

Principles and Practice of Clinical Research

A Global Journal in Clinical Research



PPCR

ISSN: 2378-1890

Are Patients Acknowledged in Clinical Research? A Systematic Survey

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Received February 10, 2022; accepted April 13, 2022; published June 16, 2022.

Abstract:

Background: Study participants make meaningful contributions to clinical research. It is unknown if these contributions are recognized in scientific literature. Our primary aim was to assess the trends of recognition of the study participants' contributions in the acknowledgments section of clinical research articles.

Methods: We conducted a systematic survey to assess the trends in study participants and staff members—understanding staff as those who contribute to the development of the project—in acknowledgments in the scientific literature from 1990 to 2019. We included peer-reviewed original research from the top ten general and internal medicine journals with the highest impact factor.

Results: 496 studies were included in the analysis. 110 (22.2%) articles acknowledged study participants and 291 (58.7%) acknowledged staff. In the last five years there has been an increase in the recognition of study participants in both observational and experimental studies by 28.3% and 112.6%, when compared to fifteen years ago (2005-2009). The frequency of staff acknowledgment stratified by study design has remained constant.

Conclusion: Most of the clinical articles fail to acknowledge study participants' contributions to research. We encourage authors to recognize their participation when appropriate and journals to provide guidance on how to acknowledge participants and staff members.

Keywords: acknowledgment, study participants, staff members

DOI: <http://dx.doi.org/10.21801/ppcrj.2022.82.3>

INTRODUCTION

Traditionally, authors have used the acknowledgments section in scientific articles to identify those who made notable intellectual or technical contributions to a study that was not sufficient to qualify them for authorship (Kassirer, J.P., 1991). This includes moral, technical, or financial support. The technical set, which includes statistical assistance and the data processing staff, has been the most common

category. However, it has been noted that the frequency of acknowledgment reporting has decreased. (Paul – Hus, A., 2019).

Clinical research is mostly carried out by a broad team in which each member contributes by playing a unique role in the project. These roles include editors, study recruiters, statisticians, principal investigators, and, of course, study participants. When a researcher aids a research project but does not fulfill the criteria for

authorship, it is suggested to recognize the work of this researcher in the acknowledgments section. (International Committee of Medical Journal Editors, s. f.). Because of the relevance of the contribution of patients or study participants to clinical research projects, efforts have been made to include them as co-authors when they fulfill authorship criteria (Cronin, B., 2003) (Desrochers, N., 2018). Yet, when they do not, it has been suggested that their contribution to the investigation should be recognized in the acknowledgments section as well as other types of contributions (technical, moral, financial). Some authors consider the acknowledgment section as important as citations and as an intellectual debt (Cronin, B., 1993). In citations, the recognition of the intellectual work of others is done by including them in a specific section. Considering that the contribution of the study participants is crucial to the production of scientific knowledge, particularly in the clinical areas, they should receive recognition for their contributions just as other contributors receive it.

The frequency of recognition of study participants' contributions to clinical research remains uncertain. We decided to conduct a systematic survey to understand if this occurs, the frequency and the trends of recognition of the contribution of study participants and research staff in the acknowledgments section of peer-reviewed articles of top-tier clinical research journals published in the last three decades, given that both collaborate in clinical studies as much as the authors do.

MATERIAL AND METHODS

Selection criteria and process

We conducted a systematic survey to assess the trends in including study participants and staff members in the acknowledgments section in the scientific literature from January 1st, 1990, to December 31st, 2019. We included peer-reviewed original research from the ten journals with the highest impact factor on general and internal medicine. Additionally, we also surveyed the appropriate reporting guidelines for the included study designs (CONSORT for experimental studies, STROBE for observational studies, and CARE for case reports) to determine if they provided guidance on how and when to acknowledge study participants or staff members. Brief research communications were excluded, and no language restriction was applied.

The sample was obtained from a previous study whose objective was to evaluate sources of funding in the top ten highest impact factor journals (Burciaga -

Jimenez, E., 2022). In brief, we performed a multistage probability sampling to have a representative sample of the journals as we did not have a complete list of all the studies that matched the eligibility criteria. Firstly, an arbitrary sample of the top ten journals that published original research on the General & Internal Medicine category in the 2018 In Cites Journal of Citation Reports were selected (Ajeel, F., 2019). The selected journals were: The New England Journal of Medicine, The Lancet, JAMA, BMJ, JAMA Internal Medicine, Annals of Internal Medicine, PLOS Medicine, Cachexia, BMC Medicine, and Mayo Clinic Proceedings. Secondly, five random volumes of these journals were obtained. Thirdly, five issues in the previously mentioned volumes were chosen randomly. Finally, original research articles were sampled for further assessment without a formal sample size calculation. We performed a weighted analysis to ensure the sample was representative of the population as each journal published with a different frequency of volumes, issues, and number of articles. We defined as 'study participant' a person who volunteers to be part of a prospective observational study or a clinical trial or those whose information was included in any type of retrospective analysis. We defined 'staff members' as people who contributed in any way to the development of the research project (conception of the idea, design, conduction, data analysis, writing, financial support).

Data extraction

For the data collection process, two independent reviewers performed a calibration to ensure interrater reliability. Both independent reviewers worked in duplicate using a standardized extraction database and collected the following information from the individual articles: 1) study design, 2) name of the journal, 3) region (North America, Europe, Asia, Africa, Oceania, and South America), 4) frequency of acknowledgment of participants or staff members, and 5) funding source (governmental or non-governmental organization) as established in a previous study. From the journals the following information was collected using two independent reviewers working in duplicate: 1) citation rate of the journal and 2) if the journal provided instructions to acknowledge staff members or participants. For the reporting guidelines, two reviewers, working independently and in duplicate, determined if the guidelines provided guidance for authors to acknowledge study participants or staff members.

Characteristic	n=496 (%)
Journal	
New England Journal of Medicine	61(12.3)
The Lancet	61 (12.3)
JAMA	60 (12.1)
BMJ	85(17.1)
JAMA Internal Medicine	93 (18.8)
Annals of Internal Medicine	61 (12.3)
PLOS	16 (3.2)
CACHEXIA	10 (2)
BMC Med	18 (3.6)
MAYO	31 (6.3)
Region	
North America	276 (55.6)
Europe	175(35.3)
Asia	21(4.2)
Oceania	17 (3.4)
Africa	5 (1)
South America	2 (0.4)
Study design	
Observational	311 (62.7)
Experimental	167 (33.7)
Secondary	16 (3.2)
Other	2 (0.4)
Year of Publication	
1990-1999	139 (28)
2000-2009	153 (30.8)
2010-2020	204 (41.1)

Table 1. General characteristics. Trends of study participants and staff acknowledgment by region, study design, and year of publication in top-tier journals in the last 30 years.

	Study participants acknowledged	Staff acknowledged
Region		
North America (n=276)	41 (14.9%)	148 (53.8%)
Europe (n=175)	53 (30.3%)	112 (64%)
Asia (n=21)	5 (23.8%)	12 (57.1%)
Oceania (n=17)	9 (52.9%)	13 (76.5%)
Africa (n=5)	2 (40%)	5 (100%)
South America (n=2)	0 (0%)	1 (50%)
Study design		
Observational (n=311)	48 (15.4%)	172 (55.3%)
Experimental (n=167)	60 (35.9%)	112 (67.1%)
Secondary (n=16)	1 (6.2%)	6 (37.5%)
Other (n=2)	1 (50%)	1 (50%)
Total (n=496)	110 (22.2%)	291 (58.7%)

Table 2. Study participants and staff characteristics. Trends of participants and staff acknowledgment by region in top-tier journals in the last 30 years.

Outcomes

Our primary outcome was the frequency and the trends of recognition of the contributions of study participants in the acknowledgments section of the manuscripts. Our secondary outcome was the frequency and the trends of acknowledgments of staff members. As an exploratory outcome, we reported if each of the included journals and each of the appropriate reporting guidelines that corresponded to each of the included study designs provided instructions for the authors on how to write and whom to include in the acknowledgment section. We analyzed the frequency of reported acknowledgments and their association with the funding source, citation rate, or region.

Statistical Analysis

Acknowledgments of study participants and staff members were summarized as frequencies and percentages. Numerical variables were expressed utilizing means and standard deviations. X² and Student's t-test were used for categorical and numerical variables respectively to evaluate differences in acknowledgment prevalence. Pearson's correlation was performed to evaluate the variables associated with acknowledgments taking into consideration variables associated with a p-value <.05. Increases or decreases in the proportion of acknowledgments were estimated as prevalence ratios in which proportions were taken from different time periods. All the analyses were performed in R (R Foundation for Statistical Computing, Vienna, Austria).

RESULTS

General characteristics

A total of 496 studies were included in the analysis. A total of 311 (62.7%) of the studies were observational and 167 (33.7%) were experimental. The majority (276, 55.6%) of the articles originated from North America followed by Europe (175, 35.3%) [Table 1].

A total of 110 (22.2%) articles acknowledged study participants, and 291 (58.7%) acknowledged staff [Table 2]. A total of 102 (92.7%) of the studies that acknowledged study participants also acknowledged staff [OR 95CI:13.2 (6.2-28.0), p<.0001]. Only 1 (10%) of the included journals provided instruction to authors on how to recognize the contributions of patients in the manuscript. However, this was only in the corresponding instructions for case reports. Only 6 (60%) journals provided instructions on how to recognize other types of contributions when these do not meet the criteria for authorship. None of the reporting guidelines provided guidance on how and when to recognize the contributions of study participants or staff members [Table 3].

	Instructions to acknowledge study participants	Instructions to acknowledge staff
Journals		
NEJM	No	No
The Lancet	Yes*	Yes
JAMA	No	No
BMJ	No	No
JAMA Internal Medicine	No	No
ANNALS IM	No	Yes
PLOS Medicine	No	Yes
CACHEXIA	No	Yes
BMC Medicine	No	Yes
MAYO	No	Yes
Reporting Guidelines		
CONSORT	No	No
STROBE	No	No
CARE (Case Reports)	No	No

Table 3. Included instructions to report acknowledgment in journals. If an individual is cited in the manuscript, for case reports.

Trends of acknowledgments of participants and staff

Starting in 1990-2004, there was a constant frequency in reporting patient acknowledgments; however, from 2010 and onward, this frequency began to increase and in the last five years (2015-2020), there were 162% more patient acknowledgments than fifteen years ago (2005-2009). From 2000 to 2004, journals included 10 articles that acknowledged patients and from 2015 to 2020 there were 42. Furthermore, the trend of staff acknowledgments remained constant from 1990 to 2014, but in the last five years, the frequency increased

68% compared to fifteen years ago (2005-2009) [Figure 1].

When stratified by study design (observational or experimental), study participant acknowledgment has increased in the last ten years. Particularly, in 2015-2020 there was an increase in both observational and experimental studies by 28.3% and 112.6%, respectively compared to 2005-2009 in the sample. On the other hand, the frequency of staff acknowledgment stratified by study design has remained constant. In 2015-2020 staff members were more likely to be acknowledged in experimental than observational studies (18.6% vs 30.4%) respectively [Figure 2].

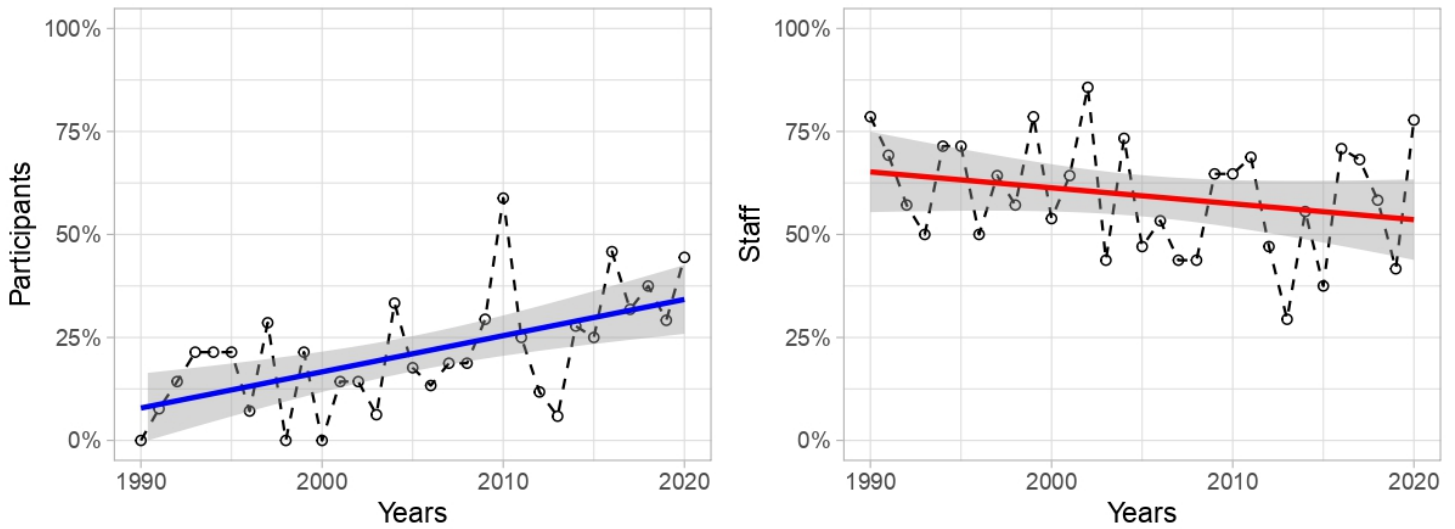


Figure 1. Trends in participants and staff acknowledgments from 1990-2014.

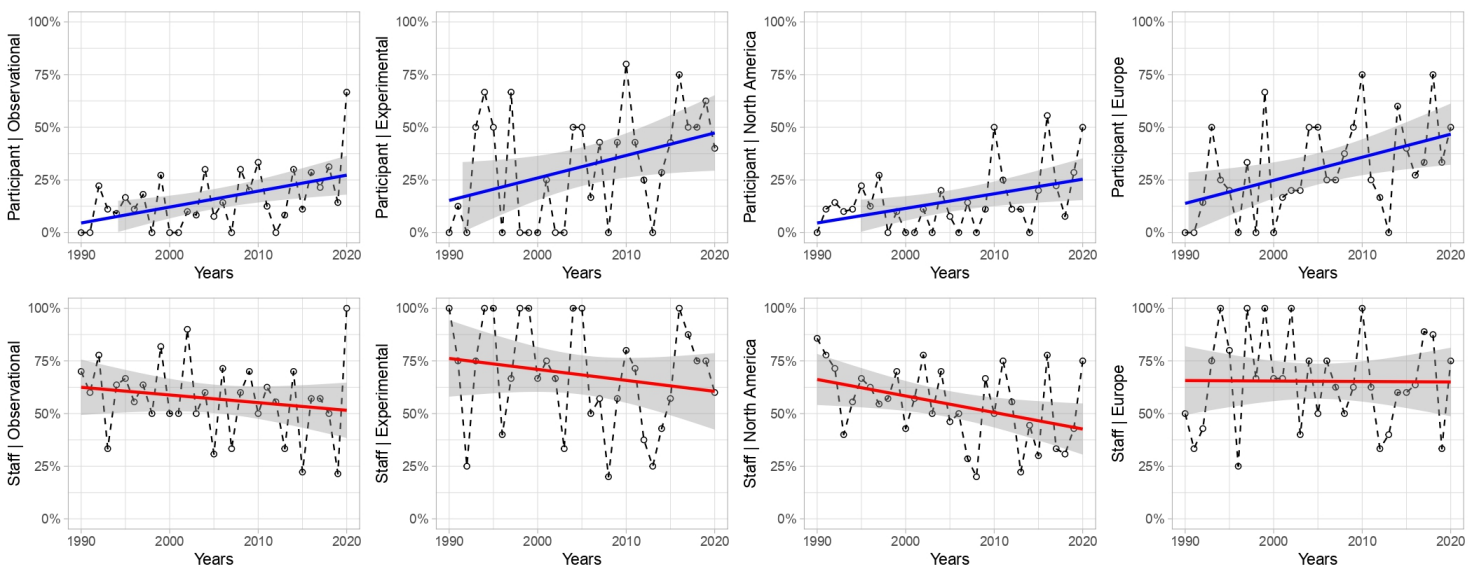


Figure 2. Trends of study participants and staff acknowledgment in experimental and observational studies from 1990 to 2014.

Similar results were observed when comparing the trend by region. Studies conducted in North America and Europe in the last five years (2015-2020) showed an increased frequency of participant acknowledgments (30.4% and 63%, respectively) compared to 2005-2009. We also found that studies conducted in Europe from 2015 to 2020 were more likely to acknowledge staff members than in North America.

Predictors of study participants and staff acknowledgment

Characteristics of the study and publication

When analyzing by study design, we found out that experimental studies were more likely to acknowledge study participants and staff members when compared to non-experimental studies [35.9% vs. 15.2%; OR CI 3.1 (2.0-4.8), $p < .001$] and [67.1% vs. 54.4%; OR CI 1.7 (1.1-2.5), $p = .007$], respectively.

When analyzed by geographic region, Oceania was the most frequent region to acknowledge study participants (9, 52.9%) followed by Africa (2, 40%), and Europe (53, 30.3%). From all the regions, studies conducted in other regions than North America were more likely to acknowledge study participants and staff members when compared to those conducted in North America, [31.4% vs. 14.9%; OR CI 2.6 (1.6-4.0), $p < .001$] and [65% vs. 53.6%; OR CI 1.6 (1.1-2.3), $p = .011$], respectively. After adjusting for study design (experimental versus non-experimental) and the number of citations (as a surrogate of the impact of the studies), a study conducted in a region other than North America was still associated with acknowledging patients [OR CI 3.5 (1.9-6.4), $p < .001$].

We found a weak inverse correlation between the number of funding sources from the government and study participants' acknowledgment ($r = -.109$, $p = .024$). When analyzing the citation rates, we found a weak positive correlation between the number of citations and participants' acknowledgments ($r = .199$, $p < .0001$). Finally, studies acknowledging participants were associated with higher citation rates (531.3 +/- 594.8 vs. 344.0 +/- 795.8, $p < .0001$).

Journal guidelines for acknowledging

A total of 133/291 (45%) articles that acknowledged staff were published in journals that gave instructions on how and when to acknowledge staff [OR 95CI: 1.7 (1.1-2.5), $p = .004$]. Similarly, 20/110 (18.2%) of the articles that acknowledged study participants were

published in journals that gave instructions on how and when to acknowledge participants [OR 95CI: 1.8 (1.0-3.3), $p = .033$].

44/110 (40%) articles that acknowledged study participants were published in journals that gave instructions on how and when to acknowledge staff [OR 95CI: 1.0 (0.6-1.5), $p = .945$]. Contrastively, 48/291 (16.5%) that acknowledged staff were published in journals that gave instructions on how and when to acknowledge study participants [OR 95CI: 2.9 (1.5-5.5), $p = .001$].

DISCUSSION

Main Findings

Despite the crucial contributions of participants to clinical research, only 2 out of 10 articles recognized it in the final publication of the scientific articles. Staff contribution is more frequently acknowledged since 5 out of 10 articles recognized it (technical, moral, or financial). This supports the idea that a gap exists in recognition between staff contributions and participant contributions that has not been adequately studied. Experimental studies and studies conducted in other regions than North America were more prone to recognize the contributions of study participants.

Comparison with previous studies

A previous evaluation performed to analyze the different categories included in the acknowledgment section failed to have study participants as a category. In this evaluation, the authors focused on reporting peer acknowledgment characteristics (Rattan, G. K., 2013). We found a significant association demonstrating that the articles that acknowledge study participants also acknowledge the staff. A prevalence of 5.45% for staff acknowledgment was previously reported in a review that included studies from 1999 to 2012. (Rattan, G. K., 2013). Our results significantly differ from these since we found that 58.7% of the included articles acknowledge staff contributions to the study. These differences can be explained since the extracted data was from a different field of study (Mohammed, F., 2020). Similar to our analysis, they found out that the journals in which these studies are published do not provide instructions on how and when to acknowledge staff contributions.

We evaluated regions with different health policies, traditions, and manners, yet we found that, across all regions, the staff had a higher percentage rate of acknowledgment compared to the study participants.

Our results showed that studies conducted in regions other than North America were more likely to acknowledge study participants and staff members in comparison with studies conducted in North America. Moreover, a previous study that analyzed the frequency of general reported acknowledgments among different geographical contexts showed the USA as the most common region to recognize these contributions compared to France, the U.K., and Spain (Salager – Meyer, F., 2011). When adjusting for study design and the number of citations, a study conducted in a region other than North America was still associated with higher rates of study participants' acknowledgments. We found a weak inverse correlation between funding sources from the government and study participant acknowledgment. This is consistent with a previous study among other clinical fields such as nanotechnology where in the last 30 years authors failed to introduce study participants in the acknowledgment section and prefer to analyze the trends of funding sources (Wang, J., 2011). In recent years, many biomedical field journals have required that all funding sources, including organization names and grant numbers, be disclosed in the acknowledgment section of a publication (Desrochers, N., 2018).

Implications of the findings

In many situations, acknowledgments remain the only space where authors can express their gratitude for the contributions of staff members if they do not meet the criteria for authorship (Richards, D.P., 2020). Without the contribution of study participants, at the expense of their disease, and even sometimes their lives, clinical research would not exist. Their contribution is always more important than that of the staff members or even the authors of every manuscript.

The contributions of study participants can be at different levels of importance. At the lowest level, we may find the contributions of study participants to studies performed through administrative data. In this case, the contribution is limited to the information included in their medical records which is managed in compliance with the HIPAA or other equivalent laws in the respective countries where the research study is conducted. At a medium level, we may find observational studies in which study participants agree to be observed and monitored for a certain period or in which study participants agree to answer baseline and follow-up questionnaires. These two levels of importance are examples of studies in which the possibility of harming the patients is null. At a higher

level, we find studies in which the probability of harming the patients increases, such as in phase 3 clinical trials, in which study participants agree to participate in studies aiming to assess the efficacy of interventions that may provide benefits to the patient at the cost of possible harms. In many cases, the benefits outweigh the harms easily, but there are other scenarios in which the benefits may be more closely balanced with the harms (Seidenfeld, J., 2008). This level of study participant contribution is significantly higher than those of observational prospective or retrospective studies. At the highest level, we have phase 1 or phase 2 clinical trials (e.g., measuring the safety of a novel vaccine) in which study participants agree to participate in studies aiming to assess the safety and efficacy of new interventions when the investigators are uncertain of the possible harms and the extent of the possible benefit. This level presents a substantially higher risk than other phases. In our study, we found a higher rate of recognition in clinical trials when compared to observational studies, which makes sense because the contribution in clinical trials is more impactful in the patients' lives.

Authors of clinical research studies should contemplate the level of contribution that study participants make to decide if they should or should not receive recognition for their contribution to the generation of knowledge. Another aspect that could be explored in future research is the perspective of study participants towards being acknowledged or not in the research manuscripts. If we consider the motivations behind the patients' willingness to participate, several studies have demonstrated that what motivates study participants to engage in research studies is to benefit others through the generation of new knowledge. When considering the reasons why study participants choose to participate in experimental research, an exploratory survey performed on older people who collaborated in clinical trials, showed that 33% of the responders were motivated to participate to help others and to support research (Tolmie, E.P., 2004). In another cross-sectional study, participants were asked to describe the reasons for their willingness to participate in research. A total of 56.3% of the respondents agreed that providing benefits for others was the main reason to collaborate (Kraft, S.A., 2017).

Strengths and limitations

To the best of our knowledge, this is the first review providing information on the acknowledgment of study participants and staff in journals of general interest. As a

strength, we included the top ten clinical medicine journals as measured by their impact factor reported by the journal citation reports. We surveyed the main reporting guidelines for experimental (CONSORT), observational studies (STROBE), and case reports (CASE). The fact that we included only ten clinical medicine journals may be a limitation since studies in lower impact journals may be more likely to acknowledge study participants' or staff members' contributions. As a limitation, region and study design were not considered when sampling the articles, therefore the rate of acknowledgment when analyzed stratified by these variables could be over-or under-represented. Finally, we did not stratify clinical trials by phase, this could also bias our estimate of the frequency of study participants' acknowledgments since clinical trials with lower phases may be more prone to acknowledge study participants as their contribution is more significant. This should be analyzed in further studies.

Conclusion

Although there has been an increase in the last few years to recognize the contributions of study participants in clinical research, we consider that most of the articles fail to acknowledge their contributions. If there are no formal guidelines on how to write the acknowledgment section in a manuscript, it will remain at the authors' discretion to recognize the contributions of the study participants and staff. We encourage authors to recognize the participation of participants and staff when appropriate and for journals to increase the guidance on how and when to acknowledge participants and staff members in clinical research articles.

Conflict of interests

None.

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