5. Establish a Health Research Ombudsman

Experience suggests that even with rules, compliance is poor. An ombudsman is required to police fulfilment of obligations including data sharing, trial reporting and the measures outlined above. The ombudsman will respond to concerns from patients and professionals and will have oversight of public funding of health research. The ombudsman will also enlist peer reviewers to conduct audits of ongoing research, akin to the role of Specialist Inspectors in the CQC. **Conclusions** The profound problems in health research are widely acknowledged. The underlying causes are dysfunctional incentives, opacity and misalignment of research with patient priorities. There is no prospect that these issues will be resolved if we cannot translate the principles in the EBM manifesto into a set of practical measures. The five actions highlighted are not a panacea but they are practical first steps in overturning the scandal of poor medical research.

3 A REVIEW OF THE MAGNITUDE OF FINANCIAL RELATIONSHIPS WITH INDUSTRY AND DISCLOSURE PRACTICES AMONG CLINICAL PRACTICE GUIDELINE AUTHORS

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Objectives Financial conflicts of interest (FCOI) with the pharmaceutical industry are associated with a sizeable, unidirectional, reproducible effect in favor of 'positive' research findings, per a recent Cochrane systematic review. In the context of clinical practice guidelines (CPG) — consensus documents that singularly guide most aspects of patient care — FCOI may result in biased treatment recommendations. Here, to derive a summary effect of the the magnitude of financial relationships with industry among CPG authors, and the accuracy of relationship disclosure, we synthesize both published and unpublished investigations.

Method Our protocol is publicly available (<https://osf.io/MXF4B/>). Using a combination of a PubMed search and expert knowledge of available studies, we gathered all published investigations of CPG author financial relationships with industry. Included studies must have used the OpenPayments database to either: 1) quantify the magnitude of financial relationship or 2) assessed the accuracy of disclosure statements among CPG authors. Raw payments data were solicited from all previous studies and converted to money received per author per 1 year. We combined raw payment data to derive summary measures of central tendency (e.g., medians with interquartile ranges (IQR)) for all four categories of OpenPayments data: General (e.g., personal fees such as speaking or honoraria), Research (e.g., direct costs), Associated research (e.g., grants), and Ownership (e.g., stock). We use Stata 15.1 and the command metaprop to conduct a fixed-effect meta-analysis of the proportion of disclosure statements that were accurate across all eligible studies.

Results All data (including area of medicine) and figures are available via OSF (<https://osf.io/MXF4B/>). A total of 10 studies (4 published, 6 under journal review by our team) with raw payments data comprising 494 CPG authors were retrieved for our analysis of the magnitude of financial relationships. Across all 494 CPG authors, the median total money received

from industry per year was \$14,286 (IQR \$105,964). Authors who received money in each category received (median, IQR): General payments \$4,141 (IQR \$20,641); Research \$3,155 (IQR \$5,396); Associated Research \$66,541 (IQR \$253,552); Ownership \$7,199 (IQR \$121,417).

A total of 9 studies investigated the accuracy of CPG author disclosure using OpenPayments database. The pooled accuracy of disclosure was 18% (95%CI 16% - 20%). One included study represented 62% of the weight in the meta-analysis. In a sensitivity analysis removing this study, the pooled accuracy of disclosure was 30% (95%CI 27% - 34%). **Conclusions** The results of this novel synthesis demonstrate that authors of medical CPGs are heavily conflicted and are likely not representative of most physicians. To curb the effects of FCOI on CPGs, international policy collaborations are necessary to 1) track payments to non-US based physician-authors; 2) improve disclosure of existing FCOIs; 3) encourage divestiture and prevention of future FCOIs.

4 MORE SYSTEMATIC REVIEWS ARE BEING REGISTERED IN PROSPERO EACH YEAR, BUT RECORDS ARE SELDOM UP-TO-DATE

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Objectives Prospective registration of systematic reviews (SRs) is useful as it increases transparency and decreases risk of bias. It also aims to prevent unintended duplication of SRs and facilitates collaboration. Thus, prospective registration is widely recommended in current guidance on SRs. Furthermore, like publishing a SR protocol, registration may increase the methodological quality of the SR.

The international prospective register for SRs, PROSPERO, is the world's first open-access online facility to register SRs. Registration is free of charge and records can easily be updated by the authors. Then a new version of the PROSPERO record is published.

Our primary objective was to determine the proportion of SRs registered in PROSPERO and the influence of publication year, review focus and country on that proportion. Our secondary objectives were a) to compare the basic characteristics of registered and non-registered SRs and b) to assess the up-to-dateness of the PROSPERO records.

Method We searched PubMed for SRs published between 2011 (launch of PROSPERO) and November 2018. We included a random sample of n = 300 SRs that would be eligible for registration in PROSPERO. We excluded scoping reviews, umbrella reviews/overviews and SRs, for which it is mandatory to publish a protocol, e.g. Cochrane reviews.

We extracted data on the following items: Country, focus (therapeutic, epidemiologic, diagnostic, prognostic or other), number of authors, and date of submission, publication and last search. If the SR was registered in PROSPERO, we also extracted the number of versions, status, and date of first and last version.

All data were analysed descriptively. Our primary analysis was based on the whole sample, while our secondary analyses were based on a) the registered and non-registered SRs and b) the identified PROSPERO records. Results

Overall, 15% (44/300) were registered in PROSPERO. This proportion has increased steadily over time and was 29% (15/52) in 2018. Therapeutic SRs were more frequently registered than SRs with another focus, with 18% (22/123) and 12% (22/177), respectively. We did not observe a clear trend regarding the country.

Median number of authors and time from submission to publication did not differ between registered and non-registered SRs. Median time from search to submission was slightly shorter in registered than in non-registered SRs (14 vs 17 weeks), but median time from search to publication was longer (51 vs 43 weeks).

Of the 44 analyzed PROSPERO records, most (82%) have been registered before the date of last search. For 23 records (52%) only one version existed, which means they have never been updated. Only six records (14%) were up-to-date, i.e. their status was 'completed and published' and a link to the publication was available.

Conclusions More SRs are being registered in PROSPERO each year, but only few records are up-to-date. PROSPERO should be further promoted among prospective authors of SRs. Current users of PROSPERO need to be reminded to keep their records up-to-date. This could be done through PROSPERO or by journals when authors submit a manuscript for a SR.

5 PREDATOR PUBLISHING OR FAKE SCIENCE? A CASE SERIES OF 75 UNSOLICITED EMAILS RECEIVED FROM 'PREDATOR JOURNALS.'

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Objectives The rise of 'fake news' has achieved notoriety in the popular press over the last few years. In the scientific press a similar problem, known as 'predator publishing' has arisen. There is currently great debate about the nature and extent of 'predator publishing.' An informal consensus would suggest that junior academics are inundated by requests for articles from journals of dubious quality. These same early career academics are thought to be particularly vulnerable to the pressure to 'publish or be damned.'

Relatively little data is published on the quantitative extent of this problem or its effect on Evidence Based Medicine. Here is described a case series of 75 sequential journal requests received by a postgraduate student over a 4-month period in response to a short letter to *Critical Care* regarding a fungal assay. The 75 paper requests were analysed for features that might make them be considered 'predatory.'

Method

1) 75 consecutive unsolicited email requests from publications requesting article submission were collected and analysed.

The emails were all received to the personal email account of an English-speaking MSc student over a three-month period.

Most cited this researcher's recent academic publications.
2) The following data was extracted from each email:

- Journal name
- Publisher
- Was the journal fee paying?
- Was the journal registered with PubMed? Medline?
- What article processing charges were there?
- ISSN
- Impact factor (Web of Science)

3) Suggestions that the publication may be a 'predator journal' were sought:

- Was the email overly flattering in tone?
- Was the journal relevant?
- Did the journal permit email submissions?
- Was the journal on 'Beal's list' of predatory publications?
- Was the journal on the BIH 'whitelist' of Open Access Journals?

4) In addition, invitations to speak at conferences/to become an editor were collated

Results 75 emails were analysed. The emails requested submissions on topics as varied as 'archives of animal husbandry and dairy science,' and 'Current Trends in Civil and Structural Engineering.'

The majority (65%) were from 5-6 publishers who have been described as 'predator publishers' elsewhere.

- All 75 journals were fee-paying
- Only 4 were registered with MEDLINE
- 23 has selected citations on MEDLINE
- 10 could not be found on PUBMED
- The mean average requested APC was \$1690
- Only 44 journals clearly displayed ISSN numbers.
- 33 of the email requests were phrased in language that could be described as effusive or sycophantic.
- Only 25 bore any relevance to the original article submitted to critical care.
- 50 of the journals accepted email submissions.
- Only 2 of the journals appeared on the BIH 'whitelist'
- 58 appeared on 'Beal's list,' a well-known archive of 'nuisance or 'predator' publications.
- 20 speaking requests, 5 editorial invitations received.

Conclusions This case series describe email requests to publish received by a junior academic over a 4-month period. During this short time the researcher received over 75 requests. The majority were from a small number of publishers, all of which have been accused of producing 'predatory journals' in the past. The vast majority appeared on easily accessed 'blacklists' and only three appeared on commonly used 'white lists.'

The evidence of this case series suggests that junior academics are exposed to 'predator publications.'

However, these papers are so easily identified as suspect that it is hard to imagine anyone being genuinely fooled by them. It would be wiser to acknowledge to remove the passive 'predator' description and acknowledge that these journals are co-produced by the scientific community.