the normal population of women.[8] Though our results need replication, this suggests that our results may be applicable to women attempting to conceive naturally.

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# Diary keeping in asthma: comparison of written and electronic methods

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## Abstract

*Objective*—To determine the extent to which symptom diaries of asthmatic patients are inaccurate or based on retrospective recall.

*Design*—Comparison of electronic and pencil and paper diaries. Both forms were completed twice daily at home for 14 days.

*Setting*—Outpatient clinic.

*Subjects*—24 asthmatic outpatients also tested for severity of asthma and for anxiety.

*Results*—More sessions were missed in the evening than in the morning for both types of diaries. Significantly more retrospective entries were made in the evening (26 entries, 14 patients) than in the morning (6 entries, 3 patients). Discrepant entries of peak expiratory flow accounted for 15% of those made on the appropriate day, and three quarters of patients made at least one discrepant entry. Variation in peak expiratory flow was significantly related to number of discrepancies and number of missing days, and anxiety score was significantly related to number of missing days. About a fifth of written entries may have errors.

*Conclusion*—Poor diary completion may result from having unreasonable expectations of patients and giving incomplete instructions. Electronic, time coded diaries could ensure better quality of records.

## Introduction

Daily recording of diary cards of subjective and objective assessments of the severity of disease is commonly used to monitor chronic conditions, such as asthma, which exhibit an intrinsic variability. Self completed diaries are preferable to single questionnaires or clinic based consultation because accurate recall of symptoms may be affected by memory bias[1] and single measures may be misleading. The validity of the diary method requires, however, that patients complete their diaries on the day stated rather than retrospectively, and that the patient's record—for example, of peak expiratory flow—is accurate. Few researchers who use this method regularly will not have doubted, at one time or other, that these assumptions are not always met. For example, symptom diaries that have been completed in blocks of different coloured ink arouse a suspicion that the patient may have been completing the diary in blocks of days rather than daily. Some researchers try to counteract this problem by frequently collecting diary forms,[2] but this is a burdensome procedure and the actual extent to which diaries are inaccurate or based on retrospective recall is unknown.

Developments in electronic diaries allow the problem of retrospective recall to be tested experimentally. The Asthma Question Box is a modified Psion Organiser that is programmed to ask patients questions about their symptoms and to allow them to record peak expiratory flow. The computer is also programmed automatically to store the actual date of data entry, without displaying this information.

The purpose of this study is to compare results from the Asthma Question Box with a conventional paper and pencil symptom diary to obtain information about missing records, retrospective completion (from an analysis of electronic date records), and accuracy (from comparison of data entry by the two methods).

## Methods

As part of a larger study in which asthmatic outpatients were told that assessments were being

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evaluated, 24 asthmatic patients (not experienced trialists) completed a paper and pencil diary and the Asthma Question Box at home, twice daily for 14 days. Patients were instructed to fill in the two diaries for 14 days, but were not told that the computer automatically records date of data entry, nor were they given instructions of what to do should they have forgotten to make the daily entry. Both types of diary required entry of twice daily measures of peak expiry flow. Patients were asked to write down the highest of three blows for the paper and pencil diary and to enter the values of all three blows into the computer. The effect of a provocative dose of histamine on forced expiratory volume ($PC_{20}$) was assessed in the clinic; the patient also completed the Spielberger test to measure dispositional anxiety.[3]

## Results

Some patients failed to record data on one or more days either on the written record or the electronic record (table I). A Friedman non-parametric analysis of variance and subsequent analysis with the Wilcoxon signed rank test of the number of missing entries for each patient for each type of diary showed that more sessions were missed in the evening than in the morning for both the written ($p < 0.05$) and electronic diaries ($p < 0.001$), but differences for neither evening nor morning in the two forms of record keeping were significant.

Retrospective completion was defined by a missing entry on the Asthma Question Box followed by two or more entries on the next day. Table II shows the raw data from one patient who on two occasions made a written record but not an electronic one, but has made two electronic records on the subsequent day. In the total sample there were six (2%) retrospective completions during the morning and 26 (9%) in the afternoon. Three patients engaged in retrospective completion in the morning (on 1, 1, and 4 occasions), and 14 patients engaged in retrospective recall in the evening (1-5 occasions). A Wilcoxon signed rank test on the number of retrospective completions per patient

TABLE I—*Missing entries in written and electronic records over 14 days (24 patients; 336 records morning and evening)*

| | Morning | Evening |
| --- | --- | --- |
| No (%) of entries missed: | | |
| Written | 17 (5) | 30 (9) |
| Electronic | 18 (5) | 47 (14) |
| No of patients who missed entries: | | |
| (No of entries missed): | | |
| Written | 7 (1·8) | 12 (1-9)* |
| Electronic | 10 (1-5) | 17 (1-10)*** |

*$p < 0.05$, ***$p < 0.001$, morning $v$ evening sessions.

TABLE II—*Example of recorded data (peak expiratory flow (l/min) measured morning and evening) for written diary and electronic diary for one patient. Blanks indicate missing data*

| Written diary | | | Electronic diary | | | | Discrepancies | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Date* | Morning | Evening | Date† | Morning | Date† | Evening | Morning | Evening |
| 20/3/92 | 220 | 300 | 20/3/92 | 220 | 20/3/92 | 300 | 0 | 0 |
| 21/3/92 | 250 | 250 | 21/3/92 | 250 | 21/3/92 | 250 | 0 | 0 |
| 22/3/92 | 225 | 250 | 22/3/92 | 275 | 22/3/92 | 250 | 50 | 0 |
| 23/3/92 | 200 | 250 | 23/3/92 | 200 | 23/3/92 | 275 | 0 | 25 |
| 24/3/92 | 200 | 275 | 24/3/92 | 200 | 24/3/92 | 275 | 0 | 0 |
| 25/3/92 | 200 | 250 | 25/3/92 | 200 | [26/3/92 | 200] | 0 | |
| 26/3/92 | 200 | 250 | 26/3/92 | 200 | [26/3/92 | 250] | 0 | |
| 27/3/92 | 220 | 225 | 27/3/92 | 225 | 27/3/92 | 225 | 5 | 0 |
| 28/3/92 | 250 | 250 | 28/3/92 | 260 | | | 10 | |
| 29/3/92 | 225 | 250 | 29/3/92 | 225 | 29/3/92 | 250 | 0 | 0 |
| 30/3/92 | 225 | 250 | 30/3/92 | 225 | [31/3/92 | 250] | 0 | |
| 31/3/92 | 225 | | 31/3/92 | 220 | [31/3/92 | 250] | 5 | |
| 1/4/92 | 220 | 250 | | | | | | |
| 2/4/92 | 200 | 225 | 2/4/92 | 225 | 2/4/92 | 225 | 25 | 0 |
| Total: | | | | | | | | |
| Valid entries | 14 | 13 | | 13 | | 8 | | |
| Discrepancies | | | | | | | 5 | 1 |

*Entered by hand.     †Automatic and unseen entry.

showed significantly more ($p < 0.002$) retrospective completions in the evening.

Discrepant entries were defined by a discrepancy between the written and electronic records of peak expiratory flow (table I). Excluding days when patients had made multiple electronic entries (where the data are ambiguous), there was no significant difference between frequency of discrepant entries in the morning compared with the evening. The total number of discrepant records was 75 (15% of those not made on multiple entry days), and 75% of patients made at least one (1-9) discrepant entry. The mean discrepancy where a discrepancy occurred was 39 (3-200) l/min.

To explore possible reasons for the different kinds of error reported above the following calculations were made for each patient: total number of missing days, total number of retrospective completions, and total number of occasions on which a discrepancy occurred between written and electronic records. These totals were then correlated with each patient's period maximal diurnal variation in peak expiratory flow (maximum evening value minus minimum morning value divided by maximum evening value), $PC_{20}$ histamine, and anxiety score. The patients studied had a range of asthma severity, with maximal period diurnal variation in peak expiratory flow ranging from 23 to 79% and from 0·11 to 102·0 mg/ml being required to cause a 20% drop in forced expiratory volume ($PC_{20}$). Significant ($p < 0.05$) correlations were found between variation in peak expiratory flow and number of discrepancies ($r = 0.45$), between peak expiratory flow variability and number of missing days ($r = 0.41$), and between anxiety score and number of missing days ($r = 0.47$).

## Discussion

We compared the quality of data entry for a paper and pencil diary and an electronic diary. Although the requirement for a double diary entry may have increased errors, our data showed that patients are more likely to make retrospective entries in the evening and are more likely to miss data in the evening than in the morning, but errors in data entry (inferred from discrepancies between the two forms of entry) are no more likely in the evening than the morning. Adding the percentage of retrospective completions and the percentage of errors (discrepancies) provides an estimate of the maximum percentage of errors that could occur for the entries in paper and pencil diaries such as those used in clinical trials: 2%+15%=17% for the morning and 9%+15%=24% for the evening. As discrepancies may well overestimate the number of errors that actually occur in a trial (for example, the electronic rather than the written record may be erroneous), the minimum estimate is that provided by retrospective completions alone—namely, 2% in the morning and 9% in the evening.

Examination of the correlations between the various measures of diary quality and other indices provides some insight into the antecedents of diary quality. The numbers of missing and of discrepant entries were correlated ($r = 0.42$, $p < 0.05$), and both of these were also correlated with variability in peak expiratory flow; this variability also correlated with missing data. It may be that a trait of general carelessness (apparently associated with anxiety) manifests as poor quality diary entry, as well as erratic usage of medication resulting in greater maximal variation of peak expiratory flow. The antecedents of retrospective completion are less clear as this variable was not significantly associated with any other.

This study shows that the quality of diary completion is often poor. Rather than blaming patients

for being too slap happy, it may be that accurate completion of a diary is an unreasonable expectation of patients, who like all humans, are prone to forget. It would make sense to design studies that accommodate human forgetfulness and error and, in particular, to provide instructions that tell the patient what to do when a day is missed. Coupled with such instructions, electronic, time coded diaries could provide a better method for ensuring the quality of diary records.

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# Diagnosis and management after life threatening events in infants and young children who received cardiopulmonary resuscitation

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## Abstract

*Objective*—To determine the mechanisms and thereby appropriate management for apparent life threatening events treated with cardiopulmonary resuscitation in infants and young children.

*Design*—Prospective clinical and physiological study.

*Setting*—Royal Brompton Hospital or in patients' homes, or both.

*Subjects*—157 Patients referred at median age 2·8 months (range 1 week to 96 months), 111 (71%) had recurrent events, 44 were born preterm, 19 were siblings of infants who had died suddenly and unexpectedly, and 18 were over 12 months old.

*Interventions*—Multichannel physiological recordings, including oxygenation, in hospital (n=150) and at home (n=61). Additional recordings with electroencephalogram, video, or other respiratory measures were used to confirm diagnoses. Management involved monitoring of oxygen at home, additional inspired oxygen, anticonvulsant treatment, or child protection procedures.

*Main outcome measures*—Abnormalities on recordings compared to published normal data and their correlation with clinical events; sudden death.

*Results*—53 of 150 patients had abnormalities of oxygenation on hospital recordings, 28 of whom had an accompanying clinical event. Home recordings produced physiological data from 34 of 61 patients during subsequent clinical events. Final diagnoses were reached in 77 patients: deliberate suffocation by a parent (18), hypoxaemia induced by epileptic seizure (10), fabricated history and data (Munchausen syndrome by proxy; seven), acute hypoxaemia of probable respiratory origin (40), and changes in peripheral perfusion and skin colour without hypoxaemia (two). Four patients died: three suddenly and unexpectedly (none on home oxygen monitors) and one from pneumonia.

*Conclusions*—Identification of mechanisms is essential to the appropriate management of infants with apparent life threatening events.

## Introduction

An apparent life threatening event has been defined as "an episode that is frightening to the observer and that is characterised by some combination of apnea (central or occasionally obstructive), color change (usually cyanotic or pallid), marked change in muscle tone, choking, or gagging".[1] When mouth to mouth resuscitation is needed there is a particularly high risk of subsequent sudden death. In one survey 10 of 76 patients with such events died.[2] We have used physiological recordings in hospital and at home to identify mechanisms for these events and report our findings in a subgroup that received mouth to mouth resuscitation.

## Patients and methods

Over 44 months 157 patients (96 boys) who had suffered one or more events out of hospital and received mouth to mouth resuscitation were referred for clinical management to our department at the Royal Brompton Hospital. One hundred and thirteen had been born at term and the others at a median gestational age of 32 weeks (range 24-36); none of the latter had been discharged from their neonatal unit on additional inspired oxygen. Median postnatal age at referral was 2·8 months (range 1 week to 96 months); 128 were 6 months and under and 18 were over 12 months of age. Forty six patients had a single event, 59 had two-five, 21 had six-10, and 31 had more than 10 events before referral.

Conditions considered as triggers for events, such as infections, anaemia, and biochemical disturbances, were excluded or treated. In some cases electroencephalography (EEG), standard electrocardiography, 24 hour electrocardiography, barium swallow, or oesophageal pH studies were undertaken but failed to identify abnormalities considered relevant to the events. In 19 a previous sibling had died suddenly and unexpectedly. In nine patients suffocation was suspected at referral.

### PHYSIOLOGICAL RECORDINGS IN HOSPITAL

Long term (8 hours to 3 weeks) analogue tape recordings of arterial oxygen saturation ($Sao_2$) (Nellcor N-200 modified to provide beat to beat data), the plethysmographic (pulse) waveforms (to validate $Sao_2$), breathing movements (Graseby capsule), electrocardiograms, and skin (transcutaneous) $po_2$ with the sensor heated to 43°C (Kontron 821S) were performed on 150 patients.[3] Recordings were printed on an ink jet chart recorder (Siemens Mingograf) at 3·1 mm per second.

Seven did not undergo recordings. Reasons were suspected deliberate suffocation (by a parent) in two, a single event in two older children (13 and 48 months), and lack of inpatient facilities in three. In one of the latter, death occurred after referral but before admission.

### PHYSIOLOGICAL RECORDINGS AT HOME

Thirty nine patients with recurrent events but normal recordings in hospital, 20 with abnormal

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