

# **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'**

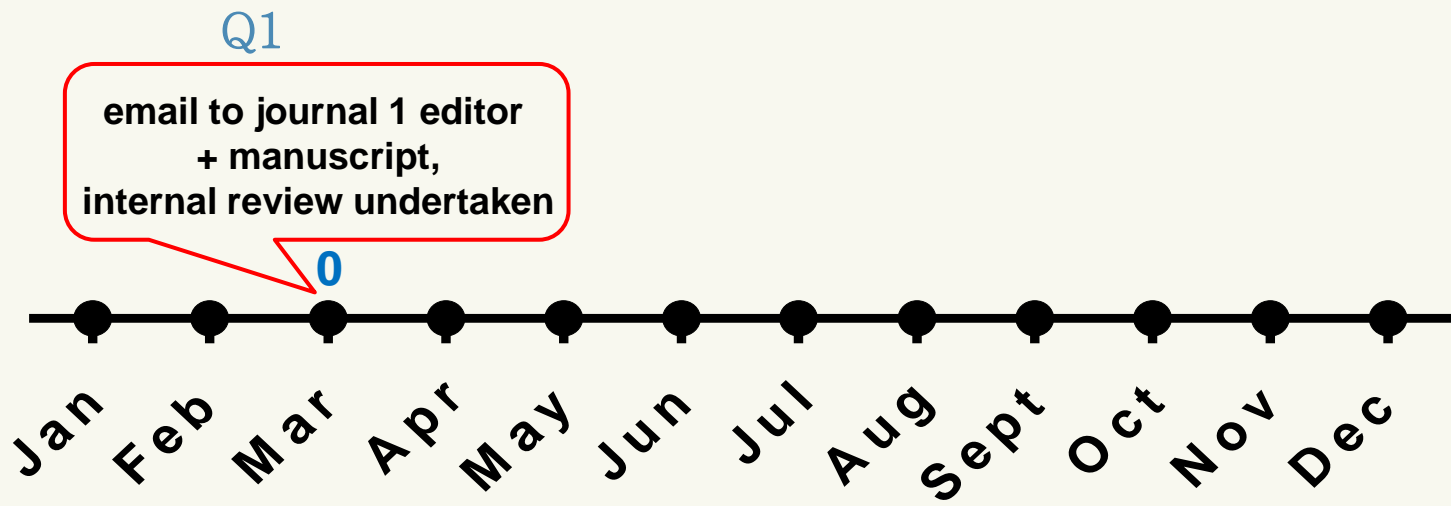
*Dylan, Mississippi*

**'The play's the thing.**

**Wherein I'll catch the conscience of the king'**

*Shakespeare, Hamlet*

2013



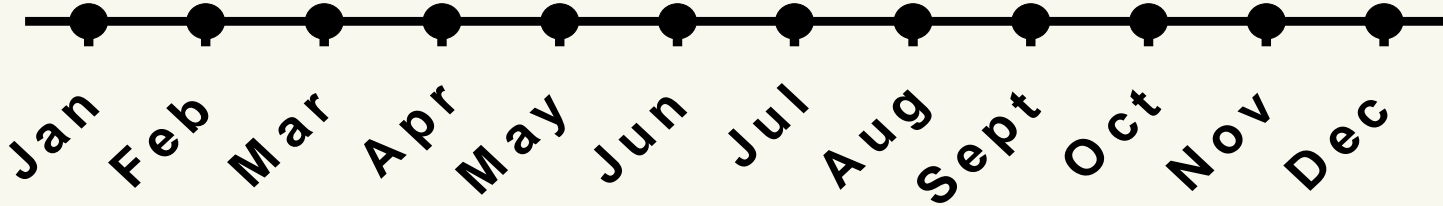
What should the first move have been?

Q1

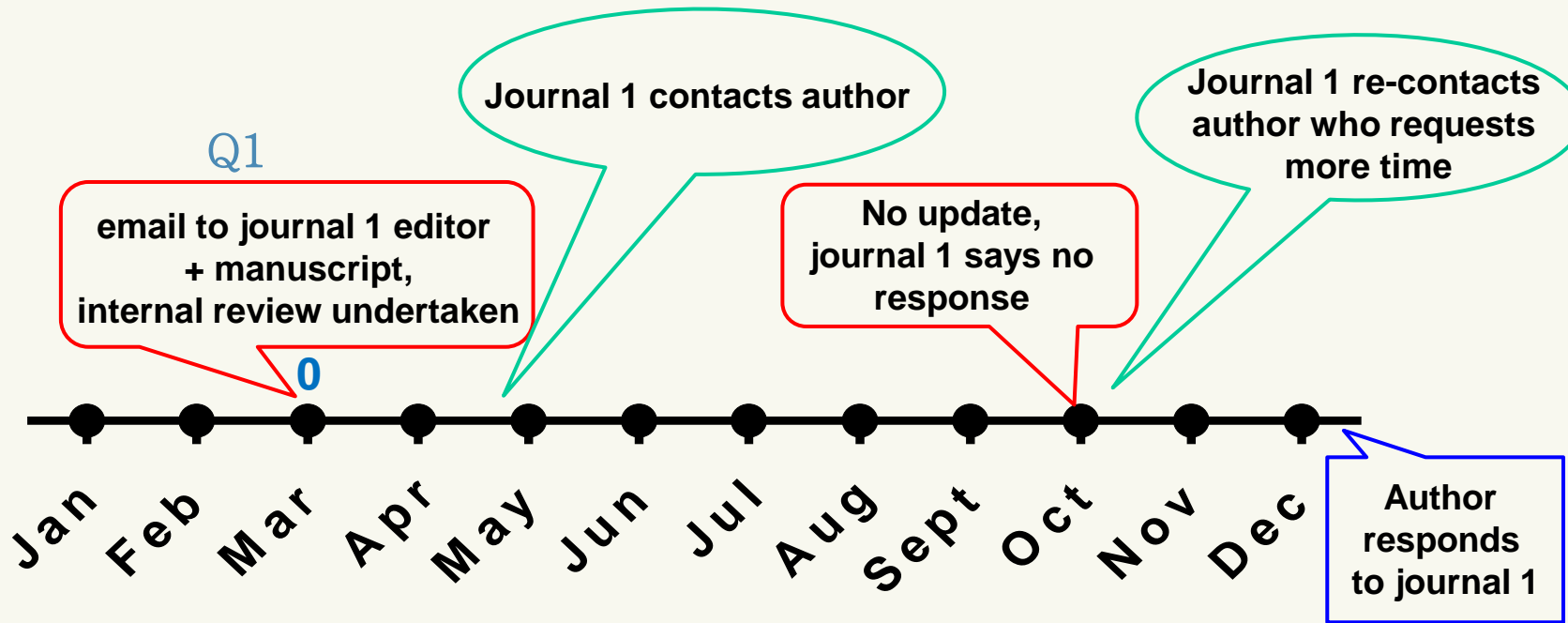
email to journal 1 editor  
+ manuscript,  
internal review undertaken

0

2013



2013



Q1

email to journal 1 editor + manuscript, internal review undertaken

0

Journal 1 contacts author

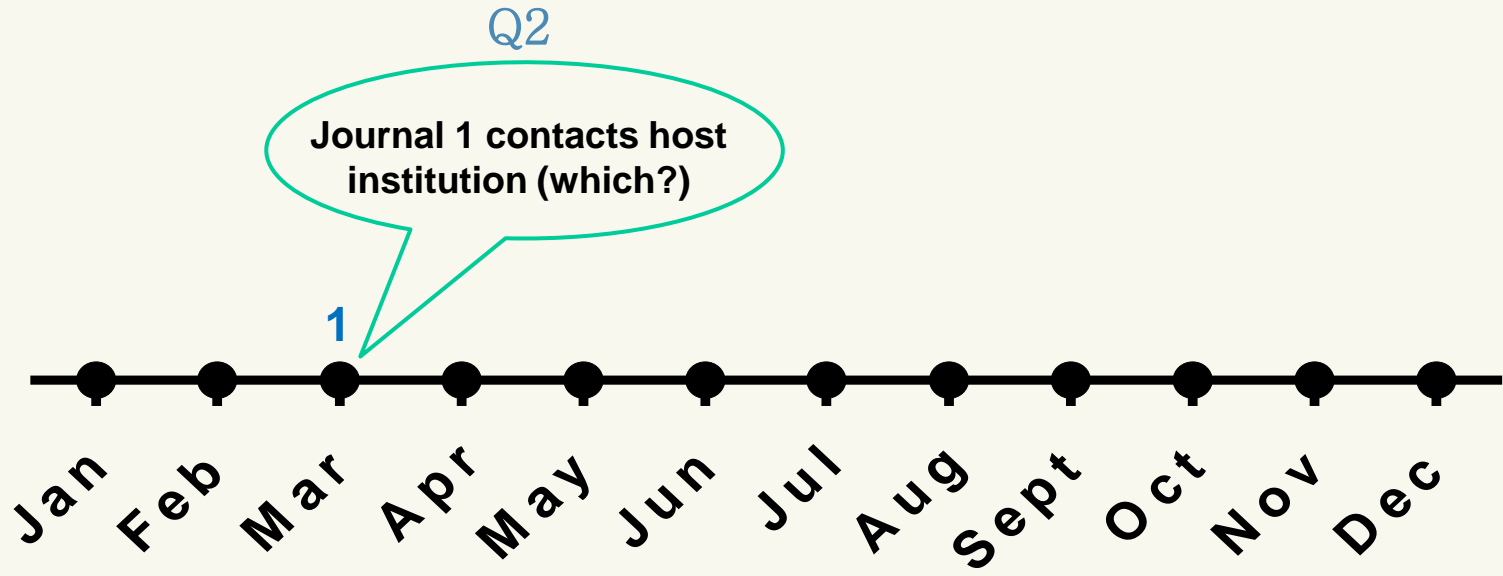
No update, journal 1 says no response

Journal 1 re-contacts author who requests more time

Author responds to journal 1

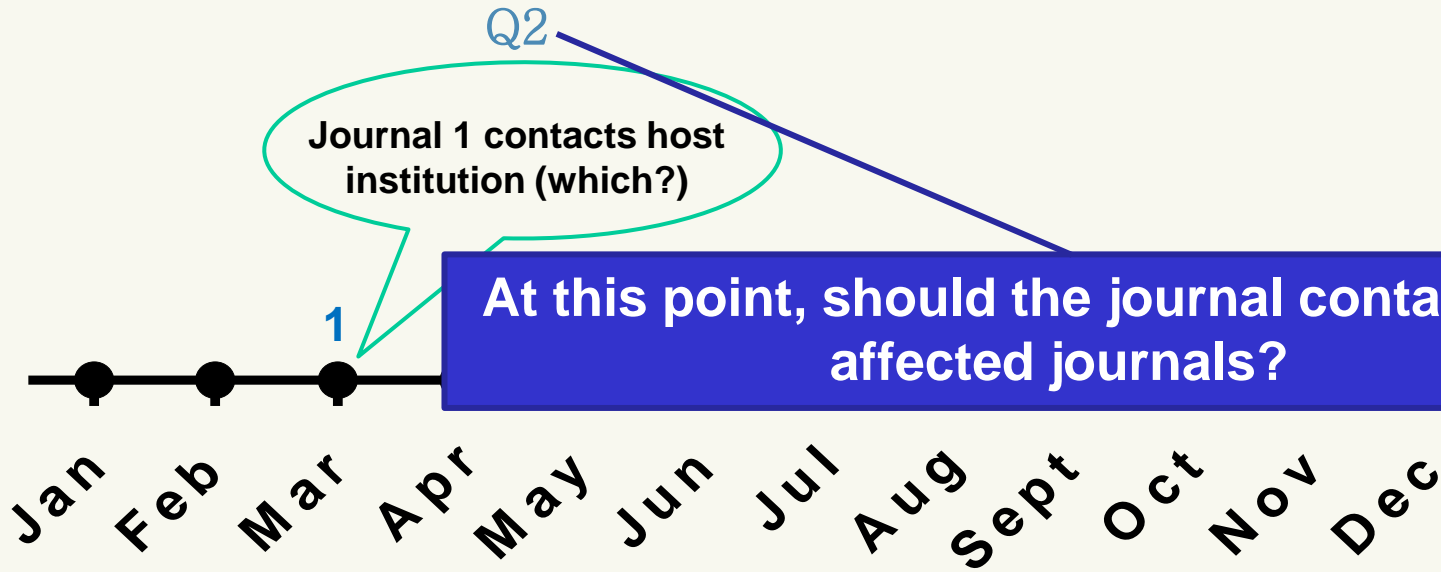
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2014

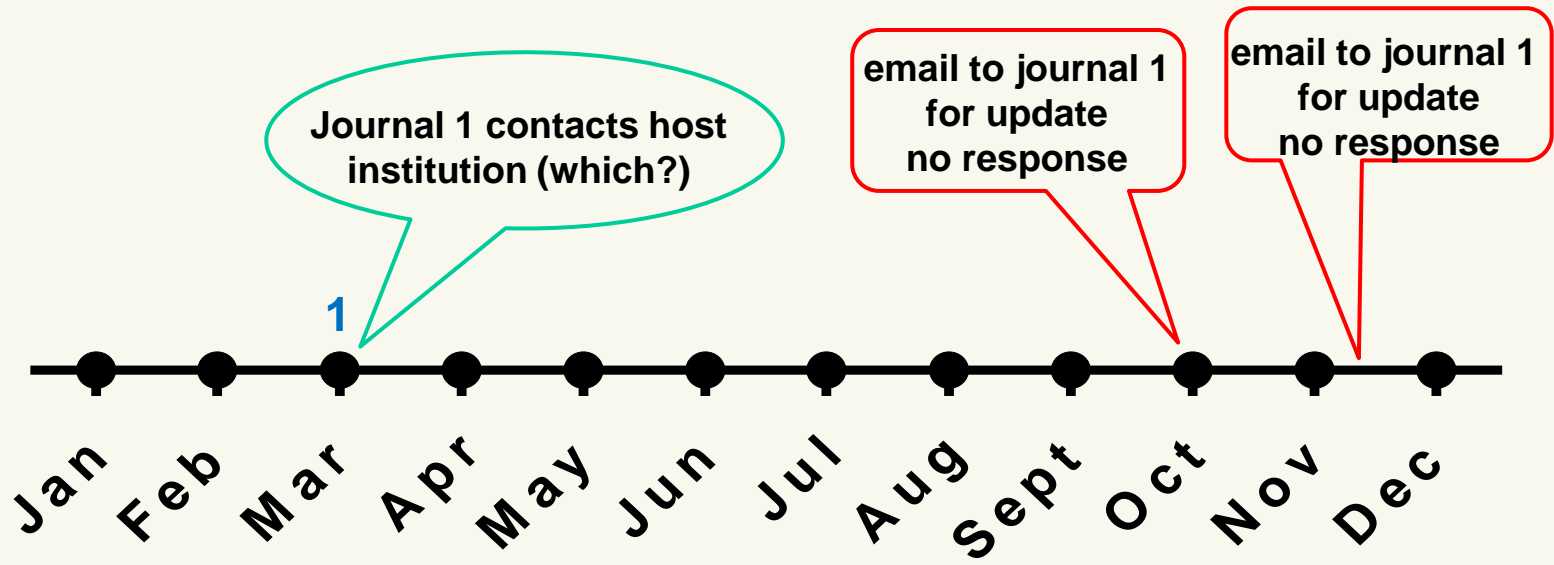




2014

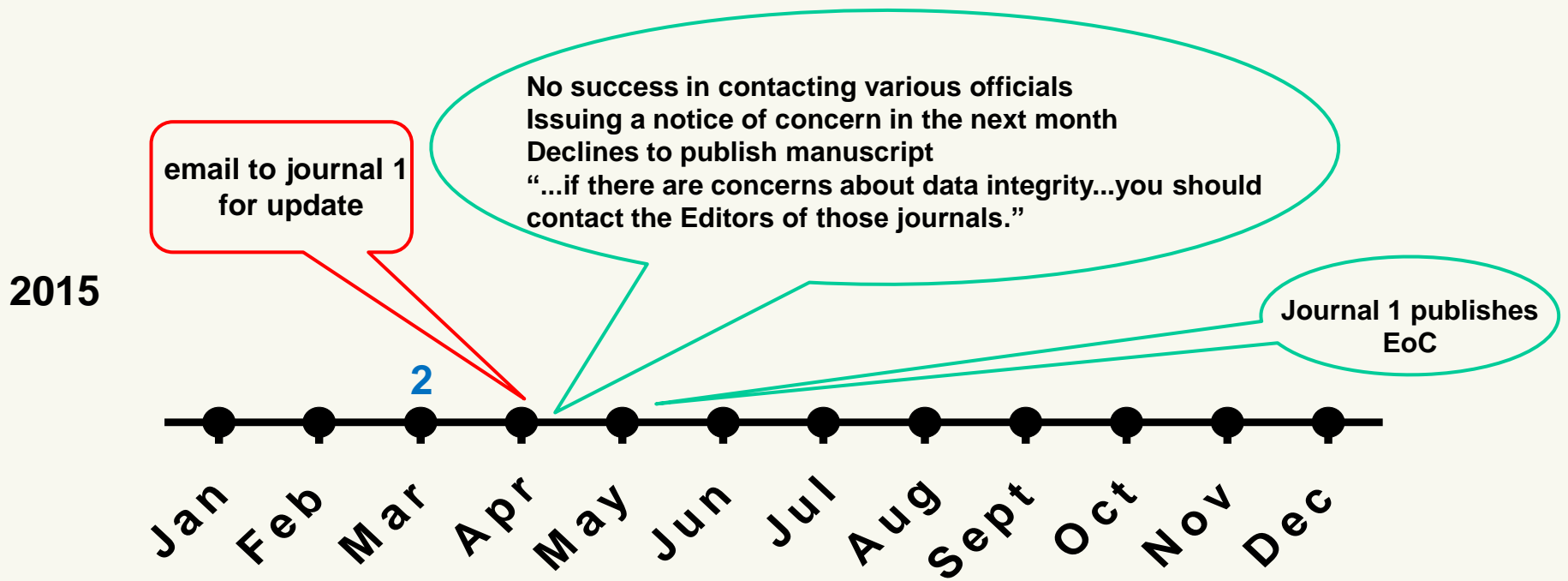


2014



# Now is the winter of our discontent

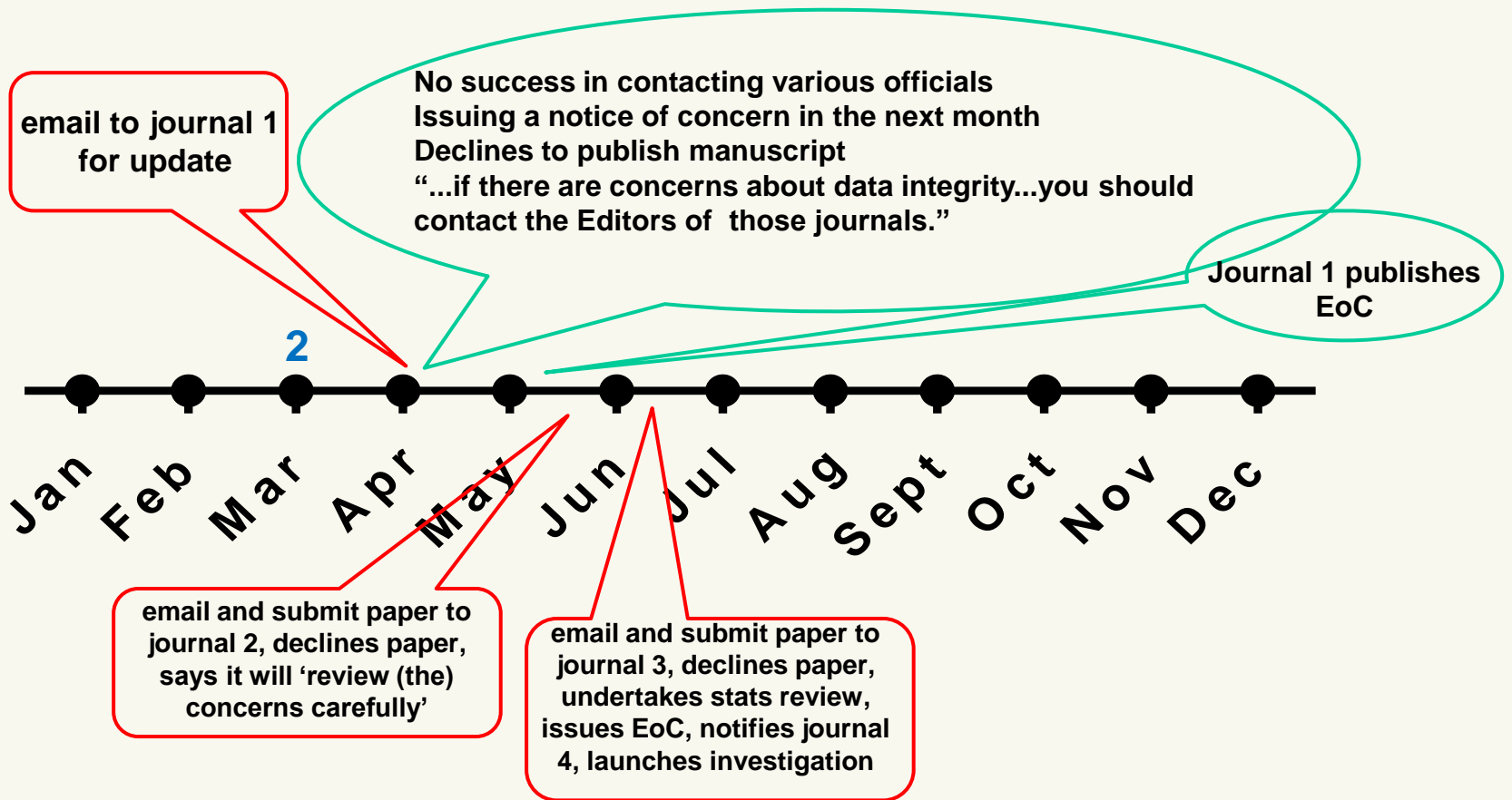
*Shakespeare, Richard III*



# Now is the winter of our discontent

*Shakespeare, Richard III*

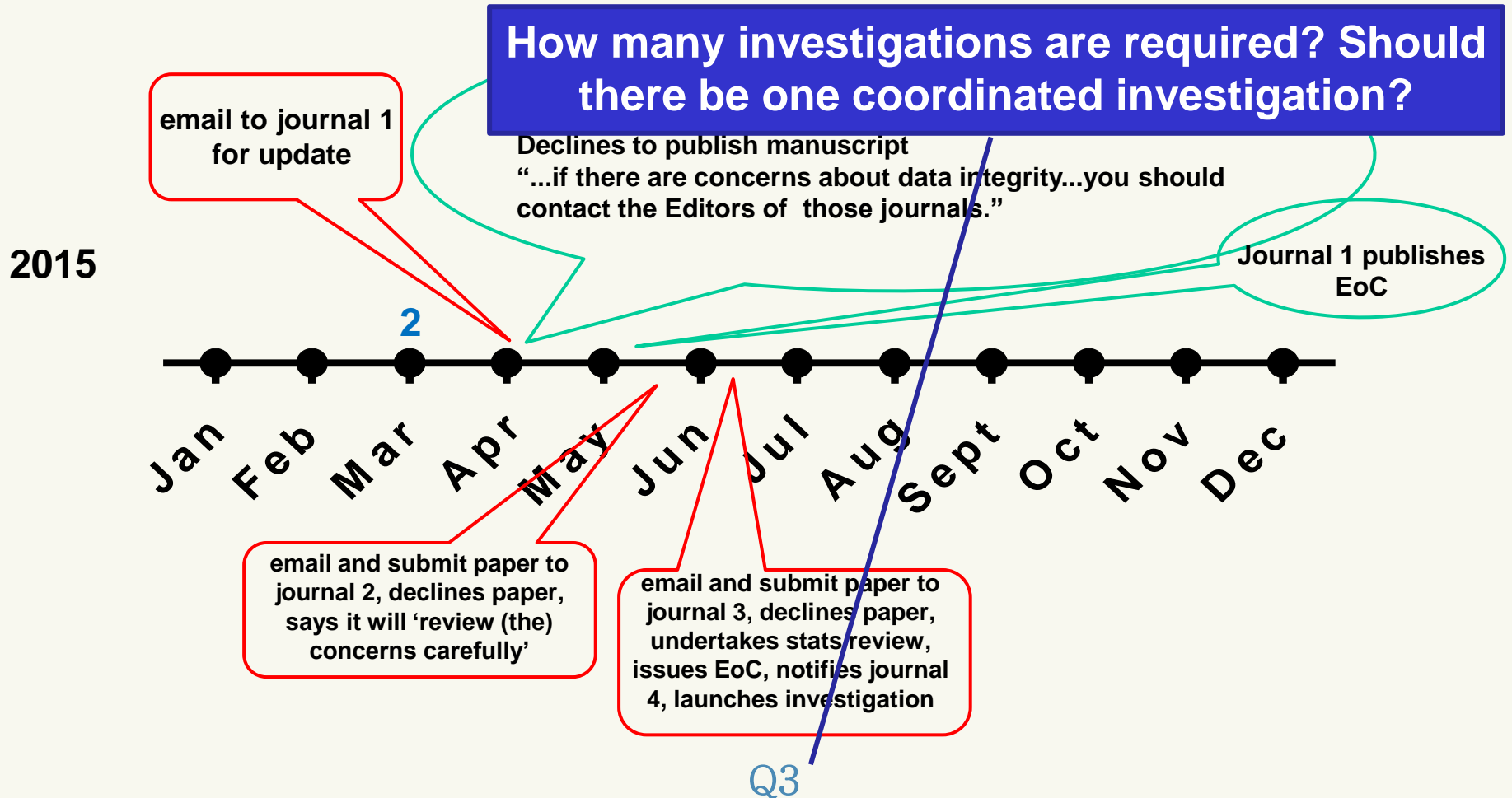
2015



Q3

# Now is the winter of our discontent

*Shakespeare, Richard III*

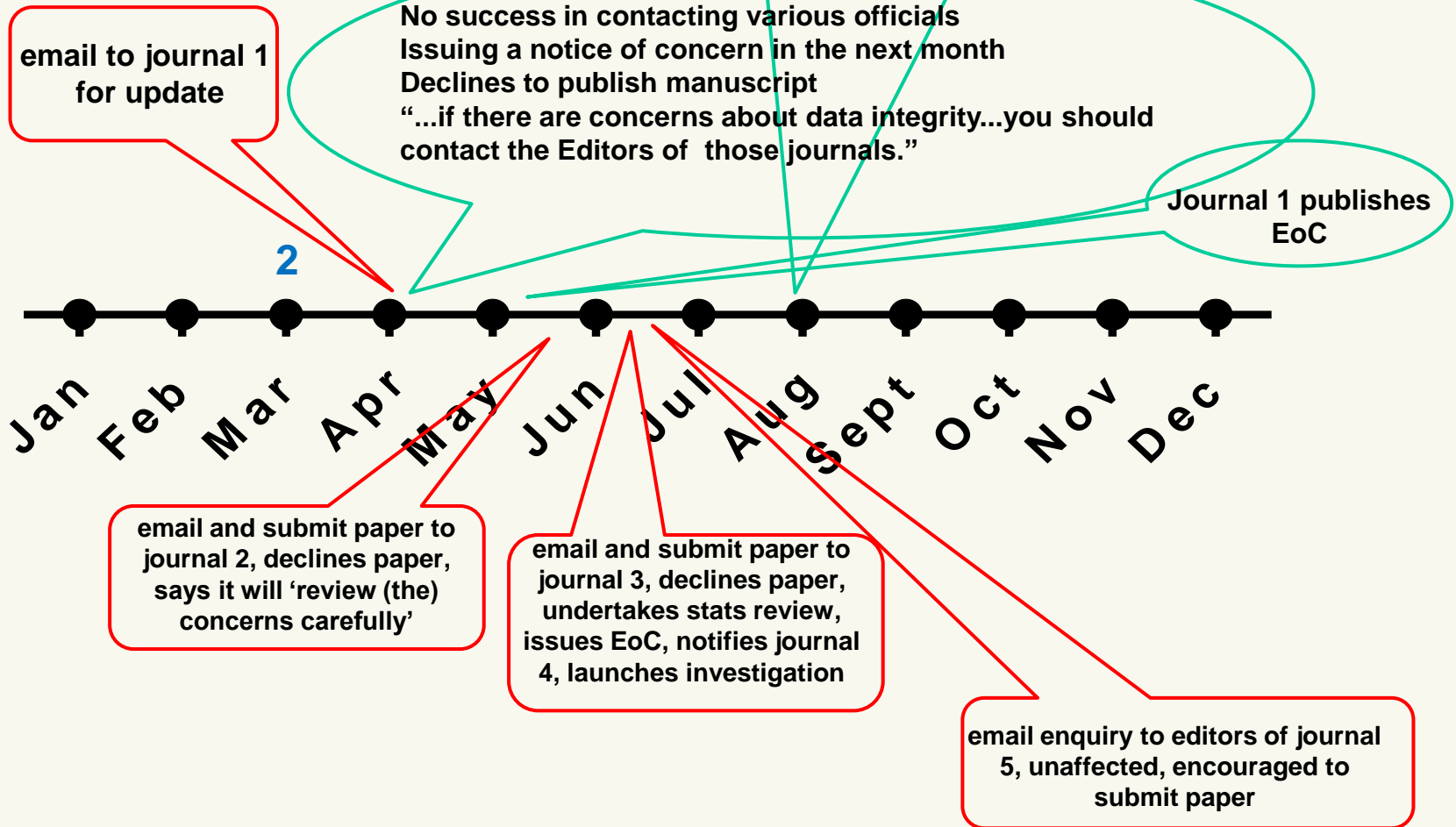


**Now is the winter of  
our discontent**  
*Shakespeare, Richard III*

Q5

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"

2015



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

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

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

2015

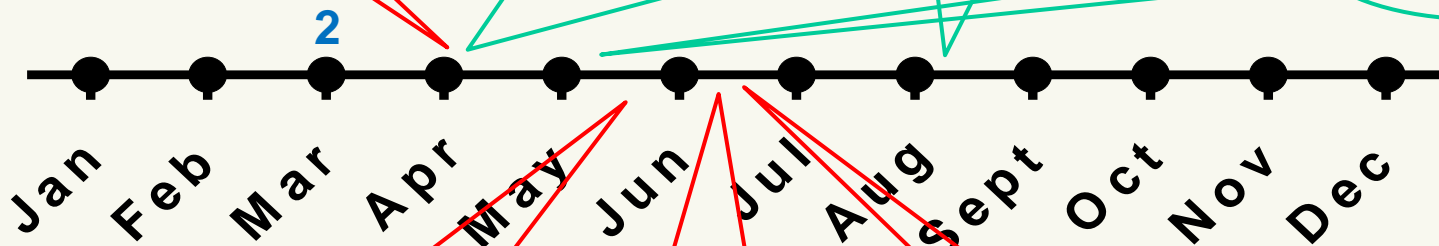
Q4

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."

Journal 1 publishes  
EoC



email to journal 1  
for update

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

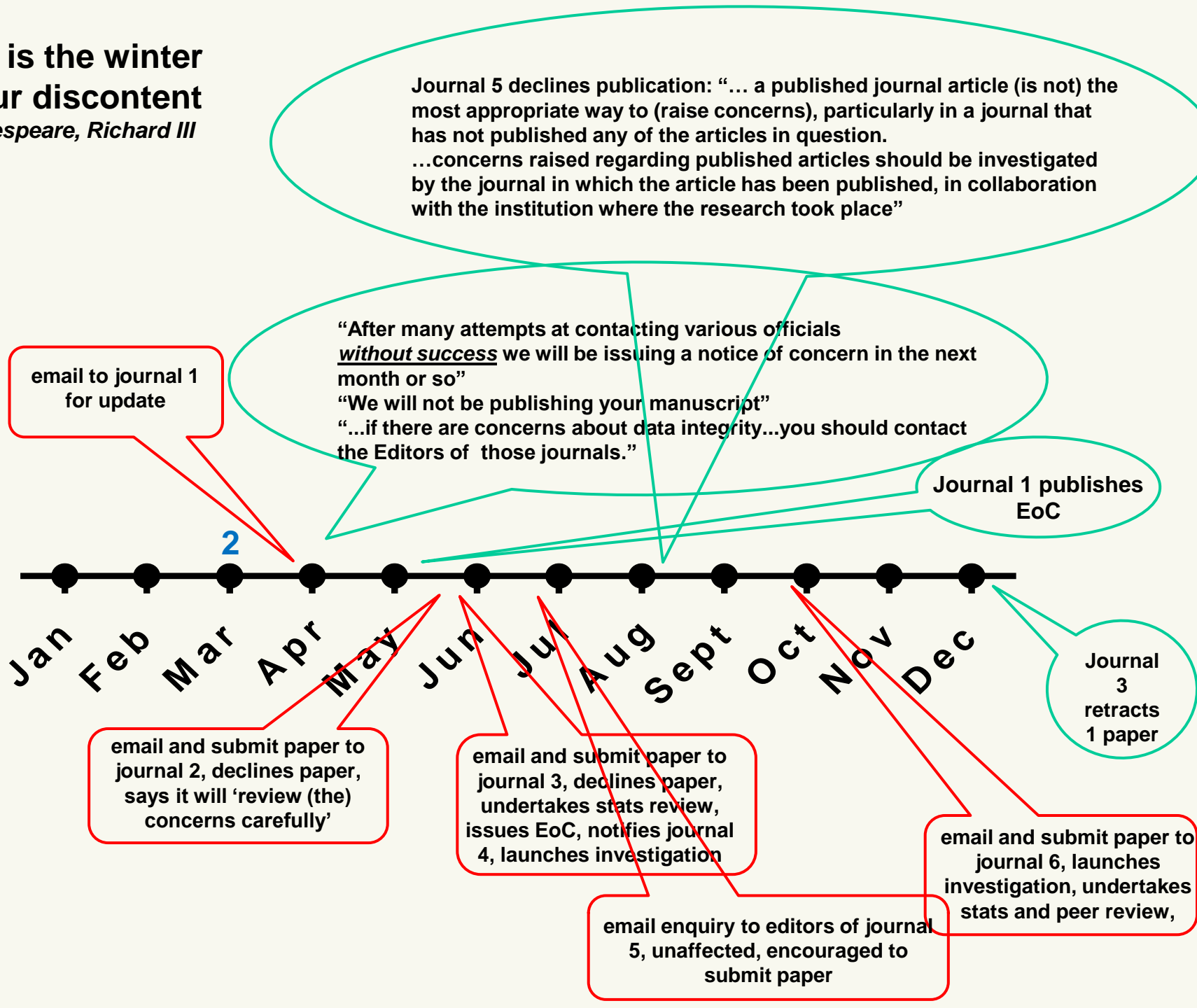
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# Now is the winter of our discontent

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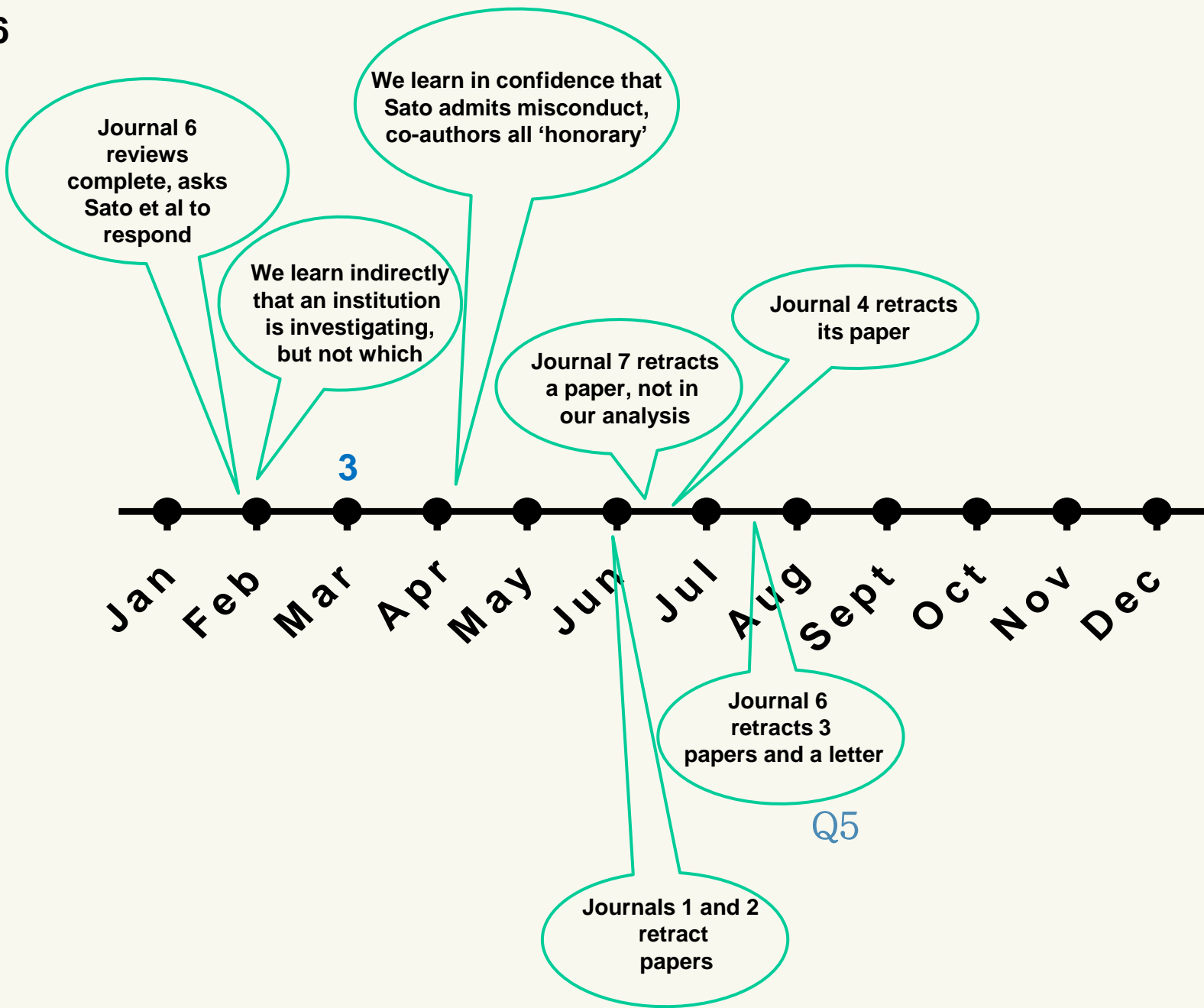
email and submit paper to journal 3, declines paper, undertakes stats review, issues EoC, notifies journal 4, launches investigation

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

email and submit paper to journal 6, launches investigation, undertakes stats and peer review,

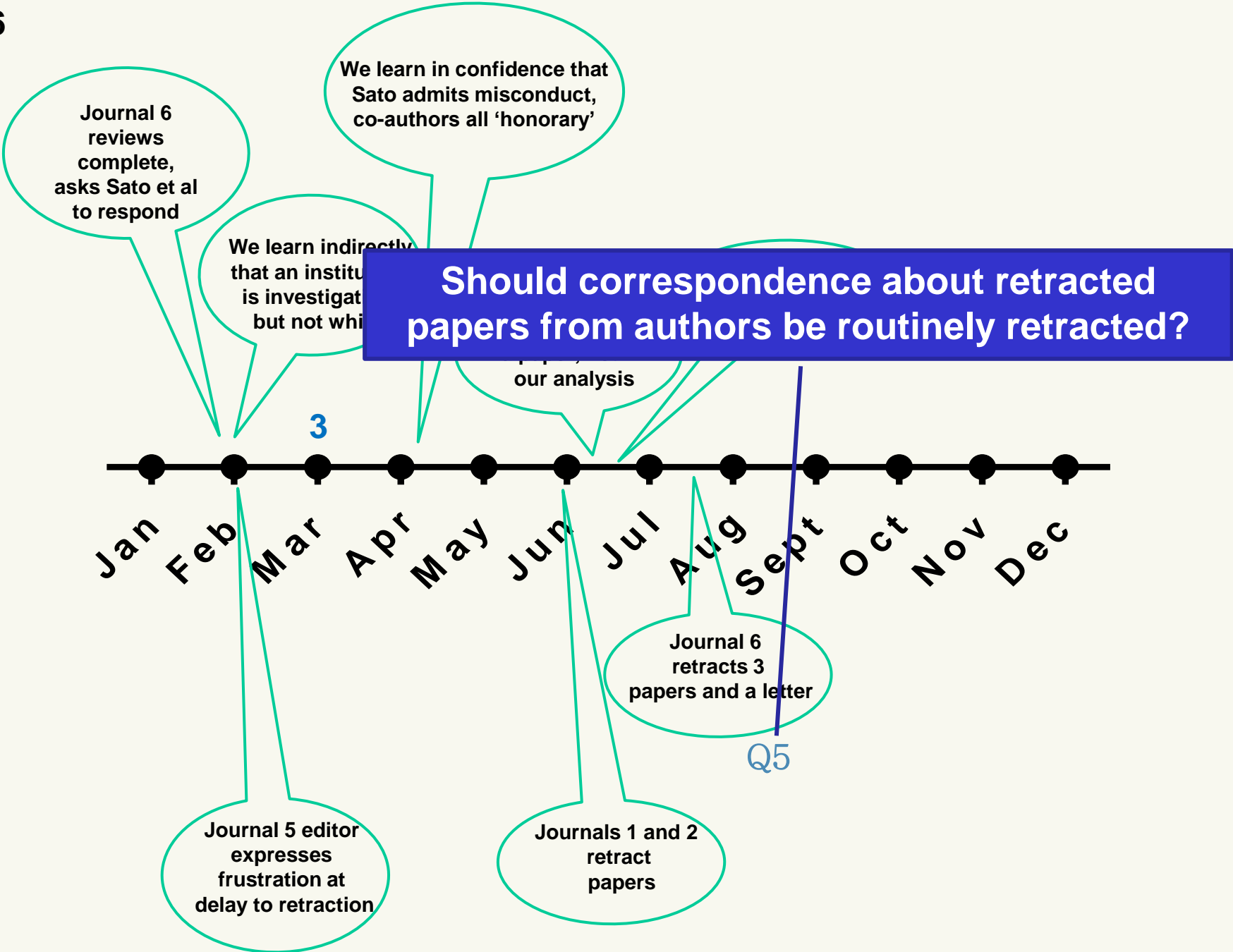


2016

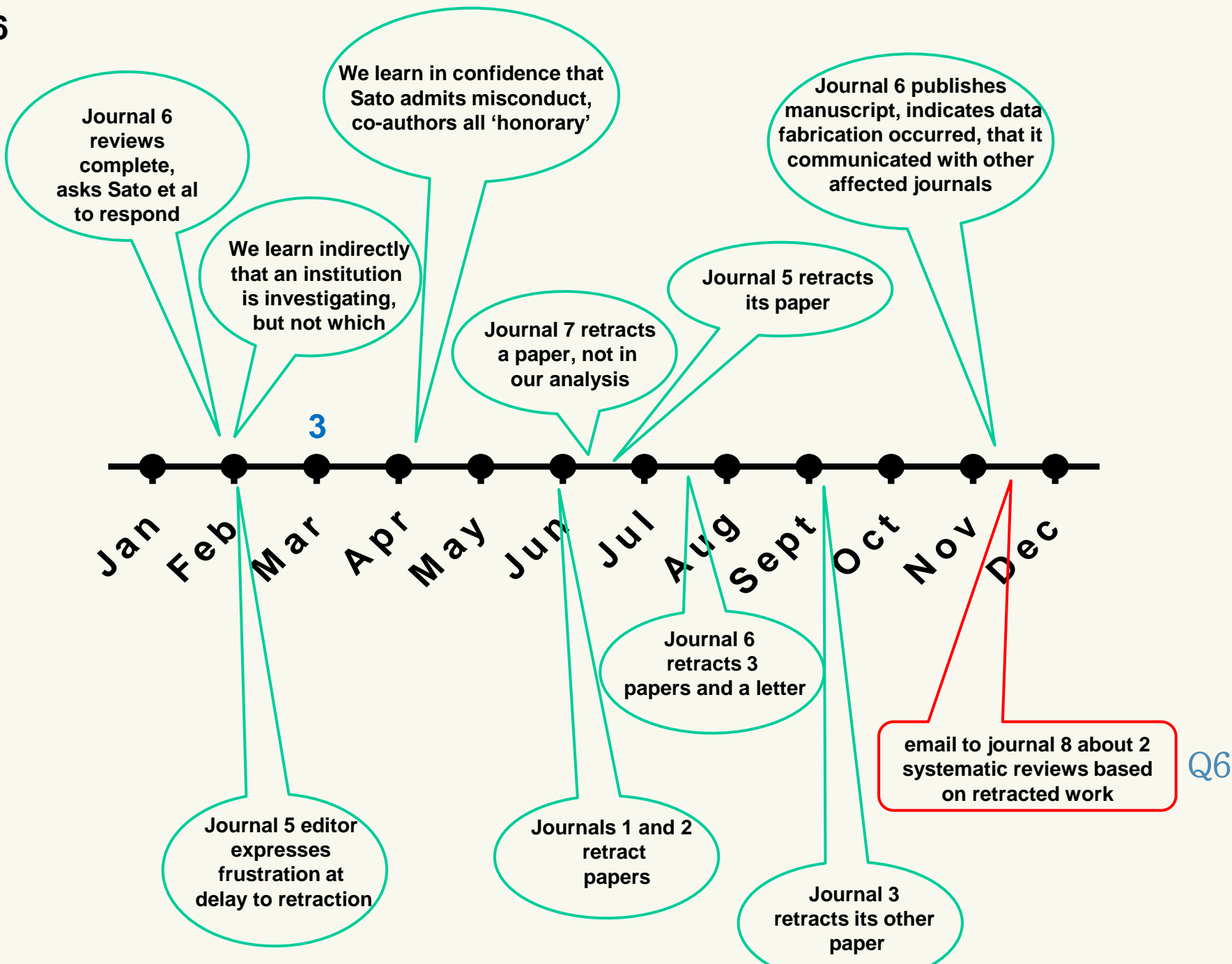


2016

**Should correspondence about retracted papers from authors be routinely retracted?**

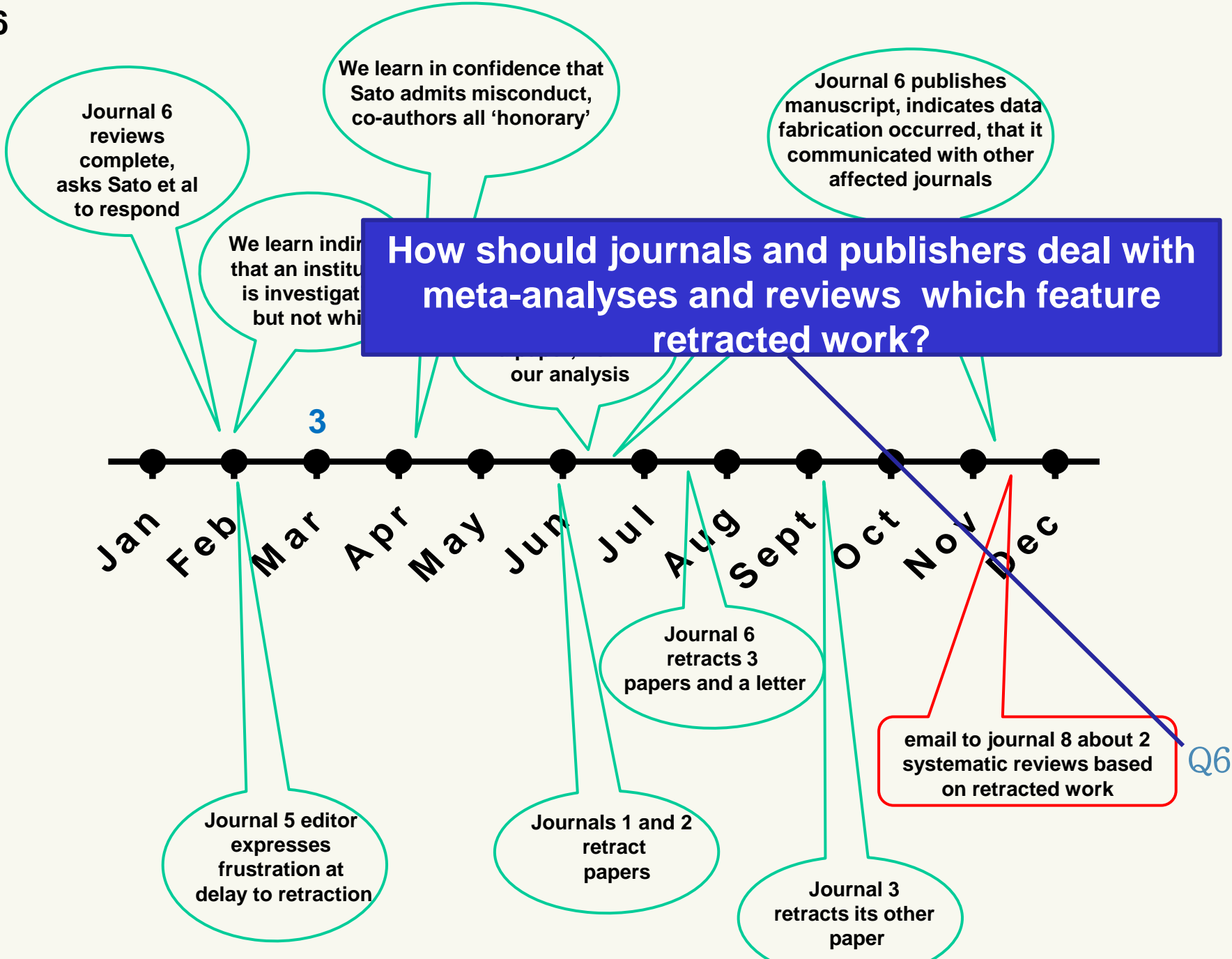


2016



2016

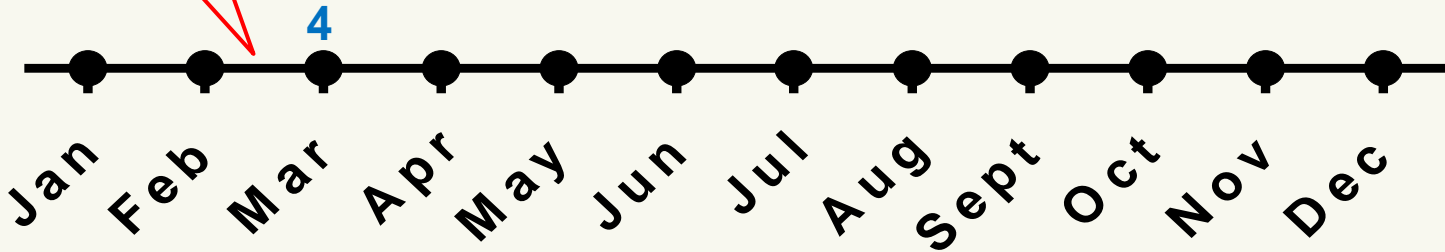
**How should journals and publishers deal with meta-analyses and reviews which feature retracted work?**



2017

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

Q7

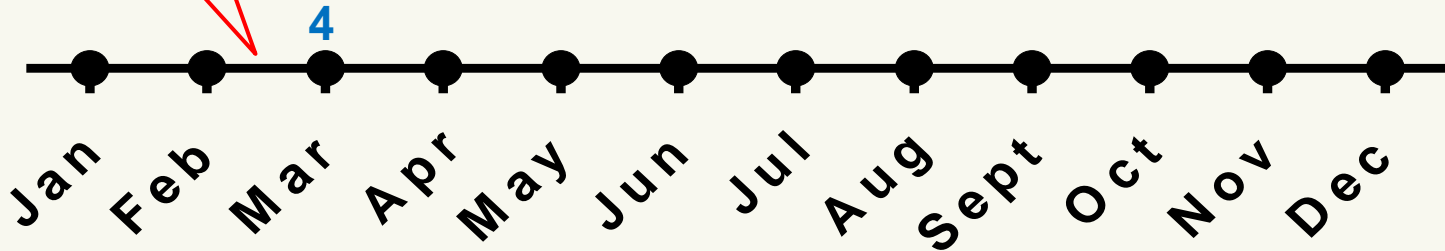


2017

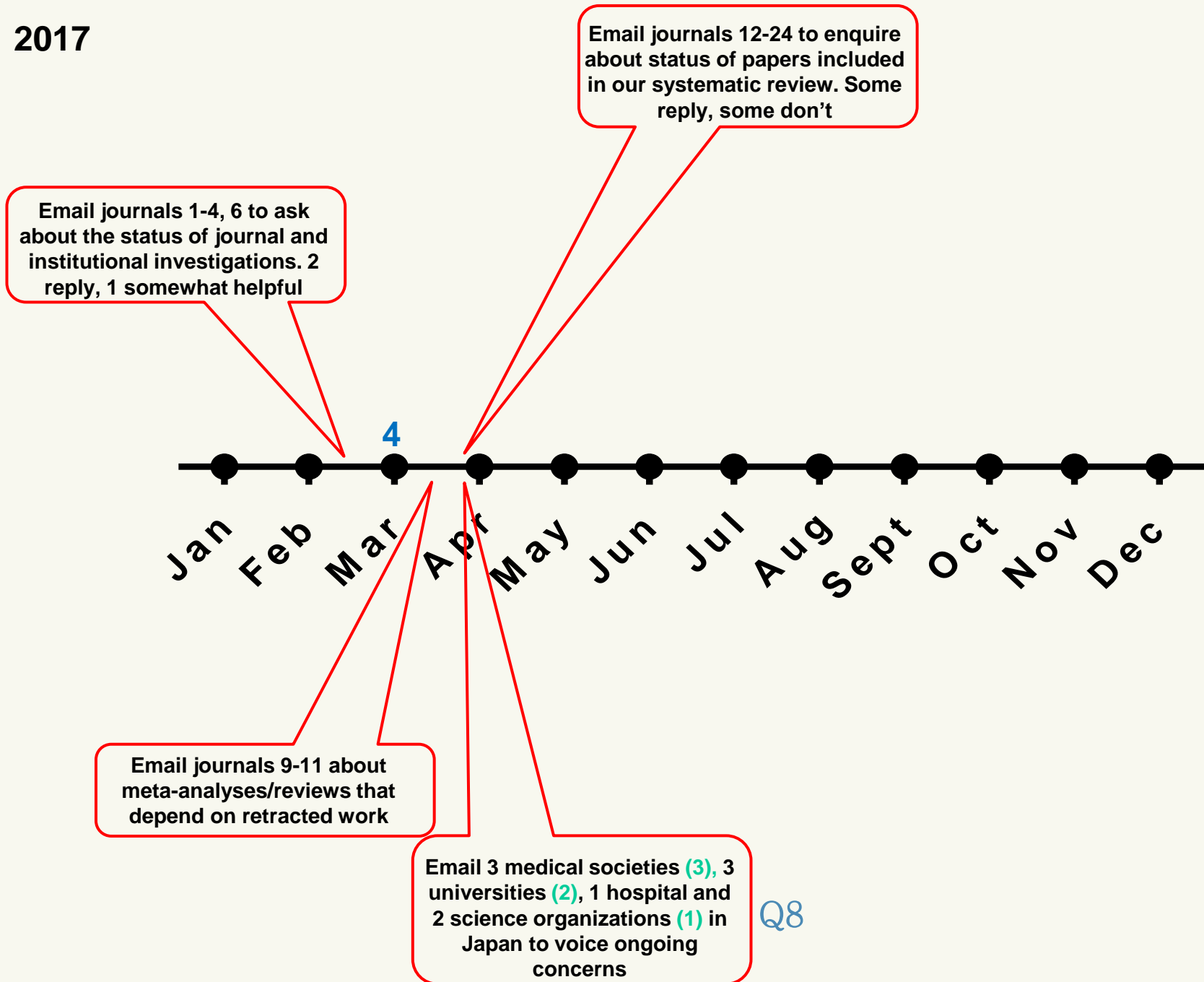
Should journals and publishers be more forthcoming in the face of unresolved concerns when their own investigations are complete?

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

Q7



2017



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

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

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

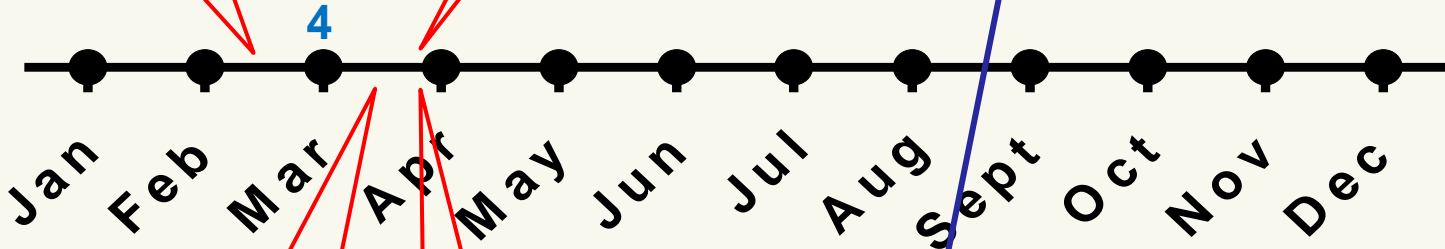
Q8

2017

Email journals 13-25 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

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?



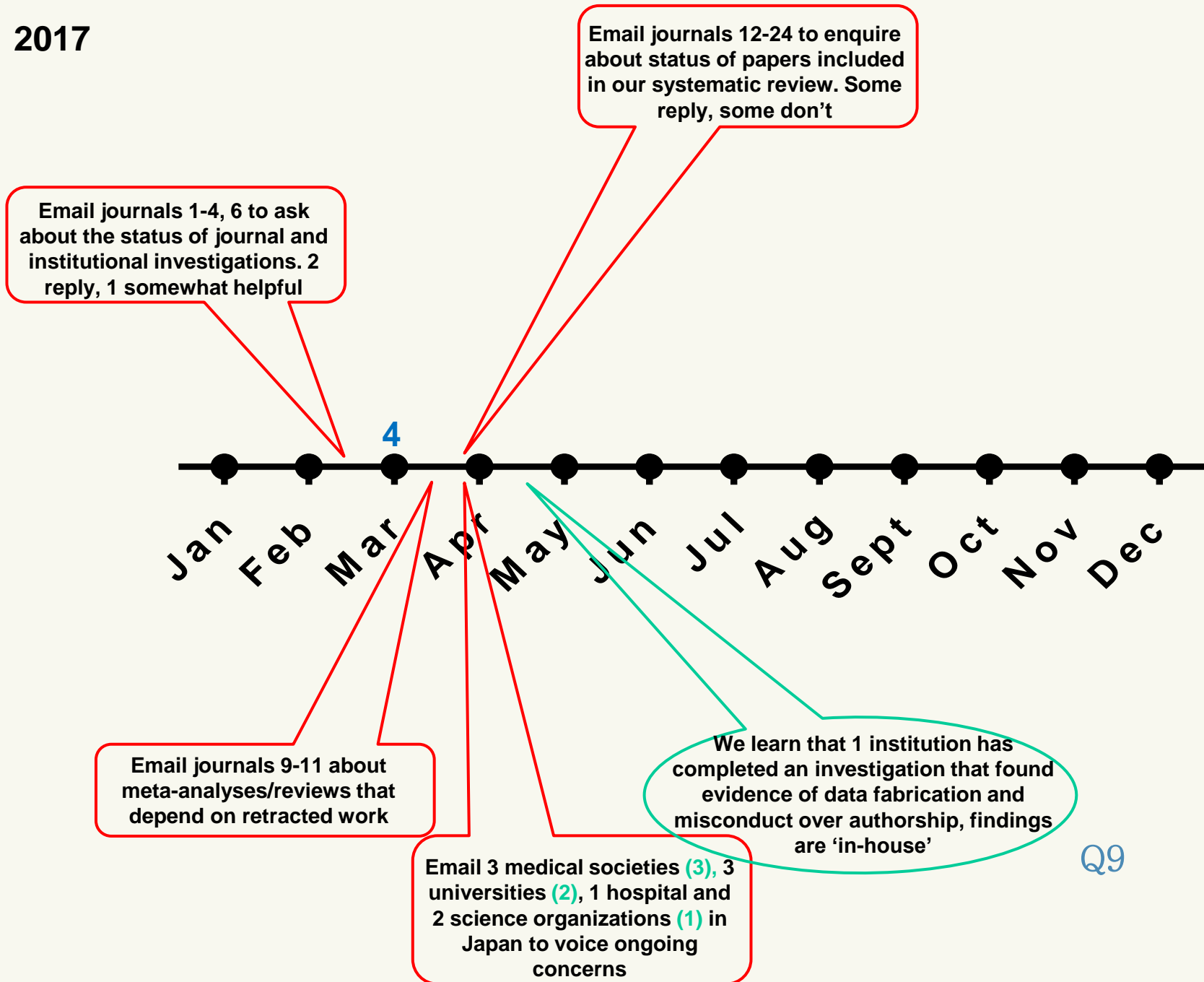
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Q8



2017



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4

Jan Feb Mar Apr May Jun Jul Aug Sept Oct Nov Dec

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

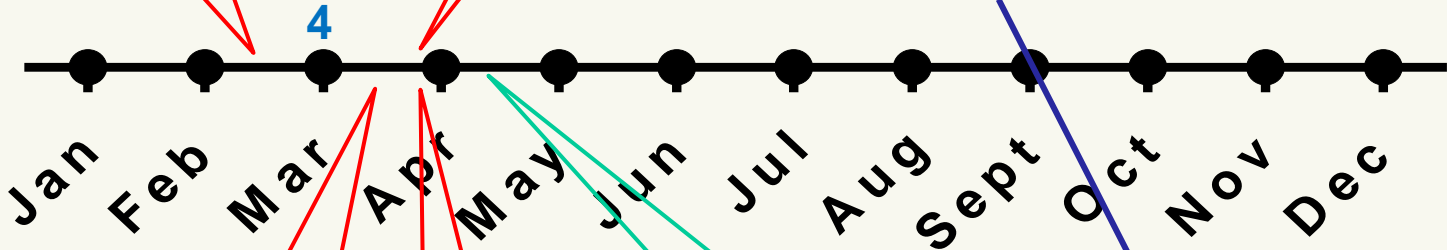
Q9

2017

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

How do we deal with this knowledge?



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

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Q9

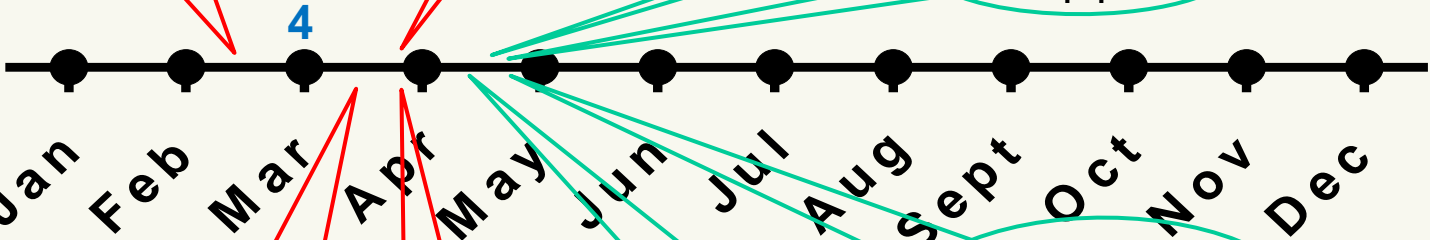
2017

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

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 it's paper



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

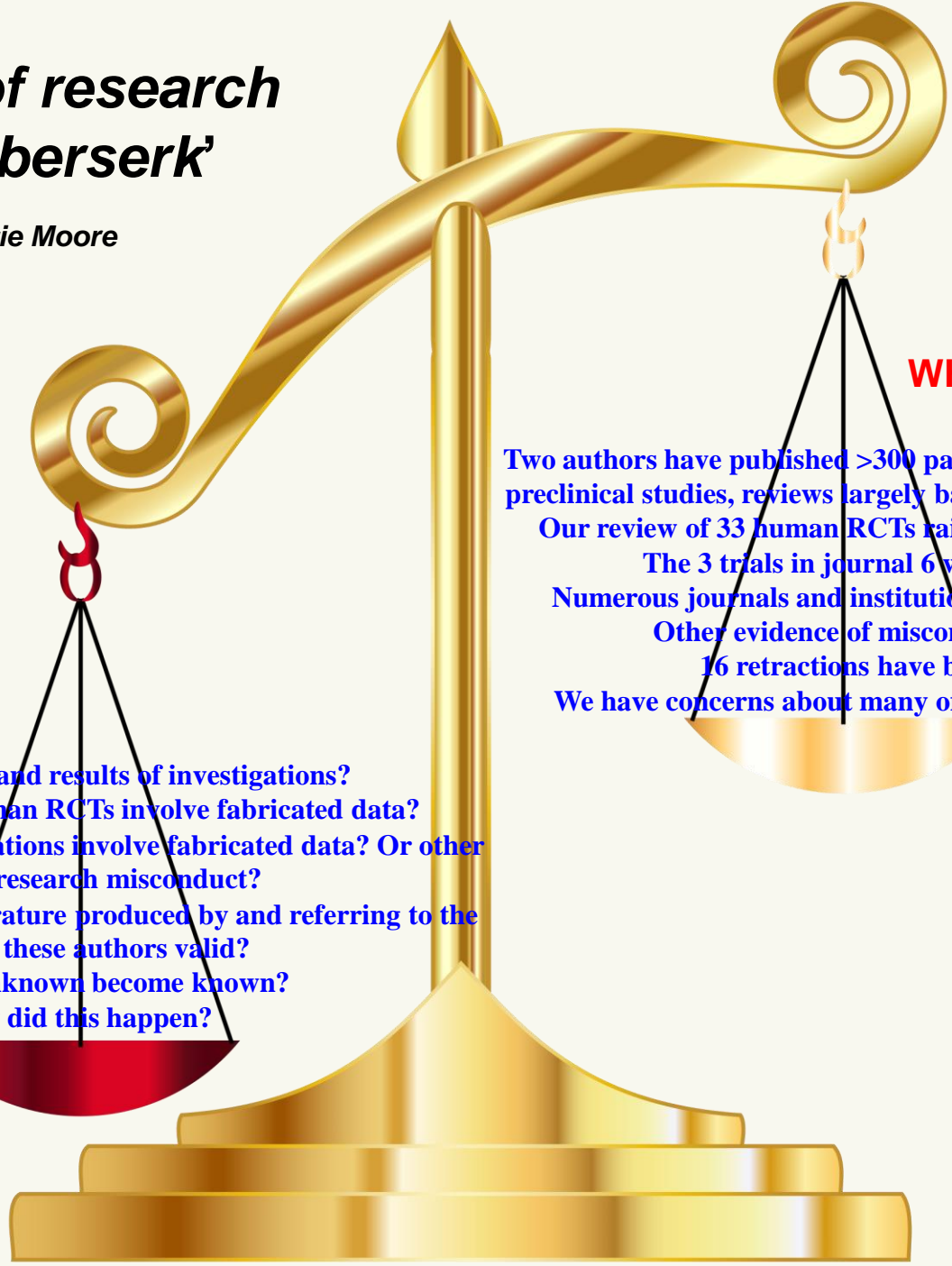
Email 3 medical societies (3), 3 universities (2), 1 hospital and 2 science organizations (1) in Japan to voice ongoing concerns

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

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

# ***‘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 retractions have been issued.  
We have concerns about many of the other publications

## **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?