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Original article

Clear aligner therapy informed consent forms: A quality and readability evaluation

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Summary

Objective > The aim of the present study was to evaluate the quality and readability of content contained within clear aligner therapy (CAT) informed consent forms.

Methods > CAT informed consent forms were identified via an online search. The presence of details related to CAT-related processes, risks, benefits and alternatives in each form was recorded. A 4-point Likert type scale was used to determine the quality of content (QOC). The readability of content was evaluated with the Simple Measure of Gobbledegook (SMOG) and Flesch Reading Ease Score (FRES).

Results > A total of 42 forms satisfied selection criteria. Nineteen (45.2%) were authored by companies who provided aligners to patients via clinicians. The QOC regarding CAT-related treatment processes [median 2.0; IQR 0, 2] and benefits [median 2.0; IQR 1, 2] was adequate. The QOC scores regarding treatment alternatives, consequences of no treatment and relapse were poor. There was no difference (P = 0.59) in the median (IQR) QOC of the informed consent forms provided by direct-to-consumer (DTC) aligner providers [10 (8.25, 16.25)] and non-DTC aligner providers [12 (10, 14)]. The median (IQR) SMOG score was 12.1 (10.9, 12.7) and FRES was 39.0 (36.0, 44.25).

Conclusions > The QOC of the evaluated forms was incomplete and poor. The content was difficult to read and failed to reach recommended readability standards. Consent is unlikely to be valid if it is based solely on the content of the forms. Clinicians need to be aware of the limitations of informed consent forms for CAT particularly in relation to alternatives, prognosis, risks, and the need for long-term maintenance of results.

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Introduction

Recent decades have seen a move away from a paternalistic environment of healthcare provision, where the healthcare provider 'knows best' [1]. That patients are autonomous individuals who have the right to decide what happens to their own bodies is widely accepted in contemporary healthcare systems [2]. However, the validity of the decision-making process is contingent on the individual being fully informed of four key aspects: the nature, risks, benefits and alternatives to a proposed intervention [3]. In addition, the individual must have the capacity to freely make the decision. Age does not preclude valid consent. In many jurisdictions, an individual under the age of 18 can validly consent an intervention if deemed to be competent to make that decision – even in the absence of, or contravention to, parental assent.

Furthermore, the outcomes of court cases from different jurisdictions have indicated that the information, particularly regarding risks, related to an intervention must be tailored so that the information or risks that is of particular relevance or importance to the individual is communicated clearly [3–6]. Failure to validly consent to treatment can result in patient harm and disappointment and/or regulatory and legal proceedings against the healthcare provider [7–9].

Although a signed consent form is not a legal requirement for orthodontic treatment, it is good practice to record the consent process and confirmation of the patient's agreement to the proposed intervention [8,9]. However, a signed form, per se, does not necessarily indicate consent is valid. Valid consent requires effective continuing communication between the healthcare provider and patient to ensure that the patient fully comprehends the benefits, risks, limitations and alternatives to the proposed intervention [1]. The signed informed consent form can serve to facilitate this process by outlining the relevant information [10].

Clear aligner therapy (CAT) has become increasingly commonplace in contemporary orthodontic practice [11,12]. Its proposed appeal includes the appliance's aesthetic appearance and the ease of patient management of oral hygiene and dietary practices. Proposed shortcomings include a greater reliance on patient compliance with CAT wear protocols compared with fixed appliance therapy, purported challenges in effectively managing some malocclusion traits and the need for additional series of aligners to achieve the clinician's treatment objectives [13]. A recent development has seen the emergence of direct-to-consumer (DTC) CAT [14]. This involves the provision of aligners to patients with minimal or no direct clinician involvement [15].

Not only should the content in an informed consent form be comprehensive, evidence-based and accurate, it must also be easy to read [10]. Literacy relates to the ability to read [16]. Research indicates that low levels of literacy are prevalent in many countries including the US, UK, and Australia [17]. The development of easy-to-read health information, therefore, aims to minimise inequity by ensuring that those with low literacy are not excluded from the benefits of the information [10,14].

Recent studies have indicated that the content contained within informed consent forms regarding orthodontic treatment in general and orthognathic surgery may be too difficult for many to read [10,18]. Information regarding the quality and readability of content contained within informed consent forms about CAT is lacking. The aim of the study was to ascertain the quality and readability of content within the informed consent forms about CAT.

Method

Ethical approval for the present investigation was not required as consent forms publicly available on the Internet only were evaluated. The study followed STrengthening the Reporting of OBservational studies in Epidemiology (STROBE) guidelines for reporting of cross-sectional surveys [19].

Search strategy

The term 'clear aligner treatment informed consent form' was entered into three Internet search engines – Google, Bing and Yahoo on January 1st, 2024. The inclusion criteria were informed consent forms that specifically related to CAT and written in the English language. Exclusion criteria included forms that were duplicates or were part of the documentation for participation in a research study. The unique resource locator of the first 150 links from each search was recorded on a Microsoft (Redmond, Wash, US) Excel spreadsheet. Each link was checked for the presence of a CAT informed consent form. Details regarding the author of the consent form, the website within which it was contained, country of intended readership and the number of words contained in each form that satisfied selection criteria were documented.

Presence of content

An assessment tool was developed by the research team, based on instruments used in previous similar research [2,20]. Each form was evaluated for the presence of details regarding the CAT treatment process, benefits and alternative treatments (including no treatment).

Each form was also evaluated for the presence of 10 orthodontic treatment risks, which were identified as key by 264 orthodontists in a recent study (*table I*) [7].

In addition, the presence of the following content was determined:

- the requirement for post-CAT lifelong retention;
- the presence of images intended to support the text;
- the potential impact on speech and salivation;

Table I
Orthodontic treatment risks

1.	Appliances breakage/loss
2.	Consequences of no treatment
3.	Demineralisation
4.	Failed tooth movements
5.	Gingivitis
6.	Pain
7.	Relapse
8.	Root resorption
9.	Treatment duration
10.	Ulceration

- the possible need for additional aligners on completion of wear of the initial prescribed series of aligners;
- the need for discussion of specific risks relevant to the patient;
- whether the option of no treatment was provided.

Quality of content

The content related to the CAT process, benefits, alternative treatments and the 10 risks were subjected to a quality of content (QOC) evaluation with a 4-point scoring system analogous to that used in a recent study [20]. Scores were based on the accordance with current pertinent evidence (*table II*) [21–24].

Table II
QOC score

Score	Description
0	No and/or erroneous content
1	Inadequate content
2	Adequate content
3	Comprehensive evidence-based content

QOC: quality of content.

Readability

The text contained within each form was copied and pasted onto a Microsoft Word document. The content was reformatted to a standardised protocol to ensure accurate readability evaluation [14]. The reformatted text was assessed via the online readability calculator (www.readabilityformulas.com). The scores from the Simple Measure of Gobbledegook (SMOG) and the Flesch Reading Ease Score (FRES) were calculated [10,25].
The SMOG score is derived from a formula using the number of words containing three or more syllables and the number of sentences in each text.
The FRES is computed via a formula using the mean sentence length and the mean number of syllables per word [26].

Table III
Formula and ease of reading categories of the SMOG and FRES tools

Formula/category	SMOG	FRE
Formula	$1043 \times \sqrt{(C \times (30/S))} + 3.1291$	$206.835 - (1015 \times ASL) - (84.6 \times ASW)$
Category[1]		
Easy	4th–6th grade	90–100 – 'very easy'
		80–89 – 'fairly easy'
		70–79 – 'easy'
Average	7th–9th grade	60–69 – 'standard'
Difficult	> 10th grade	50–59 – 'fairly difficult'
		30–49 – 'difficult'
		0–29 – 'very difficult'

SMOG: Simple Measure of Gobbledegook; C: number of words with 3 syllables; S: number of sentences; FRES: Flesch Reading Ease Score; ASL: average sentence length; ASW: average number of syllables per word.
[1]Category of reading difficulty as defined by the US Department of Health and Human Services criteria [27].

The SMOG score corresponds to the number of years spent within the US public school system that the written content would be expected to be understood [26].

The FRES is a number between zero and 100, with higher numbers indicating that the text that is easier to read. *Table III* outlines the formulae for the SMOG and FRES and the category of ease of readability to which a 'score' corresponds [10].

Several organisations have recommended that written health information should be written at a reading age approximating 11 years or less to minimise sub-optimal comprehension [27–29]. This equates to a SMOG score $\leq$ grade 6 and a FRES > 70 [16,27,28].

Prior to formal data acquisition and analysis, six forms were evaluated by five orthodontist colleagues to ensure that the instrument was appropriate for evaluating informed consent forms.

Statistical analysis

Descriptive statistics were computed through GraphPad Prism 10.0 (GraphPad Software Inc., La Jolla, CA, USA). The Shapiro-Wilks test indicated a non-parametric distribution of data. The results are presented in medians, interquartile ranges (IQR) and percentages. The Mann-Whitney test was used to test differences in medians between groups for statistical significance. The Spearman correlation test was used to test association between groups.

Intra-correlation coefficient (ICC) testing was carried out to determine intra- and inter-rater reliability of the presence and QOC of nine informed consent forms six weeks after the initial evaluation. As per Landis and Koch's scale, ICC scores less than 0.4 correspond to poor-to-fair agreement and scores between 0.41 and 0.60 equate to moderate agreement. A score between 0.61 and 0.80 was deemed excellent whereas a score between 0.81 and 1.0 was deemed almost perfect [30]. A *P*-value < 0.05 indicated statistical significance.

Results

Figure 1 shows that 42 informed consent forms satisfied selection criteria.

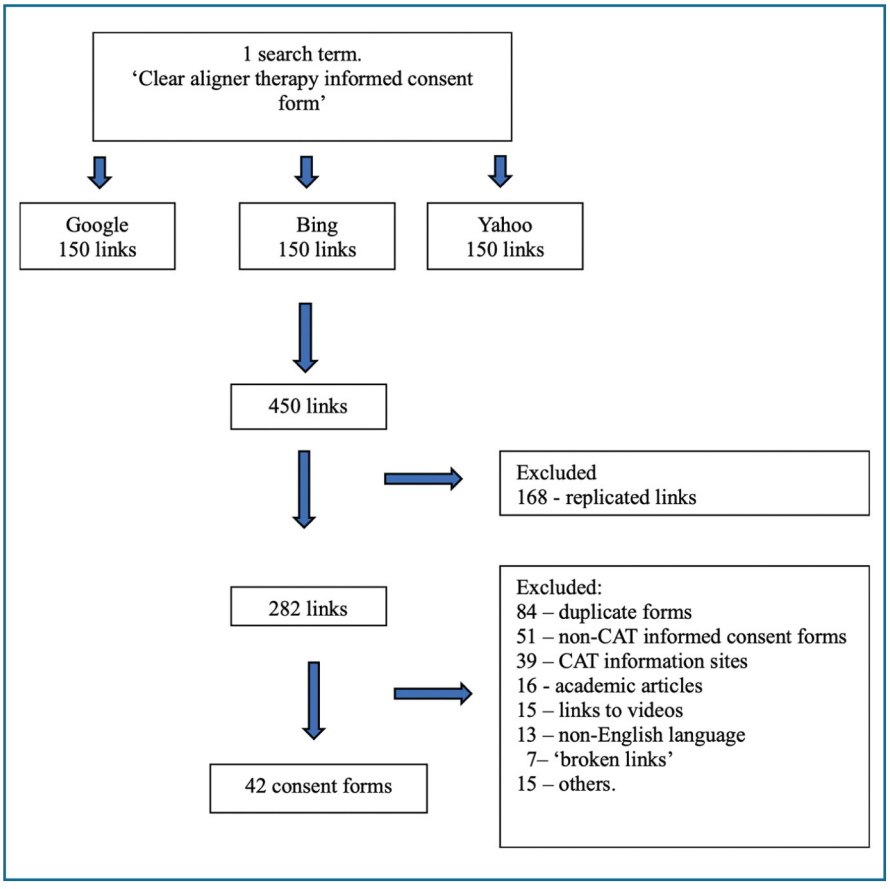

FIGURE 1

Flow diagram for informed consent form selection

Table IV
Demographic statistics of informed consent forms (*n* = 42)

Country	*n* (%)	Website source	*n* (%)	Author	*n* (%)
Aus	9 (21.4)	GDP	4 (9.5)	Lab/company	4 (9.5)
		Lab/company	1 (2.4)	Unclear	5 (11.9)
		Ortho	3 (7.1)		
		MDC	1 (2.4)		
India	2 (4.8)	Lab/company	2 (4.8)	Lab/company	2 (4.8)
NZ	1 (2.4)	DTC	1 (2.4)	DTC	1 (2.4)
UK	7 (16.7)	Lab/company	3 (7.1)	Lab/company	6 (14.3)
		Ortho	2 (4.8)	DTC	1 (2.4)
		MDC	1 (2.4)		
		DTC	1 (2.4)		
US	23 (54.8)	GDP	7 (16.7)	Lab/company	13 (31.0)
		Lab/company	7 (16.7)	DTC	2 (4.8)
		Ortho	7 (16.7)	Unclear	8 (19.0)
		DTC	2 (4.8)		
Total	42 (100)		42 (100)		42 (100)

n: number; %: percentage; Aus: Australia; GDP: general dental practice; Lab: laboratory; Ortho: orthodontic practice; MDC: multi-disciplinary clinic; NZ: New Zealand; DTC: direct-to-consumer; UK: United Kingdom; US: United States.

Table IV shows that most of the forms were sourced from websites in the US (*n* = 23; 54.8%) and that six (9.6%) were authored by the manufacturers of DTC aligners.

Table V outlines the results regarding the presence of, and the QOC scores, related to the treatment details, benefits, alternatives and risks.

The median (IQR) number of risks present per form was 8 (7, 9; min 3, max 9).

No form contained information on all 10 risks. Nine risks were present in 12 (28.6%) forms. The median (IQR) QOC score per form was 12 (9.75, 14; min: 3, max: 21). There was no difference (*P* = 0.59) in the median (IQR) QOC of the informed consent forms provided by DTC aligner providers [10 (8.25, 16.25)] and non-DTC aligner providers [12 (10, 14)].

The requirement for post-CAT lifelong retention was stated in nine (21.4%) forms.

Images, intended to support the text, were present in two (4.8%) forms. The potential impact on speech (*n* = 32; 76.2%) and salivation (*n* = 32; 76.2%) was described in most forms.

The possible need for additional aligners on completion of wear of the initial prescribed series of aligners was indicated in 14 (33.3%) forms.

Information regarding refusal to consent was provided in two (4.8%) forms.

Two forms (4.8%) referred to the need for discussion of specific risks relevant to the patient. Information that the orthodontic treatment was being provided by a general dentist, and not an orthodontist, was contained within two (4.8%) forms.

Four (9.6%) forms indicated that no treatment was an option. The median (IQR) words per form was 1509 (1093, 1931; min 532, max 4099). The median (IQR) SMOG score was 12.1 (10.9, 12.7; min 8.5, max 16.7) and the median (IQR) FRES was 39.0 (36.0, 44.25; min 15.0, max 60.0). The scores from the two readability instruments were closely correlated (r = −0.94; 95% CI: −0.94 to −0.89; *P* < 0.0001).

Figure 2 shows that almost all forms were difficult to read according to the US Department of Health and Human Services criteria [27].

There was no difference (*P* = 0.26) in SMOG scores between the forms from US links [12.26 (10.88, 12.7)] and those from links outside the US [11.55 (10.79, 12.6)].

There was no difference (*P* = 0.71) between the median (IQR) SMOG scores of the forms related to DTC aligners [11.53 (11.09, 12.35)] and the forms related to non-DTC aligners [12.14 (10.84, 12.8)].

Table V

Determination of the presence of consent aspects and QOC scores (*n* = 42)

Aspect	Present (*n* = 42)	QOC (min 0, max 3)
	n (%)	Median (IQR)
Treatment details	26 (61.9)	2.0 (0.0, 2.0; min 0, max 3)
Benefits	33 (78.6)	2.0 (1.0, 2.0; min 0, max 3)
Alternatives	9 (21.4)	0.0 (0.0, 0.0; min 0, max 3)
Risks		
1. Appliances breakage/loss	24 (57.1)	1.0 (0.0, 1.0; min 0, max 2)
2. Consequences of no treatment	2 (4.8)	0.0 (0.0, 2.0; min 0, max 2)
3. Demineralisation	38 (90.5)	1.0 (1.0, 2.0; min 0, max 3)
4. Failed tooth movements	39 (92.9)	1.0 (1.0, 2.0; min 0, max 3)
5. Gingivitis	39 (92.9)	1.0 (1.0, 2.0; min 0, max 3)
6. Pain	37 (88.1)	2.0 (0.0, 2.0; min 0, max 3)
7. Relapse	40 (95.2)	1.0 (1.0, 2.0; min 0, max 3)
8. Root resorption	30 (71.4)	1.0 (1.0, 2.0; min 0, max 3)
9. Treatment duration	34 (81.0)	2.0 (1.0, 2.0; min 0, max 3)
10. Ulceration	34 (81.0)	2.0 (1.0, 2.0; min 0, max 3)

QOC: quality of content; *n*: number; %: percentage; IQR: interquartile range; Min: minimum; Max: maximum.

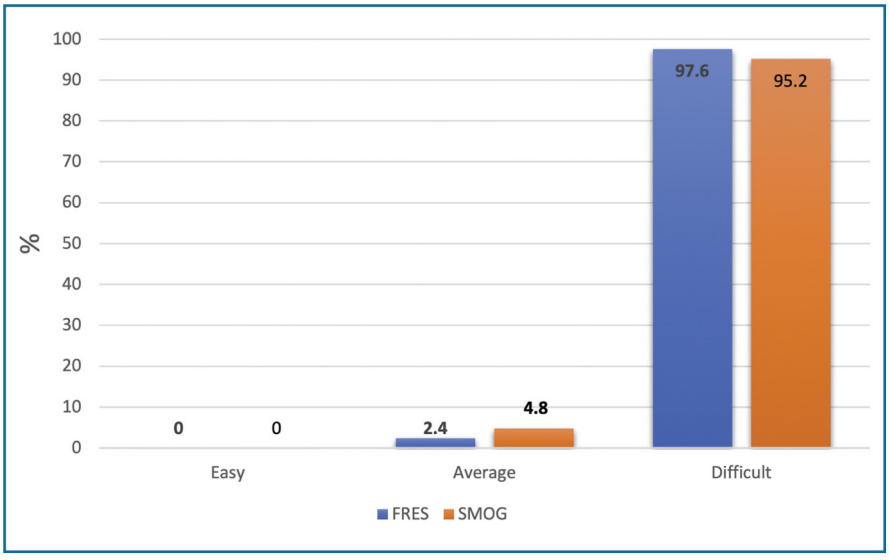

Figure 2

The % informed consent forms per category of reading difficulty as defined by the US Department of Health and Human Services criteria (*n* = 42)

n: number; %: percentage; FRES: Flesch Reading Ease Score; SMOG: Simple Measure of Gobbledegook.

There was no correlation between the FRES and word count (r = −0.022; *P* = 0.17) and a weak correlation SMOG score and the word count (r = 0.38; *P* = 0.01).
There was no correlation between the word count of the forms and the QOC of the forms (r = 0.06; *P* = 0.69). There was no correlation between the SMOG scores and the QOC scores (r = 0.11; *P* = 0.50) and between the FRES and QOC scores (r = −0.11; *P* = 0.49).
ICC intra-rater (0.88–1.0) and inter-rater scores (0.82–0.98) for the presence of consent aspects and QOC scores were excellent.

Discussion

The present study is the first to assess the quality of content and readability of informed consent forms related to CAT. The findings indicated that the quality of the forms was sub-optimal with important information regarding treatment risks lacking and information written at a level too difficult for many to understand. The acceptance that valid consent is an integral part of the decision-making process and the global ubiquity of CAT provision highlight the relevance of the present study.
Most of the forms in the present investigation were authored by the manufacturers of CAT systems. This may have been unsurprising given commercial companies play a prominent role in the delivery of CAT globally – either provided by dental clinicians or directly to the consumer [11,12]. Discourse, however, is necessary within the orthodontic profession regarding the appropriateness of appliance manufacturers providing informed consent forms for use by clinicians with patients.
Most forms were sourced through links with an intended target readership in the US. This replicated the findings in studies assessing the quality of orthodontic information on the Internet and reflects the popularity of the Internet as a source of health information in that country [10,14].
A validated instrument to assess the quality of informed consent forms is lacking. A tool based on a previous study that assessed informed consent forms on dental intervention and a recent qualitative investigation that determined the 10 risks that over 200 orthodontists deemed necessary for inclusion in the informed consent process was, consequently, developed [2,7]. In addition, aspects of CAT wear identified by patients as important to them were included in the assessment [11,31,32].
Disclosure of information regarding the treatment process, benefits, alternatives, including no treatment, and risks is essential to ensure valid consent [1]. Although the present study found that the information regarding the CAT process and benefits was adequate, information regarding the alternatives to, and risks of, CAT were sub-optimal. For example, although most forms provided information on post-CAT retention, only 21.4% indicated that retention is lifelong. Several investigations have indicated that the lack of patient knowledge regarding the need for indefinite wear of retainers is a source of discontent among patients who have completed orthodontic treatment [31,33].
Recent research has indicated that one or more series of additional aligners is routinely required after the initial series to achieve the outcome desired by the treatment provider [11–13]. Information in this regard was provided by just one-third of the forms assessed in the present survey. Future iterations of CAT informed consent forms should consider the inclusion of unambiguous information regarding the likelihood of additional aligners for completion of treatment.
Just 4.8% of the forms referred to the need for discussion of the specific risks that are of relevance to the patient. Disclosure of this information is critical for valid consent and is a consequence of several legal rulings which determined that treatment providers need to communicate the details of those risks by ensuring that these are tailored to the patient's values, needs and the evidence base [1,4,5].
The present investigation indicated that the QOC in consent forms related to DTC was deficient. This corresponded with the findings of other studies, which determined that the quality of information provided by DTC aligner providers was poor [14,34]. This is of note as DTC aligner treatment is provided without clinician oversight and the consent form may be the patient's only information source [1]. Recent publications have highlighted the inadequacies of current regulatory and legal processes in many jurisdictions that may preclude the protection of patients utilizing DTC services from harm [15,35,36].
Comprehensive evidence-based content is of limited use, however, if the information is difficult to read. Two readability tools were utilised in the current study.
The FRES is a universally accepted tool for quantifying readability.
The SMOG tool is a validated readability instrument that precisely measures readability as well as accurately assessing the grade level necessary for complete text comprehension [10].
A reading age equating to approximately 10–12 years has been recommended by several organisations [27–29]. This acknowledges that literacy, which is a key component of health literacy, is universally low. It is also intended to ensure that (potential) patients are not excluded from understanding information that contributes to validly consenting to treatment. However, the scores from the two readability tools used in the present study indicated that the readability of the content in the assessed forms approximated to that of 17–18 years. Future research is required to develop informed consent forms that are easy to read [10]. The development of easily readable consent forms using non-jargon text with shorter words and sentences while maintaining the required information, however, presents considerable challenges [14]. The adoption of images to aid comprehension, as used in two of the forms in the present study, may be helpful in this regard [3].
The present investigation shares the shortcomings of cross-sectional surveys on the Internet. A search on an alternative date may have yielded alternative forms for evaluation. The

high number of duplicate forms, however, indicated that many of the evaluated forms are widely utilized globally. In addition, although the evaluators aimed to adhere to the evidence base in their assessment of the content, the potential for bias cannot be completely excluded. Moreover, as only consent forms written in the English language were evaluated the findings are not generalisable to forms written in other languages. However, rigor was applied in the development of the QOC tool, and strong intra- and inter-rater scores were recorded.

Conclusions

The quality of content of the forms evaluated in the present study was incomplete and poor. The content was difficult to read and failed to reach the readability standards recommended by many organisations. Consent is unlikely to be valid if it is based solely on the content of the forms. Clinicians need to be aware of the limitations of informed consent forms for CAT. Research is required, ideally including the involvement of patients with the orthodontic profession, to ensure the development of relevant, evidence-based and easily readable content is contained within consent forms.

Availability of data and materials: The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

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Contribution: MJM: concept and design of the work; acquisition, analysis and interpretation of data; drafting and revision of the article; critical review of the important intellectual content.
SJ: analysis of data; drafting and revision of the article; critical review of the important intellectual content.
XJ: critical review of the important intellectual content drafting and revision of the article.
DH: critical review of the important intellectual content drafting and revision of the article.
LJ: critical review of the important intellectual content drafting and revision of the article.

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