PATIENT FOCUSED
MEDICINES DEVELOPMENT

BoGP
2nd edition

The PFMD
Book of Good Practices

2nd edition I 2019

@The_Synergist
@PFMDwithPatient

#PEQualityGuidance
#PEQualityCriteria

www.PatientFocusedMedicine.org
October 2019

Message from PFMD

Dear reader,

Patient Focused Medicines Development (PFMD) was established in 2015 out of a need that was expressed by many stakeholders in various roundtable discussions. This need was eventually translated into a dedicated organisation that aims to drive systematic patient engagement and involvement forward in the research, development and delivery of medicines.

Today we are very proud that you are reading the Book of Good Practices, as this too was born from a need expressed by many stakeholders. As patient engagement is becoming a norm instead of an exception or a one-off practice, there was a need to share knowledge about

- how other organisations have involved patients in their activities,
- what can be considered as high quality patient engagement, and
- how can different organisations reach the level of patient engagement that is both meaningful to patients but also to the research and development processes so that the output or outcomes will serve the end users better.

The PFMD Patient Engagement Quality Guidance, that was launched in 2018, introduces 7 Quality Criteria for good patient engagement that can be used to plan patient engagement activities, or to assess the level of patient engagement in ongoing or completed activities. Where the Patient Engagement Quality Guidance serves as a tool to help you to do patient engagement, the Book of Good Practices serves as a set of real life cases from a variety of organisations, that illustrate in detail how they have done it. These cases have been chosen from a big pool, assessed by an external group of reviewers and chosen to be included because they exemplify exceptionally well the 7 Quality Criteria. For detailed descriptions of the criteria and explanations for icons used, check the annexes at the end of the book.

The Book of Good Practices will be growing year by year with new cases. To contribute to this work, you can also submit your patient engagement experiences to the PFMD team.

We hope this book will inspire and help you in your patient engagement journey. We encourage you to explore all the tools at your disposal within PFMD and Synapse - the mapping and networking tool, and connect with us for more guidance if needed.

We'd like to extend our thanks to all the reviewers, all case owners and all readers for making the Book of Good Practices possible.

PFMD Team

PATIENT FOCUSED MEDICINES DEVELOPMENT

ENVISION PHARMA GROUP

Patient involvement in preparing clinical research peer-reviewed publications or results summaries: A systematic review

Organisation: Envision Pharma

The PFMD
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THE BOOK OF GOOD PRACTICE INITIATIVES ARE ALSO AVAILABLE IN SYNAPSE.

TO DOWNLOAD THE FULL BOGP, PLEASE VISIT:
https://involvement-mapping.patientfocusedmedicine.org/book-of-good-practices

PATIENT FOCUSED MEDICINES DEVELOPMENT

ENVISION PHARMA GROUP

Patient involvement in preparing clinical research peer-reviewed publications or results summaries: A systematic review

Organisation:
Envision Pharma

Basic Information

Background and need for project

Patient involvement is being encouraged throughout the development lifecycle of new medicines and devices. Many stakeholders (eg, patients, carers, regulators, payers, drug and device companies) have welcomed patient involvement as an important and fundamental change in the development lifecycle, and have promoted the potential benefits that meaningful, transparent, and ethical interactions with patients could bring. As with any change, however, research should be conducted to ensure the potential benefits and harms of patient involvement are understood, and that evidence-based best practices can be identified.

Compared with research on patient involvement in the clinical trial process, there appears to have been relatively limited research on patient involvement in peer-reviewed publication process. Publications can affect patient care and we and others have shown that patients are engaging with the peer-reviewed literature. Consistent with this interest from patients, medical journals are striving to facilitate greater patient involvement in the peer-reviewed publication ecosystem (e.g. as authors, peer-reviewers, readers). The extent of published evidence on patient involvement in peer-reviewed publications, however, is not known.

In addition to sharing clinical trial results through the peer-reviewed publications, results can also be

shared through clinical trial results summaries. The forthcoming regulatory requirement in Europe to provide plain language clinical trial results summaries has driven strong interest in this method of results sharing. The extent of published evidence on patient involvement in clinical trial results summaries, however, is not known.

This systematic literature review is directed toward audiences who want to know the size and quality of the evidence base that exists to guide patient involvement in peer-reviewed publications and clinical trial results summaries.

Objectives and anticipated benefit/outcomes

Our primary objective is to quantify the number of peer-reviewed publications that investigated the effect of patient involvement on preparing peer-reviewed publications.

Our secondary objectives are to:

a. Quantify the number of peer-reviewed publications that investigated the effect of patient involvement on preparing regulatory-standard clinical trial results summaries.
b. Evaluate the quality of the evidence reported in the eligible publications.
c. Describe the number and the background (e.g. patient experts, clinical trial participants, patient advocacy group members) of patients contributing to the preparation of the publications or results summaries.
d. Categorise the type of patient involvement (e.g. as authors, as non-author contributors).
e. Describe the number and type of patient involvement outcomes assessed (e.g. benefits, harms, best practice recommendations, other).

By conducting this world-first systematic review, we will be able to raise awareness of the size and quality of the evidence base that exists to guide best practice for involving patients in preparing peer-reviewed publications and clinical research results summaries. This robust review will allow us to share recommendations for maximising the benefits and minimising the harms of involving patients in publications and results summaries.

Methodology

This systematic review was registered in the PROSPERO database (PROSPERO 2018 CRD42018084452), conducted according to a pre-specified protocol, and will be reported in compliance with best-practice reporting guidelines for systematic reviews (PRISMA guidelines) and research involving patients (GRIPP2 guidelines). To minimise the risk of research waste, we searched (5 June 2017) the PROSPERO database to ensure we were not duplicating a planned or ongoing systematic review. We also registered our review on SYNAPSE, the Patient Focused Medicines Development (PFMD) repository for patient engagement initiatives (https://involvement-mapping.patientfocusedmedicine.org/initiatives/first-systematic-literature-review-planned-and-conducted-with-patient-experts-on-patient-involvement-in-preparing-clinical-trial).

Within this study, 'patient' was defined in broad terms, based on an existing definition [PFMD/National Health Council, 2017] and input from our patient partners.

For this research, 'patient' refers to "people having or at risk of having medical condition(s), whether or not they currently receive medicines or vaccines to prevent or treat a disease" as well as "the family and those voluntarily caring for those with the medical condition(s), patient advocates, and patient groups."

Further details on the methodology can be found on the PROSPERO record.

Stakeholders involved

To co-create this systematic review, our research and publication team involved multiple stakeholders as equal partners. Stakeholders represented patients, publication professionals, academic researchers, medical journal editors, and medical affairs staff.

Which phases of research, medicines development, lifecycle or disease management does your PE project cover?

- **Research and discovery phase**
- **Pre-clinical phase**
- **Clinical study phase 1-3**
- **Health technology assessment**
- **Regulatory review and approval or registration phase**
- **Post-registration/ -launch activities**
- **Other**

Other: Peer-reviewed publications are generated throughout the medicines development lifecycle; they are used in submissions to regulatory and health technology assessment organisations. Clinical research results summaries are generated throughout clinical trial phases.

Which stakeholders does this initiative involve?

Patients and carers

Policymakers

Health technology assessment organisations

Research funders

Patient advocates, patient organisations and associations

Regulators

Pharmaceutical companies or industry

Other

Healthcare professionals

Payers

Researchers

Other: Medical journal editor; Medical affairs service provider

The quality of patient engagement

1. Shared purpose

What did you do to achieve this criterion?

The shared purpose of this project was agreed to:

1. Verbally - at the author candidate calls and during the author kick-off meeting
2. In writing – every author signed an official Authorship Agreement that outlined the shared purpose of the project.

What is your stated "shared purpose"?

To conduct the first systematic literature review on patient involvement in preparing clinical research peer-reviewed publications or results summaries.

How have you confirmed with all stakeholders that your purpose is understood, that contributions have influenced the original plans and that disagreements have been addressed?

All stakeholders had to sign the Authorship Agreement, which was written in plain language to enhance understanding by all authors – patient authors and non-patient authors. By signing the Agreement, stakeholders had to confirm they understood the purpose of the project, the expected contributions they would need to make, and what rules would need to be followed to ensure the quality of the project would lead to a successful outcome.

Opportunities to influence the original plan were provided during development of the protocol, at authorship meetings, and during the development of presentations and the publication of the results.

Have you reviewed the shared purpose and its understanding among stakeholders?

Yes, at multiple time points.

- Before the project started (e.g. during the author candidate calls and author kick-off meeting).
- During the project (e.g. at authorship calls).
- After the project (e.g. the Patient Authorship Experience Tool); this tool will be completed by all authors at the end of the project. We developed this tool based on the PFMD Patient Engagement Quality Guidance Tool and incorporated patient and non-patient author feedback as part of a co-creation process.

2. Respect and accessibility

How have you addressed respect and accessibility in this project?

To help ensure respect and accessibility in this publication project, we:

- Prepared a plain language Authorship Agreement
- Prepared a plain language summary of the Good Publication Practice 3 guidelines

- Clarified payment considerations in the Authorship Agreement
- Provided practical ways to meet as authors and gain feedback from authors (e.g. set up webinars, provided instructions for joining, setting – where possible – 'generous deadlines' for author review and feedback cycles)
- Providing electronic copies of documents to all authors
- Ensured all authors were aware of the rules of conduct when working together as co-authors on a publication (e.g. via the Authorship Agreement, GPP3 plain language summary)

How have you assessed with stakeholders that they acknowledge mutual respect, and that access to engagement has been optimised?

At authorship meetings, we proactively asked patient authors (and non-patient authors) for feedback and, if they were unable to attend a meeting, they were invited to share their feedback via other means (e.g. a 1-to-1 call, via email).

Where possible, efforts were also made to meet and engage with patient authors face to face (e.g. at conferences) to help build rapport and respect.

Testament to the respect shown to patient authors, they were also invited to present at conferences (i.e. demonstrating respect for the unique and valuable insights patient authors could bring, not just to this project, but to other projects).

The Patient Authorship Experience Tool that we developed for this project (to be completed by patient and non-patient authors on project completion) specifically asks about respect and accessibility.

3. Representativeness of stakeholders

A number of authors on the publication are employees of Envision Pharma Group. Patient diversity is one of the core principles (see below) that Envision employees must respect when partnering with patients, as has been done in this project.

Our Principles for Partnering with Patients*

4. Substantial involvement

We will seek to involve patients substantially (eg, early, often, usefull). We will avoid tokenistic involvement.

3. Ethical involvement

We will build trust with patients by complying with relevant guidelines and regulations.

2. Patient diversity

We recognise that patients differ (eg, in health literacy, culture, demography) and that our partnerships should reflect that diversity.

1. Respectful partnership

We respect the unique and valuable insights of our patient partners and their right to contribute to, and benefit from, robust and relevant evidence. We respect our pharmaceutical partners who strive to enhance patient outcomes. We are a trusted partner to patients and clients.

5. Leveraging technology

We will develop and use Envision's technology solutions to promote, document, and track effective and ethical involvement.

6. Co-learning

We will build trust with patients by complying with relevant guidelines and regulations.

7. Co-creating

We will work WITH patients to create content and solutions that are trusted and valued.

8. Evidence-based enhancement

We will contribute to and support evidence-based best practices to enhance patient involvement.

We involved authors from Europe, North America, and the Asia Pacific region. Our authorship team comprised female and male authors, with a range of ages and ethnic backgrounds. All authors were well educated.

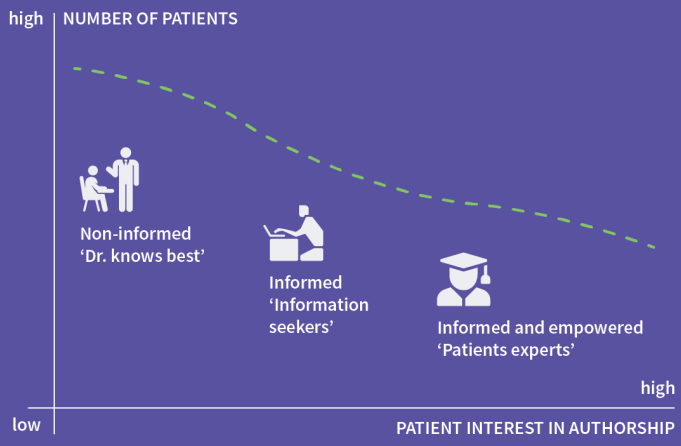
The patient authors we sought to partner with had to be representative of the patients most likely to be interested in the topic of this systematic review i.e. informed and empowered patients who may be interested in authoring peer-reviewed publications or clinical research results summaries (see schematic below).

We recognise that these patients, who are leaders in their field and recognised for their expertise in empowering patients, do not represent the whole spectrum of patients. However, the patient authors on this project do represent the patients most likely to be interested in and benefit from this project. In the years to come, as more patients become informed and empowered partners in the publication ecosystem, a broader outreach strategy could be used.

Patients as authors
Patient diversity and representativeness

Diversity: Which patients may be most interested in authoring peer-reviewed publications?
Representativeness: Are there patients represented on your publication authorship team?

Consensus is lacking in terms of a model that captures patients diversity. Models such as Amstein's Ladder of Citizen Participation or the IAP2 Public Participation Spectrum, have been criticised. No model has been co-created with patients to capture patients diversity in the publication ecosystem.



How did you check that the representation of stakeholders in your project supported achieving project outcomes?

The Patient Authorship Experience Tool that we developed for this project (to be completed by patient and non-patient authors on project completion) specifically asks about the representation of stakeholders.

4. Roles and responsibilities

What did you do to achieve clarity and communication as well as regular check-points on roles and responsibilities?

Before the project

The roles and responsibilities of all authors (patient and non-patient authors) were outlined in written

documents before the project started:

1. Written Authorship Agreement
2. Plain language summary of Good Publication Practice guidelines

During the project

We also had regular checkpoints (e.g. author calls) during the project so that responsibilities (e.g. providing feedback on documents) could be clarified and reinforced. Communication was encouraged during the calls and at any time between calls (eg, 1-to-1 calls, emails) if any author required further information / explanation.

After the project

The Patient Authorship Experience Tool that we developed for this project (to be completed by patient and non-patient authors on project completion) specifically asks about roles and responsibilities, and transparency in communication and documentation.

How did you check that all participants understood what their roles and responsibilities are, and what is expected of them?

All authors (patient and non-patient authors) had to review and sign the Authorship Agreement to document that they understood their roles and responsibilities.

At what frequency have you checked this in?

As noted above, checks on understanding roles and responsibilities and what was expected of all authors (patient and non-patient authors) were built into this project ie, before, during, and after the project.

5. Capacity and capability for engagement

What did you do to support building the required capacity and capability for engagement?

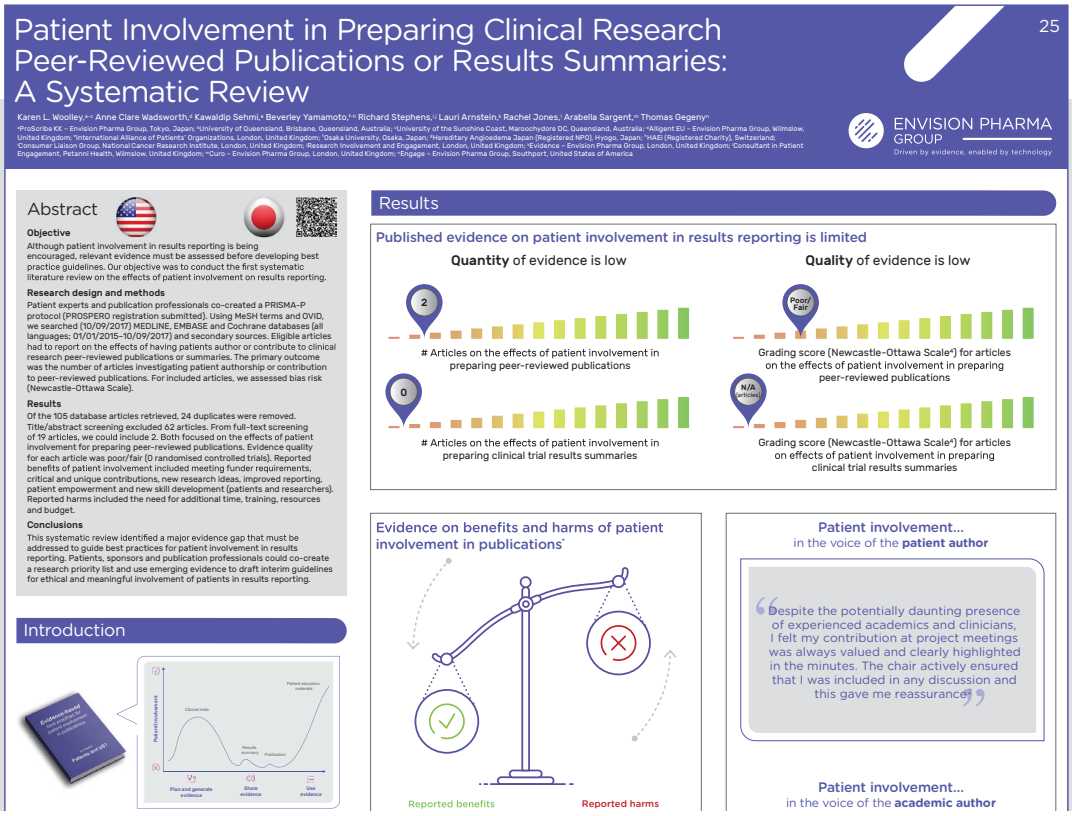
All authors on this project had to have the capacity and the capability to meet authorship criteria. We had to select author candidates who we believed would:

- Dedicate the time required to participate as an author and
- Have relevant expertise to make unique and valuable contributions as authors

Meeting authorship criteria is a key principle of Good Publication Practice and is a requirement to publish in respected peer-reviewed medical journals. We had to make sure, before starting this project, that the patient authors (and indeed non-patient authors) could meet the authorship criteria. It is unethical to have 'guest authors' (i.e. individuals who are named as authors, but do not have meet authorship criteria).

The capacity and capability requirements for this project are reflected in the authorship criteria. These criteria were outlined for all authors in the Authorship Agreement and in the plain language summary of the Good Publication Practice guidelines.

To help build additional capabilities among the authors, we provided examples and information on some of the recent innovations in publishing (e.g. QR codes to video clips, translated language audio/print summary; infographics; protocol registration repositories). We included a number of these innovative features in a research poster presentation (extract on the next page) that we co-created with patient authors on this project.



How did you check that all stakeholders have what they need to contribute effectively and meaningfully?

During author calls and informal discussions (before and during the project) we checked that all stakeholders had the time and information needed to make substantial contributions as authors.

The Patient Authorship Experience Tool that we developed for this project (to be completed by patient and non-patient authors on project completion) specifically asks about capacity and capability for engagement.

6. Transparency in communication and documentation

What did you do to achieve and implement processes for timely communication and updated documentation throughout the project?

- To facilitate timely delivery and storage, electronic copies of materials for this project (e.g. outlines, drafts, meeting agendas and minutes) were circulated to all authors.
- Authorship meetings were held several times a year and contact with authors was made between meetings, as required.
- A dedicated team was identified to schedule author meetings, prepare agendas, prepare and circulate the minutes.
- A dedicated and secure file directory was established to store all documents related to this project.
- A publication plan was prepared that highlighted timelines and potential conferences and journals to present and publish the results from this project. Patient authors were specifically asked to nominate conferences most relevant to their stakeholder groups where they might want to present the results.

- Whenever possible, 'generous deadlines' were provided and key dates were clearly highlighted in meeting minutes and cover emails.
- Given the involvement of professional medical writers in this project and the commitment to plain language principles, information was communicated clearly and concisely.
- While some authors were bilingual, all authors were comfortable communicating in English so all communication was in English.
- In terms of complying with international guidelines for external communications, all authors were aware that peer-reviewed journals require disclosure of author names and any financial or nonfinancial competing interests. We recognise that this requirement may deter some patients from being involved as authors in publications, but full disclosure is typically required.

How did you validate that your communication and documentation plans were useful and appropriately implemented?

The Patient Authorship Experience Tool that we developed for this project specifically asks about transparency in communication and documentation.

7. Continuity and sustainability

What did you do to achieve this criterion?

To ensure continuity of the project and relationships from the beginning to the end, a publication plan was developed. This plan identified key milestones for presenting and publishing our research and these 'external communication points' helped build a sense of teamwork and a focus on delivering high-quality output.

To help share the learnings from this project, we have committed to presenting and publishing our research.

We have included a specific section in the publication of this project of 'lessons learned' that we hope will help other researchers as they conduct further studies on patient involvement in publications.

We are also consulting with our patient authors as to their interest in presenting at conferences, after this project concludes, to help inspire (if not challenge) research funders and researchers to involve patients as authors.

In terms of sustainability, we are also striving to provide practical support and training to help more patients become authors (eg, working with EUPATI to prepare a publications module for their curriculum; providing publication training for patient advocates at medical conferences).

How did you gather feedback on what you have done?

We have asked our patient authors about their interest in presenting at conferences to share their experience and 'lessons learned'. The response from our patient authors has been positive and they have already presented at a number of meetings (e.g. a Forum in London; publication conferences in Japan and the US). We see this sharing of information as an important component of continuing our relationship with patient authors, from whom we have learned so much. We want others to learn from patient authors as well!

How did you check that your planning to secure continuity and sustainability was appropriate also for the stakeholders you've involved in the project?

The Patient Authorship Experience Tool that we developed for this project (to be completed by patient and non-patient authors on project completion) specifically asks about transparency in communication and documentation.

Results and outcomes

This project has been successful, in terms of

1. Involving patients as co-researchers and co-authors of this systematic review
2. Using a robust method (systematic review) to collect and analyse evidence to guide best practices for patient involvement in reporting clinical research results. This has allowed us to identify:
    a. Potential benefits and harms of involving patients as authors
    b. Evidence-based best practice recommendations for involving patients as authors
3. Identifying challenges for conducting research in this area and proposing solutions

The first stage of the systematic review has been completed. The results have been presented at an international conference focused on ethical and effective publication practices (International Society for Medical Publication Professionals – 14th Annual Meeting; April 30-May 2, National Harbor, Maryland, USA; poster presentation attached). Patients were involved in all stages of preparing the presentation and co-authored the research abstract and presentation.

The second stage of the systematic review is nearing completion. All data have been collected and the target journal has been selected. Manuscript preparation is underway and will be submitted this year (2019).

Evidence based on our experience of this project will be collected via the Patient Experience Authorship Tool. This survey instrument is being completed by patient and non-patient authors. The results will provide useful information on:

- What our team did well to facilitate patient authorship success
- Where we could improve the experience for patient and non-patient authors
- The utility and validity of a practical tool that is based on the PFMD Patient Engagement Quality Guidance tool, but focused on the publication element of medicines development.

Positive impact for specific medicines development phases

Publications are a key element of any successful medicines development program. They are relevant to during the research and discovery phase, the clinical trial phase, the registration and reimbursement phase, and the post-registration phase. By having patients involved in publications, medicines development may:

- **Better** – patient-authored publications could help identify, prioritise, and publicise unmet needs most relevant to patients. As one of our patient co-authors stressed to our project team, the Discussion section of the manuscript is where research priorities are described (e.g. areas for further research). If patients are not involved in publications, then opportunities to include patient-prioritised research ideas in the peer-reviewed literature (read by key stakeholders) are being lost.
- **Faster** – patient co-authors may help ensure authors submit manuscripts to the most appropriate target journal. Doing so would avoid delays in manuscript rejections and re-submissions. Non-patient authors can be tempted to submit manuscripts to high-impact journals because being published in these journals can enhance academic careers. However, high-impact journals reject most manuscripts and this practice of 'vanity journal selection' wastes time and money (e.g. resubmission time and costs).

Patient co-authors may be much more focused on timely publishing than vanity publishing.

- **Gain broader public support** – patient co-authors can be strong advocates for complementing scientific publications with plain language summaries of those publications. Plain language summaries (vs. scientific abstracts/publications) are more likely to be accessed, read, understood, and shared by the public. These summaries can help raise public awareness of the need for robust research, as well as the challenges involved – they can highlight the benefits and the limitations of the research (i.e. maintain hope, but minimise hype). Patients have called for more plain language summaries and to have these summaries readily available (i.e. open access). The voice of the patient in publications and in plain language summaries of these publications could help build greater public understanding of and support for research.

Patient involvement in publications is still a very new and evolving area and we do not know if patient involvement in publications would have any material effect on the cost of medicines development. This is an area for future research. The additional time and costs of involving patient authors (e.g. patient author training, development of plain language documents/tools) may be offset by better and faster medicines development.

Direct or indirect positive impact for patients

Positive effects for patients from this project include:

- Providing patients with access to robust evidence proving that patients can be involved as authors on peer-reviewed publications. This evidence can be used to counter the argument that 'patients can't be involved in publications because they can't meet authorship criteria'.
- Providing patient authors and non-patient authors with evidence-based best practice recommendations to facilitate successful involvement of patient in publications.
- Confidence that patients can provide unique and valuable contributions to communicating clinical research results.
- Helping patients set and communicate priorities for research and have these priorities embedded in the peer-reviewed literature.
- Development of new skills (e.g. planning and preparing publications, use of innovative communication tools, such as infographics, QR codes, video abstracts etc.)
- Development of new relationships (e.g. trusted and mutually respectful relationships with co-authors)

Direct or indirect positive impact for stakeholders involved in the project (other than patients)

Non-patient (eg, academic) authors can benefit from this project, because they can:

- Gain a better appreciation of the unique and valuable contributions patient authors can make to publications.
- Demonstrate to employers, funders, patients, and the public that they have involved patients as true partners ie, authorship requires regular, substantial, and valuable contributions by all authors, including

patient authors (this cannot be tokenistic involvement or the publication could be retracted for misconduct e.g. if patients were 'guest authors').

- Target a broader range of journals for their publication – more journals (e.g. The BMJ, Research Involvement and Engagement) are actively looking to publish robust research with patients involved as co-researchers and co-authors.
- Attract greater attention to their research by broader stakeholder groups (e.g. patients, patient advocacy organisations, the public, the media, etc.) by preparing plain language summaries of their publications with their patient co-authors and having patient co-authors raise awareness of their research (e.g. via their networks, which would extend and complement traditional academic networks). We have shown that patients may raise awareness of published research more than healthcare professionals (figure below).

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Who engages with patient-centered, peer-reviewed publications? Tweeting of JAMA Patient Pages

Karen L. Woolley PhD[a, b, c, d], Elise Magatova PhD[a], Yukiko Homma MPharm[e], Emma A. Platt PharmD[f], Paul Lane PhD[g]

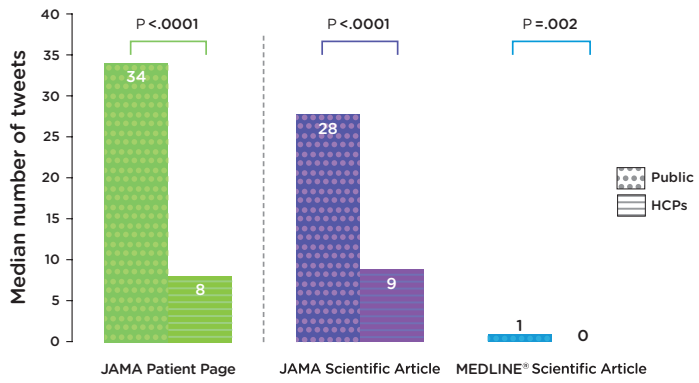
[a] ProScribe Pty Ltd; [b] Adjunct Professor, University of Queensland, Australia; [c] Adjunct Professor, University Sunshine Coast, Australia; [d] Government Director, Sunshine Coast Hospital and Health Service; [e] ProScribe K.K.; [f] Excel Scientific – Envision Pharma Group; [g] Consulting Solutions – Envision Pharma Group

ENVISION PHARMA GROUP
Driven by evidence, enabled by technology

Results

Public outperforms HCPs

The public tweets more than HCPs about JAMA Patient Pages AND about related scientific articles



Lessons learned

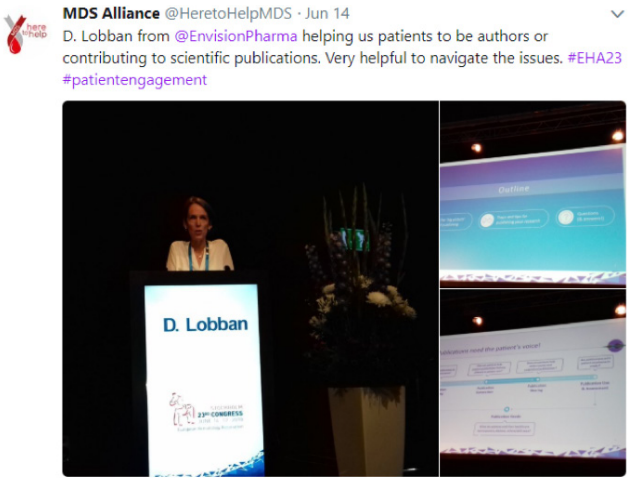
We have learned, directly through experience and indirectly through a systematic review of the literature, that patients can provide unique and valuable insights as authors on peer-reviewed publications. **We now have clear evidence and experience to challenge the belief, held by some, that 'patients can't meet authorship criteria'** and can, therefore, be excluded from the publication ecosystem. This is neither true, nor desirable. We and others can now use evidence to challenge this barrier to patient involvement.

We have also learned that practical tools and plain language documents can and should be prepared to facilitate ethical and effective involvement of patients in publications. Developing these tools and documents has taken time, effort, and resources, but they can be re-used and shared to benefit others.

Given the success of this project, we will be following the same processes and using the same tools for future publication work with patient co-authors. Where possible, however, we would look to improve on what we did and the feedback from the Patient Authorship Experience Tool will be most helpful in this regard. We can use this feedback to help us share 'lessons learned' not just with our team, but with the broader community (e.g. patients who are interested in authorship, non-patient authors who are interested in partnering with patients as co-authors).

We have already incorporated a number of the lessons that we have learned through this project into a publications training session for patient advocates (European Hematology Association, Stockholm, June 14 2018). This was the first publications training session for these patient advocates and the insights and lessons shared were very well received (patient advocate tweeted about the value of this publications training (Twitter output below). We have now been invited to prepare the first dedicated publications module for patient advocates being trained through the European Patients Academy (EUPATI).

During this project, we have also learned that publication professionals (e.g. Certified Medical Publication Professionals) are ideally positioned to help smooth the way for involving patients in publications. This was a somewhat fortuitous finding based on the fact that a number of authors happened to be Certified Medical Publication Professionals. To gain this certification, they are tested on their knowledge of ethical and effective publication practices. Publication professionals have to know the ethical guidelines that govern publication planning and preparation. As we found through the systematic review and our experience, patient authors benefit from having a trusted 'go to' person on the publication team.



The publication professional can be the 'go to' person, supporting and mentoring patient authors as they gain experience in publication planning and preparation. In a promising sign of support for patient authors, when publication professionals were asked should patients become more involved in publications, the answer was a resounding yes (see the 'hands up' vote in the pictures below from the 2018 meetings of the

International Society for Medical Publication Professionals; top panel, US meeting; bottom panel, EU meeting). We have already started to share our lessons and learnings with publication professionals and the broader community by starting a hashtag (#GPP4) on Twitter. We hope that the fourth version of the Good Publication Practice guidelines can include a section on patient involvement in publications.

One challenge that we experienced, but one this is not easily overcome, is having sufficient time to work on this project. As authors, we are completing this project as volunteers, which can require working after hours and on weekends. We recognise that this situation would not be tolerable for all research teams and authors. We welcome further discussion about this issue to help ensure patient authors and their non-patient co-authors can conduct and publish research during working hours (e.g. have dedicated and protected time to work on publications). The voice of the patient in publications is too important to allow it to become muffled or muted by practical issues.

@EnvisionPatient

About the organisation

Envision the Patient is the patient-focused team within Envision Pharma Group, a global medical communications company. We support our clients to work with patient partners, ethically and effectively, in medicines development. We are dedicated to powering patients voices in publications and medical affairs, as well as contributing to and supporting evidence-based best practice to enhance patient involvement in publications.

Professor Karen Woolley is our Global Lead, Patient Partnerships. As well as being a hospital director and a leader in patient research, Karen has a strong background in publications and medical affairs, and experience in industry. Amanda Boughey, our Global Patient Partnership Director, has extensive third-sector experience at Cancer Research UK. Dr Lauri Arnstein, Patient Partnership Liaison, is a medical doctor, medical writer and plain language content expert. Anne Clare Wadsworth (Global Business Unit Head at Envision) and Dr Dawn Lobban (Divisional Lead at Envision) bring expertise in publications and medical affairs strategy and delivery, alongside a passion for patient involvement. Together, we have 85 years of experience in health and medical communications, 14 years of experience in patient involvement and strategy, and 18 years of experience working with patient groups and front-line patient services. We would also like to acknowledge the many Patient Champions across Envision who support our work!

Annex 1: How to read the Book of Good Practices

The Book of Good Practices cases are all structured in the same way as the Patient Engagement Quality Guidance. You will find that each case has a basic description, followed by icons to show in which phases of medicines continuum they fit in and which stakeholders they have involved in their work (see description of icons below). In section 2 these cases will describe how they reached each of the 7 Quality Criteria. You will see from the wheel in the beginning, which of the Quality Criteria they exemplified in (judged by an external group of reviewers). Finally, you will find the results and outcomes of each case and the lessons learned.

Which phases of research, medicines development, lifecycle or disease area does this PE project cover?

Research and discovery phase | **Pre-clinical phase** | **Clinical study phase 1-3** | **Health technology assessment** | **Regulatory review and approval or registration phase** | **Post-registration/ -launch activities** | **Other**

- ✔ **Research and discovery phase**
  1. unmet medical needs identification
  2. disease understanding [patient experience of the disease]
  3. drug discovery, non-clinical and candidate-identification phase
- ✔ **Pre-clinical phase** (including non-clinical, pre-clinical research, safety and efficacy tests)
- ✔ **Clinical study (phase 1-3)**
- ✔ **Health technology assessment**
- ✔ **Regulatory review and approval or registration phase** (including submitting for market authorisation request and approval)
- ✔ **Post-registration / -launch activities**
  - clinical study phase 4,
  - drug safety monitoring and pharmacovigilance,
  - Pricing and reimbursement
  - real-world evidence generation,
  - adherence,
  - patient education,
  - patient and carer support programmes,
  - disease management,
  - public health,
  - marketing insights
- ✔ **Other**

Which stakeholders does this PE project involve?

Patients and carers | **Policymakers** | **Health technology assessment organisations** | **Research funders**

Patient advocates, patient organisations and associations | **Regulators** | **Pharmaceutical companies or industry** | **Other**

Healthcare professionals | **Payers** | **Researchers**

- ✔ **Patients and carers** (including caregivers, and family members)
- ✔ **Patient advocates, patient organisations and associations**
- ✔ **Healthcare professionals** (including clinical investigators, general practitioners , specialists, pharmacists and nurses)
- ✔ **Policymakers**
- ✔ **Regulators**
- ✔ **Payers**
- ✔ **Health technology assessment organisations**
- ✔ **Pharmaceutical companies or industry** (including medical devices and biotech companies)
- ✔ **Researchers** (academic researchers and investigators)
- ✔ **Research funders**
- ✔ **Other** (for example, contract research organisations (CRO) and hospitals)

Annex 2: Descriptions of the Patient Engagement Quality Criteria

1. Shared purpose

This refers to the project's aims and outcomes that all stakeholders taking part should agree on before starting the project. Consider putting in place processes to help facilitate discussions between all stakeholders to identify each other's values, expectations and objectives, and review and discuss priorities in the planning of the project. It can be valuable to enable stakeholders to exchange views openly to understand the scope and objectives of the project, acknowledging that some of their objectives may differ. All parties concerned should also have a shared written description of the common goals of the project.

2. Respect and accessibility

This refers to (1) respecting each other, and respectful interactions within the project to be established among partners, and (2) openness to and inclusion of individuals and communities (to the project) without discrimination. Considerations to ensure good conditions to implement the project should be made from the beginning. For example:

- simplification of wording
- budget and payment considerations
- cultural adaptations to procedures
- practicalities such as meeting timing, location and format
- accessibility of project materials
- written co-developed rules of conduct

Accessibility to participate may be facilitated by enabling multiple ways to involve stakeholders who could benefit from and/ or contribute to the project. For example, patients with cognitive impairment might need more time to go through project material, or need printed versions rather than electronic documents or PDFs for easier reading.

3. Representativeness of stakeholders

This refers to the mix of people you involve, which should reflect the needs of the project, and the interests of those who may benefit from project outputs (for example, target population). Consider diversity in expertise, experience, demographics, and other relevant criteria for inclusion. When selecting PE stakeholders, patients, attention will be given to awareness of the diversity required to achieve visible representative voice.

4. Roles and responsibilities

This refers to the need for clearly agreed, and ideally co-created roles and responsibilities, in writing, addressing that all aspects of project needs will be established upfront and revisited regularly.

Annex 2: Descriptions of the Patient Engagement Quality Criteria

5. Capacity and capability for engagement

This refers to (1) capacity as having relevant and dedicated resources from all stakeholders (for example, providing a dedicated point of contact by the sponsor and having allocated sufficient time by all stakeholders to allow genuine engagement); and (2) capabilities for all stakeholders to enable meaningful engagement. (For example, the level of knowledge, expertise and training stakeholders might need to deliver PE activities throughout the project).

Consider supporting stakeholders to build the required capacity and capabilities for this project in different forms of training both with sponsor organisations and with each stakeholder (for example, helping to understand the context, processes, involved terminology etc.).

Both capacity and capability building are intended to facilitate participation and lower barriers to collaborate. Stakeholders can be given access to learning resources and given dedicated support (if needed). Capability needs may vary depending on the project needs, but also e.g. personal circumstances of PE representatives.

6. Transparency in communication and documentation

This refers to the establishment of communications plan and ongoing project documentation that can be shared with stakeholders. Communication among stakeholders must be open, honest and complete.

In addition, adequate up-to-date documentation must facilitate communication with all stakeholders throughout the project. Consider proactively and openly sharing progress updates throughout the project externally. In addition, communicating outcomes of the project to all stakeholders and how their contribution was of value to the success of the project is critical.

7. Continuity and sustainability

This refers to the smooth progression of the project, as well as efforts to maintain ongoing relationship with stakeholders. Consideration should be given for the role of stakeholders beyond a single project. When starting the project, consider including in your project plan the actions needed for maintaining expected flow of the project from beginning to end.

Create a plan to nurture relationships with your partners and stakeholders involved during the project, and when needed and requested, beyond the project as well. For all stakeholders successful planning and personal and organisational resilience should be anticipated.