The evolution of patient-centered outcomes research

Caroline Halford, Adis Publishing Manager
Email: caroline.halford@springer.com

MedComms Networking Event, 2 November 2016
www.MedCommsNetworking.com
The Patient-Centered Outcomes Research Institute (PCORI) defines **patient-centered outcomes research** as:

“Help[ing] people and their caregivers communicate and make informed health care decisions, allowing their voices to be heard in assessing the value of health care options.”
Shift from disease-centric to patient-centric…. Why?

• **Poor medication adherence** in the real-world
  
  • 50% of patients do not take their medications as prescribed
  
  • In the US, nonadherence to medications causes 125,000 deaths annually and accounts for 10% to 25% of hospital and nursing home admissions
  
• Negative perceptions about clinical trials have meant **low engagement and sub-optimal retention within clinical trials**

• Increasing **consumerization of healthcare**

ISMPP 2015 meeting slides
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3068890/
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1681370/
Shift from disease-centric to patient-centric.... Why?

• Poor medication adherence in the real-world
  
  • 50% of patients do not take their medications as prescribed
  
  • In the US, nonadherence to medications causes 125,000 deaths annually and accounts for 10% to 25% of hospital and nursing home admissions

COMMUNICATION IS KEY

ISMPP 2015 meeting slides
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3068890/
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1681370/
“Often, new products are created or healthcare delivery process changes without incorporating patient input. This can lead to a solution that is not helpful to patients.”

Vera Rulon, Director, External Medical Communications, Pfizer

http://www.pharmavoice.com/article/patient-engagement-0615/
Development of patient-centred outcomes research (PCOR)

• **1990s**: Patient-centricity entered the lexicon

• **2001**: IOM designated "patient-centeredness" as a goal for 21st century health care

• **2010**: Patient Protection and Affordable Care Act 2010 places new emphasis on measuring patients’ experiences of care and using that information to improve care

• **2010**: PCORI established by congress. Recognises that:
  • Research has not yet answered the many questions that patients face
  • People want to know which treatment is right for them
  • Patients need information that they can understand and use

• **2016**: EMA mandates patient summaries for all clinical trials

**Pharma are now actively involved in partnering with patients**

Global patient engagement market is estimated to reach $13.7 billion by 2019

https://www.scholarsstrategynetwork.org/sites/default/files/ssn_basic_facts_cleary_on_patient-centered_care_0.pdf

ISMPP 2015 Annual Meeting
Example of social media engagement: Celgene’s “Life’s an Itch”
AZ: Patient-reported opinions about clinical tolerability (PROACT)

- Patient-clinician communications tool.
- Pilot study for patients recruited to phase 1 oncology trials in the UK
- Messages analyzed and anonymized - made available to the sponsor in an analytics module for decision-making.
- Patient focus group was engaged to provide feedback on communication needs during early clinical trials and the PROACT concept.

Many more examples of patient involvement during the R&D phases!

- **EUPATI 2014 case reports**
- **GSK**: Qualitative interviews around psoriasis “before the novel device was further developed and to confirm that indeed the device concept would appeal to patients.”
- **Amgen**: Migraine Panel “to make participation in clinical trials more accessible for migraine patients”
- **Janssen**: HIV patients involved in every step of the R&D process (research to post-launch)
- **Merck**: Qualitative patient interviews to understand impact of living with a disease, to inform development of novel treatments
- **Novartis**: Advisory Board meeting with patient organizations to address patient-relevant endpoints

ISMPP 2015 meeting
https://www.eupati.eu/workshop/workshop-interaction-patients-regulators-industry/
**The Patient: Patient-Centered Outcomes Research**

- **Co-editors in Chief:** John Bridges and Chris Carswell
- **Published in Association with** Johns Hopkins Bloomberg School of Public Health
- **Aims and scope:** To publish outcomes research to enhance therapy in a patient-centered manner.
  - To examine the needs, values and role of the patient in an increasingly complex healthcare landscape in which funding and decision-making are requiring ever-greater awareness of the patient’s perspective.
- **Impact Factor:** 2.227.
BMJ’s Patient Partnership initiative

- Launched 2014
- Patient advisory panel, editorial board, editor
- Authors should document how they involved patients in the study and in the dissemination of study results
- Patient peer review (alongside scientific peer review)
- Patient blogs
- “What your patient is thinking” series
- Authors asked to co-produce educational papers with patients

http://www.bmj.com/campaign/patient-partnership
BMC’s Research Involvement and Engagement

- “An interdisciplinary, health and social care journal focusing on patient and wider involvement and engagement in research, at all stages.”
- First journal co-produced by all key stakeholders (patients, academics, policy makers and service users).
- Editors in Chief:
  - Sophie Staniszewska: leads PPI and Experiences of Care Programme at the RCN Research Institute, University of Warwick.
  - Richard Stephens: survivor of two cancers, a heart emergency and sundry of other health challenges.
- Open peer review by patients and academics.
- All articles require a Plain English summary
Pharmacotherapy for Weight Loss, and Eating Behavior: a Patient and Physician Perspective

Authors
Piper L. Miguel, E.V. Ed J. Hendrick

Abstract
This article, co-authored by a patient and physician who regularly encounters and treats individuals with obesity and with her frustration living with the disease, discusses the application of pharmacotherapeutic interventions in managing weight and eating behavior. The patient details the challenges of maintaining a significant weight loss and how these challenges can be managed through proper diet and exercise programs. The physician discusses the application of pharmacotherapy in the context of a team approach to patient care and highlights the importance of patient education. The article concludes with a discussion on the potential benefits and risks associated with the use of pharmacotherapeutics in the management of obesity.

Living with Psoriatic Arthritis: A Patient’s and Physician’s Perspective

Authors
Alan Simmons, J. A. Fleischmann

Abstract
This article, co-authored by a psoriatic arthritis (PsA) patient and a physician who regularly encounters and treats PsA patients, discusses the patient’s experience of living with the disease, from diagnosis through living with the disease day-to-day and other people’s reactions to their treatment experiences and responses. The physician adds to this by providing his experiences in treating PsA with biologics, and the importance of patients working together with their rheumatologists to maximize the efficacy of treatments and improve patients’ quality of life.

Keywords
The Patient’s Guide to Psoriasis Treatment. Part 3: Biologic Injectables

Abstract

Part 1: UVB Phototherapy

http://link.springer.com/journal/13555/topicalCollection/AC_7fe0c06d51bf15e930b6cda6b462602c
Rise in patient-friendly dissemination of data

• Cochrane reviews: plain language summaries (PLS)
  • Authors must supply PLS for each Cochrane systematic review. Available in several different languages.

• Annals of Internal Medicine: "Summaries for Patients"
  • Brief, non-technical summaries of studies and clinical guidelines.

• JAMA: For patients
  • ‘Patient pages’ - collections of articles for patients.

• Elsevier:
  • Some journals now publishing patient lay summaries
  • Patient Engagement Solutions

• More
  • More journals are publishing PLS and patient-friendly materials

Don’t forget the EMA patient lay summaries!
Conclusion

• Drug developers are now moving towards a co-creation setting between manufacturers, HCPs and patients/patient advocacy groups
• Many opportunities to partner with your clients with PCOR
• Look out for what patient advocacy groups are saying
• Watch out for patient conferences (e.g. Patient Summit)
• Sign up for alerts, e.g. EUPATI, ISMPP (webinars, meetings)

• Publishing PCOR
  • There are many journals that welcome PROs or PCORs
  • There are also opportunities to publish patient resources
  • Journals may be looking for evidence of PCOR in the future. And if they aren’t – patient groups might be
• EMA-mandated patient lay summaries are imminent
Contact details

**Caroline Halford**
Adis | Springer Healthcare Ltd
Adis Publishing Manager

---

Springer Healthcare Ltd | Chowley Oak Business Park | Tattenhall | Chester | CH3 9GA, UK
Tel: +44 (0)1829 772741
E-mail: caroline.halford@springer.com

---

[www.springer.com/adis](http://www.springer.com/adis) and [www.adis-rapidplus.com](http://www.adis-rapidplus.com)
Follow us on Twitter: [www.twitter.com/AdisRapidPlus](http://www.twitter.com/AdisRapidPlus) or [www.twitter.com/AdisJournals](http://www.twitter.com/AdisJournals)