Patient compliance with paper and electronic diaries

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Information in practice

Patient non-compliance with paper diaries

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Doctors often ask patients to recall recent health experiences, such as pain, fatigue, and quality of life.[1] Research has shown, however, that recall is unreliable and rife with inaccuracies and biases.[2] Recognition of recall's shortcomings has led to the use of diaries, which are intended to capture experiences close to the time of occurrence, thus limiting recall bias and producing more accurate data.[3]

The rationale for using diaries would be undermined if patients failed to complete diaries according to protocol. In this study we used a newly developed paper diary that could objectively record when patients made diary entries in order to compare patients' reported and actual compliance with diary keeping. For comparison, we also used an electronic diary designed to enhance compliance in order to assess what compliance rates might be achieved.

Methods and results

We recruited 80 adults with chronic pain (pain for ≥3 hours a day and rated ≥4 on a 10 point scale) and assigned 40 to keeping a paper diary and 40 to an electronic diary. On satisfying the eligibility criteria, each patient was assigned to the next training session for which he or she was available, regardless of which diary it was for. We conducted one training session for each diary each week, with each training session for the paper diary matched by time and day of the week with an electronic diary training session. Participants were paid $150 and gave their informed consent; patients given the paper diary were not told that compliance would be recorded electronically.

The paper diary comprised diary cards bound into a DayRunner Organizer binder. The cards contained 20 questions drawn from several common pain instruments and included fields to record time and date of completion. The diary binders were unobtrusively fitted with photosensors that detected light and recorded when the binder was opened and closed; these were extensively tested and validated. The electronic diary was a Palm computer with software for data collection in clinical trials and presented identical pain questions via a touch screen and recorded time and date of entries. This system (invivodata) incorporated several features to maximise compliance, including auditory prompts, and has demonstrated good compliance.[4]

Patients were instructed to complete daily entries at 10 am, 4 pm, and 8 pm within 15 minutes of the target times. With the electronic diary, entries could not be initiated outside the designated 30 minute windows. We considered paper diary entries to be compliant if they were made within the 30 minute windows. A more liberal secondary outcome allowed a 90 minute window around the target times. Reported compliance was based on the time and date that patients recorded on their paper diary cards. Actual compliance was based on the electronic record (from the record of diary binder openings for paper diaries). Paper diary entries were deemed compliant if the binder was opened or closed at any point during the target time window. We also assessed "hoarding" with the paper diary, defined as days when the diary binder was not opened but for which diary cards were completed.

After three days' familiarisation, the participants began 21 days of diary keeping with weekly feedback. Participants completed an average of 20.5 days, and the table shows compliance rates. With the paper diary, reported compliance was 90%, but actual compliance was 11% (20% with the wider 90 minute window). With the electronic diary, actual compliance was 94%. Hoarding was common with the paper diary: 32% of days contained no diary openings, yet reported compliance (30 minute window) for these days was 92%. Most of the 40 patients (75%) had at least one day of hoarding.

Compliance rates for 80 patients' record keeping in paper and electronic diaries

	Paper diary (n=40)	Electronic diary (n=40)
30 minute window		
Total No of episodes*	2445	2435
No of excluded episodes	126	7
Mean per cent compliance (95% CI)†:		
Actual‡	11 (8 to 14)	94 (92 to 96)
Reported	90 (86 to 94)	
90 minute window		
Total No of episodes	2445	
No of excluded episodes	134	
Mean per cent compliance (95% CI)†:		
Actual	20 (14 to 25)	
Reported	95 (92 to 98)	

*Participants using paper diaries should have completed 2445 diary entries within the designated time windows. Of these, 114 were eliminated because the diary was open for more than 45 minutes, and 12 were eliminated because laboratory visits overlapped with time windows. Participants using electronic diaries should have completed 2435 entries, but 7 overlapped with laboratory visits.
†Compliance statistics were calculated separately for each participant and then averaged.
‡Compliance was significantly higher in the electronic diary group ($t(73)=29.97$, $P<0.0001$).

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Commentary

This study shows that concerns about compliance with paper diaries are justified.[5] Although patients reported high compliance, actual compliance was low and hoarding was common. The excellent compliance achieved with the electronic diary indicates that low compliance was not due to this particular sample or to an overly burdensome protocol. Overall, these results call into question the validity of paper diary records.

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Competing interests: AAS is vice-chair of the Scientific Advisory Board of invivodata, SS is a founder of invivodata, and MRH is director of scientific affairs at invivodata, which provides electronic diary support for clinical trials.

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INFOPOINTS

Improving the use of clinical databases

The need for high quality clinical databases has been thoroughly documented.[1–3] They offer the opportunity to carry out evaluative research and clinical audit, inform the planning and management of services, and provide individual clinicians with accurate estimates of the outcome of care that can be shared with prospective patients.

Despite these potential benefits, clinical databases have generally had few supporters and have attracted considerable scepticism and criticism. Much of the doubt about their value arises from a tendency to treat them all alike. As with all forms of information or methods of inquiry, both good and bad examples exist.

In an attempt to promote both the quality of clinical databases and their use, we have created a website where visitors can find out what databases exist (initially restricted to the United Kingdom) and be provided with an independent assessment of their scope and quality. To enable us to achieve the latter, a multidisciplinary group developed and tested an assessment instrument designed to achieve three objectives—to inform potential users of a database's scope (inclusion criteria, geographical area and time period covered, and mandatory and optional variables included), how it can be accessed (contact details of custodian), and its methodological strengths and weaknesses. All this information is obtained by a trained interviewer to ensure an independent assessment is obtained.

This Directory of Clinical Databases (DoCDat) allows visitors to search for and identify databases that may be suitable for their purpose, whether that be evaluative research, clinical audit, supporting shared decision making models, or strategic planning of services. The website allows searches to be made on the basis of one or more medical conditions, a healthcare intervention, and a geographical area. The information provided on the coverage and accuracy of the identified databases enables an assessment to be made as to their suitability. The need for such a service has recently been recognised by the UK government.[4]

DoCDat provides only an overview of each clinical database, albeit one based on an independent assessment rather than on the views of the database custodians. To delve deeper it is necessary for a potential user to find out more from the database custodian, whose contact details are provided in the DoCDat entry. While adding more databases is the top priority, it is also essential to update and maintain all the entries. This is done by requesting information of changes from database custodians as they are instituted and by an annual inquiry initiated by DoCDat staff.

Enabling greater access and use of existing clinical databases is the immediate aim of DoCDat, but another aim is to improve their quality. Our experience suggests that some database custodians have rather limited knowledge and understanding of the methodological issues relating to database quality. DoCDat aims to advise, where appropriate, on how quality can be improved. This can be facilitated by putting database custodians in contact with one another to enable practical experiences to be shared.

The Directory of Clinical Databases (DoCDat) is available at **www.lshtm.ac.uk/docdat**

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Competing interests: Both authors work on DoCDat and wish to see it succeed.

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