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Informed consent and ethics committee involvement in case reports and case series: cross-sectional meta-research study

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Abstract

Background Although the research should guarantee the protection of privacy and personal data, case reports and case series frequently lack the involvement of the ethics board and informed consent that includes the required information. This study aimed to analyze the reporting about informed consent and ethics committees in case reports and case series.

Methods This cross-sectional meta-research study analyzed case reports and case series published in 2021, indexed in PubMed, and available as open-access articles. Extracted variables included authorship details, country, journal name, number of cases, and documentation of informed consent and ethics committee approval.

Results This study analyzed 2053 case reports and case series. Most articles (86%) reported a single case. Statements about informed consent were reported in 79% of cases. Informed consent was primarily obtained from patients (74%). Statements about an ethics committee were reported in 46% of articles. In 24% of articles, it was reported that approval was obtained from an ethics committee. Case reports were significantly more likely to include a statement on informed consent than case series. On the contrary, case series were significantly more likely to report ethics committee statements than case reports.

Conclusion The findings reveal inconsistencies in ethics reporting, with 46% of articles mentioning ethics committee involvement and varying justifications for exemption. While 79% of articles reported informed consent, further improvements in transparency and standardization are needed. Clear guidelines on ethical approval requirements and consent documentation should be established to enhance the quality and ethical rigor of case reports.

MeSH keywords Case Reports, Case Series, Ethics, Informed Consent, Institutional Review Board, Meta-Research, Publishing Trends

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Background

Case studies, case reports, and case series are descriptive studies that illustrate innovative, unusual, or atypical features found in patients in clinical practice. They may also lead to the development of new research topics [1]. In addition, such observations must be original in some manner and contribute to our understanding of the disease being researched to be worthy of publication [2].

A case report is unique since it communicates a patient's medical condition, which is typically a very personal issue [2]. Consequently, authors and editors should handle private information with utmost care and attention. They have an ethical responsibility to protect patients' medical information. One of the essential principles of contemporary medical ethics is confidentiality, and patients anticipate that any personal information they provide to authors will be kept private [3]. Because of that, it is crucial to let the patients know where and how their experiences and specific medical information will be communicated as part of the study process. Before engaging in the study, each patient must be informed of the research structure, possible benefits and risks, and other relevant study details [4].

The key to the ethical publication of case reports is a patient agreement, a crucial element of publication. Patients give their agreement in the form of informed consent. Informed consent is also an important element of the interaction between the patient and the author. It is the interaction between the legal affirmation of a person's right to self-determination and the ethical concept of autonomy [5].

In addition to informed consent, an ethics committee (i.e., an Institutional Review Board, IRB) can provide additional privacy and ethical protections [3]. This institutional structure might offer authors advice and oversight during the research process [2]. Namely, ethics committees can serve an important role by ensuring that the informed consent process is sufficiently robust, that appropriate steps are taken to protect patient privacy, and that the case is presented in a way that minimizes potential harm or stigma to the patient or community. For example, in borderline or complex cases (e.g., involving rare diseases, vulnerable populations, culturally sensitive topics, or easily identifiable cases), a brief ethics consultation or expedited review may help identify potential issues the authors may not have considered. Moreover, institutional ethics oversight can help standardize decisions on when formal consent or anonymization is enough and when additional review is warranted.

A unique aspect of ethical oversight in case reports and case series is that ethics review, when sought, is inherently retrospective. These publications describe clinical encounters that have already occurred, with no prospective study design, hypothesis testing, or planned data collection beyond what was done for clinical care. As such, traditional ethics committee review processes, which were designed primarily for prospective research involving interventions, may not always be a perfect fit for case-based reporting and a proportional measure.

Whether authors should seek ethics committee approval for publishing a case report may depend on several factors, and there is no universally accepted standard. Authors should consider local institutional policies, which may vary significantly. Some institutions require formal IRB exemption letters even for single-patient case reports, while others leave the decision to the discretion of the authors or department heads. In many institutions and jurisdictions, single case reports are not considered "research" in the regulatory sense and may be exempt from formal ethics committee review. However, this exemption does not mean ethical considerations can be overlooked. These discrepancies may be influenced by national laws, such as the General Data Protection Regulation (GDPR) in the European Union, institutional policies, and professional ethical standards. The threshold for perceived ethical risk, particularly regarding privacy, identifiability, and patient consent, also varies.

The primary ethical concern in case reports relates to patient privacy and confidentiality. Even when data are anonymized, specific details may risk patient identification, particularly in rare or unusual cases. Informed consent is, therefore, considered a minimum ethical requirement. Yet, questions arise in complex cases where consent cannot be obtained (e.g., the patient is deceased or unreachable), or when anonymization is incomplete. Ethics committees can offer proportionate oversight in such situations, helping authors assess whether the benefits of publication outweigh potential risks to the patient or their family.

Furthermore, many journals now require authors to state whether ethics approval was obtained or deemed unnecessary, placing additional responsibility on researchers to justify their decisions transparently. Ultimately, while ethics committee approval may not be mandatory for all case reports, seeking guidance, particularly in ethically complex or ambiguous cases, can help ensure that patient rights are respected and that the publication aligns with accepted ethical standards.

In 2006, Schroter et al. analyzed reporting of ethics committee approval and patient consent in articles published in five general medical journals between February and May 2003. The analysis included 370 articles reporting various study designs. Ethical approval was not mentioned in 31%, and consent was not mentioned in 47% of the articles. For case reports and case series, the authors indicated that ethics approval "is not required". Thus, for those types of articles, they only analyzed whether patient consent was mentioned. They found that 93% of

case reports and 83% of case series did not mention consent [6]. In a sample of 480 case reports and case series published from 2006 to 2017, Tran et al. found that 27% reported having IRB approval and 39% reported they obtained informed consent [7].

We could not find more recent studies that have analyzed the ethics and consent of case reports and case series. Understanding how often and in what manner ethics committee involvement is reported in case reports and case series is important for several reasons. First, it helps identify current practices and inconsistencies in ethical oversight, which can inform the development of more precise, consistent guidance for authors and institutions. Second, the findings are relevant to journal editors and peer reviewers, who play a key role in upholding publication ethics and meeting appropriate ethical standards. Third, ethics committees may benefit from greater insight into the ethical challenges specific to case-based publications and how their involvement is being documented.

This study aimed to analyze the reporting about informed consent and the involvement of an ethics committee in a large sample of case reports and case series.

Methods

Study design

This was a cross-sectional meta-research study.

Protocol

The study protocol was designed prospectively and published on Open Science Framework on February 2, 2023 (https://osf.io/r8mh4/).

Ethics

We analyzed publicly available research reports. Thus, approval of an ethics committee was not necessary for this study.

Eligibility criteria

We analyzed scholarly articles labeled as a case report or a case series in the title, published in 2021, indexed on PubMed and available open access. We randomly selected 10% of the records for our analysis. For randomization, we used web site www.randomizer.org.

Search

We searched PubMed with the syntax "case report"[Title] OR "case series"[Title]. Additionally, we used a PubMed filter for "free full text" and a period for time from January 1, 2021 to December 31, 2021. The search was conducted on February 3, 2023.

Screening

One author checked the records eligibility and to ensure that the words "case report" or "case series" in the title may not have been used in another context or for corrections, retractions, comments or any other type of article that does not describe the presentation of one or more cases. A second author checked all excluded papers. In case of doubt, the decision to include the article was made by agreement between the two authors. When needed, a third author was included in the discussion. We reported the number of articles excluded during screening and the reasons for exclusion.

Data extraction

We designed a data extraction form specifically for this study. Two authors independently tested the form on 20 articles from the included sample. The form was iteratively revised until it was considered adequate.

Two authors independently extracted data from the first 100 articles. Data were compared, and since there were no major discrepancies between the two authors, one author resumed extraction of all records, and another author verified 10% of all extractions.

The following data were extracted: last name of the first author, country of the corresponding author, journal name, does the article describe one case or several cases (if the article describes several cases, how many), availability of information regarding informed consent (Yes/No) [If yes, the information was extracted verbatim and then categorized; If yes, whether a patient or another person (i.e. a caregiver) provided consent], availability of information regarding ethics committee (i.e. IRB) (Yes/No) [if yes, the information was extracted verbatim and then categorized].

We extracted information as they were reported. We did not make assumptions that a lack of reporting of informed consent/ethics review necessarily implies that the study has not obtained consent/has not been reviewed.

Data analysis

Descriptive statistics, including frequencies and percentages for the variables, were used. The chi-square test was used to test differences in the frequency of informed consent use and the involvement of an ethics committee between case reports and case series. MedCalc software (MedCalc Software Ltd., Ostend, Belgium) was used for data analysis.

Raw data

The raw data collected within the study are available in Supplementary file 1.

Table 1 Characteristics of included articles (*N* = 2053)

Variable	*N* (%)
Affiliation of the corresponding author	
China	402 (20)
USA	264 (13)
Japan	206 (10)
India	129 (6.3)
Italy	115 (5.6)
Republic of Korea	78 (3.8)
Germany	57 (2.8)
Iran	52 (2.53)
UK	41 (2.0)
Morocco	41 (2.0)
Saudi Arabia	36 (1.8)
Spain	33 (1.6)
Indonesia	33 (1.6)
Brazil	28 (1.4)
Taiwan	28 (1.4)
Canada	25 (1.2)
France	23(1.1)
Nepal	22 (1.1)
Australia	21 (1.1)
Portugal	21 (1.1)
Other	398 (19)
Journal where the article was published	
Int J Surg Case Rep	102 (4.9)
Medicine (Baltimore)	86 (4.2)
Cureus	81 (3.9)
World J Clin Cases	74 (3.6)
Clin Case Rep	66 (3.2)
J Med Case Rep	57 (2.8)
Eur Heart J Case Rep	54 (2.6)
Ann Med Surg (Lond)	36 (1.7)
J Surg Case Rep	32 (1.6)
Front Pediatr	29 (1.4)
Front Oncol	28 (1.4)
Radiol Case Rep	27 (1.4)
J Orthop Case Rep	24 (1.2)
Front Neurol	23 (1.1)
Urol Case Rep	22 (1.1)
Other	1312 (64)
How many cases did the article present?	
1	1758 (86)
2	66 (3.2)
3	60 (2.9)
4	32 (1.6)
> 4	137 (6.7)

Results

The search retrieved 21,599 articles. We randomized 10% and got 2161 articles. After screening, 103 were excluded because they did not report a case report or case series. Finally, 2053 articles were included in the analysis.

Characteristics of included articles

20% of the corresponding authors were affiliated with China, followed by the USA and Japan. The articles were published in 588 different journals. Most of the included articles were published in journals International Journal of Surgery Case Reports, Medicine (Baltimore) te Cureus. The majority of articles (86%) contained report of a single case report (Table 1).

Table 2 Reporting information about informed consent

Variable	*N* (%)
Statement about the informed consent reported in the total sample? (*N* = 2053)	
Yes	1630(79)
No	423 (21)
Statement about the informed consent reported in case reports? (*N* = 1758)	
Yes	1420(81)
No	338 (19)
Statement about the informed consent reported in case series? (*N* = 295)	
Yes	210 (71)
No	85 (29)
Category of statements reporting on the informed consent (*N* = 1630)	
1. Patient(s) provided written informed consent for publication of the article and accompanying images	479 (29)
2. Patient(s) provided written informed consent	267 (16)
3. Consent was obtained or waived by participant(s)	68 (4.1)
Individual(s) that provided informed consent (*N* = 1630)	
Patient	1206
Patient's parents	(74)
Legal guardian/next of kin	98 (6.0)
Unclear	97 (5.9)
Patient's family	73 (4.4)
Patient and family	25 (1.5)
Patient and parents	18 (1.1)
Patient or legal guardian/next of kin	13 (0.7)
Patient and legal guardian/next of kin	11 (0.6)
Pet's owner	6 (0.3)
Patient's caregivers	5 (0.3)
Patient or family	4 (0.2)
	1 (0.06)

Reporting informed consent

Statements regarding informed consent were reported by 79% of the articles. In case reports it was reported in 81% of the articles, compared to 71% in case series (Table 1). The chi-square test revealed a statistically significant difference in the reporting of informed consent between case reports and case series ($\chi^2 = 19.67$, df = 1, $p < 0.0001$), with case reports being more likely to include a statement on informed consent than case series.

Those articles mostly (29%) indicated that patient(s) provided written informed consent for publication of the article and accompanying images. The next most common category of statements (16%) indicated that patients provided written informed consent, without specifying what they consented to. In most articles, informed consent was provided by a patient (74%), followed by a patient's parents (6%) and legal guardian or next of kin (5.9%) (Table 2).

The involvement of an ethics committee involvement

Less than half of the articles reported a statement about an ethics committee (46%). This was reported in 44% of case reports, compared to 57% of case series (Table 3). The chi-square test showed a statistically significant difference in the reporting of ethics committee statements between case reports and case series (χ^2 = 17.33, df = 1, $p < 0.0001$), with case series being more likely to report ethics committee statements than case reports.

Among those articles, most indicated that an ethics committee approved the study. The second most common category of statements (28%) indicated that formal ethical approval for case reports is not required in accordance with the institutional policy. The remaining statements were categorized as unclear because it was unclear from those statements whether the ethics committee approved or waived the study. An example of such statements is: "*Institutional Review Board for Human Subjects monitored the publication of this case study*" (Table 3).

Table 3 Reporting information about an ethics committee involvement

Variable	*N* (%)*
Statement about an ethics committee reported in the total sample (*N* = 2053)?	
Yes	939 (46)
No	1114 (54)
Statement about an ethics committee reported in case reports? (*N* = 1758)	
Yes	771 (44)
No	987 (56)
Statement about an ethics committee reported in case series? (*N* = 295)	
Yes	168 (57)
No	127 (43)
Did ethics committee statement report that the authors obtained approval of an ethics committee?	
Yes	492 (24)
No	368 (18)
Unclear	79 (3.8)
Reasons for not obtaining an ethics committee approval (*N* = 231)	
Formal ethical approval for case report not required in accordance with the institutional policy	91 (28)
It is not explained why ethical approval is not required	49 (13)
Exemption from ethical approval, but it is not explained why it was exempt.	42 (11)
Ethical review and approval was not required for the study on human participants in accordance with the local legislation and institutional requirements.	33 (8.9)
Not required because the patient provided written informed consent for the publication of this report	10 (2.7)
The article does not contain any experiments with human participants.	6 (1.6)

*Percentages may not add up to 100% due to rounding

Discussion

This study analyzed 2,053 case reports and case series from various medical journals, focusing on geographic distribution, publication characteristics, and ethical considerations. Most articles reported a single case. A statement about informed consent was reported in most cases, primarily obtained from patients. Less than half of the articles reported a statement about an ethics committee. A quarter of articles reported that ethics committee approval was obtained.

Informed consent was reported in 79% of the articles, with most indicating that the patient provided written consent for publication and accompanying images. This is a much larger percentage compared to the findings of Schroter et al. about the presence of a statement about informed consent in a sample of articles published in 2003. Their analysis indicated that 7% of case reports and 17% of case series mentioned consent [6]. It should be highlighted that their sample was much smaller, as they included 370 articles, whereas there were 25 case reports and 12 case series [6].

Of note, Schroter et al. did not analyze the presence of statements regarding an ethics committee in case reports and case series, as they labeled that ethics approval is not required for those study designs [6]. However, this may not be the case for every institution.

Tran et al. analyzed ethical approval and informed consent reporting in a sample of 480 case reports and case series published on PubMed in 12 consecutive years from 2006 to 2017. Among the included studies, 27% reported having IRB approval, 7.3% reported adhering to the Helsinki declaration, and 39% reported obtaining informed consent [7].

In our study, 46% of articles contained a statement about an ethics committee, but 24% reported that an ethics committee approval was obtained. Compared to 27% of articles with IRB approval from the study of Tran et al. [7], our result was slightly lower than in the sample of studies from 2006 to 2017.

Our findings may reflect a growing awareness of the ethical responsibilities of medical researchers in ensuring patient consent for publication, but no change in terms of ethics committee (or IRB) approval. An alternative explanation could be that journals nowadays require consent statements more frequently than in the past. This may also be part of a broader cultural shift in research ethics, research practices, privacy laws, and regulations rather than being solely related to researchers' sense of responsibility or awareness. Our sample may have different results because the authors were adhering to journal policies and institutional guidelines.

The lack of statements about ethics committee involvement in more than half of the articles could be attributed to several factors, including authors' awareness about the

topic, institutional policies, journal policies, and editors' and peer-reviewers' awareness. An explanation could be that authors may not be aware of the ethical considerations regarding case reports, so they may not include statements about ethics in the manuscript. On the contrary, it is also possible that researchers were aware of ethical implications and therefore report on informed consent, but ethics review is not considered necessary.

Furthermore, reporting may not be reflective of real-world practice. It is possible that an ethics committee reviewed the case study or a case report, and that patients provided consent, but that the authors did not report it in the manuscript.

Our findings indicate a significant discrepancy in the reporting of ethical considerations between case reports and case series. Specifically, case reports were significantly more likely to include a statement on informed consent, while case series were substantially more likely to report ethics committee involvement. These differences highlight variability in ethical reporting practices, which may be influenced by editorial policies, ethical oversight expectations, and differences in how case reports and case series are perceived within the research and publishing community.

The higher frequency of informed consent statements in case reports may stem from the fact that case reports typically focus on a single patient, making individual patient consent a critical ethical component. Many journals that publish case reports have strict policies requiring explicit patient consent documentation, ensuring that authors confirm permission to publish identifiable information, including clinical details and images.

Conversely, the higher frequency of ethics committee approval in case series suggests that case series may be perceived as more formal research investigations, often requiring institutional ethical oversight. While individual case reports are generally considered descriptive and non-experimental, case series, especially those involving multiple patients, systematic data collection, or retrospective analyses, may be subject to stricter regulatory requirements, necessitating review by ethics committees or IRBs. Some institutions and journals classify case series as retrospective research studies rather than anecdotal reports, leading to increased scrutiny regarding ethical approval.

The disparity in reporting practices may also reflect unclear or inconsistent guidelines across journals regarding the necessity of ethical approval for case reports versus case series. While many guidelines explicitly require informed consent for case reports, policies regarding ethics committee approval for case series are more variable, depending on study design, data sources, and journal requirements. This inconsistency can lead to heterogeneous reporting, where ethical approval is documented in some case series but omitted in others.

From a broader perspective, both informed consent and ethics committee approval are essential components of ethical research conduct. This applies not only to large-scale studies but also to case reports and case series, which, although often perceived as less formal, are still forms of research. The underreporting of either aspect, whether in case reports or case series, raises concerns about transparency, accountability, and adherence to ethical standards in biomedical publishing.

Institutional policies may not require formal ethical approval for case reports, or there may be a belief that such approval is unnecessary when patient consent is obtained. While some institutions may exempt case reports from ethical review, this does not negate the importance of ethical oversight, as these reports still involve human participants whose confidentiality and rights must be safeguarded.

Journals are usually considered to have an essential role in ensuring transparent reporting. Journal policies should help authors clearly report ethical aspects. Editors and peer reviewers can facilitate the implementation of these policies. However, it needs to be acknowledged that the ethics review practices are primarily shaped by national laws, institutional regulations, and broader legal frameworks. Journals can encourage ethical rigor through editorial policies and peer-review processes, but they do not have the authority to dictate whether ethics committee approval is required in a given jurisdiction. Therefore, journal policies should strive to promote clarity and consistency in ethical reporting. However, broader systemic changes, such as harmonized international guidance or institutional standards, are needed to reduce ambiguity and ensure consistent ethical practices across regions.

Committee on Publication Ethics (COPE), a body that promotes integrity in scholarly research and its publication, published advice on "*Ethical approval requirements for case study reports*" in 2022 [8]. The COPE acknowledged a lot of variety in how ethical approval for case reports is reported in different journals. They gave an example that some articles state the study was determined not to require ethics committee approval or IRB review, particularly if it was a retrospective review [8].

Furthermore, COPE highlighted that there are two ethical aspects to case reports. One of those aspects is whether ethics approval is required for the study, and the second whether consent was given for publishing personal details and images to be published. The COPE advises that there are "many grey areas" on ethics approval for case studies and that they encourage authors to always ask for approval of an ethics committee (or IRB) when a study is based on human participants. However, they acknowledge that some ethics committees,

institutions, and governments do not consider that reports of a single case report that arises during usual clinical practice are research [8].

COPE advised that journals should provide clear policies about when they expect approval of an ethics committee and which declarations are expected from authors upon manuscript submission. Furthermore, COPE advises journals to collect information about informed consent [8].

Related to the COPE advice, a critical conceptual consideration in the ethical evaluation of case reports and case series is whether such work constitutes research involving human participants or whether it is more accurately characterized as the secondary use of personal information. This distinction has implications for whether a formal ethics review is required. Recognizing this distinction is essential for developing proportionate ethical requirements and ensuring that privacy protections are applied adequately.

The findings of this study underline the need for a more standardized approach to reporting ethical considerations in medical case reports. The discrepancies in reporting informed consent and ethics committee approval highlight the need for clearer guidelines on the ethical conduct of case report research. Future research should focus on developing best practices that ensure consistency and transparency in the ethical review process, especially for smaller studies like case reports, which often fall outside traditional research frameworks.

Limitations and future directions

This study has several limitations. First, this was a cross-sectional meta-research study, meaning it provides a snapshot of case report characteristics from 2021 but does not capture trends over time. It would be more advantageous to analyze longitudinal patterns to assess changes in reporting practices. However, comparison with prior similar research can give insight into relevant trends [6, 7]. Second, the study only included open-access case reports indexed in PubMed, which may limit the generalizability of findings to subscription-based or non-indexed journals. Excluding case reports from other databases or non-English publications may introduce selection bias. Third, we included articles that were labeled as case report/series in the title. By using this pragmatic search strategy, we might have missed relevant articles.

Fourth, data extraction relied primarily on a single author, with verification conducted on only 10% of the records. While initial testing showed no major discrepancies, this approach may increase the risk of minor errors or missed details. A fully independent dual-extraction process could strengthen reliability. Fourth, the study relied on self-reported ethics and consent statements in published articles. Some authors may have omitted or inaccurately reported this information, leading to potential underestimation of ethical approvals or informed consent documentation. Finally, the random selection of 10% of available case reports ensures a manageable dataset but may not fully capture the diversity of case reports in medical literature. A larger sample or an analysis of all available case reports would provide a more comprehensive picture. Nevertheless, this study included a much larger sample size than prior similar studies [6, 7].

Conclusion

This study offers a detailed insight into ethics reporting in the global landscape of medical case reports published in 2021. Further improvements in transparency and standardization are needed. Clear guidelines on ethical approval requirements and consent documentation should be established to enhance the quality and ethical rigor of case reports.

Acronyms

COPE	Committee on Publication Ethics
GDPR	General Data Protection Regulation
IRB	Institutional Review Board

Supplementary Information

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Supplementary Material 1: Supplementary file 1. Raw data collected within the study

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Author contributions

LP: Study design; MV, MC, LP: data collection and analysis; MV, MC, LP: data interpretation; MV, MC, LP: writing and revising the manuscript for intellectual content; MV, MC, LP: approved final version of the manuscript.

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Data availability

The raw data collected within the study are available in a Supplementary file 1.

Declarations

Ethics approval

We analyzed publicly available research reports. Thus, approval of an ethics committee was not necessary for this study.

Protocol

The study protocol was designed prospectively and published on Open Science Framework on February 2, 2023 (https://osf.io/r8mh4/).

Consent to participate

Not applicable. This study did not include human participants.

Consent to publish
Not applicable. This study did not include any human participants.

Competing interests
The authors declare no competing interests.

Clinical trial registration
Not applicable. This study was not a clinical trial..

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