Diary Design Considerations: Interface Issues and Patient Acceptability

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Brian Tiplady

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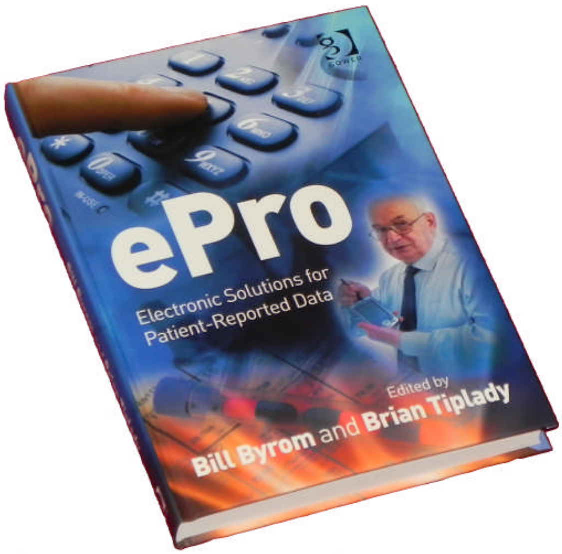

ePro

Electronic Solutions for
Patient-Reported Data

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Introduction

In 1993, the first Personal Digital Assistants (PDAs), hand-held computers with pen interfaces appeared and a number of research groups began to use them to collect data directly from patients, either to take home to use as symptom diaries, or for collecting questionnaire data in the clinic.

We were by no means the first in the field that became known as ePRO. Others had used clamshell organisers, touch-screen computers and telephone-based systems for some years, and the earliest systems for obtaining data directly from patients using a computer go back much further (see, e.g. Lucas et al., 1976; French and Beaumont, 1987; Siegel et al., 1988; Taylor et al., 1990; Hyland et al., 1993). But the PDA had a compelling combination of portability and ease of use that greatly stimulated the growth of this type of data collection.

One of the earliest questions raised was whether patients could handle the technology. Sure, we researchers all found the devices easy to use, but what about the elderly, particularly if they had poor eyesight? What about those who had never used a computer and who might feel threatened by this type of system? So when we carried out studies evaluating the use of PDAs we included a questionnaire asking patients how they found the technology and whether they preferred electronic or paper. We were pleased to find that patients generally liked the devices, found them easy to use, and preferred the electronic method to paper (Drummond et al., 1995; Tiplady et al., 1997). This conclusion was equally valid for elderly patients and for those who were unfamiliar with computers.

This finding has been repeatedly confirmed. For example Rabin et al. (1996) compared 36 women with overactive bladder symptoms with 36 age-matched women who used computerised and written paper voiding diaries. More than 98 per cent of the patients and 80 per cent of controls preferred the computer version. The sample included women up to 84 years old. Johannes et al. (2000) compared a menstrual diary set up on a handheld PC with a paper diary in 24 women. 70 per cent of women preferred the electronic diary, compared with 9 per cent who preferred paper. Hufford et al. (2002; see also Stone et al., 2003) present data from 80 patients aged 18–70 who completed either a paper or electronic pain diary. Each patient used only one type of diary, so preference data could not be obtained, but a high level of acceptability and ease of use was found for both paper and electronic diaries. Aiello et al. (2006) studied 86 women over 50 who used a tablet-PC based breast cancer screening questionnaire. The great majority of the women preferred the PC to paper, and this was true both for those aged 60 or over (89 per cent) and those under 60 (93 per cent). Meacham et al (2008) reported greater diary compliance amongst elderly patients compared to middle aged or younger, in a meta analysis of 10 studies using Interactive Voice Response (IVR) pain dairies.

But acceptability and ease of use are not inherent properties of electronic diaries and questionnaires – they require careful design and an ability to take the user perspective into account. I will review here some of the issues that need to be addressed to develop a robust user interface that will be suitable for data collection with the wide variety of patients enrolled in clinical trials. I shall present these issues from the point of view of a system designer, but the principles I shall outline are just as important for those who select a system from a vendor or specify the details for a particular study protocol.

The design principles I shall describe apply equally when developing an ePRO system from scratch or when transferring an existing paper instrument to electronic mode. However, when migrating from paper to electronic there is an additional constraint; the electronic instrument should be equivalent to the paper original. New instruments may be developed from the start in electronic format, and doubtless this will increase, but at present the majority of instruments are migrated from paper to electronic mode, so this is an important concern.

User interface issues are important in a number of different ways, which can affect both the conduct of the study and the completeness and quality of the data obtained. I shall deal with the following:

1. skills required to use the system;
2. legibility of material presented;
3. organisation of the instrument;
4. cognitive load;
5. taking the patient's perspective.

I shall deal in most detail with screen-based systems, as most of my experience has been with this type of data collection. The principles, and some of the details, are equally applicable to other types of system, for example telephone-based methods which Bill Byrom, Keith Wenzel and James Pierce discuss in more detail in Chapter 7 of this volume, and to web-based methods. Some of the ideas in this chapter were developed jointly with my colleague Mikael Palmblad (Palmblad and Tiplady, 2004).

Skills

It is often thought that systems based on computers will be problematic for computer-naïve or 'technophobe' users. Older patients are often assumed implicitly to belong to one or both of these groups, though the present 65 year old author wishes to dissent from this view! The numbers of people who have never used a computer is declining, but still significant. Government statistics show that 61 per cent of UK households had access to the internet in 2007 compared to 47 per cent in 2002 (National Statistics, 2007). Computer use is not identical to internet access, but these numbers give a general indication of familiarity with computers. In a study carried out in 2002, Begg et al. (2003) found that about a third of the 32 female patients recruited for a post-surgical diary study had never used a computer. All of the computer-naïve women were over 40. Thus we still need to allow for those who are unfamiliar with computers even in the developed world. And of course many clinical trials are carried out in countries where computer use is lower than this.

The answer to the skill problem is actually very simple – don't require any computer-related skills! Figure 8.1 below, gives an illustration of a screen layout that might be used with a patient. The first thing to note is that a single question is shown. With very short and simple questions it is sometimes possible to have more than one on a screen at a time, but as a general rule with the small screens of handheld computers, one question is presented to the patient at a time with the patient tapping on a 'next' button to move on to the next question.

Several things can be seen from this example. Firstly, the screen shows all the information needed by the patient to answer the question. Secondly everything is laid out within the limits of the screen size. There are no scroll bars or drop-down menus. This is important if computer-naïve users are to be able to use the system comfortably after a minimum of training, as regular computer users often under-estimate the effort required to initially master such controls. Finally, the area to be tapped is large, and explicitly defined by the border of the response box. There are no little check boxes next to the selected text. This makes it easier for the patient to understand what is required.

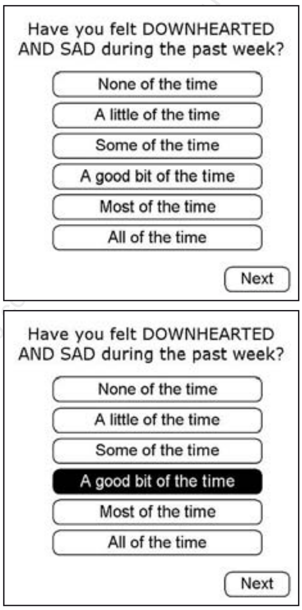

Figure 8.1 A question from the Psychological General Well-Being Index (PGWB: Dupuy et al., 1984)

Note: Patients make their responses by tapping on the screen with a stylus. The selected option is highlighted by reversing the black and white parts of the response box. The patient can change the selected option by tapping on a different box. Once the intended choice is selected, the patient taps 'Next' to move to the next question.

Legibility

I said previously that all information required by the patient should be visible on the screen, and that scroll bars should be avoided. This raises a potential problem. The example previously does not have too much text, and fits easily on the screen of a small handheld such as a Palm E2. Not all questionnaires are so modest in their requirements, and many have considerably more text per question. Up to a point this can be accommodated by making text smaller, but that point is quickly reached.

Several approaches are possible. One is to use scroll bars or drop-down option selection and accept the training load required to initiate new users to the method. This would require not only training but a demonstration that the training had been effective and that the patients are using the controls without adding sufficient extra load to affect their performance in completing the questionnaire. It would also be necessary to show that visibility effects, bias towards the options initially visible in the display, (Couper et al., 2004) are not occurring.

A second approach is to split the question and present the question on one screen and the responses on the next. This has the danger that patients will not remember all the required information at the point they are making their responses. This is a real danger, since screen splitting would only be considered if the amount of text is comparatively large. Again it would be necessary to demonstrate that patients could deal adequately with this layout in practice. One recent report suggests that screen splitting may lead to real problems in practice (Juniper et al., 2009).

The best approach is again a simple one. Use a device with an adequate screen size. This has been a problem in the past, as there was very limited availability of devices with screen size between that of the handheld and a small laptop. However there are now a wide range of devices available with varying screen sizes that are suitable for ePRO use. These are less portable than handhelds, such as the Palm, but in practice this is seldom an issue as the longer questions are generally found in quality of life or health economic questionnaires carried out at a clinic visit rather than taken home by the patient.

Organisation

Even when a large screen is used, the space available is likely to be less than that available on an A4 sheet of paper, and some changes to the way the instrument is ordered and laid out are likely to be necessary. One example has already been mentioned, the presentation of one question on the screen at a time. This is in contrast to a layout commonly used for paper as well as web-based questionnaires where questions with similar response options are grouped together with the response options in horizontal rows. See Figure 8.2, for an example of a questionnaire laid out in this way.

As well as the change from a group of questions to single questions, there is often a change from a horizontal response layout to a vertical one, and instructions that are common to a group of questions are often given at the start of the group on a separate screen. Paul Beatty discusses the implications of these changes for paper-electronic equivalence in Chapter 2 of this book. I shall concentrate here on the user interface aspects.

Placing instructions on a separate screen might seem to raise the same problems as raised above for screen splitting. This could be a problem, but there is an important difference. When the question is split from the response, the patient must remember what is involved in the current question, which is of course different from the previous one. Thus the memory load the patient must handle is constantly changing. By contrast, instructions stay the same for a group of questions, and often for the entire questionnaire, so the memory load is constant. This involves much less processing; much less cognitive load, than changing information. Nonetheless it is desirable to limit this load as far as possible by placing the most important information, such as the assessment period, on each screen and limiting the amount of information presented on the initial screen. I will discuss cognitive load in more detail below.

Presenting questions one at a time on the screen is likely to reduce the sense of linkage between adjacent questions. This may be a good or a bad thing. Where the grouping is simply based on convenience, for example, of questions which have similarly phrased responses, or what will fit on a page, then grouping itself may introduce a subtle form of bias due to the tendency of questions within a group to correlate more highly with each other than questions not in the group (see e.g. Couper et al., 2001). These effects are generally small but if anything, single item presentation should improve the psychometric properties of the scale in such a case.

In other cases, the grouping is conceptually important, for example where questions are clearly samples of a larger category. An instance of this is the Health Assessment Questionnaire, where activities are assessed in groups such as hygiene, grip or eating. Two groups from this questionnaire are shown in Figure 8.2.

In this case the grouping is an important part of the questionnaire design and contributes information to the patient that is relevant in making the response. It can be maintained in the electronic version by placing the group heading at the top of each question screen and also on the initial instruction screen where this is used. Thus the information available to the patient is as similar as possible in both electronic and paper versions.

The change from vertical to horizontal arrangements of text-based response options seems unlikely to have much impact on the user experience. Both left-right and top-down text arrangement are familiar in most societies, and both layouts are common in paper and web-based questionnaire designs. There is some evidence of effects of horizontal or vertical layout on responses to visual (line) analogue scales, but these effects appear to be small (Breivik and Skloglund, 1998; Stephenson and Herman, 2000).

Please check the response which best describes your usual abilities OVER THE PAST WEEK:

	Without ANY <u>difficulty</u>	**With SOME <u>difficulty</u>**	**With MUCH <u>difficulty</u>**	**UNABLE <u>to do</u>**
DRESSING AND GROOMING				
Are you able to:				
• Dress yourself, including tying shoelaces and doing buttons?	☐	☐	☐	☐
• Shampoo your hair?	☐	☐	☐	☐
ARISING				
Are you able to:				
• Stand up from a straight chair?	☐	☐	☐	☐
• Get in and out of bed?	☐	☐	☐	☐

Figure 8.2 Two of the groups of activities assessed by the Health Assessment Questionnaire Disability Index (HAQ-DI: Fries et al., 1980)

Electronic systems allow the behaviour of the application to depend on the patient's response. Navigation will be discussed below, but another example is the way missing data are handled. In some circumstances it is appropriate to allow patients to leave a question out. Common examples are questions about personal or sensitive issues such as financial income or sexual activities. When a missing response is allowed, there should always be an explicit 'I prefer not to answer' option, so it is clear that the omission was intentional.

In other situations, missing data is undesirable. Fallowfield (1996) has identified missing data as the main quality issue with quality of life data, and electronic methods can help to ensure data completeness. The instructions for many quality of life scales encourage patients to give the best answer they can if none seems to fit exactly. An ePRO application can be programmed to give this encouragement just when it is needed, by bringing up a message box when the 'Next' button is pressed with no response option selected. A typical message might be 'If you are not sure how to answer a question, please choose the response that is closest to how you feel at the moment'. Warning messages can also appear if inconsistent response combinations are chosen.

When we set up our early ePRO applications, we were concerned about whether patients would object to a response being required. These studies invited patient feedback but no resistance to this was encountered in a series of over 800 patients. Thus ePRO applications can combine methods to ensure data completeness with patient acceptability.

Cognitive Load

The task required of the patient in answering questionnaires is often a significant one, and is easily underestimated. Apparently simple questions may actually require considerable amounts of effort to interpret. For an example see Paul Beatty, Chapter 2 in this volume. Except for the simplest here and now questions, responses are not immediately available in the patient's mind but must be constructed. These issues are discussed by Shields, Stone and Shifffman in Chapter 1 of this volume. Cognitive load refers to the processing effort required for interpretation of questions and response options, the construction of the response and any ancillary tasks required by the questionnaire (e.g. remembering or referring back to a previously given definition or instructions concerning time period).

To a considerable extent, the cognitive load is dependent on the questionnaire rather than the mode of administration, but a number of aspects of user interface design can affect the load required of the patient when completing an ePRO application. One example has already been mentioned, that of material that the patient must remember. If information given on one screen must be used by the patient to interpret material on a subsequent screen, this material must be both *held* in memory and *processed*. This combined requirement is the definition of working memory, and a classic series of studies by Baddeley and co-authors (see e.g. Baddeley, 1986) documented the degree to which such memory loads could interfere with the performance of concurrent tasks. The degree of interference is greater for changing memory loads than for constant ones. To avoid this type of interference, as far as possible all information needed by the patient should be explicitly available on the response screen. For a more detailed discussion of this (see Palmblad and Tiplady, 2004).

Interference will also occur if the patient is required to perform any sort of concurrent task. Making the response can be considered a concurrent task to formulating the response. Normally the response is so simple; ticking a box, circling yes or no, tapping on a text button on screen, that the load associated with this is trivial, but it may not always be so. I have already suggested that we should avoid requiring computer skills in order to make our systems easy for all patients to use, but computer-specific methods or conventions such as scroll bars, drop-down menus, or responding using a mouse, are likely to impose additional load on patients for whom these methods are not completely automatic.

Another task that may be required is presented by feedback. Feedback is generally considered a good thing, but any message that appears on the screen has to be read and the patient usually has to take some action, such as tapping an OK box to close the message and continue with the questionnaire. Thus there should always be a good reason for providing this sort of information. One use of feedback is to inform patients of invalid selections. For example a question that asks patients if they have experienced any of a number of symptoms may allow several of the response boxes to be selected. There may also be a 'none of the above' box. If 'none of the above' is checked as well as one or more symptoms, a message may appear warning the patient of the inconsistency. Such messages can be useful, but in many cases it is better to construct the question in such a way that only valid choices can be entered in the first place. By example, a numeric entry for the question 'How many days did you have diarrhea in the past week' could use a generic numeric entry and then warn the patient if a number greater than 7 was entered. However a neater solution is to design the response options so that only numbers from 0–7 can be entered in the first place.

Navigation that requires patients to make choices also constitutes a concurrent task. Most of us are familiar with forms, often from the taxman, with instructions like 'If YES continue with the next question, if NO, go to question 37'. At best such conditional logic increases the complexity of the user's task, at worst it can lead to errors and lost data. This is an area where electronic methods can greatly simplify the patient's task, as the branch points do not need to be seen by the patient at all. The device simply offers the next question that is appropriate to the situation, and all the patient sees is a series of questions one after the other. Thus the cognitive load can actually be decreased by using electronic methods.

Telephone-based Systems

An alternative approach to ePRO is to use the patient's own telephone as a data collection device. Patients call a toll free or free phone study number, which can even be dialed by the system, and hear a spoken script with the instructions, questions and response options. They might, for example rate symptom severity using a numeric code 'If your symptoms have been mild today, press 1. If moderate, press 2, if severe, press 3'. Readers will recognise this as similar to the automated call systems widely used by commercial organisations, and the underlying technology is the same, being referred to by the acronym IVR, for interactive voice response. While the details of constructing an IVR system are substantially different, many of the basic considerations for developing a system that is easy to use are similar to those for screen-based systems. A great advantage of IVR is that patients are already familiar with telephones and will not have to learn any new skills. IVR also mirrors the aural administration of questions as asked by a physician. IVR administration partially overcomes the issue of literacy as many patients may be functionally literate, that is they understand the spoken word but may have limited reading comprehension skills. A possible disadvantage is that many of the commercial systems currently in use are poorly thought out from a user perspective. Patients who have been frustrated by such in the past may not approach a clinical trial system with an entirely positive attitude. But good IVR systems can be developed, and again the need is for careful design and the ability to take the user perspective into account.

These are voice-based systems so the first issue is to get the voice right. Clearly patients must find it easy to understand what is said, so speed of presentation must be considered, and speakers with strong regional accents avoided. The question of accents, however, goes well beyond intelligibility of speech. Listeners respond differently to accents from different regions. Thus in a British context, speakers with accents from industrial areas of England may tend to be rated as of lower status and less pleasant than those with Received Pronunciation (Giles, 1970). The gender of the speaker does not, in general, seem to be an issue but there are situations in which it can be important. Thus in a questionnaire about sensitive sexual issues it may be preferable to use a speaker of the same sex as the respondent. Intonation is also important: the voice must be appropriately moderate in emphasis. In clinical trials you do not wish to introduce a therapeutic effect. The voice recording should neither be too 'high' or happy nor too 'low' or sad. This is something that is easily managed with instructions and standards for voice recording, but it is something of which system designers must be cognisant.

An important difference between screen-based and IVR systems is that IVR material is presented serially and must be remembered by the patient. With information on a screen or paper the patient can look back at the beginning of the text. With IVR, methods of going back must be explicitly provided, for example 'To hear these options again, press 9'. Such options should be used in a consistent way throughout the application, and careful thought given to how instructions for using them are given. It is not uncommon for IVR systems to repeat the question should the patient not respond in the expected time interval. This is a viable alternative to 'To hear these options again, press 9.'

There is a converse issue. Patients will typically use the application many times. This means that as they get familiar with it they will remember what they have heard. A common source of frustration with IVR systems is having to wait for a section of text to end before being allowed to make a response. I know – I frequently use a teleconferencing system that won't let me enter my security code until the instruction has ended. I've probably only heard it a hundred times, but it seems like much more! There is a balance here between the convenience of the respondent and being sure that she/he really does remember the options correctly. One idea to consider is to use a short definition that is presented in full, and a longer clarification that can be interrupted. There are other possibilities such as requiring that the question be uninterruptible, but permitting the response descriptions to be interruptible or having uninterruptible questions and responses the first few times, for example three, an instrument is administered and then making the questions and/or responses interruptible. The designer should balance ease-of-use with the need to ensure that the patient is taking account of all the necessary information.

One possibility in designing an IVR system is to get the patient to confirm that choices have been correctly entered. Typically the responses are read back to the patient, who keys in a Yes or No. If no, the question can be re-presented. This feature can be useful, but again can be tedious for the patient to use. If you have a few items that are critical, e.g. primary outcome measures, it could be worth confirming just these items.

Some types of question cannot be implemented directly using an IVR system, for example where graphic displays are required. Thus if your paper questionnaire has a visual analogue scale, you will have to think carefully about what you want to measure. Visual analogue scales are generally scored from 0 to 100, for example with 0 meaning 'no pain' and 100 meaning 'worst possible pain'. However the patient using the scale does not see these numbers, just a line with 'no pain' and 'worst possible pain' at the ends. Technically it is straightforward to ask the patient to enter a number between 0 and 100 into the phone keypad. But it raises two questions. Firstly, are patients comfortable doing this, do they feel they can meaningfully assign a number to their pain? We can ask the patients whether they do or not. Secondly, does it actually mean the same thing; do we get the same number, within experimental error, for the two types of rating. Damian McEntegart gives details of how to answer this question in Chapter 9 of this book.

There is an alternative approach to visual analogue scales. The current trend is towards replacing them with other scale types. The IMMPACT recommendations for pain assessment, for example, state: 'VRS (Verbal Rating Scale) and NRS (Numeric Rating Scale) measures tend to be preferred over VAS measures by patients. Furthermore, VAS measures usually demonstrate greater amounts of missing and incomplete data than NRS measures, presumably because NRS measures are less abstract and easier to understand.' (Dworkin et al., 2005). Numerical and verbal rating scales are straightforward to implement on IVR.

IVR systems should tell the patients how long the call is expected to last, and in a longer assessment it is a good idea to give feedback on progress, such as: 'You are now half way done with today's assessment.' An appropriate concluding statement should be made so the patient understands the assessment is complete, such as: 'Thank you for your call today. Today's assessment is complete. Please remember to call tomorrow for your next assessment between six and ten pm.'

Patients complete their assessments in a real world where doorbells ring at unexpected times, children wake up, and nature calls. So it is a good idea if patients can put the system 'on hold' or call back in and complete an assessment without having to go back to the very beginning.

A Patient-centred Approach

Patient Reported Outcomes aim to assess the patient's point of view of illness and treatment. It is equally important to put the patient at the centre of things when designing, specifying or selecting an ePRO solution. But the idea of 'the patient' is itself problematic. Patients vary. We have young and old, male and female, robust and frail, computer experts and those who have never used a computer, those with poor eyesight or tremor, those in pain, anxious, or fatigued by disease or its treatment.

Does this mean that we have to design or specify different applications for every target group, taking into account their abilities and limitations? In some case we may need to, and we certainly need to ensure that our target patient groups can use our ePRO systems effectively. But it is my belief that we can go a very long way with an inclusive approach to system design. As a starting point, let me go back to the beginning of the chapter and my suggestion that we get round the issue of computer skills by not requiring them. Suppose we set up a system on a handheld that is so simple that a completely computer-naïve patient can use it after a few minutes training. This is not an unreasonable expectation. I have seen it happen many times. What if we give this to someone who has been using computers for as long as they can remember? Will they have a problem? It hardly seems likely.

In general if we design an application for those who are most likely to have problems and make it easy to use for them, then the rest of us will have no difficulty. This inclusive approach can be applied to a wide range of design considerations. I'll give a few examples, but the approach is a broad one.

About 1 per cent of the male population cannot see the difference between red and green. So if you use these colours as the only way to convey important information, this minority will not get it. It is always possible for the designer to use other cues. Colour is great when used to enhance and emphasise, but is risky as the sole source of information. Yes, it may only be 1 per cent but a percent here and a percent there, and soon you have a substantial proportion of people affected. And quite a lot more people have a degree of colour anomaly, making it harder, but not impossible, to distinguish red/green differences. Why make it more difficult than it needs to be for *anyone*?

People with tremor or poor eyesight may have trouble with small tick boxes beside the response text. Tick boxes in electronic applications have always puzzled me. It is a completely paper-based way of entering choices. With pen and paper you have to make a mark somewhere, and it shouldn't be *on* the text, as this would obscure it and might be confused with crossing out the unwanted choice, so you provide a tick box. With electronic entry you have to tap or click somewhere, but there is no need for the mark to go exactly where the tap is. It's much more logical to tap anywhere in the text area and highlight the entire selected text, rather than having a box to one side, as in Figure 8.1. It also makes the area to be tapped bigger than if you have a tick box. This makes it easier if you have tremor – and no harder if you don't.

ePRO systems often have alarms to remind patients when to make their entries. Hearing loss is common in, though by no means confined to, older patients and often involves particular frequencies. A useful trick is to make alarm signals run up and down through the frequency range. Alarms can also start relatively quiet, and get steadily louder. These techniques again make using the system easier for those with a degree of hearing loss without making it harder for those with robust hearing.

This inclusive, patient-centred approach can be summed up as follows:

- Think it through from the patient's point of view.
- Design for the person who is likely to find the system most difficult to use. Then the rest of us won't have any problems.
- Do not make it harder than it needs to be for anyone.

Good user interface design has an importance that goes beyond a desire that our patients should be comfortable with the systems we ask them to use, important though that is. It is an essential part of ensuring a properly run clinical trial programme. If substantial numbers of patients are unable or unwilling to use ePRO systems, it could have an effect on clinical trial recruitment. At best this could make it more difficult to run studies but it could also introduce a source of bias, especially if those not included in the study tend to be elderly; a group who should be fully represented in most trial programmes not least because they consume a good deal more medicine than younger people and are more likely to suffer from adverse effects. Thus the clinical trial population should represent the population of those who will take the medicine once marketed, and our methods should be suitable for use with all types of patient who meet study recruitment criteria.

Fortunately, the experience from many researchers over the past decades has shown that this goal is eminently attainable. The patient's voice is becoming increasingly important in clinical research, and the approach outlined here may help to keep it centre stage.

Summary

Creating ePRO systems that are easy for patients to use requires careful design and ability to think the system through from the patient's perspective, plus an inclusive approach to design that takes into account the differences among patients. If we design systems that can be used by patients who do not use computers, or those with tremor or poor eyesight, the rest of us will have no problems. In practice this means attention to presentation, legibility and size of the area to be tapped with a screen-based system, voice type and speed for IVR; to what the user has to do, response choices and navigation, and to what the user has to remember while using the system. Systems can be complex yet simple to use. Using these principles it is possible to set up ePRO systems that can be used successfully by a wide range of patients. Many studies have shown that patients find such systems easy to use and often prefer them to paper. ePRO systems can thus be used in large scale clinical research programmes without limiting recruitment or skewing the characteristics of the patient group being studied.

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