**Title**

Adherence Of Medical Case Reports Published In 2015 In PubMed Indexed Indian Journals To CARE 2013 Guidelines

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**Abstract**

**Background**

A case report is the scientific documentation of a single clinical observation and is useful for both advancing knowledge and as a medical education tool. In 2013, an independent group of researchers developed a checklist called the CARE guidelines to standardize reporting of case reports and improve their quality and transparency. The present study was carried out with the primary objective of assessing adherence to CARE guidelines among PubMed indexed Indian medical journals in one year with a secondary objective being to assess the extent of endorsement of these guidelines by the journals.

**Methods**

We searched PubMed for case reports published in 2015 in Indian medical journals. Case reports published in that one year, indexed by PubMed, belonging to medical stream and those that were currently active and journals that had an impact factor were included for analysis. Case series and those journals that were published from India but for another country were excluded. Total adherence score and classification of adherence as excellent, very good, good and poor as also adherence to individual components of the checklist were the outcome measures. We tested the association between the type of journal and impact factor with adherence by using the chi-square test and generated crude odds ratios. All analyses were done at 5% significance.

**Results**

A total of 162 journals were identified by the search strategy of which 36 satisfied the selection criteria. In these n = 36 journals, n = 1178 case reports were published. Based on the total percent score, no case report had excellent, 19% had good, 70.7% average and 10% poor adherence respectively. Among the sub-items, the best adherence was seen in the clinical findings [97.9%], followed by key words [88.5%] and introduction [71.5%]. The items with extremely poor adherence were patient perspective [0%], informed consent [2.8%] and timeline [4.6%]. Journals with an impact factor more than 1 had better adherence relative to those with an impact factor lower than 1. Only one journal’s website mentioned the CARE guidelines.

**Conclusion**

Greater awareness needs to be created among author, peer reviewers and editors about using these guidelines. As informed consent is a metric of autonomy, all three stakeholders must ensure its reporting.

**Main paper**

**Background**

A case report is defined as the scientific documentation of a single clinical observation [1]. The use of these case reports has been and will always remain an important tool for advancing clinical knowledge as also for teaching and training purposes. Additionally, its inherent strength lies in its ability to weave together two narratives – that of the patient and the other of the treating physician [2]. Hence presenting case reports appropriately in medical literature is important.

In 2013, for the first time, standards for the reporting of case reports called the CARE [CAse REport] guidelines were developed by an independent international group of experts [3]. The idea behind them was to improve completeness and transparency of publication so that well written case reports would then, subsequently, inform provision of healthcare and provide early signals of safety and benefit [4]. At the present moment, unlike the CONSORT guidelines, only a limited number of journals internationally have published and/or endorsed these guidelines. Against this backdrop, we carried out the present study with the primary objective of assessing adherence of case reports to CARE guidelines among PubMed indexed Indian medical journals in one year. A secondary objective was to assess the extent of endorsement of these guidelines by the journals.

**Methods**

*Ethics* –We submitted the study protocol to the Institutional ethics committee who deemed it exempt from review [as data was available in the public domain].

*Selection criteria* *and study sample*–We conducted the study for the year 2015 as this would be two years after the guidelines were introduced. Inclusions were 1) Case reports published in that one year, 2) Indian journals from medical specialities indexed by PubMed, 3) Journals were currently active and with an impact factor. Case series and those journals that were published from India but for another country were excluded.

*Search strategy*- We searched the Medline/PubMed database using the search strategy {India\* AND medicine [Mesh] NOT “Specialities, Surgical” [Mesh], India [publisher] AND health occupations [Mesh], India [pl] NOT India [publisher] AND health occupations [Mesh]}.

*Use of the checklist, scoring and calculation of adherence* – We used the 13 item CARE checklist [5] and individual components were allocated weighted scores and a total score per report was calculated. We then converted the total score into a percent total score. Case reports were classified as having excellent, good, average or poor adherence if the scores fell into the following ranges respectively [100-90%, 89-70%, 69-50% and 49% or lower]. Adherence for the sub-items of the CARE guidelines was similarly calculated. All of these were done through consensus in a series of meetings among the authors. Journals identified *via* the search were classified as general medical, speciality or super-speciality journals and then divided into those with an impact factor more than 1 or less than 1.

*Outcome measures*- The proportions of case reports in each adherence category [excellent, very good, good and poor] was analyzed. Likewise, proportions of case reports that adhered to each sub-item of the CARE guidelines was also analyzed.

*Statistical analysis* – We applied both descriptive and inferential statistics. The total score was expressed as mean and standard deviation [SD] while the number of journals in each category was expressed as proportions. The association between the type of journal and impact factor with adherence was assessed using the chi-square test and crude odds ratios with 95% Confidence Intervals [CIs] generated. All analyses were done using Microsoft Excel and a ‘p’ value of less than 5% was considered significant.

*Post study search –* At the point of writing the paper, we looked at all the journal websites once again to see if they endorsed the CARE guidelines.

**Results**

*Demographics* – A total of n = 162 journals were identified by the search strategy. Of these, 126 [77.8%] were excluded for the following reasons – surgical or non-medical journals [n=37], not currently indexed [n=33], not currently active [n=24], published from India but for another country [n=20] and did not publish case reports [n=12]. There were n=6 general medical, n = 21 speciality and n = 09 superspeciality journals. Twenty-nine journals had an impact factor below one while the remaining n = 7 had an impact factor more than 1. A total of n=36 Indian medical journals formed the final sample and n = 1178 case reports were published in these journals in 2015. Table 1 gives the breakup of numbers of case reports published in each of these journals.

*Overall adherence of case reports [n=1178]* – The overall percent adherence score {expressed as mean [SD]} for all journals was 61.2% [9.2]. It was seen that 10.3% case reports had poor adherence, 70.7% average and 19% good adherence. No case report fell into the excellent adherence category.

*Adherence of sub-items of the CARE checklist*– The best adherence was seen in the clinical findings 97.9%, followed by key words 88.5% and introduction 71.5%.The items with extremely inadequate/poor adherence were patient perspective 0%, informed consent 2.8% and timeline 4.6%. Graph 1 depicts adherence of all case reports to individual components of the CARE checklist.

*Association of adherence with impact factor* – It was seen that case reports published in journals with an impact factor of more than 1 had better adherence score relative to those published in journals with an impact factor less than 1 {cOR 16.4 [9.3,17.8], p <0.001}

*Association of adherence {expressed a Mean [SD]} and type of journal* – Speciality journals had better overall adherence relative to general medical journals {64.81 [8.7] *vs* 58.15 [7.9], p < 0.001}.Similarly, speciality medical journals also had better overall adherence relative to superspeciality journals {64.81 [8.7] *vs* 59.14 [9.4], p < 0.001}.

*Analysis of journal websites* – At the point of the study no journal from the study sample had endorsed CARE guidelines. A repeat search January 2018, done at the point manuscript writing showed that 1/36 endorsed the CARE guidelines. The need for informed consent prior to publication was mentioned by 26/36 [72%].Six of these journals needed consent only for publishing photographs.

**Discussion**

We evaluated the adherence to the 2013 CARE checklist of 36 Indian medical journals identified *via* a PubMed search and found that almost three quarters of them had only “average” adherence to the guidelines; only 3% case reports mentioned informed consent from the patient prior to publication and only one journal mentioned the guidelines on its website.

Our findings are similar to observations made by other authors. Kaszkin-Bettag [2012] evaluated the n= 150 case reports on metastasizing basal carcinoma and found the quality to be uneven. The case reports did not mention drugs used for chemotherapy. When mentioned, doses, duration and chemotherapy cycles were missed [6]. Kljakovic [2002] in an audit of case reports published in general practice and general medical journals similarly found that only 5% case reports reported informed consent [7]. As both these audits preceded the publication of the CARE guidelines, one may expect an improvement in quality of reporting subsequent to their publication. Given that this has not happened, greater awareness needs to be created among authors, reviewers and editors about the need to adhere to and endorse these guidelines.

Journals with an impact factor of more than 1 had better quality reporting. The journal impact factor [with all its fallacies] is used as a surrogate metric of quality of the journal. We are unable to explain the reason for this. However, the difference may or may not be a true difference as the number of journals in the greater than 1 impact factor category were only 7. What is more relevant is that with most Indian journals, editors usually work at middle or senior level positions at teaching institutes attached to university hospitals and editorial responsibility is added onto to an existing full-time job. This is the likely cause of inadequate attention paid to case reports and their publication leading to low adherence as also a reflection of the inadequate quality of peer review.

Of all the findings, the poor reporting of informed consent is the most distressing. This may represent one of two things- consent was taken, but not reported with the latter being more serious. It is also possible that per editorial policy, consent reported by authors was not mentioned in the publication. Once editors adhere to CARE guidelines, this issue will be taken care of and there will be uniformity and transparency in reporting informed consent.

Unlike consent for participation in a clinical trial or undergoing a medical procedure, publication of case report may reveal identity and issues of privacy and confidentiality come up. Hence taking the consent of the patient before publishing is an ethical imperative [8]. This is also now mandated by the recently released National Ethical Guidelines for Biomedical and Health Research involving Human Participants released in 2017 by the Indian Council of Medical Research [9]. Material within the case report may be identifiable [the face for example] or non-identifiable when anonymized [X-rays, CT scans].Wherever the identity of the individual is at risk of being revealed, this must be explicitly stated in the consent form and the patient counseled and consented [as per ICMR guidelines 2017 10.8.2].Ethical concerns about informed consent and confidentiality are best protected by the author(s), the journal editor and peer reviewers to whom the case report is submitted. Some journals published outside the country mandate that the case report be reviewed by the patient to permit editing or removal of any material that he /she would not want to disclose [10].They suggest creating consent forms, including an additional consent for potentially identifiable information, and an opportunity for the patient/representative to actually review and approve the manuscript [11] and putting them up on their websites. While this may not always be possible in India given the differential cultural context and literacy levels, informed consent is an imperative with the patient receiving an adequate explanation about the risks of revealing identity or disclosure of sensitive, private information where applicable. Among all the sub-items of the CARE checklist, this is probably the most important of all and must be given due attention by authors, peer reviewers and editors.

Our study is limited by including only those articles published under the “Case Report” section of journals. We could have thus missed out case reports published under other sections such as “letter to editor”, “images in medicine”, “case snippets” or even “e-case reports”. and that too M We did not include surgical case reports as there exist a different set of guidelines for them called the Surgical CAse Reports [SCARE] guidelines [12].Also, the study wasdone only two years after the publication of the guidelines and this time period may have been inadequate for both dissemination and awareness.

In summary, an audit of Indian medical journals publishing case reports showed inadequate adherence to the CARE 2013 guidelines. This can be addressed by creating greater awareness about using these guidelines. As informed consent is a metric of autonomy, all three stakeholders- authors, peer reviewers and editors must ensure it’s reporting in all case reports.

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**Conflict of interest**

None

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**Table: 1**

**Demographics of the n = 1178 case reports**

|  |  |  |
| --- | --- | --- |
| **Type of journal** | **Number** | **Number of case reports expressed as a percent** |
| Speciality | 21 | 497 [42.2] |
| Superspeciality | 09 | 281 [23.9] |
| General medical journals | 06 | 400 [33.9] |
| **Impact factor** | | |
| More than or equal to 1 | 7 | 147 [12.5] |
| Less than 1 | 29 | 1031 [87.5] |

**Figure: 1**

Adherence of individual sub-items of the CARE checklist among the case reports (n = 1178)