Toward a more valid account of functional text quality: The case of the patient information leaflet*

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Abstract

Patient drug and treatment information leaflets are an important adjunct to primary health care for medical practitioners to use with patients. To assess comprehensibility of these documents, readability formulas are still used by medical researchers but are arguably of limited value. Checklists to guide the development of printed information, even when based on a systematic review of the literature, have not provided the desired guidance. An approach based on a systemic functional linguistics framework is offered here as one that can provide insight and directions for the improvement of these materials.

A set of 18 rheumatology drug leaflets was analyzed at the levels of genre, discourse semantics, and some aspects of the lexicogrammar, so as to identify their characteristics and possible shortcomings as comprehensible documents for patients.

While the drug information leaflet was identifiable as a genre with potentially up to nine structural moves, there was a high degree of variability in inclusion of moves, rhetorical functions within moves, and use of headings. The quality of patient information material can be improved by using an analysis that takes account of suitability of generic structure and rhetorical functions, specialization of lexis, status relations, macro-Theme, lexical density, and modalization. A usability strategy should be employed to support the directions provided by the analysis.

Keywords: written health-care materials; patient information leaflets; systemic functional linguistics; genre; readability; usability strategy.

1.   Introduction

The role of supplementary written drug and treatment information in a patient-centered approach to health care has been generally accepted as

an important adjunct to spoken information (Meade and Smith 1991; Paul et al. 2001; Hill and Bird 2003). An information leaflet provides a patient with a tangible record to which they can refer, check understanding, and use as a basis for asking further questions (Glenton 2002). There continues to be debate, however, about the quality and usefulness of the material, supplied variously by hospitals, individual practitioners, and professional organizations (Smith et al. 1998; Payne et al. 2000). Much of the health-care literature focuses on statistical estimates of readability of patient information leaflets (e.g., Davis et al. 1990; Meade and Smith 1991; Payne et al. 2000; Buchbinder et al. 2001). While their use appears still to be recommended to improve medical information, for example, by the Australian National Health and Medical Research Council, it is conceded that it is not possible from the formula to recommend the appropriate level at which to pitch 'most consumer documents' (NHMRC 2000). A number of problems have been identified with the use of such formulas. They take no account of nontextual dimensions such as context (prior knowledge, purpose for reading), cultural differences (Bruce and Rubin 1988), and visual elements. They do not measure any of the 'top-down' factors involved in reading comprehension such as recognizing the structure and organization of a text (Spiro et al. 1980), or such 'bottom-up' decoding factors as density of information (not word length) and appropriateness of language (Paul et al. 2003).

Buchbinder et al. (2001) used Fog and SMOG readability scores to estimate readability and appraise content of rheumatology patient information leaflets according to certain criteria. A total of 195 rheumatologists were asked to send in copies of the written drug information they routinely provided to patients to supplement oral communication when commencing them on therapy. Despite the acceptance in the literature of the role of patient information leaflets, the Buchbinder et al. (2001) survey found that almost half of the 43% of the rheumatologist group who did respond did not routinely provide written materials for their patients. Thus, the target body of practitioners as a whole is not attempting to produce the supplementary information that patients say they want and need (Paul et al. 2001), that may promote longer-term increase in knowledge (Barlow and Wright 1998; Hill and Bird 2003), and that has been found to have some therapeutic benefits (Macfarlane et al. 2002).

Bypassing readability formulas, a growing body of work has undertaken a more qualitative assessment of medical information for patients. This has included the development of a checklist of content and design characteristics for printed health education materials by means of a systematic review of the available literature (Paul and Redman 1997; Paul et al. 1997). In the latter study, the comment was made that 'there may

be some aspects not accounted for, or not able to be accounted for by the characteristics covered in the literature' (Paul et al. 1997: 158). Paul et al. (2003) reviewed the effectiveness of print material, with particular emphasis on effects on knowledge, attitudes, and behavior. They found that both the 'content' items identified as important from their systematic review, and the design of the leaflets, had little impact on their effectiveness. Wright (1999b) has explored distinctive features of the way users read health-care materials as functional documents, and stresses the importance of performance-based design, testing materials with members of the target audience. Related studies have been conducted on communication barriers in public health education, focusing on patient package inserts (Askehave and Zethsen 2003). Patient information leaflets have also been examined to determine their effectiveness for older readers (Hartley 1999a, 1999b).

While there has been a considerable body of systemic functional linguistics (SFL)-influenced research into medical discourse, the majority has focused on oral discourse (see, for example, doctor–patient discourse in Candlin and Candlin 2003). SFL research into written medical discourse has investigated medical research articles (e.g., Nwogu 1997); and aspects of nurse–patient/patient's family discourse, both oral and written (Kealley 2000).

The present study focuses on drug information leaflets, revisiting a subset of the previously examined corpus in Buchbinder et al. (2001). While the purpose of these leaflets was not explicitly stated in the majority of cases, it appeared to be to provide supplementary information about a particular therapy. It is possible that other purposes remained implicit: for example, pre-empting further patient queries, or creation of goodwill in the sharing of knowledge and information. In the previous study, 91 different documents routinely provided to patients by members of the Australian Rheumatology Association were investigated. The authors of the documents were individuals/hospitals (15), the Australian Arthritis Foundation, the periodical *Current Therapeutics*, and a drug company (one each). No documents were dated, nor did they provide information about how up-to-date the information was.

An earlier paper (Clerehan et al. 2005) re-examined the leaflets in order, first, to present useable findings for practitioners from the initial stages of the investigation; and second, to outline a set of probes that could be employed to guide their development of patient information material. The aim of the present paper is to conduct a detailed analysis of the leaflets, based on a systemic functional linguistics approach, to take account of the full range of relevant textual elements. This type of approach, it is proposed, together with a usability strategy similar to the one developed

here, provides us with comprehensive information for identifying the characteristics and possible shortcomings of drug information leaflets.

2.   Method

As it was not considered practical to perform intensive linguistic analysis on all 91 documents, those leaflets relating to the most commonly prescribed drug, methotrexate, were selected, giving a total of 18. The leaflets were analyzed by the authors according to the framework outlined below, and a sample of these was cross-checked by a colleague for generic structure, move identification, heading analysis, and lexical density count.

An SFL-based approach was employed to determine the characteristics of the leaflets in order to identify those features that, as far as one could tell from what was primarily a text-based analysis, may or may not be contributing to the fulfillment of writer and reader objectives. The theory allows us to make an exhaustive textual analysis, not all of which may be useful for the problem at hand. Thus, we have chosen those specific analyses that would appear potentially the most fruitful at the genre, discourse-semantic, and lexicogrammar levels.

3.   Theoretical framework

Patient information leaflets provided by clinicians may be regarded as a specific instance of the genre of health-care information materials, with drug information leaflets as a subset. If we regard genre as a (more or less) stabilized communicative event with a known purpose (Swales 1990), exemplars of a genre will exhibit patterns of similarity in terms of 'structure, style, content and intended audience' (Swales 1990: 58). Genre analysis research tells us that readers' reception of a text will be affected by their predictions of those patterns (Berkenkotter and Huckin 1995). To create a patient information leaflet as an effective functional text, a writer needs to structure the text in such a way that it is appropriate to readers' needs. Frame theory predicts a certain commonality between individuals in the way they approach a particular type of text (Paltridge 1997). So, for the drug information leaflet, the patient frame may be something like: 'doctor using knowledge to assist patient with information that will guide behavior and help prevent any adverse events'. For our present purposes, we intend to investigate just how 'stabilized' are the text patterns in the corpus before us: that is, to what degree there appears to be a conventional text structure for the patient information leaflet.

Context of culture	Context of situation		
Genre	Register		
	Field (content)	Tenor	Mode
Schematic structure of text: patient information leaflet	Use of drug: dosage, side effects, and so on	Professional relationship: expert 'informing' lay person	Leaflet, hand-out or letter, written to be read: i.e., text constitutes *whole* of relevant activity, though often follows face-to-face consultation

Figure 1.   *Model of systemic functional text evaluation: Upper dimensions of analysis*

3.1.   *Levels of analysis*

The negotiation between text and context is the means by which the reader constructs meaning. The context of culture encompasses knowledge, values, and practices within society that impact upon language used in a text, and shape the way the text is organized at the macro level (Eggins 1994). This leads to expectations about, for instance, ways the information may be structured (and thus extracted) efficiently, role relationships in the text, and the likely lexical items that will be encountered. These will be discussed below.

The concept of register is used to describe how key situational aspects impact on the type of language used (Halliday 1994). To develop a register description of these texts, we need to identify what is most fruitful to examine in our focus on the activity being talked about (field), in the status and role relationships involved (tenor), and in the channel of communication (mode) (see Figure 1).

In addition to the generic structure, the stratum most useful for our purposes is the discourse semantics. For the evaluation of drug information leaflets at the level of the discourse, we will focus on technicality of lexis, role and status relations, macro-Themes (headings) and lexical density, and pragmatic features of the texts. For the evaluation of these texts at the lexicogrammar level, a Transitivity analysis of how the clause represents experience would offer further insights into participants and processes, but for reasons of space this has not been included here. In the following, we analyze some aspects of Mood and Theme. For Mood, interpersonal meanings of roles and relationships are realized in declarative/interrogative clause structure, degrees of certainty or obligation, and use

Discourse			Lexicogrammar		
Technicality of lexis	Status relations	Macro-Theme, lexical density	Transitivity	Mood	Theme
✓	✓	✓		✓	✓

Figure 2.   *Model of systemic functional text evaluation: Lower dimensions of analysis (elements of the discourse semantics and lexicogrammar used in this study have been marked with a tick)*

of attitudinal words. Under Theme, we consider the patterns of foregrounding in the organization of the clause (Halliday 1994) in sample texts (see Figure 2).

3.2.   *Discourse level*

3.2.1.   *Specialization of lexis.*   Specialization of lexis is included under field as it is a way of encoding 'what is being talked about'. The connection can also be seen, however, with elements of participant role relationships (status relations). That is, lexical choices (whether well or ill judged) are made by the writer of a medical information document in the expectation of the level of technicality required to achieve his/her communicative objectives.

3.2.2.   *Author–reader identities and status relations.*   Interpersonal relationships indicate the author's assumptions about the relative status of writer and reader in the real world. This can be seen in how appropriate it is for the medical-expert writer to be assertive/directive or conciliatory/collaborative in their 'advice', and who is seen to carry responsibility in the world of action.

3.2.3.   *Visual aspects, headings, and lexical density.*   While not a linguistic consideration, the visual presentation needs to be taken into account in our assessment of the quality of the texts (Schriver 1997; Paul et al. 2004: 701). In addition, headings as a type of macro-Theme (Martin 1992) will also be evaluated.

One of the differences between written and spoken language is that of the density with which information is presented (Halliday 1985). According to Halliday (1985), the average lexical density (or content-bearing words per clause) for spoken English is between 1.5 and 2, and for written English between 3 and 6, *depending on the level of formality*

of the writing (Halliday 1985: 80; our italics). This is given by the number of lexical items divided by the number of clauses. The figures themselves will depend on criteria for deciding what is a lexical item. It is hypothesized that, with the presence of medical field-specific terminology, the lexical density for this corpus might be toward the upper end.

3.3. *Lexicogrammar level*

3.3.1. *Mood.* Mood refers to how interpersonal meaning is realized at the clause level, so some interpersonal meanings in the drug information leaflets may include what the writer takes to be matters of 'fact', but some may be tempered by degrees of likelihood, obligation, and so on. At certain points, the writer may also wish to indicate attitude (Martin 2000).

3.3.2. *Theme.* The Theme in a clause is 'the starting point of the message' (Halliday 1994), typically containing familiar or 'given' information. Here, we take it as the element of the clause that comes first, before the process (verb); the remainder, the Rheme, then developing the Theme. Identification of Themes in functional texts such as drug information leaflets will enable us to see what the writer takes to be an appropriate starting point for the purposes of their message.

4. Results and discussion

4.1. *Genre*

The drug leaflets were examined to determine their generic structure. Nine possible generic stages or 'moves' at the macro level were identified, signifying for the most part distinct communicative purposes (see Table 1). The percentage of texts in which the move was present is also shown. The typical associated rhetorical elements are listed, with the most commonly occurring first in each case (e.g., for Background on Drug, 'define/ explain' was most common, followed by 'describe'). Example sentences from the move sections in the texts are also given.

Account of Side Effects and Dosage Instruction are the moves that appeared most consistently. The next most frequently appearing moves were Constraints on Patient Behavior (this included information about drug interactions), Background on Drug, and Information regarding Monitoring. The Information regarding Monitoring move was sometimes difficult for the analysis to distinguish, as this move, while still identifiable, sometimes overlapped with other moves. The offer of clinical

Table 1. *Generic structure of patient information leaflets: Moves, rhetorical functions, and examples (N = 18)*

Generic structure: Moves	Presence in total no. of texts (%)	Rhetorical functions	Examples
1. Background on Drug (BD)	61	Define/explain, describe (in general)	MTX is available in two brands
			In high doses it has been used over the years in the treatment of certain cancers
2. Summary of Use of Drug (SU)	33	Describe(/define) (specifically)	[MTX] is used to lessen inflammation
3. Dosage Instructions (DI)	100	Inform,	MTX is prescribed as 2.5 mg tablets
		Instruct	The weekly dose should be taken with a meal
4. Outline of Benefits of Drug (OB)	22	Inform	This improvement includes a decrease in the number of painful and swollen joints
5. Account of Side Effects (AS)	95	Inform	There may be a fall in white cells, red cells and platelets
6. Information regarding Monitoring (IM)	66	Instruct,	Blood tests will be necessary for the first four weeks
		Inform	Usually it can be avoided by initially using . . .
7. Constraints on Patient Behavior (CB)	83	Instruct,	Alcohol should be severely limited
		Explain	It is generally not necessary to discontinue your MTX over the operation time
8. Storage Instructions* (SI)	5	Instruct	Keep Ledertrexate out of reach of children
9. Clinical Contact Available (CC)	33	Offer,	If I can be of any further assistance, please do not hesitate to contact me
		Instruct	See your local doctor one week after starting MTX

* One instance only

contact appeared in only one-third of the documents; and it could be argued that the possibility of contacting their doctor is generally understood by patients, though this cannot be regarded as certain. A Storage Instructions move was found in only one text and would be possibly more in place as a part of consumer product information than clinical drug and treatment information.

The rhetorical functions, while associated with particular moves, were not confined to one move only: they reappeared in different combinations throughout the nine identified moves. So, for example, within the Clinical Contact move, patients may be offered a service ('please do not hesitate to contact me') or instructed to initiate a meeting ('see your doctor'). In the latter example, it is also not clear whether this refers to the specialist or the general practitioner. As the identity of the writer was not always clear (i.e., whether it was the treating rheumatologist or somebody else), neither was the nature of the action required of the patient. Variation in rhetorical functions between and within moves can lead to problems with this interpersonal language (see Mood, below). This may be more or less serious: within moves, arguably, there may be less concern for patients over the difference between *describe* and *define* in Summary of Use of Drug than between *instruct* and *inform* in Information regarding Monitoring (see clause examples in Table 1).

The notion of generic structure potential is elaborated by Paltridge (1997), drawing on Hasan (1989), to present how the structural elements of a given text operate: what elements can or must occur, where they can/ must occur, and how often. The generic structure potential for the genre of rheumatology drug information leaflets is as follows: (BD) ∧ (SU) ∧ (OB) ∧ (DI) ∧ AS ∧ (CB) ∧ (IM) ∧ (CC) ∧ [(SI)]. Round brackets denote optional presence of enclosed elements; square brackets denote fixed position (Paltridge 1997, based on Swales 1990 and Hasan 1989). The occurrence of the identified moves in the leaflets must be said to be highly variable. Fixed positions were rare, and not one of the documents contained every move (see Table 2 for sample of generic structure analysis). In two documents, eight of the moves were present. The only 'obligatory' moves appeared to be Dosage Instructions and possibly Account of Side Effects (present in all but one—note-form—leaflet). Storage Instructions has been counted as being in fixed position, but was present in only one leaflet. Thus, while there is some commonality of approach as befits a 'genre' proper, authors manifested variability in their decisions as to which elements were required and in what order.

The most minimal structure was three moves, occurring in five documents. These moves were Dosage Instructions, Account of Side Effects, and Constraints on Patient Behavior (the latter referring to the changes

Table 2.   *Generic structure (actual) of patient information leaflets 13 and 16: Move sequences*

Text 13: Actual structure	Text 16: Actual structure
BD ʌ DI ʌ IM ʌ AS ʌ CB ʌ SU ʌ CB	DI ʌ BD ʌ AS/CB ʌ AS+ ʌ IM

Key	ʌ = fixed sequence
	+ = extended account
Background on Drug (BD)	
Summary of Use of Drug (SU)	Information regarding Monitoring (IM)
Dosage Instructions (DI)	Constraints on Patient Behavior (CB)
Outline of Benefits of Drug (OB)	Storage Instructions (SI)
Account of Side Effects (AS)	Clinical Contact Available (CC)

in behavior the doctor believed necessary for the drug to be safely taken). Moves that were most expanded upon were Account of Side Effects (in seven documents) and the Constraints on Patient Behavior (in three documents). When Dosage Instructions and Account of Side Effects co-occurred (that is, in all but three of the leaflets), they appeared in that sequence—though not always consecutively—in all cases except two. So, there seems to be a logic working that these are the most important moves and that they need to occur in that order. Moves that were found to recur within a given document were Information regarding Monitoring, Account of Side Effects, and Dosage Instructions. There appeared to be no textual imperative for this to be the case: these leaflets seemed merely to lack a coherent structure. An Outline of Benefits was present in only 22% of the leaflets. Six of the 18 leaflets were identified as containing some combined moves. While this was usually only once per leaflet, it further suggests some indecisiveness in textual organization by the writers.

The most common opening move was Background on Drug (12 instances), followed by a small number of leaflets that commenced with Dosage Instructions (5) or Account of Side Effects (1). When the Clinical Contact move appeared, with one exception, it was always in final position; when it was not present, the most common final move was Constraints on Patient Behavior.

4.2.   *Discourse level*

4.2.1.   *Specialization of lexis.*   In a number of leaflets, statements were made that lacked an awareness of the level of understanding of a lay reader (see also Askehave and Zethsen 2003). Such terms included a 'non-productive cough', 'asymptomatic' effects, 'live vaccination', 'killed vaccine', 'blood platelets'. In an example such as the following, 'Metho-

trexate may cause a reduction in the number of white cells or platelets in the blood', it is possible that readers unfamiliar with 'platelets' may read 'or' as alternative and think this is the technical term for white cells.

To ignore the likely level of understanding of a (lay) reader means that the use of semitechnical terms too can raise issues—for example, 'Mechanism of Action' as a heading, in preference to 'how it works'—a point likely to be highlighted in reader-focused evaluation just as much in text based. This expression can be viewed as an example of grammatical metaphor, where something that could be represented as a verb has been encoded as a noun and thereby given a level of abstraction (Halliday 1985). In one leaflet, the patient is told that methotrexate should not be taken 'in the presence of' certain diseases. 'Concomitant drug use', likewise, could have been reframed with no semitechnical lexis utilized.

From the perspective of field, there was inconsistency from one document to another on common treatment and behavioral issues. In one, the patient was told 'Care should be taken with alcohol while you are on methotrexate'—the kind of care not specified. In others, the patient was told that it is important to 'limit your intake of alcohol to less than one glass a day of light beer while taking methotrexate'; or 'Refrain from use of alcohol'. In others, alcohol was not mentioned. There are, therefore, problems of commission and omission (Schriver 1990).

4.2.2. *Author–reader identities and status relations.* As we have said, the context of situation is taken to be that of a doctor–patient relationship where the doctor is providing the patient with information about the use of a drug. There are various possibilities for status relations in the texts: expert–lay, giver–taker of orders, adviser–coparticipant in health care. There are thus options for the degree of solidarity being created (Martin 2000), involving the use of status markers. Part of the realization of status relations in the texts might be termed *author identity: acknowledged/unacknowledged*. As indicated earlier, the actual authors of the documents may be individuals, hospitals, or other organizations. It is not known what, in a given context for each of these leaflets, the patient is told about the author of the leaflet they are given. From analysis of the texts themselves, the writer's *persona* is given as 'medical expert', but most author *identities* are unacknowledged. In the one letter-format text, a personal relationship with the patient is presumed ('This letter serves to follow on from our recent conversation'). Only two other leaflets of the 18, however, use 'I' or 'me' at any time to make any reference to the identity of the author, who remains as the disembodied persona of 'the expert'.

Just as there is lack of definition regarding the identity of the author, in parallel fashion, it is clear that a number of the documents appear not to have been written with the patient as the anticipated audience. There was variety in reference to the reader as 'you' in some; or, in those that seem to have been written with another clinician as the intended audience, 'the patient' or 'patients'. As we have seen in Table 1, there may be different rhetorical elements within the same generic move. This may not always matter, but it does appear to be linked to the apparent recycling of some of these documents originally intended for another doctor rather than a patient, so the relations are, apparently, doctor–doctor. This can lead to confusing information (for the patient) such as: 'The blood tests can be used for six months at a time using the Rule 3 exemption notation on the pathology request form'. It can also result in instructions under 'Monitoring' that may totally confuse the patient, as it is not clear who is expected to carry out the monitoring.

The nature of the status relations established could be seen also to vary within a given document. In some, switches in tone—or distribution of power—can be discerned, for example: 'This letter serves to follow on from our recent conversation [. . .]. It is mandatory that you restrict your alcohol consumption . . .'. Here the role switches from a solidarity relationship between equals (Martin 2000), one giving advice, to that of power asymmetry, with one giving orders and one taking them (compare with the more equal 'you need to restrict yourself to X drinks per week'). In other leaflets, the pragmatics of the relations have been given some thought: five of the documents used a more informal question–answer format to address an imagined patient, for example, 'What precautions are necessary?', 'How do I take it and how often?'.

Authors in a number of the documents seemed torn between telling the patient what the patient specifically might need to know, and showing that the doctors know everything there is to know. So, for example, one leaflet acknowledges 'There is no way of predicting whether you will or will not get benefit from MTX and the only way out is to try it'. The same leaflet, however, is also concerned to inform the patient that methotrexate is used for 'psoriatic arthritis, reactive arthritis, systemic lupus erythaematosus and polymyositis': patient interest in this information is by no means guaranteed if the drug may not even work for their own condition. There were further instances of formal, heavily nominalized, lexically dense prose, combined with no indication for the individual about what to do with the information, for example: 'Many rheumatologists co-prescribe folic acid which has been shown to reduce adverse effects without compromising efficacy'.

In the current corpus, where the disembodied voice of the expert often gave the appearance of making factual statements, there were, in fact, judgments being made (Martin 2000), which from the patient's position might be difficult to interpret in terms of their seriousness or significance: 'It [the drug] is only used in severe disabling disease'; 'The exact action of methotrexate is uncertain'; 'Methotrexate has no effect on the female reproductive system. It is harmful to the unborn child'. There were also instances where the intrusion of the status relations appeared to impede any of the solidarity with the reader that the writer of the text was attempting to create. This occurred, for example, in the right to judge represented in the following: 'Nausea, vomiting, loss of appetite and diarrhoea may occur. This is normally mild'.

Many documents, particularly functional ones, make use of metadiscourse to signpost the reader's movement through and around the text. In the present sample, there were only two instances of this:

(1) This booklet will help you understand **what** LEDERTREXATE (methotrexate) is, **when** it is used for Rheumatoid Arthritis, **how** it should be taken and **what** may be the most important side effects. (Boldface in the original.)

(2) The following questions are the ones most often asked by people who are about to commence Methotrexate treatment.

Thus, metadiscourse was rarely utilized by authors to orient the reader to the text, nor was it associated with any particular move in the texts.

4.2.3. *Visual aspects, headings, lexical density.* The leaflets ranged in length from half a page (three leaflets), one page (seven leaflets), two pages (five leaflets), three pages (two leaflets), to a six-page folded leaflet. Of the 18 documents, one (the folded leaflet) made use of graphical material. One-third of the patient information leaflets made use of longer paragraphs (seven lines +). One made use of white space as a layout feature to set off the headings that appeared in a left-hand column.

Thirteen were in the form of discursive prose, one of these in letter form. The remaining five were in note form, one using bullet points, one numbers, and one dashes, and two with 'implied' bullet points, an example of which appears in Figure 3. A total of five from the corpus used enumeration unnecessarily, that is, where the order of information was unimportant (e.g., in a list of combined comments and instructions). A number used reduced clauses, for example, the first two points in Figure 3.

This was the only leaflet that used capitalization throughout. All except four used 12-point font for the body of the text; these four used a smaller font. Just under 40% used inconsistent formatting in the body of the text,
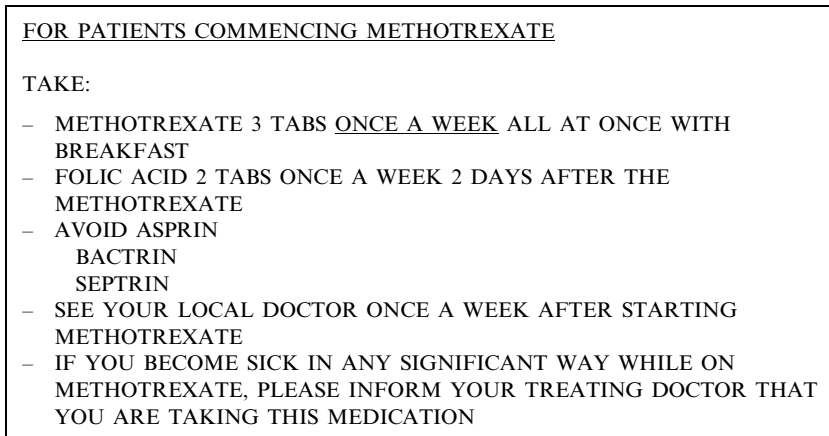

FOR PATIENTS COMMENCING METHOTREXATE

TAKE:

– METHOTREXATE 3 TABS <u>ONCE A WEEK</u> ALL AT ONCE WITH
  BREAKFAST
– FOLIC ACID 2 TABS ONCE A WEEK 2 DAYS AFTER THE
  METHOTREXATE
– AVOID ASPRIN
     BACTRIN
     SEPTRIN
– SEE YOUR LOCAL DOCTOR ONCE A WEEK AFTER STARTING
  METHOTREXATE
– IF YOU BECOME SICK IN ANY SIGNIFICANT WAY WHILE ON
  METHOTREXATE, PLEASE INFORM YOUR TREATING DOCTOR THAT
  YOU ARE TAKING THIS MEDICATION

Figure 3.   *Sample patient information leaflet*

usually concerning bolding the font and underlining. Headings were not
always differentiated orthographically from highlighted information: the
text in Figure 3, for example, uses underlining both for a heading and
for emphasis. In another, one paragraph commenced with the words,
'SIDE EFFECTS', in bold font and capitalized, when the paragraph
actually concerned, not side effects at all, but information regarding
monitoring.

   Headings in documents, while related to field, may be considered as
instances of macro-Themes and thus related to Mode, following Martin
(1992). Their role is particularly important in any assessment of commu-
nicative effectiveness within a functional text. Headings in the leaflets
were deemed inconsistent or inappropriate if they used taxonomies that
did not appear to be coherent; technical or ambiguous language; or in-
consistent formats. Following analysis, 44% of headings were deemed to
be adequate/appropriate and 28% inconsistent/inappropriate. A total of
28% of the leaflets used no headings. Given the importance of headings as
a way of assisting readers to see directions, as 'access structures' in a doc-
ument (Charrow 1988; Wright 1994), it is surprising that fewer than half
were judged as using them adequately, and that 28% used none at all.
Only one of the leaflets was in the format of a personal letter and thus
would be less likely to have headings. Figures 4 and 5 show examples of
headings extracted from two of the leaflets, represented with original font
and bolding, and manifest some of the weaknesses observed.

   'Contra-Indications', 'Preliminary Screen', and 'Toxicity Monitoring'
are technical/semi-technical; 'Action' is obscure. The reasoning for the

```
┌─────────────────────────────────────────────┐
│  Dosage                                       │
│  …                                            │
│  Contra-Indications                           │
│  …                                            │
│  Warnings                                     │
│  …                                            │
│  Side effects and Action                      │
│  …                                            │
│  SAFETY MONITORING                            │
│  Preliminary Screen        Toxicity Monitoring│
│  …                                            │
└─────────────────────────────────────────────┘
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Figure 4. *Headings: Example 1*

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┌───────────────────────────────┐
│  [No heading for first para]   │
│  Dose                          │
│  …                             │
│  Side Effects                  │
│  …                             │
│  Effects                       │
│  …                             │
│  Use of Folic Acid             │
│  …                             │
│  Operation                     │
│  …                             │
└───────────────────────────────┘
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Figure 5. *Headings: Example 2*

disjunction between 'Warnings' and 'Safety Monitoring' is not intuitively clear; and the use of upper case for 'SAFETY MONITORING', presumably with some affective overtones, breaks with consistency.

In this example, the meaning of 'Effects' in relation to 'Side Effects' is unclear, and the meaning of 'Operation' ambiguous. It is not apparent why 'Use of Folic Acid' should be at this level of the hierarchy. The random nature of the headings in a majority of the leaflets points to further difficulties for readers in accessing the generic structure.

A lexical density analysis was carried out to determine how much of a conceptual load was identifiable in the texts. This was of interest given the particular combination of the relatively informal nature of the channel (a leaflet), the potential seriousness of the information for the patient, and the intricacies of the expert–lay relationship. It was found that the majority of the documents fell in the upper end of the scale, that is, away from the 'spoken-like' end of the continuum and toward the written academic end (Halliday 1985) (see Table 3).

Table 3.   *Lexical density reading (N = 18)*

Lexical density reading*	No. of texts
3.0–3.9	0
4.0–4.9	5
5.0–5.9	9
6.0+	4

* In the case of patient information leaflets of more than one page, the first page only was analyzed for lexical density. Abbreviated note-form phrases (i.e., nonclauses) were not analyzed for lexical density.

If the lowest level for all types of written English is estimated at 3, then, even given the need for medical terminology, these leaflets would appear to be aimed at a more academic, scientific reader.

There was found to be a relationship between move at the genre level and lexical density. Moves that typically were realized in lexically dense discourse were Background on Drug and Account of Side Effects, while lower lexical density was found in Dosage Instructions and Clinical Contact Available moves. Examples of clauses with high lexical density are the following (lexical items are given in italics):

(3)   *Arising* out of its *use* in *cancer*, the *drug gained* a *reputation* for *causing damage* to the *liver*, . . .

(4)   A *baseline liver biopsy* should be *considered* with *history* of *significant alcohol consumption*, *hepatitis*, *jaundice* or *liver disease*.

(5)   . . . the *drug* should be *stopped* for *1 menstrual cycle* prior to *conception*, and *90 days* for *males*.

Examples of clauses with low lexical density are as follows:

(6)   Do not *take aspirin* while on *methotrexate*.

(7)   . . . and this *restriction* should not have any *effect* on *medication*.

(8)   The *dose* therefore has to be *individually adjusted*, . . .

High lexical density may also happen to be associated with longer clauses, but it is the density of the information needing to be processed that is at issue, not the length of the clause.

Many rheumatology patients will be familiar with the words or phrases that are associated with their illness but, arguably, there is still no reason why health-care professionals should not strive to make these documents—which ideally accompany or follow a consultation—as conversation-like as possible. This means using a greater number of

clauses, thus distributing the information in a less concentrated manner; and making use of more verbs in proportion to nouns.

4.3. *Lexicogrammar level*

4.3.1. *Mood.* Health-care advice poses special problems for writers, as readers may be emotionally involved where their health is at stake and their prior (field) knowledge and beliefs about their illness may or may not be correct (Wright 1999b). Therefore, the affective dimension of the advice and the medical expert's assumptions about the level of knowledge become prominent. These elements can be expected to impact on the interpersonal language used at the level of the lexicogrammar by patterns of Mood such as modalization (obligation/probability), modulation (usuality), and clause choices such as declaratives, imperatives, and interrogatives. The two types of clauses evident in this corpus are declaratives ('Methotrexate is prescribed as 2.5 mg tablets') and imperatives ('Discuss this with your doctor'). There are also interrogatives in the five leaflets with questions-and-answer hyper-Themes, as noted earlier. Any confusion in the text, particularly with imperatives, can make cooperation problematic (see Figure 3, where the inconsistent parallel form confuses the doctor–patient roles and responsibilities).

The variation in status relations discussed in 4.2.2 is realized at the lexicogrammatical level in the blurring that occurs in the way 'shouldness' is represented (Iedema 1997). To illustrate, there are examples of interpersonal grammatical metaphor where an imperative is implied, but the bald order is avoided: in a statement from one leaflet such as 'Taking more than the prescribed dose *could* be dangerous . . .', the question arises as to whether this is simply information (a statement of probability), or an instruction realized in a grammatical metaphor whose congruent realization is 'Do not take' (cf. Iedema 1997). From the one leaflet, a set of declarative and imperative clauses relating to *obligation* are laid out as follows in what one would take to be an ascending order of gravity:

(9) I also *want* the patient to take . . .
   . . . then it is *best* to stop the drug . . .
   . . . the drug *should* be stopped . . .
   The patient *must* be monitored with . . .
   It is *extremely important* that the patient *must not* have . . .

Whether this is an accurate reflection of the writer's actual intentions, however, remains unknown. It is possible that this is a fairly random assigning of significance, and thus problematic for the reader to try to prioritize.

In one leaflet, the patient is told 'it is very important for young women to avoid pregnancy' while taking the drug. This appears to be a further instance of grammatical metaphor where an imperative ('don't get pregnant') is realized as a declarative. There is no indication of how young she needs to be, or what to do if she fails to avoid it. In any case, judging by the unmarked formatting, it is presumably less significant than the need to limit alcohol to less than one glass per day (previous sentence), as that is not only in bold font but also underlined. The blurring of the analytical (stating facts) and the hortatory (Iedema 1997) may obscure what the patient is supposed to do with information: for example, 'there may be a fall in red cells, white cells and platelets. However, this is more common with much higher doses' (is this sharing information, or warning against overdosing?); 'In men a REVERSIBLE fall in sperm count can occur' (warning or encouragement?). The clinical context, in contrast to the bureaucratic (Iedema 1997), raises issues of authority and objectivity, which are not easily distinguishable.

In the patient information literature, adjuncts of usuality (frequency descriptors) are another source of potential confusion. Berry et al. (2002), in four general population studies, demonstrate how qualitative descriptions of common frequency terms led to gross overestimations of risk. In Pander Maat and Lentz (1994), 'seldom' was interpreted by patients as being much closer to the drug labeling company's meaning for 'sometimes', particularly when the quantifying term was not softened by mitigating information about the possible side effects. Information about side effects has to be clear so patients are able to identify them, but needs to be expressed so that patients do not become unnecessarily anxious. In one of the current sample, a complication described as 'very rare' is clarified as occurring in no more than 1% of people. So, in another, where we are told, 'very rarely hair loss may occur', it is not clear whether that can be expected in fewer than 1% of cases or not. The reader is told 'Less commonly methotrexate can cause gastric ulcers, gum inflammation and mouth ulcers'. This is 'less common' than gastrointestinal problems, but there is no way of knowing how often these occur in the first place. In the following: 'Nausea—this usually only lasts 24 hrs. following medication', it is not clear for the patient if 'usually' denotes a recurring pattern or not. Approximative quantifying expressions can affect attitudes and behavior in ways the writer did not intend.

Nausea lasting *only* 24 hours (adjunct of intensity) will be a bleak prospect for some, and the writer may not be achieving his/her communicative goals by appearing to minimize the issue. In the entire corpus, there appeared to be only very occasional comment adjuncts from the writers: that is, additional interpersonal elements adding an expression of attitude

to, or evaluation of, a proposition as a whole. In addition to the absence of overt interpersonal or evaluation of propositions, there appeared to be little indication in any of the leaflets that there were ever any contentious areas where even experts may disagree. A world of facts was presented, such that even lack of knowledge ('The exact action of Methotrexate is uncertain') was put forward in such a way as to ascribe the lack of knowledge to no-one. That is, there was little indication to patients of how expert opinion may be formed, how sources and strength of evidence matter—or that there were any further sources that may be consulted (see also Glenton 2002). Whether, or how much, this matters in terms of patients' acceptability of the document would need to be further tested (see below).

4.3.2. *Theme.* The clause may be analyzed for the Theme or starting point of the clause, and what is being said about it (the Rheme). The concept of what can be understood by writer and reader to be a starting point (Halliday 1994) can give us insight into what a doctor expects will be understood or known already by the patient. Analysis of Themes in relation to generic stages demonstrates how the lower stratum realizes the upper. The following examples are taken from moves identified as Accounts of Side Effects (Themes underlined):

(10) If the patient develops a rash or severe nausea with the drug, or if the patient develops mouth ulceration, then the drug is best ceased. Rarely MTX can also cause pneumonitis, and this must be suspected if the patient develops acute shortage of breath.

(11) Various side effects can develop with MTX which you should be aware of. The most common are nausea after the once weekly dose, oral ulcers and effects on the bone marrow in which the body fails to produce certain blood elements. MTX can leach the body of an important vitamin known as folic acid. I have therefore suggested that you take folic acid supplements 5 mg. tablet once daily.

Differences in Theme selection in patient information leaflets illustrate for the reader what the writer is intent on foregrounding at the clause level. Apart from 'the drug/MTX', which appears as a common Theme in each Account of Side Effects, the texts may be distinguished by their differences in Theme selection. For the first text, the point of departure—Halliday's 'starting point'—is chiefly textual ('if', 'then', 'and'), following a cause and effect progression, and topical ('the patient' and 'the drug'), with one interpersonal ('Rarely'). The persona here is that of the medical expert, but there is nothing revealed regarding author identity. The second writer selects topical Themes, relating to what the patient can expect, and

includes personal language: 'you', 'the body', and 'I'. The effect here is that the text appears to take the personal relationship between (an identified) physician and patient as the starting point and builds the information around that.

5.   Summary of findings

The leaflets originate from a diversity of sources, and a large part of the difficulty with them as texts arises from the fact that there is a general lack of clarity regarding the identity of the author—who may be an individual practitioner, 'a hospital', or other organization. Even though they were provided to the second author of the present paper as *patient* information leaflets, a number of these appear to have been written for other doctors and used for patients as well, perhaps for convenience. Without direct access to their authors' intentions, it is not possible to state with certainty the purpose(s) of these texts; however, clarifying information for patients about the use of the drug is assumed to be the purpose at a general level. The variability observed in the leaflets at the discourse and lexicogrammar levels suggests that, if there are broadly agreed underlying purposes, these are not being achieved.

The relevant elements of the linguistic theory for the assessment of patient and drug information leaflets were identified as generic structure and rhetorical functions, specialization of lexis, status relations, macro-Themes, lexical density, and modalization. There was concordance between the texts to the extent that the patient information leaflet was identifiable as a genre with up to nine structural moves possible; however, only one move (Account of Side Effects) appeared to be 'obligatory'. This indicates that there is little agreement between practitioners on the desirable organization of information about taking the drug. Similarly, Buchbinder et al. (2001) found that in 91 leaflets, nine specific content items—such as dose, expected time to improvement—thought by the authors to be important for patients, had variable representation as well. The significance of this lack of uniformity can only satisfactorily be resolved by systematic reader-focused evaluation to elicit what it is that patients want.

The fact that, in most of the identified moves, more than one rhetorical element is involved, suggests that there may be problems presented for the reader at both the discourse and lexicogrammatical levels, when within the same move they may be receiving different signals (e.g., *instruct* and *inform*). A clause beginning with 'Usually the starting dose is …' does not make it clear to the reader whether this applies in their case.

In a functional text, the objectives of the communication govern what takes place at all the other levels in the document, including headings and how technical the lexis needs to be. Headings (macro-Themes) in a functional document are important because they are signposts by which the patient attempts to make sense of the document in response to the questions they have (Wright 1999a). When they are inconsistent or inappropriate, this hampers the effectiveness of the text. And while it needs to be acknowledged that patients need to deal with some level of technicality in order to comprehend essential elements of their condition and how it might be treated, there were a number of instances in this corpus where needless technicality may have been impeding the understanding—of poor readers particularly (Charrow 1988).

Readers, whether they believe they know the author of a patient information leaflet or not, will form an impression of the identity of the author and his/her understanding of the relationship from the way the leaflet is written. Patients may be confused as to authorship: is this someone who knows their individual situation or not? In a number of instances, the patient appears not to be the intended audience for the leaflet. Readers may comprehend what they read, but make the decision that this information does not apply to them (Wright 1999a). This is where relations established between doctor and patient by way of the text are crucial. These were not always consistent even within a given document.

There was variability in text length. It is reasonable to expect that there is a finite amount of information that will be useful to the rheumatology patient: the use of longer paragraphs within a (comparatively) short document may add unnecessarily to the cognitive load (Tuovinen and Sweller 1999). Conversely, it is possible that there is a lower limit below which the patient will feel they lack sufficient information to feel comfortable (Punchak and Kay 1988). With respect to other formatting features, bullets and numbering were used fairly randomly. Bullets should be used only for the listing of items where the order and relations between them are not important; and numbering for the listing of items where the order is important, or when a taxonomy actually exists (e.g., 'Instructions').

The information contained in the leaflets was found to be densely packed. The lexis used in the majority of the leaflets can be identified as being less 'spoken-like' and far more toward the written academic end of the spectrum. Arguably, the language used for a broad audience needs to be nearer the spoken end. This may mean a longer text, but patient acceptance of length would need to be tested empirically in any case. In addition to problems of commission, there may also be problems of omission (Schriver 1990). There may, for instance, be a set of items of information

that covers what all rheumatology patients would like to see included: for example those identified in the corpus by Buchbinder et al. (2001), and also by Punchak and Kay (1988), such as side effects and what to do about them, problems with drug interactions, and so on.

It was not always clear that interpersonal language was deployed with consistent intentions on the part of authors. Words and phrases bearing affective meaning are particularly sensitive, but those words carrying usuality (frequency) and probability also need to be used with particular care, and further research conducted into the way patients read them. Clinicians may operate from different assumptions about the most appropriate starting point for patients, as suggested by the Theme analysis, and what it is patients want and need from written information. That is not necessarily to praise one approach and condemn another, but simply to point out that this may be another issue that needs to be empirically tested with real patients.

6. Developing a model for the evaluation of patient information publications

The mathematical model of communication that styles patients as in need—not of empowerment, but of 'education'—constrains our ability to develop theoretically sound approaches to printed information (Dixon-Woods 2001). In the evaluation of patient information leaflets, formula-based estimates of reading difficulty may have the great attraction of being simple to use, but they are not helpful for the reasons outlined above. The notion that if patient information materials were labeled with readability levels, patients could be assigned more appropriate materials (Davis et al. 1990) thus seems a misplaced hope. In the case of medicine labeling, helpful prescriptive guidelines exist to enable consumers to have 'a helpful and consistent way of searching for information' (Sless and Wiseman 1994). But whether it is feasible or desirable to have very prescriptive guidelines to the same degree for medical practitioners writing patient information leaflets is another issue.

A systematic review performed on the research into patient information leaflets yielded a checklist of 'content and design' characteristics (Paul et al. 1997); but without any underlying theory of how language functions, it is difficult for the terminology to pinpoint where problems lie, as found by Paul et al. (2003). The value of an SFL-influenced approach is that, for a given genre (such as patient information leaflets), analysts can use only what they need from the theory to assess text (as in Clerehan et al. 2005). A linguistic theory on its own, however, is not enough.

Alternative media and document design issues and, crucially, a strategy for patient evaluation also need to be addressed.

6.1. *Alternative media*

If electronic form is used, hypertext offers the opportunity to customize, at least at the level of generic structure. The possibility of less language-based, or at least less print-based modes of information—mentioned briefly in the NHMRC document (2000) and in Wright (1999b)—is a fruitful direction. Taking the generic structure of documents seriously would facilitate the adoption of broad templates available on databases or multimedia presentations on CD-ROM, such that, when readers encounter a heading such as 'Background' they could make an individual decision as to whether that section contains information that satisfies their needs or not. Additional benefits would include relatively easy up-dating of the material. For print form, it is important for thought to be given as to how reduced the prose can workably be. Clinicians familiar with their subject may be used to thinking in dot point form, but compressed note form may not be so accessible for patients who lack the background understanding.

Patients' ability physically to read a document could be impeded by a number of factors, such as illness or age or low literacy. For these reasons, consideration could be given to the pooling of resources relating to a certain drug to enable the creation of materials that employ multimedia (including audio), or the Internet, and—in multicultural contexts—include at least key points in the main languages in translation (see also Hulst and Lentz 2001; Glenton 2002).

6.2. *Document design issues*

Design issues (Hartley 1994, 1999a) such as layout, font size and style, and use of visual material may also impact upon patients' capacity to comprehend patient information leaflets (for a detailed discussion, see Schriver 1997, especially chapter 5). Four documents used fonts of less than 12 point, contravening the Royal National Institute for the Blind recommendation that documents be produced in at least a 12-point font (Albert and Chadwick 1992). The use of visual material is also a topic-specific element: instructions involving procedures would seem to invite a visual aid, whereas in the instance of drug information for rheumatology patients, there would appear to be a less clear-cut case (see also Wright 1999a: 97). Only one of the patient information leaflets attempted to use

visual material: photographs of doctors and patients and one line drawing of a shoulder joint. Research into readers' use of adjunct material points to the fact that it is highly context dependent (Wright 1994). The value of visual aids for rheumatology leaflets could be tested by the use of patient protocols (see below).

6.3. *A strategy for patient evaluation*

With appropriate supplementation, a linguistically based model for the assessment of patient and drug information publications can contribute important understandings not provided by other means (Clerehan et al. 2005). To strengthen the power of the model, it is important to incorporate feedback from the target user in the document design process. The significance of gleaning information from users is well recognized, leading to procedures of assessing functional text that are termed 'reader-focused' (Wright 1999a; Schriver 1989, 1990). For a population of rheumatology patients, representative sampling should include a range of educational and cultural/linguistic backgrounds, and include older patients (Hartley 1994, 1999b). Where the views of the user are not sought, Schriver (1989) goes so far as to assert that text-focused methods alone typically provide little, if any, information about how the document is working at the paragraph and whole-text level (Schriver 1989: 244). Yet readers cannot be expected to detect all of the problems within a text, nor diagnose the precise nature of the difficulty.

Both text-focused and reader-focused approaches—and alternative strategies within these—are included in the Lentz and Pander Maat (1992) Functional Text Evaluation Scheme. Influenced by Schriver's work, they map the requirements of the task and some types of textual criteria, but are also reader-focused, concerned to access key aspects of reader response. To address the problem of how to account for the specific type of text and communicative objectives, they attempt to differentiate by developing what they call 'critical relevance', related to the 'specific objectives of the text'; and also 'general relevance'. The features they identify—of content, structure, and style—are very broad, and the optional nature of the categories suggests that it is possible, for example, to examine style unrelated to the objectives of the text.

While the matrix they have developed is an excellent example of thinking through what a usable typology might look like—and it is a long way ahead of the unidimensional checklists often proffered—it still lacks the strength provided by a systematic language framework that can identify elements for analysis. We have revised their model (Figure 6), including
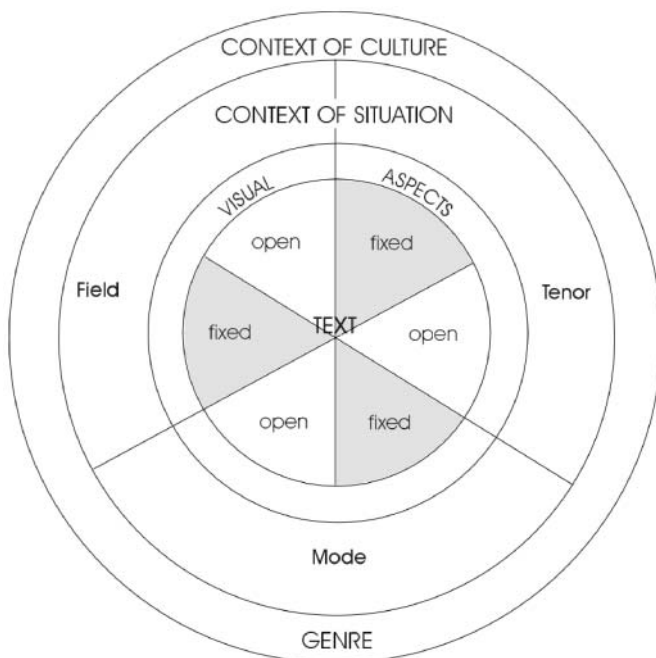
Figure 6.   *Model of text-focused evaluation (after Lentz and Pander Maat 1992)*

the *visual aspects of layout* as nonlanguage elements that can be assessed using guidelines as desired (see, for example, Hartley 1994, 1999b; Schriver 1997).

For document development and revision, as argued in this paper, a soundly based text-focused approach can be relied upon to yield good information about text quality. In this model, the text-focused evaluation allows for the analysis of pre-identified criteria (fixed) or for selection of whichever features are deemed relevant in a particular case (open). For our purposes, in SFL terms, for an evaluator to use a 'fixed' criteria approach would mean including all phenomena at each stratum of the analysis—a process arguably best suited to the SFL scholar. The 'open' strategy would mean using, as we have done here, only those forms and levels of the analysis that were judged to yield most usable insight for a particular corpus of documents.

The reader-focused evaluation takes in the reader's process of comprehending and responding; their assessment of features of the text-as-product; and their views, aired in interaction with other readers (see Figure 7).
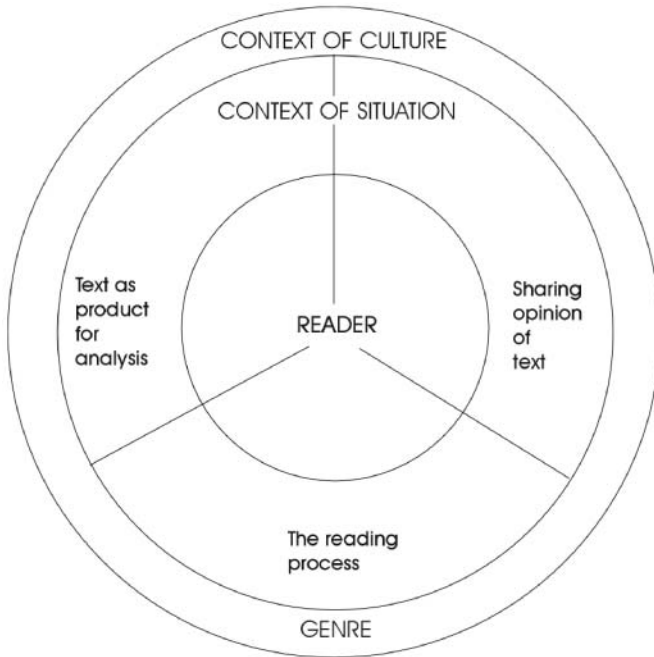
Figure 7.   *Model of reader-focused evaluation*

Reader-focused evaluation can then study the reader's real-time response to the document (process), or their written responses to the document after reading (product), or their views about certain textual features (opinion). These can then be reconstrued within the SFL framework, as per Figure 6.

Both of these approaches—the text focused and the reader focused—are considered necessary. With the degree of variety and/or inconsistency evident in the sample of rheumatology patient information materials, reader-focused evaluation is essential to assess the full significance of this. While resources will impact upon which strategies—or combination—can be used in any given setting, reader-focused evaluation methods need to provide good generalizability to the whole patient group. One *process*-focused testing method is the use of read-aloud protocols to facilitate revisions (Schriver 1990). A simple *product*-focused assessment is requesting readers to paraphrase or summarize what they have read, and afterwards explain their decisions (De Jong and Schellens 1998). In a focus group setting, this may give rise to the airing and discussion of opinions, the third component of the Lentz and Pander Maat (1992) reader-focused strategy.

7.   Conclusion

The patient information leaflets in this corpus were characterized by high variability in generic structure, and a potentially confusing set of rhetorical elements within and between generic moves. Technicality of lexis, problematic use of interpersonal meanings, high lexical density, and aspects of document presentation were identified as affecting the potential of the leaflets to hold up as quality functional documents. Further work could usefully investigate whether the aspects of the language identified here prove to be features of other corpora of patient information documents.

Besides these richer methods of revising and evaluating, as we have discussed, the usefulness of statistical readability measures and stylistic guidelines or checklists has been justifiably questioned. This paper argues, however, that there is a role within a given medical information field (such as rheumatology) for guidelines based on a systematic framework such as that outlined here, for improved outcomes.

Despite the difficulties in developing quality informational texts for patients, there are theoretically sound ways forward. Using a linguistic analysis together with a usability strategy (both text- and reader-focused) can provide insight into key problem areas. It is recommended that there be cooperation between health-care providers in a given field and others such as applied linguists, to produce both empirically tested and theoretically based patient information materials.

Note

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