Society of Medical Education & Research

2021, Volume 1, Page No: 152-160
ISSN: 3108-5059

Asian Journal of Ethics in Health and Medicine

Assessment of Informed Consent and Institutional Ethics Review in Published Case Reports and Case Series

Siti Nur Aisyah[1]*, Ahmad Firdaus[1], Nur Hidayah[1]

[1]Department of Health Ethics, Faculty of Medicine, Universitas Indonesia, Jakarta, Indonesia.

***E-mail** ✉ siti.aisyah@gmail.com

Abstract

Research is expected to uphold strict safeguards for individuals' privacy and personal information, yet many case reports and case series are produced without formal ethical review or consent that provides all essential details. This study set out to investigate how often these types of publications disclose obtaining patient permission and ethics committee involvement. This meta-research, using a cross-sectional design, examined open-access case reports and case series from 2021 that were indexed in PubMed. The study collected information such as author and journal characteristics, the country of origin, the number of patients described, and whether the publications reported obtaining informed consent or receiving approval from an ethics committee. The analysis covered 2,053 case reports and case series. The majority of publications (86%) described only one patient. Information regarding informed consent appeared in 79% of the articles, and in most of those instances (74%) the consent came directly from the patients. Mentions of ethics committee involvement were found in 46% of the publications, with 24% indicating that formal approval had been obtained. Case reports were substantially more likely than case series to include an informed consent statement, whereas case series were more likely to reference ethics committee oversight. The results show uneven reporting of ethical considerations: only 46% of publications referred to ethics committee involvement, and the reasons given for exemption were inconsistent. Although informed consent was documented in 79% of cases, there is still a need for better clarity and uniformity in how these details are presented. Establishing explicit standards for when ethical approval is required and how consent should be reported would help strengthen the transparency and ethical quality of case reports.

Keywords: Informed consent, Institutional ethics, Explicit standards, Ethics committee involvement

Introduction

Case studies, case reports, and case series serve as descriptitableve research tools that highlight noteworthy, uncommon, or unexpected clinical observations. They can also spark new avenues of scientific inquiry [1]. To merit publication, these reports must present something original and contribute meaningfully to the understanding of the condition being described [2].

Access this article online https://smerpub.com/

Received: 07 August 2021; **Accepted:** 14 November 2021

How to cite this article: Aisyah SN, Firdaus A, Hidayah N. Assessment of Informed Consent and Institutional Ethics Review in Published Case Reports and Case Series. Asian J Ethics Health Med. 2021;1:152-60. https://doi.org/10.51847/5ooQas6yE4

Because case reports involve sharing details about an individual patient's health—information that is inherently personal—authors and editors must handle such material with great care. Protecting patient confidentiality is a central ethical obligation, and patients reasonably expect that any information they provide will be safeguarded [3]. For this reason, individuals should be informed in advance about how their medical details and experiences will be used, what the publication process entails, and any potential risks or benefits associated with sharing their information [4].

A cornerstone of ethical case reporting is the patient's permission, typically obtained through informed consent. This process reflects both the legal protection of a person's right to make autonomous decisions and the ethical principle of respecting individual autonomy [5].

Beyond consent, ethics committees—such as Institutional Review Boards (IRBs)—can offer an additional layer of protection for patient privacy and ethical integrity [3]. These bodies can guide authors through challenging decisions and help ensure that consent procedures are adequate, that privacy risks are minimized, and that the report is presented in a way that avoids unnecessary harm or stigmatization [2]. Ethics consultation may be especially valuable in more complex scenarios, such as cases involving vulnerable groups, culturally sensitive issues, rare diseases, or situations in which patients could be easily identified. Ethics oversight can also help institutions establish consistent practices regarding when consent alone is sufficient and when formal review is necessary.

A distinctive aspect of ethics review for case reports is that it occurs after clinical care has already taken place. Because these publications are based on past clinical encounters rather than prospective research, traditional ethics review frameworks—designed mainly for interventional studies with preplanned methodologies—may not always be the best fit.

Whether ethics approval is required for a case report depends on multiple factors, and no universal standard exists. Institutional policies vary widely: some require formal IRB exemption letters even for single-patient reports, while others allow authors to decide independently. In many settings, individual case reports do not meet regulatory definitions of "research" and may therefore be exempt from formal review. However, exemption does not eliminate the need for ethical vigilance. National laws (such as the EU's GDPR), institutional rules, and professional norms all influence how these decisions are made, particularly regarding privacy, risk of patient identification, and the ability to obtain consent.

Privacy and confidentiality remain the primary ethical concerns. Even when reports are anonymized, rare or unusual cases may still allow readers to infer a patient's identity. Because of this, informed consent is considered a baseline requirement. Nevertheless, ethical questions arise when securing consent is not possible—for example, when a patient has died or cannot be contacted. Ethics committees can help authors weigh the necessity and potential benefits of publication against the risks it may pose to patients or their families.

Moreover, many journals now require explicit statements about whether ethics approval was obtained or deemed unnecessary, increasing the responsibility of authors to justify their decisions clearly. Although ethics review is not obligatory for all case reports, seeking advice—especially in ambiguous or ethically sensitive situations—can help ensure that the publication respects patient rights and aligns with ethical norms.

Earlier research highlights the significance of these issues. Schroter and colleagues (2006) examined ethics statements and consent reporting in 370 medical articles published in 2003, finding that ethical approval was omitted in 31% and patient consent in 47% of cases. For case reports and case series, the authors noted that ethics approval was typically considered unnecessary and therefore analyzed only consent reporting, which was absent in 93% of case reports and 83% of case series [6]. In a later study of 480 case reports and case series published from 2006 to 2017, Tran *et al.* found IRB approval mentioned in 27% of cases and informed consent in 39% [7].

More recent data on ethical and consent reporting practices in case-based literature appear to be lacking. Assessing how often—and how clearly—ethics approval and consent are documented is important for several reasons. It helps reveal current practices and inconsistencies, supports the creation of clearer guidance for authors, informs journal editors and reviewers responsible for maintaining ethical standards, and provides insight for ethics committees regarding the challenges specific to case-based publications. The objective of the present study was to examine how frequently case reports and case series report obtaining informed consent and involving an ethics committee.

Materials and Methods

Study design

This study used a cross-sectional meta-research design.

Protocol

On February 2, 2023, the prospectively developed study protocol was published on the Open Science Framework (https://osf.io/r8mh4/)

Ethics

As our analysis used only publicly accessible research documents, no review or approval from an ethics committee was needed.

Eligibility criteria

We examined open-access publications from 2021 indexed in PubMed that identified themselves as case reports or case series in the title. A 10% sample was drawn at random for analysis using the website www.randomizer.org.

Search

Our PubMed search used the title keywords "case report" OR "case series," along with the "free full text" filter and a publication date range from January 1 to December 31, 2021. This search was completed on February 3, 2023.

Screening

One researcher reviewed all records to confirm that titles containing "case report" or "case series" were not being used in another context—such as for corrections, retractions, comments, or other article types that do not present actual patient cases. A second researcher then verified all items that had been excluded. When uncertainty arose, both reviewers reached a joint decision, and a third author was consulted if necessary. We documented how many articles were removed during the screening process and the specific reasons for their exclusion.

Data extraction

A customized data-extraction form was created for the purposes of this study. Two researchers initially piloted the form on a set of 20 eligible articles, revising it through several iterations until it met the requirements of the project.

For the main extraction process, two authors independently collected For this study, we developed a study-specific data extraction form. Two authors first tested the form independently using 20 articles from the eligible sample, and it was refined over multiple rounds of revision until it was judged to be satisfactory.

During the primary data-extraction phase, two authors independently extracted information from the first 100 articles. After comparing their results and observing that there were no major disagreements, one author proceeded to extract data from all remaining articles, while the second author conducted a verification check on 10% of the completed extractions.

The following information was collected: the surname of the first author, the country of the corresponding author, the journal name, whether the article presented a single case or multiple cases (and, for multi-case reports, the number of cases), whether informed consent was reported (Yes/No) [if reported, the exact wording was recorded and later categorized, including whether consent was obtained from the patient or another individual such as a caregiver], and whether an ethics committee or IRB was mentioned (Yes/No) [and if mentioned, the text was copied verbatim and subsequently categorized].

All data were extracted exactly as provided in the articles. We did not interpret the absence of a statement on informed consent or ethics review as proof that consent had not been obtained or that ethics oversight had not occurred. Their results were compared, and because no substantial discrepancies were found, one author continued extracting data from the remaining articles, while the second author checked a 10% sample of all completed entries.

The variables recorded included: the first author's surname, the corresponding author's country, the journal in which the article appeared, whether the publication described a single case or multiple cases (and, if applicable, the number of cases), the presence or absence of an informed-consent statement (with any text provided copied verbatim and later categorized, including whether consent was given by the patient or by someone else such as a caregiver), and whether an ethics committee or IRB was mentioned (with any reported wording also captured verbatim and categorized).

All information was taken exactly as stated in the articles. We did not assume that missing reports of consent or ethics review meant that consent had not been obtained or that no review had occurred.

Data analysis

Descriptive statistical methods were applied, summarizing variables using counts and percentages. To compare how often informed consent was reported and how frequently ethics committee involvement was mentioned in case reports versus case series, we performed chi-square tests. All analyses were carried out using MedCalc software (MedCalc Software Ltd., Ostend, Belgium).

Results and Discussion

The initial search returned 21,599 articles. From these, a 10% random sample comprising 2,161 articles was selected. Screening excluded 103 records that did not describe a case report or case series, resulting in a final dataset of 2,053 articles included in the analysis.

Characteristics of included articles

Among the corresponding authors, 20% were affiliated with institutions in China, with the next most common countries being the United States and Japan. The articles were distributed across 588 journals, with the largest number published in International Journal of Surgery Case Reports, Medicine (Baltimore), and Cureus. A majority of the publications (86%) reported on a single case **(Table 1).**

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

Variable	Category	N (%)
Corresponding author affiliation	China	402 (20)
	USA	264 (13)
	Japan	206 (10)
	India	129 (6.3)
	Italy	115 (5.6)
	South 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 of publication	*International Journal of Surgery Case Reports*	102 (4.9)
	Medicine (Baltimore)	86 (4.2)
	Cureus	81 (3.9)
	World Journal of Clinical Cases	74 (3.6)
	Clinical Case Reports	66 (3.2)
	Journal of Medical Case Reports	57 (2.8)
	European Heart Journal: Case Reports	54 (2.6)
	Annals of Medicine and Surgery (London)	36 (1.7)
	Journal of Surgical Case Reports	32 (1.6)
	Frontiers in Pediatrics	29 (1.4)
	Frontiers in Oncology	28 (1.4)
	Radiology Case Reports	27 (1.4)
	Journal of Orthopaedic Case Reports	24 (1.2)
	Frontiers in Neurology	23 (1.1)
	Urology Case Reports	22 (1.1)
	Other	1,312 (64)
Number of cases reported per article	1	1,758 (86)
	2	66 (3.2)

	3	60 (2.9)
	4	32 (1.6)
	>4	137 (6.7)

Reporting informed consent

Approximately seventy-nine percent of the articles included in this study reported information on informed consent. When considering the type of article, consent statements were present in about eighty-one percent of case reports, whereas around seventy-one percent of case series included them **(Table 2).** Chi-square analysis revealed a statistically significant difference between the two types ($\chi^2 = 19.67$, df = 1, $p < 0.0001$), showing that case reports were more likely to report informed consent than case series.

Among the consent statements, the largest portion, twenty-nine percent, specifically indicated that patients had provided written consent for publication of the article and any accompanying images. The second most common category, sixteen percent, mentioned that written consent had been obtained but did not clarify what the consent covered. In terms of who provided consent, the majority were the patients themselves (seventy-four percent), followed by parents (six percent) and legal guardians or next of kin (around six percent) **(Table 2).**

Table 2. Reporting information about informed consent

Variable	Category	N (%)
Informed consent reported in the total sample (N = 2,053)	Yes	1,630 (seventy-nine percent)
	No	423 (twenty-one percent)
Informed consent reported in case reports (N = 1,758)	Yes	1,420 (eighty-one percent)
	No	338 (nineteen percent)
Informed consent reported in case series (N = 295)	Yes	210 (seventy-one percent)
	No	85 (twenty-nine percent)
Type of informed consent statements (N = 1,630)	Patients provided written consent for publication of the article and accompanying images	479 (twenty-nine percent)
	Patients provided written consent (unspecified)	267 (sixteen percent)
	Consent obtained or waived by participant(s)	68 (approximately four percent)
Individuals providing informed consent (N = 1,630)	Patient	1,206 (seventy-four percent)
	Patient's parents	98 (six percent)
	Legal guardian or next of kin	97 (approximately six percent)
	Unclear	73 (four point four percent)
	Patient's family	25 (one point five percent)
	Patient and family	18 (one point one percent)
	Patient and parents	13 (less than one percent)
	Patient or legal guardian/next of kin	11 (less than one percent)

Patient and legal guardian/next of kin	6 (less than one percent)
Pet's owner	5 (less than one percent)
Patient's caregivers	4 (less than one percent)
Patient or family	1 (less than one percent)

The involvement of an ethics committee involvement

Only 46% of the articles mentioned anything about ethics committee approval. This information was present in just 44% of case reports but in 57% of case series **(Table 3).** The difference was highly significant according to the chi-square test ($\chi^2 = 17.33$, df = 1, $p < 0.0001$), meaning case series were substantially more likely than case reports to include a statement about ethics committee review.2.6sFast

Table 3. Reporting information about an ethics committee involvement

Variable	N (%)**
Overall sample (N = 2053)	
Mention of an ethics committee statement anywhere in the article	
• Yes	939 (46%)
• No	1,114 (54%)
By article type	
Case reports (N = 1,758)	
• Ethics committee statement present	771 (44%)
• No ethics committee statement	987 (56%)
Case series (N = 295)	
• Ethics committee statement present	168 (57%)
• No ethics committee statement	127 (43%)
Among articles that included an ethics committee statement (N = 939)	
Did the statement clearly indicate that formal approval had been obtained?	
• Yes, approval was obtained	492 (24% of total sample)
• No approval obtained	368 (18%)
• Unclear or ambiguous	79 (3.8%)
Reasons given for not obtaining formal ethics committee approval (N = 231 cases where approval was stated as not required)	
Institutional policy does not require formal approval for case reports	91 (28%)
No explanation provided for why approval was not needed	49 (13%)
Claimed exemption, but no reason for exemption provided	42 (11%)
Ethical review not required per local laws or institutional rules	33 (8.9%)
Not required because the patient gave written informed consent for publication	10 (2.7%)
Article contains no human participant research/experiments	6 (1.6%)

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

Among the papers that mentioned an ethics committee at all, most clearly said the study had been approved. The next largest group (28%) simply claimed that case reports don't need formal ethical review according to their institution's rules. The rest were labeled ambiguous because readers couldn't tell if the committee had actually approved the work or merely waived the requirement. A typical vague example was: "The Institutional Review Board for Human Subjects monitored the publication of this case study" **(Table 3).** We reviewed 2,053 case reports and case series published in a variety of medical journals, looking at where they came from, how they were published, and how ethics were handled. Most described just one patient. Patient informed consent was mentioned in the majority of papers. Ethics committee review, however, was brought

up in fewer than half of them, and only around one in four articles explicitly confirmed that approval from an ethics committee had actually been granted.

Informed consent

Informed consent statements appeared in 79% of the articles, with the vast majority specifying that patients had given written permission for the publication of their details and any related images. This rate is dramatically higher than what Schroter *et al*. found in their examination of consent reporting in articles from 2003. Their review showed that only 7% of case reports and 17% of case series referenced consent [6]. It's worth noting that their dataset was far smaller, covering just 370 articles overall, including only 25 case reports and 12 case series [6].

Schroter *et al*. notably skipped any assessment of ethics committee statements in case reports or series, reasoning that such designs typically don't demand ethical clearance [6]. That said, this assumption doesn't hold true across all organizations.

For context, Tran *et al*. looked at ethical approval and consent documentation in 480 case reports and series pulled from PubMed over 12 straight years (2006–2017). In their set, 27% mentioned IRB approval, 7.3% noted compliance with the Helsinki Declaration, and 39% confirmed obtaining informed consent [7].

In our analysis, 46% of the articles referenced an ethics committee in some way, though just 24% explicitly confirmed that approval had been secured. This edges slightly below the 27% IRB approval rate reported by Tran *et al*. in their 2006–2017 cohort [7].

These results might signal an uptick in researchers' recognition of the need to secure and document patient consent for sharing their stories publicly, without a parallel shift toward routine ethics committee (or IRB) sign-off. Another possibility is that modern journals are enforcing consent requirements more stringently than before. This could tie into wider evolutions in research ethics norms, publication standards, data privacy rules, and legal mandates—rather than just individual researchers stepping up their game. Variations in our sample could stem from authors following specific journal rules or local institutional directives.

The absence of ethics committee mentions in over half the papers might trace back to a mix of influences, such as authors' limited familiarity with the issues, varying institutional rules, journal expectations, or even editors' and reviewers' oversight. For instance, some writers might overlook the ethical nuances of case reporting and skip related disclosures. On the flip side, others could grasp the consent angle well enough to include it but view ethics review as optional or irrelevant.

What's more, what gets written up may not mirror what actually happened. It's entirely plausible that ethics boards did vet certain case studies or that consent forms were signed, but the details never made it into the final paper.

Our data reveal a stark divide in how ethical elements are handled between case reports and series. Case reports were far more prone to featuring consent statements, whereas series were much more likely to note ethics committee involvement. This gap points to uneven habits in ethical documentation, potentially driven by journal guidelines, varying levels of scrutiny, and differing views on the "seriousness" of these formats in academic and publishing circles.

Case reports' stronger emphasis on consent likely arises from their laser focus on one person's experience, where getting that individual's buy-in is ethically non-negotiable. Plenty of case-report-friendly journals enforce ironclad rules demanding proof of consent, verifying that authors have the green light to disclose sensitive info like medical histories or photos.

By contrast, the bump in ethics approvals for series could reflect a sense that they count as more structured inquiries, often warranting official ethical checks. Unlike the narrative, one-off style of many case reports, series—particularly those pooling data from several patients, involving methodical tracking, or drawing on past records—might trigger tougher oversight. Certain institutions and outlets treat series as proper retrospective studies, not just casual anecdotes, prompting closer ethical examination.

These reporting inconsistencies might also spring from patchy or conflicting journal instructions on when ethical sign-off is truly needed for reports versus series. Consent mandates for reports are often crystal clear, but ethics review rules for series can swing wildly based on methodology, data origins, and outlet preferences. Such flux fosters spotty documentation, with some series spelling out approvals while others gloss over them.

Zooming out, both consent and ethics board vetting are cornerstones of responsible research, even for seemingly low-key outputs like reports and series. These aren't "lesser" endeavors—they're still scholarly work with real people at the center. Skimping on reporting either element, regardless of format, erodes trust,

accountability, and fidelity to ethical benchmarks in medical literature.

Some organizations might waive formal reviews for case reports outright, or folks might assume consent alone covers it. True, exemptions exist in spots, but that doesn't diminish the value of ethical guardrails: these pieces still handle real human stories, demanding vigilant protection of privacy and dignity.

Journals play a pivotal gatekeeping role here, pushing for open ethical disclosures through their guidelines. Editors and reviewers can help enforce that. Yet it's key to remember that ethics workflows are largely molded by country-specific laws, campus rules, and overarching legal setups. Outlets can nudge toward better practices via submission checks and review rigor, but they can't override local determinations on review necessity. Thus, journal standards should aim for straightforward, uniform reporting on ethics. Still, tackling the root issues—like unified global protocols or aligned institutional benchmarks—will be crucial to iron out confusion and lock in reliable ethics across borders.

In 2022, the Committee on Publication Ethics (COPE)—a group championing honesty in research and publishing—issued guidance on "Ethical approval requirements for case study reports" [8]. They pointed out the wild inconsistencies in how journals handle ethics disclosures for case reports, citing cases where papers declare no review was needed, especially for backward-looking analyses [8].

COPE also flagged two core ethical angles for these works: first, whether the project itself demands ethics clearance; second, whether folks okayed sharing their personal info and visuals. They noted "plenty of gray zones" around approvals for case studies and urged authors to seek committee (or IRB) input whenever human subjects are involved. That said, they conceded that some boards, schools, and regulators don't classify single-case narratives from routine care as "research" at all [8].

COPE recommended that journals spell out exactly when they want ethics nods and what authors must declare at submission. They also pushed for outlets to routinely verify consent details [8].

Tying into COPE's points, a key debate in judging the ethics of reports and series boils down to whether they qualify as human-subjects research or more like reusing private data for secondary purposes. This line-drawing matters hugely for deciding if full reviews apply. Getting it right helps craft fair, scaled-back ethical demands while still shielding privacy properly.

All told, this work spotlights the urgency for tighter, more uniform ways to flag ethical steps in medical case reporting. The uneven handling of consent and approvals screams for sharper directives on running these ethically. Looking ahead, studies should zero in on crafting gold-standard protocols that deliver steady, upfront ethics checks—especially for modest-scale efforts like case reports, which too often slip through standard research nets.

Limitations and future directions

This study has a number of limitations. First, because it employed a cross-sectional meta-research design, it only reflects the characteristics of case reports published in 2021 and does not account for changes over time. A longitudinal study would be better suited to evaluate shifts in reporting practices, although comparisons with previous research can provide some context regarding trends [6, 7].

Second, only open-access case reports indexed in PubMed were included, which may reduce the generalizability of the findings to subscription-based or non-indexed journals. Omitting studies from other databases or non-English publications could also introduce selection bias.

Third, our inclusion relied on articles labeled explicitly as “case report” or “case series” in the title. This practical search method may have missed relevant studies that used different terminology.

Fourth, data extraction was largely performed by a single author, with only ten percent of entries cross-checked by another author. Although initial testing showed minimal discrepancies, this approach could allow minor errors or overlooked details. A fully independent dual-extraction process would likely increase accuracy and reliability.

Fifth, the study relied on authors’ self-reported statements regarding ethics approval and informed consent. Some publications may have failed to report or may have inaccurately described these elements, which could lead to an underrepresentation of ethical oversight. Finally, limiting the dataset to a random ten percent of all available case reports allowed for manageable data handling but may not fully capture the variety of case reports across the literature. Evaluating a larger portion, or all available reports, would give a more complete overview. Nevertheless, this study examined a

considerably larger sample than previous comparable analyses [6, 7].

Conclusion

This study provides an in-depth overview of how ethics are reported in medical case reports worldwide in 2021. There remains a need for greater consistency and transparency in reporting practices. Establishing clear standards for when ethical approval is required and how consent should be documented would help improve both the quality and ethical integrity of case reports.

Acknowledgments: The study described in this manuscript is based on the Master of Nursing thesis of Matea Valešić. At the time of the manuscript writing, the thesis was not yet defended.

Conflict of Interest: None

Financial Support: None

Ethics Statement: None

References

1. Sayre JW, Toklu HZ, Ye F, Mazza J, Yale S. Case reports, case Series - From clinical practice to Evidence-Based medicine in graduate medical education. Cureus. 2017;9(8):e1546.
2. Shevell MI. The ethics of case reports. Paediatr Child Health. 2004;9(2):83–4.
3. Thomson RJ, Camm CF. The importance of consent in case reports. Eur Heart J Case Rep. 2021;5(2):ytaa560.
4. Rees M, Corson SL. Publication of medical case reports and consent. Case Rep Womens Health. 2017;15:A1–2.
5. Cornock M. Case reports and ethics: focus on consent, privacy and author- ship. Case Rep Womens Health. 2021;32:e00358.
6. Schroter S, Plowman R, Hutchings A, Gonzalez A. Reporting ethics commit- tee approval and patient consent by study design in five general medical journals. J Med Ethics. 2006;32(12):718–23.
7. Tran L, Thanh Huan V, Tai LLT, Safi A, Ahmed ME, Algazar MO, et al. Reporting ethical approval in case reports and case series in 12 consecutive years: a systematic review. Health Care Sci. 2024;3(5):298–311.
8. Committee on Publication Ethics (COPE). Ethical approval requirements for case study reports. 2022. Available at: https://publicationethics.org/guidance/case/ethical-approval-requirements-case-study-reports