Evolution of reported patient and public involvement over time in randomised controlled trials in major medical journals and in their protocols: meta-epidemiological evaluation

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ABSTRACT

OBJECTIVE

To investigate the reporting and evolution of patient and public involvement (PPI) in randomised controlled trials published over time in major medical journals and in their trial protocols.

DESIGN

Meta-epidemiological evaluation.

DATA SOURCE

PubMed was searched for articles reporting randomised controlled trials published since 2015 in four major medical journals and their corresponding peer reviewed protocols.

ELIGIBILITY CRITERIA FOR SELECTING STUDIES

The first 10 randomised controlled trials published each year in each journal were included.

DATA EXTRACTION

Data extraction focused on involved stakeholders, description and extent of PPI activities/processes, and recognition of PPI contributions. Published articles and protocols were assessed for consistency of the reported PPI in both.

RESULTS

Of the 360 published articles reporting randomised controlled trials and 299 respective protocols, PPI was only reported in 64 (18%) articles and 56 (19%) protocols. When PPI was reported, patients and their representatives were mainly involved, with the most common PPI activity being participation in trial committees (44/64 PPI reporting articles; 39/56 protocols). PPI primarily occurred during the trial development phase, including feedback on study design, review of study materials, and assessment of feasibility. Protocols occasionally had more detailed information than the published articles, but in most cases the PPI contributions were often vague without detailed information on specific outcomes and the effect on decision making within the randomised controlled trial. Recognition of PPI contributions was more frequent in published articles (n=37; 58%) than in protocols (n=18; 32%), mainly in the acknowledgment section.

CONCLUSION

This study found limited PPI reported in randomised controlled trials published in major medical journals and in their respective protocols, underscoring the need for consistent, detailed, and transparent PPI reporting practices in clinical research.

STUDY REGISTRATION

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WHAT IS ALREADY KNOWN ON THIS TOPIC

Patient and public involvement (PPI) is crucial for enhancing the efficiency and relevance of randomised controlled trials (RCTs) and ensuring that research meets the real needs and preferences of patients

Existing evidence indicates an increasing emphasis on PPI, but systematic data on the nature and extent of reported PPI in RCTs and in their corresponding protocols remain limited

WHAT THIS STUDY ADDS

PPI was reported in fewer than 20% of articles reporting RCTs or their protocols

Detailed information on PPI roles and contributions was lacking, and inconsistencies existed between planned PPI activities in protocols and what is reported in published articles

Standardised PPI reporting practices are needed to ensure consistent, detailed, and structured descriptions, ultimately enhancing the transparency and impact of PPI in clinical research

Introduction

Patients' perspectives are an important source of information alongside clinical and economic evidence in healthcare decision making.[1] Hence, patient and public involvement (PPI) in clinical research, particularly in randomised controlled trials, is increasingly regarded as essential for evidence based decision making that resonates with the needs and preferences of patients.[1 2]

Incorporating PPI in randomised controlled trials can help to tailor study protocols to achieve more meaningful outcomes, improve recruitment, and reduce dropout rates.[3 4] It also fosters patient centred healthcare by empowering patients and the public to play a more active role in their healthcare decisions and facilitating shared decision making.[5 6] Despite the recognised benefits of PPI, a gap remains in our understanding of the nature, extent, and evolution of PPI in randomised controlled trials. Although emphasis on PPI is growing, systematic data on this topic are still limited.[7-9]

Randomised controlled trials published in major general medical journals tend to be extremely influential on medical science and clinical practice guidelines owing to their high citation rates.[10] These journals publish a lion's share of the most impactful randomised controlled trials, in which the presence or lack of PPI may have a disproportionate effect on how influential medical evidence is produced. Additionally, protocols for these trials are often publicly available, but whether PPI is more commonly included in protocols than in published articles and whether PPI reporting differs between the two remain unknown.

We did a meta-epidemiological evaluation to systematically review the reporting and evolution of PPI in highly influential randomised controlled trials and their protocols. We defined PPI as active involvement of patients, care givers, or the public in all stages of research, from planning and designing trials to implementing and reporting results, as distinct from their roles as study participants.

Methods

Search strategy and sampling

We systematically searched PubMed to provide a comprehensive sample of articles reporting randomised controlled trials published between 2015 and 2023 in four major medical journals irrespective of their disease areas: *The BMJ*, *JAMA*, the *New England Journal of Medicine*, and *The Lancet*. The search combined each journal's name [SO] with PubMed's filter specifically targeting randomised controlled trials. After ranking the articles chronologically according to their publication year, a researcher (AV) selected the first 10 randomised controlled trials published each year for each journal after screening titles and abstracts. This sampling strategy offered a structured, reproducible method that minimised selection bias and provided a balanced representation of randomised controlled trials across multiple years and journals. The study protocol was registered before data extraction in Open Science Framework.[11]

Data extraction

We extracted data from the full text articles, including appendices. If the corresponding protocol was referenced, either in the appendix or as separate peer reviewed article, we also included it in the data extraction. We used a structured data extraction form, containing descriptive parameters (for example, article title, journal, year, disease area) and content parameters (for example, reported PPI stakeholders, description and extent of PPI activities/processes, and recognition of PPI contributions). Two researchers (AV and IW) did a pilot extraction of 45 (13%) randomised controlled trials independently and double blinded, to optimise and validate the effectiveness and comprehensiveness of the data extraction form. As no discrepancies were identified, the extraction framework remained unchanged and we included the pilot data in the final analysis.

Data analysis

We explored patterns and trends in PPI reporting across journals and over time. We used descriptive analyses to evaluate how the proportion of randomised controlled trials reporting PPI in articles, protocols, both article and protocol, and either article or protocol or both has changed between 2015 and 2023, with the year of publication as the independent variable and the presence of PPI reporting (yes/no) as the dependent variable. We used logistic regression models with a binominal distribution in R to examine these trends. A narrative synthesis identified recurring themes and descriptions in PPI.

Patient and public involvement

The study was supported by the patient representative Claudia Louati from the European Patients' Forum, who provided valuable feedback on the study design and results. More specifically, the patient representative reviewed the study protocol and confirmed the relevance of the research questions and methodology, thereby ensuring its patient centredness. The patient representative was also actively involved in critically revising and editing the manuscript for its readability, accuracy, and relevance. These critical insights ensured that the patient's voice was integrated into the final publication and throughout our research.

Results

Reported PPI

Of the 360 articles (supplementary figure A), 299 (83%) referred to their corresponding protocols. PPI was reported in only 64 (18%) articles and 56 (19%) protocols. For 36 trials, PPI was reported in both the article and its protocol, but with notable inconsistencies in PPI reporting between the two. Overall, 84 (23%) of 360 trials reported PPI in either the article or protocol or both.

Stakeholders involved in reported PPI

More than half of the articles with reported PPI (n=40; 63%) and half of the protocols (n=28; 50%) described involving a single type of stakeholder. The highest number of different types of stakeholders involved in a single article or protocol was five (see supplementary tables A-D).

Among the 64 articles reporting PPI, patients were the most frequently identified stakeholder group engaged in PPI (n=30; 47%). However, detailed descriptions of patients' specific disease or condition were often lacking, with only seven articles offering more specific details. Furthermore, 25 (39%) articles referred to the involvement of patient advocates or representatives from patients' organisations such as Independent Cancer Patients' Voice.[12] The general public was also referenced (n=16; 25%), often with vague and general terms such as public or lay members. Occasionally, more specific descriptions were provided, such as regional politicians or teachers.[13 14]

Protocols sometimes provided more detailed descriptions of the specific patients involved in PPI than did the articles, although these were still insufficient. Protocols were also more likely to characterise PPI contributors as trial participants (n=17; 30%).

Description and extent of reported PPI

Most articles (n=15; 23%) and protocols (n=16; 29%) described one single study activity/process involving PPI, with a maximum of 13 study activities/processes (see supplementary table E). As shown in table 1, PPI information in the articles, when provided, was often

not or only moderately detailed. By contrast, protocols typically provided more detailed information, with a median of 159 (interquartile range 75-273) words compared with 85 (49-129) in articles. Only 21 randomised controlled trials provided highly detailed PPI information, with only three doing so in both the article and the protocol.

Extent of PPI descriptions is categorised as follows: no PPI reported (no mention of PPI in article or protocol); not detailed PPI (minimal or vague PPI descriptions); moderately detailed PPI (some PPI descriptions but without comprehensive information or explanations of specific outcomes or their impact on study's decisions); highly detailed PPI (comprehensive PPI descriptions including specific outcomes and their impact on study's decisions).

The most common study activity/process with PPI was participation in trial committees (for example, steering, trial management, or data monitoring committee), reported in nearly 70% of both articles (n=44) and protocols (n=39) that included PPI (fig 1; supplementary tables F-H). However, specific roles and contributions were generally broad and vaguely described without detailed information on specific outcomes and the effect on decision making within the randomised controlled trial. Study design was also frequently mentioned, with PPI focused on developing and refining interventions, including feedback on format, usability, content, and duration. Furthermore, PPI informed data collection forms, inclusion criteria, and follow-up arrangements. PPI was also mentioned in the development and reviewing of study materials, such as participants' information sheets and consent forms, to ensure readability and comprehensiveness. Regarding study feasibility, patients provided feedback on the burden of participation, frequency of visits, and acceptability of interventions during pilot studies.

Protocols more often mentioned qualitative studies exploring patients' perceptions on unmet medical needs, satisfaction with care, and expectations of treatment. PPI in study conduct, such as advising on trial set-up, progress, and management, was also more common in protocols. Conversely, PPI aimed at aligning study outcomes and measures with patients' priorities (for example, quality of life and pain scores[15]) and concerning recruitment and retention was more often reported in articles than in protocols.

Recognition of PPI contributions

Formal recognition of PPI contributions was more frequent in articles (n=37; 58%) than in protocols (n=18; 32%). The highest number of sections recognising PPI in a single article or protocol was five (see supplementary tables I and J).

PPI recognition through authorship was rare. Instead, many articles and protocols recognised PPI contributions in the acknowledgment section. The level of detail ranged from general acknowledgments to more specific mentions of PPI contributors and their roles, with individuals occasionally named. Even when listed as authors or in the contributions statement, PPI was not always clearly indicated, with affiliations

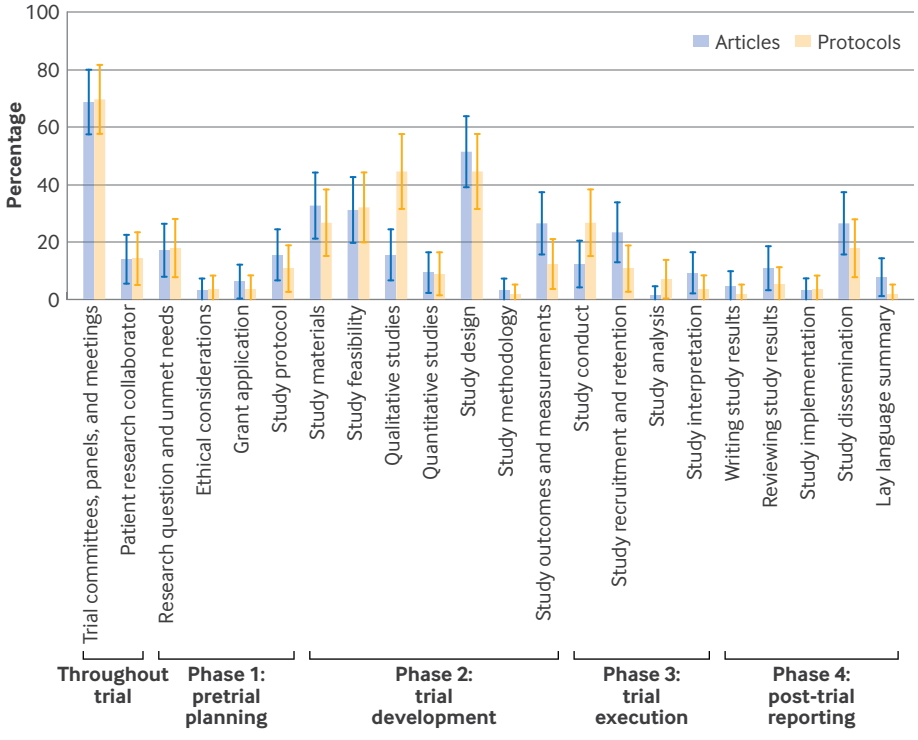

Fig 1 | Comparison between study activities/processes described in articles (n=64) and protocols (n=56) reporting patient and public involvement, with 95% confidence intervals. Qualitative studies involve interviews and focus group discussions; quantitative studies involve surveys

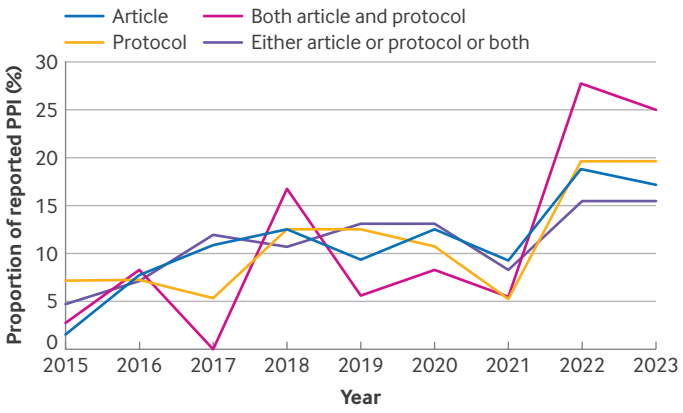

Fig 2 | Evolution over time of reported patient and public involvement (PPI) in articles (total n=64), protocols (total n=56), both article and protocol (36/64 articles and 36/56 protocols), and either article or protocol or both (total n=84). Forty articles were sampled for each year from 2015 to 2023. Trends were modelled in R using logistic regression with year as continuous variable, resulting in P values of 0.003 for articles, 0.009 for protocols, P<0.001 for both article and protocol, and 0.02 for either article or protocol or both. Protocols were classified according to publication data of corresponding published article

merely listing names or patients' organisations without specifying these PPI roles (for example, Cancer Support Community[16]). Sometimes, protocols provided clarity by stating details of these PPI roles (for example, "MBe reviewed the results and provided patient perspective"[17]). Only occasionally were PPI roles explicitly detailed in the author's affiliations (for example, "patient and public contributor"[18]). Notably, online articles in *The BMJ* provided more detailed affiliations, including additional information indicating authors' PPI roles.

Factors influencing reported PPI

Time

Logistic regressions confirmed an increasing overall trend in PPI reporting over time (fig 2; supplementary table K). The highest levels of PPI reporting were observed in the past two years, but it has not yet exceeded 30%.

Journals

The BMJ, a journal that has required a PPI statement since 2014,[19] accounted for the large majority (n=49; 77%) of PPI reporting in articles. Of the 90 BMJ articles analysed, 10 articles (published in 2015) lacked a PPI statement, although one of these reported PPI elsewhere. Of the articles that did include a PPI statement, 32 reported no PPI and 48 reported PPI in the statement. However, the high level of PPI reporting was less consistent and pronounced in the protocols (n=27; 48%). By contrast, the other journals that do not require PPI statements reported PPI more often in protocols rather than in the articles (supplementary figure B).

Discussion

Overall, less than 20% of randomised controlled trials described PPI in both published articles and corresponding protocols. Although protocols occasionally provided more detailed information than did articles, most lacked clarity on specific PPI contributions, outcomes, and the effect on decision making within the randomised controlled trial. PPI reporting increased over time, but it never exceeded 30%. Articles in *The BMJ* reported PPI far more frequently than did those in the other major medical journals. However, PPI was often absent in the protocols, suggesting that some PPI activities/processes were not initially planned or documented.

Comparison with other studies

The dearth of PPI reporting has also been observed in other studies focused on specific medical specialties. For instance, Estrup and colleagues found similar levels of PPI reporting (18%) in intensive care trials (2019-22),[20] whereas Owyang and colleagues reported only 0.4% in randomised controlled trials in orthopaedic surgery (2013-20).[21] Even in journals with mandatory PPI reporting, reporting rates did not exceed 40%.[22 23] Although the lack of PPI reporting does not necessarily imply the absence of PPI, previous research suggests that limited PPI may result from inadequate planning and implementation, rather than from under-reporting.[24] Our study provides new insights by investigating both articles and protocols across four major medical journals, revealing variability and inconsistency in PPI reporting between the two.

When involved, patients, patient advocates, and patient representatives were the primary stakeholder groups engaged in PPI activities, followed by members of the public. Few articles and protocols explicitly named PPI contributors, limiting personalised recognition and undervaluing their contributions. However, privacy concerns or trial regulations may prevent specific naming of contributors. To avoid misinterpretation, publications should clarify when the lack of recognition is not an oversight but is due to consent or compliance. Conversely, PPI that may include potential conflicts of interest or advocacy, or

Table 1 | Extent of patient and public involvement (PPI) descriptions in articles and protocols

	Protocols			
Articles	No PPI reported	Not detailed PPI	Moderately detailed PPI	Highly detailed PPI
No PPI reported	276	6	10	4
Not detailed PPI	12	3	6	4
Moderately detailed PPI	13	2	11	3
Highly detailed PPI	3	0	4	3

might influence other activities—for example, patients also involved in regulatory processes—should be transparently disclosed, ideally by name.

PPI mainly occurred in the development phase of randomised controlled trials, particularly in trial committees (69%), a remarkably higher rate than reported by Husson and colleagues (40%) and Price and colleagues (38%).[22 24] Although other studies also emphasised PPI at the beginning of randomised controlled trials (for example, setting research agendas), these pretrial PPI activities were less prominent in our study.[20 25] Notably, PPI was minimal in the post-trial reporting phase, such as writing and reviewing study results, despite literature indicating its crucial role in making research findings more meaningful and accessible to patients.[26-28]

The number of PPI activities/processes reported per randomised controlled trial has varied greatly. Some studies comprehensively covered multiple PPI areas, but many focused on just one or two areas. Moreover, PPI descriptions often lacked depth, likely owing to the limited space imposed by journals in articles and the lack of standardised guidance on PPI reporting.[21] Although protocols are not restricted and allow for more extensive and detailed reporting, most still provided little or no mention of PPI. A potential gap exists between planned and actual PPI activities, and PPI is often under-reported in articles, undermining its value. This inconsistency in reporting may hinder the systematic assessment and comparison of PPI practices across clinical research.

Recognition of PPI in authorship was rare, and even acknowledgments, mainly recognising PPI, were sparse and often anonymous, consistent with previous studies.[22 24] Some contributors may have had dual roles, such as being both researchers and care givers, but these perspectives were not always clearly reported.[29] Including PPI members as authors, in compliance with recommendations from the International Committee of Medical Journal Editors, and detailing their roles would better reflect their significant involvement and demonstrate deeper levels of engagement.

Limitations and strengths of study

Our meta-epidemiological analysis has some limitations. PPI reported by authors may be inaccurate, misclassified, overestimated, or understated, especially if journals do not mandate PPI statements. We did not verify reported PPI with the involved stakeholders to understand their perspectives on the described PPI. Therefore, tokenistic or ineffective PPI activities/processes could not be indicated. To mitigate this risk, we reviewed both articles and protocols to gain a more comprehensive understanding of both actual and planned PPI. Many lacked detailed and clear PPI descriptions, complicating classification into pre-specified categories, with some activities overlapping. Additionally, some randomised controlled trials did not reference peer reviewed protocols and we did not search for protocols posted elsewhere, which would lack journal level peer review. To ensure a diverse representation of disease areas, our analysis focused on the first 10 randomised controlled trials published each year in four major medical journals, which may affect the generalisability of our findings.

Implications and conclusions

PPI is crucial for ensuring that research meets patients' needs and preferences.[30] However, consistent, detailed, and structured PPI reporting is still lacking in clinical trials and protocols. PPI was rarely integrated throughout the entire randomised controlled trial process, often being introduced too late or with limited involvement in key phases. The omission of PPI in protocols raises more concerns about the accuracy and consistency of PPI reporting. To fill this gap, standardised PPI reporting practices are essential to appropriately recognise and enhance meaningful PPI. Broader adoption of PPI statements by journals and adherence to existing guidelines such as the GRIPP (Guidance for Reporting Involvement of Patients and the Public) checklist may lead to more detailed and consistent PPI reporting.[31] Moreover, integrating mandatory PPI reporting into CONSORT (Consolidated Standards of Reporting Trials) and SPIRIT (Standard Protocol Items: Recommendations for Interventional Trials) guidelines could further strengthen the importance of PPI in both published articles and their protocols, enhancing its visibility and perceived value in clinical research.[32 33]

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Contributors: AV, PS, IH, JPAI, and TA were involved in the planning and development of the study design. AV, IW, PS, IH, JPAI, and TA were involved in the conduct of the study, including data collection and analysis. AV wrote the first draft of the manuscript. All authors critically reviewed and edited the draft of the manuscript and approved the final version. JPAI and TA share last authorship. AV and TA are the guarantors. The corresponding author attests that all listed authors meet authorship criteria and that no others meeting the criteria have been omitted.

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Competing interests: All authors have completed the ICMJE uniform disclosure form at https://www.icmje.org/disclosure-of-interest/ and declare: no support from any organisation for the submitted work; no financial relationships with any organisations that might have an interest in the submitted work in the previous three years; no other relationships or activities that could appear to have influenced the submitted work.

Ethical approval: This study did not involve any human or animal participants, and therefore, ethical approval was not required. The research was based solely on the analysis of previously published literature.

Data sharing: All data, including the full dataset, are available from the corresponding author (alice.vanneste@kuleuven.be).

Transparency: The lead author (the manuscript's guarantor) affirms that the manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as originally planned (and, if relevant, registered) have been explained.

Dissemination to participants and related patient and public communities: The authors plan to disseminate the study and study results to research institutions, medical associations, and patient

and public communities. The article will be presented at scientific meetings and conferences, as well as other opportunities for dissemination.

Provenance and peer review: Not commissioned; externally peer reviewed.

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Web appendix: Supplementary materials