

# Familiarity of Non-industry Authors With Good Publication Practice and Clinical Data Reporting Guidelines

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## ABSTRACT

**Objective:** To evaluate the familiarity of non-industry authors with guidelines for good publication practice and clinical data reporting.

**Research design and methods:** Non-industry authors for  $\geq 1$  publications in the last 2 years involving a single communications agency completed a 9-question online survey that evaluated experiences with professional medical writers and familiarity with guidelines (not, a little, somewhat, or very familiar).

**Results:** Of 287 authors contacted, 8% (23/287) responded to  $\geq 1$  questions. Among respondents, 65% and 30% had received editorial assistance on  $\leq 2$  and 3-5 publications, respectively; 48% received significant or full-service (including outline, drafts, copy edit) assistance. Fifty percent or more of respondents were somewhat or very familiar with ICMJE and GPP guidelines, while  $>50\%$  of respondents were not or a little familiar with GPP2, CONSORT, EMWA, and AMWA guidelines. Many respondents (27%-68%) were not familiar with  $\geq 1$  of the guidelines. Only 23% of respondents indicated that their institution has a specific policy regarding use of professional medical writers. A majority (77%) agreed that there is a role for professional medical writers in medical publications. High levels of satisfaction with professional medical writers were reported; 83% were very or extremely satisfied with overall writing quality and 96% were very or extremely satisfied with grammar and writing style.

**Conclusion:** A significant proportion of non-industry authors were not familiar with key guidelines governing good publication practice and clinical data reporting.

## INTRODUCTION

- A range of guidelines and best practices have been developed that relate to medical publications
  - Authorship and/or data reporting criteria from the International Committee of Medical Journal Editors (ICMJE)<sup>1</sup> and the CONSolidated Standards Of Reporting Trials (CONSORT)<sup>2</sup>
  - Good Publication Practice (GPP)<sup>3</sup> guidelines and their most recent update (GPP2)<sup>4</sup>
  - Guidelines for professional medical writers from the European Medical Writers Association (EMWA)<sup>5</sup> and the American Medical Writers Association (AMWA)<sup>6</sup>
- Most publication planners and professional medical writers receive education on these standards via internal education programs at communications agencies and industry departments, as well as professional organizations, such as the International Society for Medical Publication Professionals (ISMPP)
- Anecdotal experience suggests that non-industry authors are not as familiar with these guidelines and standards

## OBJECTIVE

- To evaluate the familiarity of non-industry authors with key guidelines for publications and data reporting, as well as their experiences working with professional medical writers

## RESEARCH DESIGN AND METHODS

- Non-industry authors for 1 or more publications in the last 2 years involving a single communications agency were contacted via e-mail and asked to complete a 9-question online survey (Table 1)
  - Types of publications included abstracts, posters, primary manuscripts, and review articles
  - The e-mail included an unsubscribe option
- Survey questions evaluated the following:
  - Familiarity with guidelines (not, a little, somewhat, or very familiar)
  - Policies and attitudes regarding professional medical writers
  - Experiences with professional medical writers
- Respondents were asked to think of all of their experiences with professional medical writers, not just those with a single communications agency
- Survey responses were anonymous

Table 1. Survey Questions

- In the past 2 years, how many projects have you worked on that involved editorial assistance from a professional medical writer?
  - 0-2
  - 3-5
  - 6-10
  - $>10$
- When working with professional medical writers, what extent of assistance have you usually received?
  - Minimal assistance (eg, copy edit, style for journal)
  - Moderate assistance (eg, initial outline, reference package)
  - Significant assistance (eg, drafts)
  - Full-service assistance (all of the above)
  - A range of assistance, depending on the project
- In general, how satisfied have you been with the following aspects of the assistance provided by professional medical writer (not at all, a little bit, somewhat, very, or extremely satisfied)?
  - Function as liaison with authors and sponsor
  - Function as liaison among authors
  - Overall satisfaction with service (eg, scheduling of calls, promptness of response)
  - Grammar and writing style
  - Incorporation of direction and comments
  - Accuracy
  - Level of scientific rigor
  - Level of detail
  - Overall satisfaction with writing
- Thinking of all of your experiences working with professional medical writers, how consistent have experiences been?
  - Very consistent - always receive same quality and level of service
  - Somewhat consistent - generally receive same quality and level of service
  - Not very consistent - wide variations in quality and level of service

## RESULTS

### Respondent characteristics

- A total of 287 authors were contacted (Table 2), and 8% (23/287) responded to 1 or more questions
- Most respondents were from the United States (52%) or the United Kingdom (13%)
- Among respondents, 65% had received editorial assistance on 2 or fewer publications, and 30% had received editorial assistance on 3 to 5 publications
  - Nearly half (48%) reported receiving significant or full-service assistance, including an outline and drafts at their direction, and copy edit services

### Familiarity with guidelines

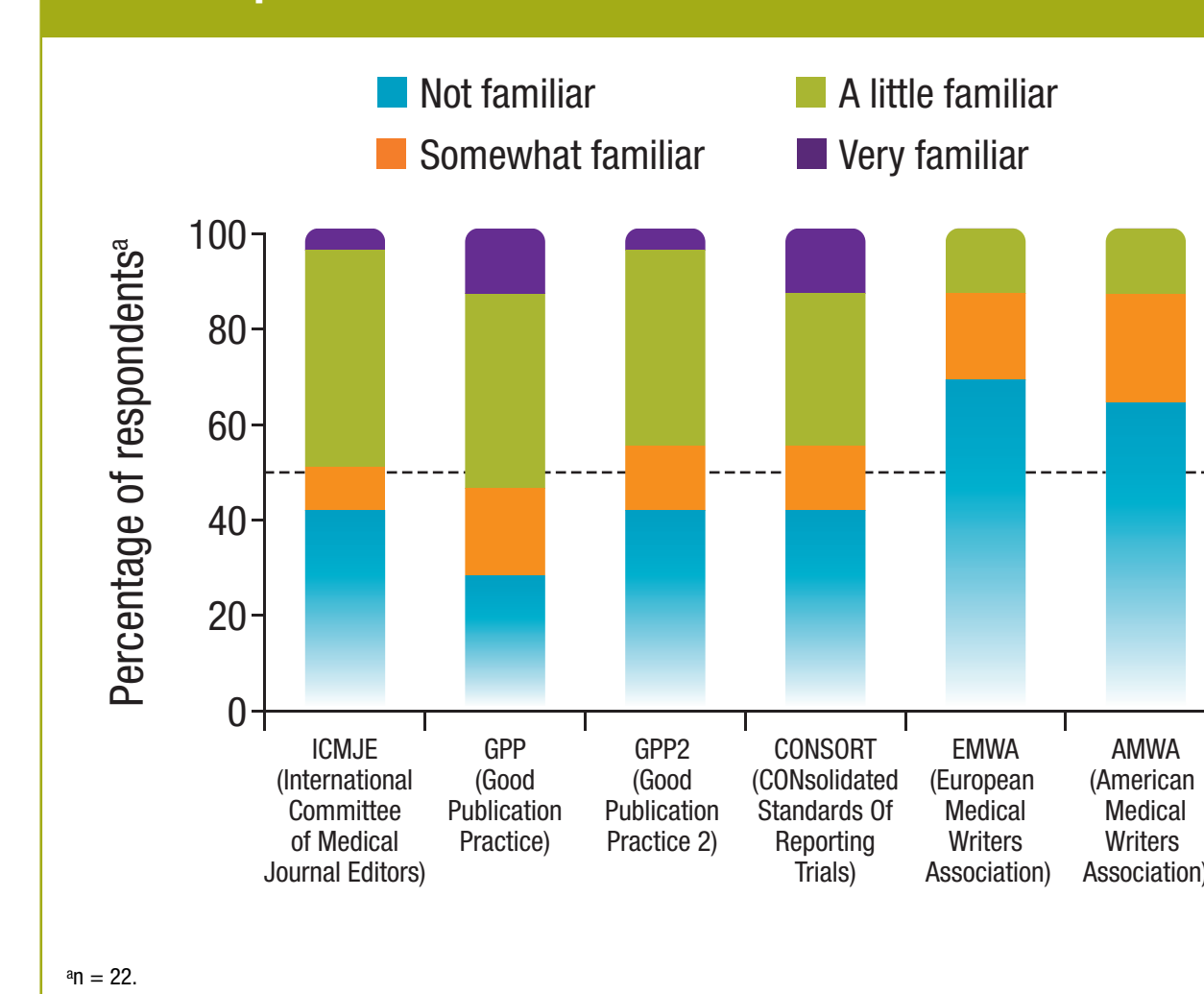
- Fifty percent or more of respondents were somewhat or very familiar with ICMJE Uniform Requirements and the original GPP guidelines, while more than 50% of respondents were not or a little familiar with GPP2, CONSORT, EMWA, and AMWA guidelines (Figure 1)
- Many respondents (27%-68%) were not familiar with 1 or more of the guidelines

Table 2. Respondent Characteristics

Parameter	n (%)
Total authors contacted	287 (100)
Responded to $\geq 1$ questions	23 (8)
Undeliverable	11 (4)
Unsubscribe	6 (2)
Geographic location of respondents <sup>a</sup>	
United States	12 (52)
United Kingdom	3 (13)
Canada	1 (4)
South Africa	1 (4)
Israel	1 (4)
China	1 (4)
Not provided	4 (17)
Number of projects with editorial assistance among respondents <sup>a</sup>	
0-2	15 (65)
3-5	7 (30)
6-10	0 (0)
$>10$	1 (4)
Level of editorial assistance among respondents <sup>a</sup>	
Minimal assistance (eg, copy edit, style for journal)	4 (17)
Moderate assistance (eg, initial outline, reference package)	1 (4)
Significant assistance (eg, drafts)	4 (17)
Full-service assistance (all of the above)	7 (30)
A range of assistance, depending on the project	7 (30)

<sup>a</sup>Totals may not sum to 100% because of rounding. <sup>n</sup> = 23.

Figure 1. Familiarity of non-industry authors with guidelines related to publications.



<sup>n</sup> = 22.

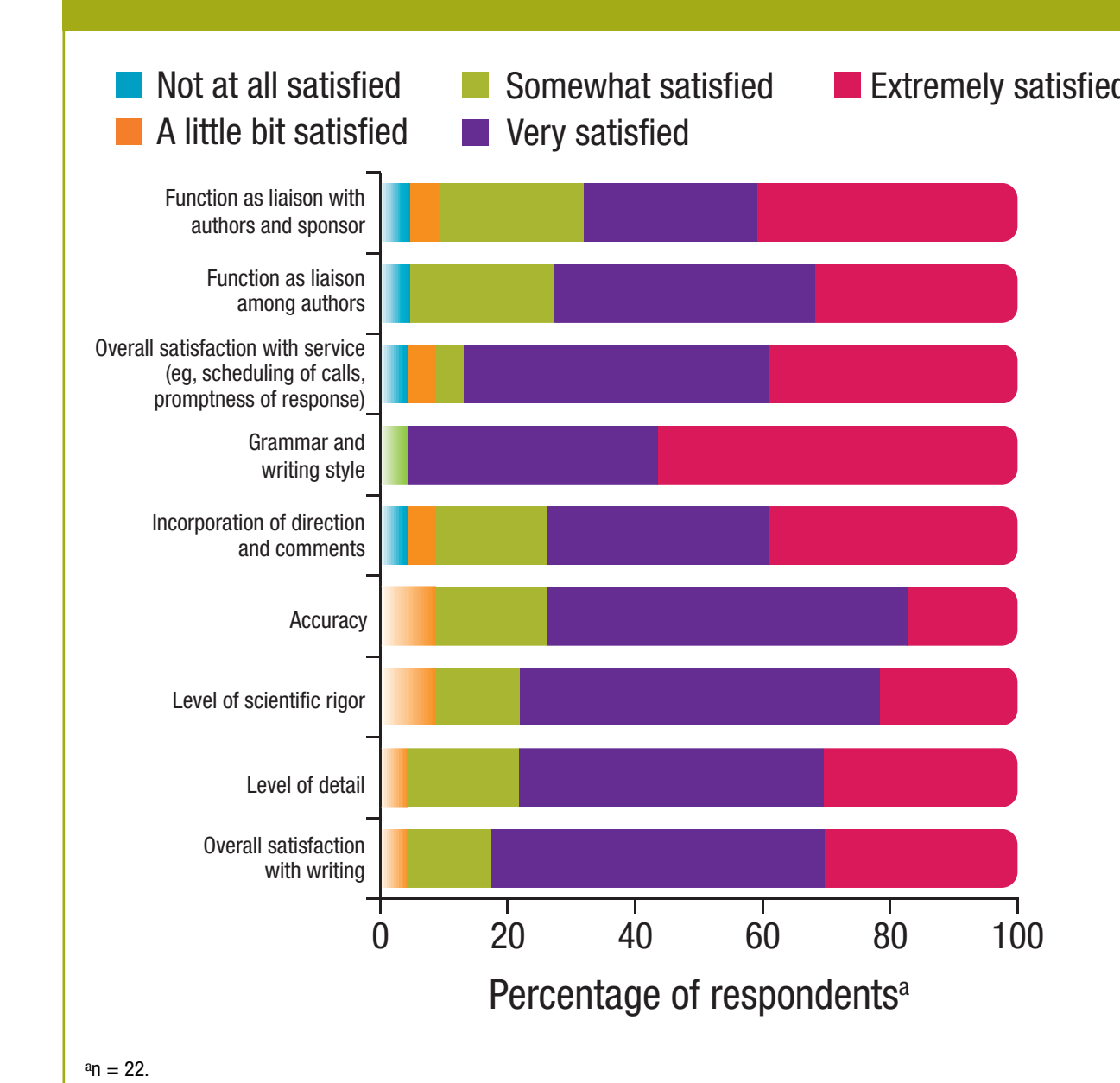
### Policies and attitudes regarding professional medical writers

- Only 23% of respondents indicated that their institution has a specific policy regarding use of professional medical writers
  - Additional feedback provided by respondents to this question included that they were unsure if institutional policies existed, that there are many institutional policies of which they are not aware, and that policies specify that there must be no conflicts of interest
- A majority (77%) agreed that there is a role for professional medical writers in medical publications
  - An additional 18% of respondents did not provide a 'yes' response, but provided the following feedback regarding the role of professional medical writers:
    - Facilitation of review process
    - Act as a third party, independent of industry sponsor, to coordinate between authors who may have their own issues and priorities
    - Assistance for time-strapped physicians (n = 2)

### Experiences with professional medical writers

- High levels of satisfaction with professional medical writers were reported (Figure 2); 83% were very or extremely satisfied with overall writing quality and 96% were very or extremely satisfied with grammar and writing style
- A majority of respondents (70%) reported that the level of service they received was very consistent (always receive same quality and level of service)

Figure 2. Satisfaction of respondents with professional medical writers.



<sup>n</sup> = 22.

## LIMITATIONS

- The response rate to the survey was low (8%) and may limit the ability to generalize these results
  - The response rate was generally in line with what we have historically observed for this type of survey (5%-10% with e-mail invitation without compensation)
- The list of authors was obtained from a single communications agency and may not be generalizable to the overall academic community
- Most authors were from the United States and the United Kingdom

## CONCLUSIONS

- A significant proportion of non-industry authors were not familiar with key guidelines governing good publication practice and clinical data reporting
- A majority of non-industry authors agreed that there is a role for professional medical writers in medical publications and reported high satisfaction with the services that they have received

## IMPLICATIONS FOR PUBLICATION PLANNERS

- There is an ongoing need for professional medical writers, communications agencies, and industry to educate academic researchers, investigators, and authors on (1) guidelines relative to good publication practice, (2) working with professional medical writers, and (3) data reporting

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All authors are employees of MedErgy HealthGroup, Yardley, PA. All authors met ICMJE criteria for authorship, and all those who met those criteria are listed as authors.