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

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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

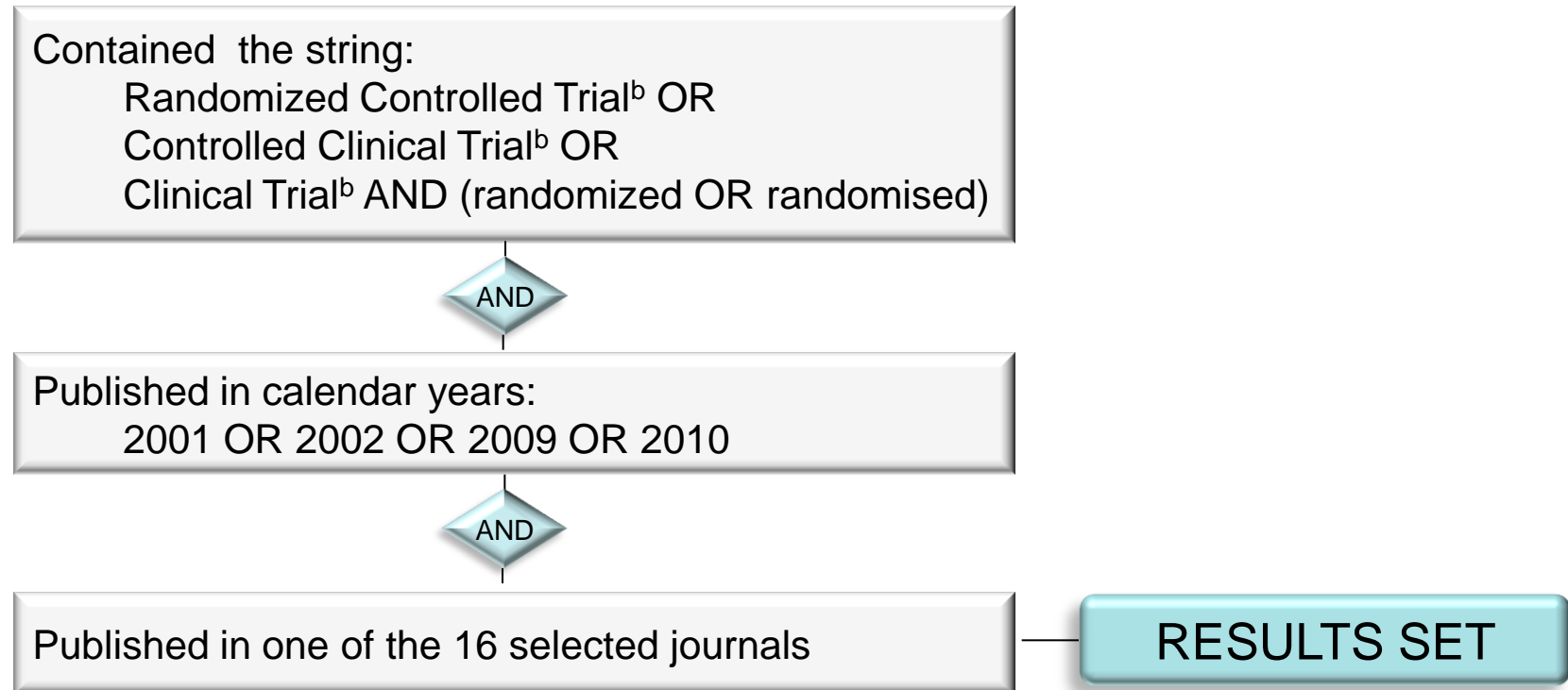
TA= therapeutic area; RCT= randomized controlled trial

Therapeutic Area and Journal Selection

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

Search Strategy

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



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?

^aSearch was performed on November 18, 2010; a final update for 2010 articles was performed on February 18, 2011

^bSearch 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**

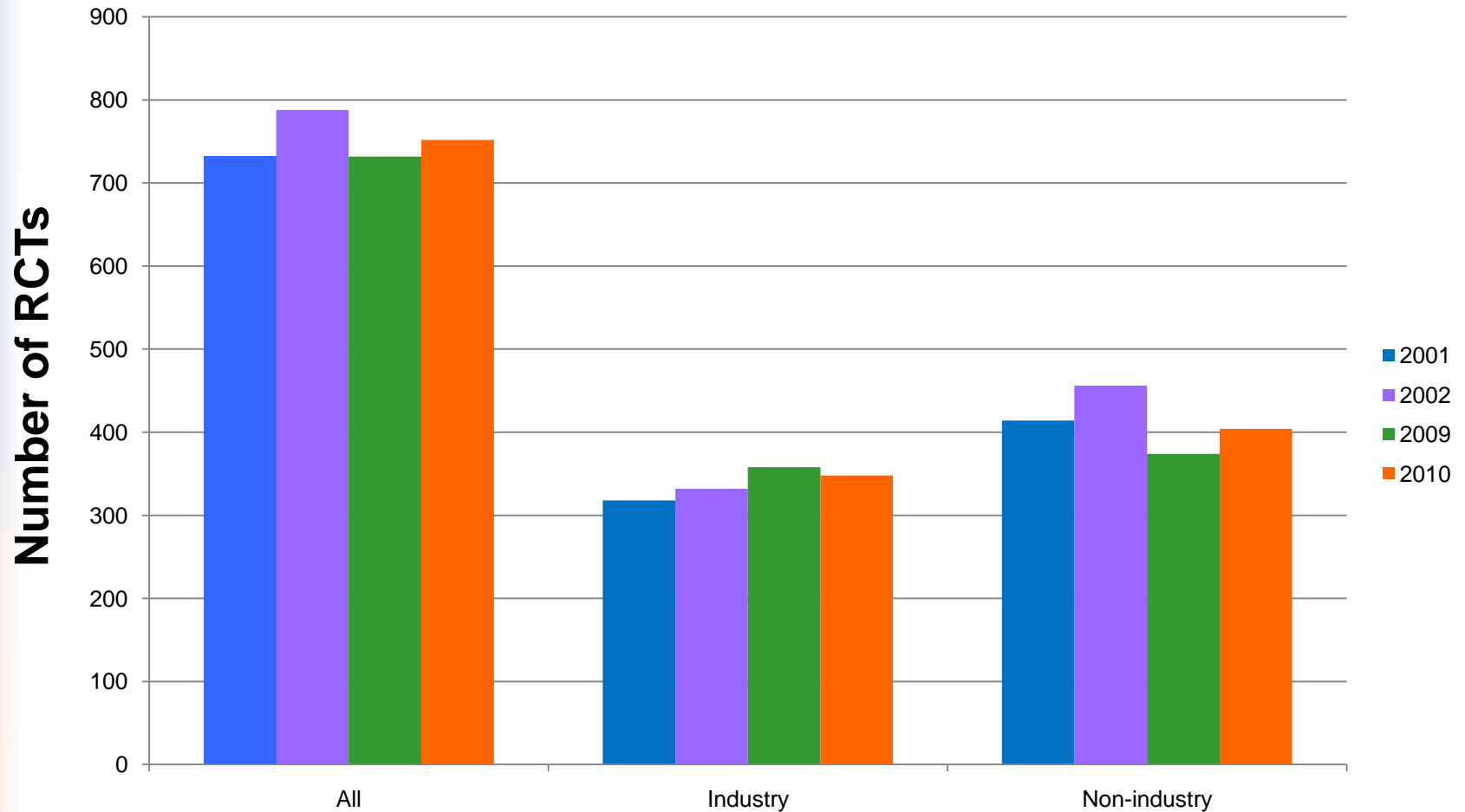
Articles of RCTs by Journal

	2001/2002 n = 1520	2009/2010 n = 1484	Total N = 3004
Articles included in the analysis, n			
<i>Ann Intern Med</i>	39	56	95
<i>Arch Dermatol</i>	19	16	35
<i>Arch Neurol</i>	16	10	26
<i>Arch Ophthalmol</i>	30	32	62
<i>Blood</i>	61	46	107
<i>Circulation</i>	236	134	370
<i>Clin Infect Dis</i>	61	60	121
<i>Gastroenterology</i>	46	57	103
<i>Hepatology</i>	35	40	75
<i>J Allergy Clin Immunol</i>	68	55	123
<i>J Clin Endocrinol Metab</i>	198	151	349
<i>J Clin Oncol</i>	182	294	476
<i>JAMA</i>	121	99	220
<i>Lancet</i>	180	170	350
<i>N Engl J Med</i>	157	228	385
<i>Thorax</i>	71	36	107

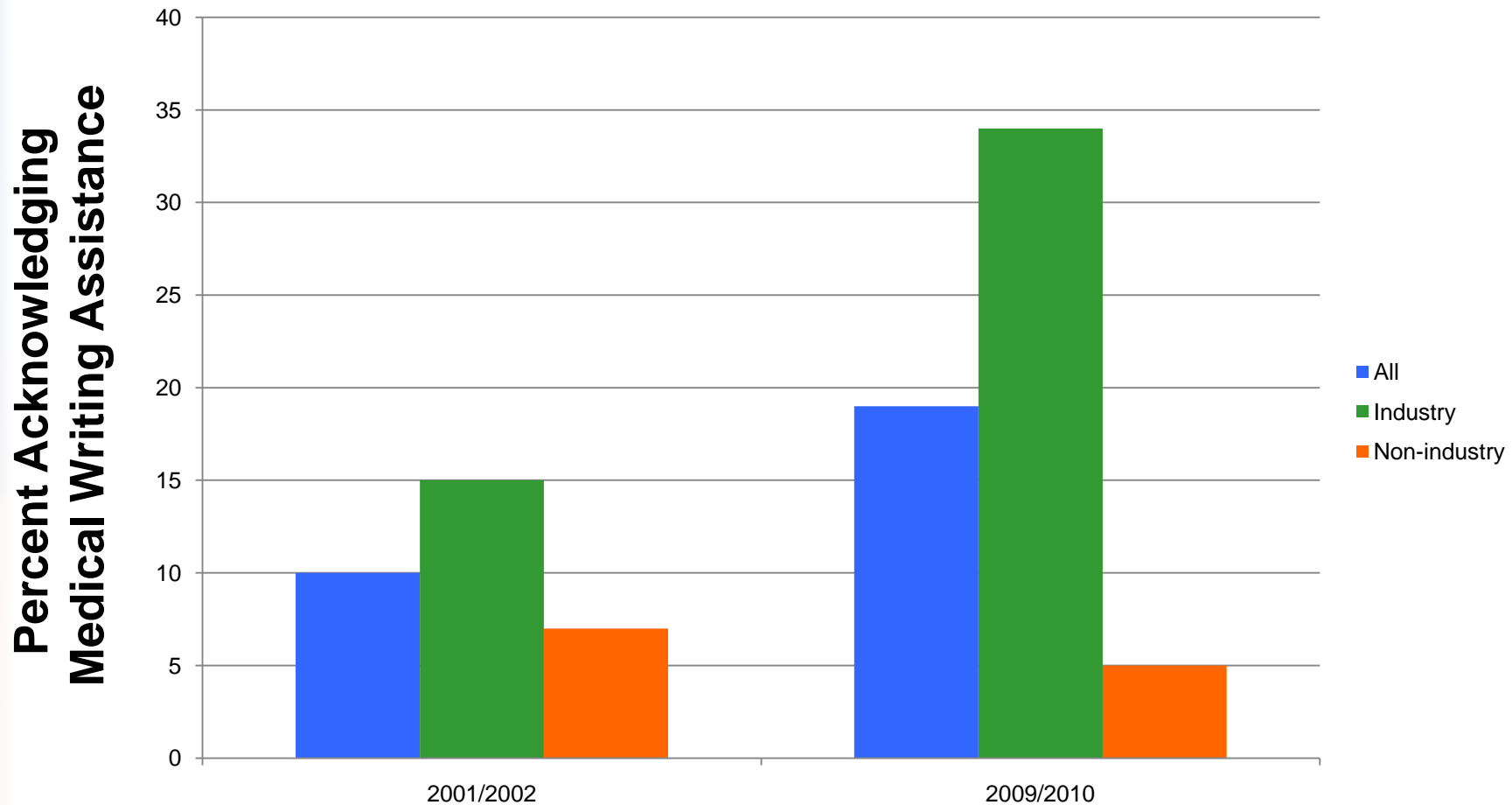
Medical Writing Acknowledgement From Industry- And Non-Industry Funded Articles

	2001/2002 n = 1520	2009/2010 n = 1484
Articles with a medical writing/editorial assistance acknowledgement, n (%)	153 (10)	282 (19)
Articles funded by industry, n (% of total)	650 (43)	706 (48)
Articles with a medical writing/editorial assistance acknowledgement, n (%)	96 (15)	241 (34)
Articles with an industry author, n (% of total)	290 (19)	372 (25)
Articles with a medical writing/editorial assistance acknowledgement, n (%)	60 (21)	196 (53)
Articles not funded by industry, n (% of total)	870 (57)	778 (52)
Articles with a medical writing/editorial assistance acknowledgement, n (%)	57 (7)	41 (5)

Number of RCTs Published Did Not Change Between the Time Points Assessed



Acknowledgement of Medical Writing Support Increased from 2002-2009



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

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