

## Research Methods

# Patient perspectives on engagement in shared decision-making for asthma care

Hazel Tapp<sup>a,\*</sup>, Diane Derkowski<sup>b</sup>, Melissa Calvert<sup>c</sup>, Madelyn Welch<sup>a</sup> and Sara Spencer<sup>d</sup>

<sup>a</sup>Department of Family Medicine, Carolinas HealthCare System, Charlotte, NC, USA, <sup>b</sup>Transplant Center, Carolinas HealthCare System, Charlotte, NC, USA, <sup>c</sup>Mecklenburg County Asthma Coalition and <sup>d</sup>Elizabeth Family Medicine Patient Advisory Board, Carolinas HealthCare System, Charlotte, NC, USA

\*Correspondence to Hazel Tapp, Department of Family Medicine, Carolinas HealthCare System, 2001 Vail Avenue, 4th Floor, Suite 400, Mercy Medical Plaza, Charlotte, NC 28207, USA; E-mail: [hazel.tapp@carolinashealthcare.org](mailto:hazel.tapp@carolinashealthcare.org)

### Abstract

**Introduction.** Engagement of patient and advocacy group stakeholders is increasingly considered essential to meaningful outcomes research. Patient-centred research benefits from partnership formation between patients, clinicians and research team members. Here, we describe the rationale for engaging patients on a research team and a case study of patient engagement on an asthma shared decision-making study.

**Methods.** Here, we describe a case study of patient engagement in outcomes research and examine the variety of roles patients are engaged in and the associated impact on the study.

**Results.** Patients assisted the project at various levels and were integrated into the research team by (i) advising on study development; (ii) assisting with design and usability of study materials, including the toolkit, patient surveys and dissemination strategies; and (iii) advocacy via membership in external disease-specific organizations and participating in outcomes research conferences. Patients were engaged both individually and as members of a patient advisory board. Primary lessons learned were the importance of building a trusting partnership with patients through understanding perspectives, being aware of clearly explaining patients' roles, research methods and jargon, providing training, listening to patients' needs and understanding what the partnership means from a patient perspective.

**Conclusions.** For the case study described, patient engagement directly influenced multiple aspects of the study, including study design, implementation, data analysis and dissemination through incorporation of the patients' and caregivers' input and concerns.

**Key words:** Dissemination, focus groups, patient advisory boards, primary care, patient engagement, patient experience

### Background

Engagement of stakeholders such as patients and advocacy groups is increasingly considered essential to successfully pursuing meaningful outcomes research. Effective patient engagement in research requires a clear purpose, role and structure of engagement, mutual understanding and trust and systematic process improvement evaluation throughout the study (1). Patients can be involved at all stages of the research project, such as developing the research question and

study design to ensure the project, and its results will be useful and important to patient and stakeholder communities through active participation in dissemination and policy development.

Several models describe the role of patients and stakeholders in research. Research methods, such as community-based participatory research (CBPR) (2), comparative effectiveness research (3,4) and patient-centred outcomes research (5), span the continuum of engaged research and encourage extensive patient and stakeholder

involvement. The Patient-Centered Outcomes Research Institute (PCORI) places great importance on the engagement of patients and other stakeholders in the research process (6). The term 'patient' can include patients with lived experience, family members and caregivers (7,8).

Most frequently used methods to engage patients in outcomes research are focus groups, interviews, surveys and serving on a study board or advisory council (9). Patients attending clinics or other patient care facilities are approached to determine their opinions and beliefs on the types of studies needed (10).

Patient partners are most commonly involved in topic solicitation, question development, study design and data collection, though some contribute to data analysis, results interpretation and dissemination (9). Commonly reported contributions included changes to project methods, outcomes or goals; improvement of measurement tools; and interpretation of qualitative data (11). While social media has been suggested as an avenue of translating research evidence into clinical practice, few studies currently engage patients in dissemination efforts through social media channels (12). In CBPR, stakeholders typically form an advisory board addressing protocol, recruitment procedures and selected outcomes. Participants educate study personnel about the community and help with execution of study intervention (13,14). Participants can help with understanding the community; e.g. photovoice is a method to engage a community to facilitate community change that involves community members reflecting on their environment through photographs (15).

While most studies reported mainly positive effects of engagement, a smaller number described potential challenges or adverse effects of engaging patients. Investigators often identified communication and shared leadership strategies as 'critically important' facilitators, while lack of stakeholder time was the most commonly reported challenge (16). Early lessons learned included the importance of continuous and genuine partnerships, strategic selection of stakeholders and accommodation of stakeholders' practical needs (16). Challenges are mainly reported as related to retention, patient frustration with the lengthy process of research and time and effort commitment (17). Studies also cited logistics such as extra time needed to complete research, time constraints of patients and researchers and incremental funding needed for patient engagement and tokenistic engagement (17).

While the benefits of engagement have been widely discussed, there is a lack of evidence on the impact and outcomes of patient engagement (18,19). Research dedicated to identifying the best methods to achieve engagement is lacking (9,18). This paper describes a case example of the roles and impact of patients working with a research team throughout an asthma-shared decision-making implementation research project. The rationale for patient engagement in this case study is based on the PCORI engagement rubric (8), which illustrates how input from patient and stakeholder partners can be incorporated throughout the entire research process and a pragmatic framework for authentic involvement of patients from existing patient and family advisory councils (11).

### Case study

Poor outcomes and health disparities related to chronic diseases such as asthma result in part from the difficulty of disseminating new evidence and patient-centred care delivery methods such as shared decision-making into clinical practice. The Asthma Dissemination Around Patient-Centered Treatments in North Carolina (ADAPT-NC) study is a multicentre outcomes research study funded by PCORI to test implementation strategies for dissemination of a shared decision-making toolkit designed to improve outcomes for patients with asthma.

During a previous asthma implementation study called Asthma Comparative Effectiveness (ACE), several patients volunteered with the team. These patients gave input on the adaptation of the shared decision-making toolkit and evaluation materials such as surveys (20,21). Results added to the literature showing improved outcomes for patients with asthma (20–23). This led to an application for PCORI funding of a dissemination study to explore further the best approaches to implementing this evidence into practice (24). In addition to re-engaging several patients or caregivers who had already collaborated on the previous ACE study, we reached out to new patients known to the research team and a patient advisory board located within a primary care practice. The aim of this paper is to describe various patient roles and impact within this large outcomes research study.

### Methods

This is a case study of the engagement of patients in a statewide project studying implementation of a shared decision-making toolkit for patients with asthma. Sixteen patients from a variety of backgrounds were engaged in partnership with the research team (Table 1). Each of the 16 patients participated in one or more of the study phases, such as project design, approving protocols, intervention implementation, study management, data analysis and dissemination. Patients who became involved typically fell into one of the four groups: lived experience patients, caregiver advocates, research participants and patient advisory board members.

Lived experience patients are patients with specific disease knowledge and understanding. Several patients with asthma had connected with the research team during the previous study; they were able to continue to advise us as we began to plan the ADAPT-NC study.

Caregiver advocates are caregivers of patients with complex medical conditions or diseases such as asthma. One caregiver advocate is a patient who founded an asthma awareness organization named in memory of her child. Through her advocacy, this patient plans and fundraises for asthma awareness events, writes and speaks about her experiences, is a board member of the local asthma-focused coalition and has presented at national meetings with the research team. This patient also became fully integrated with the team through attending weekly meetings with the research team during the planning and implementation of ADAPT-NC, became research certified for HIPAA compliance and assisted the team with the study.

Research participants are patients or caregivers who attend disease-specific research study activities, such as focus groups, and express interest in engagement in the research process. One patient was recruited at the end of a focus group and expressed interest in serving the project by attending a series of monthly statewide conference calls.

Finally, patient advisors are those already involved in general patient advocacy such as being members of a community group or patient advisory board. During the time of the first ACE asthma study, a patient advisory board was started at one of the outpatient practices. The board serves primarily to comment on issues related to the practice, such as the way the practice functions and serves patients. The board was contacted quarterly and members were very engaged and willing to give feedback to the team on all stages of the development and execution of the ADAPT-NC study.

### Results

Sixteen patients became involved as patient stakeholders in this case study. These stakeholders served various roles, such as study design,

**Table 1.** Summary of patient engagement: types of patients, recruitment, roles and perspectives

Lived experience patients (3)	<p>Broad group description: patients with specific disease knowledge and understanding through lived experience. Recruited through health care system stakeholder assistance.</p> <p>Role and input into project: planning including initiation of project, patient-centred outcomes, toolkit input, dissemination strategies, advocacy and policy development.</p> <p>Patient thoughts: I was diagnosed with asthma in my early 20s. I am a very well-controlled asthma patient and I am able to lead a very active lifestyle, including running several marathons.</p> <p>Specific examples of patient input: this patient was instrumental in pre-award idea development and present throughout research project. Recommended that patient survey should be shortened to one question. Suggested changes to simplify wording on toolkit. Commented on progress of all aspects of project.</p>
Caregiver advocates (1)	<p>Broad group description: caregivers of patients with complex medical conditions or diseases such as asthma. Recruited through partnering with or contacting asthma advocacy groups.</p> <p>Role and input into project: this patient attended project meetings, gave input into patient-centred approaches, assisted with data interpretation and analysis, contributed to dissemination strategies and was involved in advocacy and policy development.</p> <p>Patient thoughts: 'With all that I have gone through with caring for my children with asthma, it was an easy choice to engage with the team. I have become more engaged in raising asthma awareness. Each year, on the anniversary of my daughter's birthday, I ask people to post an inspiring story with [a dedicated] hashtag in memory of my daughter who passed away from asthma'.</p> <p>Specific examples of patient input: training in quantitative analysis by research team. Analysis of patient focus groups looking for themes and subthemes. Member of other advocacy groups such as PCORI Evidence to Action Network, Tobacco Free Mecklenburg and Mecklenburg County Asthma Coalitions (MCAC), developed video of patient engagement role for PCORI and gave input into posts on the MCAC website and social media pages. Suggested setup of Instagram account and short videos on Periscope. Shares information on personal Instagram, Facebook and Twitter accounts. Along with having brochures or pamphlets in patient waiting rooms, suggested making brochures available in Mecklenburg County recreation centres. Wrote and published book on experiences of having children with severe asthma.</p>
Research participants (2)	<p>Broad group description: patients or caregivers who attend disease-specific research study activities. Recruited through focus groups. These patients expressed interest in engagement in the research process.</p> <p>Role and input into project: patient representative on the study conference calls between the research team and the practices receiving the facilitator-led intervention.</p> <p>Patient thoughts: I appreciate being a part of the phone call. I am able to better understand the complexities of implementation, and as a patient, I can help guide the practices in thinking about how patient schedules are set up and to take into account the patient's point of view and the staff's needs when implementing visit schedules.</p> <p>Specific examples of patient input: gave input into qualitative themes chosen by the research team to ensure they were patient centred. Monitored calls and commented on the use of facilitators and spread of intervention. Commented on the major themes that emerged from the call. Emphasized the need to address school calendar, winter flu season and spring allergy season in asthma visit scheduling.</p>
Patient advisory board (10)	<p>Broad group description: patients already involved in general patient advocacy such as members of a community group or patient advisory board. These patients were recruited through provider recommendations and focus groups at an outpatient family medicine teaching practice.</p> <p>Role and input into project: quarterly updates given to PAB meeting.</p> <p>Patient thoughts: Comments given: the shared decision-making tool is important for us to better understand our treatment plan and be involved in the decision with the provider. We appreciate the study will help understand how facilitators can affect implementation. This study also allowed us give input on another shared decision-making initiative that helps elderly patients decide to discontinue medications.</p> <p>Specific examples of patient input 'around dissemination strategies': find smiley, approachable people for dissemination who are trusted by both patients and medical community and totally committed to sit at tables and network at community events. Repetition of the message is important. Magnets and bracelets can be useful as a signal of common support. Brochures should be in the exam room as well as waiting rooms. Patients would like to take them away for distribution to friends and family. A trifold brochure was felt to be most effective printed material. Patients do want study results as long as they are simply stated. Make sure the magic word 'asthma' is first, large and bold on the brochure. For example, 'Do you have asthma?' Be careful of acronyms. Have a central place to explain abbreviations on documents. One patient suggested the brochure be attached to other discharge material or attached to pre-visit material such as the asthma control survey in medical office visits.</p>

data analysis and design and implementation of dissemination strategies (Table 1). The participating patients fell into one of the four categories: lived experience patients, caregiver advocates, research participants and patient advisory board members.

### Lived experience patients

One of the lived experience patients, who works as a health care professional and has asthma, had previously volunteered with the research team on the ACE project and continued her involvement

throughout the ADAPT-NC study. In describing her motivation for the study, this patient reported that:

I have been a patient with asthma for over 20 years and am grateful to be very well controlled. I have a vested interest in helping people with asthma. I hope to be an inspiration, advocate, and role model to others with asthma and show that an active lifestyle is definitely possible. Volunteering with researchers is a positive experience. I have been involved for more than five years now in many aspects of the project. I have attended four national

meetings, including a patient engagement in research conference, and have engaged with other patient partners to share our experiences and learn from others.

This patient partner has been involved from the initial research idea to the implementation phase and participated as a patient representative in monthly conference calls. This patient contributed to the intervention design in several ways such as suggesting changes that simplified a patient survey and assisting in dissemination through health fairs and presenting at outcomes research meetings.

### Caregiver advocates

A patient caregiver was involved by attending meetings either in person or via conference call, reviewing transcripts from focus groups, summarizing common themes presented in the transcripts, critiquing dissemination strategies, attending dissemination conferences, being a member of local advocacy organizations and assisting in other capacities as needed. As an individual asthma advocate, the patient frequently shared experiences with the research team and the lessons learned about asthma to community organizations. This direct contact with an asthma caregiver allowed the research team to gain a fuller understanding of typical daily struggles of a parent of multiple children with severe asthma, which was motivating to the team. The caregiver patient has contributed to the dissemination strategies employed by the project by giving feedback and suggestions on how to best advertise the study and its results to a target population with known disparities in asthma outcomes, from the perspective of a patient and the parent. Additionally, the caregiver patient has described the work she undertook and her perspectives on the research partnership at local meetings, advocacy events and national outcomes research meetings.

### Research participants

One patient served as a patient representative on a research project meeting held monthly between staff at practices engaged in the facilitated approach to care facilitated by the research team. This patient was able to give a patient perspective on the calls, help prioritize items for future calls and help in the subsequent analysis of how the calls assisted the practices during toolkit implementation.

Importantly, in order to fully participate across the project, two patients who were most involved in the research project through attending weekly or monthly research meetings where research needs arose and expressed that they would like to be part of the qualitative analysis team working on focus group analysis. They agreed and expressed willingness to train in research ethics certifications in order to be a part of this qualitative analysis of study data. This is a necessary institutional review board (IRB) requirement for all research team members involved in data collection and analysis. This online, self-paced human subjects research training was available through a collaboration between the health care system and the Collaborative Institutional Training Initiative (CITI).

### Patient advisory board members

Members of a patient advisory board located in an outpatient family medicine centre were routinely consulted throughout the project. For example, regarding dissemination strategies, patient members gave feedback about the importance of the team having a presence at community events benefitting asthma awareness. They clarified dissemination approaches such as best locations of results brochures, stating they would be more likely to take and read a pamphlet about asthma in the waiting room than read an informational poster. The patients asked the research team to avoid or clearly define acronyms in all

study materials prepared for dissemination. Drafts of the results brochure were brought to patient advisory board meetings and members marked on and reviewed each section, emphasizing that the brochure should maintain a patient-centred focus. They asked that more space be dedicated to explaining asthma and shared decision-making and less to complex research terms about study design.

Three patients were involved in evaluation of the patient role and discussion of best practices. Through involvement in the project, these patients were able to extend their expertise as patient partners through connecting with a national asthma-focused network that sought their input on best practices for patient engagement. Overall, these patients expressed that gaining trust was considered key to building a cooperative continuity relationship with the research team. Trust was built in the following ways: (i) PCORI emphasizes willingness to compensate patients' time and enable equal status such as offering co-investigator roles to patient partners. Patients were compensated through gift cards and salary for data analysis. (ii) Trust also involved using language the patients could understand, even during sometimes frantic research meetings where acronym use was abundant. We made sure to pause meetings if necessary to explain our updates more clearly and the meaning of acronyms used. (iii) Adopting patients' input was crucial as well; patients gave input such as to simplify surveys and be aware of intrusiveness of research. Their input was operationalized wherever possible. (iv) All meetings with patients involved had the permanent agenda item 'patient voice' to allow and encourage whatever they wanted to bring to the table. These patients have commented that when their input is adopted, they feel they are 'believed in', their experience as a patient is validated and they have a true sense of collaboration, such as when materials are changed based on their input. These trusting relationships worked well to also bring awareness and invaluable knowledge that was helpful for the research team.

Patient engagement benefitted the study through the incorporation of the patient voice right from study conception and design that led to a research study designed to be meaningful to patient concerns. One patient partner reviewed drafts of the shared decision-making toolkit and suggested word changes on the pages about asthma education to be more concise and health literate for patients. In designing the facilitated intervention to implement the toolkit in medical practices, an asthma patient volunteered to be in a training video and gave constructive feedback about the pacing of using the full toolkit. While planning strategies for results dissemination, several patients supported the use of social media to reach audiences online and offered to share posted information on their own personal accounts. Patient engagement in the study design contributed to the adoption of a more patient-centred one-question survey about treatment decisions made during asthma visits. Patients involved with advocacy groups connected the research team to community events that focused on asthma awareness, allowing the research team to target community members most affected by asthma outcomes for disseminating study results and general asthma education. Attending these events helped research team members expand their reach beyond traditional networking sources and discover and cultivate relationships with community members allowing for further dissemination and policy change initiatives.

### Conclusions

Overall, patient engagement in this study directly and positively influenced multiple aspects of the study, including study design, implementation, data analysis, and dissemination through incorporation of the patients' and caregivers' input and concerns.

Patients engaged in research may occupy one or more study roles depending on their background, strengths and interests. For the asthma-shared decision-making case study described, patient engagement led to refinements of the intervention in various phases of the project.

One of the main limitations of the study may be that the way this study recruited and involved patients may not be readily generalizable or feasible. Members of the patient advisory board had previously been recruited as part of a systemwide initiative to engage patients throughout the health care system. Since these patients were already readily available to the research team, this may make this case study less generalizable. Another limitation for patient involvement in general is the issue of recruiting and facilitating involvement of the patients who represent the vulnerable populations most affected by the disease. Having patients and caregivers from a variety of backgrounds is important to consider; teams in primary care research should have patients who represent the vulnerable populations their project hopes to address (1). This study involved a diverse population of patients with no prior experience in research who had first-hand experience of many of the most adverse outcomes that can arise with asthma. A limitation may be that the patients most heavily involved with the study had backgrounds in health care (not related to asthma) or advanced professional degrees. One unavoidable limitation is the inability to postulate how much less patient-centred or effective aspects of the study would have been without the patient input. Another limitation is retention and time commitments. One HIPPA trained patient who initially wanted to work with us more extensively on data analysis was offered a full-time job elsewhere and was less able to be as involved as she had hoped.

Potential future directions for patient engagement in research include patient involvement in areas such as IRBs, consent document development, health literacy input and input into all other research areas will further improve our ability to conduct patient-centred research. Involvement of patients throughout research and other improvement projects offers invaluable opportunities to contextualize study impact through the patient voice. This study describes the overall impact of patient partnership on a large outcomes research study where the patient–research team partnership directly and positively enhanced many aspects of the research process.

## Acknowledgements

We sincerely thank all the patient members of the Patient Advisory Board at Elizabeth Family Medicine, Carolinas HealthCare System. We would also like to thank all involved in the PCORI initiated asthma Evidence to Action network.

## Declaration

Funding: Research reported in this publication was funded through a Patient-Centered Outcomes Research Institute (PCORI) Award (CD-12-11-4276). The opinions in this publication are solely the responsibility of the authors and do not necessarily represent the views of the Patient-Centered Outcomes Research Institute (PCORI), its Board of Governors or Methodology Committee. Ethical approval: this asthma study was approved by the Carolinas HealthCare System Institutional Review Board. Conflicts of interest: none.

## References

1. Wilson P, Mathie E, Keenan J *et al.* *ReseArch with Patient and Public involvement: a RealisT evaluation - the RAPPORT study*. Southampton, UK: NHIR Research Library, 2015.
2. Viswanathan M, Ammerman A, Eng E *et al.* Community-based participatory research: assessing the evidence. *Evid Rep Technol Assess (Summ)* 2004; (99): 1–8.
3. Sullivan P, Goldmann D. The promise of comparative effectiveness research. *JAMA* 2011; 305: 400–1.
4. Concannon TW, Fuster M, Saunders T *et al.* A systematic review of stakeholder engagement in comparative effectiveness and patient-centered outcomes research. *J Gen Intern Med* 2014; 29: 1692–701.
5. Burke JG, Jones J, Yonas M *et al.* PCOR, CER, and CBPR: alphabet soup or complementary fields of health research? *Clin Transl Sci* 2013; 6: 493–6.
6. Frank L, Forsythe L, Ellis L *et al.* Conceptual and practical foundations of patient engagement in research at the patient-centered outcomes research institute. *Qual Life Res* 2015; 24: 1033–41.
7. Patient-Centered Outcomes Research Institute. <http://www.pcori.org/research-we-support/pcor/> (accessed on 8 October 2016).
8. PCORI Engagement Rubric 2016. <http://www.pcori.org/sites/default/files/Engagement-Rubric.pdf> (accessed on 8 December 2016).
9. Shippee ND, Domecq Garces JP, Prutsky Lopez GJ *et al.* Patient and service user engagement in research: a systematic review and synthesized framework. *Health Expect* 2015; 18: 1151–66.
10. Jones JM, Nyhof-Young J, Moric J *et al.* Identifying motivations and barriers to patient participation in clinical trials. *J Cancer Educ* 2006; 21: 237–42.
11. Fagan MB, Morrison CR, Wong C, Carnie MB, Gabbai-Saldate P. Implementing a pragmatic framework for authentic patient–researcher partnerships in clinical research. *J Comp Eff Res* 2016; 5: 297–308.
12. Tunnecliff J, Ilic D, Morgan P *et al.* The acceptability among health researchers and clinicians of social media to translate research evidence to clinical practice: mixed-methods survey and interview study. *J Med Internet Res* 2015; 17: e119.
13. Chang C, Minkler M, Salvatore AL *et al.* Studying and addressing urban immigrant restaurant worker health and safety in San Francisco's Chinatown district: a CBPR case study. *J Urban Health* 2013; 90: 1026–40.
14. Camelo Castillo W, Hendricks J, dosReis S. Engaging Hispanic caregivers in research: a framework to design culturally sensitive approaches for engagement in patient-centered outcomes research. *Value Health* 2015; 18: A815.
15. Hergenrather KC, Rhodes SD, Cowan CA, Bardhoshi G, Pula S. Photovoice as community-based participatory research: a qualitative review. *Am J Health Behav* 2009; 33: 686–98.
16. Forsythe LP, Ellis LE, Edmundson L *et al.* Patient and stakeholder engagement in the PCORI pilot projects: description and lessons learned. *J Gen Intern Med* 2016; 31: 13–21.
17. Lavallee DC, Wicks P, Alfonso Cristancho R, Mullins CD. Stakeholder engagement in patient-centered outcomes research: high-touch or high-tech? *Expert Rev Pharmacoecon Outcomes Res* 2014; 14: 335–44.
18. Domecq JP, Prutsky G, Elraiyah T *et al.* Patient engagement in research: a systematic review. *BMC Health Serv Res* 2014; 14: 89.
19. Esmail L, Moore E, Rein A. Evaluating patient and stakeholder engagement in research: moving from theory to practice. *J Comp Eff Res* 2015; 4: 133–45.
20. Tapp H, Hebert L, Dulin M. Comparative effectiveness of asthma interventions within a practice based research network. *BMC Health Serv Res* 2011; 11: 188.
21. Tapp H, Kuhn L, Alkhazraji T *et al.* Adapting community based participatory research (CBPR) methods to the implementation of an asthma shared decision making intervention in ambulatory practices. *J Asthma* 2014; 51: 380–90.
22. Kuhn L, Reeves K, Taylor Y *et al.* Planning for action: the impact of an asthma action plan decision support tool integrated into an Electronic Health Record (EHR) at a large health care system. *J Am Board Fam Med* 2015; 28: 382–93.
23. Tapp H, Shade L, Mahabaleshwarkar R *et al.* Results from a pragmatic prospective cohort study of adults and children: shared decision making improves outcomes for children with asthma (accepted for publication). *J Asthma* 2016; 4: 1–11.
24. Tapp H, McWilliams A, Ludden T *et al.* Comparing traditional and participatory dissemination of a shared decision making intervention (ADAPT-NC): a cluster randomized trial. *Implement Sci* 2014; 9:158.