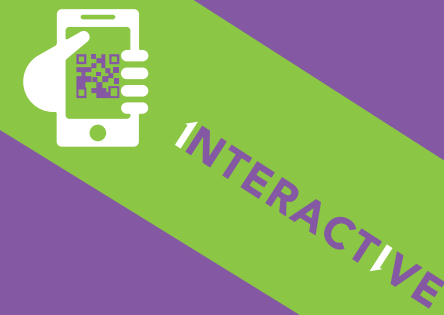


# Transparency and Completeness in the Reporting of Stakeholder Involvement in the Development and Reporting of Research Reporting Guidelines

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## Abstract

**Objective:** The Guidance for Developers of Health Research Reporting Guidelines recommend multidisciplinary stakeholder involvement, transparent and complete reporting, and updating guidelines based on feedback. Developers are accountable for stakeholder engagement, but how broad and meaningful is such engagement? Our objective was to provide empirical feedback to developers by investigating (1) the involvement of those ultimately affected by guidelines (eg, patients and carers) and regular end users of guidelines (eg, publication professionals), and (2) the transparency and completeness of reporting stakeholder involvement.

**Design:** For this prospective study, conducted from September 2016 to January 2017, we included every reporting guideline for the main study types, as listed on the EQUATOR Network website. We pilot-tested a standardized data collection spreadsheet to extract data from the corresponding guideline publications. We quantified patient, carer, and publication professional involvement and used statisticians (listed as stakeholders in the Guidelines) as a control group. We assessed reporting transparency and completeness using the AGREE Reporting Checklist for documenting stakeholder involvement. For qualitative insights, we interviewed leaders from nonprofit, international, patient advocacy (International Alliance of Patients' Organizations [IAPO]) and publication professional (Global Alliance of Publication Professionals [GAPP]) organizations.

**Results:** Of the 33 guideline publications, the mean (SD) number of authors was 9 (SD 5.7, min 3, max 30) (median, 7; IQR, 5-11) and the mean (SD) number of working group members was 45 (SD 38.4, min 5, max 147) (median, 30; IQR, 23-43). Statisticians were authors for 24% (8/33) of the publications and were working group members for 15% (5/33). Patients, carers, and publication professionals were rarely identified, either as authors (0, 0, and 0, respectively) or working group members (0, 1 [3%], and 0, respectively). Reporting stakeholder involvement was deficient (eg, for statistician involvement, only 25% of publications met AGREE Recommendations). Leaders from IAPO and GAPP were not aware of having been invited to participate in developing guidelines, but thought that their stakeholders could provide unique and important insights. They encourage guideline developers to contact them to facilitate meaningful involvement.

**Conclusions:** Guideline developers have rarely involved stakeholders affected by guidelines (patients, carers) or those regularly using guidelines (publication professionals) in the development process. The involvement of these key stakeholders could enhance the credibility, dissemination, and use of guidelines. If patients, carers, and publication professionals were represented by other stakeholders (which is not ideal given potential conflicts of interest), this was not documented; readers do not know who represented whom. The transparency and completeness of reporting of stakeholder involvement should be improved.

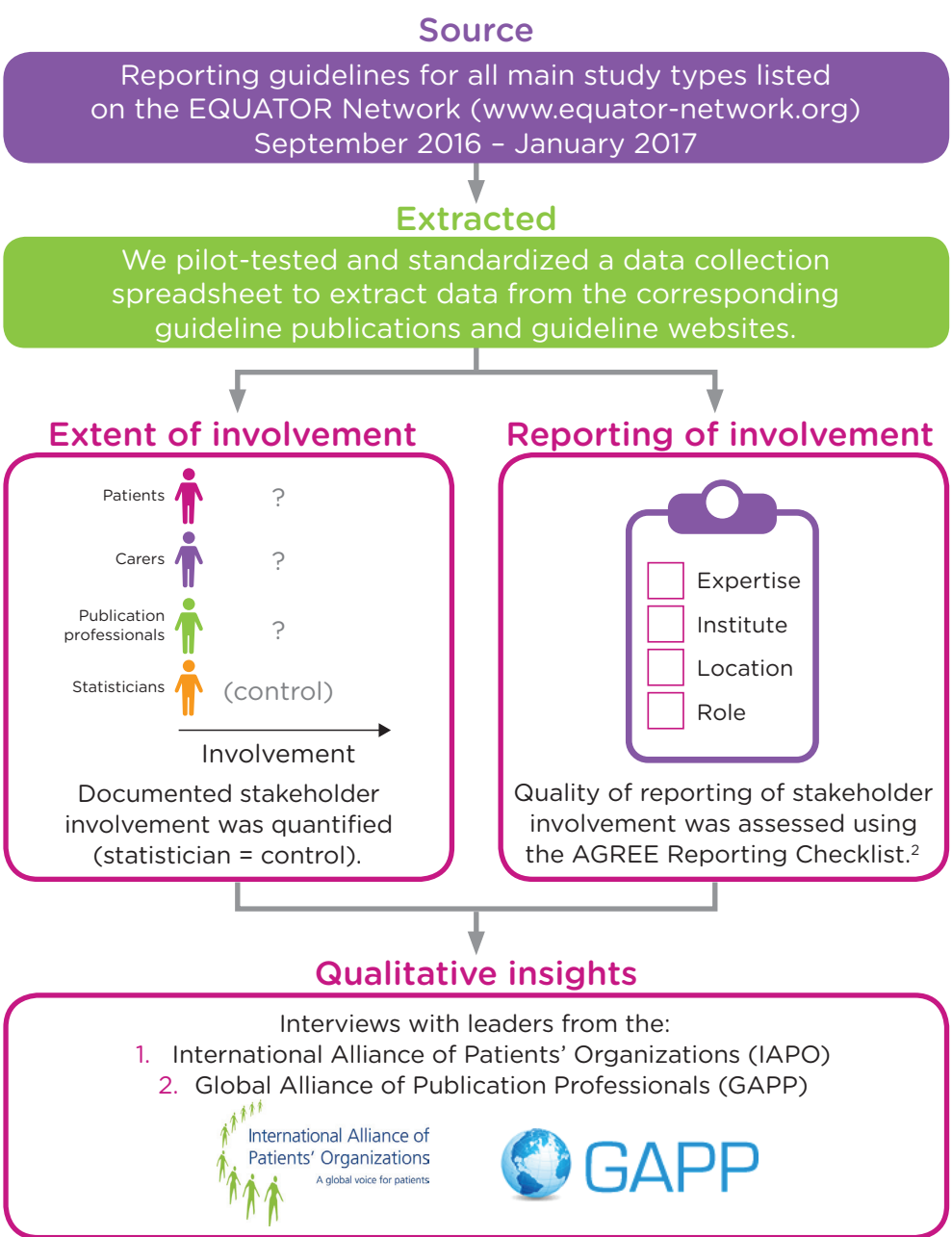
## Background

**“Most reporting guidelines have been developed by an international multidisciplinary group... participants will usually include statisticians, epidemiologists, methodologists, content experts, journal editors, and perhaps consumer representatives.”**

Moher et al. *PLoS Med.* 2010

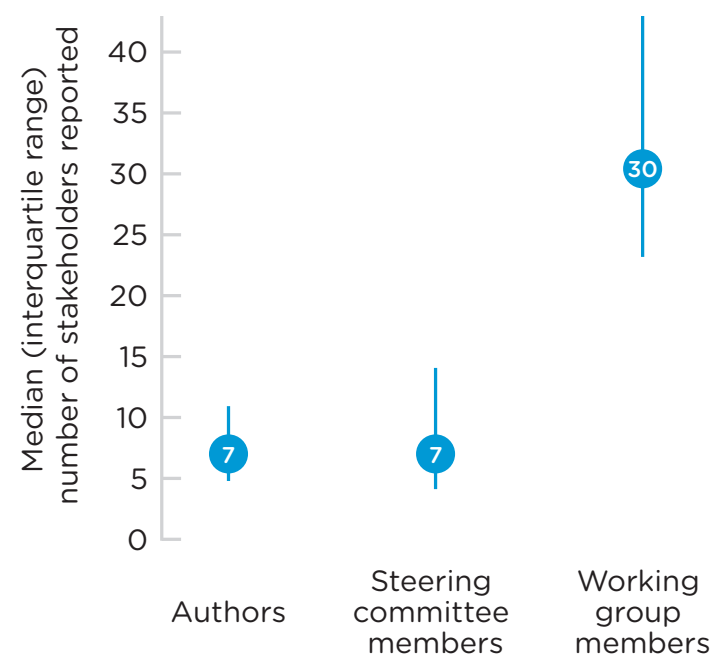
- Developers of research reporting guidelines should involve multidisciplinary stakeholders in the development process and should clearly and transparently document stakeholder involvement.<sup>1,2</sup>
- Patients and carers are stakeholders who are affected by reporting guidelines.<sup>3</sup>
- Publication professionals are stakeholders who raise awareness of and adhere to reporting guidelines.<sup>4</sup>
- Purpose:** To investigate the involvement of patients, carers, and publication professionals in developing research reporting guidelines and the quality of reporting their involvement.

## Methods

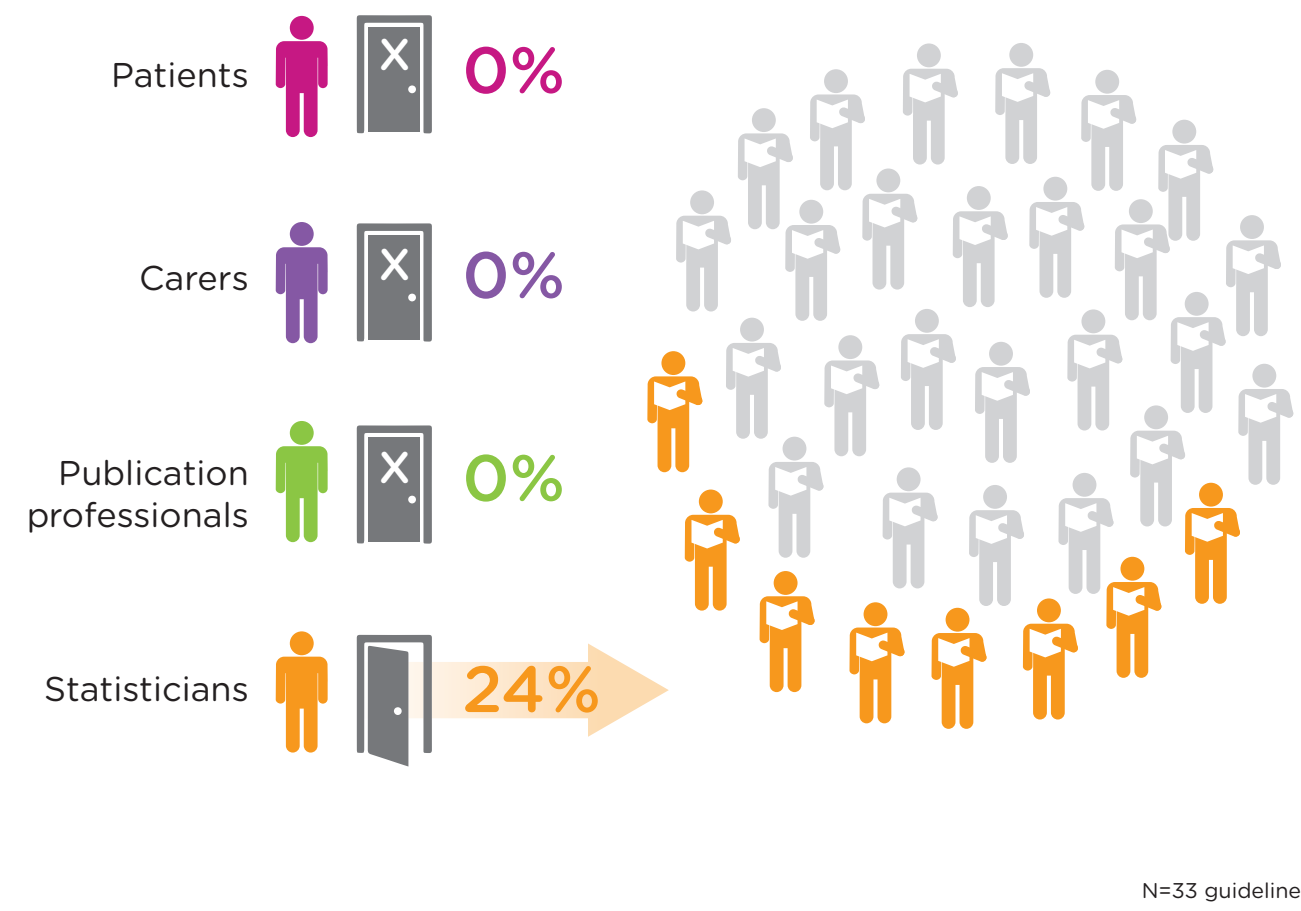


## Results

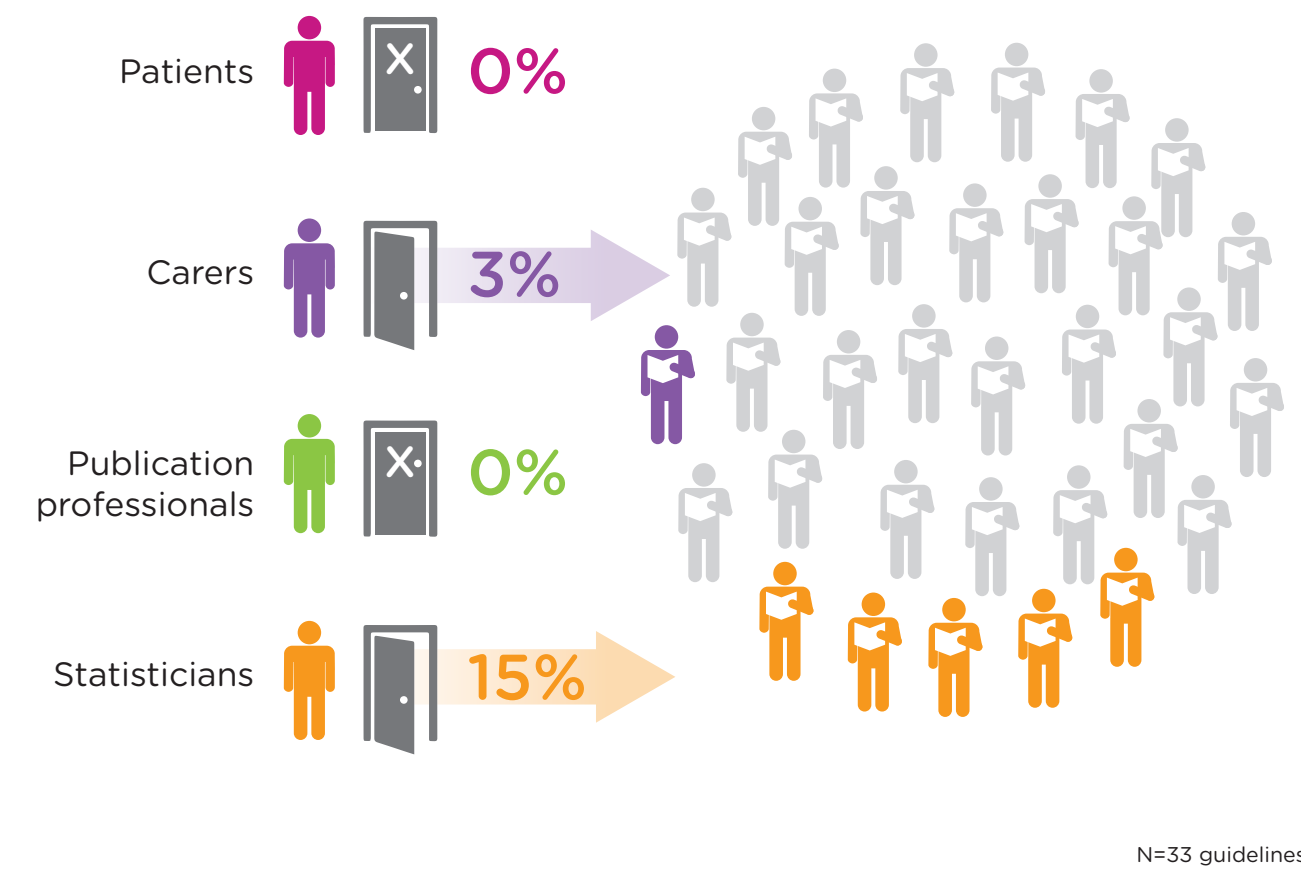
There were 33 guideline publications; most had multiple stakeholders



Patients, carers, and publication professionals were not reported as authors of reporting guidelines



Patients, carers, and publication professionals were rarely reported as members of working groups or steering committees



## Reporting of stakeholder involvement was deficient

- All stakeholders**
- Author information consistent with the AGREE Recommendations was evident for only 9% (3/33) of reporting guidelines.
  - Items most commonly not reported were expertise and role.



- Carers**
- Carer representative information consistent with the AGREE Recommendations was not evident.
  - One carer representative was named as a working group member on one guideline.



- Statisticians (control)**
- Statistician information consistent with the AGREE Recommendations was evident for only 25% (7/28) of reporting guidelines.
  - Statisticians were potentially identifiable\* as authors of 28 reporting guidelines.

\*Inferred from authors' institutes when reporting was not complete or transparent



- Publication professionals**
- Publication professional information consistent with the AGREE Recommendations was not evident.
  - One publication professional was potentially identifiable\* as an author or other stakeholder on four reporting guidelines.

\*Inferred from our personal knowledge of the publication professional's company name, as reporting was neither complete nor transparent



Leaders from organizations representing patients, carers, and publication professionals:

- Could not recall ever having been invited to help develop research reporting guidelines.
- Believed their members could offer unique insights to enhance reporting guidelines.
- Welcomed invitations to contribute to future guideline development.
  - These views were also endorsed by leaders from the American Medical Writers Association, the European Medical Writers Association, and the International Society for Medical Publication Professionals during the development of the Joint Position Statement on the Role of Professional Medical Writers (released January 17, 2017).



## Conclusions and implications

**“It is important to seek feedback and criticism from all stakeholders regarding the reporting guideline [...]”**

Moher et al. *PLoS Med.* 2010

### Conclusions

- Patients, carers, and publication professionals have rarely been involved in developing research reporting guidelines.
- Leaders of organizations representing these stakeholders welcome the opportunity for meaningful engagement with guideline developers.
- The transparency and completeness of reporting stakeholder involvement in guideline development should be improved.

### Implications

- Meaningful engagement of patients, carers, and publication professionals could enhance guideline credibility, dissemination, and use.
- What rationale is there to exclude these stakeholders from future guideline development when:
  - Patients and carers are becoming more involved in other areas of research<sup>3</sup> and the peer-reviewed literature<sup>5</sup>?
  - Publication professionals can enhance the quality<sup>6,7</sup> and integrity<sup>8</sup> of reports, and can have stronger knowledge of guidelines than authors<sup>4,9</sup>?

**“...it is also a challenge to get the patient voice in the peer-reviewed literature.”**

Alan Weil, Editor-in-Chief, *Health Affairs* (Patients' and Consumers' Use of Evidence)



## Limitations

- Most reporting guidelines were developed before the availability of the AGREE Reporting Checklist.<sup>2</sup>
- Potential involvement of statisticians and publication professionals had to be inferred because of incomplete and nontransparent reporting.

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