

**PILs Project Summary Report:**

**Ensuring the Readability and  
Understandability and Efficacy of Patient  
Information Leaflets**

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## **The PILs Project Summary Report**

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# The PILs Project Summary Report

## ***Introduction***

The aim of this summary report is to offer an overview of the tasks undertaken, research methods employed and the conclusions reached through the process of ensuring the readability, understandability and efficacy of the PILs leaflets for PRODIGY Phase Two.

## ***Outline of this Report***

Each section in the report contains a brief overview of the aims, methods employed and findings. It is broken into the following sections:

- Important Findings
- Background to the Report
- Glossary
- Reviews of the Literature
- Consultation with Patient groups and General Practitioners
- Software Validation and Leaflet Acceptability Testing
- Revising PILs using Watchword and Wordweb
- Conclusions
- Appendices describing and listing the patient groups consulted, members of the PILs evaluation team, the Watchword software and recommendations for further reading.

[Important Findings](#)

## **Important Findings**

*might be worth saying which part of the report these are found in.*

- Patient information leaflets do affect health outcomes; patients want them and use them.
- The giving of patient leaflets is an under-utilised resource by health professionals.
- Many leaflets have been poorly written in the past.
- Computer analysis of Patient Information Leaflets (PILs) using Watchword will predict fairly well those leaflets which may need adjustment.
- The analysis indicates that use of specialised medical vocabulary is likely to be a particular problem.
- Written materials along with oral instructions have been shown to be one of the most effective means of patient education. However, much of the available health education material requires a Year 10 reading ability (US and UK education system). This roughly translates into an average 15 year old's or higher level of reading ability. The reading age of the general population in the UK has been estimated to be on average 9 years of age (the equivalent of Year 4 at school).
- Research to date suggests a considerable gap in the readability of existing health education publications and the reading level of the general population.
- The literature reveals that there is very little research which actually goes beyond the application of readability formulae to materials. Very few studies involve the participation of those for whom the materials are to be used: the patients themselves.
- PILs was well received by both Prodigy GPs and patient groups.

## **Background to the Report**

The project described in this paper developed from the work of the PRODIGY (Prescribing Rationally with Decision-Support in General Practice Study), an NHS Executive-funded project to develop and evaluate a computerised decision support system for General Practice. The first version of the PRODIGY system, which was tested in practices at the beginning of 1996 included a small number of non-drug leaflets as 'prescribing options' for a small number of conditions covered by PRODIGY (Purves 1996). The General Practitioner participants on the project quickly identified these as an innovative and useful management tool for patient care and requested the inclusion of a comprehensive set of leaflets.

Responding to requests made by GPs using the pilot PRODIGY system is an integral part of the project development process, therefore the project team decided to address the issue of providing a set of leaflets. A search was conducted in the medical field (including the Internet) as well as examining the possibility of producing a PRODIGY specific set of leaflets. Finally one product stood out as being particularly suitable for the PRODIGY users. This was the PILs Compendium written by Tim Kenny and Beverley Kenny, two General Practitioners in Newcastle upon Tyne. PILs is a product of PIP (Patient Information Products) and has developed over a number of years to currently include over 270<sup>2</sup> leaflets and contact details of over 500<sup>2</sup> patient groups.

However before use of the PILs Compendium was ratified it was decided that four tasks should be completed:

- Reviews of the Literature
- Consultation with Patient Groups and General Practitioners
- Software Validation and User Testing of PILs
- Revision of PILs

The first task was the commissioning of two reviews of the literature and a mini-report dealing with various issues including a general review of medical patient information literature, a specific review of the readability and understandability literature and a mini-report outlining recommendations from the education field in the authoring of patient information (p11).

There was then a consultation exercise with the relevant patient organisations and with the general practitioners on the project (p13).

The third task was the completion of a Readability and Understandability testing programme for the content of the leaflets. This was conducted within the University of Newcastle using specialist expertise and the Watchword software tool (p24). The Watchword tool was adapted and used to facilitate the editing of the leaflets, with funding from the NHS Executive PRODIGY project (p16).

The fourth task involved the author Tim Kenny putting into practice the lessons learned through the reviews of the literature and the consultation process using the software tools identified (p10).

## **Glossary**

### **PILs**

PILs (Patient Information Leaflets) in this summary refers to the proprietary product authored by Tim and Beverley Kenny and is also a proprietary product available from Oxford University Press on CD ROM. PILs are leaflets designed to be printed from a computer database. The sub-set used in PRODIGY replaced the non-drug patient information leaflets from Phase One.

### **PRODIGY**

PRODIGY (Prescribing Rationally with Decision Support in General Practice Study) is an NHS Executive pilot project which is developing and evaluating computerised prescribing and management support for use by General Practitioners in consultations. PILs or the non-drug patient information leaflets are offered to the GP as a therapeutic choice in the therapeutic options section of the recommendations.

### **Readability**

Readability relates to whether text can be read successfully. Both technical accuracy and comprehension are involved, as people are often able to read elements of information without being able to integrate them into a meaningful whole.

### **Understandability**

The understandability of text is determined by the features that make it easier or harder for readers to make sense of it. It relates to the interpretation of meaning that the person has taken from a word or passage and its integration into a meaningful whole. Understandability is usually assessed by asking readers to give an account of what they have read or by various forms of comprehension test.

### **Cloze Testing**

Cloze testing is the 'clozing' (closing) or filling in the gaps in sentences. It is a test of understanding and in order to succeed in the task the reader must make use of context. For further information about Cloze testing see Taylor 1953.

### **Difficulty Index**

The Watchword Difficulty Index is a measure of readability based on weighted combinations of word and sentence length. A 'reading age' scale is used, calibrated to give average reading ages at which the passages can be read with at least 95% accuracy. For further information about Watchword please refer to p24.

### **Vocabulary Index**

The Watchword Vocabulary Index is a measure of readability based on the percentage of words falling outside a core vocabulary list. A 'reading age' scale is used, calibrated to give average reading ages at which the passages can be read with full understanding of the words used. For further information about Watchword please refer to p24.

### Readability Score

This is the average of the Vocabulary and Difficulty scores produced by Watchword described above. The target Readability score was 12 years/Year 7 or under.

### Reading Age or Grade

Reading Age is the reading level, in years, for an average person of that calendar age.

Reading Grade is slightly different as it is originally based on the Grade Level system used in the USA, many European countries and more recently in the UK. A Reading Age of 12 years is equivalent to the national average performance in Year 7 at an English or Welsh school, S1 at a Scottish or Northern Irish school or 7th Grade in the USA.

The table below offers a means of comparison.

Age (calendar years)	Year at school (England & Wales)	Year at school (Scotland & N. Ireland)	School Grade (USA)
4-5	Reception	P1	Kindergarten
5-6	1 (Primary School)	P2	1 <sup>st</sup> Grade
6-7	2	P3	2 <sup>nd</sup> Grade
7-8	3	P4	3 <sup>rd</sup> Grade
8-9	4 (Junior School)	P5	4 <sup>th</sup> Grade
9-10	5	P6	5 <sup>th</sup> Grade
10-11	6	P7	6 <sup>th</sup> Grade
11-12	7 (Secondary School)	S1	7 <sup>th</sup> Grade
12-13	8	S2	8 <sup>th</sup> Grade
13-14	9	S3	9 <sup>th</sup> Grade
14-15	10	S4	10 <sup>th</sup> Grade
15-16	11	S5	11 <sup>th</sup> Grade
16-17	12 (Sixth Form)	Scottish Highers/NI A- levels	12 <sup>th</sup> Grade

Note that the USA grade levels are not strictly equivalent to UK age-groups (in the USA more children in a year group are promoted or held back depending on their progress).

## **Reviews of the Literature**

*This section outlines the aims and findings of the literature reviews and mini-report that were carried out to support the development of the project.*

### *What were the aims of the reviews and mini-report?*

The reviews of the literature and the mini-report were intended to inform the development, editing and future authoring of the PILs compendium and other patient information. The three tasks undertaken are outlined below:

- a general review of medical patient information literature
- a review of the readability and understandability literature
- a mini-report outlining recommendations from the education field in the authoring of patient information

### *What were the findings of the general review?*

The general review of the literature was conducted by Tim Kenny. It examined in particular the role that computer generated leaflets could play. Its findings were that patients want more information but health professionals tend to under-utilise the option of 'prescribing' an advice leaflet. Also that leaflets should be maintained, reviewed and referenced and that the best way of achieving this might be by using computer software. The main findings are listed below:

- Patient information leaflets do affect health outcomes; patients want them and use them.
- The giving of patient leaflets is an under-utilised resource by health professionals.
- Many leaflets have been poorly written in the past; there is now an increasing level of advice on how to remedy this.
- Patient information leaflets should be peer reviewed, contain references, be dated, give an objective measure of readability and be evaluated.
- Clinical trials should be considered for patient information leaflets to demonstrate their effectiveness in health outcomes.
- Computerisation may increase the number of leaflets stored, 'noticed', retrieved easily and given to the patient.
- The computer tagging of patient records will become an increasingly useful tool in auditing and researching the use and effects of patient information leaflets.
- Any author writing new patient information leaflets intended for a wide audience should consider producing them in an electronic format in addition to any paper format.

### *What were the findings of the review of the readability and understandability literature?*

The review of the literature on patient information leaflet readability and understandability was conducted by Jill Clark. It examined in particular the relevant literature on patient information and education. It found that the gap between the readability of patient information and the reading levels of the general population was considerable. Another main finding was that the issues of understanding were widely overlooked and that the majority of studies in the evaluation of patient information had not involved any patients. The main findings are listed below:

- written materials along with oral instructions have been shown to be the most effective for patient education. However, much of the available health education material requires a 12 years of age/Year 7 or higher level of reading ability. Research to date suggests a considerable gap in the readability of existing health education publications and the reading level of the general population.
- the importance of matching patient education materials with patient reading comprehension levels has been documented in such diverse areas as cancer education and back pain.
- research findings also reinforce the need to recognise that older adults may have more difficulty understanding health information than younger adults.
- there are gaps in the research studies which highlight the need for the providers of written health-care materials to be more aware of their target audience.
- the search of the literature also revealed that there is very little research which actually goes beyond the application of readability formulae to materials and there are limitations to this approach. Very few studies involve the participation of those for whom the materials are to be used: the patients themselves.

### *What were the findings of the mini-report?*

The mini-report comprised general advice derived from the literature by Doug Newton and Lynn Newton outlining the qualitative aspects of style and presentation as they might be applied to patient information. The main findings are listed below:

- the *presentation* of information is crucial: it should be always be presented in a *considerate* manner. This includes the information area and the words both in terms of their complexity and their vocabulary. Strings of words vary in their ability to communicate. The aim should be to produce strings of words which enable frustration-free reading.
- there is a strong requirement for *support* for understanding which would include the structure of the target information, the purpose of the structure and the reasons why the structure serves the purpose. There is more to understanding than the comprehension of words and sentences. The information has to hang together and relate to the reader's existing knowledge to be meaningful. The goal should be to create text which helps the reader make these connections and reduce the load on working memory.

- the use of individual *variation* in information processing habits, preferences and styles is crucial, including drawing attention to particular words and phrases by use of underlining or italics for instance. The aim should be to allow different types of readers equal access to reading and understanding the text. (Mobley 1980, Newton 1990, Hartley 1994).

## **Consultation with Patient groups and General Practitioners**

*This section outlines the aims, methods used and findings of the consultation process conducted with patient groups and the general practitioners involved in the PRODIGY project.*

### *What was the aim of consulting the patient groups and GPs?*

There were multiple aims for the consultation process. These were to ensure that the clinical content, type of language and approach of the leaflets was correct and to assess the views of the those issuing the leaflets and whether they thought that the use of the PILs leaflets in particular was a good idea.

### *How was the consultation process carried out?*

The consultation process involved General Practices involved in the PRODIGY trial, major patient organisations and other more specialised patient groups. A full paper set of PILs and a questionnaire were sent to General Practices involved in the PRODIGY trial. The full set of PILs and the same questionnaire were also sent to four major organisations (The [Patient Association](#), the [Long term Medical Conditions Alliance](#), [Community Health Council](#) and the [Association of British Pharmaceutical Industry \(ABPI\)](#)~~list them~~). In addition 53 more specialised patient organisations (~~generally those for example those~~ dealing with specific conditions) also received copies of individual leaflets considered relevant to their work, along with the [survey questionnaire](#).

132 sets of leaflets and comments forms were sent out in November 1996 to GP PRODIGY sites. Of these, 38 (25%) replies were received. A small number of sites chose not to answer the questions as put in the questionnaire but wrote back with their overall comments. Fifty three groups/organisations were contacted and 27 (50%) groups responded. Of the four major patient organisations contacted, only the Patient Association and the Long term Medical Conditions Alliance responded. These two groups did not comment on the content of the leaflets but indicated that it was the responsibility of individual groups to do so. Of the 53 specialised groups targeted, 27 groups responded, 3 choosing not to fill in the questionnaire but giving general comments by letter. Table 1 overleaf shows the findings.

### *What were the findings of the consultation process?*

The patient groups and GPs who responded were generally enthusiastic about the concept of the computer generated leaflets. Patient groups tended to be more critical about the content of the leaflets. The GPs were more concerned about organisational issues such as printing. The main findings of the work are shown also in the Table 1.

Table 1: Responses to questions on the content, structure and usefulness of PILs

Questions	PRODIGY GPs		Patient Groups	
	Yes	No	Yes	No
Is there anything you feel is essential to include but is omitted?	5 (14%)	28 (80%)	18 (75%)	2 (8%)
Is there anything you feel should be left out that is included?	2 (6%)	30 (86%)	11 (46%)	11 (46%)
Is there anywhere where you feel the style of the language is not appropriate (eg patronising/confusing)?	2 (6%)	30 (86%)	12 (50%)	9 (37%)
Do you feel there is anything factually incorrect?	3 (8%)	30 (86%)	16 (67%)	6 (25%)
Do you feel that these are generally appropriate leaflets to give to patients from a GP following a consultation?	33 (94%)	2 (6%)	17 (71%)	5 (21%)
Do you feel that GPs would generally like and use these leaflets?	32 (92%)	3 (8%)	18 (75%)	2 (8%)
Do you think that patients would find these leaflets useful?	34 (97%)	0	21 (87%)	1 (5%)

Each question, in addition to the yes/no format, gave space to expand on reasons for the answer. The length of some of the leaflets had been an issue of concern before the mailshot, but the overwhelming majority of the respondents (35 GP sites and 27 Patient organisations) stated that the length of the leaflets was ‘about right’.

Two general questions asked for any further comments or suggestions about the leaflets in general and about the incorporation of the leaflets into PRODIGY. 37 separate comments were included with the GP replies. They were grouped into the following general categories:

- Omissions, inaccuracies and suggestions for new titles
- Readability issues
- Printing issues
- Functionality issues
- Absence of diagrams
- Messages of encouragement/approval

In contrast to the GP respondents, and possibly because of the targeting of the mailshot to interested parties, the patient groups' responses contained a high level of comment in addition to the yes/no answers. In general the organisations were more critical and the majority felt that either essential information had been omitted or that there were some errors in content and style. Space does not permit inclusion of all the comments but on the whole the criticisms were constructive and helpful. Despite their comments, the majority still felt the leaflets were appropriate and would be found useful by patients and doctors although four respondents stipulated this only if their suggested changes were made.

The main findings are listed below:

- The aim of the consultation exercise was to evaluate the clinical content, tone and approach of PILs and investigate the response of those who would be issuing the leaflets.
- GPs involved in PRODIGY, major patient organisations and more specialised patient groups were consulted.
- Findings were overwhelmingly favourable, with 92% of the responding PRODIGY GPs believing that GPs generally would like and use these leaflets.
- Patient organisations also strongly welcomed the idea of GPs using computer generated PILs, but made many more comments on the clinical content of the leaflets.

## Software Validation and Leaflet Acceptability Testing

*This section describes Readability and Understandability testing programme for the content of the leaflets, including the process of validating the Watchword software.*

### *What is Watchword?*

~~The text of the leaflets is entered in MS Word and ..... Watchword analyses samples of text, using algorithms based on word and sentence length, repetition of words and vocabulary range. It produces an overall reading age readability level and separate scores of reading difficulty and vocabulary. It allows users who are writing text to assess the effects on readability of excluding technical or other specified vocabulary and of redrafting through editing in MS Word.~~ The Watchword software assessed here was adapted from existing software to assess the readability and understandability of PILs.

### *What was the aim of the testing?*

Verifying the readability and understandability of the large number of PILs was a substantial task and it was clear that Watchword had the potential to be an invaluable tool to the evaluation process. However, the team needed to ensure that the software did indeed fulfil its purpose.

Watchword was therefore validated by comparing its findings with an assessment~~ta~~ of readability and understandability of ~~??~~specimen PILs made using a group of volunteer older people. Research was also carried out with the same group of patients to investigate the preferred layout for patient information leaflets.

### *How was the testing carried out?*

Fifty nine volunteers participated in the research ~~and they were members of an existing research cohort of the NEAR group (North East Age Research) based at the University of Newcastle. who were they? Any relevant characteristics...~~ The research was carried out by Rob Wilson and Jill Clark, under the direction of David Moseley, ~~members of the PILs evaluation teamthe assistance of the NEAR group (North East Age Research), who carried out three main types of test.~~

### *What tests were used?*

The three main types of tests used two were a test of leaflet *readability*, one a test of leaflet *understandability* and a test of preferred leaflet *presentation*.

These tests are described in greater depth overleaf.

### *Test of Readability*

The test of readability used on the NEAR group were the Cloze test and the Underlining test. The Cloze was a test developed by Taylor (1953) and involves the test subject attempting to fill in blank spaces where words have been removed. The blank spaces occurred every fifth word (not including medical terms) the aim being to gauge the level that individual words supported the reading of the whole text. The Underlining test was developed by David Moseley (~~especially for this research?~~) and involves the test subject underlining words that they do not recognise in order to pinpoint possible areas of reading difficulty.

### *Test of Understanding*

The test of understanding used on the NEAR group was the Sentence Verification Technique (SVT) (Royer et al 1979). This involved the test subjects in reading a previously unseen leaflet. The group's understanding of the leaflet is then examined using test statements which ranged from direct quotes from the original text through meaning changes to complete falsehoods. Subjects were asked to decide (using a Yes/No scale) whether statements had been contained in the text they had just read. Its aim was show the level that the test subjects had understood the text.

### *Test of Preferred Presentation*

The test group were shown three possible layouts for the same PILs leaflet using an overhead projector and asked to express their individual preference using a simple form.

### *What were the findings?*

~~The findings were supplemented by previously recorded Mill Hill 'A' test scores Explain or leave out.~~

The findings showed that the Watchword software accurately identified the leaflets that the test group subjects found difficulty with. This allowed the software to be used with the complete set of leaflets. The findings also showed that the test subjects overwhelmingly preferred one style of presentation of leaflet.

The main findings are listed below:

- In general, many PILs were likely to be readable in their present form although this should not preclude further simplification and development.
- The analysis also indicated that use of specialised medical vocabulary is likely to be a particular problem.
- The data showed a correlation between the Cloze (Taylor 1953, Moyle 1970, Harrison 1979) test scores and the readability score; both of which are significant factors. In use the cut-off point might be 12 years/Year 7 on the vocabulary index, accompanied by 10 years/Year 5 on the difficulty index. It should be noted that for the purposes of the first PILs Watchword edit the aim was to reach an average difficulty and vocabulary score of under 12 years/Year 7.
- There was a strong preference for a particular layout of text, in which the key information is summarised as key points at the start of the leaflet and repeated for emphasis at the end.
- Computer analysis of PILs (using Watchword), on the results of this testing series, will accurately identify most leaflets which may need adjustment.

## Revising PILs using the Watchword and Wordweb Software

This section describes the use of the Watchword and Wordweb software to edit the PILs leaflets in order to lower the reading age and increase their understandability.

*What were aims of the revision process?*

The aims of the revision process were to update and revise PILs in light of comments received in the consultation process and reduce the readability score of all PILs to 12 years/Year 7 or below. This was achieved using the comments from GPs and Patient groups, new clinical evidence and the software described below.

*Why use Watchword?*

As previously identified the task of scoring the 200 leaflets by hand was an unrealistic one. Computer software has been used for a number of years to evaluate the readability of text, for instance in early versions of MS Word. Watchword has been designed by David Moseley, an expert in the field, to evaluate text and offers sensitive measures to assess readability and understandability. It also offers significant additional assistance for editing text through its ability to be used with word processing software (MS Word).

*Why use Wordweb?*

Wordweb is an electronic thesaurus which offers a significant improvement on the existing thesaurus that comes with MS Word. The thesaurus was initially developed at the University of Princeton and adapted for use by Antony Lewis. The Freeware version can be downloaded from the Net at <http://www.netword.demon.co.uk/wordweb/>

*How was the Software used?*

The Watchword software was used by Tim Kenny to edit the leaflets to be included in the PRODIGY Phase Two therapy options. The software calculates a vocabulary and difficulty score (with and without excluded words). An average of which is then used as a measure of readability.

The Watchword software also displays all words in the selected leaflet that are not present in its core dictionary (excluded words). This then allows the author to exclude words that have been identified and replace them with words of similar meaning using suggestions from the Wordweb thesaurus and to edit in MS Word.

The author can then re-calculate the score to assess whether the leaflet has been edited sufficiently to come under the target readability score. For PRODIGY Phase Two PILs the aim was to have an average reading age score of under 12 years/Year 7 for each leaflet.

Please see Appendix 3 for an example taken from one leaflet (Gout) before and after editing.

### *What were the results of the editing process?*

The results of the editing process were the reduction of the average readability score of all leaflets to 11.23 (Standard Deviation 0.68) from a starting point of 11.46 (Standard Deviation of 0.8).

Although the overall reduction in readability score was quite low, 32 (18%) of the total leaflets were edited to reduce the individual readability score to the agreed target of 12 years/Year 7. As a direct result 95% of the final release of PILs in PRODIGY reached the agreed target readability score.

The relatively low level of overall reduction fails to show the significant revisions made on the 32 leaflets that were above the target score of 12 years/Year 7. It must also be borne in mind that the Watchword software was not the only basis by which the leaflets were revised. Comments made by the Patient Groups and the GPs sometimes resulted in a slight rise in the readability score. The process was regarded as a success in the strict time frame allowed by the PRODIGY project release date. The Watchword evaluation process demonstrated that the subjective decision made by its author to keep the original set of PILs as simple as possible had been largely achieved. The leaflets were then released to the participating practices in the Phase Two PRODIGY pilot and have since been updated.

The main findings are listed below:

- The use of the Watchword software in conjunction with Wordweb significantly improved the editing process.
- The use of Watchword and Wordweb helped ensure that 95% of PILs reached the agreed readability score target of 12 years/Year 7.
- Further editing is being undertaken to lower the leaflets readability score even further to an ideal figure of 10 years/Year 5.
- The leaflets are in daily use in over 180 English general practices.

## Conclusions

~~With the emphasis of health and social care increasingly focused on what individuals can do for themselves it is important that they are supported in this in every way possible. Use of the techniques described above, we believe, has enhanced the production of PILs and can improve the production of other patient information material. Patient information in all its forms seems set to be a key factor in the future of healthcare provision.~~

~~However this remains a developing method and is part of a wider interest, academic and commercial, in the provision of patient information. The literature reviews highlighted that~~ Evaluation studies of patient information ~~it~~ appear ~~to~~ have historically tended to focus on one or two of the aspects of what ~~our~~ ~~the~~ ~~experience~~ and the evidence shows to be a complex process of evaluating information. The current ~~philosophy~~ appears to be that information for patients is a good and useful thing for health professionals and their patients. However the efficacy of Patient Information has not been adequately proven, not least because of the inadequate involvement of the theoretical beneficiaries (the patients themselves) and the poorly written material currently being used. ~~Unless~~ ~~P~~ patient information ~~must~~ ~~be~~ taken seriously and there ~~fore~~ ~~by~~ rigorously evaluated ~~otherwise~~ ~~the~~ the full benefits to the health profession and more importantly their clients will remain unrealised.

~~Patient Information evaluation studies have historically tended to focus on one or two of the aspects of the complex process of rigorously evaluating Patient Information.~~ Taking a common example ~~recently~~ identified ~~in the reviews~~, ~~the~~ aspects of readability have been thoroughly discussed in both the Patient Education and the wider education literature. Previous reviews have listed a number of formulae for testing the readability of a piece of text (Klare 1971, Tefki 1987). However as ~~only~~ ~~a~~ ~~small~~ ~~number~~ ~~minority~~ of the identified studies ~~recognis~~ ~~identifi~~ed this is a limited approach if ~~understandability~~ is not subsequently measured (Doak et al 1980). Measuring readability also has limitations (Michielutte et al 1990).

The consultation process with the General Practitioners and the Patient Groups is one of the largest conducted and has been adopted as a central plank in the ongoing revision and maintenance of PILs. The use of Watchword and Wordweb for the revision of PILs has also been continued and is used by the author, Tim Kenny, in the drafting of new PILs titles. It is hoped that funding can be obtained in the interim to extend Watchword's functionality and revalidate the algorithms with a different patient group from the NEAR test group. A self-completion survey evaluation of patient attitudes to PILs is ongoing.

This report shows that the process has delivered both an academically sound and practical means by which patient information can be evaluated, edited and released with increased confidence that the text is comprehensible by the majority of the UK population. The report also shows that the use of computers in the authoring, editing, delivery and maintenance of leaflets is a sensible way forward.

~~The proposed approach, which would offer the most rigorous method to evaluate patient information, would involve six key stages. These stages would be:~~

- ~~• Initialisation~~
- ~~• Assessment~~

- ~~Testing and Validation~~
- ~~Evaluation in Use~~
- ~~Re-Testing, Re-Validation, Re-Assessment & Updating~~
- ~~Trialing (Clinical/Qualitative)~~

~~As the literature reviews revealed very few patient information studies have addressed even three of these six identified stages. Therefore it could be argued that the literature on patient education and information is speculative, without rigour and therefore fundamentally flawed. This is not necessarily the of the those who have produced it is rather a product of the way that patient education has been viewed as being less important and less clinically relevant than drug treatments for instance – compare the amounts of money spent. This is despite arguments that good patient information can increase compliance, etc and reduce health overheads in the longer term.~~

~~The paper will now describe the six proposed stages in greater depth:~~

#### *~~Initialisation~~*

~~Stage one in the process it includes reviewing the relevant literature both clinical and cultural (evidence based medicine and lay theories), strategic decision regarding the means and context of communication (where the material is to be used has a bearing on its content, presentation and the limitations that therefore may apply) and initial authoring of the material.~~

#### *~~Assessment~~*

~~The second phase consists of a assessment of the readability and understandability ideally using computer software which can then be validated at a later stage. It should also involve a consultation process with the possible stakeholders either concerned with the content matter (patient organisations) or the context where the information is intended to be communicated (in general practice the context gatekeepers might be General Practitioners). Edits bearing in mind the comments generated should be made at this stage.~~

#### *~~Testing and Validation~~*

~~The third phase involves the testing of the leaflet with groups of lay people. Ideally this process would involve those who had/have the condition as well as a group who did not necessarily. Although ideally this should occur in the context where the information is to be issued it is usually more convenient to conduct large scale testing in a laboratory environment. There is evidence to~~

suggest that if an individual is interested in the text then they tend to make greater efforts to understand the material. Conversely there is also evidence that if an individual is under stress then it actually reduces their reading and understanding capacity. The validation of the software algorithms should also happen at this stage if necessary. Amendments derived from this process should be made at this stage.

#### *Evaluation in Use*

This fourth stage involves the pilot release of the third draft of the leaflets in the intended sphere. All aspects of the information in use should be examined these include content, readability, understandability, acceptability of the transmission process, previous use of patient information etc. The subjective views of context gatekeepers regarding the relative success of the information should also be gathered. If computers are used to issue the information in some way it would also be advantageous to measure the level of transmission objectively to compare with other measures.

#### *Re-Testing, Re-Validation, Re-Assessment and Updating*

At this stage the aim would be to repeat the tests carried out in stage three to re-validate the scores generated and if software is being used, to re-validate it also. The update process would be used to assess and weigh the feedback collected during the 'evaluation in use' stage and to also amend the leaflets in the light of any additional information that had been published in the journal literature. The results of this process should then be re-circulated to the content and context stakeholders. The completed product could then be used as the basis for the final stage.

#### *Trialing (Clinical/Qualitative)*

The final stage of the approach would seek to examine the information's *impact* on patient care, patient behaviour and corresponding health outcomes. This final evaluation could take the form of a separate randomised controlled clinical trial, part of a larger clinical trial, take a longitudinal approach for example examining consultation behaviour and patient behaviour over time. The focus of the research at this stage might be measures of health outcomes, retention and accuracy of retention of the health information and changing patterns of use of health care resources (if applicable). Qualitative work could examine the relative impact of information regarding a condition by whether it was chronic/acute, examining patterns of lay health beliefs as compared to the medical model perhaps reflected in the information.

#### *Comment*

With the emphasis of health and social care increasingly focused on what the individual can do for themselves it is important that this is supported in every way possible. Use of the methodology

~~described above, we believe, will greatly enhance the production of patient information material which seems to set to be key factor in the future of healthcare provision.~~

## Appendix 1 - Contacted patient groups

(\* = responded)

<b>Organisation</b>	<b>Relevant leaflets</b>
Alcohol Concern	Alcohol leaflet
Alcoholics Anonymous	Alcohol leaflet
Al- Anon Family Groups (UK & Eire)	Alcohol leaflet
ASH (Action on Smoking and Health)	Smoking the facts Smoking tips on stopping
Quitline	Smoking the facts Smoking tips on stopping
*International Glaucoma Association	Glaucoma
*Mind over matter (Testicular cancer)	Testicular self examination
Save Our Sons (Testicular Cancer)	Testicular self examination
British Deaf Association	Glue ear
*National Deaf Childrens Association (NDCS)	Glue ear
*Age Concern	Dementia in the elderly Stroke
Alzheimers Disease Society	Dementia in the elderly
*The Stroke Association	Stroke
*British Liver Trust	Hepatitis A
*British Diabetic Association	Diabetes
*British Heart Foundation	Aspirin Heart disease prevention Cholesterol and Health Exercise why its important Smoking the facts Smoking tips on stopping Angina AF and digoxin Heart failure Hypertension Myocardial infarction

<b>Hypothyroidism support group</b>	Hypothyroidism
<b>National Asthma Campaign</b>	Asthma
<b>*National Osteoporosis Society</b>	Osteoporosis
<b>*British Polio Fellowship (The)</b>	Polio immunisation
<b>*Herpes Virus Association (The)</b>	Genital Herpes Cold sores and acyclovir
<b>*British Migraine Association (The)</b>	Migraine (3 leaflets)
<b>Arthritis Care</b>	Osteoarthritis Gout
<b>National Back Pain Association</b>	Cervical spondylosis
<b>Raynauds and Scleroderma Association</b>	Lumbar back pain
<b>*Cry sis</b>	Raynauds phenomena
<b>*Enuresis Resource And Information Centre (ERIC)</b>	Baby colic
<b>CITA (Council of Involuntary Tranquilliser Addiction)</b>	Bedwetting (4 leaflets)
<b>Fellowship of Depressives Anonymous</b>	Benzodiazepines Depression
<b>Manic Depression Fellowship</b>	Antidepressants Depression
<b>*MIND</b>	Antidepressants Depression
<b>*Acne Support Group</b>	Benzodiazepines Antidepressants
<b>*National Eczema Society</b>	Acne Rosacea
<b>Psoriasis Association (The)</b>	Atopic eczema Eczema patches Psoriasis
<b>Association of Continence Advice</b>	Dithranol leaflet
<b>Incontact (National Action on Incontinence)</b>	Incontinence (3 leaflets)
<b>Association of Breast Feeding Mothers</b>	Incontinence (3 leaflets)
<b>*Foresight (pre-conception)</b>	Breast feeding
<b>Hysterectomy Support Network</b>	Pre-conception advice

<b>*Issue (National Fertility Association)</b>	Hysterectomy
	Infertility a basic understanding
<b>*La Leche League</b>	The sperm count
<b>*Miscarriage Association</b>	Breast feeding
<b>*NAPS (Pre menstrual syndrome)</b>	Miscarriage
<b>*National Endometriosis Society (The)</b>	PMS leaflet
<b>Arthritis and Rheumatism Council</b>	All 28 leaflets in the Gynaecology section
	Osteoarthritis
	Gout
<b>British Lung Foundation</b>	Cervical spondylosis
	Asthma
<b>*Depression Alliance</b>	Chronic bronchitis
	Depression
<b>*Family Heart Association</b>	Antidepressants
	Heart disease prevention
<b>*Family Planning Association</b>	Cholesterol
<b>Brook advisory centres</b>	All 12 leaflets on contraception
<b>*Migraine Trust</b>	All 12 leaflets on contraception
<b>Women's Health Concern</b>	Migraine (3 leaflets)
	28 leaflets on gynaecology problems

## Appendix 2 - About the Watchword Software

### Background

The Watchword software was adapted from a simpler version specified for Acorn computers in 1986 by David Moseley, Reader in Applied Psychology in the Department of Education at Newcastle University. It was developed for use with IBM-compatible PCs with funding from the NHS Executive PRODIGY (Prescribing RatiOnally with Decision-Support In General practice study) project. One of the results from Phase 1 of the PRODIGY project was a request on the part of the participating GPs for more advice leaflets. The PRODIGY team examined the currently available products, including the Internet, and decided on the Patient Information Leaflets compendium (PILs) developed independently by a member of the team, Dr Tim Kenny a GP in Newcastle upon Tyne. Tim Kenny has used Watchword to revise existing leaflets and continues to do so as an aid to writing new ones.

### What it does

Watchword is designed for use with Microsoft Word. It analyses samples of text, using algorithms based on established approaches to assessing readability (word and sentence length, word repetition and vocabulary range). It produces an overall reading age readability level and separate age-normed indices of reading difficulty and vocabulary. It allows users who are composing text to assess the effects on readability of excluding technical or other specified vocabulary and of redrafting through editing in Word. Experience gained in authoring and revising Patient Information Leaflets shows that it is a powerful and flexible aid to writing, especially when used in conjunction with an electronic thesaurus.

### How it was developed

The present version was developed as part of an internal collaboration at the University of Newcastle led by the Sowerby Centre for Health Informatics. The work was commissioned by the team and carried out by a programmer then working at the University of Northumbria. The software then went through an evaluation process, with an independent test group using the PILs leaflets, in an attempt to validate the algorithms. The results of this testing were very encouraging. There were high correlations between the group's scores and the scores generated by the Watchword software. The group plan to release the results of this testing in the very near future. The software was then assessed for its usability by members of the team and comments were made to the programmer who altered the software accordingly.

### What is its availability?

The software currently is in Phase 2 of its development and the PILs evaluation team are looking into further sources of funding to develop the software in order to improve its usability, widen its applicability, extend its functionality and to re-test its validity. A decision regarding the availability of Watchword will be made when the product has been finalised.

## Appendix 3 Gout Leaflet original and post editing

### GOUT (Original)

#### **What is Gout?**

Gout is a condition which causes inflammation and pain in one or more joints. It affects about two or three in every thousand adults. Men are much more commonly affected than women. It has a tendency to run in families. Treatment is usually effective and further attacks usually preventable.

#### **What are the symptoms?**

Gout often comes in 'attacks'. These can arise quite suddenly over a few hours, typically leading to severe pain over one or more joints. The classical and most common joint affected is the one between a big toe and the adjacent foot bone. In this situation, walking is very painful and even the weight of bedclothes can be quite uncomfortable. The joint will normally be swollen and the overlying skin will look inflamed and often red. However, any joint can be affected and if left untreated the attack may last several days before easing. Less severe attacks can occur which may mimic other forms of arthritis.

#### **What causes gout?**

A chemical in the bloodstream called uric acid (urate) is responsible. This is a normal breakdown constituent of many foods that are eaten. A slightly faulty metabolism (body chemistry) in some people causes the levels to be high. If the level becomes too high tiny crystals are formed which are then deposited in joints causing painful inflammation. In some people a high level is only present when aggravated by other things such as dehydration or excess alcohol. Some prescribed drugs can also cause the level of uric acid to rise and aggravate gout in some people, the most common being diuretics ('water tablets').

#### **Is it serious?**

Anyone who has suffered a gout attack will know the pain is a serious pain! However, the condition itself is not normally serious and is usually easily treated. Complications only rarely develop if left untreated. For example, uric acid stones may form in the kidney causing kidney stones and sometimes mild kidney damage. However, high blood pressure commonly develops in up to 50% of people with gout in later life. Skin lumps (topaceous gout) due to uric acid crystal deposits under the skin are now becoming uncommon due to effective treatments.

#### **What can I do if I have gout?**

- \* If overweight, losing some can in some people decrease the uric acid level and cure the problem.
- \* Limit excess alcohol intake. Total abstinence is not necessary, but excess amounts makes gout worse.
- \* If relevant, consider any medicines or drugs that are being taken, particularly diuretics ('water tablets'). Sometimes they increase the level of uric acid causing gout.
- \* Have your blood pressure checked at least once a year, as high blood pressure is more common in people with gout.

#### **Treating gout attacks**

*Anti-inflammatory drugs.* These are commonly prescribed and are usually very effective. These drugs are commonly used for many types of arthritic conditions (including gout) where there is pain or inflammation. Most gout attacks will stop very quickly (often within 12-24hrs) with a short course. Many people with gout like to have a supply on 'stand by' just in case an attack happens. They are usually needed only for a few days until the attack has completely

gone. Most people can take short courses of anti-inflammatory drugs without any problems. The most common side effect from these drugs is an upset stomach or heartburn so to reduce this possible problem it is wise to take these drugs with food.

*Colchicine*. This is an alternative effective drug if anti-inflammatory drugs cause problems or side effects.

### **Preventing gout attacks**

Many people will only have an occasional attack of gout. They may have just a small increase in the level of uric acid in the blood which rarely reaches a level for crystals to form causing a gout attack. In such people, having some anti-inflammatory drugs available is all that is required to treat each attack. However, if gout attacks occur more frequently then a drug can be taken regularly (every day) to prevent the attacks occurring.

*Allopurinol (Zyloric)*. This is the common drug prescribed to prevent gout attacks. It will not have any effect on an 'acute' attack. It works by gradually lowering, and then keeping low, the uric acid level in the blood. It takes two to three months to work to its full effect and then needs to be taken continuously (each day) to maintain the normal uric acid level. When first taken, allopurinol can occasionally cause a temporary rise in uric acid and cause a gout attack. For this reason it is not normally started during a gout attack but usually commenced when the acute attack has settled. Sometimes, in addition, an anti-inflammatory drug is prescribed for the first few weeks after starting allopurinol just in case it causes a gout attack. However, once the level of uric acid has been brought down, taking allopurinol regularly is usually very effective in preventing gout.

The dose required varies from person to person. A blood test may be taken to check that the level of uric acid has come down at the given dose. If an acute attack of gout happens while taking allopurinol, anti-inflammatory drugs can still be taken to relieve the attack as described above. However, this may be an indication that the dose of allopurinol may need to be increased and it would be advisable to discuss this with a doctor.

Side effects are uncommon with allopurinol and many people have complete prevention of gout attacks while taking a daily dose. Should side effects occur, other drugs with a similar action are sometimes prescribed eg Probenecid, sulphinyprazone.

## **GOUT (Revised Version)**

### **What is Gout?**

Gout is a painful inflammation of the joints. It affects about two or three in every thousand adults. It tends to run in families and men are more commonly affected than women. Gout can usually be treated and further attacks can often be prevented.

### **What are the symptoms?**

Gout often comes in `attacks`. Attacks can come on suddenly over a few hours and may cause severe pain in one or more joints. Any joint can be affected. The most commonly affected joint is the one between the big toe and the foot bone. This makes walking very painful and even the weight of bedclothes can hurt. The joint usually swells and the skin next to the joint may look red and inflamed. If left untreated the attack may last several days before easing. Less severe attacks can occur which may mimic other forms of arthritis.

### **What causes gout?**

Gout is caused by a chemical in the blood called uric acid. Uric acid is usually harmless and is produced when we eat certain foods. It is passed out with the urine. With some people, the amount of uric acid in the blood builds up. Slightly raised levels usually cause no problems. From time to time the level may become too high. With high levels of uric acid, tiny grit-like crystals of uric acid form. These crystals collect in the joint and cause swelling and pain. They irritate like a piece of grit in the eye does. For most people with gout, the build up of uric acid is an `in built` problem that cannot be prevented. For some people, the build up of uric acid may have a reason. For example, uric acid may build up if you do not have enough water in your body (dehydration). Too much alcohol can also cause uric acid levels to rise. Some drugs, like water tablets (diuretics) or aspirin, may make the level of uric acid rise and bring on gout.

### **Is it serious?**

Although gout can be very painful, it rarely causes other problems even if not treated. In a few people, uric acid crystals sometimes form kidney stones. These might damage a kidney but this is uncommon. Sometimes the crystals form harmless bumps under the skin. About half the people who have gout also have high blood pressure in later life.

### **What can I do if I have gout?**

☞ If you are overweight, try to lose some. This can help lower the uric acid level.

☞ Large amounts of alcohol may make gout worse. There is no need to stop drinking alcohol altogether, but cutting down may help.

☞ If you are taking any medicines or drugs, check whether they are a cause of gout. Some may increase the level of uric acid. The most common culprits are diuretics (water tablets) and aspirin taken at low dosage..

☞ Have your blood pressure checked at least once a year. High blood pressure is more common in people with gout.

### **Treating gout attacks**

*Anti-inflammatory drugs.* These drugs are painkillers but also reduce inflammation They are commonly used for many conditions including gout. Most gout attacks will stop very quickly with a short course of anti-inflammatory drugs. Many people with gout like to have a supply of tablets on 'stand by' just in case an attack happens. Pain is usually eased within 12-24 hours. They are usually needed only for a few days until the inflammation and pain have

completely gone. Most people can take short courses of these drugs without any problems. The most common side effect is an upset stomach or heartburn. Because of this it is best to take these drugs with food.

*Colchicine*. This is an alternative drug which is used for gout attacks. It is usually used if there are problems or side effects with anti-inflammatory drugs.

### **Preventing gout attacks**

Many people will only have an attack of gout every now and then. They may have just a small increase in the level of uric acid in the blood. Only rarely does it reach a level for crystals to form causing a gout attack. In such people, having some anti-inflammatory drugs available is all that is required to treat each attack. For some people gout attacks occur more frequently. In this situation a drug called allopurinol can be taken every day to prevent attacks occurring.

*Allopurinol (Zyloric)*. This drug is commonly prescribed to prevent gout attacks. It works by lowering the level of uric acid in the blood. It takes two to three months to work to its full effect. It then needs to be taken each day to keep the uric acid level normal and prevent gout attacks. It will not have any effect on a gout attack as it is not a painkiller. When first taken, allopurinol can sometimes cause a gout attack. This is because it may cause the level of uric acid to rise slightly before it then falls. For this reason it is not normally started during a gout attack. It is best to start it after an attack has settled. Sometimes an anti-inflammatory drug is prescribed for the first few weeks after starting allopurinol just in case it causes a gout attack. Once the level of uric acid has been brought down, taking allopurinol each day is usually very effective in preventing gout attacks.

The dose of allopurinol needed varies from person to person. A blood test may be taken to check that the level of uric acid has come down. If not, the dose may need to be increased. If an attack of gout happens while taking allopurinol, anti-inflammatory drugs can still be taken to relieve the pain. This may be an indication that the dose of allopurinol may need to be increased. If this happens it would be best to discuss this with a doctor.

Side effects are uncommon with allopurinol. Many people have complete prevention of gout attacks while taking a daily dose. Should side effects occur, other drugs with a similar action are sometimes prescribed, for example, probenecid or sulphinpyrazone.

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## Further Reading

Doak L.G. & Doak C.C. (1980), 'Patient comprehension profiles: recent findings and strategies', *Patient Counselling and Health Education*, 2, pp. 101-106.

Harrison, C. (1979), 'Assessing the readability of school texts', IN E. Lunzer & K. Gardner (eds), *The Effective Use of Reading* (London: Heinemann Education Books).

Hartley, J. (1994), 3rd edition, 'Designing Instructional Text' (Kogan Page, London).

Klare, G.R. (1971), 'Assessing readability', *Reading Research Quarterly*, 10, pp. 62-102.

Mobley, M. (1980), 'The readability of school text books', *Language for Learning*, 2(1), pp. 11-19.

Moyle, D. (1970), 'Readability - the use of Cloze procedure' IN J. Merritt, ed., *Reading and the Curriculum* (London: Ward Lock)

Michielutte, R., Bahnson, J. & Beal, P. (1990), 'Readability of the public education literature on cancer prevention and detection', *Journal of Cancer Education*.

Newton, D.P. (1990), 'Teaching with Text: Choosing, Preparing and Using Textual Materials for Instruction' (Kogan Page, London)

Purves, I.N, Sowerby, M. (1996) 'PRODIGY Interim Report' *Journal of Informatics in Primary Care*, Sept, pp. 2-8.

Royer, J.M., Hastings, C.N. and Hook, C. (1979), 'A sentence verification technique for measuring reading comprehension', *Journal of Reading Behavior*, 11, pp. 355-363.

Taylor, W.L.(1953), 'Cloze Procedure - a new tool for measuring readability', *Journalism Quarterly*, 40, pp. 415-433.

Tefki, C. (1987) 'Readability formulas: an overview' *Journal of Documentation*, 43, pp. 261-273.

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