# Patient Involvement... Or Not?

### Analysis of 'Patient Involvement' statements in clinical trial publications in The BMJ

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#### **Abstract**

#### **Objective**

In 2014, The BMJ introduced a mandatory 'Patient Involvement' statement in the Methods section of research articles. We investigated the extent of patient involvement described in clinical trial research publications in The BMJ. Our primary objective was to quantify patient authorship.

#### Research design and methods

We searched PubMed (journal: The BMJ; publication type: clinical trial; dates: 2015/01/01-2016/12/31) and electronically exported all retrieved articles. Non-research articles were removed. Two authors categorised patient involvement based on the verbatim 'Patient Involvement' and Acknowledgements sections in each publication. Results were cross-checked.

#### Results

Of the 62 articles retrieved, 10 were non-research articles. Reported patient involvement was generally low. Involvement was lowest for authorship (1.9%; 1/52) and highest for thanking patients for their participation (57.7%; 30/52).

#### **Conclusions**

Despite The BMJ's requirement, reported patient involvement in clinical trial publications remains low. Patient authorship is being encouraged, but remains rare. Advocacy efforts for meaningful patient involvement during research, including publication planning and preparation, must continue.

### Introduction

• Empowered patients are advancing the publication ecosystem and advocating for increased involvement in publications







### **VIEW VIDEO**

- Since 2014, The BMJ has required a 'Patient Involvement' statement in the methods section of research articles
- The BMJ classify patient involvement as a range of activities, ranging from acknowledgement of participation to full authorship



Patient involvement (ie, with or by patients) differs from more passive forms of patient participation or engagement (ie, to, about or for patients)<sup>1</sup>

Purpose: To quantify the extent of patient authorship in clinical trial publications in The BMJ

## Methods

- This case study of The BMJ is part of a broader Envision-led 'patient involvement in publications' research programme
- Research articles from *The BMJ* were retrieved, exported and analysed
- The type and extent of patient involvement was assessed for each article



articles

removed

Social media

analysis

### Acknowledgements and Disclosures

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2016

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- · All authors participated in the research, were actively involved in preparing the abstract and provided approval for submission. All authors support not-for-profit associations promoting patient engagement or publication professionals. KW has served on the ISMPP Board of Trustees, KW has shares in Johnson & Johnson, RJ has shares in AstraZeneca, All authors acted in a voluntary capacity. Envision Pharma Group provided limited financial support for

### Results

Of the 52 articles evaluated, 13 (25%) reported no patient involvement\*

#### RESEARCH

Patient choice in opt-in, active choice, and opt-out HIV screening: randomized clinical trial.

#### Patient involvement

No patients were involved in setting the research question or the outcome measures, nor were they involved in recruitment, or the design and implementation of the study. There are no plans to involve patients in dissemination

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\*5/13 studies (38%) included a 'Patient Involvement' statement but reported that they did not involve patients; 8/13 studies did not include a 'Patient Involvement' statement.

Is this acceptable?



1 out of the 52 articles evaluated (1.9%) had a patient co-author

#### RESEARCH

Shared decision making in patients with low risk chest pain: prospective randomized pragmatic trial

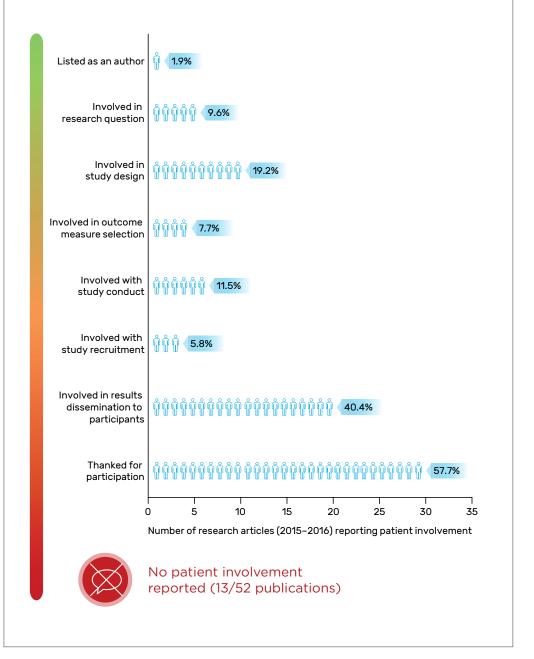
Erik P Hess, 1.2.3 Judd E Hollander, 4 Jason T Schaffer, 5 jeffrey A Kline, 5 Carlow A Torres, 6 Deborah B Diercks, Russel Jones, Kelly P Owen, Zachary F Meisel, Michel Demers, Annie Leblanc, Milay D Shah,11 Jonathan Inselman,3 Jeph Herrin,13 Ana Castaneda-Guarderas,1.2.14 Victor M Montori<sup>2.15</sup>

#### Patient involvement

The patient and caregiver advisers were engaged at the highest level possible - partner - and included as co-investigators on the application for funding, members of the investigative steering committee, and assisted in interpretation of the data, review of the final manuscript for important intellectual content, and approval of the final manuscript for submission, thus meeting the criteria for authorship and inclusion in the manuscript as co-authors

Is this the ideal?

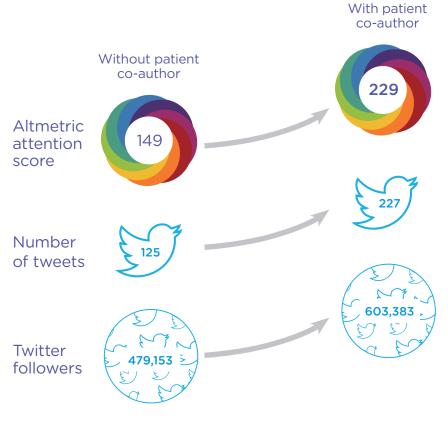
### A wide range of patient involvement types were reported



### Additional Analyses

### Could patient authorship enhance publication metrics?

 A post-hoc analysis showed that social media metrics were higher for the 1 article with a patient co-author compared with the 51 articles without a patient co-author



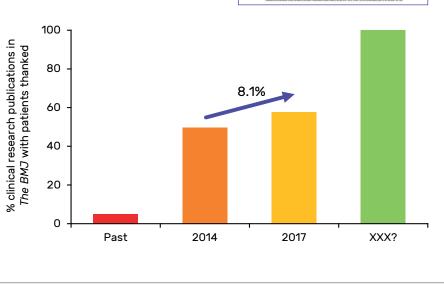
 Although this sample is limited, our results support further investigation of the impact of patient authorship on the reach of publications

### 'Patient Involvement' reporting rates have increased, but scope remains for improvement

 Compared with our earlier research,2 the number of articles including a thank you to patients has increased, but:

Is <10% increase in</li> 3 years sufficient? When can we expect to achieve ~ 100%... and in journals beyond *The BMJ*?





### Limitations

- · This is an analysis of a single journal, which has mandated reporting of patient involvement in publications; we anticipate that reporting in other journals could be less frequent
- This study evaluates patient involvement that was reported rather than submitted to *The BMJ*. Without peer review at *The BMJ*, reporting may have been less frequent
- The low frequency of articles with patient authorship limits impact analysis, including exploratory assessment of publication metrics

### Conclusions and Implications

- Patient involvement in publications remains limited and highly variable, even for journals such as The BMJ that actively welcome it
- Further evidence is needed on the potential benefits and harms of patient involvement in publications, to support the ongoing debate and inform best practice
- Publication professionals need guidance and practical tools to enable them to confidently engage patients as publication partners
- As publication <u>professionals</u>, what are we doing to involve patients as essential publication partners?
- How are we collaborating with patient advocacy organisations?

### References

- 1. INVOLVE what is public involvement in research? Available from: http://www.invo.org.uk/ find-out-more/what-is-public-involvement-in-research-2/ [Accessed January 2018].
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