

# BMJ Open Assessing the readability and patient comprehension of rheumatology medicine information sheets: a cross-sectional Health Literacy Study

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## ABSTRACT

**Objectives** Patients are often provided with medicine information sheets (MIS). However, up to 60% of patients have low health literacy. The recommended readability level for health-related information is  $\leq$  grade 8. We sought to assess the readability of MIS given to patients by rheumatologists in Australia, the UK and Canada and to examine Australian patient comprehension of these documents.

**Design** Cross-sectional study.

**Setting** Community-based regional rheumatology practice.

**Participants** Random sample of patients attending the rheumatology practice.

**Outcome measures** Readability of MIS was assessed using readability formulae (Flesch Reading Ease formula, Simple Measure of Gobbledygook scale, FORCAST (named after the authors FORd, CAylor, STicht) and the Gunning Fog scale). Literal comprehension was assessed by asking patients to read various Australian MIS and immediately answer five simple multiple choice questions about the MIS.

**Results** The mean ( $\pm$ SD) grade level for the MIS from Australia, the UK and Canada was  $11.6\pm 0.1$ ,  $11.8\pm 0.1$  and  $9.7\pm 0.1$  respectively. The Flesch Reading Ease score for the Australian ( $50.8\pm 0.6$ ) and UK ( $48.5\pm 1.5$ ) MIS classified the documents as 'fairly difficult' to 'difficult'. The Canadian MIS ( $66.1\pm 1.0$ ) were classified as 'standard'. The five questions assessing comprehension were correctly answered by 9/21 patients for the adalimumab MIS, 7/11 for the methotrexate MIS, 6/28 for the non-steroidal anti-inflammatory MIS, 10/11 for the prednisone MIS and 13/24 for the abatacept MIS.

**Conclusions** The readability of MIS used by rheumatologists in Australia, the UK and Canada exceeds grade 8 level. This may explain why patient literal comprehension of these documents may be poor. Simpler, shorter MIS with pictures and infographics may improve patient comprehension. This may lead to improved medication adherence and better health outcomes.

## INTRODUCTION

Health literacy is defined as the 'capacity to obtain, process and understand written and oral health information and services needed

## Strengths and limitations of this study

- Readability of medicine information sheets (MIS) from three countries (Australia, UK and Canada) was assessed.
- While readability formulae only measure the number/complexity of words/sentences, Australian patient literal comprehension of MIS was also assessed.
- The study population was from a regional community and may not be representative of a more urban population.

to make appropriate health decisions'.<sup>1</sup> Low health literacy has been associated with poorer health-related knowledge, increased hospitalisations, reduced immunisations, poorer health status and higher mortality.<sup>2</sup> Patients with poor health literacy are less likely to successfully manage chronic disease<sup>3</sup> and have greater difficulty in following instructions for prescription medications.<sup>4</sup> Higher health literacy has been associated with increased medication adherence.<sup>5,6</sup>

Although the importance of health literacy and patient-physician communication on health outcomes is well recognised, many patients have difficulty in understanding what their physicians tell them.<sup>7</sup> Immediately after leaving a consultation with their specialist, patients were able to recall less than half the information just provided to them.<sup>8,9</sup> The provision of written health information in addition to verbal information significantly increases patient knowledge and satisfaction.<sup>10</sup> Written information may also lead to increased adherence with treatment.<sup>9</sup> However, designing effective written health information remains challenging due to differences in patient literacy levels.

The recommended level of reading difficulty for health-related written material is inconsistent. Some agencies have

recommended up to eighth grade level<sup>11</sup>—the average reading level of an adult in the USA,<sup>12 13</sup> whereas others have suggested levels as low as fifth grade to be more inclusive of those with limited literacy.<sup>14</sup> No national guidelines exist in Australia, although the South Australian government has recommended up to eighth grade level.<sup>15</sup> Despite these inconsistencies, many studies have found written health information provided to patients often exceeds these levels.<sup>16–19</sup> While there is greater access to health-related information on the internet, this often also exceeds recommended readability levels.<sup>20 21</sup>

Literacy levels in Australia are poor, with up to 60% of the population having low literacy skills<sup>22 23</sup>—defined as the ‘minimum required for individuals to meet the complex demands of everyday life’.<sup>24</sup> The International Adult Literacy Survey found 57% of Canadians fall into the lowest two literacy categories.<sup>25</sup> In the UK, just under one in six adults has the literacy of an 11-year-old.<sup>26</sup> A study of over 200 rural and urban Australian rheumatology patients found that 15% of patients had low health literacy and up to one-third of patients incorrectly followed dosing instructions for common rheumatology drugs.<sup>23</sup> Ten per cent of patients with rheumatoid arthritis (RA) who attended an urban community-based Australian rheumatology practice had inadequate/marginal functional health literacy or a reading age at or below the US high school grade equivalent of seventh–eighth grade.<sup>27</sup> Up to 24% of rheumatology patients at a US medical centre had a reading level of eighth grade or less.<sup>28</sup> In 2002, one in six rheumatology patients at a Scottish hospital were illiterate and struggled to understand education materials and prescription labels.<sup>29</sup> These findings are concerning, as rheumatologists often use medications such as methotrexate (MTX) or expensive biological therapies with severe side effects, even death,<sup>30</sup> if taken incorrectly.

Given the importance of health literacy and its relationship to health outcomes and medication adherence, we sought to assess: (i) the readability of patient medication information sheets (MIS) given to patients by Australian rheumatologists and (ii) patient comprehension of these documents.

We also compared the readability of the Australian MIS to similar documents given to rheumatology patients in the UK and Canada.

## METHODS

### Assessment of readability

Text from the MIS of commonly prescribed rheumatology medications available on the Australian Rheumatology Association (ARA) website<sup>31</sup> was imported into a Microsoft Word document and readability assessed using Readability Studio (Oleander Software).<sup>18 32–35</sup>

Non-essential text including logos, headers, footers, hyperlinks and contact information was deleted prior to analysis as these may have adversely affected readability scores. Readability was assessed using a range of measures

such as the Flesch Reading Ease formula, Simple Measure of Gobbledygook (SMOG) scale, FORCAST (named after the authors FORd, CAylor, STicht) and the Gunning Fog scale. The Flesch Reading Ease formula calculates an index score of a document based on sentence length and number of syllables. It is often used for school textbooks and technical manuals. The standard score is between 0 and 100, with a high score indicating the document is easier to read<sup>36</sup> (however, it is possible to also gain minus scores and scores over 100). The SMOG formula calculates grade level and reader age based on complex word density and assigns a grade level (fourth grade to college level).<sup>33 37</sup> It is particularly useful for secondary age readers and attempts to predict 100% comprehension, whereas most other formulae predict 50%–75% comprehension. Consequently, SMOG may produce grade level scores one to two grades higher than other formulae.<sup>33 37</sup> The Gunning Fog formula calculates grade level and reader age based on number of sentences, their mean length and number of complex words (three or more syllables).<sup>38</sup> The FORCAST readability formula was initially used for assessing technical documents by calculating the grade level of text based on number of monosyllabic words. It is the only test not designed for running narrative, for example multiple choice quizzes and applications. As sentence length is not considered, there may be some variability in grade level compared with other readability formulae.<sup>33</sup>

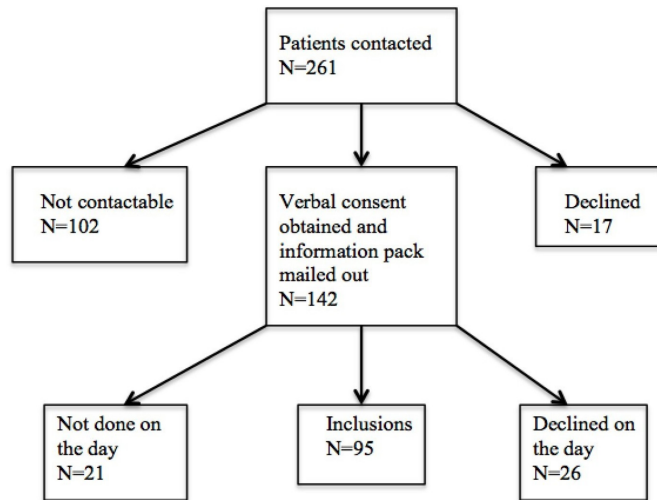
It was felt the above four formulae allowed comprehensive assessment of an MIS by focussing on various aspects: Flesch Reading Ease—sentence length and syllable number, SMOG—complex word density, Gunning Fog—sentence number/length and complex words and FORCAST—number of monosyllabic words and non-dependence on running narrative.

The readability of 10 corresponding MIS of a sample of commonly prescribed rheumatology medications published in the UK by Arthritis Research UK<sup>39</sup> and from Canada published by Rheuminfo<sup>40</sup> was also assessed as above. These 10 MIS were representative of the MIS available on both these websites.

### Assessment of literal comprehension

Coffs Harbour is a growing regional city of 70 000 people located half-way between the Australian capital cities of Sydney and Brisbane. Its medical specialists provide services to another 50 000 people from the surrounding area. Rheumatology services are provided by two rheumatologists (PKKW and HB) under the auspices of the Mid-North Coast Arthritis Clinic (MNCAC). The MNCAC has over 16 000 patients on its computerised database.

A random sample of patients referred to the MNCAC was asked to read one ARA MIS<sup>31</sup> containing information about one of the following medications which the patient was unfamiliar with: online supplementary material 1 MTX,<sup>41</sup> online supplementary material 2 non-steroidal anti-inflammatory drugs (NSAIDs),<sup>42</sup> online supplementary material 3 adalimumab (ADA),<sup>43</sup> online



**Figure 1** Inclusions and exclusions.

supplementary material 4 abatacept (ABA)<sup>44</sup> or online supplementary material 5 prednisone.<sup>45</sup> All consecutive patients scheduled for a randomly selected consulting day were contacted via telephone by an investigator (MO or ET). Patients (n=261) were asked whether they were interested in study participation to determine what they understood after reading information from the doctor. Responses are outlined in [figure 1](#). Those who expressed interest in study participation were mailed information about the study and a consent form to be returned in a stamped preaddressed envelope (n=142). Those who agreed to participate were assessed on the day of the planned consultation (n=95). There was no difference in gender or age between those included compared with those not contactable (data not shown). Comprehension was assessed by asking the patient to answer five multiple choice questions (see online supplementary material 6) about the content of the one ARA MIS they had just read. These questions were designed by two rheumatologists (PKKW, HB), a rheumatology nurse (DF) and an education academic with expertise in literacy (JJ). The questions were trialled on small focus groups of patients. A time limit of 15 min in a quiet well-lit room was provided. If needed, study participants could refer back to the MIS while answering the questions.

### Patient and public involvement

Previous work by us found that up to 15% of patients had low health literacy and up to one-third of patients incorrectly followed dosing instructions for common rheumatology drugs.<sup>23</sup> These findings prompted us to conduct this study which examined the readability of MIS routinely used in our clinical practice. Furthermore, some of our patients had previously commented that the ARA MIS were difficult to understand. A summary of study results will be disseminated to all study participants. Patients were not involved in the recruitment to and conduct of the study. However, many study participants indicated they hoped their study involvement would lead

to the development of better written material for future patients.

### Statistical analyses

Descriptive summary statistics (mean  $\pm$ SD and median  $\pm$ IQR range, as appropriate) were used to analyse parameters. Student's t-test (unpaired) was used to compare means of normally distributed parameters. The Mann-Whitney U test was used to compare medians of groups. For all statistical tests,  $p < 0.05$  was considered significant. Data analysis was undertaken using GraphPad Prism V.6 (GraphPad Software).<sup>46</sup> The correlation (r value) between comprehension score and various parameters (age, gender, postcode, highest level of education) was performed using STATA (Stata V.11.1, StataCorp).

## RESULTS

### Assessment of readability

The mean ( $\pm$ SD) grade level for the ARA MIS calculated using Readability Studio was  $11.6 \pm 0.1$  with a mean reading age of  $16.6 \pm 0.1$  years ([table 1](#)). (These were obtained by calculating the mean of the FORCAST, Gunning Fog and SMOG mean grade level and reading age. Due to the heterogeneity of these instruments, the mean of each of these measures is available in the relevant table). The mean ( $\pm$ SD) Flesch Reading Ease score of  $50.8 \pm 0.6$  indicated the ARA MIS were either 'fairly difficult' or 'difficult'<sup>33</sup> ([table 1](#)). Overall, difficult sentences (>22 words) and complex words ( $\geq 3$  syllables) made up 9.0% and 18.4% of the text, respectively ([table 2](#)).

As the validity of the above readability assessment measures has been questioned due to over-reliance on sentence and word length,<sup>47 48</sup> we proceeded to assess patient literal comprehension of the ARA MIS.

### Assessment of comprehension

A total of 261 patients were contacted, with 95 study participants ([figure 1](#)). Mean ( $\pm$ SD) age of study participants was  $60 \pm 13.2$  years, with 71/95 (75%) women and 24/95 (25%) men ([table 3](#)). Nineteen of the 95 (20%) patients had a university degree ([table 3](#)). Only 9/21 (43%) and 13/24 (54.2%) patients correctly answered all five questions for adalimumab and ABA, respectively ([table 3](#)). Only 7/11 (63.6%) of patients correctly answered all five simple questions assessing literal comprehension of the MTX MIS ([table 3](#)). Questions assessing comprehension of the prednisone MIS were correctly answered by most participants (10/11; 90.9%). Of concern, only 21.4% (6/28) of patients correctly answered all questions assessing comprehension of the NSAID MIS. Responses to the five NSAID questions are shown in [figure 2](#).

Highest level of education achieved ( $r=0.33$ ,  $p=0.001$ ) and age ( $r=-0.3$ ,  $p=0.0002$ ) correlated moderately strongly with a higher comprehension score.

### Comparison of readability scores for Australian, UK and Canadian MIS

Given our findings, we sought to determine using Readability Studio what the readability scores were for MIS used

**Table 1** Readability scores for Australian Rheumatology Association Medicine Information Sheets

Medication	Flesch Reading Ease * (0–100)	FORCAST grade level	FORCAST reader age (years)	Gunning Fog grade level	Gunning Fog reader age (years)	SMOG grade level	SMOG reader age (years)	Mean grade level†	Mean reader age† (years)
Abatacept	49	11.2	16–17	12.3	17–18	12.4	17–18	12.0	17.2
Adalimumab	46	11.2	16–17	12.7	17–18	12.8	17–18	12.2	17.2
Allopurinol	53	10.8	15–16	10.5	15–16	11.5	16–17	10.9	15.8
Apremilast	56	10.6	15–16	11.3	16–17	11.7	16–17	11.2	16.2
Azathioprine	50	10.7	15–16	11.6	16–17	12.2	17–18	11.5	16.5
Bisphosphonates intravenous	49	11.1	16–17	12.1	17–18	12.2	17–18	11.8	17.2
Bisphosphonates oral	49	11.2	16–17	12.2	17–18	12.3	17–18	11.9	17.2
Bosentan	59	10.4	15–16	11.0	16–17	11.5	16–17	11.0	16.2
Certolizumab	46	11.1	16–17	12.8	17–18	12.9	17–18	12.3	17.2
Colchicine	53	11.1	16–17	11.7	16–17	11.7	16–17	11.5	16.5
Cyclophosphamide	53	10.7	15–16	10.8	15–16	11.8	16–17	11.1	15.8
Ciclosporin	54	10.7	15–16	11.8	16–17	12.0	17–18	11.5	16.5
Denosumab	50	11.0	16–17	11.9	16–17	12.1	17–18	11.7	16.8
Etanercept	48	11.1	16–17	12.7	17–18	12.8	17–18	12.2	17.2
Febuxostat	54	10.7	15–16	10.8	15–16	11.7	16–17	11.1	15.8
Golimumab	48	11.1	16–17	12.8	17–18	12.8	17–18	12.2	17.2
Hyaluronic acid	51	11.1	16–17	11.8	16–17	11.9	16–17	11.6	16.5
Hydroxychloroquine	49	10.9	15–16	11.6	16–17	11.7	16–17	11.4	16.2
Infliximab	49	11.1	16–17	12.5	17–18	12.6	17–18	12.1	17.2
Leflunomide	54	10.7	15–16	11.6	16–17	12.2	17–18	11.5	16.5
Methotrexate	52	10.9	15–16	11.4	16–17	12.3	17–18	11.5	16.5
Mycophenolate	50	11.0	16–17	11.6	16–17	12.5	17–18	11.7	16.8
NSAIDs	58	10.6	15–16	11.0	16–17	11.3	16–17	11.0	16.2
Prednisone	51	10.9	15–16	11.2	16–17	11.9	16–17	11.3	16.2
Rituximab	48	11.3	16–17	12.3	17–18	12.5	17–18	12.0	17.2
Sulfasalazine	50	10.9	15–16	11.4	16–17	11.9	16–17	11.4	16.2
Teriparatide	49	10.9	15–16	11.6	16–17	12.1	17–18	11.5	16.5
Tocilizumab	47	11.1	16–17	12.0	17–18	12.5	17–18	11.9	17.2
Tofacitinib	46	11.1	16–17	12.1	17–18	12.2	17–18	11.8	17.2
Ustekinumab	54	10.8	15–16	11.5	16–17	12.0	17–18	11.4	16.5
Mean	50.8	10.9		11.8		12.1		11.6	16.6
SD	0.6	0.0		0.1		0.1		0.1	0.1

\*Flesch Scale Value: very easy (90–100), easy (80–89), fairly easy (70–79), standard (60–69), fairly difficult (50–59), difficult (30–49), very confusing (0–29).

†Mean of FORCAST, Gunning Fog and SMOG scores.

FORCAST (named after the authors FORd, CAylor, STicht); NSAIDs, non-steroidal anti-inflammatory drugs; SMOG, Simple Measure Of Gobbledygook.

in other countries. The mean ( $\pm$ SD) grade level for 10 of the commonly used UK MIS was  $11.8\pm 0.1$  with a reader age of  $16.9\pm 0.1$  years (table 4). The mean Flesch Reading Ease score was  $48.5\pm 1.5$  classified as 'difficult'. Readability of the Canadian MIS was easier with a mean ( $\pm$ SD) grade level of  $9.7\pm 0.1$  and mean ( $\pm$ SD) reader age of  $14.8\pm 0.1$

years (table 5). The mean ( $\pm$ SD) Flesch Reading Ease score for the Canadian MIS was  $66.1\pm 1.0$  classified as 'standard'.<sup>33</sup>

There was no significant difference in mean grade levels between the Australian and UK MIS ( $p=0.10$ ). However, the mean grade level of the Canadian MIS ( $9.7\pm 0.1$ )

**Table 2** Word and sentence statistics for Australian Rheumatology Association Medicine Information Sheets

Medication	No. of sentences	No. of difficult* sentences	Mean sentence length (no. of words)	Total no. of words	No. of complex† words
Abatacept	133	8 (5%)	12.1	1612	314 (19.5%)
Adalimumab	125	11 (8.8%)	12.6	1576	315 (20%)
Allopurinol	124	10 (8.1%)	12.2	1507	252 (16.7%)
Apremilast	92	9 (9.8%)	11.9	1095	184 (16.8%)
Azathioprine	118	9 (7.6%)	13	1539	273 (17.7%)
Bisphosphonates intravenous	95	11 (11.6%)	12.6	1199	217 (18.1%)
Bisphosphonates oral	112	11 (9.8%)	13	1456	277 (19%)
Bosentan	107	11 (10.3%)	11.4	1219	214 (17.6%)
Certolizumab	125	12 (9.6%)	13	1624	320 (19.7%)
Colchicine	123	8 (6.5%)	11.6	1426	260 (18.2%)
Cyclophosphamide	118	12 (10.2%)	12.4	1469	266 (18.1%)
Ciclosporin	102	8 (7.8%)	12.1	1235	227 (18.4%)
Denosumab	110	10 (9.1%)	12	1317	243 (18.5%)
Etanercept	124	11 (8.9%)	13.1	1621	321 (19.8%)
Febuxostat	120	12 (10%)	12.4	1484	255 (17.2%)
Golimumab	123	12 (9.8%)	12.9	1588	316 (19.9%)
Hyaluronic acid	81	4 (4.9%)	11.3	919	181 (19.7%)
Hydroxychloroquine	87	9 (10.3)	12	1046	184 (17.6%)
Infliximab	138	13 (9.4%)	13.1	1807	344 (19%)
Leflunomide	111	10 (9%)	12.9	1427	254 (17.8%)
Methotrexate	156	20 (12.8%)	13.4	2097	375 (17.9%)
Mycophenolate	141	15 (10.6%)	12.1	1712	334 (19.5%)
NSAIDs	137	14 (10.2%)	12.8	1750	266 (15.2%)
Prednisone	128	12 (9.4%)	13	1668	292 (17.5%)
Rituximab	132	9 (6.8%)	12.3	1627	318 (19.5%)
Sulfasalazine	124	9 (7.3%)	12.1	1497	276 (18.4%)
Teriparatide	114	13 (11.4%)	11.5	1310	238 (18.2%)
Tocilizumab	130	12 (9.2%)	12.7	1654	311 (18.8%)
Tofacitinib	111	7 (6.3%)	12	1336	249 (18.6%)
Ustekinumab	114	8 (7%)	12.3	1406	259 (18.4%)
Mean	118.5	10.7 (9.0%)	12.4	1474.1	271.2 (18.4%)
SD	3.0	0.5	0.1	44.6	9.0

\*Difficult sentence:  $\geq 22$  words.

†Complex word:  $\geq 3$  syllables.

NSAIDs, non-steroidal anti-inflammatory drugs.

was less than that of the corresponding Australian MIS ( $11.7 \pm 0.1$ ,  $p < 0.0001$ ).

The Australian MIS were the longest (mean  $\pm$ SD, number of words= $1474.1 \pm 44.6$ ) (table 2) compared with the UK (mean  $\pm$ SD, number of words= $922.4 \pm 109.6$ ) (table 6A) and Canadian MIS (mean  $\pm$ SD, number of words= $297.7 \pm 19.2$ ) (table 6B). The Australian MIS also had the highest percentage of complex words (three or more syllables, 18%), compared with the UK (16%) and Canadian (14%) MIS.

## DISCUSSION

We showed that the readability of commonly used rheumatology MIS given to patients in Australia, the UK and Canada exceeded eighth grade level—the recommended level for a low-literacy population.<sup>11 15</sup> The Canadian MIS assessed were easier to read, although remained slightly above eighth grade level. We found that in a population of patients attending a regional private rheumatology practice where only 20% of participants possessed a university degree, patient comprehension of the Australian MIS was

**Table 3** Assessment of patient literal comprehension (n=95 patients)

Age (years, mean $\pm$ SD)	60.0 $\pm$ 13.2
Sex (F/M)	71/24
Highest level of education	no. (%)
$\leq$ Year 10	39 (41)
Year 10–12	15 (16)
Subdegree, eg, TAFE, apprenticeship	22 (23)
University degree	19 (20)
Median total score (max=5)	4
No. with all correct answers (ie, 5/5)	no. (%)
Adalimumab	9/21 (43)
MTX	7/11 (63.6)
NSAIDs	6/28 (21.4)
Prednisone	10/11 (90.9)
Abatacept	13/24 (54.2)

MTX, methotrexate; NSAID, non-steroidal anti-inflammatory drugs; TAFE, technical and further education.

poor, with up to 79% of patients failing to correctly answer all five simple questions assessing literal comprehension of commonly prescribed rheumatology medications. As expected, a higher level of education achieved was associated with better comprehension ( $r=0.33$ ,  $p=0.001$ ). This, along with high readability scores, suggested that current

Please tick () the **ONE BEST** answer (a-d) to each of the following questions: (note – correct answer ticked)

Non-steroidal anti-inflammatory drugs (NSAIDs) include medications such as Nurofen, **Brufen**, **Voltaren**, Naprosyn and Celebrex.

1) Non-steroidal anti-inflammatory drugs (NSAIDs)

- a) reduce joint pain, swelling and stiffness
- b) ~~prevent~~ damage to your joints
- c) ~~strengthen~~ your bones
- d) ~~will~~ cure your arthritis

No. with correct answer 26/28 (93%)

2) Non-steroidal anti-inflammatory drugs (NSAIDs)

- a) ~~can~~ be combined with other NSAIDs
- b) ~~can~~ be continued long-term without review
- c) often cause gut side effects such as nausea, vomiting and bleeding
- d) ~~should~~ be continued during surgery

No. with correct answer 17/28 (61%)

3) Non-steroidal anti-inflammatory drugs (NSAIDs)

- a) may increase the risk of heart attack and stroke
- b) ~~prevent~~ attacks of arthritis
- c) ~~have~~ no effect on blood pressure
- d) ~~are~~ safe in someone with kidney problems

No. with correct answer 24/28 (86%)

4) Non-steroidal anti-inflammatory drugs (NSAIDs) should be used

- a) ~~for~~ 4 weeks only
- b) for the shortest time possible
- c) ~~until~~ the script runs out
- d) ~~for~~ however long to get rid of the pain

No. with correct answer 12/28 (43%)

5) Bleeding from inside the gut while taking a non-steroidal anti-inflammatory drug (NSAID)

- a) ~~can~~ be completely prevented by taking the NSAID with food
- b) ~~should~~ stop if you continue taking the NSAID
- c) ~~doesn't~~ cause any problems and can be ignored
- d) can be associated with abdominal pain and indigestion

No. with correct answer 14/28 (50%)

**Figure 2** Answers to NSAID questions.

ARA MIS may be too difficult for many patients to understand. While comprehension of the Canadian MIS was not performed, this would provide useful information about the effectiveness of these easier-to-read materials.

The Canadian MIS were simpler, more 'readable' and included pictures. Many studies have shown that incorporating pictograms into patient information material improves patient comprehension.<sup>49–54</sup> One study of 60 patients showed that pictograms improved comprehension of patient information sheets from 40% to 93%.<sup>50</sup> Another strategy to improve MIS readability is to shorten the document. However, a shorter, simpler MIS may remove important information and be inadequate for patients with high literacy. Yet, studies have shown both low and high literacy groups recalled information best when the text was easy.<sup>55</sup> These findings suggest that written materials designed for patients with low health literacy may also be useful for a general audience.

It is important to consider the primary purpose of providing written health-related information to a patient. Although the provision of information as part of patient education to facilitate informed patient treatment decisions is important, worry over potential medicolegal exposure from a treatment-related adverse event continues to drive complexity of written materials.<sup>56</sup>

Potential limitations of this study include the type of population studied and the measures used to assess readability. All study participants were from Coffs Harbour, a large regional community on the east coast of Australia. Although one may expect literacy levels to be lower in a rural setting, previous work from our centre showed no difference in health literacy between our patients compared with an urban rheumatology private practice in a capital city.<sup>23</sup>

There has been criticism of readability formulae such as the Flesch Reading Ease formula, SMOG scale and the Gunning Fog scale.<sup>48 57–59</sup> Readability formulae are usually based solely on word length or syllable number. They may therefore fail to adjust for patient familiarity with vocabulary associated with their illness, therefore overestimating the difficulty of written information when read by patients familiar with their disease.<sup>57 59</sup> By necessity, health-related written material uses text characterised by polysyllabic technical jargon, which elevates readability formulae scores.<sup>60</sup> For example, exchanging 'adalimumab' for 'Humira' in the Australian MIS increases the Flesch Reading ease score from 46 to 50 and reduces the Gunning Fog score from 12.7 to 12.5 (the SMOG remains unchanged at 12.8). Readability formulae fail to account for the stylistic properties of text as well as grammatical errors, which influences the readability of written text. Textual coherence, that is, the relationship and connection between sentences within a document and the relationship between the reader and practitioner are also unaccounted for. Finally, readability formulae do not usually consider visual and design factors which may influence MIS readability or patient comprehension.<sup>61 62</sup> While the Flesch Reading

**Table 4** Readability scores for Arthritis Research United Kingdom Medicine Information Sheets

Medication	Flesch Reading Ease* (0–100)	FORCAST grade level	FORCAST reader age	Gunning Fog grade level	Gunning Fog reader age (years)	SMOG grade level	SMOG reader age (years)	Mean grade level †	Mean reader age † (years)
Abatacept	46	10.9	15–16	13.1	18–19	13.2	18–19	12.4	17.5
Adalimumab	47	11.1	16–17	12.1	17–18	12.5	17–18	11.9	17.2
Bisphosphonates	53	11.1	16–17	11.9	16–17	12.3	17–18	11.8	16.8
Denosumab	42	11.7	16–17	12	17–18	12.6	17–18	12.1	17.2
Etanercept	49	11	16–17	11.9	16–17	12.4	17–18	11.8	16.8
Hydroxychloroquine	41	11.2	16–17	12.5	17–18	12.5	17–18	12.1	17.2
Leflunomide	53	10.8	15–16	11.9	16–17	12.2	17–18	11.6	16.5
Methotrexate	51	10.8	15–16	12.1	17–18	12.4	17–18	11.8	16.8
Prednisolone	55	11.1	16–17	11.3	16–17	11.6	16–17	11.3	16.5
Sulfasalazine	48	10.8	15–16	11.9	16–17	12.2	17–18	11.6	16.5
Mean	48.5	11.1		12.1		12.4		11.8	16.9
SD	1.5	0.1		0.1		0.1		0.1	0.1

\*Flesch Scale Value: very easy (90–100), easy (80–89), fairly easy (70–79), standard (60–69), fairly difficult (50–59), difficult (30–49), very confusing (0–29).

†Mean of FORCAST, Gunning Fog and SMOG scores.

FORCAST (named after the authors FORd, CAylor, STicht); SMOG, Simple Measure Of Gobbledygook.

Ease formula tends to over-estimate readability of health-related material due to its lower level of expected comprehension criteria,<sup>58</sup> the SMOG formula is appropriate for assessing health-related written information as it has been validated against 100% comprehension.<sup>58</sup> One approach to addressing these limitations is the use of a more holistic linguistic framework for assessing

written patient information which incorporates structure, factual content and visual aspects of the material as well as the relationship between writer and reader.<sup>48</sup> This method has been validated using RA medication leaflets in an Australian cohort of patients with RA.<sup>63</sup> However, the education level of patients in that study exceeded that seen in our cohort, with 17/27 (63%)

**Table 5** Readability scores for Canadian Medicine Information Sheets

Medication	Flesch Reading Ease* (0–100)	FORCAST grade level	FORCAST reader age (years)	Gunning Fog grade level	Gunning Fog reader age (years)	SMOG grade level	SMOG reader age (years)	Mean grade level †	Mean reader age † (years)
Abatacept	65	10	15–16	8.5	13–14	10.3	15–16	9.6	14.8
Adalimumab	61	10.1	15–16	9.8	14–15	10.2	15–16	10	15.2
Bisphosphonates	63	10.2	15–16	9.5	14–15	10	15–16	9.9	15.2
Denosumab	66	9.6	14–15	9.6	14–15	10	15–16	9.7	14.8
Etanercept	64	10.1	15–16	9.9	14–15	10.3	15–16	10.1	15.2
Hydroxychloroquine	72	8.8	13–14	8.4	13–14	9.5	14–15	8.9	13.8
Leflunomide	67	9.9	14–15	9.4	14–15	9.9	14–15	9.7	14.5
Methotrexate	66	9.8	14–15	9.5	14–15	10.1	15–16	9.8	14.8
Prednisolone	69	10.2	15–16	9.8	14–15	10.1	15–16	10	15.2
Sulfasalazine	68	9.3	14–15	9.1	14–15	9.7	14–15	9.4	14.5
Mean	66.1	9.8		9.4		10.0		9.7	14.8
SD	1.0	0.1		0.2		0.1		0.1	0.1

\*Flesch Scale Value: very easy (90–100), easy (80–89), fairly easy (70–79), standard (60–69), fairly difficult (50–59), difficult (30–49), very confusing (0–29).

†Mean of FORCAST, Gunning Fog and SMOG scores.

FORCAST (named after the authors FORd, CAylor, STicht); SMOG, Simple Measure Of Gobbledygook.

**Table 6** Word and sentence statistics for (A) UK and (B) Canadian Medicine Information Sheets

Drug	No. of sentences	No. of difficult* sentences	Mean sentence length (no. of words)	No. of words	No. of complex† words
<b>(A) UK</b>					
Abatacept	66	18 (27%)	17.1	1130	206 (18%)
Adalimumab	71	10 (14%)	15.3	1086	191 (18%)
Bisphosphonates	36	10 (28%)	15.7	566	92 (16%)
Denosumab	8	2 (25%)	14.4	115	22 (19%)
Etanercept	81	16 (20%)	15.8	1282	214 (17%)
Hydroxychloroquine	60	13 (22%)	15.3	916	159 (17%)
Leflunomide	63	12 (19%)	16.1	1016	157 (15%)
Methotrexate	75	13 (17%)	16.2	1212	193 (16%)
Prednisolone	60	15 (25%)	17	1020	131 (13%)
Sulfasalazine	53	12 (23%)	16.6	881	132 (15%)
Mean	57.3	12.1 (21%)	15.95	922.4	149.7 (16%)
SD	6.7	1.4	0.3	109.6	18.7
<b>(B) Canadian</b>					
Abatacept	25	0	11.1	278	38 (14%)
Adalimumab	31	0	11	341	47 (14%)
Bisphosphonates	30	0	10	301	41 (14%)
Denosumab	24	0	10.3	246	34 (14%)
Etanercept	31	0	10.9	339	48 (14%)
Hydroxychloroquine	21	0	9.3	195	23 (12%)
Leflunomide	34	0	10	339	46 (14%)
Methotrexate	32	0	11.2	357	47 (13%)
Prednisolone	36	0	10.1	363	53 (15%)
Sulfasalazine	21	0	10.4	218	27 (12%)
Mean	28.5	0	10.43	297.7	40.4 (14%)
SD	1.7	0.0	0.2	19.2	3.1

\*Difficult sentence:  $\geq 22$  words.

†Complex word:  $\geq 3$  syllables.

having completed tertiary studies compared with 19/95 (20%) in ours.

In view of the potential limitations of readability formulae, we were careful to assess patient literal comprehension of various ARA MIS. As suggested by the relatively low readability scores of the ARA MIS, patient literal comprehension of a selection of the ARA MIS was poor. Due to the simplicity of the five questions posed to the patients, we hoped a satisfactory score would be correct answers to all five questions. However, this only occurred in 21% of patients for NSAIDs and 40%–60% of patients for the MTX, ADA and ABA MIS.

Despite the confines and limitations of readability formulae, we believe they remain an important guide when developing written patient information or revising original drafts. This has been validated by several studies that used these formulae to simplify existing written patient information—resulting in enhanced patient comprehension.<sup>64 65</sup> We hope the results of this study will

encourage clinicians from rheumatology and all other specialities to consider the health literacy of their patients and readability of the written information they provide, particularly given the potential of technology to improve patient education.

## CONCLUSION

Medication information sheets currently used by many rheumatologists in Australia, the UK and Canada exceed eighth grade level—the recommended level for a low-literacy population. This may explain why patient comprehension of the information contained in these materials is limited. Comprehension may be improved using simpler, shorter words and sentences with greater use of pictures and infographics. This may lead to greater patient medication adherence, understanding of their condition and reduced medication-related errors. It is hoped our findings will encourage all healthcare professionals to



consider the appropriateness of written healthcare material provided to patients. The health literacy of patients should always be considered when communicating a management plan.

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