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Trial lay summaries were not fit for purpose

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Abstract

Background and Objectives: To establish if trial lay summaries are suitable for lay readers.

Methods: A random sample of 60 randomized controlled trial (RCT) reports (15%) from the National Institute for Health and Care Research (NIHR) Journals Library, UK, were selected from 407 available ones. We extracted the lay summary and determined the readability using the previously validated Flesch Reading Ease Score (FRES), Flesch-Kincaid Grade Level (FKGL), Simplified Measure of Gobbledegook (SMOG), Gunning Fog (GF), Coleman-Liau Index (CLI), and Automated Readability Index (ARI) readability scales. This provided us with a reading age. We also assessed the compatibility of the lay summaries with the Plain English UK Guidelines and the National Adult Literacy Agency Guidelines, Ireland.

Results: No lay summary met the recommended reading age for health care information of 11−12 years. None of them were considered ''easy'' to read, in fact over 85% were considered ''difficult'' to read.

Conclusion: The lay summary is a key document for disseminating trial results to a broad population who may not necessarily have the medical or technical jargon to read a trial report. Its importance cannot be overstated. Assessing readability in conjunction with plain language guidelines is relatively easy and therefore an immediate change to practice is feasible. However, since specific skills are required to write lay summaries that meet the required standards, it is important that the need for such expertise is recognized and supported by research funders.

Keywords: Trials; Communication; Lay summaries; Readability; Plain English; Patient and public involvement

1. Background

The European Union's 2014 Clinical Trials Regulation (EU CTR), which came into full effect on 31 January 2021, includes a requirement for the submission of lay summaries in reports of randomized controlled trials (RCTs) [1]. A lay summary is a summary of the trial written in plain English [2]. This means using clear language that

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What is new?

Key Findings

- We have shown no trial lay summary, from a random sample of 60 trial reports, met the recommended reading age of 11−12 years for healthcare information.
- By applying the SMOG readability scale, which was developed specifically for assessing healthcare material, to a random sample of 60 lay summaries, more than 85% of trial lay summaries were difficult to read, and the remaining 15% were of average reading difficulty. No lay summary was easy to read.

What this adds to what was known?

- We know that involving patients and the public in the research process, including dissemination of results is essential. We have shown that the key patient facing summary document, the trial lay summary, is not suitable for a lay audience.

What is the implication and what should change now?

- Trialists need to ensure the lay summary is suitable for lay audiences. We make nine recommendations for future practice.

all readers can understand. This helps readers who are not scientifically or medically trained to understand the complex medical information they are reading [3]. Since lay summaries are written for the public, there may be considerable variation in scientific knowledge, general and health literacy levels, and numeracy skills. A lay summary is important in the context of reporting and disseminating trial results because it allows those participating in the trial, and others who want to know more about the trial, to understand the results. The EU CTR [1] mandates the inclusion of 10 elements in the lay summary: 1. Clinical trial identification; 2. Name and contact details of the sponsor; 3. General information about the trial; 4. Population of subjects (trial participants); 5. Investigational medicinal products used; 6. Description of adverse reactions and their frequency; 7. Overall results of the trial; 8. Comments on the outcome of the clinical trial; 9. Indication if follow-up clinical trials are foreseen; and 10. Indication where additional information could be found. While the EU CTR states that the lay summary should be understandable to a lay person, it does not specify a recommended reading age or provide guidance on what is understood by writing in plain language.

The 2017 publication, ''Summaries of Clinical Trial Results for Laypersons, recommendations of the expert group on clinical trials for the implementation of the [*sic* EU CTR]… [4]'', specifies some general principles for lay summaries, that is, the target audience (the general public), the layout, style, language, readability (age 12 years and upwards) and the use of plain language. Similarly, the most recent ''Good Lay Summary Practice'' guidelines (2021) [5], adopted by the Clinical Trials Expert Group (CTEG), a working group of the European Commission representing Ethics Committees and National Competent Authorities, talks about the reading age mentioned by the expert group in the 2017 publication and highlights the need to use the reading age in conjunction with plain language guidelines. The Good Lay Summary Practice guidelines provide guidance on the use of plain language. Both are consistent with the Irish National Adult Literacy Agency (NALA) [6] and the Plain English UK [7] guidelines. These provide information on sentence length, use of passive verbs, font type and size, heading style, line spacing and justification of text. This is to ensure clear language, that all readers can understand, is used in documents that meet their standards [6,7]. They have the following recommendations: mean sentence length <20 words, proportion of passive verbs $<10\%$, use of a non-Sans Serif font, use of a font size of at least 12-point, use of headings consisting uppercase and lowercase letters, use of 1.5-line spacing and use of justified text.

In terms of readability, the Good Lay Summary Practice guidelines [5] recommend writing lay summaries with a reading age of 12 years and upwards. This is similar to that recommended for general healthcare information [8], prescribed as 11−12 years. Prior studies have shown though that many patient facing documents do not achieve this reading age [9,10]. A recent study on the readability of patient information leaflets and informed consent forms found that they were inappropriately complex and there was poor compliance with plain language guidelines produced by literacy agencies [9].

The purpose of our study was to assess the readability and plain English compatibility of a sample of lay summaries from the National Institute for Health and Care Research (NIHR) reports of randomized trials. Our study will contribute to the evidence base for appropriate reporting and dissemination of clinical trial results.

2. Methods

We generated a list of all studies published in the NIHR library between 2016 and 2021. The NIHR Journals Library does not offer the option for a bulk download of search results therefore PubMed was used as a source of NIHR publications. The term ''NIHR'' was used in the Publisher field to identify 445 articles from four journals (Health Services and Delivery Research, Public Health Research, Efficacy

and Mechanism Evaluation, and Programme Grants for Applied Research) from 2016 to 2021. The term ''Health Technology Assessment (Winchester, England)'' was used in the Journal field to identify 473 articles from that journal for the same dates. The total of 918 publications in 143 PubMed was close to the 917 publications given on the NIHR Journals Library website on the date of the search, 18 January 2022. Only RCTs were included, and this reduced the number of studies to 407.

We randomly selected 60 RCTs from the original 407 using the Number Generator (https://numbergenerator.org/randomnumbergenerator/1-408). We set ourselves a target of 15% of the total. We wanted a sample that was large enough to say something meaningful but not so large that it could not be completed in a 2-month window, the time allowed by the funders, the Health Research Board Trial Methodology Research Network (HRB TMRN), for the student scholarship. 15% (60 trials) seemed a reasonable compromise between sample size and feasibility. The data we extracted were stored in an MS Excel file.

To test the readability, we took the PDF for each of the 60 RCTs and copied and pasted the lay summary into the online tool WebFX (https://www.webfx.com/tools/readable/#enter-text-tab). This provided us with a score for the Flesch Reading Ease Score (FRES), Flesch-Kincaid Grade Level (FKGL), Simplified Measure of Gobbledegook (SMOG), Gunning Fog (GF), Coleman-Liau Index (CLI), and Automated Readability Index (ARI) readability scales. These readability tests were developed for various purposes including healthcare [11]. They have been extensively validated and used in healthcare and health promoting settings [12]. These tests use different readability formulae to give a score. The FRES and FKGL look at sentence length and syllables per words. The GF looks at sentence length and complex words used. A complex word is a word containing three or more syllables excluding proper nouns, combinations of hyphenated words, or two syllable words made into three with -es and -ed endings. The CLI and the ARI focus on letters per words and sentence length [13]. Finally, the SMOG [14] which was developed specifically for assessing healthcare material looks at complex words in three 10 sentence samples, one from the beginning, one from the middle and one from the end. The formula contains a factor to correct if there are less than 30 sentences in the text [15].

The recommended reading age for health care information is 11–12 years [8] and ''Summaries of Clinical Trial Results for Laypersons, recommendations of the expert group on clinical trials for the implementation of the [*sic* EU CTR…] [4]'', recommends trial results be accessible to people from the age of 12 years and upwards. The USDHHS (US Department of Health and Human Services) recommends health materials to be written at or below a sixth grade level, which equates to 11–12 years old [16]. This means the ideal score should be $\leq$6.9 for the FKGL, GF, CLI and SMOG. The FRES is a 100-point scale with higher scores meaning a more easily understood piece of writing and therefore the ideal score would be $\geq$80 which equates to 11–12 years old. The USDHHS have categorized reading level into easy, average and difficult. A reading level below 12 years old is considered ''easy to read''. A reading level from 12 to 15 years old is classified as ''average difficulty'' and above 15 years old as ''difficult'' [16]. Table 1 displays the reference ranges for each scale used in this study.

We assessed the compatibility of the lay summaries with the Plain English UK [2] and NALA [6] guidelines. There were six criteria common to both: sentence length, font

Table 1. Reference ranges for readability scales

FKGL, GF, SMOG, CLI or ARI readability scale scores	FRES readability scale score	US grade level	UK grade level	Age	USDHHS reading level
0–1		First Grade	Year two	6–7 yr old	Easy[a]
2–3		Second Grade	Year three	7–8 yr old	
3–4		Third Grade	Year four	8–9 yr old	
4–5		Fourth Grade	Year five	9–10 yr old	
5–6	90–100	Fifth Grade	Year six	10–11 yr old	
6–7[a]	80–89[a]	Sixth Grade[a]	Year seven[a]	11–12 yr old[a]	
7–8	70–79	Seventh Grade	Year eight	12–13 yr old	Average
8–9	60–69	Eighth Grade	Year nine	13–14 yr old	
9–10		Ninth Grade	Year ten	14–15 yr old	
10–11	50–59	Tenth Grade	Year eleven	15–16 yr old	Difficult
11–12		Eleventh grade	Sixth form	16–17 yr old	
12–13		Twelfth grade	Sixth form	17–18 yr old	
13–17	30–49	College	University	18–22 yr old	
17+	0–29	College graduate	University graduate	22+ yr old	

[a] Recommended reading level.

Table 2. Guidelines for Plain English UK and NALA

Guideline	Recommendation
Mean sentence length	<20 words
Use of passive verbs	<10%
Font type	Use a Sans Serif font
Font size	At least 12-point
Use of uppercase and lowercase letters in headings	Use both uppercase and lowercase letters
Line spacing	1.5 line spacing
Justified text	Do not use justified text

type, font size, line spacing, the use of passive verbs and the use of justified text. In addition, Plain English UK provided guidance on the use of uppercase and lowercase headings. These criteria are also found in the European Commission Good Lay Summary Practice guidance document [5]. We tested the 60 lay summaries for compatibility of the seven different criteria. We used the Verb Finder tool (https://app.inkforall.com/verb-finder) to find the total number of verbs used. To ascertain the proportion of passive verbs we used the Datayze online tool (https://datayze.com/passive-voice-detector). We were able to establish the font type in Adobe Acrobat Pro 2017. Headings and text were examined individually in each lay summary and the use of upper- and lower-case letters and justified text was recorded as present or not. To determine whether a font size of at least 12 point was used and to see if 1.5 line spacing was used we converted the 60 NIHR PDFs to MS Word. Table 2 displays the NALA and Plain English UK guidelines and their recommendations.

2.1. Analysis

We used descriptive statistics, proportions, means and standard deviations (SD), median, and interquartile range. We also established the number of lay summaries that met the criteria of the Plain English UK and the Irish NALA guidelines. Ethical approval was not required for this retrospective observational study.

3. Results

Table 3 shows the readability scores for the six scales alongside the recommended scores. None of the 60 trial lay summaries met the recommended reading age of 11–12 years for health literature. In fact, taking all the readability scales into account, the lowest reading age was 13.5 years and the highest was 23 years. The SMOG [11], which was developed specifically for assessing health-care materials, shows a mean reading age of 16.5 years. No lay summary was easy to read; in fact, over 85% were difficult to read.

In terms of compatibility with the plain English guidelines in the UK and Ireland, none of the lay summaries complied with all seven of the recommendations. When compared to the recommendations: 40% had a mean sentence length of less than 20 words; 0% used 1.5 line spacing; 80% had a percentage of passive verbs that was less than 10%; 100% used a Sans Serif font; 0% used a font size ≥12 point; 100% used headings with uppercase and lowercase letters; 100% avoided the use of justified text.

4. Discussion

Describing the results of trials in a way that everyone can understand is essential if we wish to be inclusive and engage potential clinical trial participants in research. It is equally as important to those that participated in the trial, and the end users of any tested drug or therapy. We know this because trial participants have repeatedly highlighted it as a concern [17,18]. A UK study on the relative importance of information items in Participant Information Leaflets found that participants considered information on "What will happen to the results of the study?" more

Table 3. Readability scores for six readability scales and reading difficulty

Category	FRES	FKGL	GF	SMOG	CLI	ARI
Recommended Score	≥80	≤6.9	≤6.9	≤6.9	≤6.9	≤6.9
Mean	42.77	12.59	15.73	11.46	13.97	13.05
Standard deviation	9.64	1.96	2.23	1.60	1.66	2.32
Median	43.75	12.45	15.45	11.2	14.2	12.7
IQR	35.78–49.03	11.38–13.80	14.10–16.93	10.30–12.40	13.0–15.20	11.58–14.45
Mean reading age	20.5	17.5	20.5	16.5	19	18
Reading Difficulty (n = 60)						
Easy[a] (Age 10–12)	0	0	0	0	0	0
Average (Age 12–15)	2	3	0	9	1	5
Difficult (Age 15–22+)	58 (97%)	57 (95%)	60 (100%)	51 (85%)	59 (98%)	55 (92%)

[a] Recommended reading level/age.

Table 4. Summary of Competencies of Enabling Good Lay Summary Development[5;30]

Competency	Level
Scientific Knowledge	
General knowledge of clinical trials and clinical research (phrases etc.)	Intermediate
Knowledge about the disease	Intermediate
Knowledge about the trial intervention (its clinical background and development)	Intermediate
Knowledge about clinical research methodology	Intermediate
Knowledge about reporting of safety data in clinical study reports and other sources	Intermediate
Knowledge about biomedical statistics	Basic
Communication skills	
Knowledge about the language the lay summary is being written in	Advanced
Experience in writing for lay audiences	Advanced
Knowledge about how to avoid bias in communicating trial results	Intermediate
Writing and editing skills	Advanced
Knowledge of plain language/health literacy principles	Advanced
Translation skills and ability to translate into lay language in the target language	Advanced
Knowledge of existing guidance for lay summaries	Advanced
Ability to transfer statistical results into lay language	Intermediate
Quality control skills/knowledge	Basic
Visual design skills	Intermediate
Good scientific graphic design principles	Intermediate
Accessibility principles (for example, for people with visual impairment)	Intermediate
Legal/compliance knowledge	Basic
Knowledge of the applicable regulations	Advanced
Knowledge about validating the lay summary with users (user testing)	Intermediate
Knowledge about patient involvement in advising on trial design and patient-facing material, including patient information documents and the LS	Advanced

important than "Will my taking part in the study be kept confidential?" and "What will happen if I don't want to carry on with the study?" [18]. A study on the impact of return of results on participants' views and expectations about their original decision to participate found that for some trial participants it highlighted that their original expectations had not been met. Some participants felt betrayed by the staff involved in the trial, that their trust had been damaged, and that they had not fully understood the implications of taking part in the trial [17]. Thus, providing sufficient information in a way that is understandable to potential participants is vital throughout the whole trial process, from recruitment, to the very end when results are disseminated to participants [19]. Lay summaries are supposed to be written for people with low health literacy [5], defined as the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions [20]. Our study has shown that in a random sample ($n = 60$) of lay summaries from 407 NIHR trial reports, no lay summary met this requirement. Eight-five percent were difficult to read, none were easy to read and the remaining 15% were of average reading difficulty. Thus, we are not currently meeting the standards expected or the needs of people with low health literacy—most people.

While we considered all of the most common readability scales, the SMOG is the readability scale most relevant for trial reports as it was designed specifically for healthcare materials [14]. SMOG had the "best" score of all the scales, showing a mean reading age of 16.5 years, however this is still well above the recommended age of 11–12 years [8]. Thus, presenting the 'best' score is a conservative estimate of the current situation. Writing lay summaries, in a way that is uninterpretable for some who may access them goes against the four fundamental principles of ethical research; beneficence (help persons and act for their benefit), nonmaleficence (do not harm), autonomy (the power to make rational decisions and moral choices) and justice (fair, equitable and appropriate treatment of persons). By writing lay summaries at a reading age/level that most lay people cannot understand, we are removing their ability to make informed choices and decisions about trials results as well as potentially alienating them from participating in trials in the future.

One caveat, and this is highlighted by the recent Good Lay Summary Practice guidelines [5], is that relying on readability scales alone without measuring context, difficulties of concept, or the coherence of the text is to be avoided. This arises due to the formulae applied to calculate the readability scales, for example, the average number of words per sentence, number of syllables per word. Thus,

a short sentence can produce a low reading age, but it may be incoherent. Readability scores should only be used as a supplement to gauge the reading level in addition to applying plain language guidelines. Also, lay summaries should be user tested on the intended audience, as per the ''Summaries of Clinical Trial Results for Laypersons, recommendations of the expert group on clinical trials for the implementation of the [*sic* EU CTR] [4].

Trial participants, patients, and the public also have much to offer to improve the current poor practice. The Good Lay Summary Practice guidelines [5] devote a section to patient involvement during the development of lay summaries. It outlines four key stages: planning (advice on selection of patient-relevant secondary endpoints; advice on the lay summary dissemination strategy); development (advice on the suitability of results presentation for patients; advice on terminology used by patients; advise on graphics and layout preferences; user testing); translation (advice on national terminology and acceptability; advice on cultural adaptions of graphics and presentation; user testing in the national language); dissemination (advice on national dissemination channels). Of equal relevance is the experience of the patient and public involvement members at each stage of the lay summary process. This should be decided by the trial team, patient and public involvement representative and the sponsor. Individuals with different diseases, stages of disease, experience of different therapies, ages, knowledge of clinical trials, trial methodology or statistics should be considered, as well as those unfamiliar with trials. They should be remunerated appropriately for their time. What we are saying is, one size does not fit all, and variation in experience is necessary to write an age appropriate, understandable lay summary.

There are several guidelines on how to write in plain English. We focused on two, Plain English UK, because the lay summaries we examined were from NIHR trial reports, and NALA, though most are overlapping, and none contradict each other. Most notably, no lay summary was at the recommended font size and none of them used the recommended line spacing. These are simple fixes, and the trial community simply must do better. This does however demonstrate again that writing lay summaries is not simple. The skills required for writing for lay people/members of the public, are fundamentally different to those needed for scientific writing. Trial teams are experienced in writing scientific summaries, but this does not mean these skills can be translated to writing for a lay audience. The Good Lay Summary Practice guidelines [5] outline the competencies required for enabling good lay summary development (Table 4). It is now time to consider funding experts with these competencies and skills in writing lay summaries, so we are assured we are reaching our target audience. This should be allowed for in academic trials at the grant application phase and funders need to recognize that this is a specialized skill and support employment of experts. Sponsors of commercial trials also need to take responsibility and support this.

Until things change, and funding for writing lay summaries is supported and prioritized, there is an available lay summary template with sample lay text in the ''Summaries of Clinical Trial Results for Laypersons, recommendations of the expert group on clinical trials for the implementation for the implementation of Regulation (EU) No 536/2014 on clinical trials on medicinal products for human use'' [4]. This is freely available online and we recommend using it to guide lay summary development. It includes the 10 EU CTR [1] mandated elements: 1. Clinical trial identification; 2. Name and contact details of the sponsor; 3. General information about the trial; 4. Population of subjects (trial participants); 5. Investigational medicinal products used; 6. description of adverse reactions and their frequency; 7. Overall results of the trial; 8. Comments on the outcome of the clinical trial; 9. Indication if follow-up clinical trials are foreseen; and 10. Indication where additional information could be found.

We know trial participants want to receive trial results. We know also that our trial populations vary substantially. While the lay summary is important for all the reasons we have outlined previously, there will be those among the trial population who would prefer a more technical summary of trial results. We thus recommend disseminating both the lay summary and scientific summary to trial participants to give them choice.

4.1. Strengths and limitations

The key strength of our study is the random sample of trial reports which included national and multinational trials of different designs, therapies and investigational medicinal products. Sixty lay summaries is a reasonable number of trials from which we believe our results give a meaningful message. Our study also has some weaknesses. We were unable to determine if patients and the public had been consulted in the writing of the lay summary before publication. Our sample includes trials from NIHR reports only which is UK-based. However, many of the trials in the sample were multinational and though we don't believe our findings would be any different, we simply don't know. To truly assess how the lay summaries are understood, as per the Good Lay Summary Practice guidelines [5], testing the readability of these lay summaries on a sample of patients and the public would have been beneficial. However, it was beyond the scope of this project. We assessed the plain language compatibility of the NIHR lay summaries with the Irish National Adult Literacy Agency (NALA) [6] and the Plain English UK [7] guidelines. These lay summaries may have been presented to patients and the public in documents/formats different from the NIHR report, but we simply do not know if this was the case. This is a limitation of the study.

5. Implications for practice

We recommend.

1. Using a team approach to write the lay summary (including patients and the public) to ensure the Good Lay Summary Development Competencies (Table 4) [5] are met.
2. Following the suggested template with sample lay text in the "Summaries of Clinical Trial Results for Laypersons, recommendations of the expert group on clinical trials for the implementation for the implementation of Regulation (EU) No 536/2014 on clinical trials on medicinal products for human use" [4].
3. Using the freely available webtool (https://www.webfx.com/tools/read-able/#enter-text-tab) when preparing lay summaries to establish their readability on the SMOG scale.
4. Using the SMOG scale in conjunction with the Good Lay Summary Practice guidelines [5] and plain language guidelines for each language in which the lay summary will be disseminated.
5. Involving trial participants, patients and the public in the planning, development, translation and dissemination of lay summaries.
6. Including participants with a variety of experience for these activities, for example, individual patients who have experience of the disease/therapy area, patients/participants experienced in trial methodology, patient advocates, and members of the public with no experience of trials at all.
7. User testing the lay summary with trial naïve patients and members of the public. This will ensure lay summaries use plain understandable language and are inclusive and suitable for all who wish to access them.
8. Funding experts to write lay summaries.
9. Disseminating both the lay summary and the scientific summary to trial participants so those who wish to read a more technical summary can do so.

6. Implications for future research

It would be worth replicating our study using lay summaries from trials led in countries outside the UK, though some of the studies included here were multinational. We think there is a general problem but confirming it would be best.

7. Conclusion

Providing a lay summary, in accordance with the EU CTR is mandated. The lay summary is a key document for disseminating trial results to a broad population who may not necessarily have the medical or technical jargon to read a trial report. In our study, none of the lay summaries complied with the recommended reading age of 11−12 years for healthcare information. This means when disseminating trial results via the lay summary, we are abiding by the regulations but excluding the intended audience. Trialists need to do better, and we provide nine suggestions to improve practice. The simplicity of checking the readability of a lay summary, applying plain language guidelines and user testing a lay summary means changing practice is straightforward. A little funding would go a long way to facilitate this change in practice. With funders and sponsors on board to fund the production of lay summaries, this much needed change could be straightforward, and easy.

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