An observational study of papers published in *PLOS ONE* and studies posted to a trial registry.

Nicole White *

School of Public Health and Social Work, QUT

and

Thiru Balasubramaniam, Richi Nayak

To add

and

Adrian Barnett

School of Public Health and Social Work, QUT

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Abstract

The text of your abstract. 200 or fewer words.

Keywords: 3 to 6 keywords, that do not appear in the title

1 Introduction

An ideal statistical analysis will use appropriate methods to create insights from the data and inform the research questions. Unfortunately many current statistical analyses are far from ideal, with many researchers using the wrong methods, misinterpreting the results, or failing to adequately check their assumptions (**??**). Some researchers take a "mechanistic" approach to statistics, copying the few methods they know regardless of their appropriateness, and then going through the motions of the analysis (**?**).

Many researchers lack adequate training in research methods, and statistics is something they do with trepidation and even ignorance (**??**). However, using the wrong statistical methods can cause real harm (**??**) and bad statistical practices are being to used abet weak science (**?**). Statistical mistakes are a key source of waste in research and partly explain the current reproducibility crisis in science (**?**). Even when the correct methods are used, many researchers fail to describe them adequately, making it difficult to reproduce the results (**??**). Poor statistical methods might not be caught by reviewers, as they may not be qualified to judge the statistics. A recent survey of editors found that only 23% of health and medical journals used expert statistical review for all articles (**?**), which was little different from a survey from 22 years ago (**?**).

There is guidance for researchers on how to write up their statistical methods and results. The International Committee of Medical Journal Editors recommend that researchers should: "Describe statistical methods with enough detail to enable a knowledgeable reader with access to the original data to judge its appropriateness for the study and to verify the reported results" (**?**). More detailed guideance is given by the SAMPL and EQUATOR guidelines (**??**) with the latter covering all apsects of the paper. Both of these guidelines were led by Doug Altman, who spoke often and for many years about the need for better statistical reporting. The awareness and use of these guidelines could be improved. There were 256 Google Scholar citations to the SAMPL paper (as at 15 March 2021) which is a good citation statistic for most papers, but is low considering the millions of papers that use statistical analysis.

Two statisticians on this paper (AB and NW) have heard researchers admit that they have copied-and-pasted their statistical methods sections from other papers, regardless of

whether they are appropriate. The aim of this paper is to use text-mining methods to analyse the content of statistical methods sections included in common research outputs. Results are then evaluated to estimate the extent that researchers are using cut-and-paste or 'boilerplate' statistical methods sections. Boilerplate text is that "which can be reused in new contexts or applications without significant changes to the original" (**?**). Use of these methods sections indicates that little thought has gone into the statistical analysis.

2 Methods

2.1 Data sources

We used two openly available data sources to find statistical methods sections: research articles published in *PLOS ONE* and study protocols registered on the Australian and New Zealand Clinical Trials Registry (ANZCTR). Data sources were chosen as examples of common research outputs that include descriptions of statistical methods that were used, or are planned, for analysing study outcomes.

2.1.1 Public Library of Science (PLOS ONE)

PLOS ONE is a large open access journal that publishes original research across a wide range of scientific fields. Article submissions are handled by an academic editor who selects peer reviewers based on their self-nominated areas of expertise. Submissions do not undergo formal statistical review. Instead, reviewers are required to assess submissions against several publication criteria, including whether: "Experiments, statistics, and other analyses are performed to a high technical standard and are described in sufficient detail" (**?**). All reviewers are asked the question: "Has the statistical analysis been performed appropriately and rigorously?", with the possible responses of "Yes", "No" and "I don't know".

Authors are encouraged to follow published reporting guidelines such as EQUATOR, to ensure that chosen statistical methods are appropriate for the study design, and adequate details are provided to enable independent replication of results.

All *PLOS ONE* articles are freely accessible via the PLOS Application Programming Interface (API). This enabled us to conduct searches of full-text articles and analyse data

on articles' text content and general attributes such as publication date and field(s) of research. Statistical methods sections were extracted using a two-step approach:

Step 1: Targeted API searches were completed using the R package 'rplos' (**?**). Search queries targeted analysis-related terms, combining the words "data" or "statistical" with one of: "analysis", "analyses", "method", "methodology" or "model(l)ing". Terms could appear anywhere within the main body of the article, to account for the placement of relevant text in different sections, for example, in the *Material and Methods* section versus *Results*. Search results were indexed by a unique Digital Object Identifier (DOI). Attribute data collected per DOI included journal volume and subject classification(s).

Step 2: *PLOS ONE* does not prescribe standardised headings to preface statistical methods sections. To address this, we performed partial matching on available headings against frequently used terms in initial search results: 'Statistical analysis', 'Statistical analyses', 'Statistical method', 'Statistics', 'Data analysis' and 'Data analyses'.

Data included in our analysis were downloaded on 3 July 2020. For records that did not pass Step 2, we reviewed where initial search terms appeared in the full-text, to evaluate the likely proportion of statistical methods sections that were missed.

2.1.2   Australia and New Zealand Clinical Trials Registry (ANZCTR)

The ANZCTR was established in 2005 as part of a coordinated global effort to improve research quality and transparency in clinical trials reporting; observational studies can also be registered. All studies registered on ANZCTR are publicly available and can be searched via an online portal (`https://www.anzctr.org.au`).

Details required for registration follow a standardised template (**?**), which covers participant eligibility, the intervention(s) being evaluated, study design and outcomes. The information provided must be in English. Studies are not peer reviewed.

For the statistical methods section, researchers are asked to provide a "brief description" of the sample size calculations, statistical methods and planned analyses, although this section is not compulsory (**?**). Studies are reviewed by ANZCTR staff for completeness of key information, which does not include the completeness of the statistical methods sections.

All studies available on ANZCTR were downloaded on 1 February 2020 in XML format. We used all the text available in the "Statistical methods" section. We also collated basic information about the study including the study type (interventional or observational), submission date, number of funders and target sample size. These variables were chosen as we believed they might influence the completeness of the statistical methods section, because we expected larger studies and those with funding to be more complete, and we also were interested in changes over time.

Studies prior to 2013 were excluded as the statistical methods section appeared to be introduced in 2013. Some studies were first registered on the alternative trial database *clinicaltrials.gov* and then also posted to ANZCTR. We excluded these studies because they almost all had no completed statistical methods section as this section is not included in *clinicaltrials.gov*.

Statistical methods sections were missing for some studies downloaded from ANZCTR, including a small number of sections labelled as "Not applicable", "Nil" or "None". We therefore examined if there were particular studies where this section was more likely to be missing. Analysis considered a logistic regression model estimated in the Bayesian framework [**?**; www.r-inla.org], with missing statistical methods section (yes/no) as the dependent variable. Date, study type (observational or interventional), number of funders and target sample size were used as independent variables. Results were reported as odds ratios with 95% credible intervals (CI).

2.2   Full-text processing

Text cleaning aimed to standardise notation and statistical terminology, whilst minimising changes to article style and formatting. R code used for data extraction and cleaning is available from `https://github.com/agbarnett/stats_section`.

Mathematical notation was converted from Unicode characters to plain text. For example, the Unicode character corresponding to θ (<U+03B8>) was replaced with 'theta'. Common symbols outside of Unicode blocks including '%' (percent) and '<' ('less-than') were similarly converted into plain text. General formatting was removed, including carriage returns, punctuation marks, in-text references (e.g. "[42]") centred equations, and

other non-ASCII characters. Text contained inside brackets was retained to maximise content for analysis, with brackets removed. Common stop words including pronouns, contractions and selected prepositions were removed. We retained selected stop words that, if excluded, may have changed the context of statistical methods being described, for example 'between' and 'against'.

We compiled an extensive list of statistical terms to standardise reported descriptions of statistical methods. An initial list was compiled by calculating individual word frequencies and identifying relevant terms that appeared at least 100 times. Further terms were sourced from index searches of three statistics textbooks (**?**, **?**,**?**). Plurals (e.g., 'chi-squares') unhyphenated (e.g., 'chi square') and combined (e.g. 'chisquare') terms were transformed to singular, hyphenated form (e.g., 'chi-square'). Common statistical tests were also hyphenated (e.g., 'hosmer lemeshow' to 'hosmer-lemeshow'). The final list is provided in Supplementary File 1.

2.3 Clustering algorithm

Text from statistical methods sections was analysed using Non-Negative Matrix Factorization (NMF). NMF is an established approach for topic modelling, and provides an effective solution for text-based clustering when dealing with high-dimensional data (**?**, **?**). In this section, we outline key details of NMF and its strengths compared with other text-based clustering methods.

For N studies, let $P \in R^{M \times N}$ denote a content matrix, representing text from statistical methods sections as M unique terms. Text clustering algorithms for identifying common topics across studies requires P to be represented with a vector space model. In our case, unique terms in P are modelled using the tf*idf (term frequency $\times$ inverse document frequency) weighting schema, to account for the relative importance of common and rare terms.

A common problem facing text clustering algorithms is the curse of dimensionality due to the high number of terms in the doc$\times$term matrix representation (**?**, **?**). Applying text-based methods based on distance, density or probability therefore face difficulties in high-dimensional settings (**?**, **?**,**?**). Specifically, distances between near and far points becomes

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negligible (**?**). This behaviour directly affects the performance of distance-based clustering methods such as k-means (**?**) in accurately identifying subgroups (topics) present in the data. Furthermore, sparseness associated with high-dimensional matrix representations does not allow for differentiation between topics based on density differences (**?**, **?**).

To address these limitations, NMF deals with high-dimensional data by mapping it to a lower-dimensional space. This mapping this achieved by approximating P with two factor matrices: $W \in R^{M \times g}$ and $H \in R^{N \times g}$ (**?**), such that $P \approx WH^T$. The number of subgroups of common topic inferred from the data is given by g.

The matrix factorization process approximates the lower dimensional non-negative factor matrices W and H such that they can represent high dimensional P with the least error. Estimation of W and H is achieved by optimising an objective function; for NMB, the Fronbeius norm is used, equivalent to minimising the sum of squares for all elements of P:

$$\min \frac{1}{2}\|P - WH\| = \sum_{i=1}^{M} \sum_{j=1}^{N} \left(P_{i,j} - (WH)_{i,j} \right)^2 \tag{1}$$

Following estimation, H contains the information regarding topic membership for all studies. In our case, topic membership $(1, \ldots, g)$ for a statistical methods section is inferred from the maximum coefficient value in the corresponding row of H, also known as the topic coherence score. For our two datasets, we applied NMF with $g = 10$.

2.4   Content analysis

Clustering results were visualised by word clouds to summarise frequently occurring terms associated with topic membership. Whilst these results were useful for inferring common themes across statistical methods sections, they did not indicate evidence of boilerplate text beyond the use of common terms. Follow up analysis therefore considered similarities in text between sections assigned to the same topic.

We used the Jaccard similarity index to compare the statistical methods section with the highest topic coherence score with all other sections assigned to the same topic. Indices were calculated at the sentence level, to account for instances of boilerplate text within larger methods sections. We chose the Jaccard index as an easy to interpret measure,
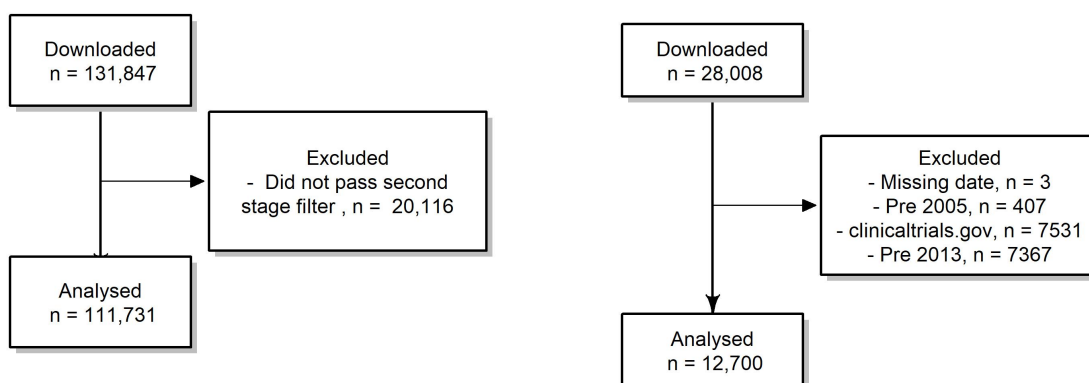
Figure 1: Search results for PLOS ONE (left) and ANZCTR (right).

which summarises the similarity between two sentences by the number of words common to each sentence (intersection), divided by the number of words that appeared in either sentence (union). Instances of boilerplate text were defined by a Jaccard index of 0.9 or higher and a difference in word count of plus or minus three words.

3 Results

3.1 PLOS ONE

API searches returned 131,847 results (DOIs) (Figure 1). After partial matching, 111,731 (85%) statistical methods sections were identified. In the final sample, 95,518 (85%) DOIs returned an exact match against common section headings: 64,133 for 'statistical analysis', 13,380 for 'statistical analyses' and 13,627 for 'data analysis'.

Search results varied by journal volume (Figure 2A). The total number of API search results peaked at volumes 8 (n = 19,045) and 9 (n = 19,045) in years 2013 and 2014. This trend aligned with the total number of papers published in *PLOS ONE* over the same period. The percentage of records that included a statistical methods section by volume based on our proposed matching criteria varied between 64% (volume 2) and 86% (volume 9). All DOIs included Biology and life sciences (n = 107,584), Earth sciences (n = 7,605) and/or Computer and information sciences (n = 5,190) in their top 3 subject classifications
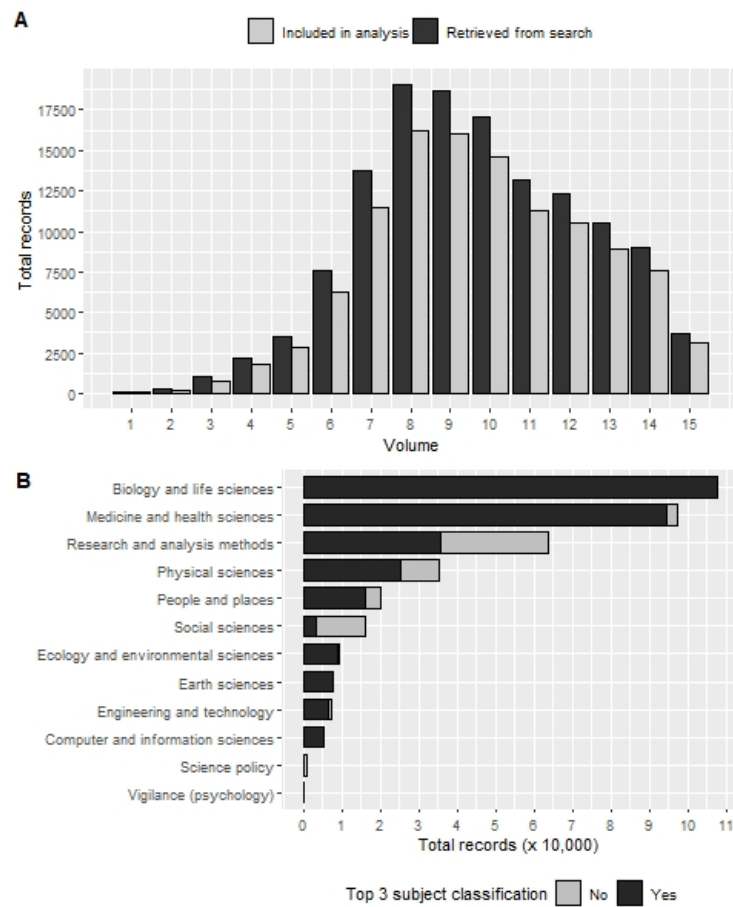
Figure 2:   A: Search results by PLOS ONE volume; B: Subject classifications assigned to full-text recorded included in the analysis

(Figure 2B).

Statistical methods sections had a median length of 127 words and inter-quartile range of 61 to 254 words. 7,450 articles (7%) had a statistical methods section of 500 words or more. 19,461 articles (17%) had statistical methods sections with 50 words or less, equal to the length of this paragraph.

For studies excluded based on section headings, initial search terms appeared in Introduction (number), Results (number) only. xxx appeared in the Methods section without a section heading and xxx had a non-standard section heading. [TODO].

The topic clouds for ten clusters are in Figure 3. Frequently occurring words reflected the use of statistical software (topics 3 and 5), descriptive statistics (topic 6), group based hypothesis testing (topics 1 and 4) and definitions of statistical significance (topics 1 and 9). Statistical methods sections related to regression (topic 2) and meta-analysis (topic 7) were also identified. Examples of boilerplate text for selected topics are presented in Table 1.

Topics related to statistical software differentiated between Prism GraphPad (topic 3: n = 9974; 8.6%) and SPSS (topic 5: n = 9648; 8.3%). Within topic 3, the sentence "GraphPad Prism (Graphpad Software, San Diego, CA) was used for all analyses" was found in 1,941 studies. Similar phrasing was identified for topic 5: "SPSS software version 17.0 (SPSS, Chicago, IL, USA) was used for statistical analysis", with similar text found in 441 studies.

Figure 3: Topic clouds for ten clusters for PLOS ONE

Table 1: Example boilerplate text from PLOS ONE datase (sentence level). Statistical methods text corresponds to the DOI with the highest topic coherence score within a topic

Topic	Statistical methods text	Matching DOIs
Topic 1	Students t-test was used for statistical analysis.	29
	A p value of < 0.05 was considered statistically significant.	1883
Topic 3	GraphPad Prism (Graphpad Software, San Diego, CA) was used for all analyses.	1941
Topic 4	Significant differences were determined using analysis of variance (ANOVA) followed by tukey post-hoc tests for multiple comparisons.	2216
Topic 5	SPSS software version 17.0 (SPSS, Chicago, IL, USA) was used for statistical analysis.	441
Topic 6	All results are expressed as means $\pm$ standard deviation ($\pm$ SD).	102
Topic 9	Statistical significance was determined by Students t-tests.	49
	*p < 0.05, **p < 0.01, ***p < 0.001.	6

Definitions of statistical significance featured strongly in topic 1 (n = 3784; 3.2%) and topic 9 (n = 6195; 5.3%). Topic 1 reflected applications of two-tailed and unpaired Student's t-tests, however, instances of boilerplate text emphasised the 5% level of statistical significance (1). In contrast, Topic 9 focused on multiple thresholds for declaring statistical significance by asterisk: "$^*p < 0.05$, $^{**}p < 0.01$ and $^{***}p < 0.001$", a practice that has been criticised (**?**).

Group-based hypothesis testing was a recurring theme across topics, with text descriptions varying based on method(s) used. One-way analysis of variance also featured strongly in topic 4 (n = 10212; 8.8%), combined with common methods for performing post-hoc multiple comparisons. Based on the Jaccard index, 1 in 5 studies were matched to the sentence "Significant differences were determined using analysis of variance (ANOVA) follwo by Tukey post-hoc tests for multiple comparisons". Frequently occurring words in topic 6 (n = 4764; 4.1%) reflected mentions of descriptive statistics for summarising continuous variables, namely means with standard deviations or standard errors.

3.2   ANZCTR

We downloaded 28,008 studies. The numbers of excluded studies are shown in Figure 1. Of the 12,700 included studies, 9,523 (75%) had a statistical methods section. The median length of sections was 129 words with an inter-quartile range of 71 to 219 words.

Odds ratios and 95% credible intervals for study characteristics included in the logistic regression model are presented in Table 2. Observational studies were less likely to have a missing statistical methods section compared with interventional studies. Missing sections became less likely over time. Studies with more funders and a larger target sample size were less likely to have a missing statistical methods section.

The clustering algorithm found groups that were purely sample size calculations (topic 2, n = 1834), pilot studies (topic 5, n = 834), safety/tolerability studies (topic 6, n = 524), intervention studies (topic 8, n = 1020) and repeated measures ANOVA (topic 10 = 852). Examples of boilerplate text are provided in Table 3 .

Some methods sections were only one word, including "ANOVA", "t-test", "SPSS" and even "SSPS". There were cases where the exact same method section had been re-used in a

Figure 4: ANZCTR topic clouds.

Table 2: Logistic regression results for study characteristics associated with missing statistical methods sections in ANZCTR

Variable	Odds ratio	95% CI
Study type = Observational	0.78	(0.69, 0.89)
Date (per year)	0.90	(0.88, 0.91)
Number of funders	0.80	(0.74, 0.86)
Target sample size (per doubling)	0.90	(0.88, 0.92)

different study. For example, in topic 7 (n = 333), 232 sections stated 'descriptive statistics' or 'descriptive statistics used' with no additional details provided. Other instances with expanded descriptions of methods included topic 3 (n = 1277) outlining descriptive analyses only, and topic 6 (n = 524), for hypothesis testing methods, statistical significance and software.

In other cases, text had been slightly modified to account for changes in primary and secondary outcomes. Examples of these text changes were found in topic 2 (n = 1834) and topic 4 (n = 909); identified instances related to sample size calculations for patient recruitment to different studies (see Supplementary File 3).

Since studies included in this dataset outlined planned analyses, we suspected that some studies did not specify statistical methods because they had yet to consult with a statistician. Targeted searches for the term "statistician" across all topics returned xx matching records, with examples including "A statistician employed by hospital was used" and "Pilot study at this point will use a statistician professionally to determine sample size calculations as required".

Table 3: Example boilerplate text from ANZCTR dataset

Topic	Statistical methods section
3	Comparisons between categorical variables will be made either using chi square or Fisher exact test. Continuous data will be compared using the Student's t-test or Mann-Whitney U test. Two sided p values of less than 0.05 will be considered statistically significant.
	The Mann-Whitney U, Student t, 1-way ANOVA, and Kruskal-Wallis tests will be used to compare continuous variables where relevant. The Fisher exact and Pearson's Chi-square test will be used to compare proportions as appropriate.
5	Pilot study
	No formal sample size calculation was performed
7	Descriptive statistics
	Descriptive statistics used
9	Linear mixed models will be used to analyse the data.
10	Repeated measures of ANOVA
	Pre-, during, post- and follow-up variables will be subjected to mixed methods and repeated measures analyses to determine significant changes over (group and) time.

4 Discussion

The first line in many statistical analysis sections in *PLOS ONE* was the software used and some entire sections in ANZCTR only stated the software, implying that the software is the most important detail. As Doug Altman said, "Many people think that all you need to do statistics is a computer and appropriate software" (**?**). This is far from the truth, and whilst it is important for researchers to mention the software and version used for reproducibility purposes, it is a minor detail compared with detailing what methods were used and why.

A frequent theme in the boilerplate statistical methods is the definition of statistical significance, nearly always using a p-value at the 5% level. This widespread use of statistical significance is troubling giving the bright-line thinking it engenders (**?**) and the common misinterpretations of p-values (**?**).

Despite the extensive array of statistical tests available, many authors are reporting the same few methods.

One reason these inadequate sections get published is that most journals do not use statistical reviewers, despite empirical evidence showing they improve manuscript quality (**?**).

A related paper has criticised vague statistical methods sections because they deprive readers and reviewers for the opportunity to confirm that the appropriate methods were used (**?**). These authors checked hundreds of papers using ANOVA and found that 95% did not contain the information needed to determine what type of ANOVA was performed. This lack of information could well be because the authors used a boilerplate statistical methods section that was missing key details.

If authors shared their code then this would provide an alternative route for checking what statistical methods were used. This is not a perfect solution, as we still want authors to accurately report their methods, but it does increase transparency. However, a recent paper found that code sharing was very low in biomedical papers, with just 2% of a sample of over 6,000 papers sharing code (**?**).

Many researchers are using lazy practice by copying a standard "boilerplate" statistical methods section, likely cut-and-pasting from other researchers or projects. This is a strong

sign of the ritualistic practice of statistics where researchers go through the motions rather than using conscientious practice (**?**). This is concerning because using the wrong statistical methods can reduce the value of study, or worse, invalidate the entire study. These mistakes are avoidable and are wasting of thousands of hours of researchers' time and the time of patients and volunteers. Poor statistical practice is a key driver of the ongoing reproducibility crisis in science (**?**).

4.1 Limitations

We did not check whether papers used the correct methods, and for some simple studies a 'boilerplate' statistical methods might be adequate.

We examined papers where there was a statistics section, and we missed papers that used statistical analysis but did not include a statistical analysis section. Reiterate outcomes of random sample checking here.

We only examined one large journal and one trial registry and hence our results may not be generalisable to all journals or registries, especially those that consistently use a statistical reviewer.

We searched the full text of *PLOS ONE* papers but not the supporting information which may contain statistical methods sections for some papers. The search terms we used to find statistical methods appeared in the supporting information titles for xxx papers (x%). We did not include the supporting information because it is less structured than the paper and could be in PDF or Word format.