



The evolution of patient-centered outcomes research

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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**

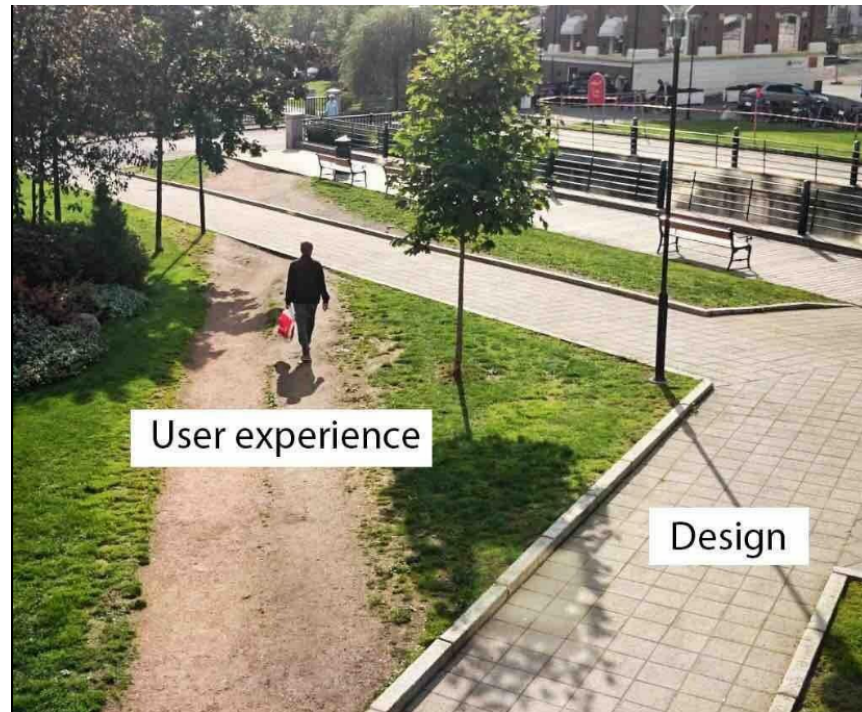
http://www.medscape.com/viewarticle/763663?src=trendmd_pilot&trendmd-shared=1
<http://hitconsultant.net/2014/10/06/patient-engagement-market-reach-13-7b-by-2019/>
ISMPP 2015 meeting slides
<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3068890/>
<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1681370/>

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COMMUNICATION IS KEY

http://www.medscape.com/viewarticle/763663?src=trendmd_pilot&trendmd-shared=1
<http://hitconsultant.net/2014/10/06/patient-engagement-market-reach-13-7b-by-2019/>
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“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

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

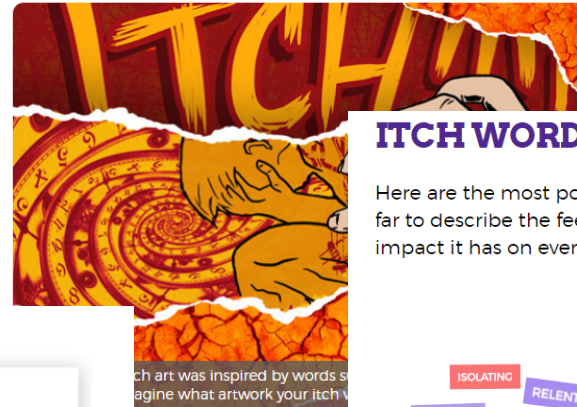
Pharma are now actively involved in partnering with patients

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

Example of social media engagement: Celgene's "Life's an Itch"

INTRODUCING...

Life's an
ITCH



ITCH WORD CLOUD

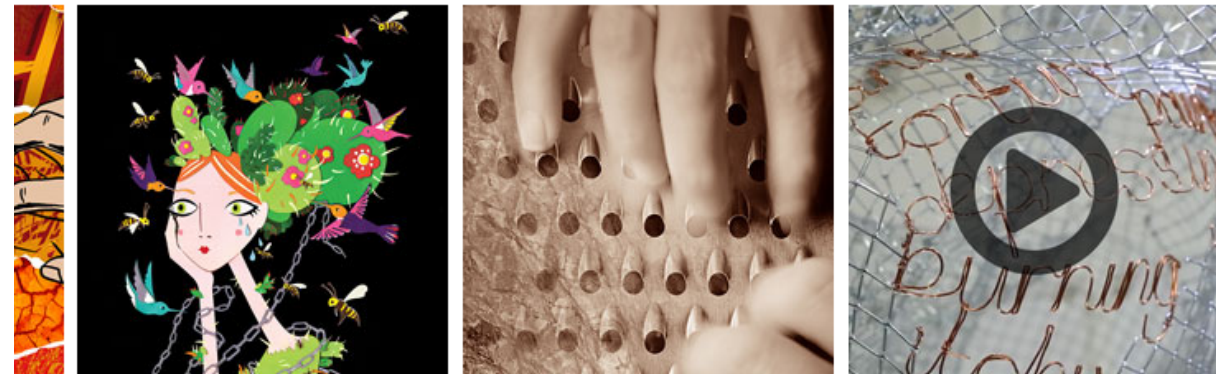
Here are the most popular words used so far to describe the feeling of itch and impact it has on everyday life.

Key PHYSICALLY SOCIALY EMOTIONALLY



Art was inspired by words you use to describe what artwork your itch looks like.

Art:



Life's an ITCH Discussion Tool

This tool can be used as a discussion aid for people with psoriasis during consultations with your GP / Nurse or Dermatologist.

Where does your psoriasis 'itch'?
Please shade the areas of your body where you most frequently experience 'itch'.

How often do you experience 'itch'?
Tick the box which applies.

At what times of the day do you normally experience 'itch'?
Tick all those that apply.

What factors make your 'itch' worse?
Tick all those that apply.

How intense/painful is your 'itch'?
Mark on this scale the level which indicates the intensity of your 'itch'.

How does it make you feel when your psoriasis is itching?
Tick all those that apply.

Does 'itch' have an impact on your sleep?
If so, how would you describe that impact?

AZ: Patient-reported opinions about clinical tolerability (PROACT)



- “Development and Evaluation of a New Technological Way of Engaging Patients and Enhancing Understanding of Drug Tolerability in Early Clinical Development: 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

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

BMC's *Research Involvement and Engagement*



- *“An interdisciplinary, health and social care journal focussing 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

Adis Rapid+ journals: patient/physician perspective articles



[Advances in Therapy](#)
July 2016, Volume 33, [Issue 7](#), pp 1262-1266

Pharmacotherapy for Obesity and Eating Behavior: a Patient and Physician Perspective

Authors [Authors and affiliations](#)

Piper L. Miguelgorry, Ed J. Hendricks 

[Open Access](#) | [Commentary](#)
[First Online: 31 May 2016](#)
[DOI: 10.1007/s12325-016-0349-y](#)

Part of the following topical collections:

- [Patient and Physician Perspectives](#)

Abstract

This article, co-authored by a patient and a medicine specialist, discusses the patient's experience with obesity and with her frustration living with the disease. The specialist physician who helped her lose weight discusses the importance of maintaining a significant weight loss and the application of diabetes reversal in such cases. He also discusses his case.



[Rheumatology and Therapy](#)
June 2016, Volume 3, [Issue 1](#), pp 1-4

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

Authors [Authors and affiliations](#)

Alan Simmons, Roy Fleischmann 

[Open Access](#) | [Commentary](#)
[First Online: 19 December 2015](#)
[DOI: 10.1007/s40744-015-0024-9](#)

Cite this article as:
 Simmons, A. & Fleischmann, R. Rheumatol Ther (2016) 3: 1. doi:10.1007/s40744-015-0024-9

 
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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


Dermatology and Therapy: Psoriasis Patient Resource series



[Dermatology and Therapy](#)
September 2016, Volume 6, [Issue 3](#), pp 325–331

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

Authors [Authors and affiliations](#)

Michael Abrouk , Mio Nakamura, Tian Hao Zhu, Benjamin Farahnik, Rasnik K. Singh, Kristina M. Lee, Margareth V. Jose, John Koo, Tina Bhutani, Wilson Liao

[Open Access](#) | PATIENT GUIDE

First Online: [29 July 2016](#)

DOI: [10.1007/s13555-016-0131-8](#)

Cite this article as:

Abrouk, M., Nakamura, M., Zhu, T.H.
Dermatol Ther (Heidelb) (2016) 6: :
[doi:10.1007/s13555-016-0131-8](#)

Part of the following topical collections:

- [Psoriasis Patient Resources](#)

Abstract



Part 1: UVB Phototherapy

CLOSE 

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

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