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COMMENTARY

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Improving COVID-19 vaccine-related health literacy and vaccine uptake in patients: Comparison on the readability of patient information leaflets of approved COVID-19 vaccines

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Abstract

What is known and objective: Preparation of patient-facing materials of a complex topic, such as describing new vaccines for COVID-19, is difficult to accomplish. This study examined the readability of patient information leaflets accompanying approved COVID-19 vaccines.

Comment: Readability of patient-facing literature by the medicines regulator in the United States and the United Kingdom describing the recently US (FDA) and UK (MHRA) COVID-19 approved vaccines (Pfizer/BioNTech, AstraZeneca, Moderna) was assessed employing 10 metrics. Analyses showed that showed that this material had a Flesch Ease of Reading score of 53.5 and 54, respectively and a Flesch-Kincaid reading age of between 7th and 8th Grade (12–13 year olds) and between 8th and 9th Grade (13–14 year olds), respectively. When compared to a recent study on COVID-19 information on healthcare websites, the vaccine literature readability was favourable.

What is new & conclusion: Adoption of readability calculators and scrutiny of materials of their readability will help authors develop materials with improved understanding for COVID-19 vaccine recipients, carers and family, potentially leading to improved health literacy and vaccine uptake.

1 | WHAT IS KNOWN AND OBJECTIVE

Readability is the ease with which a reader can understand a written text. With the current COVID-19 pandemic, this is particularly important for patients, carers and families, who are trying to understand numerous sources of medical literature associated with the pandemic and/or their condition if they have been infected with the virus. When approving a medicine, the regulatory body normally requests two documents from the pharmaceutical organization, namely the Summery of Product Characteristics (SPC) and the Patient Information Leaflet (PIL). The SPC is intended for use with healthcare professionals who wish to use the approved medicine and is thus written in a scientific/medical manner, which may be difficult to understand for the layperson. To compensate for this, the patient information leaflet (PIL) is included, which is based on the SPC, but is written in a manner that resonates with the patient and helps the patient or carer better understand the medicine and improves the patient's interaction with the medicine.

Recently, three approved COVID-19 vaccines (Pfizer/BioNTech, AstraZeneca & Moderna) have been approved in the United Kingdom by the UK medicines regulator, namely the Medicines and Healthcare Products Regulatory Agency (MHRA) (https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency). Each of the descriptions of these vaccines is accompanied with a Regulatory Approval Statement, which includes a section on Information for UK recipients. The package leaflet contains six sections including (i) what the vaccine is what it is used for, (ii) what you need to know before you receive the vaccine, (iii) how the vaccine is given, (iv) possible Side Effects, (v) how to store the vaccine and (vi) contents of the pack and other information.

In the USA, regulatory approvals, which have been authorized for emergency use, have been granted by the FDA (https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-vaccines). In the FDA website, each vaccine is accompanied with a "Fact Sheet for Recipients and Caregivers".

It was therefore the aim of this study to examine the readability of patient-facing information materials, as provided by the UK and US Medicines Regulatory Agencies.

2 | COMMENT

Patient-facing information documents for COVID-19 vaccine recipients, patients and carers were sourced from the MHRA (UK) and FDA (USA) websites, relating to COVID-19 vaccines that had been recently approved in their respective countries, as shown (Table 1). Information from these sources was copied and pasted into the subscription-based readability (ContentPro) calculator (www.readable.com) and a readability assessment carried out examining 10 readability metrics, in accordance with the software instructions. Calculated readability parameters for each of the vaccines in each jurisdiction are shown in Table 1.

Of the 10 metrics examined, four of these parameters (Number of words, Number of sentences, Words per sentence & Syllables per word) were absolute measurements, whereas the remaining six metrics were calculated parameters. Readability can be quantified by several metrics, of which the Flesch-Kincaid Reading Ease[1] is the most commonly used. This metric gives a score of 0–100, with 0 being unreadable and 100 being most readable. It is based on the average number of syllables per word and the average number of words per sentence. Scoring between 70 and 80 is equivalent to school grade level 8 and college graduates can understand documents with a score of 0–30. This means text with a score of 60–70 should be fairly easy for the average adult to read. This index is commonly used by marketers, research communicators and policy writers, which helps them assess the ease by which a piece of text will be understood and engaged with, by their readership. A derivative of the Flesch Reading Ease score is the Flesch-Kincaid Grade Level index, which is a widely used readability formula which assesses the approximate reading grade level of a text. If a text has a Flesch-Kincaid Grade Level of 8, this means the reader needs a grade eight level of reading or above to understand it. Even if the reader is advanced, a lower Grade Level score means that content is less time-consuming to read.

When applied to the COVID-19 patient-facing vaccine literature, we can see that the UK and USA Regulators are very similar in their Reading Ease score (54 vs 53.5, respectively). This is in contrast to a Flesch Ease of Reading Score of 36.8 for the UK guidance to healthcare professionals (data not shown), with a Flesch-Kincaid Grade Level of 11.5. The Flesch-Kincaid Grade Level of the patient vaccine literature was between 7th and 8th Grade (12–13 year olds) for the US FDA literature and slightly older, that is between 8th and 9th Grade (13–14 year olds) for the UK MHRA literature. If we compare the Flesch-Kincaid Ease of Reading score with a check on

TABLE 1 Comparison of readability scores of United Kingdom and United States approved COVID-19 vaccines

	Flesch reading ease	Flesch-Kincaid grade level	Gunning-fog index	SMOG index	Reach (%)	Grade	Number of words	Number of sentences	Words per sentence	Syllables per word	Reading time (s)
UK regulator (MHRA)											
Pfizer/BioNTech	56.9	8.1	9.1	10.2	84	B	1344	122	11	1.6	358
AstraZeneca	50.5	8.7	9.5	10.7	81	B	1570	155	10.1	1.7	418
Moderna	54.5	8.5	9.2	10.7	82	B	1437	127	11.3	1.7	383
Mean	54.0	8.4	9.3	10.5	82.3	B	1450.3	134.7	10.8	1.7	386.3
US regulator (FDA)											
Pfizer/BioNTech	53	7.6	7.1	9.6	85	A	1670	228	7.3	1.7	445
Moderna	54	7.7	7.5	10.1	85	A	1623	195	8.3	1.7	432
Mean	53.5	7.65	7.3	9.85	85	A	1646.5	211.5	7.8	1.7	438.5

the abstract of a recently published COVID-19 Vaccine trial in the New England Journal of Medicine, [Interim Results of a Phase 1–2a Trial of Ad26.COV2.S Covid-19 Vaccine. N Engl J Med. 2021 Jan 13. doi: 10.1056/NEJMoa2034201],[2] the score here is 45.6, with Grade Level of 10.7. Other parameters calculated included the Gunning-Fog Index and the SMOG index. The Gunning-Fog Index is similar to the Flesch-Kincaid scale, as it also compares syllables and sentence lengths, where a Gunning-Fog score of 5 is readable, 10 is hard, 15 is difficult and 20 is very difficult. From Table 1, both regulators managed to articulate the necessary information with a score of less than 10 (hard), with the US regulator presenting an easier to read score of 7.3 vs 9.3 by the UK regulator.

The SMOG index is based on the number of polysyllabic (containing more than two syllables) words in a sample of 30 consecutive sentences. SMOG scores are one to two grades higher than results attained using some of the other readability formulas since it is based on 100% comprehension ability compared to a lower percentage. For instance, if a particular material has SMOG readability grade of 6, it means it will be comprehensible to all individuals with sixth-grade reading skills.[3] For a seminal review of readability indices and their arithmetic basis/algorithms, please see Badarudeen and Sabharwal.[1]

When we compare the readability scores of these vaccine reading materials against a recent survey of readability of health websites on COVID-19, we can see that these vaccine reading materials are vastly superior than most of the website scrutinized in this recent study.[3] For example, the study cites the US Centers for Disease Control and Prevention (CDC) to have a Grade Level of 16, which is very difficult to read, equating to a 22 year old reading level and a college graduate, followed by the US National Institutes of Health (NIH), with Grade score of 13, which is difficult to read, equating to an 18–19 year olds reading ability and that of a college level entrant.[3] Therefore, overall, the regulators and authors of the vaccine patient-facing materials have succeeded in preparing complex information in a manner that achieves relatively favourable readability scores, when compared to similar healthcare website resources.

3 | WHAT IS NEW

The last 50 years have seen the steady evolution of guidelines, laws and requirements, all supporting the use of plain language, culminating in the Plain Writing Act of 2010. Adoption of plain language approaches to scientific and medical communication will further support patients in their understanding of the background, diagnosis and treatment of their disease conditions. The availability of free and subscription-based readability calculators now allows a simple and effective way to quantitatively measure and correct written text and web-based resources for the benefit of patients.

4 | CONCLUSION

Preparation of patient-facing materials of a complex topic, such as describing new vaccines for COVID-19, is difficult to accomplish. Adoption of readability calculators and scrutiny of materials of their readability will help authors develop materials with improved understanding for COVID-19 vaccine recipients, carers and family, potentially leading to improved health literacy and vaccine uptake.

CONFLICTS OF INTEREST

None declared.

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