



ETHICS ARTICLE

How *Annals of Dermatology* Has Improved the Scientific Quality and Ethical Standards of its Articles in the Two-Year Period since October 2018

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Annals of Dermatology has not been deposited in PubMed Central (PMC) since October 2018 due to inadequate scientific quality, including the absence of informed consent in three case reports with patients' photos. This study examined the readiness of *Annals of Dermatology* to be deposited in PMC again by analyzing the 13 issues published from October 2018 to August 2020. The journal's scientific quality and ethical standards were assessed, and adherence to these standards was documented. In total, 259 articles were analyzed for ethical standards, including institutional review board (IRB) approval, an informed consent statement, and disclosure of conflicts of interest. Scientific quality was also checked for each article. Of the 129 original articles or brief reports presenting research on human subjects or human-derived materials, 111 studies received IRB approval and/or obtained informed consent. The other seven studies were data analyses or studies of purchased cultured cells. One study that used a post-circumcision foreskin sample contained no statement describing permission from the patient's family, but the researchers were found to have obtained informed consent. In all 152 case presentations, the authors obtained informed consent. All seven animal experiments received Institutional Animal Care and Use Commit-

tee approval. One review article did not disclose conflicts of interest, but this was an editorial error. Two systematic reviews adopted the PRISMA guidelines. In conclusion, the present publication policies, scientific quality, and ethical standards of the journal are top-tier internationally. *Annals of Dermatology* may be ready to apply to PMC again. (**Ann Dermatol 32(5) 353 ~ 359, 2020**)

-Keywords-

Conflict of interest, Dermatology, Disclosure, Informed consent, Research design, Research ethics committees

INTRODUCTION

Background/rationale: *Annals of Dermatology* launched in 1989 as an English-only journal. It is the official journal of the Korean Dermatological Association and the Korean Society for Investigative Dermatology. There is also another official journal of the Korean Dermatological Association, the *Korean Journal of Dermatology*, which has been published since 1960 with full-texts in Korean or English. The two journals have different aims and scopes. The English-language journal pursues the goal of becoming an internationally top-tier journal, while the Korean journal is a vehicle of information transfer for physicians and residents in Korea. The meticulous editing and recruitment of high-quality articles were the basis for *Annals of Dermatology* to be indexed in Science Citation Index Expanded (SCIE) in 2008. It was also indexed in Scopus in 2009 and searchable from the first issue in the Scopus database. Another leap was deposition of the full-text to PubMed Central (PMC)—a database of full-text JATS XML-based biomedical journals in English—since June 3, 2010. The full-text

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of issues published since 2008 were searchable in PMC and PubMed.

After being listed in PMC and PubMed in 2010, the journal's impact factor began to increase sharply. It reached 1.393 in 2013, corresponding to the 48.4th percentile in the category of dermatology (Fig. 1). This experience of *Annals of Dermatology* exemplifies a consistent trend, according to which the citation frequency of local journals increases after they are indexed in PubMed¹.

In 2018, the editorial board applied to list the journal in MEDLINE. However, its application failed. The United States National Library of Medicine Literature Selection and Technical Review Committee (LSTRC) mentioned the lack of informed consent in patients' photos, which showed lesions on the face and body. Furthermore, this information was transferred from the LSTRC to the PMC staff. Although the editors published errata for those articles that acknowledged the incomplete anonymity of the photos²⁻⁴, those corrective steps were not accepted. Therefore, starting in October 2018, *Annals of Dermatology* could no longer deposit XML files to PMC. Consequently, the journal could no longer be indexed in PubMed. However, PMC indicated that reapplication to PMC would be possible in October 2020 after making improvements in scientific integrity and ethical standards.

When I heard this news from the editor-in-chief, my heart was broken. In 2006, I began to produce PMC XML files for medical journals to deposit in PMC along with staff members of the Korean Association of Medical Journal Editors. After the successful production of PMC XML files, many English-language medical journals from Korea, including *Annals of Dermatology*, have been deposited in PMC since November 20, 2009. On September 3, 2020,

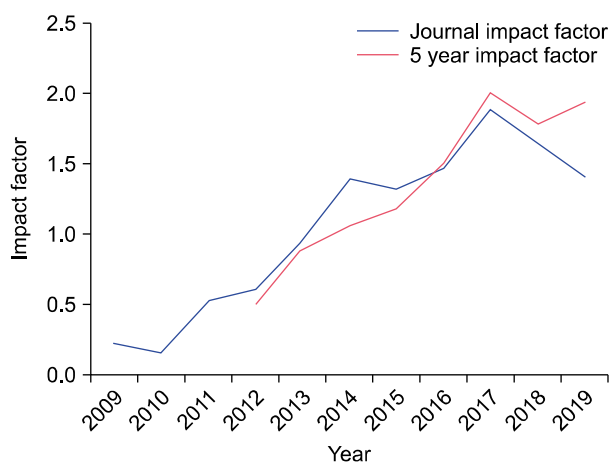


Fig. 1. Journal impact factor and 5-year impact factor of *Annals of Dermatology* from Journal Citation Reports® [cited 2020 Aug 28].

the number of currently indexed PMC journals from Korea reached 127.

Objectives: This study aimed to examine the readiness of *Annals of Dermatology* to be deposited in PMC again by analyzing the 13 issues that were published from October 2018 to August 2020. Specifically, the journal's scientific quality and ethical standards were assessed, and the journal's adherence to these standards was documented. This analysis will provide evidence of the editors' laborious work to upgrade *Annals of Dermatology* into a top-tier journal. Ethical standards, including statements of informed consent, institutional review board (IRB) approval for studies of human subjects or human-derived materials, and disclosure of conflicts of interest, were checked. Furthermore, the scientific and editorial quality of articles' content were checked, including whether studies were described according to reporting guidelines and whether a clinical trial data sharing statement was present.

MATERIALS AND METHODS

Ethics statement: As a literature-based study, neither IRB approval nor informed consent was required.

Study design: This study involved a content analysis of journal articles according to the selection criteria for PMC and issues pointed out in the previous review by the PMC journal selection committee.

Data sources/measurement: The target articles were published in *Annals of Dermatology* from October 2018 to August 2020. The following items were measured: IRB approval or informed consent for human subject studies, Institutional Animal Care and Use Committee (IACUC) approval for animal experiments, and conflicts of interest. The following other items were assessed: journal policy, research and publication ethics, scientific soundness, figures and tables, the quality of English writing, style and formatting, editors and authorship, publication frequency, reporting guidelines, the journal website, publication types, and readership statements.

Statistical methods: Descriptive statistics were applied.

RESULTS

The raw data are presented in Dataset 1, including publication month, the number of pages, publication type, whether humans were the study subjects, whether informed consent was obtained, IRB approval, whether animals were the study subjects, IACUC approval, study design, statistics used, presence of a clearly stated hypothesis, description according to specific reporting guidelines, and the presence of a clinical trial data statement.

Publication types in the 13 issues from October 2018 to August 2020: The number of articles was 295. The number of brief reports was 138 (46.8%), followed by that of original articles (91, 30.9%) and case reports (58, 19.7%). There were two errata and one corrigendum (Fig. 2). One supplementary issue in August 2019 consisted of 27 brief reports. The number of review articles was five.

Ethics statement in review articles: Of the five review articles, one contained a statement on having obtained informed consent because a photograph of a patient's face was included⁵. The other four articles consisted of one history article, a pathway study, a literature review, and a systematic review (Dataset 1).

Ethics statement in original articles: Of the 91 original articles, 11 articles (12.1%) did not have human subjects or analyze human-derived materials. Six described animal experiments that were approved by the IACUC of the authors' institutions. Two were meta-analyses, one was an analysis of genetic data, one was a consensus study by dermatologists on diagnostic guidelines, and one dealt with an herbal product. For the 80 articles that described research on human subjects or human-derived materials, the status of IRB approval and the presence of informed consent statements is summarized in Table 1.

Obtaining informed consent and/or IRB approval is a crite-

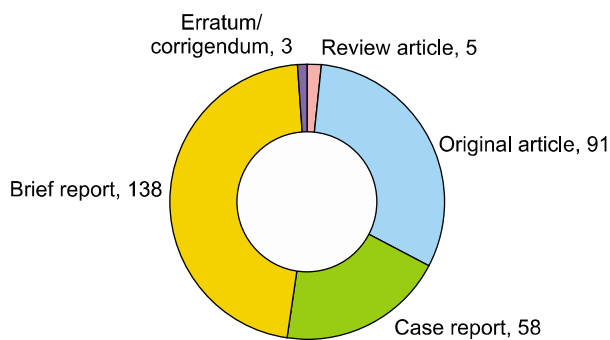


Fig. 2. Publication types of 295 articles published in *Annals of Dermatology* from October 2018 to August 2020.

Table 1. Description of informed consent and institutional review board (IRB) approval from 80 original articles presenting research on human subjects or human-derived materials in issues from October 2018 to August 2020 of *Annals of Dermatology*

IRB approval	Informed consent		Sum
	Yes	No	
Yes	39	30	69
No	3	8	11
Sum	42	38	80

Values are presented as number.

rior required to fulfil ethical standards for articles on human subjects or human-derived materials. There were eight articles for which neither IRB approval nor having obtained informed consent was mentioned. Six of these articles dealt with purchased cultured cells, and therefore did not require informed consent. One was a study of open genome data, for which informed consent is also not required. The other study analyzed cultured keratinocytes collected from foreskins obtained during circumcision of children⁶.

Description of informed consent in case reports: The 58 case reports all contained statements of informed consent.

Ethical statement of brief reports: Of the 138 brief reports, 94 articles were case presentations, for all of which informed consent was obtained (Dataset 1). Another five reports were non-human subject studies, including one animal experiment approved by the IACUC of the authors' institutions, one letter to the editor, two nationwide data-based studies, and one container contamination study. The other 39 articles were studies of human subjects or human-derived materials with a variety of study designs. The presence of statements of informed consent or IRB approval is presented in Table 2.

Out of the nine brief reports with neither IRB approval nor an informed consent statement, seven were laboratory experiments with purchased cultured cells. One was the suggestion of another diagnosis, and the other was a Google trends analysis.

Approval by the Institutional Animal Care and Use Committee for animal experiments: Eight of the original articles and brief reports described animal experiments, including one experiment that also used cultured cells. The IACUC of the authors' institutions approved all animal experiments.

Disclosure of conflicts of interest: Of the 295 articles, two errata and one corrigendum were not required to disclose conflicts of interest. Of the remaining 292 articles, one review did not disclose conflicts of interest⁷.

Table 2. Description of informed consent and institutional review board (IRB) approval from 39 brief reports presenting research on human subjects or human-derived materials in issues from October 2018 to August 2020 of *Annals of Dermatology*

IRB approval	Informed consent		Sum
	Yes	No	
Yes	10	20	30
No	0	9	9
Sum	10	29	39

Values are presented as number.

Compliance to the scientific and editorial quality standards considered by PMC

Journal policies: The journal's aims and scope, peer review, process, ethical policies, commercial sponsorship, and financial conflicts of interest were clearly described on the journal's homepage (<https://anndermatol.org>). The practice of complete adherence to ethical policies was described as above. The Principles of Transparency and Best Practice in Scholarly Publishing 3rd version was precisely described on the journal homepage.

Article content: The aims, rationale, methods, study design, conclusion, discussion, and references were all clearly described. The study designs are presented in Dataset 1. Some remarkable articles included a review article on the gut microbiome associated with inflammatory skin diseases, which provided comprehensive and recent information in this rapidly evolving area⁷; and a case-control study investigating the skin and gut microbiota in acne patients before and after receiving oral minocycline, which also provided information relevant to the hot issue of microbiome studies⁸.

Figure and table quality: The figures and tables had a high resolution and were easy to read.

Language quality (i.e., English editing): Professional native English speakers checked that the content of all articles was readable and logical.

Formatting and organization: Two professional manuscript editors checked all articles during the editorial process for adherence to the journal's style and format.

Editorial board and authorship: Complete information on the editorial board and authors was available. The members of the editorial board are all specialists in dermatology research from eight countries. The authors were from 26 countries from the first issue in 2018 to the August 2020 issue.

Publication schedule: The journal has been published at a regular interval. No delay was reported.

Compliance to the reporting guidelines: Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA), CAse REport (CARE), Consolidated Standards of Reporting Trials (CONSORT), and Animal Research: Reporting of In Vivo Experiments (ARRIVE) were standard guidelines for systematic reviews and meta-analyses, case reports, clinical trials, and animal studies, respectively. Two meta-analysis articles were described according to the PRISMA guideline^{9,10}. Two randomized control studies did not mention the CONSORT guideline^{11,12}. The CARE guideline was not mentioned in 152 case report, and the ARRIVE guideline was not mentioned in seven articles on animal experiments. However, the above articles gen-

erally mentioned the items contained in the reporting guidelines as part of the content description, although the entire list of items was not listed under a subheading.

Clinical trial data sharing policies: The journal encouraged authors to include a data availability statement in the manuscript (e.g., a link to a data repository). The authors also had the option to explain why data may not be shared. However, two randomized controlled studies did not provide a data availability statement^{11,12}.

DISCUSSION

Key results: The number of articles published from October 2018 to August 2020 was 295, of which 80 original articles presented research on human subjects or human-derived materials. Of those 80 studies, 72 were approved by the IRB or had obtained informed consent. The other seven studies were data analyses or studies of purchased cultured cells that did not require informed consent or IRB approval. One study used foreskin that had been removed after circumcision and did not contain a statement of permission from the patient's family⁶. All 58 case reports obtained informed consent. The 39 brief reports with human subjects or that studied human-derived materials contained statements of informed consent or IRB approval. The IACUC approved all seven animal experiments. Statements of data availability were not present in two randomized controlled studies^{11,12}. One review article omitted a statement on conflicts of interest⁷. For the text description, two systemic reviews adopted the PRISMA guideline^{9,10}. The randomized controlled studies, case reports, and animal experiments did not contain point-by-point descriptions of the items contained in the corresponding reporting guidelines.

Interpretation and suggestion: First, this article demonstrates that *Annals of Dermatology* adhered to the relevant ethical standards for the 295 articles published from October 2020 to August 2020. The journal maintained ethical standards completely except for two articles: in one article, the skin tag after the circumcision was used for cell preparation⁶, and in the other article, conflicts of interest were not mentioned⁷. According to the Bioethics and Safety Law of the Republic of Korea, in cases with minimal risk to a human subject, the requirement for informed consent can be exempted if the IRB grants permission¹³. The use of foreskin after circumcision may be covered under this regulation. According to the United States Electronic Code of Federal Regulations (e-CFR) Title 45 Section 46.104. Exempt research¹⁴, obtaining the foreskin after circumcision can be exempted from informed consent because it is a case in which "information, which

may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects.” The editorial office asked the authors of this article⁶ whether they had received written informed consent from the patient’s family. The informed consent statement was submitted by the authors to the editorial office, and a corrigendum was published to clarify the situation¹⁵.

IRB approval is not generally mandatory for studies using purchased cultured cells, because it is unnecessary to consider the privacy of such cells, but some institutions may ask members to get IRB approval. Therefore, whether IRB approval is required depends on each institution’s ethics policies.

In the review article without a disclosure of conflicts of interest⁷, the topic was the gut microbiome’s relationship with human health and inflammatory skin diseases, and the study was authored by dermatologists from the United States. There was neither funding nor a description of commercial products. This was a literature-based review article, so it is quite likely that there were no conflicts of interest, even though the authors did not include a declaration stating that this was the case. It was found that the absence of a description of conflicts of interest was an editorial error. The editorial office published an erratum for this review article¹⁶.

Scholarly journals are recommended to state that they adhere to the Principles of Transparency and Best Practice in Scholarly Publishing 3rd version. Nonetheless, not many society journals have adopted these principles. Fifty-nine SCIE journals published by Korean academic societies were searched to determine whether they followed these principles, with the following result: “Most items in the publication ethics category were not well-practiced, except for authorship and intellectual property. All items in the profit model category were infrequently implemented”¹⁷. These principles involve the clarification of the scholarly journal’s publishing policies, including ethics policies. The situation is the same as other countries’ academic society journals listed in Journal Citation Reports^{®18}. Since 2018, some journals in Korea have adopted these principles and disclosed them on the journal homepage, such as *Annals of Pediatric Endocrinology & Metabolism* and *Journal of Educational Evaluation for Health Professions*^{19,20}. The present description of the principles for *Annals of Dermatology* is excellent.

The scientific quality of articles was very high or top-tier. The items to be improved are the fulfillment of the report-

ing guidelines and statements of data availability for clinical trials. For reporting guidelines, it is better to list the guideline items in the description in the text. Out of the 295 articles, only two meta-analyses contained a description according to the PRISMA guideline. Therefore, it is recommended to ask authors to structure the text according to the relevant reporting guidelines if there is an appropriate reporting guideline that corresponds to the research design, as mentioned above.

Two articles were randomized controlled studies^{11,12}. According to the ICMJE’s clinical trial data sharing policies, manuscripts submitted to ICMJE journals that report the results of clinical trials should contain a data sharing statement as of July 1, 2018²¹. It is not mandatory to share the data, but it is strongly recommended to disclose the data sharing policy. In a survey of Korean editors, the most frequent reason for adopting a data sharing policy was to follow international trends²². Of 170 journals from Korea indexed in both 2018 ScimagoJR and the Web of Science Core Collection, 20 journals, including *Annals of Dermatology*, had adopted clinical trial data sharing policies following the International Committee of Medical Journal Editors. However, statements of data sharing were found in two of these 20 journals²³. This means that the practice of requiring a statement of data sharing policies is not well established in Korea. Various ways exist to describe supplemental data²⁴. If data are deposited in a repository site such as Harvard Dataverse, a digital object identifier is provided for the dataset itself, so that continuous linking and citing are possible²⁵. It is recommended that *Annals of Dermatology* present a statement of clinical trial data sharing as has been suggested for other scientific journals, as in the following examples²⁴:

“Example 1. The clinical trial data of this article will not be shared.

Example 2. The clinical trial data of this article are available upon reasonable request to the corresponding author.

Example 3. All of the individual participant data collected are available from a data repository immediately after publication without an end date. The study protocol, statistical analysis plan, informed consent form, clinical study report, and analytic code are also available. Anyone can access the data, and the data can be used for any purpose.”

Comparison with previous studies: It is difficult to find other articles that analyzed the adherence of specific journal articles to ethical standards. This may be because editors or ethics editors routinely check the manuscripts for their adherence to ethical standards, including IRB approval, obtaining informed consent, funding, and conflicts of interest before review.

Limitations: Although the process of checking ethical

standards is simple and lucid, the evaluation of scientific quality is subjective, especially for article content. It depends on an individual's competency in scientific reasoning, research training, experience of peer-review, and journal editing experience. Therefore, the level of each item for scientific quality may vary among reviewers.

Conclusion: All 295 target articles fulfilled the ethical standards for scholarly publications except for two articles. One of those articles was a literature review that omitted a disclosure of conflicts of interest, and the other article did not contain a statement that informed consent was obtained for the use of foreskin after circumcision. The omission of the disclosure of the conflicts of interest was confirmed to be an editorial error, which was fixed by an erratum. The case involving the use of foreskin was not associated with the patient's safety or privacy, meaning that the requirement for informed consent could be exempted. However, the authors submitted the written informed consent statement to the editorial office, and the journal published a corrigendum. As for reporting guidelines, two meta-analysis articles were described according to the PRISMA guideline, but there was no mention of reporting guidelines in the texts of the randomized controlled trials, case reports, and animal experiments. A statement of the clinical trial data sharing policy for randomized controlled trials should be provided, according to international standards. Although there remains room for improvement, the journal's publication policies, scientific quality, and ethical standards were top-tier internationally. *Annals of Dermatology* may be ready to reapply to PMC.

CONFLICTS OF INTEREST

The author has nothing to disclose.

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DATA SHARING STATEMENT

Dataset 1. A raw data file is available from Harvard Dataverse: <https://doi.org/10.7910/DVN/NOW6SG>

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