Trends in Medical Writing Acknowledgment in Medical Journals Over the Last Decade

Mee Rhan Kim\textsuperscript{a*}, Jon Nilsen\textsuperscript{a*}, Geoff Smith\textsuperscript{a*}, Ali Hassan\textsuperscript{b}, Scott Silbiger\textsuperscript{a}, Michele Vivirito\textsuperscript{a}, Meera Kodukulla\textsuperscript{a}

\textsuperscript{a}Amgen Inc., Thousand Oaks, CA
\textsuperscript{b}Complete Healthcare Communications Inc., Chadds Ford, PA
*Authors contributed equally
Introduction

• Incomplete or improper reporting of medical writing support in medical literature has led to increased scrutiny and negative press over the past few years

• Changes in publication policies were implemented by journals, pharma/biotech/medical device companies, and other organizations to be more aligned with ICMJE publication guidelines

• In June 2010, the US Senate Committee on Finance published a Minority Staff Report “Ghostwriting in Medical Literature” authored by Senator Grassley
  • Assessed reporting trends and policies from 1999-2001, 8 journals, 10 top US medical schools
  • Concluded pharma influence remains hidden in medical literature
  • Concluded medical schools do not provide sufficient oversight to medical writing assistance

• In a report by Nastasee, an overall 2-fold increase in the frequency of medical writing acknowledgement was observed in 2007 from 2002 (CMRO 2010:26 suppl 1:S6)

• We sought to further investigate this trend in medical writing acknowledgement by measuring more frequent timepoints
Methods

Three step process to determine trend in medical journals:

1) Identification of journals to survey
2) Article search for specific criteria of clinical trials published in these journals
   - Search years 2001 and 2002
   - Search years 2009 and 2010
3) Review each article identified for specific criteria
   - Randomized controlled trial
   - Funding source (ie, industry)
   - Acknowledgment of medical writing support
   - Pharma/biotech/medical device industry author
Methods

12 top TAs for drug development identified by Pharmaprojects

Each TA was matched to a MeSH term

Top journal (by impact factor) for each MeSH term
- Peer-reviewed original research
- ≥150 RCTs published overall
- Published in years covered in this analysis

Add top 4 general medicine journals by impact factor

TA= therapeutic area; RCT= randomized controlled trial
## Therapeutic Area and Journal Selection

<table>
<thead>
<tr>
<th>TA</th>
<th>MeSH term</th>
<th>Journal</th>
</tr>
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<tbody>
<tr>
<td>Alimentary</td>
<td>Digestive system diseases</td>
<td>Gastroenterology</td>
</tr>
<tr>
<td>Blood/clotting</td>
<td>Hematology</td>
<td>Blood</td>
</tr>
<tr>
<td>Cardiovascular</td>
<td>Cardiology</td>
<td>Circulation</td>
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<tr>
<td>Dermatological</td>
<td>Dermatology</td>
<td>Arch Dermatol</td>
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<tr>
<td>Metabolic</td>
<td>Hepatology</td>
<td>Hepatology</td>
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<tr>
<td>Hormonal</td>
<td>Endocrinology</td>
<td>J Clin Endo Metab</td>
</tr>
<tr>
<td>Immunological</td>
<td>Allergy and Immunology</td>
<td>J Allergy Clin Immunol</td>
</tr>
<tr>
<td>Anti-infective/</td>
<td>Anti-infective agents OR Antiparasitic</td>
<td>Clin Infect Dis</td>
</tr>
<tr>
<td>Antiparasitic</td>
<td></td>
<td></td>
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<tr>
<td>Anticancer</td>
<td>Medical oncology</td>
<td>J Clin Oncol</td>
</tr>
<tr>
<td>Musculoskeletal</td>
<td>Musculoskeletal diseases</td>
<td>Archives of Neurology</td>
</tr>
<tr>
<td>Respiratory</td>
<td>Respiratory System agents</td>
<td>Thorax</td>
</tr>
<tr>
<td>Sensory</td>
<td>Sensory aids</td>
<td>Arch Ophthalmol</td>
</tr>
<tr>
<td>General Medicine</td>
<td>n/a</td>
<td>New Engl J Med</td>
</tr>
<tr>
<td>General Medicine</td>
<td>n/a</td>
<td>Lancet</td>
</tr>
<tr>
<td>General Medicine</td>
<td>n/a</td>
<td>JAMA</td>
</tr>
<tr>
<td>General Medicine</td>
<td>n/a</td>
<td>Ann Intern Med</td>
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</tbody>
</table>
Search Strategy

Peer-reviewed articles reporting results from RCTs in the 16 journals were identified in NLM/PubMed using the following search strategy:

- Contained the string:
  - Randomized Controlled Trial
  - Controlled Clinical Trial
  - Clinical Trial
  - AND (randomized OR randomised)

- Published in calendar years: 2001 OR 2002 OR 2009 OR 2010

- Published in one of the 16 selected journals

The resulting database was reviewed to assess if the article:
- Reported results of a randomized controlled trial?
- Was funded by Pharma/Biotech/Medical device industry?
- Acknowledged medical writing support?
- Had a Pharma/Biotech/Medical device industry author?

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Search was performed on November 18, 2010; a final update for 2010 articles was performed on February 18, 2011.

Search for these terms was limited to the [ptyp] (Publication type) field.
Results

3505 articles retrieved in NLM/PubMed search

501 articles excluded because did not report on RCTs
- 152 from 2001
- 151 from 2002
- 83 from 2009
- 115 from 2010

3004 articles evaluated in this analysis
- 732 from 2001
- 788 from 2002
- 732 from 2009
- 752 from 2010
### Articles of RCTs by Journal

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<tr>
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</thead>
<tbody>
<tr>
<td>Ann Intern Med</td>
<td>39</td>
<td>56</td>
<td>95</td>
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<td>Arch Dermatol</td>
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<td>Arch Ophthalmol</td>
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<td>Blood</td>
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<td>46</td>
<td>107</td>
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<tr>
<td>Circulation</td>
<td>236</td>
<td>134</td>
<td>370</td>
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<tr>
<td>Clin Infect Dis</td>
<td>61</td>
<td>60</td>
<td>121</td>
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<tr>
<td>Gastroenterology</td>
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<td>57</td>
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<td>Hepatology</td>
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<td>40</td>
<td>75</td>
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<tr>
<td>J Allergy Clin Immunol</td>
<td>68</td>
<td>55</td>
<td>123</td>
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<tr>
<td>J Clin Endocrinol Metab</td>
<td>198</td>
<td>151</td>
<td>349</td>
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<tr>
<td>J Clin Oncol</td>
<td>182</td>
<td>294</td>
<td>476</td>
</tr>
<tr>
<td>JAMA</td>
<td>121</td>
<td>99</td>
<td>220</td>
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<tr>
<td>Lancet</td>
<td>180</td>
<td>170</td>
<td>350</td>
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<tr>
<td>N Engl J Med</td>
<td>157</td>
<td>228</td>
<td>385</td>
</tr>
<tr>
<td>Thorax</td>
<td>71</td>
<td>36</td>
<td>107</td>
</tr>
<tr>
<td>Article Type</td>
<td>2001/2002 n = 1520</td>
<td>2009/2010 n = 1484</td>
<td></td>
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<td>----------------------------------------------------------------------------</td>
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<tr>
<td>Articles with a medical writing/editorial assistance acknowledgement, n (%)</td>
<td>153 (10)</td>
<td>282 (19)</td>
<td></td>
</tr>
<tr>
<td>Articles funded by industry, n (% of total)</td>
<td>650 (43)</td>
<td>706 (48)</td>
<td></td>
</tr>
<tr>
<td>Articles with a medical writing/editorial assistance acknowledgement, n (%)</td>
<td>96 (15)</td>
<td>241 (34)</td>
<td></td>
</tr>
<tr>
<td>Articles with an industry author, n (% of total)</td>
<td>290 (19)</td>
<td>372 (25)</td>
<td></td>
</tr>
<tr>
<td>Articles with a medical writing/editorial assistance acknowledgement, n (%)</td>
<td>60 (21)</td>
<td>196 (53)</td>
<td></td>
</tr>
<tr>
<td>Articles not funded by industry, n (% of total)</td>
<td>870 (57)</td>
<td>778 (52)</td>
<td></td>
</tr>
<tr>
<td>Articles with a medical writing/editorial assistance acknowledgement, n (%)</td>
<td>57 (7)</td>
<td>41 (5)</td>
<td></td>
</tr>
</tbody>
</table>
Number of RCTs Published Did Not Change Between the Time Points Assessed
Acknowledgement of Medical Writing Support Increased from 2002-2009

Percent Acknowledging Medical Writing Assistance

- All
- Industry
- Non-industry

2001/2002

2009/2010
Conclusions

- There was an approximate doubling in the acknowledgement frequency of medical writing/editorial assistance in RCTs from the years 2001/02 to 2009/10

- This increase was due to the increase in the acknowledgement of medical writing/editorial assistance in industry-funded articles
  - This may reflect improved reporting practices or an increase in the use of medical writing assistance

- The frequency of acknowledgement of medical writing/editorial assistance in non-industry funded articles was low and remained unchanged between the 2 time periods

- A key limitation of this analysis is that it was not possible to determine the number of manuscripts in any period in which medical writers/editors participated but were unacknowledged

- This trend in increased reporting of medical writing/editorial assistance suggests that recent publication guidelines have had a positive effect on industry publication practices
Acknowledgements

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