

no harm and John Stuart Mill's libertarian philosophy of individual sovereignty and responsibility,⁴ so that sexual health is regarded as a basic human right. It emphasises the inseparability of physical and mental health in any holistic consideration of a person's sexual wellbeing.

In this form it could be construed that the goal of sexual health is difficult or impossible to attain, given human fallibility. Previous definitions have been criticised as being applicable only to Western or European societies. Yet whenever choice is limited—be it by economic necessity (market forces), personal threat, societal norm, government legislation, religious edict, or other cultural pressures—both physical and mental aspects of sexual health suffer greatly because people are coerced into sex against their will. Indeed, the highest rates of sexually transmissible diseases and other reproductive morbidity occur where women and their rights are least valued or respected.

The need for an integrated approach to sexual health and its medical care is not a sudden, recent development but one that has been obvious to a minority of concerned clinicians and educators for at least a generation. This definition further strengthens the philosophical basis of destigmatised, holistic sexual health care, which integrates the promotion of sexual health with the provision of services for its maintenance.⁵

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- 1 World Health Organisation, 1974. Quoted in: *AIDS Action* 1991;13:1.
- 2 Hendriks A. The political and legislative framework in which sexual health promotion takes place. In: Curtis H, ed. *Promoting sexual health*. London: BMA Foundation for AIDS, 1992.
- 3 Greenhouse P. A sexual health service under one roof. In: Pillay J, ed. *Sexual health promotion in genitourinary medicine clinics*. London: Health Education Authority, 1994.
- 4 Mill JS. *On liberty*. London: JW Parker, 1859.
- 5 Stedman Y, Elstein M. Rethinking sexual health clinics. *BMJ* 1995;310:341-2. (11 February.)

Electronic diaries for asthma

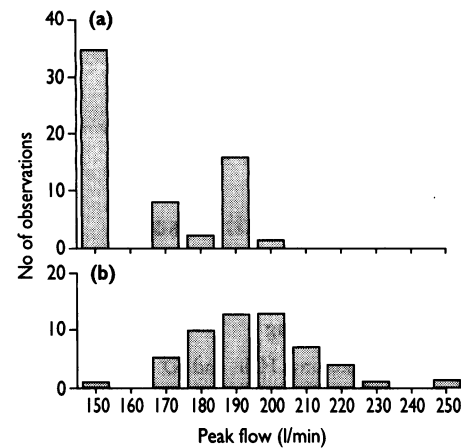
EDITOR,—Hyland and coworkers have reported the successful use of hand held computers as electronic diary cards in asthma.¹ Such devices greatly simplify data handling, and they record the time at which each entry was made. However, the use of a conventional type of computer may present problems for some patients. Pen based devices (Personal Digital Assistants, PDAs) provide an alternative that may be easier for many patients to use.

We have developed an electronic asthma diary on the Apple Newton. Entries are made by tapping choices with a stylus on the screen. Handwriting recognition is not used. We evaluated it in 13 men and nine women aged 18-70 who completed paper and electronic diaries morning and evening for four weeks each in randomised order. Peak flow (Vitalograph peak flow meter), symptoms, bronchodilator use, and night time awakenings were recorded. All patients completed a survey questionnaire at the end.

Patients found both diaries easy to use. Most preferred the electronic diary (electronic, 13; paper, 4; no preference, 5). A similar pattern was found when data were broken down by age, sex, and reported comfort with technology. Thus there is no evidence for any subgroup for which the Newton diary presents any special difficulty.

Chowieniczky *et al* have recently shown that a substantial proportion of conventional diary data may be invented.² Two lines of evidence from our study suggest a similar conclusion. Firstly, the proportion of missing data was higher for the electronic than for the paper diary (electronics, 8.9%; papers, 0.16%), raising the suspicion that

some paper entries were initially missed and then completed later. Such retrospective entry was not permitted by the Newton software. Secondly, inspection of the data suggests serious problems with paper entries for some patients. In the most extreme case, over half the peak flow values recorded on paper were the same, 35 out of 61 entries being 150 l/min—but the corresponding electronic entries were nearly complete (94%) and showed the kind of distribution expected for valid readings (figure).



Peak flow values recorded by one patient (a) on paper; (b) electronically

Pen based electronic diaries are highly acceptable to patients. As well as simplifying and speeding up data handling, they bring substantial improvements in the trustworthiness of the data obtained.

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- 1 Hyland ME, Kenyon CAP, Allen R, Howarth P. Diary keeping in asthma: comparison of written and electronic methods. *BMJ* 1993;306:487-9.
- 2 Chowieniczky PJ, Parkin DH, Lawson CP, Cochrane GM. Do asthma patients correctly record home spirometry measurements? *BMJ* 1994;309:1618.

Events per person year

A decrease in multiple events may be missed

EDITOR,—Jürgen Windeler and Stefan Lange describe the "new measure" invented in 1982 to describe osteoporotic fractures in the context of clinical trials—namely, the frequency of vertebral fracture.¹ They suggest that the number of patients developing vertebral fractures is a more appropriate end point. In their review they neglect to mention that the problems with this approach are well recognised,^{2,3} though perhaps not universally applied. Nor is the fallacy ignored by some registration authorities, and in some countries the test agents to which they refer have been refused licences for these reasons. Though we do not wish to defend the use of fractures/100 patient years, the event rate is relatively low in the context of vertebral osteoporosis. Thus few individuals will have repeated events, so that the number of patients with a fracture is proportional to the number of patients experiencing an event.² As confidence increases that changes in bone mineral density can be equated with changes in the fracture rate, at least with some therapeutic agents,⁴ the

need to study fracture end points will probably decrease.

The situation is more problematic in the bone disease of malignancy, in which event rates are much higher and the number of patients experiencing an event may not be proportional to the number of events.³ In our studies of 171 women we showed that the number of patients with metastatic breast cancer who developed vertebral fractures was decreased by 15% (44 v 52; NS) in those exposed to a bisphosphonate.⁵ The number of fractures observed, however, was decreased by 32% (58 v 90, respectively; $P < 0.025$). We reported both approaches (patients and events), since we thought that an intervention that decreased the total number of events was clinically worth while. The expression of only the number of patients who developed a vertebral fracture hides some aspect of the benefits of the intervention.

Discussions with statisticians have been of little help in advising us how to report clinically beneficial effects in a manner that is statistically acceptable. One approach has been to use expert systems that iterate the likelihood of an observed outcome arising by chance. When we applied this to our own data the probability of a difference between no treatment and treatment arising by chance was similar ($P < 0.07$) to that obtained with the less purist method that we reported. Though we agree with criticisms raised by the authors, it would be a pity if in the future the clinical importance of a decrease in multiple events was not also appreciated.

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- 1 Windeler J, Lange S. Events per person year—a dubious concept. *BMJ* 1995;310:454-6. (18 February.)
- 2 Kanis JA. Treatment of osteoporotic fracture. *Lancet* 1984;ii:27-33.
- 3 Kanis JA. What constitutes evidence for drug efficacy in osteoporosis. *Drugs and Aging* 1993;3:391-9.
- 4 Division of Metabolism and Endocrine Drug Products, Food and Drug Administration. *Guidelines for preclinical and clinical evaluation of agents used in the prevention or treatment of postmenopausal osteoporosis*. Bethesda, Maryland: FDA, 1994.
- 5 Paterson AHG, Powles TJ, Kanis JA, McCloskey EV, Hanson J, Ashley S, *et al*. Oral clodronate decreases skeletal morbidity in patients with bone metastases from breast cancer. A double blind controlled trial. *J Clin Oncol* 1993;11:59-65.

Use individual event rate adjustment for follow up time

EDITOR,—We agree with Jürgen Windeler and Stefan Lange about the importance of correct analysis of data on fractures and that the widely used sample statistic events per person year may lead to flawed results.¹ The reason is, as the authors point out, that the data may include more than one event (fracture) in the same patient and these events do not fulfil the criteria of independence, which is the basic assumption for the usual statistical tests of rates. The idea that statistical analyses can be performed when the statistical assumptions are not met is incorrect.

Windeler and Lange suggest three methods for proper analysis of data on fractures. The first is comparison of the proportions of patients with at least one fracture. This approach, however, requires often unrealistically large sample sizes. For the second approach—use of the mean number of fractures per patient in the study period—the follow up time must be taken into account. New variables thus created can be called the individual event rate (used when the follow up time is similar, at least approximately) or the individual event rate adjusted for the follow up time (number of fractures per patient divided by follow up time). The latter is especially useful when the drop out rate is