Reporting concerns about data integrity for 33 randomized trials in 18 journals from one research group: a narrative review

The Long and Winding Road (Lennon-McCartney)

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Conflict of interest statements

• None of the authors has a conflict to disclose

• All authors wish to improve the integrity of the research literature
Aims

To describe our approach to reporting concerns identified in a large set of clinical trial reports

To describe the responses of the recipients of our concerns (to date)

To describe how events unfolded (to date, caution: missing data abound)

To consider what could be improved
By March 2013...

Serious concerns about integrity/validity of data

33 RCTs, published 1997-2012, N = 6253

18 Journals, 26 Authors, 12 Institutions

‘Stick with me babe
Stick with me anyhow
Things should start to get interesting
right about now’
Dylan, Mississippi

‘The play’s the thing.
Wherein I’ll catch the conscience of the king’
Shakespeare, Hamlet
email to journal 1 editor + manuscript, internal review undertaken
What should the first move have been?

2013

Q1

email to journal 1 editor + manuscript, internal review undertaken
Email to journal 1 editor + manuscript, internal review undertaken

Q1

Journal 1 contacts author

No update, journal 1 says no response

Journal 1 re-contacts author who requests more time

Author responds to journal 1
Journal 1 contacts host institution (which?)
Journal 1 contacts host institution (which?)

At this point, should the journal contact other affected journals?
Journal 1 contacts host institution (which?)

email to journal 1 for update
no response

email to journal 1 for update
no response
email to journal 1 for update

No success in contacting various officials
Issuing a notice of concern in the next month
Declines to publish manuscript
“...if there are concerns about data integrity...you should contact the Editors of those journals.”

Journal 1 publishes EoC

Now is the winter of our discontent
*Shakespeare, Richard III*
Now is the winter of our discontent
*Shakespeare, Richard III*

2015

- **Jan**: Email to journal 1 for update
- **Feb**: Journal 1 publishes EoC
- **Mar**: Email and submit paper to journal 2, declines paper, says it will ‘review (the) concerns carefully’
- **Apr**: Email and submit paper to journal 3, declines paper, undertakes stats review, issues EoC, notifies journal 4, launches investigation
- **May**: No success in contacting various officials
- **Jun**: Issuing a notice of concern in the next month
- **Jul**: Declines to publish manuscript
- **Aug**: “…if there are concerns about data integrity...you should contact the Editors of those journals.”
- **Sep**: Q3
- **Oct**: No success in contacting various officials
- **Nov**: Declines to publish manuscript
- **Dec**:…”if there are concerns about data integrity...you should contact the Editors of those journals.”
Now is the winter of our discontent

Shakespeare, Richard III

email to journal 1 for update

Declines to publish manuscript
“...if there are concerns about data integrity...you should contact the Editors of those journals.”

email and submit paper to journal 2, declines paper, says it will ‘review (the) concerns carefully’

email and submit paper to journal 3, declines paper, undertakes stats review, issues EoC, notifies journal 4, launches investigation

How many investigations are required? Should there be one coordinated investigation?

email to journal 1 for update

Journal 1 publishes EoC

2015

Q3

No success in contacting various officials
Issuing a notice of concern in the next month
Declines to publish manuscript
“...if there are concerns about data integrity...you should contact the Editors of those journals.”
Journal 5 declines publication: “... a published journal article (is not) the most appropriate way to (raise concerns), particularly in a journal that has not published any of the articles in question. 
...concerns raised regarding published articles should be investigated by the journal in which the article has been published, in collaboration with the institution where the research took place”

No success in contacting various officials
Issuing a notice of concern in the next month
Declines to publish manuscript
“...if there are concerns about data integrity...you should contact the Editors of those journals.”

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2015

Q4

Journal 5 declines publication: “… a published journal article (is not) the most appropriate way to (raise concerns), particularly in a journal that has not published any of the articles in question. …concerns raised regarding published articles should be investigated by the journal in which the article has been published, in collaboration with the institution where the research took place”

Should journals decline academic work in the area simply because they are not involved?

Declines to publish manuscript
“...if there are concerns about data integrity...you should contact the Editors of those journals.”

email to journal 1 for update

email and submit paper to journal 2, declines paper, says it will ‘review (the) concerns carefully’

email and submit paper to journal 3, declines paper, undertakes stats review, issues EoC, notifies journal 4, launches investigation

email enquiry to editors of journal 5, unaffected, encouraged to submit paper

Journal 1 publishes EoC

No success in contacting various officials
Issuing a notice of concern in the next month
Declines to publish manuscript
“...if there are concerns about data integrity...you should contact the Editors of those journals.”

Now is the winter of our discontent
Shakespeare, Richard III

2
Now is the winter of our discontent
*Shakespeare, Richard III*

In 2015:

- Email to Journal 1 for update
- Email and submit paper to Journal 2, declines paper, says it will 'review (the) concerns carefully'
- Email and submit paper to Journal 3, declines paper, undertakes stats review, issues EoC, notifies Journal 4, launches investigation
- Email and submit paper to Journal 5, unaffected, encouraged to submit paper
- Email enquiry to editors of Journal 5
- Email to Journal 6, launches investigation, undertakes stats and peer review

Journal 1 publishes EoC

Journal 3 retracts 1 paper

Journal 5 declines publication: “...a published journal article (is not) the most appropriate way to (raise concerns), particularly in a journal that has not published any of the articles in question. …concerns raised regarding published articles should be investigated by the journal in which the article has been published, in collaboration with the institution where the research took place.”

“After many attempts at contacting various officials *without success* we will be issuing a notice of concern in the next month or so”

“We will not be publishing your manuscript”

“...if there are concerns about data integrity...you should contact the Editors of those journals.”

Now is the winter of our discontent
*Shakespeare, Richard III*
Journal 6 reviews complete, asks Sato et al to respond

We learn indirectly that an institution is investigating, but not which

We learn in confidence that Sato admits misconduct, co-authors all ‘honorary’

Journal 4 retracts its paper

Journal 7 retracts a paper, not in our analysis

Journals 1 and 2 retract papers

Journal 6 retracts 3 papers and a letter
We learn indirectly that an institute is investigating, but not which.

We learn in confidence that Sato admits misconduct, co-authors all ‘honorary’.

Journal 5 editor expresses frustration at delay to retraction.

Journal 6 retracts 3 papers and a letter.

Journal 6 reviews complete, asks Sato et al to respond.

Journals 1 and 2 retract papers.

Should correspondence about retracted papers from authors be routinely retracted?
Journal 6 reviews complete, asks Sato et al to respond

We learn indirectly that an institution is investigating, but not which

We learn in confidence that Sato admits misconduct, co-authors all ‘honorary’

Journal 6 publishes manuscript, indicates data fabrication occurred, that it communicated with other affected journals

Journal 7 retracts a paper, not in our analysis

Journal 3 retracts its other paper

Journal 5 retracts its paper

Journal 5 retracts 3 papers and a letter

Journal 6 retracts 3 papers and a letter

Journal 5 editor expresses frustration at delay to retraction

Journals 1 and 2 retract papers

Email to journal 8 about 2 systematic reviews based on retracted work
How should journals and publishers deal with meta-analyses and reviews which feature retracted work?

- January: Journal 6 reviews complete, asks Sato et al to respond.
- February: We learn in confidence that Sato admits misconduct, co-authors all ‘honorary’.
- March: Journal 6 publishes manuscript, indicates data fabrication occurred, that it communicated with other affected journals.
- April: Journals 1 and 2 retract papers.
- May: Journal 3 retracts its other paper.
- June: Journal 5 editor expresses frustration at delay to retraction.
- July: Journal 6 retracts 3 papers and a letter.
- August: Journal 3 retracts its other paper.
- September: Email to journal 8 about 2 systematic reviews based on retracted work.
- October: Journal 5 editor expresses frustration at delay to retraction.
- November: Journals 1 and 2 retract papers.
- December: We learn indirectly that an institution is investigating, but not which.

Q6: How should journals and publishers deal with meta-analyses and reviews which feature retracted work?
Email journals 1-4, 6 to ask about the status of journal and institutional investigations. 2 reply, 1 somewhat helpful
Email journals 1-4, 6 to ask about the status of journal and institutional investigations. 2 reply, 1 somewhat helpful.

Should journals and publishers be more forthcoming in the face of unresolved concerns when their own investigations are complete?
Email journals 1-4, 6 to ask about the status of journal and institutional investigations. 2 reply, 1 somewhat helpful

Email journals 9-11 about meta-analyses/reviews that depend on retracted work

Email journals 12-24 to enquire about status of papers included in our systematic review. Some reply, some don’t

Email 3 medical societies (3), 3 universities (2), 1 hospital and 2 science organizations (1) in Japan to voice ongoing concerns
Email journals 9-11 about meta-analyses/reviews that depend on retracted work

Email journals 13-25 to enquire about status of papers included in our systematic review. Some reply, some don’t

Should we have done this? Should someone else have done this? Has someone already done this? What should we do if no satisfactory investigation ensues?

Email 3 medical societies (3), 3 universities (2), 1 hospital and 2 science organizations (1) in Japan to voice ongoing concerns
Email journals 9-11 about meta-analyses/reviews that depend on retracted work

Email journals 12-24 to enquire about status of papers included in our systematic review. Some reply, some don’t

Email journals 1-4, 6 to ask about the status of journal and institutional investigations. 2 reply, 1 somewhat helpful

Email 3 medical societies (3), 3 universities (2), 1 hospital and 2 science organizations (1) in Japan to voice ongoing concerns

We learn that 1 institution has completed an investigation that found evidence of data fabrication and misconduct over authorship, findings are ‘in-house’
Email journals 1-4, 6 to ask about the status of journal and institutional investigations. 2 reply, 1 somewhat helpful.

Email journals 9-11 about meta-analyses/reviews that depend on retracted work.

Email 3 medical societies (3), 3 universities (2), 1 hospital and 2 science organizations (1) in Japan to voice ongoing concerns.

We learn that 1 university has completed an investigation that found evidence of data fabrication and misconduct over authorship, findings are ‘in-house’.

Q9: How do we deal with this knowledge?
Email journals 9-11 about meta-analyses/reviews that depend on retracted work

Email journals 1-4, 6 to ask about the status of journal and institutional investigations. 2 reply, 1 somewhat helpful

Email 3 medical societies (3), 3 universities (2), 1 hospital and 2 science organizations (1) in Japan to voice ongoing concerns

Email journals 12-24 to enquire about status of papers included in our systematic review. Some reply, some don’t

Journal 9 retracts a review

Journal 12 retracts its paper

We learn that 1 COPE signatory journal ‘does not investigate issues of misconduct’

We learn that 1 university has completed an investigation that found evidence of data fabrication and misconduct over authorship, findings are ‘in-house’

2017
‘The world of research has gone berserk’

Dylan, Nettie Moore

WHAT IS KNOWN

Two authors have published >300 papers: RCTs, cohort studies, preclinical studies, reviews largely based on their own research. Our review of 33 human RCTs raised numerous concerns. The 3 trials in journal 6 were fraudulent. Numerous journals and institutions have been informed. Other evidence of misconduct is known. 16 retraction have been issued.

WHAT IS UNKNOWN

Number, status and results of investigations?
How many of the human RCTs involve fabricated data?
Do any of the other publications involve fabricated data? Or other types of research misconduct?
Is any of the scientific literature produced by and referring to the works of these authors valid?
Will the unknown become known?
Why did this happen?
For Discussion

1. How should ‘whistleblowers’ proceed if multiple journals are involved?
2. How should journal editors and publishers proceed if multiple journals are involved? Should the index journal contact other affected journals? When?
3. How many investigations are required in this situation? Should there be one coordinated investigation? Overseen by whom?
4. Should unaffected journals decline publication of academic investigation of misconduct simply because they are not affected?
5. Should correspondence from authors of retracted papers be routinely retracted?
6. How should journals and publishers deal with meta-analyses and reviews which feature retracted work?
7. Should journals be more forthcoming with information about institutional and other investigations?
8. Should ‘whistleblowers’ contact research institutions beyond journals? Which ones? When?