

Timeliness and content of retraction notices for publications by a single research group

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Abstract

Publications of expressions of concern and retractions should be timely, accurate and comprehensive. We assessed these characteristics for 292 publications by a research group about which we submitted concerns about publication integrity to 77 journals and 29 publishers between March 2013 and February 2020. By October 2020, 115 publications were corrected (3), had expressions of concern (18), or were retracted (94). The median (95% CI) time from submission of concerns to the first journal correction was 22.1(18.2-26.9) months: this did not diminish by year of submission of concerns, varied between publishers, and was shorter for journals with higher impact factors. 84 publications of original research were retracted. The median (range) proportion of concerns raised with the journal that were mentioned in the ensuing retraction notices was 9.5% (2-49). At least 75% of retraction notices included the suggested content for 7/9, 3/9 and 3/16 items in the Committee for Publication Ethics and Retraction Watch minimum and optimal recommended formats, respectively. Thus, assessment of concerns about publication integrity was delayed and incomplete. Adherence to recommended content of retraction notices was moderate at best. Strategies are needed to improve the efficiency, accuracy and transparency of processes for resolving concerns about publication integrity.

Keywords: Publication integrity, retraction, expression of concern, academic publishing

Introduction

The integrity of published biomedical literature is critical to accurate and efficient scientific progress and clinical care. Restoring and/or maintaining publication integrity sometimes involves retracting publications. Retraction of a publication is recommended by the Committee of Publication Ethics (COPE) when it is found to be unreliable, unethical, duplicate, plagiarized, infringe copyright, or subject to compromised peer review or undisclosed competing interest(s) (Committee on Publication Ethics), but there is wide variation in approaches taken by publishing and scientific bodies (Teixeira da Silva and Dobránszki 2017). When a publication is retracted, readers are best served by a retraction notice that sets out the process(es), timeframe and reasons for the action, is quickly visible to all end-users and provides reassurance that other potentially affected publications are being assessed. Although recommendations for the content of retraction notices from COPE and Retraction Watch overlap in some items, they vary in others (Committee on Publication Ethics, Retraction Watch) (Box).

Research on publication integrity has increased in recent years. In parallel with overarching concerns (The Editors 2019a, Ellis 2015, Rennie 2010), attention has focused on permissive manuscript submission processes (Miyakawa 2020), inconsistent, opaque and inadequate publisher and institutional assessments (Grey, Avenell, et al. 2020, Grey et al. 2019, Gunsalus, Marcus, and Oransky 2018), and the impact of unreliable publications (Avenell et al. 2019). However, research on the accuracy, timeliness and quality of retraction processes and notices is limited. Even in cases of known researcher misconduct, defined as fabrication, falsification, or plagiarism, or of known unethical conduct, retraction of affected publications is incomplete (McHugh and Yentis 2019, Drimer-Batca, Iaccarino, and Fine 2019, Elia, Wager, and Tramer 2014), and the simple recommendations made by COPE for content of retraction notices are not always followed (McHugh and Yentis 2019, Moylan and Kowalczyk 2016).

Because it is uncommon for the processes leading to correction and/or retraction that are undertaken by journals and publishers to be reported, uncertainties exist as to the relationship between the concerns raised with journals and the reasons for retraction contained in the published notice, and in the length of time it takes from the first notification of concerns to public notification of corrective action. In the current work, we set out to address these uncertainties. Since March 2013, we have notified journals and publishers of concerns about the integrity of almost 300 publications by a group of researchers, more than 100 of which have been subjected to expressions of concern or retraction to date. The concerns we raised have been wide-ranging, including implausible and impossible results, failure of randomization, text duplication, unethical research, authorship misconduct, and implausible productivity (Bolland et al. 2016). In 2016, data fabrication in some studies was acknowledged (Gross 2016). Because we took a systematic approach to collating and submitting the concerns, using a publication integrity checklist (Grey, Bolland, et al. 2020), and our submissions were responsible for all but a few of the retractions, we had the opportunity to analyze the timeliness of publication correction/retraction, and the content of retraction notices in relation both to the concerns raised with the journal and to recommended formats. We have not previously reported on these aspects of the assessment and resolution of concerns about the integrity of publications by the research group in question.

Materials and Methods

Collation of submissions of concerns about publication integrity

From saved email correspondence, we collated the concerns about integrity of publications by the research group led by Yoshihiro Sato and Jun Iwamoto which we had raised with journals and/or publishers, beginning in March 2013. For each publication, we recorded the date of the first submission of our concerns. For 25/33 publications included in our systematic review (Bolland et al. 2016), the editor of *Neurology* informed us that the journal had notified the editors of the evidence for compromised integrity in the fall of 2016 (R Gross, personal communication); the other 8 publications had already been retracted. For these 25 publications we recorded the date of our submission of concerns as 30 September 2016, and we coded the concerns as those reported in the systematic review, which was published in November 2016 (Bolland et al. 2016). The Supplementary table contains an example of the format we used to notify concerns to journals.

One investigator (AG) categorized the concerns raised with the journals using the REAPPRAISED checklist for publication integrity (Grey, Bolland, et al. 2020). The checklist consists of 11 integrity domains: research governance, ethics, authorship, productivity, plagiarism, research conduct, analyses and methods, image manipulation, statistics and data, errors, and data duplication and reporting. A second investigator (AA) checked data extraction and categorizations. The investigators reached consensus in the event of disagreement.

We reviewed email responses we received from journals and publishers about the concerns we raised and recorded whether any included information that assuaged any specific concern raised by us. We also recorded whether any journals and publishers indicated they had already commenced assessment of the publication(s) in question before receiving our initial email.

Collation of journal correction notices

We collated correction notices (a composite of corrections, expressions of concern (EoC) and retraction notices up until 1 October 2020 for publications by the research group led by Yoshihiro Sato and Jun Iwamoto. We identified these notices by internet searches using author name(s) as search terms, or from communication with the publishing journal. We used the Retraction Watch database of retractions (<http://retractiondatabase.org>), which is searchable by investigator name, to verify complete ascertainment of correction notices. For each notice, we recorded type of source publication, dates of online and print publication, journal name, journal impact factor, name of publisher, and whether our research group had notified concerns to the journal. We downloaded full text versions of each notice for content analysis.

Analyses

i. Timing of journal notices of concern about publication integrity

For this analysis, we included all publications about which we had raised concerns to the journal of publication. We calculated the time to first correction, being the number of months between our first submission of concerns to the journal and the first journal online notice of concern about publication integrity, using October 1 2020 as the date of censure. In pre-

specified subgroups analyses, we determined the relationship between time to first correction and year of submission of concerns, type of study, publisher, and impact factor of retracting journal. For the publisher subgroup analysis, we excluded publishers with fewer than 10 affected publications. For the type of study subgroup analysis, we excluded the 2 corrigenda. Median time to first correction was estimated using the Kaplan-Meier method. We used log-rank analysis to assess differences between subgroups in time to first correction. Analyses were performed using Prism v8.2.1 (GraphPad Software, San Diego, CA), and $P < 0.05$ was considered statistically significant.

ii. *Content of retraction notices*

For these analyses, we included all retraction notices for publications of original research about which we had raised concerns with the journal of publication. We focused on retraction notices because expressions of concern are often published as ‘placeholder’ notices. We excluded retractions of reviews and meta-analyses because the concerns notified were always about the inclusion of retracted publications; we excluded letters and corrigenda because they were always linked to retracted publications.

One investigator (AG) coded the content of the retraction notices using the REAPPRAISED checklist. A second investigator (AA) reviewed the coding and disagreements were resolved by consensus. We then compared the publication integrity concerns that were raised with the journals of publication with those reported in the retraction notices.

Then, one investigator (AG) coded the content of each retraction notice according to each relevant comparator (COPE guideline, Retraction Watch guidelines for minimal and optimal content). Each of the COPE recommendations and the Retraction Watch minimal set of recommendations includes 9 items; the Retraction Watch optimal set of recommendations includes 16 items (Box). In each instance, a second investigator (AA) reviewed the coding and disagreements were resolved by consensus. We compared the content of the retraction notices with each of the recommended formats.

We wrote a protocol for the study, which is available upon request to the corresponding author.

Results

Figure 1 sets out the process of collation of study documents. Between 4 March 2013 and 14 February 2020, our group notified journals and/or publishers of concerns about the integrity of 292 publications by the research group led by Yoshihiro Sato and Jun Iwamoto, that were published in 77 journals by 29 publishers (Appendix). This set of documents, which was comprised of 203 original research publications (57 preclinical, 45 clinical randomized trials, 101 non-randomized clinical studies), 40 reviews or meta-analyses, 11 letters, 36 case reports and 2 corrigenda, was assessed for time from submission of concerns to first journal correction notice. By 1 October 2020, 115 of the 292 (39%) publications had a correction notice: a retraction notice (n=99), an expression of concern (n=13), or a correction (n=3). The first journal notice was a retraction for 94 publications, an expression of concern in 18, and a correction in 3.

Of the 115 publications about which our group raised concerns that had a correction notice, 90 reported original research. Eighty-four of those 90 publications had been retracted by 1 October 2020. The 84 publications were spread among 29 journals and 16 publishers, and comprised 27 human randomized trials, 36 human non-randomized studies and 21 animal randomized trials. This dataset was assessed for the content of retraction notices.

Timing of first correction notices

Figure 2 shows the time to first correction (retraction, expression of concern or correction) for the 292 publications about which our group submitted integrity concerns. The median (95% CI) time to first correction notice was 22.1 (18.2-26.9) months: only 25% had a published correction notice within 12 months of journal notification.

Supplementary Figure 1 shows the time to first correction curves for these publications, according to the pre-specified subgroups. There were significant differences between subgroups in all analyses. Time to first correction increased as time passed from the initial submission of concerns (March 2013) or the first publication of a correction notice (May 2015) (top left panel). Median times to first correction were 10 months, 17 months, 19 months and 15 months for notifications in 2013-2015, 2016, 2017 and 2018, respectively. Letters were corrected promptly (median time to first correction 6 months), and case reports rarely corrected (2/36, median time to first correction not evaluable) (top right panel). Median times to first correction were 25 and 27 months for publications of preclinical studies and clinical (human) randomized studies, respectively. These were almost twice as long as the median times to first correction for publications of non-randomized clinical studies (15 months) and reviews and meta-analyses (14 months). Median time to first correction was evaluable for only 2 publishers, Wiley (14 months) and Wolters Kluwer (11 months) (bottom left panel). Among the other publishers with more than 10 affected publications, correction notices have been published for 0% (Keio University of Medicine), 7% (Kurume University), 8% (Dove Press), 22% (Springer Nature), 26% (Elsevier), and 42% (Yonsei University College of Medicine) of affected publications. Journals with higher impact factors (>4, Science Citation Reports) published correction notices more quickly than those with lower or no impact factor (bottom right panel).

Content of retraction notices

Figure 3 sets out the concerns we raised with journals about publications of original research and those mentioned in retraction notices, by category in the REAPPRAISED checklist. Concerns from all but 1 of the 11 categories in the checklist were communicated to the journals of publication for at least 33% of retracted papers, but only 1 category, authorship, was mentioned in more than 33% of the retraction notices. For the 10 categories for which concerns were raised, the median (range) proportion of concerns raised with the journal that were mentioned in the retraction notices was 9.5% (2-49%). For only 4 categories, authorship, ethics, plagiarism and duplicate data and reporting, was the proportion of concerns raised with the journal that were mentioned in the retraction notices greater than 10%. Concerns about mathematically impossible or implausible data, and data errors, were frequently raised (82% and 69% of publications respectively) but rarely addressed in retraction notices (7% and 1%, respectively). The Supplementary table contains an example of a retraction notice which did not report the nature or details of concerns that had been raised.

In no instance did the correspondence from a journal to us address and assuage a specific concern we had raised.

Alignment of retraction notices with recommended standards

Figure 4 shows the proportions of retraction notices whose content aligned with the recommendations from COPE (top) and Retraction Watch (bottom). For the COPE recommendations, we were unable to evaluate the criterion of prompt publication because we did not know the dates on which decisions to retract were made. Overall, alignment with the evaluable COPE recommendations was moderately high, with >75% of notices containing the recommended information for 7/9 items. It was not clear who was retracting the paper in 22/84 (26%) notices. Although all retraction notices stated a reason for retraction, only 10/84 (12%) notices were factual, in that they accurately reported the scope and extent of concerns raised about the paper. Euphemistic and non-specific language was common in descriptions of the reasons for retraction (Table 1).

For the Retraction Watch recommendations, we were unable to fully evaluate the criterion of swift communication to indexes because we did not know the date on which decisions to retract were made. However, 14% (12/83) of retraction notices in PubMed-indexed journals were not found in PubMed on 1 December 2020. The criterion of statements about recent replications was not applicable to the papers we assessed. Overall, alignment with the evaluable Retraction Watch recommendations was lower than that for the COPE recommendations, particularly for the optimal format. In the minimum and optimal sets of Retraction Watch recommendations, >75% of notices contained the recommended information for 3/9 items, and 3/16 items, respectively. Fewer than 20% of retraction notices contained the recommended information for 9/16 evaluable items in the optimal Retraction Watch set.

Discussion

The current analysis focused on two important aspects of the process of correcting the scientific literature when publication integrity is compromised, timeliness and informativeness. This large set of correction notices was deficient in each aspect.

A strength of the current work is that we knew exactly what concerns had been raised, and when, about a large set of publications (292 papers, 77 journals and 29 publishers) from a single research group. Because we had raised concerns about the integrity of each publication, we were able to calculate the time between raising concerns and corrective action. We found that a median of nearly 2 years elapsed before a correction was published, despite our requests for updates in the interim. This 2 year interval may be conservative because as time progressed from the first notification of concerns in March 2013, knowledge of the case increased in the public domain, via correction notices, academic publications (Bolland et al. 2016, Bolland et al. 2018, Grey et al. 2018, Grey et al. 2019, Grey, Avenell, et al. 2020, Grey, Bolland, and Avenell 2019), blogs (Retraction Watch 2021a), and news stories (Kupferschmidt 2018), and within academic publishing, as a growing number of journals and publishers were affected. It is therefore possible that some journals and/or publishers began assessing concerns in advance of our notification. However, this was not apparent in our email exchanges with the publishers and journals.

There exists no recommended time frame for flagging investigations in process by expressions of concern or within which concerns about publication integrity should be resolved, but the interests of the general public and scientific community are best served by rapid, efficient processes. Comparisons between the Sato/Iwamoto case and others that preceded it by several years are difficult, but prolonged times to retraction have been reported in the face of established misconduct and institutional recommendations, as for publications by Joachim Boldt, Scott Reuben and Yoshitaka Fujii (Retraction Watch 2021b, McHugh and Yentis 2019). The current analyses, which demonstrate a large number of publications by the Sato/Iwamoto group whose integrity has been questioned but not resolved, suggest that publisher processes to correct the literature in a timely fashion have not improved. Rapid correction of publications is possible: 64 publications in the current dataset were retracted within 12 months of notification of concerns, and 121 Covid-19 publications have been retracted since the pandemic commenced in early 2020. Delays in public notification of concerns about publication integrity have undesirable consequences for patients, clinicians and the research community (Avenell et al. 2019). We found no evidence that the time to first correction of affected publications became shorter as knowledge of the case increased. If anything, the obverse applied. This finding suggests that, contrary to COPE recommendations (Committee on Publication Ethics), there may have been limited information sharing between affected publishers and journals. Our specific enquiries to some journals suggested that was the case. It was apparent that journals published by the same publisher did not necessarily work together. If that is correct, a more collaborative effort by affected journals and publishers would likely have produced more timely resolution of the integrity concerns.

There were notable differences between publishers in time to first correction – this might reflect differences in resources applied, in priority assigned, or in experience or expertise of relevant staff members. The former possibility is supported by the finding that journals with higher impact factors, which likely have greater resources, corrected their papers more quickly than those with lower impact factors.

We found that most of the retraction notices for publications about which we raised integrity concerns did not mention most of those concerns. It is unlikely that this discrepancy occurred because the concerns were assuaged during the assessment processes, as in no instance did a journal or publisher indicate in its correspondence with us or in the retraction note that a specific concern had been resolved. For only 4 categories - authorship, ethics, plagiarism and duplicate reporting – was the submitted concern mentioned in more than 20% of retraction notices. Concerns about impossible or implausible data or data errors were rarely addressed. Thus, readers of the retraction notices were commonly deprived of knowledge of the nature and scope of concerns about the affected publications. This finding has several implications. First, it reinforces the opacity of the process of correcting the literature: notices which are neither comprehensive nor accurate do not serve the best interests of readers. For example, readers might be more likely to dismiss the results of a retracted paper if they are made aware of concerns about data or methodological irregularities than if they are only apprised of authorship transgressions. Second, it implies that some transgressions are either considered by journals and publishers to be more influential than others, and/or more easily investigated, whilst others may not have been assessed at all. Third, it reinforces the inconsistency of the process of correcting the literature. For example, it has been publicly known for more than 3 years that Drs Sato and Iwamoto engaged in reciprocal gift authorship (Grey et al. 2018), for more than 2 years that ethical oversight of their work was absent or in doubt (The Editors 2019b), and for more than 18 months that their work featured duplicate data reporting (Grey, Avenell, et al. 2020). In each instance, publishers and journals were aware of these problems even earlier. Yet many publications which are affected by the same concerns remain uncorrected. For example, as at 1/12/2019 Scopus identified 135 publications co-authored by Drs Sato and Iwamoto, only 67 of which were retracted by October 1 2020.

The content of the retraction notices usually met the recommendations by COPE. This is perhaps not surprising, given the pre-eminence of COPE guidance to assist journals and publishers in addressing concerns about publication integrity, and the limited detail suggested in the COPE recommendations. Nonetheless, more than 25% of notices did not clarify who was retracting the paper, and only 12% included enough information about the nature and scope of the concerns about the publication to be regarded as factual. The reason(s) given for retraction rarely matched the potential reasons for retraction derived from the concerns raised, and were often couched in euphemistic and/or non-specific terms. Thus, although a reason for retraction was provided in all notices, there was very frequently failure to address or acknowledge most of the concerns, which therefore remain invisible to readers. The recommendations made by Retraction Watch are more numerous and stringent: fewer than 1 in 5 retraction notices included content that addressed more than half of the evaluable criteria in the optimal Retraction Watch recommendations. Notably, in no instance did a retraction notice report the date when the concerns were first raised, nor whether other papers by the same authors were affected. Fewer than 10% of notices fully identified which aspects of the paper were affected by concerns. The consequence of these numerous deficiencies in the retraction notices is that readers were not informed of the true extent and specific details of the problems with the integrity of the publications.

The current findings reinforce concerns about the inefficiency, inaccuracy, incompleteness and opacity of systems for ensuring publication integrity. While science espouses rigour, consistency and transparency, the mechanisms to provide quality control of scientific publications currently fail to achieve these goals. Improvements are possible. Transparent reporting of the timelines of assessing and resolving concerns, including the reason(s) for delays, should be the norm. The roles, expertise and conflicts of interest of participants in the

assessment process should be reported. Open and full reporting of the nature and scope of concerns, of the explanations provided by respondents for each concern, and of the decisions made to resolve concerns, should also be required. These changes would align the process of maintaining publication integrity with that of open peer review during manuscript submission, which is already embedded in academic publishing. COPE should revise its recommendations for content of retraction notices to assist achievement of these goals, and audit the practices of its member journals. We suggest that retraction notices should include the content suggested by Retraction Watch, itemize each of the specific concerns raised about a publication, and provide a response to each which either assuages or affirms the concern. The timelines for each part of the process should be reported. In combination with more frequent scrutiny of raw data (Carlisle 2020) and the application of independent expertise to the assessment of publication integrity concerns (Bolland et al. 2020), these changes would assist key stakeholders who rely on a robust literature, such as scientists, clinicians and patients.

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Transparency statement: AG affirms that the manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned have been explained

Data availability: Study data are either available in the public domain or can be obtained from the lead author upon reasonable request.

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Table 1. Examples of euphemistic or non-specific language used to describe reason for retraction

Terminology	Number of retraction notices (%)
“scientific misconduct” “research misconduct”	30 (36)
“integrity of the data” “concerns about data integrity” “a few/some inconsistencies about data integrity” “concerns about the underlying data” “inaccuracies in the data” “concerns about the data presented”	24 (29)
“some (parts of their) contents were published in other journals/elsewhere” “a number of issues related to data duplication” “salami publishing” “implausible reporting of the same measurements...in different manuscripts” “reused” “some of the cohorts were published elsewhere” “overlap of data”	20 (24)
“integrity of these studies/the research” “fraudulent” “many discrepancies”	7 (8)
“misconduct over authorship” “malpractice due to inappropriate authorship”	5 (6)

Box. Recommendations for content of retraction notices

COPE guidelines^a	Retraction Watch recommendations^b
<p>Be linked to the retracted article wherever possible (ie, in all online versions)</p> <p>Clearly identify the retracted article (eg, by including the title and authors in the retraction heading or citing the retracted article)</p> <p>Be clearly identified as a retraction (ie, distinct from other types of correction or comment)</p> <p>Be published promptly to minimise harmful effects^c</p> <p>Be freely available to all readers (ie, not behind access barriers or available only to subscribers)</p> <p>State who is retracting the article</p> <p>State the reason(s) for retraction</p> <p>Be objective, factual and avoid inflammatory language</p>	<p>Bare Minimum</p> <p>Include the reason for retraction, in clear, unambiguous language that differentiates misconduct from honest error</p> <p>Indicate which aspects of the paper are affected (i.e. which specific data or conclusions are invalid)</p> <p>Indicate who initiated the retraction and which authors agreed to the retraction</p> <p>Be linked prominently from all versions of the abstract</p> <p>Be freely available (not paywalled)</p> <p>Be communicated swiftly to indexes (eg PubMed, Thomson Scientific’s Web of Knowledge)^c</p> <p>Be marked clearly as a retraction, rather than erratum or corrigendum</p> <p>Indicate when the retraction notice was published (to differentiate this date clearly from when the original paper was published)</p> <p>Optimal</p> <p>Indicate when the journal was first alerted to potential problems</p> <p>Indicate whether there was an institutional investigation, and if so, the result</p> <p>Indicate whether other papers by the same group will be affected</p> <p>Only include statements about more recent replications if these have been validated by a third party^d</p> <p>Avoid euphemisms (eg for plagiarism)</p> <p>Indicate whether the authors will be sanctioned by the journal</p> <p>Indicate whether any lawsuits have been filed regarding the case</p>

a, <https://publicationethics.org/node/19896>

b, <http://retractionwatch.com/2015/05/21/what-should-an-ideal-retraction-notice-look-like/>

c, not evaluable in the current analyses

d, not applicable to the current analyses

Figure Legends

Figure 1. Collation of documents for analyses of time to first correction and content of retraction notices

Figure 2. Time to first correction of publications co-authored by Yoshihiro Sato and Jun Iwamoto. The dotted lines are 95% confidence intervals

Figure 3. Percentage of retracted publications (n=84) for which concerns were raised with journals (dark bars) and for which concerns were mentioned in the retraction notices (open bars), categorized according to the REAPPRAISED publication integrity checklist (Grey, Bolland, et al. 2020). Categories of concerns are, from left to right on the x axis, **R**, research governance; **E**, ethics; **A**, authorship; **P**, productivity; **P**, plagiarism; **R**, research conduct; **A**, analyses and methods; **I**, image manipulation; **S**, statistics and data; **E**, errors; **D**, data duplication and reporting.

Figure 4. Alignment of content of retraction notices (n=84) with recommendations by Committee for Publication Ethics (COPE) and Retraction Watch (minimum and optimal formats). Horizontal bars show the percentage of retraction notices that met the indicated criterion

Supplementary Figure. Time to first correction of publications co-authored by Yoshihiro Sato and Jun Iwamoto, according to year of submission of concerns to journal (top left), type of study (top right), publisher (bottom left) and impact factor of journal (bottom right).

Supplementary table. Example of concerns about publication integrity raised with a journal and the corresponding retraction notice

Concerns notified to journal	Retraction Notice
<p>Re: Sato Y, Honda Y, Iwamoto J. Long-term oral anticoagulation therapy and the risk of hip fracture in patients with previous hemispheric infarction and nonrheumatic atrial fibrillation. <i>Cerebrovasc. Dis.</i> 2010;29(1):73-78</p> <p>We write to raise concerns about the integrity of the above paper, because of authorship misconduct, uncertain funding support, uncertain ethical oversight, and implausible recruitment and study conduct.</p> <p>We raise these concerns in the context of wide-ranging and frequent instances of misconduct or compromised integrity in publications by authors Yoshihiro Sato and Jun Iwamoto, which have led to the retraction of > 50 publications, including 1 in <i>Cerebrovasc Dis</i>. Various types of misconduct have been reported by members of this group of researchers, including data fabrication, data duplication, self-plagiarism and inappropriate assignation of authorship.</p> <p>In regard to the above paper, our concerns are:</p> <p>Governance</p> <p>The protocol of the study was ‘approved by the Human Investigation Committee of the Mitate Hospital’. It is probable that such a committee never existed – the only research said to have been approved by this committee was that by Dr Sato and colleagues, and to our knowledge none of the investigating journals and institutions has obtained documentary evidence that the committee exists. In the Methods section it is stated that patients ‘were prohibited from taking any other drugs that could affect bone metabolism’. This is surely unethical, especially as during follow-up 17 participants suffered hip fractures.</p> <p>No funding is reported for a 5 year study of 177 patients with serious co-morbidity.</p> <p>Authorship</p> <p>Statements by both Dr Sato and Dr Iwamoto (each is attached) acknowledge that neither was involved in research published by the other between 2002 and late 2013. Honorary authorship is one of the reasons provided for several retractions of papers by these authors. Dr Honda was an honorary author on several retracted papers.</p> <p>Study conduct</p> <p>187 participants were seen every 4 weeks for 5 years, a total of 12,155 study visits, an average of 9 study visits each day. Only 2 investigators were based at Mitate Hospital, so each must have been seeing 4-5 participants every day for 5 years, just for this study. This workload is implausibly high.</p> <p>Implausible biochemical testing</p> <p>Several biochemical tests performed during the study, such as serum 25OHD, osteocalcin (bone Gla protein, BGP), undercarboxylated osteocalcin, are not part of routine practice and require specialised laboratory facilities that are extremely unlikely to be available at a hospital the size of Mitate Hospital. No analytic laboratory is identified in the paper, and no funding is reported that would support this costly exercise.</p> <p>Text duplication</p> <p>Using software designed to identify text similarity (http://splat.cs.arizona.edu/), we observed that 26% of sentences in the Introduction and Discussion sections of the <i>Cerebrovasc Dis</i> paper shared at least 50% of the words with sentences in the same sections of a paper published by the same group in <i>Stroke</i> more than 10 years earlier: Sato Y, Honda Y, Kunoh H, Oizumi K. Long-term oral anticoagulation reduces bone mass in patients with previous hemispheric infarction and nonrheumatic atrial fibrillation. <i>Stroke.</i> 1997;28(12):2390-2394</p> <p>Data errors</p>	<p>“We wish to retract the paper entitled “Long-Term Oral Anticoagulation Therapy and the Risk of Hip Fracture in Patients with Previous Hemispheric Infarction and Nonrheumatic Atrial Fibrillation” [<i>Cerebrovasc Dis</i> 2010;29:73–78] by Y. Sato, Y. Honda and I. Jun as a result of concerns about data integrity and scientific misconduct which have been brought to our attention.”¹</p>

On page 74 the non-warfarin/untreated group is reported to include 103 patients, whereas baseline data for 93 patients are reported in table 1 and 2. The text on p75 says 10 participants in the untreated group withdrew, so that 83 completed the study. These data are clearly incompatible.

Impossible data

In Table 3 the numbers of participants in the table headings do not agree with those in the footnote: 89 at 3 years versus 78 at 3 years, 83 at 5 years versus 70 at 5 years.

The calculated percentage changes in Table 3 do not consistently agree with those calculated from the differences between the values in Table 2 and 3, even allowing for missing data (see marked differences in red below). It is also striking, and highly implausible, that the 3y and 5y percentage changes for ucOC in the untreated group exactly match those for the BGP data in the same group: 4.7 SEM 1.4 and 4.9 SEM 1.2.

	3y in paper	3y calculated	5y in paper	5y calculated
ucOC				
Untreated	+4.7%	+23.3%	+4.9%	+39.5%
Treated	+2.3%	+2.3%	+4.6%	+4.6%
BGP				
Untreated	+4.7%	+41.7%	+4.9%	+62.5%
Treated	-8.3%	-16.7%	-7.7%	-22.2%
25-OHD				
Untreated	-18.2%	-18.6%	-28.8%	-29.7%
Treated	-19.4%	-19.6%	-29.5%	-29.2%

1. Retraction Statement. *Cerebrovasc Dis* 2019;47:311

Appendix - Publications by Yoshihiro Sato and Jun Iwamoto about which concerns were raised about publication integrity

A. Corrected by journal

i. Retracted

a. Original Research

1. Iwamoto J, Sato Y, Matsumoto H. Vitamin K2 improves femoral bone strength without altering bone mineral density in gastrectomized rats. *J Nutr Sci Vitaminol* 2014;60; 71-77
2. Iwamoto J, Takada T, Sato Y, Matsumoto H. Effect of risedronate on speed of sound in postmenopausal women with osteoporosis. *World J Orthop* 2013;4:316-322
3. Iwamoto J, Sato Y, Matsumoto H. Chair rising time is longer in postmenopausal women with history of nonvertebral fracture. *J Musculoskelet Neuronal Interact* 2013;13;227-234
4. Iwamoto J, Sato Y, Uzawa M, Matsumoto H. Three-year outcome of alendronate treatment in older Japanese women with osteoporosis. *Rheum Rep* 2012;4;46-50
5. Iwamoto J, Sato Y, Takeda T, Matsumoto H. Whole body vibration exercise improves body balance and walking velocity in postmenopausal osteoporotic women treated with alendronate: Galileo and alendronate intervention trail (GAIT). *J Musculoskelet Neuronal Interact* 2012;12;136-143
6. Iwamoto J, Sato Y, Uzawa M, Takeda T, Matsumoto H. Three-year experience with alendronate treatment in postmenopausal osteoporotic Japanese women with or without renal dysfunction: A retrospective study. *Drugs Aging* 2012;29;133-142
7. Iwamoto, J, Sato, Y, Takeda T, Matsumoto H. Analysis of stress fractures in athletes based on our clinical experience. *World J Orthop* 2011;2;7-12
8. Sato Y, Iwamoto J, Honda Y. Once-weekly risedronate for prevention of hip fracture in women with Parkinson's disease: A randomised controlled trial. *J Neurol Neurosurg Psychiatry* 2011;82;1390-1393
9. Iwamoto J, Sato, Y, Uzawa M, Takeda T, Matsumoto, H. Three-year experience with alendronate treatment in postmenopausal osteoporotic Japanese women with or without type 2 diabetes. *Diab Res Clin Pract* 2011;93;166-173
10. Sato Y, Iwamoto J, Honda Y. Amelioration of osteoporosis and hypovitaminosis D by sunlight exposure in Parkinson's disease. *Parkinsonism Relat Dis* 2011;17;22-26
11. Sato Y, Iwamoto J, Honda Y. An open-label trial comparing alendronate and alfacalcidol in reducing falls and hip fractures in disabled stroke patients. *J Stroke Cerebrovasc Dis* 2011;20;41-46
12. Iwamoto, J, Sato, Y, Takeda T, Matsumoto H. Return to sports activity by athletes after treatment of spondylolysis. *World J Orthop* 2010;1;26-30
13. Sato Y, Honda Y, Umeno K, Hayashida N, Iwamoto J, Takeda T, Matsumoto H. The prevention of hip fracture with menatetrenone and risedronate plus calcium supplementation in elderly patients with Alzheimer disease: A randomized controlled trial. *Kurume Med J* 2010;57;117-124
14. Sato Y, Iwamoto, J, Honda Y. Beneficial effect of etidronate therapy in chronically hospitalized, disabled patients with stroke. *J Stroke Cerebrovasc Dis* 2010;19;198-203
15. Sato, Y, Honda Y, Iwamoto J. Long-term oral anticoagulation therapy and the risk of hip fracture in patients with previous hemispheric infarction and nonrheumatic atrial fibrillation. *Cerebrovasc Dis* 2009;29;73-78
16. Iwamoto J, Matsumoto H, Takeda T, Sato Y, Yeh JK. Comparison of the effect of vitamin K2 and risedronate on trabecular bone in glucocorticoid-treated rats: A bone histomorphometry study. *Yonsei Med J* 2009;50;189-194
17. Iwamoto J, Matsumoto H, Takeda T, Sato Y, Xu E, Yeh JK. Effects of alendronate and alfacalcidol on the femoral bone mass and bone strength in orchidectomized rats. *Chin J Physiol* 2008;51;331-337
18. Iwamoto J, Seki A, Takeda T, Yamada H, Sato Y, Yeh JK. Effects of combined administration of alfacalcidol and risedronate on cancellous and cortical bone mass of the tibia in glucocorticoid-treated young rats. *Chin J Physiol* 2008;51;121-128
19. Iwamoto J, Sato Y, Uzawa M, Takeda T, Matsumoto H. Comparison of effects of alendronate and raloxifene on lumbar bone mineral density, bone turnover, and lipid metabolism in elderly women with osteoporosis. *Yonsei Med J* 2008;49;119-128
20. Iwamoto J, Takeda T, Matsumoto H, Sato Y, Yeh JK. Beneficial effects of combined administration of alendronate and alfacalcidol on cancellous bone mass of the tibia in orchidectomized rats: A bone histomorphometry study. *J Nutr Sci Vitaminol* 2008;54;11-17

21. Iwamoto J, Seki A, Takeda T, Yamada H, Sato Y, Yeh JK. Effects of alfacalcidol on cancellous and cortical bone mass in rats treated with glucocorticoid: A bone histomorphometry study. *J Nutr Sci Vitaminol* 2007;53:191-197
22. Iwamoto J, Takeda T, Sato Y, Yeh JK. Additive effect of vitamin K2 and risedronate on long bone mass in hypophysectomized young rats. *Exp Anim* 2007;56:103-110
23. Sato Y, Honda Y, Iwamoto J. Risedronate and ergocalciferol prevent hip fracture in elderly men with Parkinson disease. *Neurology* 2007;68:911-915
24. Iwamoto J, Seki A, Takeda T, Sato Y, Yamada H, Yeh JK. Effect of risedronate on the cortical and cancellous bone mass and mechanical properties in ovariectomized rats: A comparison with the effects of alfacalcidol. *J Nutr Sci Vitaminol* 2006;52:393-401
25. Iwamoto J, Takeda T, Sato Y, Shen C-L, Yeh JK. Beneficial effect of pretreatment and treatment continuation with risedronate and vitamin K2 on cancellous bone loss after ovariectomy in rats: A bone histomorphometry study. *J Nutr Sci Vitaminol* 2006;52:307-315
26. Sato Y, Honda Y, Asoh T, Iwamoto J. Longitudinal study of bone and calcium metabolism and fracture incidence in spinocerebellar degeneration. *Eur Neurol* 2006;56:155-161
27. Iwamoto J, Takeda T, Sato Y, Shen C-L, Yeh JK. Effect of pre- and post-surgery treatment with risedronate on trabecular bone loss in ovariectomized rats. *Exp Anim* 2006;55:457-466
28. Sato Y, Honda Y, Iwamoto J. Etidronate for fracture prevention in amyotrophic lateral sclerosis: A randomized controlled trial. *Bone* 2006;39:1080-1086
29. Iwamoto J, Seki A, Takeda T, Sato Y, Yamada H, Yeh JK. Comparative effects of alendronate and alfacalcidol on cancellous and cortical bone mass and bone mechanical properties in ovariectomized rats. *Exp Anim* 2006;55:357-367
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32. Iwamoto J, Seki A, Takeda T, Sato Y, Yamada H, Shen C-L, Yeh JK. Comparative effects of risedronate and calcitriol on cancellous bone in rats with glucocorticoid-induced osteopenia. *J Nutr Sci Vitaminol* 2006;52:21-27
33. Iwamoto J, Seki A, Takeda T, Sato Y, Yamada H, Yeh JK. Comparative therapeutic effects of alendronate and alfacalcidol on cancellous and cortical bone mass and mechanical properties in ovariectomized osteopenic rats. *J Nutr Sci Vitaminol* 2006;52:1-8
34. Sato Y, Honda Y, Iwamoto J, Kanoko T, Satoh K. Abnormal bone and calcium metabolism in immobilized Parkinson's disease patients. *Move Dis* 2005;20:1598-1603
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36. Sato Y, Iwamoto J, Kanoko T, Satoh K. Homocysteine as a predictive factor for hip fracture in elderly women with Parkinson's disease. *Am J Med* 2005;118:1250-1255
37. Sato Y, Honda Y, Asoh T, Iwamoto J, Kanoko T, Satoh K. Cardiac involvement in malignant syndrome in Parkinson's disease. *Eur Neurol* 2005; 54: 88-92
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82. Sato Y, Kikuyama M, Oizumi K. High prevalence of vitamin D deficiency and reduced bone mass in Parkinson's disease. *Neurology* 1997;49:1273-1278
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84. Sato Y, Maruoka H, Oizumi K, Kikuyama M. Vitamin D deficiency and osteopenia in the hemiplegic limbs of stroke patients. *Stroke* 1996;27:2183-2187

b. Reviews and meta-analyses

1. Iwamoto J, Takeda T, Matsumoto H, Sato Y. Strategy for prevention of hip fractures in patients with Parkinson's disease. *World J Orthop* 2012;3:137-141
2. Iwamoto J, Takeda T, Matsumoto H. Sunlight exposure is important for preventing hip fractures in patients with Alzheimer's disease, Parkinson's disease, or stroke. *Acta Neurol Scand* 2012;125:279-284
3. Iwamoto J, Sato Y, Takeda T, Matsumoto H. Efficacy of antiresorptive agents for preventing fractures in Japanese patients with an increased fracture risk: Review of the literature. *Drugs Aging* 2012;29:191-203
4. Iwamoto J, Sato Y, Takeda T, Matsumoto H. Effectiveness of exercise for osteoarthritis of the knee: A review of the literature. *World J Orthop* 2011;2:37-42
5. Iwamoto J, Takeda T, Matsumoto H. Efficacy of oral bisphosphonates for preventing hip fracture in disabled patients with neurological diseases: A meta-analysis of randomized controlled trials among the Japanese population. *Curr Med Res Opin* 2011;27:1141-1148
6. Iwamoto J, Matsumoto H, Takeda T. Efficacy of menatetrenone (vitamin K₂) against non-vertebral and hip fractures in patients with neurological diseases: Meta-analysis of three randomized, controlled trials. *Clin Drug Invest* 2009;29:471-479
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10. Iwamoto J, Takeda T, Ichimura S. Combined treatment with vitamin K₂ and bisphosphonate in postmenopausal women with osteoporosis. *Yonsei Med J* 2003;44:751-756
11. Iwamoto J, Sato Y, Tanaka K, Takeda T, Matsumoto H. Prevention of hip fractures by exposure to sunlight and pharmacotherapy in patients with Alzheimer's disease. *Aging Clin Exp Res* 2009;21:277-281

c. Letters

1. Sato Y, Iwamoto J, Kanoko T, Satoh K. Risedronate therapy for prevention of hip fracture after stroke in elderly women. *Neurology* 2005;65:1513-1514
2. Sato Y, Asoh T, Metoki N, Satoh K. Efficacy of methylprednisolone pulse therapy on neuroleptic malignant syndrome in Parkinson's disease. *J Neurol Neurosurg Psychiatry* 2004;75:510-511
3. Sato Y, Kaji M, Saruwatari N, Oizumi K. Hemiosteoporosis following stroke: Importance of pathophysiological understanding and histologic evidence. *Stroke* 1999;30:1978-1979

d. Corrigenda

1. Sato Y, Honda Y, Kaji M, Asoh T, Hosokawa K, Kondo I, Satoh K. Corrigendum to "Amelioration of osteoporosis by menatetrenone in elderly female Parkinson's disease patients with vitamin D deficiency" [Bone 31 (2002) 114-118] (DOI:10.1016/S8756-3282(02)00783-4). Bone 2008;43;217

ii. Expression of concern

a. Original research

1. Iwamoto J, Sato Y, Matsumoto H. Influence of gastrectomy on cortical and cancellous bones in rats. Gastroenterol Res Pract 2013;doi 10.1155/2013/381616.
2. Iwamoto J, Sato Y, Uzawa M, Takeda T, Matsumoto H. Experience with alendronate treatment for four years among Japanese men with osteoporosis or osteopenia and clinical risk factors for fractures. Ther Clin Risk Manage 2010;6;593-600
3. Iwamoto J, Yeh JK, Aloia JF. Differential effect of treadmill exercise on three cancellous bone sites in the young growing rat. Bone 1999;24;163-169

b. Reviews and meta-analyses

1. Iwamoto J, Sato Y, Takeda T, Matsumoto H. Bone quality and vitamin K2 in type 2 diabetes: Review of preclinical and clinical studies. Nutr Rev 2011;69;162-167
2. Iwamoto J, Takeda T, Sato Y. Menatetrenone (vitamin K2) and bone quality in the treatment of postmenopausal osteoporosis. Nutri Rev 2006;64;509-517

c. Letters

1. Sato Y. In reply. Arch Intern Med 2007;167;514-515
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Figure 1

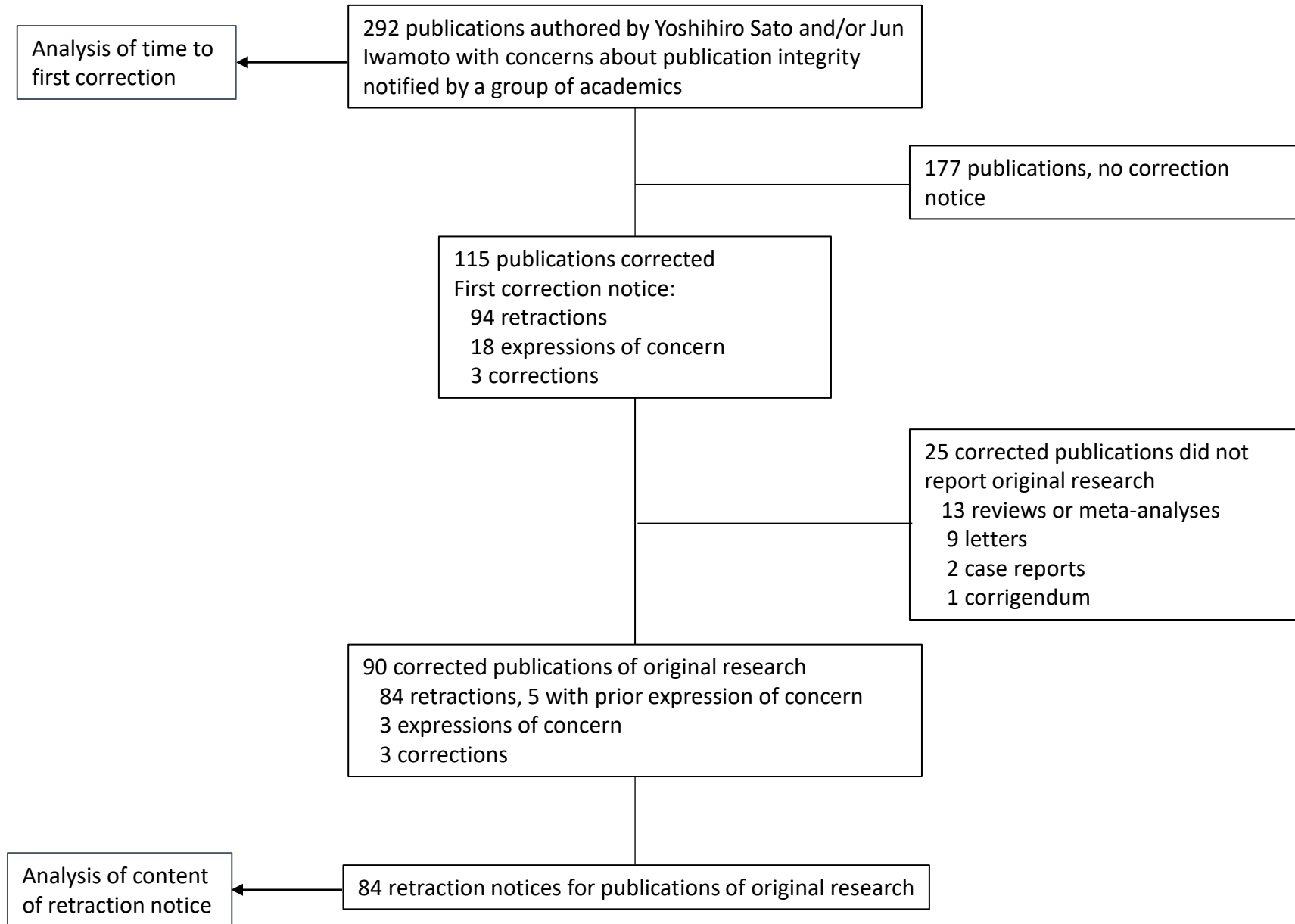


Figure 2

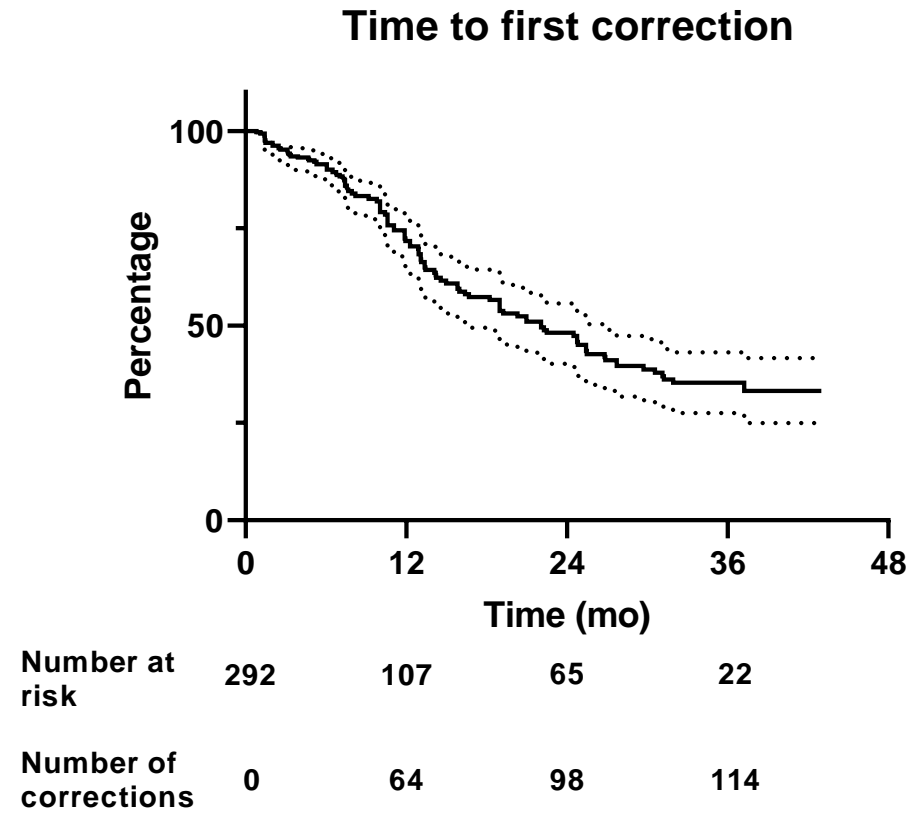


Figure 3

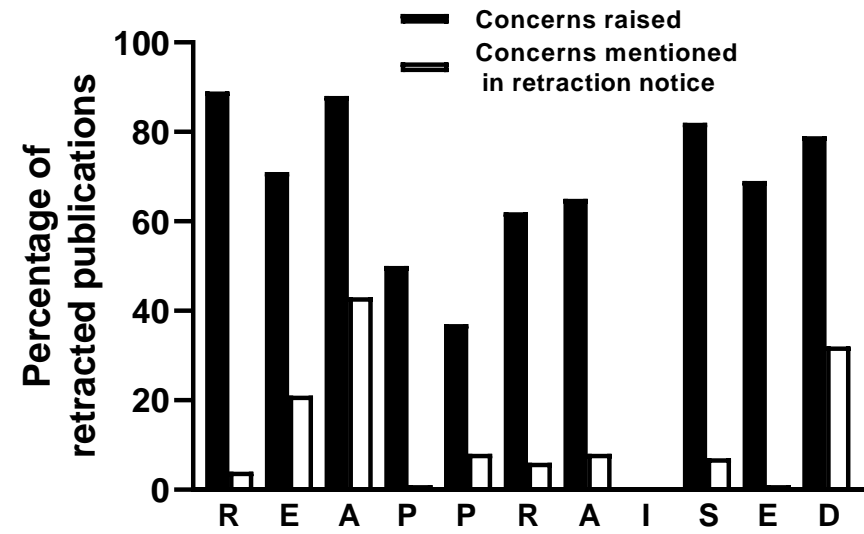
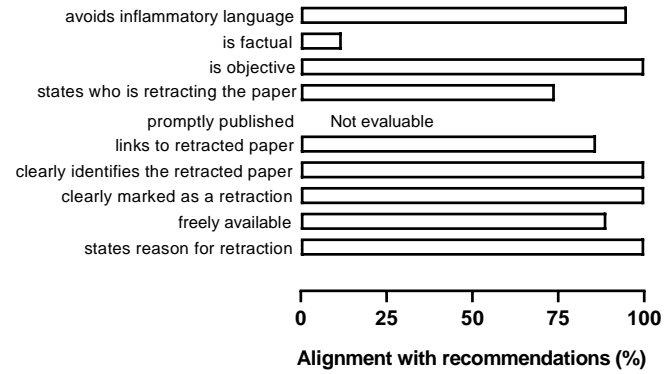
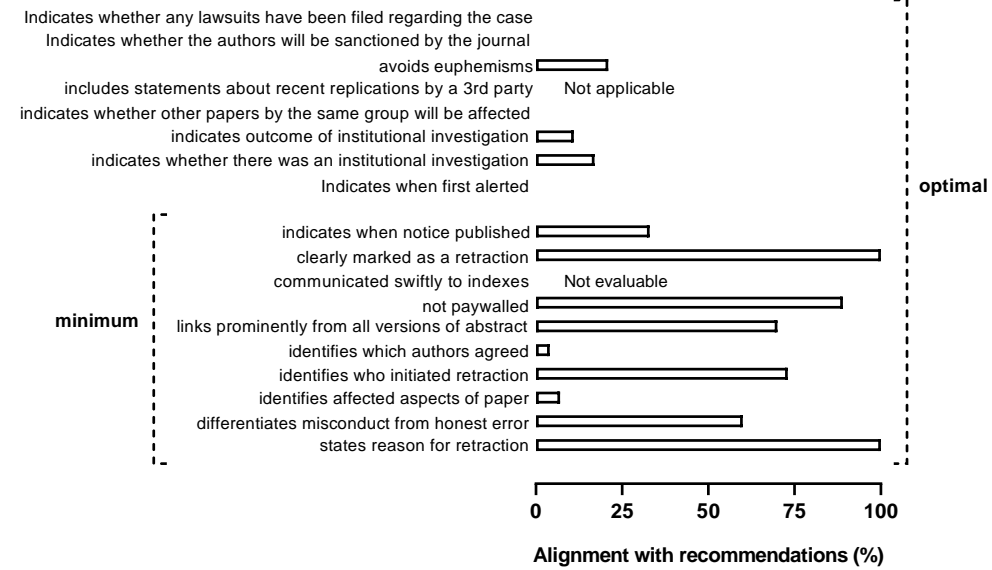


Figure 4

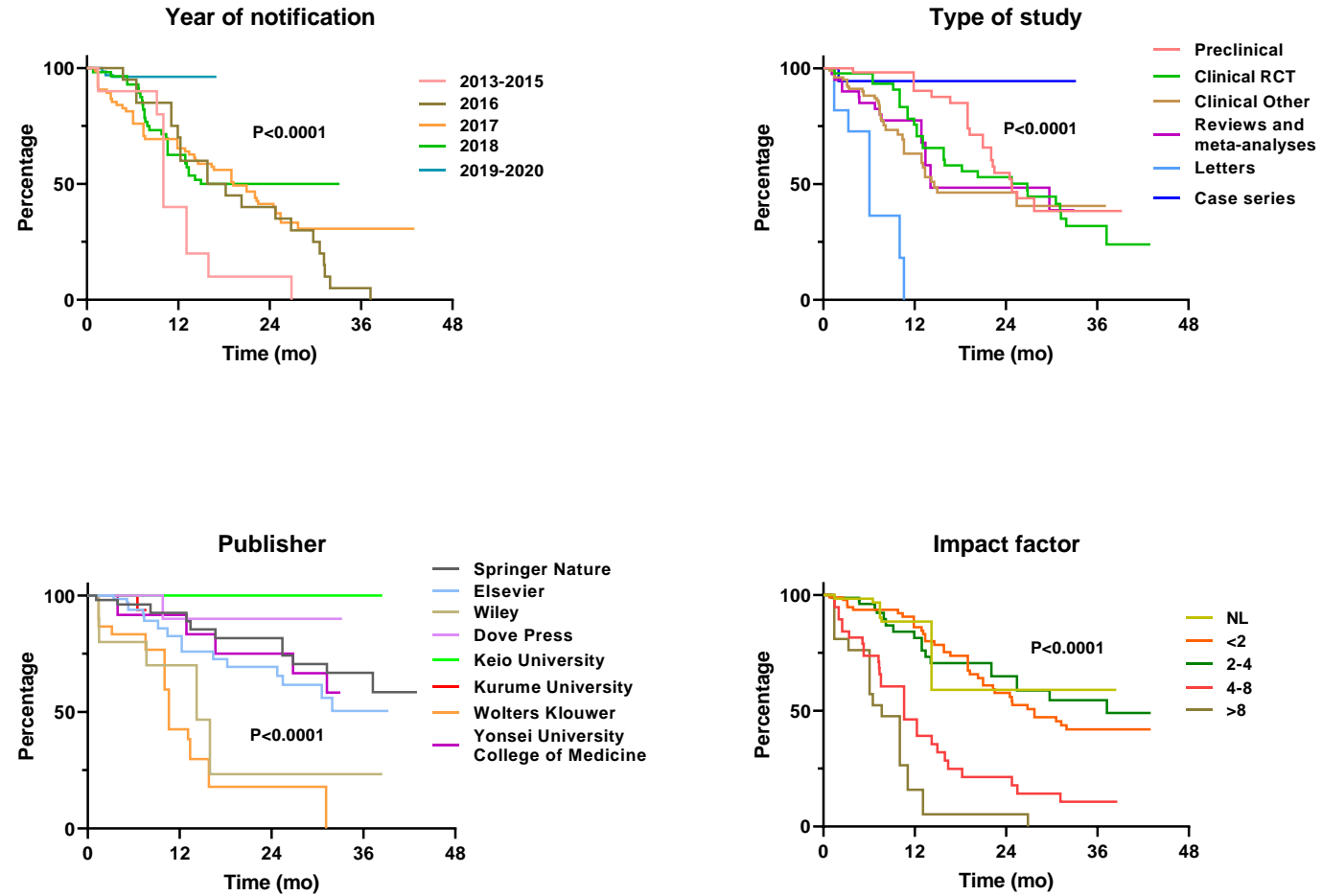
COPE



Retraction Watch



Supplementary Figure



Time to first correction of publications co-authored by Yoshihiro Sato and Jun Iwamoto, according to year of submission of concerns to journal (top left), type of study (top right), publisher (bottom left) and impact factor of journal (bottom right).