The development and evaluation of a drug information leaflet for patients with rheumatoid arthritis

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Objectives. To develop and assess the effectiveness of a drug information leaflet (DIL) for D-penicillamine (DPA) and determine whether additional verbal information provides enhanced benefit.

Methods. Three preliminary studies were undertaken: a reading age study; the development of a DIL for DPA; and a DPA knowledge questionnaire. The primary study assessed the effect of the DIL on the knowledge of 30 patients at weeks 0 and 24 after commencing DPA. A follow-up study of 100 patients randomly assigned to receive the DIL alone (control group) or with additional verbal backup (experimental group) determined the effects of additional verbal information by comparison of DPA knowledge questionnaire scores at weeks 0 and 24.

Results. The reading study showed that 12% of the sample had difficulty reading and so the DPA DIL was designed to be easy to read using the Flesch Reading Index. An assessment of knowledge of DPA prior to reading the DIL resulted in scores ranging from 0 to 13 with a median of 2 (maximum possible 14). By week 24 the median score was 10 (range 6–14), which was significant at \( P < 0.0001 \). The assessment of additional verbal backup showed that both the control group and the experimental group knew little about DPA on study entry, with a median score 2 in each group. On study exit, both groups knew significantly more (\( P < 0.001 \)) about the drug; the control group scored 9 and the experimental group 11 (not significantly different; \( P = 0.109 \)).

Conclusions. A large minority of patients have poor reading skills, but when a DIL is designed to be easy to read patients gain significant amounts of knowledge from it. Providing additional verbal explanations did bring about increases in knowledge but these were not significant.

Key words: Rheumatoid arthritis, Drug information leaflet, Knowledge, Verbal backup.
The primary purpose of this study was to test the effectiveness of a DIL for D-penicillamine (DPA), which was to be used in a study of adherence in which the DIL was an essential component [18]. A second aim was to assess whether additional verbal information enhanced any increase in knowledge.

**Patients and methods**

**Preliminary work**

Before the primary study was undertaken, three preliminary studies were carried out. In preliminary study 1, the reading ability of 100 consecutive patients with RA who were attending the rheumatology out-patient clinics at Leeds General Infirmary for follow-up appointments was assessed by use of the Holborn Reading Scale [19]. Their demographic data are displayed in Table 1; by chance all were Caucasian. The results showed that 12% of the sample had a reading age of 13 yr or below (Table 2), necessitating preliminary study 2, an assessment of knowledge on the effectiveness of drug information leaflets (DIL) for disease-modifying anti-rheumatic drugs (DMARDs).

Table 1: Demographic data

<table>
<thead>
<tr>
<th>Study</th>
<th>No. of patients</th>
<th>Group</th>
<th>Sex (M, F)</th>
<th>Age: yr (range)</th>
<th>Duration of RA: yr (range)</th>
<th>Full-time education: yr (range)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preliminary study 1</td>
<td>100</td>
<td></td>
<td>24, 76</td>
<td>59 (20–84)</td>
<td>16.0 (0.3–43)</td>
<td>10.5 (7–18)</td>
</tr>
<tr>
<td>Preliminary study 2</td>
<td>10</td>
<td></td>
<td>2, 8</td>
<td>58 (3–36)</td>
<td>15.0 (3–36)</td>
<td>10.5 (9–14)</td>
</tr>
<tr>
<td>Preliminary study 3</td>
<td>10</td>
<td></td>
<td>3, 7</td>
<td>68 (56–79)</td>
<td>17.0 (6–30)</td>
<td>10.5 (9–13)</td>
</tr>
<tr>
<td>Primary study</td>
<td>30</td>
<td></td>
<td>5, 25</td>
<td>61 (34–76)</td>
<td>8.50 (0.5–38)</td>
<td>10.5 (9–16)</td>
</tr>
<tr>
<td>Follow-up study</td>
<td>100</td>
<td>CG</td>
<td>10, 39</td>
<td>62 (34–79)</td>
<td>12.0 (0.3–45)</td>
<td>10.0 (9–14)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EG</td>
<td>17, 34</td>
<td>63 (22–74)</td>
<td>13.0 (1–37)</td>
<td>10.0 (9–16)</td>
</tr>
</tbody>
</table>

CG, control group; EG, experimental group.

In preliminary study 2, 10 consecutive patients (Table 1) attending the rheumatology clinic who had been newly prescribed DPA read the existing DPA leaflet intended for use in the primary study and found it difficult to read. It was therefore subjected to the Flesch Reading Index [20]. The patients’ assessments were upheld by the results of applying the index, which placed it in the ‘fairly difficult to read’ range. The DIL was rewritten using guidelines that render information easier to read [21] and using the ARC information sheet as a proforma. The ARC sheet was considered for use, but it was not suitable as it did not specify dose, the frequency of blood and urine tests or contact phone numbers, all imperatives for the adherence study. After four revisions, a Flesch reading ease score of 80.1 and a grade level of 4.7 was attained, placing it in the ‘fairly easy to read’ category, and in the light of the results from preliminary study 1 it was considered suitable for use.

In preliminary study 3, a DPA questionnaire was designed using a format and layout similar to that of the Patient Knowledge Questionnaire [4]. All 14 correct answers could be found in the DPA DIL. The questionnaire was tested on 10 patients whose demographic data are shown in Table 1. None experienced problems with its readability or layout, and all thought that the DIL answered all the questions they would raise when starting a new DMARD. The median score was 12.5 and the scores ranged from 6 to 14.

**Primary study**

This study comprised an assessment of knowledge of DPA. The cohort was a convenience sample comprising 30 consecutive RA patients who had been newly prescribed DPA (for demographic details see Table 1). None experienced problems with its readability or layout, and all thought that the DIL answered all the questions they would raise when starting a new DMARD. The median score was 12.5 and the scores ranged from 6 to 14.

**Follow-up study**

This study assessed the value of providing additional verbal backup to the DPA DIL. One hundred patients with RA who were about to start DPA were referred by the rheumatologists in the rheumatology out-patient clinic. The demographics of the sample are shown in Table 1.
Method of assessment. An independent assessor invited patients to take part in the study and none declined. Patients were then randomized via a computer-generated code into two groups, both being seen by the same nurse practitioner (JH). The experimental group received a DPA DIL plus a verbal explanation about their drug, and the controls were provided with the DIL alone. Randomization resulted in 51 patients in the experimental group and 49 patients in the control group. Knowledge of DPA was tested by use of the DPA questionnaire, which was provided by an independent assessor who was unaware of the group to which each patient belonged. Patients completed the DPA questionnaire on study admission (week –2) and again after 24 weeks.

Analysis

The study included both descriptive and inferential statistics. Analysis was performed using the Statistics Package for Social Sciences (SPSS Inc., Chicago, IL, USA). As the data were not normally distributed, two-tailed non-parametric statistics were applied. The Mann–Whitney U-test was used for comparison between groups and the Wilcoxon rank sum test was used to assess the significance of changes within groups. The 1% level of significance was adopted.

Results

Assessment of knowledge of DPA

During the 6 months of the study, six patients withdrew due to side-effects from DPA, leaving a total of 24 pairs of DPA questionnaires suitable for analysis. As expected, on entry to the study the majority of patients knew very little about DPA; the median score was 2 (range 0–13). Seven patients (29%) scored 0/14, four (17%) scored 1/14 and three (13%) scored 2/14. These patients constituted 59% of the total cohort. Conversely, three patients scored over 50%, one scored 8, one scored 11 and one patient scored 13/14 points. After 24 weeks patients had increased their knowledge of DPA, the lowest score being 6/14 (one patient), the highest was 13 points, scored by eight patients. The median score was now 10. These increases were statistically significant \( P < 0.0001 \).

Assessment of additional verbal backup

As expected, neither group knew much about DPA on study entry, the mean score of the experimental group being 2.80 and that of the controls 2.57 (Table 3). There was wide variation between individual patients. The range of scores was from 0 to 8 in the control group and 0 to 14 in the experimental group. However, there was no significant difference in the knowledge of the two groups at week 0 (\( P = 0.791 \)).

By week 24 both groups had increased their scores, the experimental group scoring a mean of 10.80 and the controls 9.90 (Table 3). Both groups knew significantly more about DPA on completion of the study than at the start (\( P < 0.001 \)). By the end of the research, patients in the experimental group who had received additional verbal information knew more about their DPA and its effects than those in the control group, but the difference between the two groups was not significant (\( P = 0.109 \)).

Discussion

This research has highlighted several important aspects with regard to the provision of information. It found that a large minority of patients with RA have problems with their reading. This applied to 12% of the patients in this study, similar to the proportions in the general population [22] and other RA studies [23]. These patients would find it difficult to read much of the educational literature presently provided. This highlights the necessity of testing the readability of all educational material, including DILs, before it is presented to patients. The practice of applying reading formulae to written information is ineffective, but these tools should not be seen as a universal panacea as they have their limitations and may provide a false sense of validity because of the apparent precision of the tools. For instance, they are designed to assess samples of 100 words towards the beginning, middle and end of a document; they do not assess each word within it. This can lead to great variability in reading age within the same document [24]. The application of common sense to the content and presentation, in conjunction with the opinions of patients, is also essential in designing literature that is easily understood [25].

The second finding was that the DIL written at an easily readable level was a highly effective method of increasing the patient’s knowledge of the effects and side-effects of their DPA. The provision of such information empowers patients to become more involved in the decision-making process and this is in keeping with NHS priorities. The provision of information about drug therapies has received greater attention since the EC Directive 92/27 [26] came into force in January 1999. This makes it mandatory that all medicines are supplied with a comprehensive information leaflet produced by the manufacturer. Each leaflet must contain all the information given in the Summary of Product Characteristics (formerly called the DATA Sheet), making it necessary to use extremely small print on thin paper that is multiply folded [27]. This causes difficulty for those with impaired dexterity or poor vision. There is surprisingly little research into the effectiveness of these manufacturer’s inserts, but one study has shown that many patients remain unaware of them, and only a minority will read even a part of the

### Table 3. DIL plus verbal backup

<table>
<thead>
<tr>
<th>Week</th>
<th>Group</th>
<th>Median (mean)</th>
<th>Standard deviation</th>
<th>Between groups</th>
<th>Within groups</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0</td>
<td>Experimental</td>
<td>2.00 (2.80)</td>
<td>3.50</td>
<td>0.791</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Control</td>
<td>2.00 (2.57)</td>
<td>2.54</td>
<td></td>
<td></td>
</tr>
<tr>
<td>24</td>
<td>Experimental</td>
<td>11.00 (10.80)</td>
<td>2.03</td>
<td>0.000*</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Control</td>
<td>9.00 (9.90)</td>
<td>2.46</td>
<td>0.109</td>
<td>0.000*</td>
</tr>
</tbody>
</table>

*Significant at 0.1% level.
information provided [28]. Until the shortcomings of the present manufacturers’ DILs are rectified, there will be a need for drug information to be presented in a shorter, more easily understood format, such as that used in this study.

Finally, although additional verbal explanation of DPA did enhance patient knowledge, it did not have a significant effect. This finding is in line with the results of another recently published study on NSAIDs [29]. In general, the literature on information-giving advocates the combination of written and verbal information. One author cites it as the ideal, as it maximizes the patients’ recall and understanding, and is preferred by patients [30]. One explanation for the lack of enhancement in this study is that the additional verbal backup was unintelligible to patients. However, the nurse who provided the explanation is an experienced practitioner who has been shown in previous research to be an expert communicator [13]. A second and more likely reason could be that the questions on the DPA questionnaire were designed specifically from the information provided on the DPA DIL. It may well be that an additional verbal explanation simply did not furnish the patients with a significant amount of further information.

Limitations of the study
With the advent of new drugs, DPA is not now widely used. However, this work formed part of a wider investigation of adherence in which DPA was used for methodological reasons. Its use in preference to more commonly used drugs should not invalidate the underlying scientific principles of this study.

Although improving patients’ knowledge of their drug therapies is a laudable aim, it is acknowledged that knowing and understanding are different entities and consequently it cannot be assumed from the results of this study that knowledge led to changes of behaviour. However, our subsequent study of adherence showed that behavioural changes did occur [18], and that patients who were provided with information were significantly more adherent with their DPA therapy.

One other caveat is that by chance all the patients in this study were Caucasians and so the results may not reflect the reading ability of other ethnic groups.

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References
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