The patient voice in policy research: leveraging qualitative data to understand how policy impacts patients

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Introduction

- Patients are key stakeholders in healthcare; as such, their involvement in shaping healthcare policy is important to provide a contextual perspective around its viability, practicality, and appropriateness
- Qualitative research can capture rich data on patient perspectives, experiences, and behaviors[1].
- Qualitative research is particularly well suited to understand patient interactions with policies to inform policymaking; yet there is a paucity of research in this space[2]
- In recent years, there has been increased emphasis on including patients as integral members of the research team, from drug development and regulatory decision-making,[3] to shared decision-making at the patient–provider level,[4,5] as well as publication planning and development[6]
- There is a need to include patient perspectives at a higher organizational/policy level to inform broader policies that may impact access to treatment

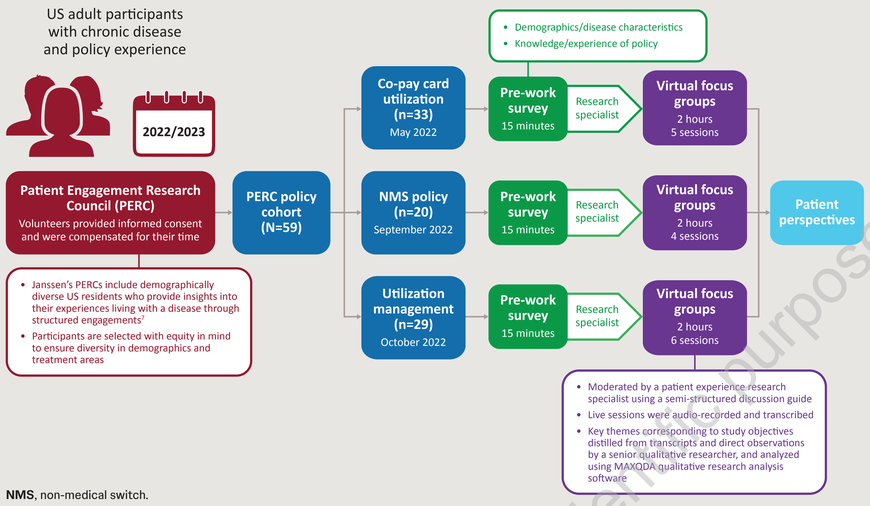
Objectives

- To evaluate how US healthcare policy impacts patients with chronic disease through exploratory focus groups, and to pilot internal guidance on compliant processes for the publication of patient perspectives as well as the inclusion of patients as authors

Methods

Qualitative exploratory focus groups

- Patients with chronic conditions invited through Janssen's Patient Engagement Research Council (PERC) program[7] discussed the impact of US healthcare policy through participation in three engagements
- The following inclusion criteria were considered for each of the three engagements:
  - **Co-pay card utilization:** PERC members with experience using a pharmaceutical manufacturer co-pay card or coupons in the past 12 months
  - **Non-medical switch (NMS) policy:** PERC members were divided into two groups based on whether they had or did not have NMS experience
  - **Utilization management:** PERC members with at least one experience with prior authorization, step edits, or formulary exclusion lists



NMS, non-medical switch.

Compliant publication of patient perspectives

Internal guidance was piloted for including patients as authors

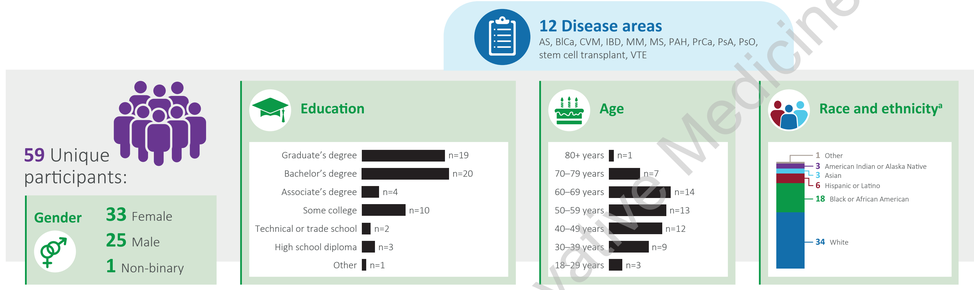
- **Invitation to patient author** — Outline clear publication objective and confirm interest in authorship
- **Author kick-off call** — Discuss scope with all authors, review ICMJE authorship criteria
- **Signed authorship agreement** — Agree on author roles and responsibilities per **ICMJE** and **GPP** recommendations
- **Author review of drafts** — Critical review of each draft with provision of comments at each stage
  - Formal company review
- **Final author approval** — Discuss any suggestions from formal review and approve final draft
- **Submission** — All authors agree to be responsible for all aspects of the work

- Internal company processes and partnerships were leveraged to compliantly publish patient perspectives on US healthcare policy
- Key internal partners (legal, healthcare compliance, regulatory, privacy) were engaged early and consulted throughout the process

GPP, Good Publication Practice; **ICMJE**, International Committee of Medical Journal Editors.

Results

Participant demographics and clinical characteristics



[a]PERC members could identify as more than one race/ethnicity.

AS, ankylosing spondylitis; **BlCa**, bladder cancer; **CVM**, cardiovascular and metabolic diseases; **IBD**, inflammatory bowel disease; **MM**, multiple myeloma; **MS**, multiple sclerosis; **PAH**, pulmonary arterial hypertension; **PERC**, Patient Engagement Research Council; **PrCa**, prostate cancer; **PsA**, psoriatic arthritis; **PsO**, psoriasis; **VTE**, venous thromboembolism.

Patient perspectives on US healthcare policy

Participants described their perspectives on navigating US healthcare policy and how it affects their healthcare utilization

Co-pay card utilization

Patients struggle to see how they could adhere to prescriptions and maintain treatment without co-pay cards

*"... If I didn't have assistance, ... I'd **always be stressed**, which would probably then cause other health issues and probably anxiety, lack of sleeping; my mental health would probably deteriorate always being worried or in pain ..."*

CVM PERC member

*"There's **no way I would have been able to afford that medicine**, and I honestly would have been like, 'you know what, thanks for the diagnosis. I think I'll just have to deal with what I have.'"*

MS PERC member

Non-medical switch

Patients feeling resigned around non-medical switch

*"...you get put into kind of a queue of everybody else that's going through the same thing, and it's **sometimes easier just to switch it** [prescription], even though that's not easy. Sometimes it's easier just to switch it and pick my battles. I'm never gonna win."*

PsA PERC member

"[NMS means] people who are not licensed to practice healthcare have made decisions ... regardless of whether your quality of life is taken into account or not.

***They're not practicing medicine. They're practicing finance**."*

IBD PERC member

Utilization management

Patients feel they have to 'suffer to prove' that they deserve treatment

*"Insurance and protocols [exclusion lists] are trying to take away my feelings of hope. I want to be healthy and do what's best for my body, but I'm not being supported... **Healthcare shouldn't be a fight**."*

MS PERC member

*"My symptoms started coming back [during step edit]... I just feel **you have to suffer to prove yourself**... It was horrible. It was **the worst period of my life by far**."*

IBD PERC member

*"I had to start on the first biologic that was offered before, which wasn't as strong, before I could step up ... In between the time that you're switching drugs, you have to be off the first drug for at least two to three months... **So I just think about all that wasted time ... we could have been working on getting my diseases under control**."*

IBD PERC member

*"[It] doesn't help medically-wise with the body when you're adding the stress that I don't feel really needs to be there ... I **think they forget** that at times and so the **patients tend to spend a lot of time on the phone with insurance** and denials and then [it's] frustrating trying to get something processed through."*

BICa PERC member

BlCa, bladder cancer; **CVM**, cardiovascular and metabolic diseases; **IBD**, inflammatory bowel disease; **MS**, multiple sclerosis; **NMS**, non-medical switch; **PERC**, Patient Engagement Research Council; **PsA**, psoriatic arthritis.

Sharing patient insights on US healthcare policy

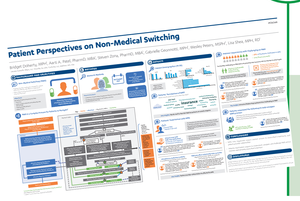
In 2023, PERC participant policy insights were utilized in various aspects of Janssen's policy work

February 2023

Prior authorization findings incorporated into a comment letter sent to the CMS during their finalization of the 2024 policy and technical changes to CMS-4201-P*[8]

September 2023

Patient co-authored manuscript highlighting how patients felt co-pay cards supported adherence to prescriptions and maintaining treatment published by *Journal of Market Access & Health Policy*[10]



June 2023

Poster presented at ISPOR 2023 showcasing experiences and impacts of NMS, including the impact on patient-provider relationships and feelings of insurance fatigue

November 2023

Patient forum on utilizing patient engagement perspectives in the development and implementation of policy research at Pharma & Patient USA 2023 (Reuters Events)

*Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, Medicare Parts A, B, C, and D, Overpayment Provisions of the Affordable Care Act, Programs of AllInclusive Care for the Elderly, and Health Information Technology Standards and Implementation Specifications

CMS, Centers for Medicare & Medicaid Services; **ISPOR**, International Society for Pharmacoeconomics and Outcomes Research; **NMS**, non-medical switch.

Conclusions

- Patient experience can enhance understanding around how policy impacts patient access to (or experience with) healthcare
- As patients are experts in their disease area, their experience and perspectives should be included in scientific publications to provide the lived experience around policy decisions
- These results highlight how developing internal capabilities and processes are critical to better incorporate the patient voice into policy making and evaluation

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Disclosures

DC is an independent consultant and a contract consultant with Janssen Scientific Affairs, LLC, a Johnson & Johnson company, and has been diagnosed with multiple sclerosis; **LS** and **BD** are employees of Janssen Scientific Affairs, LLC, a Johnson & Johnson company. **WP** is an employee of Thermo Fisher Scientific, Inc. (formerly CorEvitas, LLC), which derives its profits from interactions with pharmaceutical sponsors.

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