

# 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



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- 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

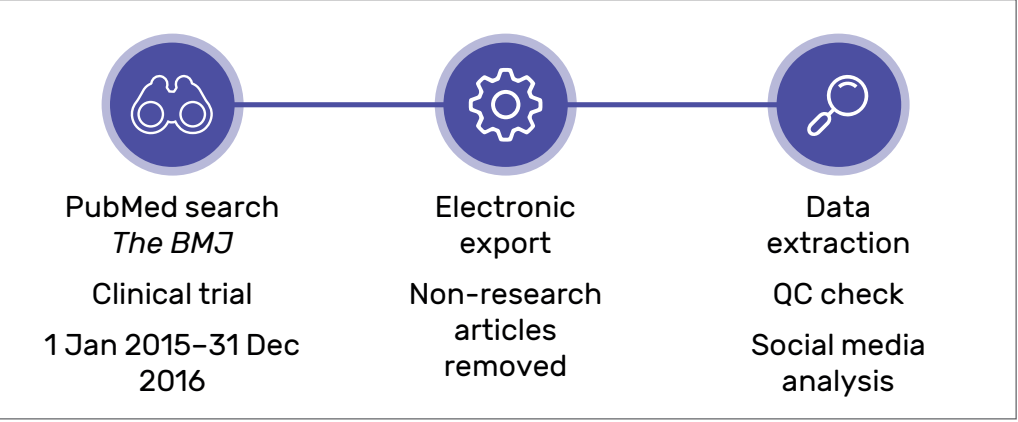


Patient involvement (ie, with or by patients) differs from more passive forms of patient participation or engagement (ie, to, about or for patients)<sup>1</sup>

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

### Methods

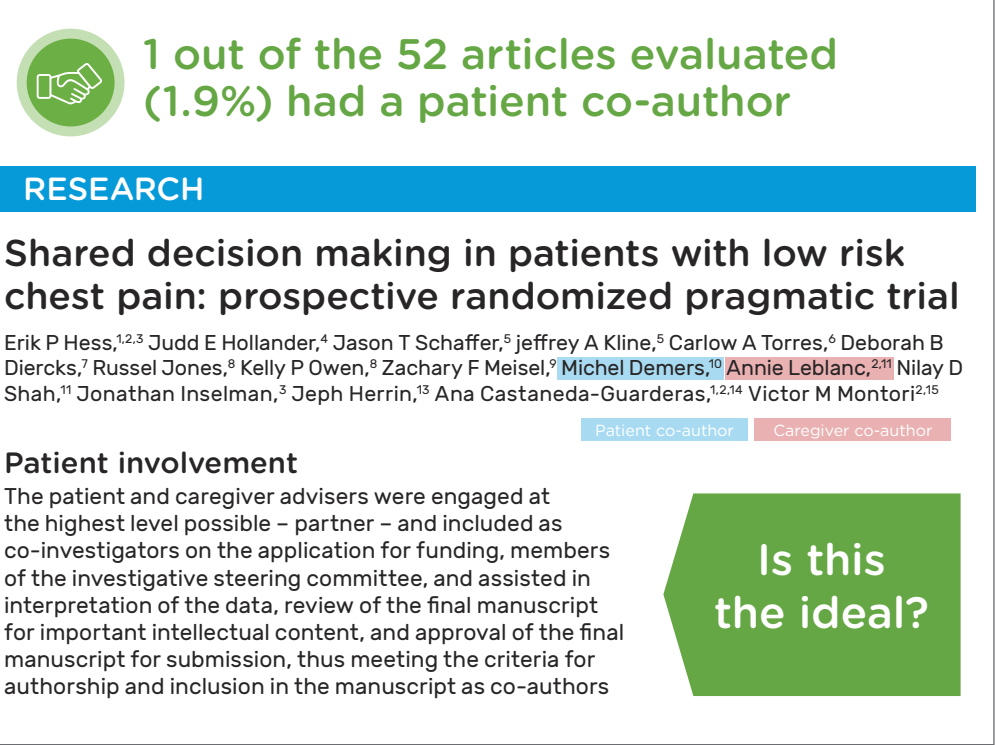
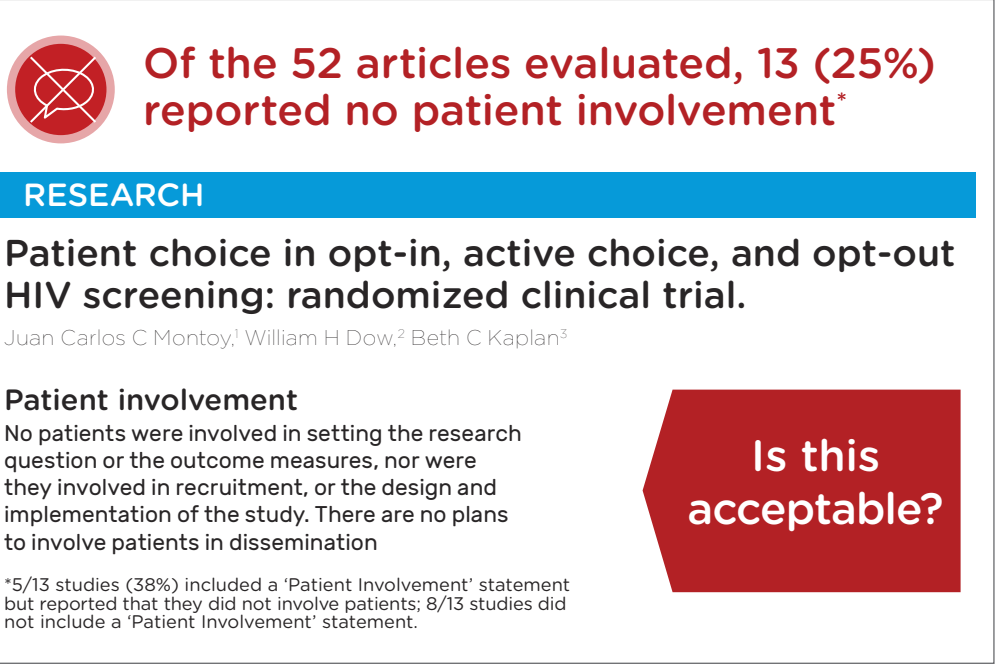
- This case study of *The BMJ* is part of a broader Envision-led ‘patient involvement in publications’ research programme
- Research articles from *The BMJ* were retrieved, exported and analysed
- The type and extent of patient involvement was assessed for each article



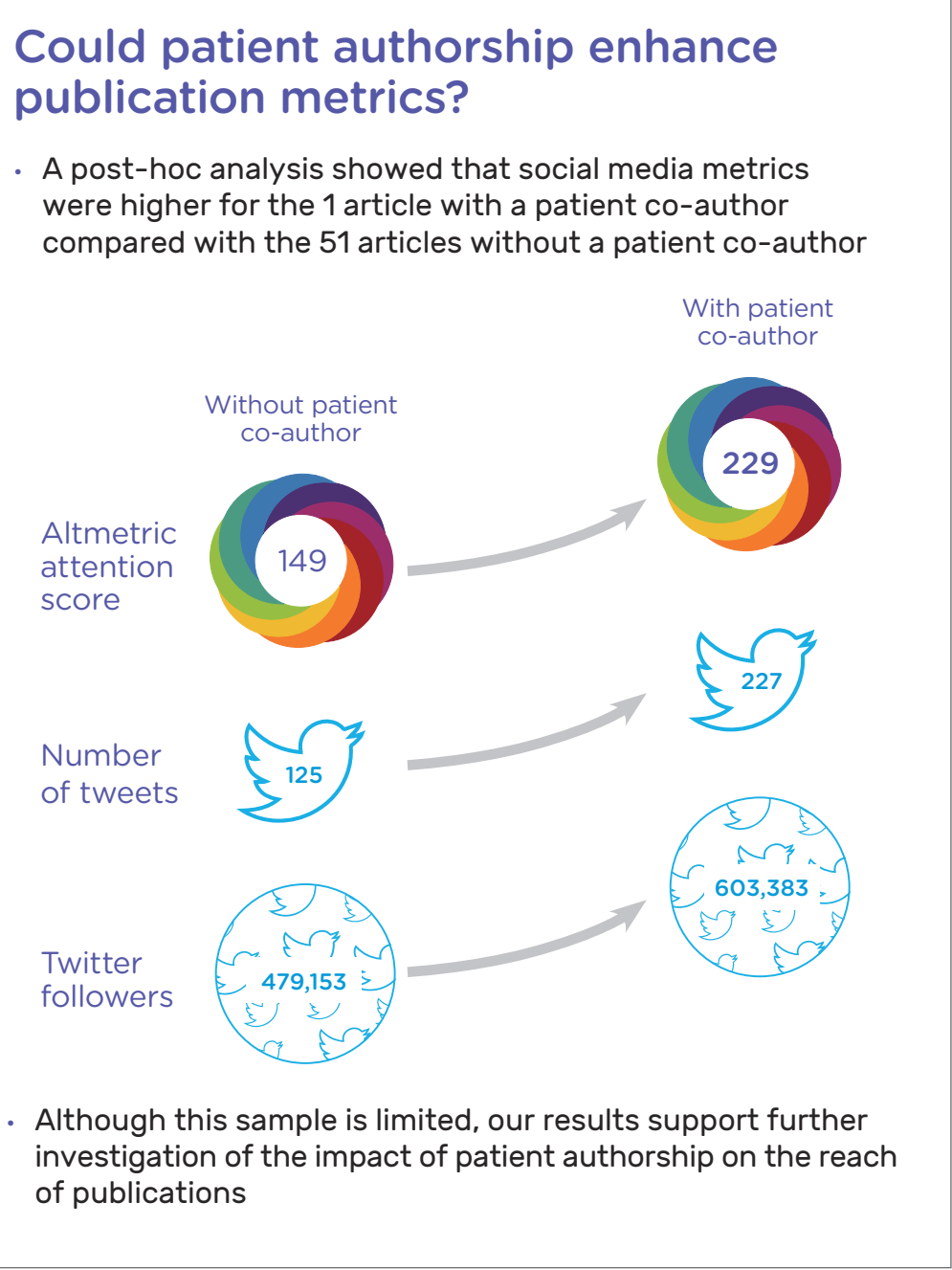
### Acknowledgements and Disclosures

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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 administrative expenses

### Results



### Additional Analyses



### 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

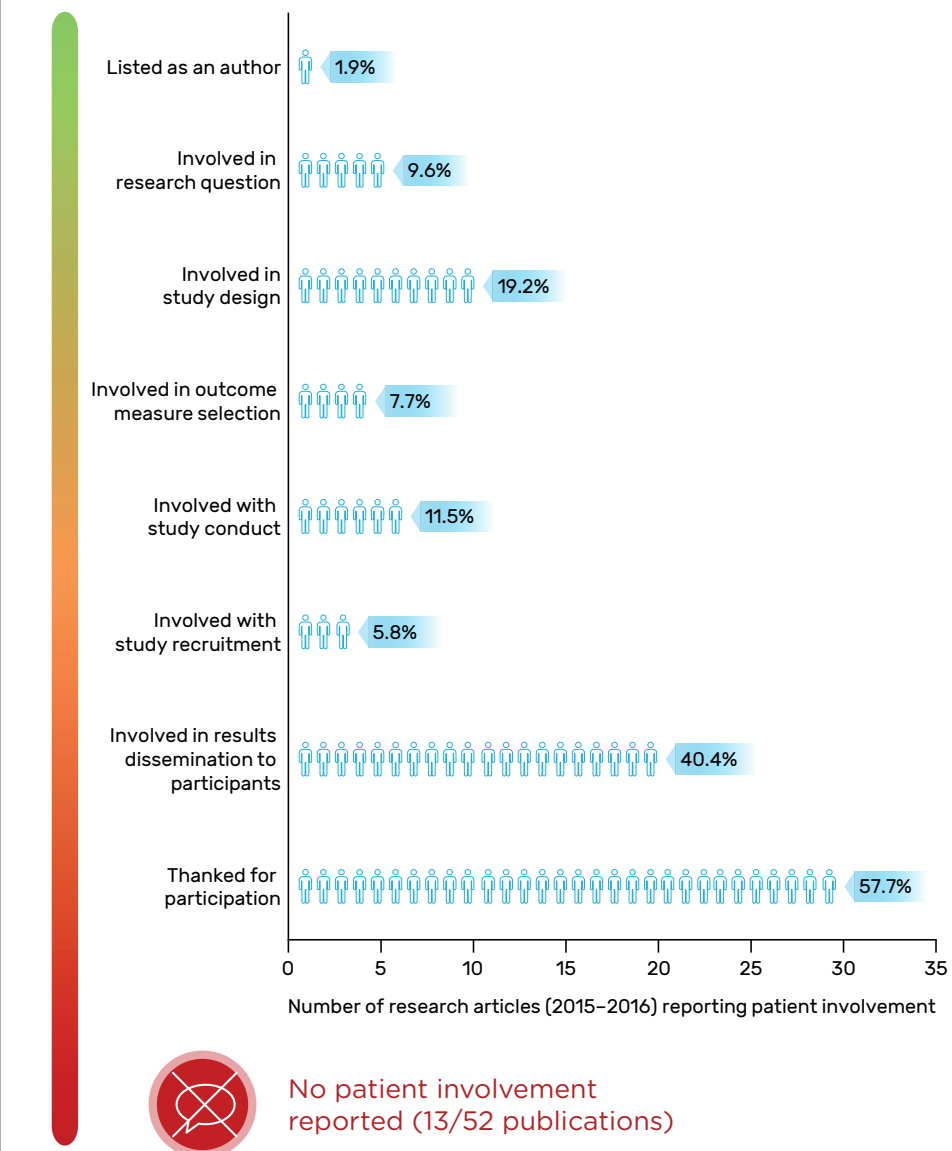
- Patient involvement in publications remains limited and highly variable, even for journals such as *The BMJ* that actively welcome it
  - Further evidence is needed on the potential benefits and harms of patient involvement in publications, to support the ongoing debate and inform best practice
  - Publication professionals need guidance and practical tools to enable them to confidently engage patients as publication partners
- As publication professionals, 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].

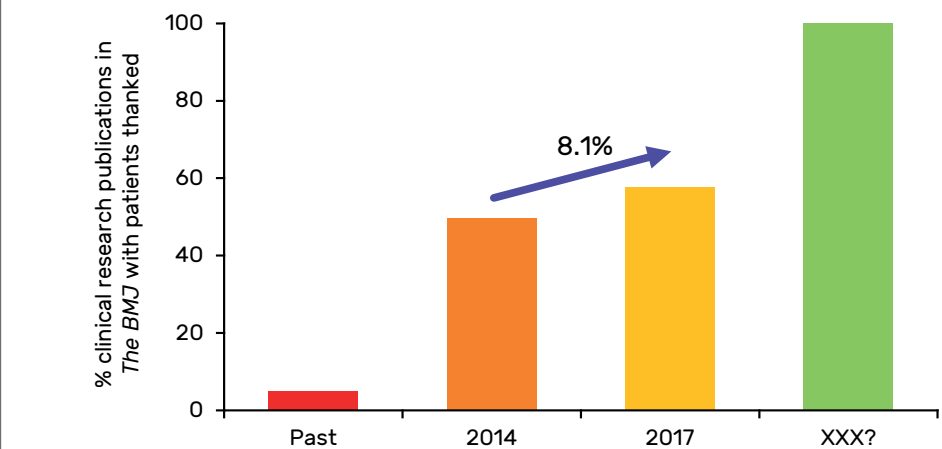
2. Bhatia R, Anthony B. Clinical trials: do the patients get the thanks they deserve? *Curr Med Res Opin*. 2015;31(Suppl 1):S19.

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



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

- Compared with our earlier research,<sup>2</sup> the number of articles including a thank you to patients has increased, but:
  - Is <10% increase in 3 years sufficient?
  - When can we expect to achieve ~ 100%... and in journals beyond *The BMJ*?



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