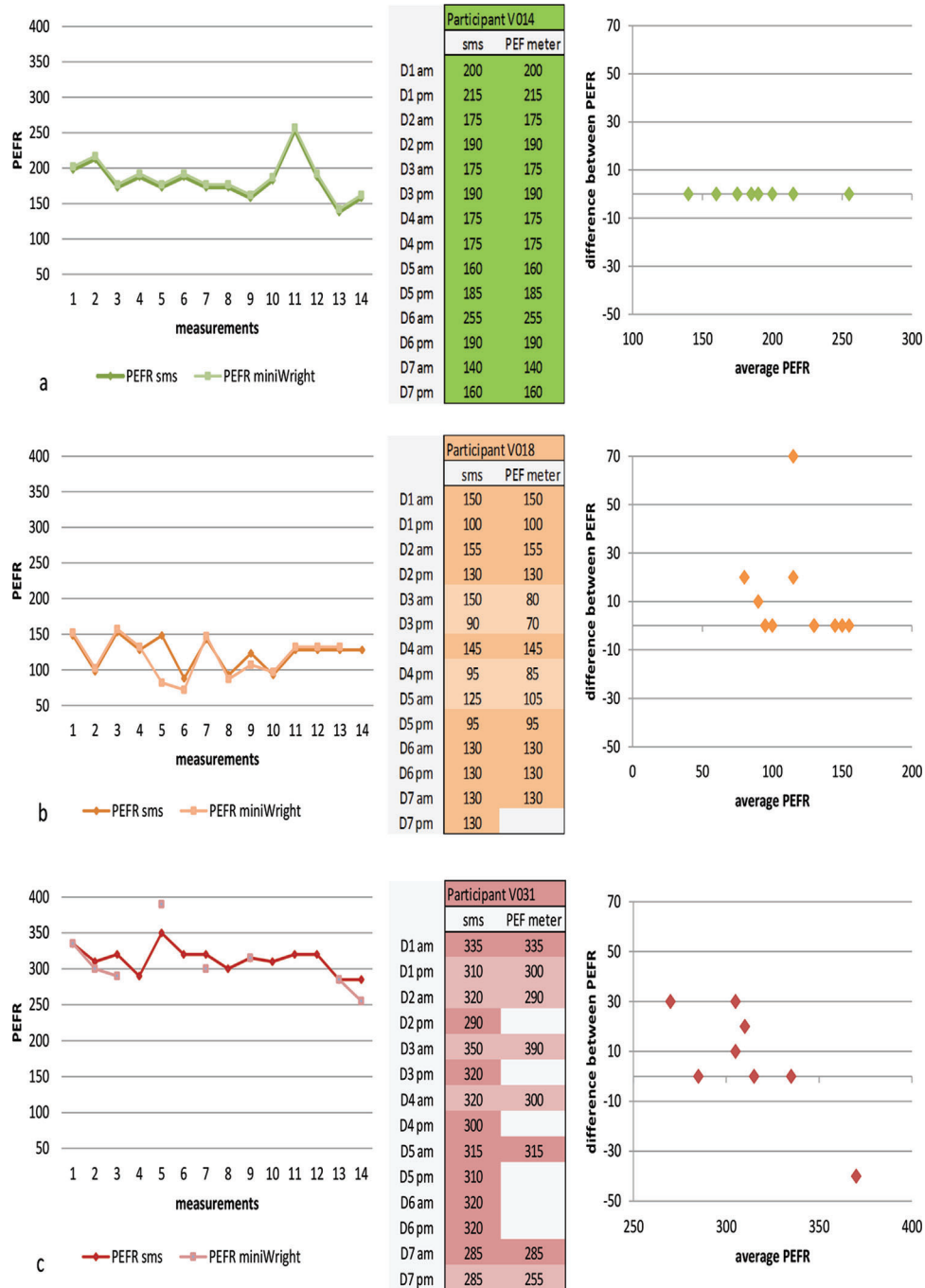


Fig. 3. Peak flow data during baseline week—comparison of data sent via SMS and digitally stored on PEF meter as diary charts (left pane), comparison of measurements (central pane) and Bland–Altman plot (right pane). a. Participant V014 with 100% “SMS-diary-compliance” and “PEFR-meter-compliance” and 100% “correct” values. b. Participant V018 with 100% “SMS-diary-compliance,” 93% “PEFR-meter-compliance” and 64% “correct” values. c. Participant V031 with 100% “SMS-diary-compliance,” 57% “PEFR-meter-compliance,” 21% “correct” values and 43% “self-invented” values.

TABLE 2—Acceptability of Using SMS for Collecting Research Data

Questionnaires					
Baseline Questionnaire					
1. How do you feel about using text messages as a way of providing information to the research team about your child's cold and asthma symptoms? (n = 22)	Very happy 16 (73%)	Happy 6 (27%)	Neutral 0	Unhappy 0	Very unhappy 0
Follow up Questionnaire					
1. Did you reply to the text messages every day? (n = 20)	All of the time 10 (50%)	Most of the time 10 (50%)	Some of the time 0	Hardly ever 0	
2. At times you did not reply to the text messages, what was the reason for it (name all)? (n = 20)	Lack of time 4 (20%)	At work 2 (10%)	Forgot about it 1 (5%)	No credit 2 (10%)	Other ^a 4 (20%)
3. Did you feel annoyed or unhappy at any stage about receiving text messages related to our research study? (n = 20)	No, never 14 (70%)	Rarely 1 (5%)	Sometimes 5 (25%)	Once a week 0	Every day 0
4. If you decided to take part in another research study, would the fact that it also uses text messaging as a way of gathering data...	Make it more likely for you to participate in the study? 11 (55%)		Not influence your decision to take part either way? 9 (45%)		Put you off from participating? 0

^amostly related to poor phone reception.

difference between reporting during the baseline week, and the first and second cold weeks (see table 3). In 8.3% (2.4, 15.5) of all cases PEFR values sent were “self-invented” and did not have a time-tagged correlate on the PEFR meter (57% in one participant) and 2.4% (0.0, 4.8) of values were missing. For the purpose of this study the actual digitally stored PEFR values were used for further analysis of data and these were available in 83% of all cases. Figure 3 shows three examples of participants’ compliance with SMS-diary and PEFR-meter and the validity of data in the form of diary charts, comparison of measurements and Bland–Altman plots. E-TABLE 1 and 2 show the median difference and 25th and 75th percentile of SMS versus PEFR meter data for all research participants.

Acceptability

92% (22/24) and 83% (20/24) of parents completed the baseline and follow up questionnaires respectively. Parents of participating children completing the baseline questionnaire were in general very familiar with the use of mobile phones and text messages: 86% (19/22) have had a mobile phone for more than five years, 59% (13/22) had a mobile phone contract and 73% (16/22) sent at least 50

SMS a month. A quarter of parents were familiar with the use of text messages in the context of appointment and school reminders, car parking, bills, surveys and buying concert tickets. None of them had used SMS in the context of a research study before.

All (22/22) parents were “very happy” or “happy” to use SMS for this study. Of the 20 parents completing the follow up questionnaire, 95% (19/20) found the system user-friendly and 55% (11/20) said that they would more likely participate in a study if it was using SMS for data collection. 25% (5/20) felt “sometimes unhappy” about receiving the SMS with “lack of time” or being “at work” mentioned as reasons. Issues with mobile phone reception (signal) were mentioned by two participating parents. See table 2 for more details.

DISCUSSION

SMS has previously been used for data collection in several medical studies. Response rates were compared between a text messaging system (80.2%) and a card response (85.6%) method in a survey about satisfaction with GP consultations.⁶ An RCT comparing SMS, paper and online diaries to collect details of weekly sexual

TABLE 3—Validity of PEFR Values During Baseline Week and First and Second Week of Cold

	Baseline week	Cold—first week	Cold—second week	All weeks
PEF sent/PEF measured/corresponding ^a	71.4 (42.9, 78.6)	50.0 (17.9, 82.1)	64.3 (32.1, 82.1)	65.5 (32.7, 82.1)
PEF sent/PEF measured/not corresponding ^b	14.3 (7.1, 28.6)	14.3 (7.1, 28.6)	14.3 (3.6, 35.7)	15.5 (10.1, 23.2)
PEF sent/PEF not measured ^c	7.1 (0.0, 21.4)	7.1 (0.0, 17.9)	7.1 (0.0, 17.9)	8.3 (2.4, 15.5)
PEF not sent/PEF measured ^d	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)
PEF not sent/PEF not measured ^e	0.0 (0.0, 0.0)	7.1 (0.0, 7.1)	0.0 (0.0, 3.6)	2.4 (0.0, 4.8)
Number of text messages	350	322	322	994

Median (25th, 75th percentile) percentages of a. correct, b. incorrect, c. self-invented, d. not sent, and e. missing values. “sent” refers to values transmitted via SMS. “measured” refers to values digitally stored on PEFR meter.

behaviour found SMS to be a convenient, timely data collection tool.⁷ A mobile phone text message service consisting of daily reminders to use an inhaler, health education tips, and safety messages was used in a feasibility and acceptability study of 32 people with asthma between 10 and 46 years of age. The system was well received.⁸ Our study is the first, to our knowledge, to collect research data using very frequent text messages between the study team and parents of younger children (5–11 years) with asthma and evaluating compliance, acceptability, and validity of data in this set up.

The parents of children participating in this study received and had to respond to 42 text messages during a baseline week and 70 text messages over fourteen days during a cold episode. In addition, children were asked to use a digital peak flow meter twice a day to record their PEFR and then transmit this information as part of this SMS diary. This clearly asked for a considerable commitment to the study. Despite this, the average “SMS-diary-compliance” during baseline period and cold episode was 93.5% and the majority of SMS transmitted PEFR data was validated by recorded digital peak flow meter data with only a small minority of data recorded inaccurately. In general, therefore, the SMS message system was a very acceptable approach for families to collecting research data.

Parents were aware that the digital peak flow meters stored the PEFR values which would be downloaded at the end of the study. It may therefore seem surprising that the overall SMS-transmission rate of correct PEFR values was only 65.5%; additionally in 8.3% of cases PEFR values appeared to be “self-invented” by parents. This phenomenon is usually a feature of falsified paper-diaries that often get retrospectively completed with invented values just before the clinic visit.¹ In a study trying to uncover barriers and benefits associated with internet-based self-management, 97 adolescents with asthma were asked to enter PEFR values daily into a designated web-application or to send them via SMS over a four-week period.⁹ They did not know that the spirometer stored the values and that data could be downloaded subsequently. The overall compliance was 90% with correct reporting of PEFR values on 79% of days. Our compliance was slightly lower, perhaps because they were not routinely followed immediately by feedback and/or therapeutic consequences as parents were advised to obtain medical advice as they would usually do. This might have negatively influenced compliance but would be an issue that could be addressed relatively easily. PEFR values were also less likely to be correctly reported in our study than in the adolescent study.⁹ Around 15% of PEFR values recorded on the peak flow meter were either wrongly transmitted via SMS and some were not sent at all. This may partly be a reflection of the study design as, due to the age of the children, parents were asked to send

the PEFR via their mobile phone and not the children themselves. This has led to a split between the performance of PEFR meter measurements by the children and the electronic transmission of the PEFR value by parents. While some children may have been closely supervised performing the PEF manoeuvre and the PEFR value immediately read and transmitted by parents, others may have performed measurements independently and only informed their parent of a value if asked for it. This would lead to an increased risk of errors that can possibly be avoided if the operator of the digital PEFR meter and the mobile phone are the same⁹ or the PEFR meter transmitted the data electronically to the researcher’s data base. However, despite a surprisingly high percentage of incorrect values transmitted via SMS, a closer look at the actual PEFR values (E-tables 1 and 2) reveals that the median difference (and 25th and 75th percentile) between SMS transmitted PEFR values and PEFR meter stored values in most cases is zero.

We believe that the instantaneous symptom reporting with this SMS system improves validity for two reasons. Firstly there is the benefit of being reminded by SMS about performing PEFR measurements and about paying attention to and scoring symptoms at the time. Secondly the need to reply by SMS at the time avoids the recall bias and retrospective filling of paper diaries and therefore adds to increased validity of reported symptoms. While one could argue that this reminder could also be a trigger for completing a paper-diary in real-time this in the end still carries the risk of retrospective completion.

The real-time capture of data appears to be well accepted and could avoid some of the pitfalls of backfilled paper diaries although the validity of the data is not absolute. Some of the discrepancies between PEFR meter values and SMS-transmitted values may be avoided in older children or teenagers who could operate both devices (PEFR meter and mobile phones) independently. Nowadays there is a large number of hardware platforms used as electronic subject diaries such as special-purpose devices for collecting one measure by button push, pen-based multifunctional portable computers, or interactive voice response systems. In the context of asthma research, devices that provide an integrated electronic diary with a peak flow meter¹⁰ and in combination with Bluetooth technology¹¹ that transfers data instantly into an e-Diary, PDA or mobile phone may be the way forward.

We noted, however, that a significant number of parents in our study population had pay-as-you-go phones and access to smartphones and instant reporting on an internet page may possibly be more difficult in some areas than others depending on the socioeconomic composition of the population. SMS messaging is a relatively low cost approach to collecting data in follow up studies involving children and young people.

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