Developing and Timing of Scientific Communications That Are Meaningful to Patients

Presented by the MAPS Patient Centricity FAWG

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Learner Outcomes

Be able to articulate why it’s important to consider a patient community audience when planning scientific and data dissemination, including incorporating their voice within it

Be confident to follow clear methodologies to incorporate the patient voice within publications and educational materials for disease state, unmet medical needs, etc

Be able to **implement best practice approaches,** including novel ways to disseminate information

Agenda

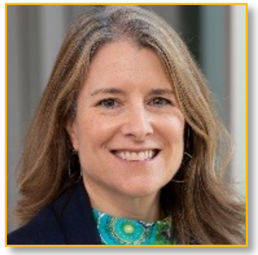
- Speaker Introductions
- Patient Community Perspectives
- Rationale
- Methodologies and Best Practices
- Real-world Examples
- Meeting Future Ambitions
- Q&A

Speaker Introductions

Tricia Gooljarsingh
VP, Medical Affairs
Fulcrum Therapeutics

Gavin Jones
Patient Engagement Lead
Lumanity

Tracy Hart
CEO
Osteogenesis Imperfecta Foundation



Alia Bucciarelli
Sr. Director Medical Affairs
Vertex Pharmaceuticals

Patient Community Perspectives

The Work Begins Early…

All patient **communities are different**

Some come to the research process **“clinical trial ready”**; some don’t

Get to know the patient communities – how they communicate internally and who the “influencers” are in the community

Work to include all patient advocacy groups in your outreach

If patient advisory panels haven’t been created… create them… **it’s an important first step!**

Communicating Data

Putting information in lay language is important but not instead of the scientific information

Use the patient advisory panels to help you develop and disseminate the information to the community

If a patient advocacy group uses social media well…**use their channels to communicate**

Know and use all communication vehicles the patient advocacy group has available

Educate the leaders of the patient advocacy groups as a separate activity – especially the board of directors

Communicating Data (cont.)

From the patient advocacy group experience – things that work:

Community updates using the **PAG YouTube channel or their website online education site**

Include industry representatives in **PAG sponsored scientific meetings; conferences and meetings**

Where appropriate, **publish information in PAG newsletters, e-news and other publications** that patient community members receive directly

Encourage industry not to “go around” patient advocacy groups and **go straight to the patient community through social media**

Trusting the Information…

Patient communities, regardless of their experience with clinical trials, are extremely well educated about their own disorder, especially those with a rare disease

Using language that shows you know the community will help gain their trust – use person first language, know the Quality of Life challenges in the disorder/disease; never assume the patient experience is the same

When possible, **use a company spokesperson with a member of the patient community** to disseminate information

The End Game…

At the end of the day, the information is what it is and needs to be communicated accurately and without bias

Patient communities may be disappointed at less than favorable results **but they will appreciate information on the "why"**

And when the information is positive **be sure to always put an action step in the communication…**what's next and what can we do as partners to make sure the information on the new therapy is available to all

Rationale

Patient Ownership of Their Own Health Outcomes

> **“Patient communities, regardless of their experience with clinical trials, are extremely well educated about their own disorder, especially those with a rare disease”**

- **Requirement to meet people’s demand for information** that can impact their health decisions
- **Recognising the shifting relationship dynamics** between patients, caregivers, and their respective healthcare professionals
- **Meeting the demand for greater accessibility** and accuracy to information to educate and sustain hope
- **Overcoming** the swathes of **inaccurate and indeed potentially dangerous information** easily accessible within the internet
- **Meeting patient community trust** in the experiences of others living and being treated to manage health conditions

Harnessing the Value of Cocreation

> **“Use patient advisory panels to help you develop and disseminate the information to the community”**

- No one knows **a patient community’s needs** better than their peers
- A partnership of scientific accuracy and patient community insights will **deliver optimal education**
- Patient organizations, advisory panels and individual advocates can help **develop accessible and meaningful information**
- **Cocreation build stronger partnerships with shared outcomes** for better education and outcomes
- **Supporting HCPs in meeting patients where they are on the educational journey** will further improve consultations, individualized healthcare decisions and outcomes

Regulatory Body Initiatives Adding to Rationale for Thoughtful Action

Food and Drug Administration’s Center for Drug Evaluation & Research Patient Focused Drug Development Program

- **Facilitating and advancing use of systematic approaches** to collecting and utilizing robust and meaningful patient and caregiver input to more consistently inform drug development and regulatory decision-making
- Encouraging identification and use of approaches and best practices to facilitate patient enrollment and minimizing the burden of patient participation in clinical trials
- **Enhancing understanding and appropriate use** of methods to capture information on patient preferences
- **Identifying the information that is most important to patients** and how to best communicate the information to support their decision-making

European Medicines Agency recommencement of EMA Policy 0070

- Intended to **make clinical trial data more accessible to patients** to support better decision-making
- After a long gestation period **this initiative was restarted in September 2023**

Methodology

Methodology

a. Compliance
b. Accuracy of information
c. Dual audience (non-specialty HCP & patients)
d. Consideration of health literacy, learning principles
e. Accessibility of information

Compliance

1. Policies and processes for partnering with patients

- Organizational patient interactions/engagement policy/SOP
- Patient engagement framework and organization’s risk tolerance
- Sustained legal and ethics counsel. If in doubt consult early with them!

2. Generation of publication plan and system/process to cocreate content (MLR or Pubs Review)

- Publication planning ensures there are no surprises and rogue publications
- Adequate resources are available
- Appropriate timing of publications and materials
- Process to engage patients early at conceptual stage and then content generation stage
- Quality checks and final reviews from authors and senior personnel

Accuracy of Information

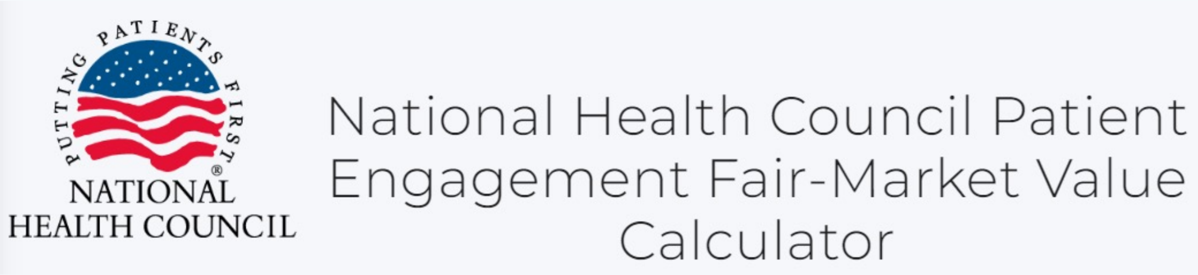
- **Inclusion of authors who are knowledgeable of medicine/science from conception through content creation and final approval**
  - Publications should have a publications review process and final review and sign off for all publications
  - All other educational materials should ensure that a MLR (Medical Legal Regulatory) review process is in place. Oftentimes IRB (Institutional Review Board) review and approval is also necessary
  - Quality check of references from primary source and data from original files
  - Ensure the materials are balanced with the benefits/risks clearly elucidated

The accuracy of the data is central to the narrative!

Compensating Patients for Their Expertise

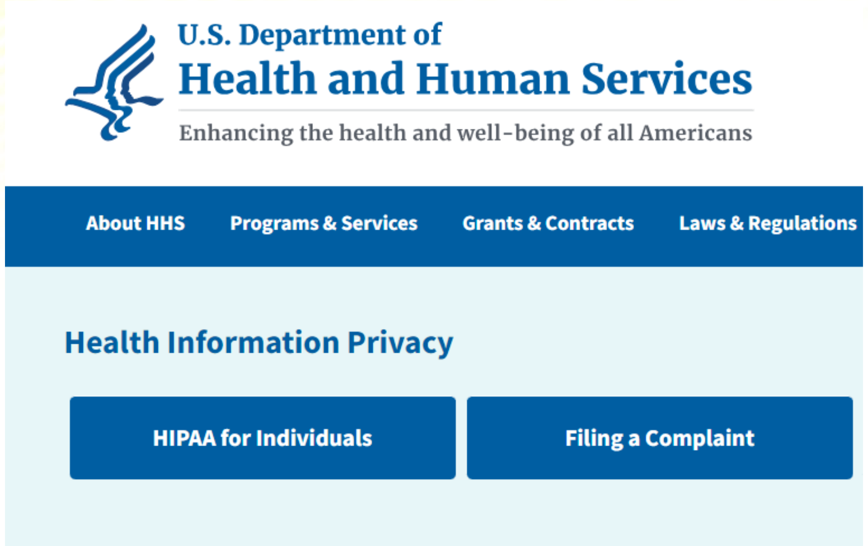
- Patients are experts in their condition
- Whilst current guidance recommends that we should not remunerate patients as co-authors, we can compensate them for their insights in planning and developing publications and other educational materials
- There are tools available that allows us to determine the Fair Market Value for compensation
- One such tool was developed by the National Health Council

https://nationalhealthcouncil.org/fair-market-value-calculator/



National Health Council Patient Engagement Fair-Market Value Calculator

Protecting Sensitive Patient Information



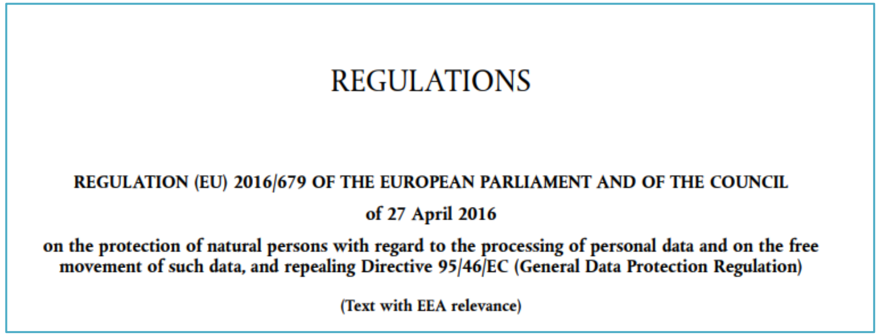
U.S. Department of
Health and Human Services
Enhancing the health and well-being of all Americans

Health Information Privacy

Protecting sensitive patient medical information

- Shared drives, sharepoints, spreadsheets with sensitive information is highly restricted, firewalled, password protected, etc

HIPPA:
https://www.hhs.gov/hipaa/index.html



REGULATIONS

REGULATION (EU) 2016/679 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 27 April 2016

on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation)

(Text with EEA relevance)

- ✓ Personal data protection
- ✓ Storage
- ✓ Permissions etc

GDPR:
https://gdpr-info.eu/

Health Literacy Is Important

Health literacy is defined as "the ability to **find**, **understand**, and **use** information and services to inform health-related decisions and actions" – *Healthy People 2030*[1]

- Health information and messages are often overly complex, making them difficult to comprehend[1]
- Patients receive information at different levels of scientific depth from various sources, leading to confusion[1]
- Only 12 percent of US adults have proficient health literacy and more than a third of US adults would have difficulty with common health tasks, such as following directions on a prescription drug label[2]
- Low health literacy is associated with a range of adverse health effects, including increased mortality, poorer self-reported health status, greater use of emergency services, higher rates of chronic diseases, and adoption of unhealthy behaviors[3]

Higher health literacy appears to positively influence health through better understanding and shared decision-making. Health organizations and systems play a critical role in health literacy because they can make it easier or more difficult for people to find, understand, and use health information and services.

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1. U.S. Department Of Health and Human Services. Healthy People 2030. https://health.gov/healthypeople/priority-areas/health-literacy-healthy-people-2030. Accessed April 2023.
2. America's Health Literacy: Why We Need Accessible Health Information. An Issue Brief From the U.S. Department of Health and Human Services. 2008.
3. Effects of health literacy interventions on health-related outcomes in socioeconomically disadvantaged adults living in the community: a systematic review. *JBI Evidence Synthesis.*18(7):p 1389-1469, July 2020. I DOI: 10.11124/JBISRIR-D-18-00023

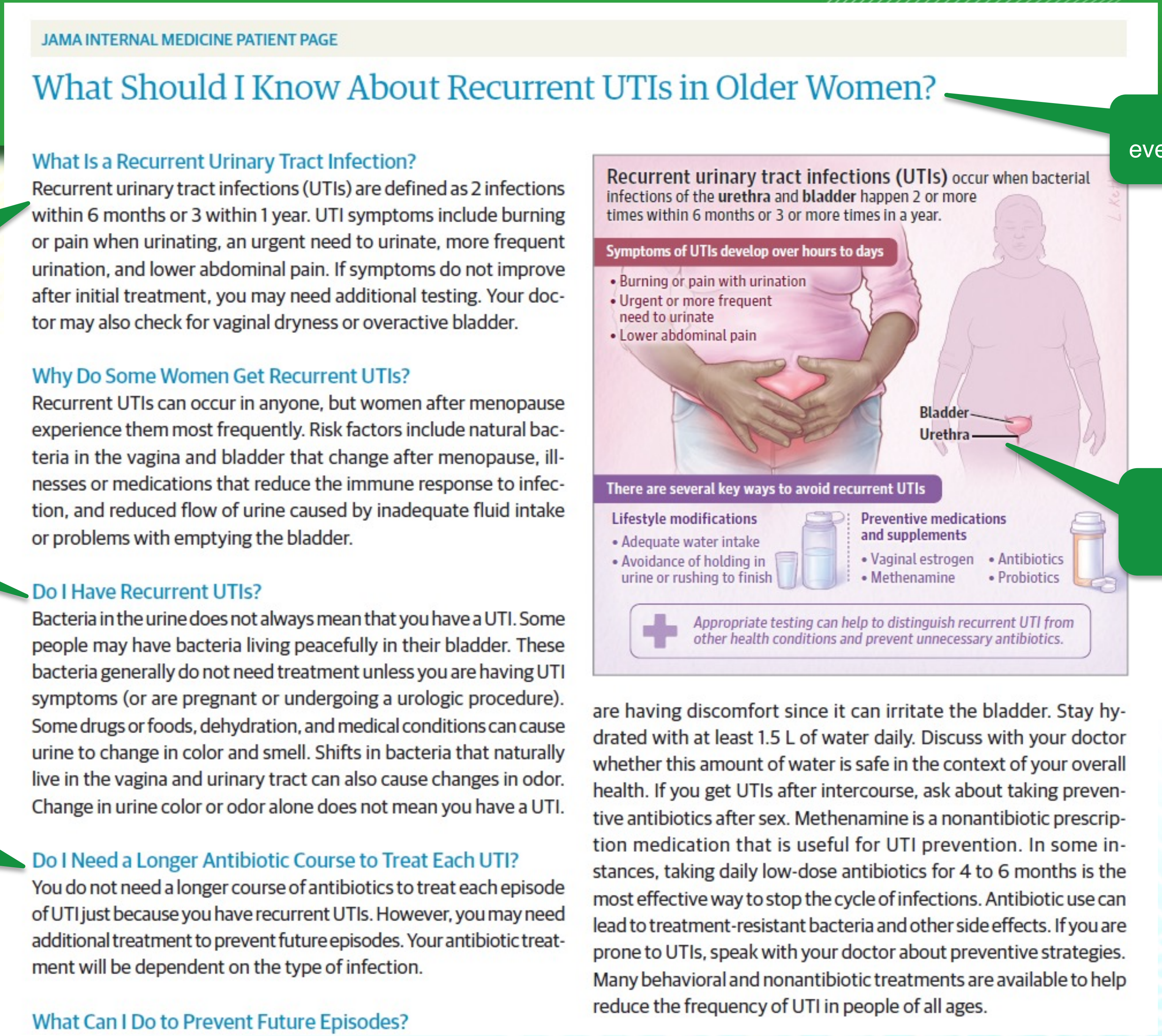
Developing Materials for Patients Looks Easy – It Takes Specialized Skills

Key Health Literacy Principles

- Know your audience and test/cocreate with them
- Follow plain language writing and design principles
  - ✓ Use common, everyday words
  - ✓ Use person-first or identity-first language
  - ✓ Write in active voice
  - ✓ Keep it short (words, paragraphs)
  - ✓ Use declarative headers
  - ✓ Use call-out boxes and lists
  - ✓ Choose the simplest chart for your data
  - ✓ Support content organization through layout
  - ✓ Use meaningful images, icons, and illustrations with labels
  - ✓ Use frequencies instead of decimals or percentages
  - ✓ Give absolute risk instead of relative risk

Key Adult Learning Principles

- "Teaching" should be learner-centered, according to their needs, objectives, and context
- Learners need clear goals and objectives of what they will achieve
- Content should be relevant and useful to real life and should be connected to experience and prior knowledge
- Learners should actively participate in learning



JAMA INTERNAL MEDICINE PATIENT PAGE

What Should I Know About Recurrent UTIs in Older Women?

Common, everyday words

What Is a Recurrent Urinary Tract Infection?

Recurrent urinary tract infections (UTIs) are defined as 2 infections within 6 months or 3 within 1 year. UTI symptoms include burning or pain when urinating, an urgent need to urinate, more frequent urination, and lower abdominal pain. If symptoms do not improve after initial treatment, you may need additional testing. Your doctor may also check for vaginal dryness or overactive bladder.

Short paragraphs

Why Do Some Women Get Recurrent UTIs?

Recurrent UTIs can occur in anyone, but women after menopause experience them most frequently. Risk factors include natural bacteria in the vagina and bladder that change after menopause, illnesses or medications that reduce the immune response to infection, and reduced flow of urine caused by inadequate fluid intake or problems with emptying the bladder.

Headers

Do I Have Recurrent UTIs?

Bacteria in the urine does not always mean that you have a UTI. Some people may have bacteria living peacefully in their bladder. These bacteria generally do not need treatment unless you are having UTI symptoms (or are pregnant or undergoing a urologic procedure). Some drugs or foods, dehydration, and medical conditions can cause urine to change in color and smell. Shifts in bacteria that naturally live in the vagina and urinary tract can also cause changes in odor. Change in urine color or odor alone does not mean you have a UTI.

Address reader directly

Do I Need a Longer Antibiotic Course to Treat Each UTI?

You do not need a longer course of antibiotics to treat each episode of UTI just because you have recurrent UTIs. However, you may need additional treatment to prevent future episodes. Your antibiotic treatment will be dependent on the type of infection.

What Can I Do to Prevent Future Episodes?

Recurrent urinary tract infections (UTIs) occur when bacterial infections of the **urethra** and **bladder** happen 2 or more times within 6 months or 3 or more times in a year.

Symptoms of UTIs develop over hours to days

- Burning or pain with urination
- Urgent or more frequent need to urinate
- Lower abdominal pain

There are several key ways to avoid recurrent UTIs

Lifestyle modifications

- Adequate water intake
- Avoidance of holding in urine or rushing to finish

Preventive medications and supplements

- Vaginal estrogen
- Methenamine
- Antibiotics
- Probiotics

Appropriate testing can help to distinguish recurrent UTI from other health conditions and prevent unnecessary antibiotics.

Meaningful illustrations with labels

are having discomfort since it can irritate the bladder. Stay hydrated with at least 1.5 L of water daily. Discuss with your doctor whether this amount of water is safe in the context of your overall health. If you get UTIs after intercourse, ask about taking preventive antibiotics after sex. Methenamine is a nonantibiotic prescription medication that is useful for UTI prevention. In some instances, taking daily low-dose antibiotics for 4 to 6 months is the most effective way to stop the cycle of infections. Antibiotic use can lead to treatment-resistant bacteria and other side effects. If you are prone to UTIs, speak with your doctor about preventive strategies. Many behavioral and nonantibiotic treatments are available to help reduce the frequency of UTI in people of all ages.

Accessibility of Information

Findable

- Landscape analysis to assess where patients go to access trusted information
- Websites and resources from **Community Based & Patient Advocacy Organizations** are typically most trusted
- Figshare is an option for self-publishing

Useable

- Consider the medium based on your audience
  - e.g. visual, motor/mobility, auditory, cognitive
- Leverage technology: phone, iPads
- Opt for bite-sized information
- Combine words, numbers, and graphics
- Audio as needed and appropriate
- Interactive for engagement, such as quizzes, gamification

Real-world Examples

Developing a Win/Win Partnership With Pharma

Challenge

- The OI community had little experience with clinical trials, and they were not used to hearing from industry.

Solution

- Ultragenyx patient advocacy staff worked with OIF to understand the OI community – they learned the best ways to communicate with the community, especially the community leaders.
- The OIF offered advice on language to use in materials and how to communicate with newly formed patient advisory panels.

Outcomes

Joint presentations, community calls, and webinars were held and were successful.

Educating Patients on the Results of a Clinical Trial

Challenge

- Data from rare neuromuscular disease to be released to patient community
- Complex data with endpoints not used in daily clinical practice

Solution

- Partner with Patient Advocacy Organization (PAO) for data release
- PAO not well versed in working with industry to release data so a lot of discussion prior to execution
- Principal investigator(PI) with experience educating patient community
- The PI explained how successfully meeting endpoints translated into meaningful clinical benefit
- Biotechnology company participated in Q and A

Outcomes

- Patients engaged and asked questions
- Post webinar survey was positive with patients eager to learn more about therapy and next phases of development
- This presentation opened up the gateway for the advocacy organization to conduct other clinical trial data readouts

Developing a Patient Lexicon to Improve Patient-facing Materials

Challenge

- People with rare diseases face a complex treatment landscape that can be difficult to navigate
- In rare disease space there are often fewer educational opportunities available to patients/caregivers
- Education materials can be overly complex and hard to understand

Solution

- Patient Lexicons to improve communication with patients and caregivers about their disease and treatment options.

We conducted research in four stages:

1. **Health Literacy Review** of terms used by the company
2. **Patient Material Audit** of patient-facing materials
3. **Social Listening** on Facebook, Twitter, Instagram, and Reddit
4. **Patient Testing** interviews in six countries

Outcomes

These lexicons provided clear, scientifically accurate, and consistent vocabulary for the creation of patient-facing materials across the organization.

By aligning internally on a vocabulary that clarified inconsistencies, complexities, and confusing language, we aimed to enhance dialogue between patients and their healthcare team.

Meeting Future Ambitions

Ambition 1: Enable Early & Consistent Engagement

Equip yourself and your colleagues **with the skills to effectively engage patient communities** (please see MAPS patient centricity FAWG training modules on this very topic!)

Collaborate closely with advocacy colleagues to set out an advocacy engagement plan optimising engagement

In first interactions, **focus solely on listening and trust building** rather than your initial needs

Recruit patient advocates onto advisory panels and publications steering committees as soon as its feasible

Maintain communication channels at a regular cadence

Ambition 2: Communicate Through Appropriate Channels With Meaningful Language

Develop a Lexicon for advocacy engagement to enable meaningful and understandable information exchange

Collaborate with PAGs to truly **meet the accessibility of the relevant patient audience**
Visual – Motor/Mobility – Auditory – Cognitive

Given the lack of conclusive evidence on the best format across patient populations, **it's best to codesign and validate with patients**

Work with PAGs to understand cohorts of less activated/engaged patients to **deliver inclusivity of education**

Ambition 3: Sustain Engagement and Cocreation

Develop a comprehensive communication timeline to provide two-way touch points at an appropriate cadence

Have **clear policies and protocols for advocacy partnering** to maintain the consistency of cross functional approaches

Involve patients in activities beyond co-authorship, eg, supporting PLS development or a podcast manuscript

Assess the impact of patient involvement and celebrate success!

Panel Q&A

Tools & Resources

- https://pemsuite.org/
- https://wecanadvocate.eu/patients-in-publications/
- FAWG patient Centricity Module/s:
  - https://medicalaffairs.org/patient-centricity-course/
  - https://medicalaffairs.org/ethics-compliance-and-governance-considerations-for-patient-engagement/
- Health Literacy - National Health Council
- The National Health Council Rubric to Capture the Patient Voice: A Guide to Incorporating the Patient Voice into the Health Ecosystem - National Health Council
- A Framework for Equity-Centered Health Communication
- The Patient Education Materials Assessment Tool (PEMAT) and User's Guide

Tools & Resources

- FDA_CDER_Patient Focused Drug Development
- External EMA Guidance Implementation of Policy 0070