

How to Develop Guidelines That Matter to Users

Guidelines with and for Users

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- PI for UF's Lewy Body Dementia Association Research Center of Excellence
- Member, Scientific Advisory Committee for Lewy Body Dementia Association
- Member, DSMBs for ATRI/ACTC and ADCS

Who are “Users”?

- Clinicians
- Patients
- Families, carers
- Consumers, general public
- Policy makers
- Researchers

Conceptual Reasons to Involve Users in Guideline Development

Patient & public involvement

Recognizes patients as experts

Rights of citizens in health policy development

Empowers & informs consumers

Development of more patient-centered & trustworthy guidelines

Different clinician types

Differing expertise

Clinicians have a role in specialty best practices

Empowers & informs users

Development of more relevant guidelines

Other users

Differing expertise

Implications for health policy

Empowers & informs users

Development of more relevant guidelines

Big Question #1:

Does it make a difference?

Insufficient resources

Need for training and support

Recruitment difficulties

Uncertainty of patient role

Does it make a difference?

Uncertainty of how to incorporate patient preferences

Patient representative feelings of isolation

Medical terminology

Difficulty recruiting representative participants

Big Question #2:

If you're going to do it, how should you do it?

Mechanisms for Engagement

	Consultation	Participation
Examples	Focus groups, interviews, surveys, public comment	Guideline development group participation, panel member
Flow of information	Unidirectional flow from consultant to guideline developers	Bidirectional exchange of information
Advantages	Can collect a variety of perspectives from a large group of people	<ul style="list-style-type: none">- Recognize unique expertise of users- Facilitate mutual learning and compromise
Disadvantages	<ul style="list-style-type: none">- Failure to recognize certain users (e.g. patients, public) as partners- Failure to give users active voice- Views offered may not undergo deliberation or inform decisions	Rely on involvement of a small number of representatives, potentially missing perspectives of uninvolved parties

Investigating the effect of PPI on guideline question development

STEP 1: Pragmatic parallel group study
Participation



Proposed guideline questions
(physician-only group)



Proposed guideline questions
(group with PPI)

STEP 2: Survey of patient representatives, physicians
Consultation

STEP 3: Public comment
Consultation

STEP 4: Finalization of guideline questions
Participation

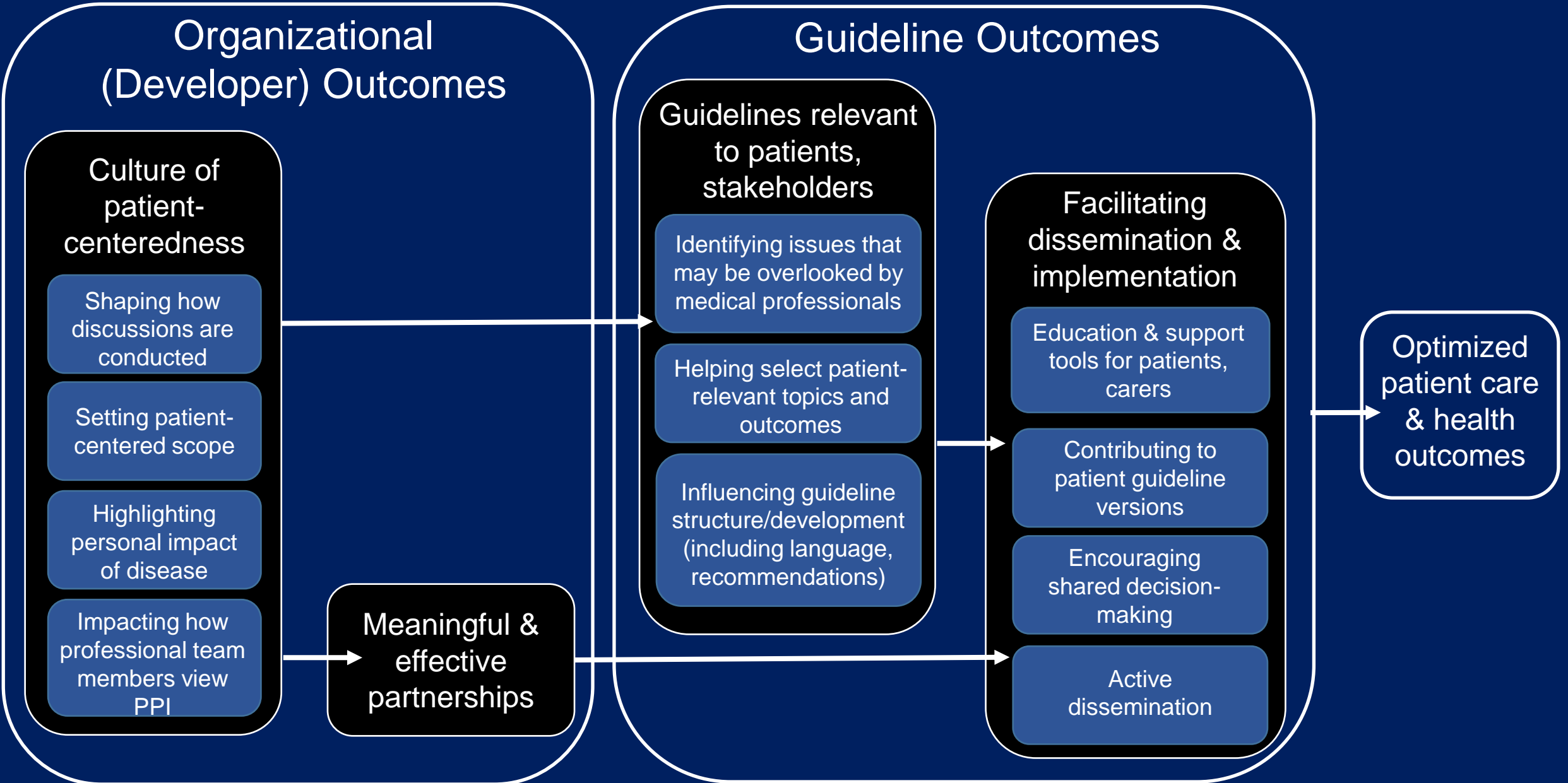
Final guideline questions
(combined group)



Parallel Group Study Results

- Proposed elements of PICOT questions largely similar between groups
- Proposed benefits and harms were largely similar between groups
 - Only group with patient engagement proposed outcomes relating to development of cognitive impairment at certain time points & progression rates
- PPI influenced:
 - Meeting conduct
 - Guideline scope
 - Inclusion of patient-relevant topics
 - Outcome selection
 - Planned approaches to recommendation development, implementation, dissemination

Conceptual model of outcomes of patient involvement in guideline development



Armstrong MJ, et al. Impact of patient involvement on clinical practice guideline development: a parallel group study. Implementation Sci 2018 13:55.

Survey of Stakeholders

- Surveyed clinicians, patients, caregivers and dementia advocates on topics relating to an evidence-based guideline on amyloid PET use
 - Topic importance was rated on a 9-point scale (GRADE)
- Patient representatives (n=107) rated all survey topics as equal to or more important than clinicians (n=114)
 - Except one item discussing potential harms of false positive diagnoses
- Differences between patient representative and clinicians were greatest when assessing:
 - Competing values of false positive and negative diagnoses
 - Value of testing asymptomatic individuals

Public Comment

- 30-day public comment period
 - Used brief protocol written in lay language
 - Included PICOT questions from both groups, proposed inclusion/exclusion criteria, key definitions, funding information, proposed author panel, disclosures
- Dissemination through American Academy of Neurology (community-wide email), outreach to other stakeholder organizations
 - American Geriatric Society, Alzheimer Association, Alzheimer Foundation of America
- 54 respondents: 35 neurologists, 1 neuro-radiologist, 1 research scientist, 17 anonymous individuals (at least 2 were patient/public)
 - Group of researchers also sent a letter to AAN during public comment period

Public Comment

- Multiple respondents voiced concern about inclusion of asymptomatic populations without cognitive symptoms
 - Test not approved for that population, outside scope of appropriate use criteria, such testing would be “ahead of its time”
- Respondents advised highlighting subtypes of other populations
- Respondents were concerned about looking at prognostic (rather than diagnostic) use of test
- Respondents voiced concern that there would not be data to answer the posed questions
- Various other comments
 - Is amyloid PET even worthwhile, how should it be graded, incorporating other diagnostic tests, etc.

Second Guideline Question Retreat

- Patient representatives accounted for 9.4% of transcript
 - Shaped how discussions were conducted, helped set patient-centered scope, highlighted personal aspect of disease, identified issues that might be overlooked by medical professionals, helped select patient-relevant topics and outcomes
- Public comment affected group discussions and nuances of final guideline questions
- Survey: Professional participants saw survey results as confirming patient-centered themes from original question development retreat
 - Importance of a diagnosis, importance of prognosis, including expected rate of decline, relevance of test for asymptomatic individuals, knowing results
 - Result: these themes kept even though negative public comment feedback

Contributions of Participation & Consultation Strategies on Guideline Question Development

Contribution	Participation	Consultation
Shaping how discussions are conducted	X	
Setting patient-centered scope	X	X
Highlighting personal impact of disease	X	
Impacting how professional team members view PPI	X	X
Identifying issues that may be overlooked by professionals	X	X
Helping select patient-relevant topics and outcomes	X	X
Confirming opinions of, and relevance to, a large group of patient stakeholders		X

Armstrong MJ, et al. Participation & consultation engagement strategies have complementary roles: a case study of PPI in CPG development. *Health Expectations* 2020; 23(2):423-432.

Limitations

- Patient representatives raised topics not clearly linked to guideline
 - Identifying issues overlooked by medical professionals vs unnecessary use of time
- Professional panelists used a small amount of time to answer patients' technical questions
- Developer time dedicated to creating a patient- and public-friendly protocol for public comment
 - But most people responding via public comment were professionals
- Survey was more successful PPI consultation strategy but required extra resources for development and dissemination

Editorial

Patient Engagement and Multidisciplinary Involvement Has an Impact on Clinical Guideline Development and Decisions: A Comparison of Two Irritable Bowel Syndrome Guidelines Using the Same Data

Abstract

Background and Aim: The value of a multidisciplinary group and patient engagement in guideline groups is uncertain. We compared the recommendations of two guidelines that used the same data during the same time frame but with different participants to obtain a “real world” perspective on influence of the composition of guideline groups.

Methods: The Canadian Association of Gastroenterology (CAG) and the American College of Gastroenterology (ACG) recently updated their clinical practice guidelines for the management of Irritable Bowel Syndrome (IBS). Both the CAG and ACG used the same methodology and methodology and were presented with the same data for interpretation. The ACG group consisted of predominantly academic gastroenterologists, while the CAG group also included general practitioners, a psychiatrist, a psychologist and a patient representative. The CAG group were also asked what components of the group were valuable.

Results: There were 14 statements with the same or similar recommendations. There were 10 statements in the CAG guideline not addressed by the ACG guideline and five recommendations where the opposite was the case. There was one statement that the two groups both addressed, but each group came to different conclusions. CAG members were in 100% agreement that involving a patient and having a multidisciplinary team was valuable and may have played a role in these differing interpretations of the same data in an IBS guideline.

Conclusions: There has been little uptake of patient involvement and multidisciplinary teams in guideline groups. However, this study provides a unique example of added benefit through broader group representation.

Keywords: *Clinical practice guidelines; IBS; Irritable bowel syndrome; Multidisciplinary team; Patient engagement*

Answers to the Big Questions

- Does it make a difference?
 - Shapes how discussions are conducted
 - Helps set patient-centered scope
 - Highlights personal impact of disease
 - Impacts how professional team members view PPI
 - Identifies issues that may be overlooked by professionals
 - Helps select patient-relevant topics and outcomes
- If you're going to do it, how should you do it?
 - Combined engagement + consultation