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EDITORIAL

The promise of electronic data capture in respiratory medicine

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In the 17th century the English physician John Floyer, himself severely asthmatic, used symptom diaries to record his own and his patients' symptoms to understand the determinants of asthma exacerbations, and inform disease management [1]. If long-term serial data on designated patients with chronic lung disease were available to physicians, it could fundamentally change clinical practice and influence the design of clinical research studies. However, methods of symptom diary data collection that frustrate patients and which require analysis by physicians before interpretation are unlikely to achieve broad success. A recent editorial in the *European Respiratory Journal* [2] drew attention to the emphasis, in current guidelines for asthma management [3] and in the conduct of clinical trials in asthma [4], of the importance of estimating ''future risk'' to patients. The concept has equal relevance in other chronic lung diseases. Guidances issued by both the European Medicines Agency and the US Food and Drug Administration [5, 6] have contemplated and encouraged the adoption of patient reported outcomes (PROs) in chronic disease research.

The report by LIU *et al.* [7] in the current issue of the *European Respiratory Journal* describes the experimental evaluation of a mobile telephone-based system compared with a paper diary for monitoring the management of adult asthmatics, and found significant clinical improvements in the electronically monitored patients. As noted in a recent meta-analysis of studies of electronic patient-reported symptom monitoring in respiratory disease [8], there are as yet an inadequate number of published reports of studies with robust designs and formal evaluation in this area, and the study by LIU *et al.* [7] is a welcome addition. The approach taken to symptom diary data collection was inexpensive and used technologies that are becoming almost universally available.

Importantly, this study also showed good patient compliance with data provision in a contemporary clinical practice. In our own research studies of chronic obstructive pulmonary disease (COPD) patients, we have observed compliance with electronic PRO provision over a 1-yr period exceeding 98% using BlackBerry smartphones [9] and over 95% using an earlier fax based system [10].

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Audits of well-conducted studies of COPD which used paper-based diaries and/or reliance on study subjects to report possible COPD exacerbations have shown that they achieved detection of only one-third to one-half of these at their inception [11–14]. Such under-detection of categorical study events through low patient self-report rates may compromise the generalisability of study findings to the population at risk. It may also reduce study efficiency, lengthen their time to completion [4] and potentially delay regulatory approval of therapies. Using electronic PROs we found that of 111 acute exacerbations occurring in a cohort of COPD patients over a 5-month period, only one was not detected at inception [10].

With paper-based symptom diaries in studies of respiratory diseases, a more sinister finding has been that significant numbers of subjects falsify data [15, 16], and that the likelihood of this occurring increases with the length of the study period. In a randomised trial of electronic symptom recording *versus* monitored paper-based recording, actual compliance was 94% in the ''electronic'' group, while faked compliance with paper-based recording was 73% [17].

In a clinical setting, as in the LIU *et al.* [7] study, cost considerations may dictate the use of technologies for PROs with cheap mass availability, whereas in research, particularly clinical trials, more stringent requirements for data control and standardisation of methods may dictate the use of more sophisticated technologies. In both cases a number of design and operational considerations may influence success.

While in the case of asthma many patients are young, dexterous and have unimpaired faculties, this may not be the case with other chronic respiratory diseases. Patients, no matter how high their level of commitment, who are presented with a data entry process that they have difficulty comprehending and completing are unlikely to comply with it. Our experience in the design of electronic PROs suggests that entry of data should be accomplished as simply as possible, preferably using only a single trackpad or similar device, and should avoid the use of keyboards or other devices such as pointers; poor visual acuity may be compensated for through selection of devices with bright clear high-contrast screens, careful font selection and judicious use of colour, shading and highlights; individual questions should be easily distinguishable from each other through such mechanisms as loading one question per screen, numbering questions and providing a sequence of two distinct backgrounds; patients should be notified if they have missed a question and also be able to

check their responses before sending a completed questionnaire.

Voice recognition technology has advanced significantly in recent years and access to either cellular or wired telephones is near universal. While the value of this technology for the collection of PROs will need to be formally evaluated, it offers significant promise at a low cost and will be of particular value when patients have a high prevalence of impaired visual acuity or poor dexterity.

E-mail questionnaires sent to patients have the advantage of low cost and may be an ideal method for collection of PROs from those patients who are equipped with computers and e-mail accounts; however this is possibly less likely in low socioeconomic groups who may be at higher risk of uncontrolled disease. Furthermore, the array of different types and ages of computer equipment likely to be encountered in a patient population may raise complex technical issues and increase the levels of support that need to be provided by staff.

The use of general packet radio service for PRO data collection used for asthma patients by LIU *et al.* [7] has advantages over other approaches, notably low cost, but may be less feasible in patients with chronic lung diseases in whom the majority are elderly and may have impaired vision and dexterity.

Patients with chronic lung disease, particularly the elderly, confronted for the first time by a request to serially enter data, may experience a lack of confidence that they will be able to use the data collection device. That confidence will be gained through the use of high-quality, well-engineered and pre-tested devices for data entry; patient and thorough instruction by clinical/study staff, which incorporates the presentation of scenarios for different data entry situations; and assurance that if devices or systems malfunction the patient is not to blame and the problem will be addressed.

During electronic PRO collection, patients should receive automatic feedback to confirm when data have been successfully transmitted. Compliance should be carefully monitored and staff should automatically be notified when data have not been received from a given patient for two sequential data entries. PRO questionnaires should include an open question asking patients if they would like staff to contact them. Once transmitted, PRO data for each subject should be integrated into a readily accessible record for each subject with pre-assigned flags set to notify staff when changes of interest occur.

Patients quite reasonably expect their health information to be treated with confidence. While the likelihood of PRO data being maliciously copied by unauthorised individuals may be low, patients may be more likely to provide their data electronically or participate in research studies using electronic PRO capture if they are confident that their data will be secure.

Neither cellular nor wired telephones are technically secure, but illicit capture of data from individual patients would require intervention at the level of the patient's telephone. Data transmitted by e-mail can be encrypted, as can data transmitted using some Smart phones. PRO data capture systems that are fully secure raise costs significantly and in the case of broad-based systems for clinical application these may not be justifiable. However, in research studies, institutional review boards or regulatory bodies may require PRO data encryption as may companies providing funding. In addition, recruitment may be enhanced if patients can be assured that their data will only be seen by authorised study staff.

Realisation of the benefits of using PRO data in broad clinical practice has not been feasible until the advent of almost universal availability of electronic data transmission. The potential to add serial data reported by respiratory patients directly to the medical record in real time can permit more effective patient monitoring and enable the onset of disease exacerbations to be detected at their inception, particularly when clinical or research staff are automatically alerted when significant changes in a patient's health occur.

In clinical research of chronic respiratory diseases, electronic PRO collection has the potential to both shorten the length of studies through efficient data management and introduce sensitive study outcomes based on continuous patient data as a possible alternative to the use of arbitrary categorical events.

Further well-conducted clinical trials of the value of electronic PRO in the long-term management of chronic lung diseases, including economic analyses should be a research priority.

STATEMENT OF INTEREST

A statement of interest for N. Johnston can be found at www.erj.ersjournals.com/site/misc/statements.xhtml

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