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How Patients Make Decisions Regarding Therapy

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Canada Future Directions in IBD

Saturday, November 7, 2020

IMAGINE
Inflammation, Microbiome & Alimentation
Gastro-Intestinal & Neuropsychiatric Effects

Objectives

Discuss key concepts in how patients make decisions

Discuss the concepts of shared decision-making

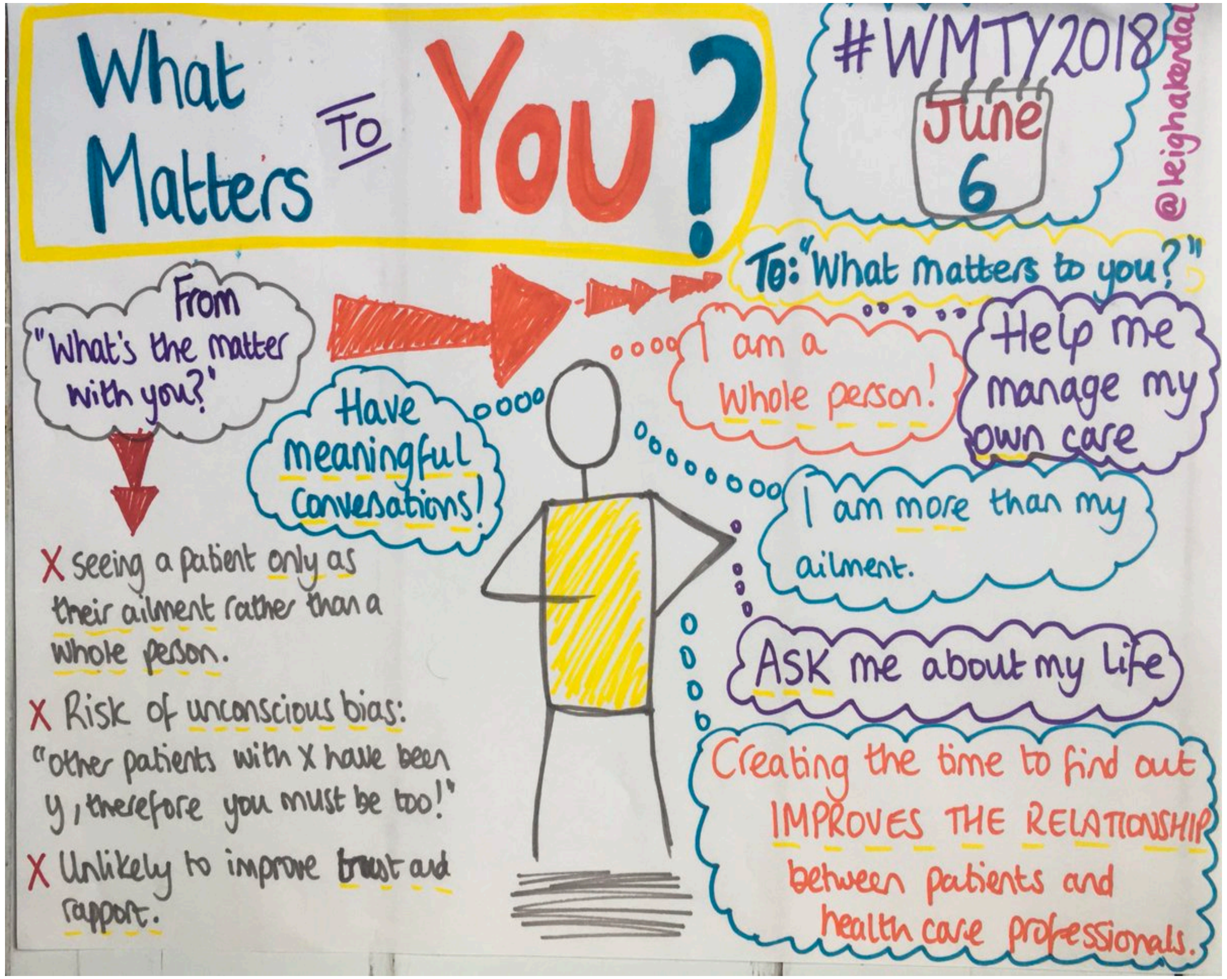
POLL
#1

Overall, how do you think most IBD patients would answer the following question: What would be your preferred approach to IBD treatment decision-making?

- ☐ I decide on my own
- ☐ I decide on my own after hearing from my healthcare provider
- ☐ It’s a shared decision between myself and my healthcare provider
- ☐ My healthcare provider decides for me

What matters most to you?

http://www.ihi.org/Topics/WhatMatters/Pages/default.aspx



What Matters To You?

#WMTY2018

June 6

@leighakendal

From "What's the matter with you?"

To: "What matters to you?"

Have meaningful conversations!

I am a Whole person!

Help me manage my own care

I am more than my ailment.

ASK me about my Life

Creating the time to find out IMPROVES THE RELATIONSHIP between patients and health care professionals.

X seeing a patient only as their ailment rather than a whole person.

X Risk of unconscious bias: "other patients with X have been y, therefore you must be too!"

X Unlikely to improve trust and rapport.

P002

IBD Partnerships: Understanding Patients vs.Clinicians Perspectives of IBD Treatment Options to Improve Shared Decision-Making

Sandra Zelinsky[1], Catherine Finlayson[2], John Chen[2]
[1]Independent Consultant, University of Calgary, AB., Patient Engagement Platform, Imagine SPOR, Canada [2] Takeda Canada Inc.

Introduction

IBD Partnerships is a novel, patient-led, mixed methods project with support and collaboration from IBD patients, clinician-scientists, and industry.
Phase 1 of the IBD Partnerships project is driven by patient perspectives to capture what matters most to IBD patients when making treatment decisions.

The aim was to understand IBD patients' perspectives and priorities when making treatment decisions to inform the development of a national patient and clinician survey.

- ***Phase 1- Patient Focus Groups (PFGs)***
- Phase 2- Surveys (Patients and Clinicians)
- Phase 3- Dialogue & Dissemination

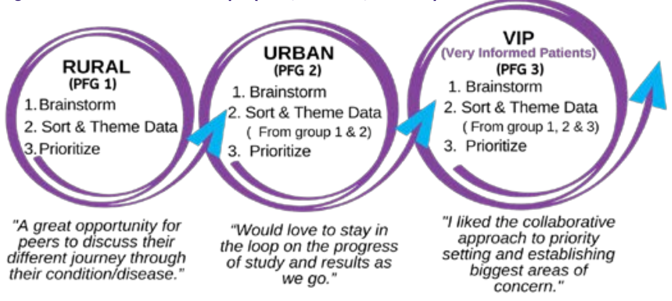
See **Figure 2.** for an overview of the IBD Partnerships project.

Methods

Phase 1, was conducted using qualitative focus groups. Patient focus groups (PFGs) were designed and led by an experienced patient engagement researcher to ensure the collective patient voice was captured and to elicit feedback as equally as possible amongst participants.

- IBD Patients (≥ 18 years of age) were recruited through the University of Calgary's IBD clinic and social media platforms. PFG's were held in three provinces: British Columbia (PFG 1), Alberta (PFG 2), and Ontario (PFG 3). PFG 1 was in a rural location and PFG 2 and PFG 3 were in urban locations.
- PFG' s were collaborative, involving participants in topic generation, data analysis, and prioritization exercises. Each PFG was 4 hours to allow time for discussions, data analysis and priority voting.
- Topics generated from PFG 1, were introduced to PFG 2 during the sorting process. Very informed patients (patients engaged in research and/or advocacy), were recruited for FG3 and given the task to sort the data from all three PFG' s, as depicted in **Figure 1.**
- Priority voting was done individually and in confidence to militate any group bias.
- Data collection included audio recordings, flip charts, and sticky note documentation. Data was collectively analyzed during the PFG' s, then later transcribed and thematically analyzed.

Figure 1. Patient Focus Groups (B.C., AB. ON., Canada)



Acknowledgements:
The authors would like to thank IBD patients, nurses and GI's who have contributed their expertise and perspectives to the IBD Partnerships project.

Disclosures of interests:
S.Zelinsky has received consultancy fees from Takeda Canada Inc.
C.Finlayson & J.Chen are employees of Takeda Canada Inc.

Results

Characteristics	Participants N=21
Age, years, mean	40.5
Sex, female, n (%)	18 (85.7)
Patients with ulcerative colitis, n (%)	10 (47.6)
Patients with crohn's disease	11 (52.4)
Age of diagnosis, mean	24.9
Duration of disease, years, mean	17
Prior biologic use, n (%)	18 (85.7)
IBD-related surgeries (lifetime), n (%)	13 (61.9)

Top 5: Patient Identified Priorities

Risks (Safety, Long-term effects)
"Safety profiles and biologics- Cancer risks for the various biologics: how do they compare across the different types of biologics (ex: anti-TNF alpha inhibitors vs. JAK inhibitors vs. interleukin antagonists)?"

Supports (Education, Evidence based information, Resources)
"What studies have taken place? How much data is available to back-up treatments? (Efficacy, long-term effects, other patients experiences)"

Side Effects (Less serious, Short-term effects)
"What are the most common side effects that PT's experience? And what are the options available to manage them if they arise for me? Are there some early side effects that you build tolerance or improve over time?"

Efficacy (Desired or intended results)
"How long is it typical to start seeing results from a biologic therapy?"

Impact (Quality of life, Lifestyle, Logistics)
"For infusions, what times are available/locations? Will this mean that I need to take time off of work?"

Focus group participants sorted the data into themes then titled and defined each theme. Participants prioritized the themes from 1 to 5 (1 being most important to 5 being least important).

Discussion

- This is a novel, patient-led study that incorporates a wide geographic representation (BC, AB, ON) and diverse patient experiences and backgrounds (rural patients treated by community clinicians, urban patients treated in tertiary-care centres, and patients experienced in research and advocacy), in a collaborative approach to topic generation, data analysis and priority voting to generate priorities that capture what matters most to patients.
- Results from the priority voting in the qualitative phase suggest IBD patients place risks (safety, long-term effects) as more important than efficacy (desired or intended results) when choosing a biologic therapy. This may be different than the relative priorities of clinicians as has been previously demonstrated.[1]
- Understanding importance of treatment attributes, from a patient-centric perspective[2] can facilitate open discussions regarding optimal treatment approach and improve the patient experience.
- Despite our recruitment efforts, a limitation of the PFG's is the uneven female to male ratio, however we expect our national survey to have a more even female to male distribution.

Conclusions

- The themes that were prioritized from the PFG's informs the relative importance of treatment attributes and the development of the surveys, which we will quantify in our national patient and clinician survey, in phase 2 of our project in 2020.
- Differences in importance of treatment attributes between patients and clinicians will be important for improved communications about the benefits and risks of treatment to improve shared decision-making for patients with IBD. This will be the basis for phase 3 of our project.

Figure 2. Overview of IBD Partnerships project

References:
1. Boeri M, et al., Clinical and Experimental Gastroenterology, 2019; 165.225.36.126
2. Montori V, et al., Health Expectations, 2006; j.1369-7625.2006.00359.x

This poster is being presented at the Crohn's Colitis Congress, Austin, Texas, USA, January 23-25, 2020, and has been funded by Takeda Canada Inc.

IBD Partnerships

Phase 1: Focus Groups

Completed!

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IBD Partnerships has been funded by Takeda Canada Inc.

Results from IBD patient focus groups: B.C., AB., ON.

Top 5: IBD patient priorities

1. **Risks (**safety, long-term effects)
2. **Supports** (education, evidence-based information, resources
3. **Side-effects** (less serious, short-term effects
4. **Efficacy** (intended or desired results)
5. **Impact** (quality of life, lifestyle, logistics)

“I think that it is important that both the patient and their doctor are the ones making the decisions regarding medications. Both parties need to be completely informed.”

Phase 2: National Surveys

Coming soon!

IBD Partnerships

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- IBD Patient survey
- IBD Healthcare Professional survey
- Online surveys will be available November 2020- February 2021

HCP'S (3 HCP'S)	Suggestions/ comments	17
	Edits added	**15**
CALGARY IN PERSON SURVEY REVIEW (6 IBD PATIENTS)	Suggestions/ comments	47
	Edits added	**43**
WILLIAMS LAKE, B.C. IN PERSON REVIEW (2 IBD PATIENTS)	Suggestions/comments	25
	Edits added	**20**
VIP'S PILOT SURVEY (5 IBD PATIENTS)	Suggestions/comments	48
	Edits added	**40**
Totals:	Total Suggestions/comments	137
	Total Edits Added	**118**

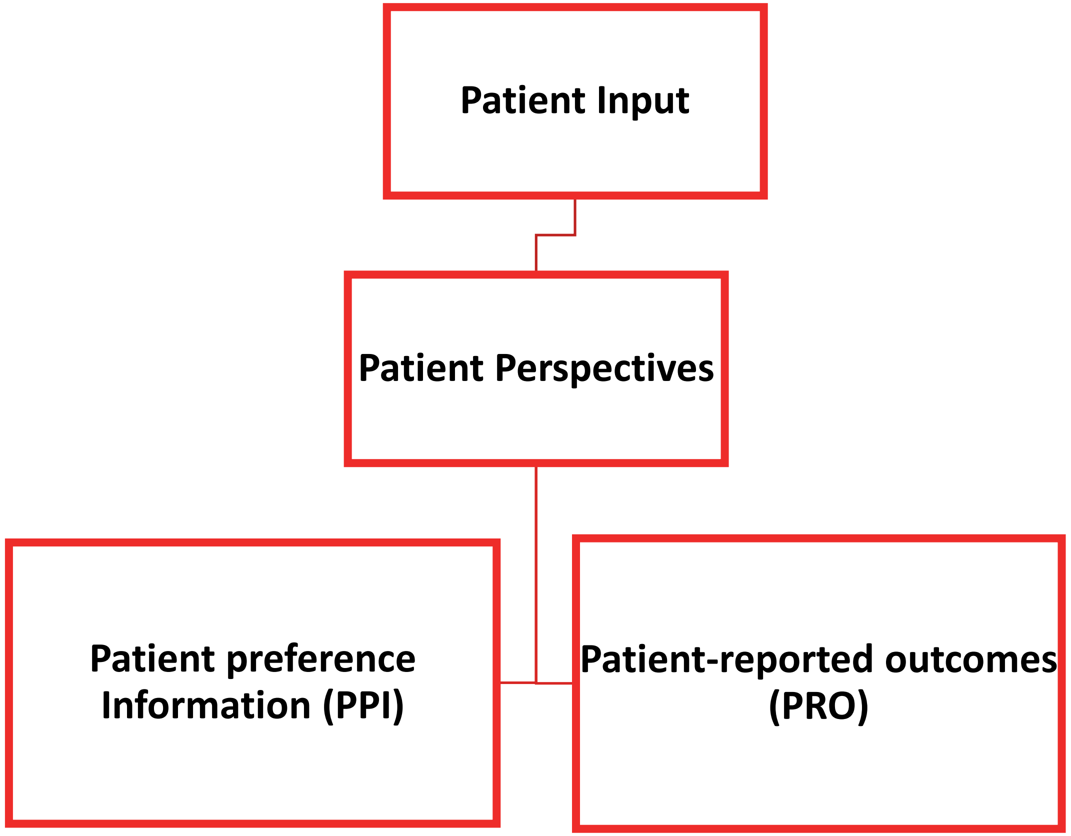
Preferences Consider Choices with Trade-Offs

Quantitative assessments of the relative **desirability** or **acceptability** of features that differ among alternative health states, health interventions, or health services using experimental survey methods … which reflects their underlying utility for that alternative.

- ***Desirability: preferences for positive outcomes or features (benefits)***
- ***Acceptability: aversion to negative outcomes or features (harms or risks)***

- FDA Final Patient Preference Guidance Document. August 24, 2016. https://www.fda.gov/media/92593/download

What Do Patient Preferences Measure?



Patient Preference Information (PPI)

PPI is an assessment of desirability or acceptability (what a patient wants)

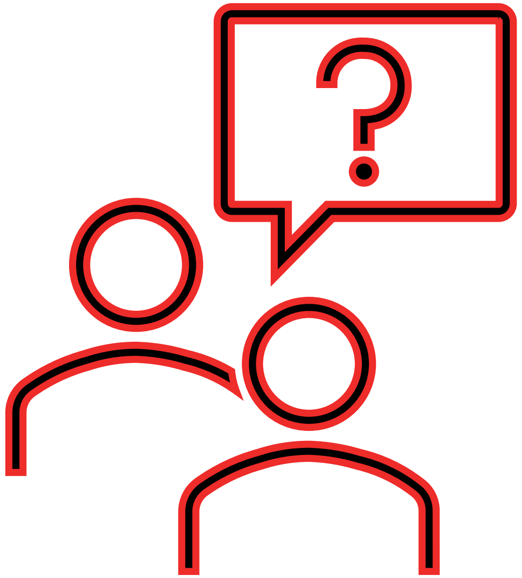
Patient Reported Outcomes (PRO)

Any report of the **status of a patient's health condition** that comes directly from the patient, without interpretation by a clinician or anyone else

PRO is a measure of a realized outcome (what it is or what it is like)

- FDA Final Patient Preference Guidance Document. August 24, 2016. https://www.fda.gov/media/92593/download

Why Consider Patient Preferences?



”Aligning health care policy with patient preferences could improve the effectiveness of health care interventions by improving adoption of, satisfaction with, and adherence to clinical treatments.”

Good Research Practices for Preferences in Health


VALUE IN HEALTH 14 (2011) 403–413

available at www.sciencedirect.com

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journal homepage: www.elsevier.com/locate/jval

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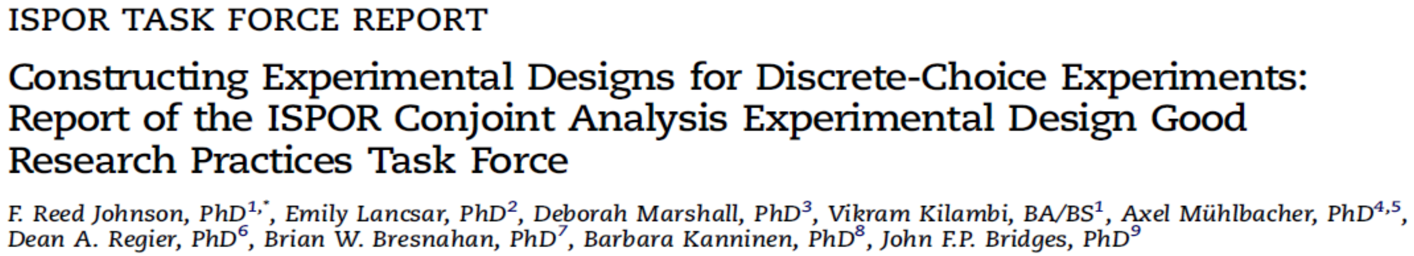
SCIENTIFIC REPORT

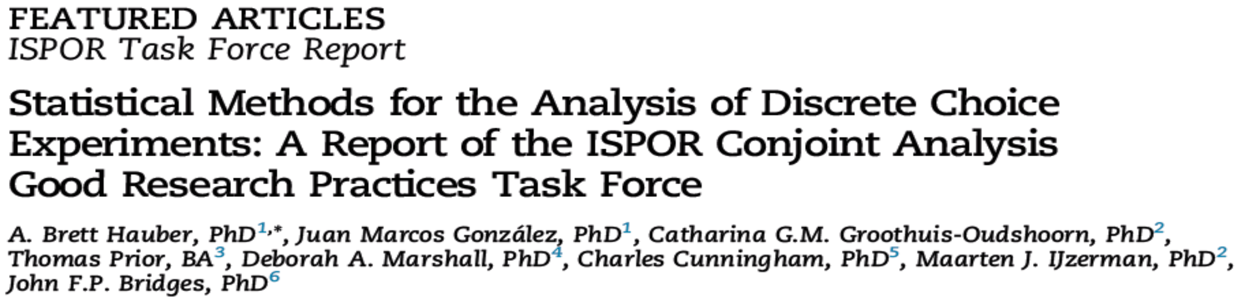
Conjoint Analysis Applications in Health—a Checklist: A Report of the ISPOR Good Research Practices for Conjoint Analysis Task Force

John F. P. Bridges, PhD[1,], A. Brett Hauber, PhD[2], Deborah Marshall, PhD[3], Andrew Lloyd, DPhil[4], Lisa A. Prosser, PhD[5], Dean A. Regier, PhD[6], F. Reed Johnson, PhD[2], Josephine Mauskopf, PhD[7]*


ISPOR TASK FORCE REPORT

Constructing Experimental Designs for Discrete-Choice Experiments: Report of the ISPOR Conjoint Analysis Experimental Design Good Research Practices Task Force

F. Reed Johnson, PhD[1,], Emily Lancsar, PhD[2], Deborah Marshall, PhD[3], Vikram Kilambi, BA/BS[1], Axel Mühlbacher, PhD[4,5], Dean A. Regier, PhD[6], Brian W. Bresnahan, PhD[7], Barbara Kanninen, PhD[8], John F.P. Bridges, PhD[9]*


FEATURED ARTICLES

ISPOR Task Force Report

Statistical Methods for the Analysis of Discrete Choice Experiments: A Report of the ISPOR Conjoint Analysis Good Research Practices Task Force

A. Brett Hauber, PhD[1,], Juan Marcos González, PhD[1], Catharina G.M. Groothuis-Oudshoorn, PhD[2], Thomas Prior, BA[3], Deborah A. Marshall, PhD[4], Charles Cunningham, PhD[5], Maarten J. IJzerman, PhD[2], John F.P. Bridges, PhD[6]*

Coming Soon!

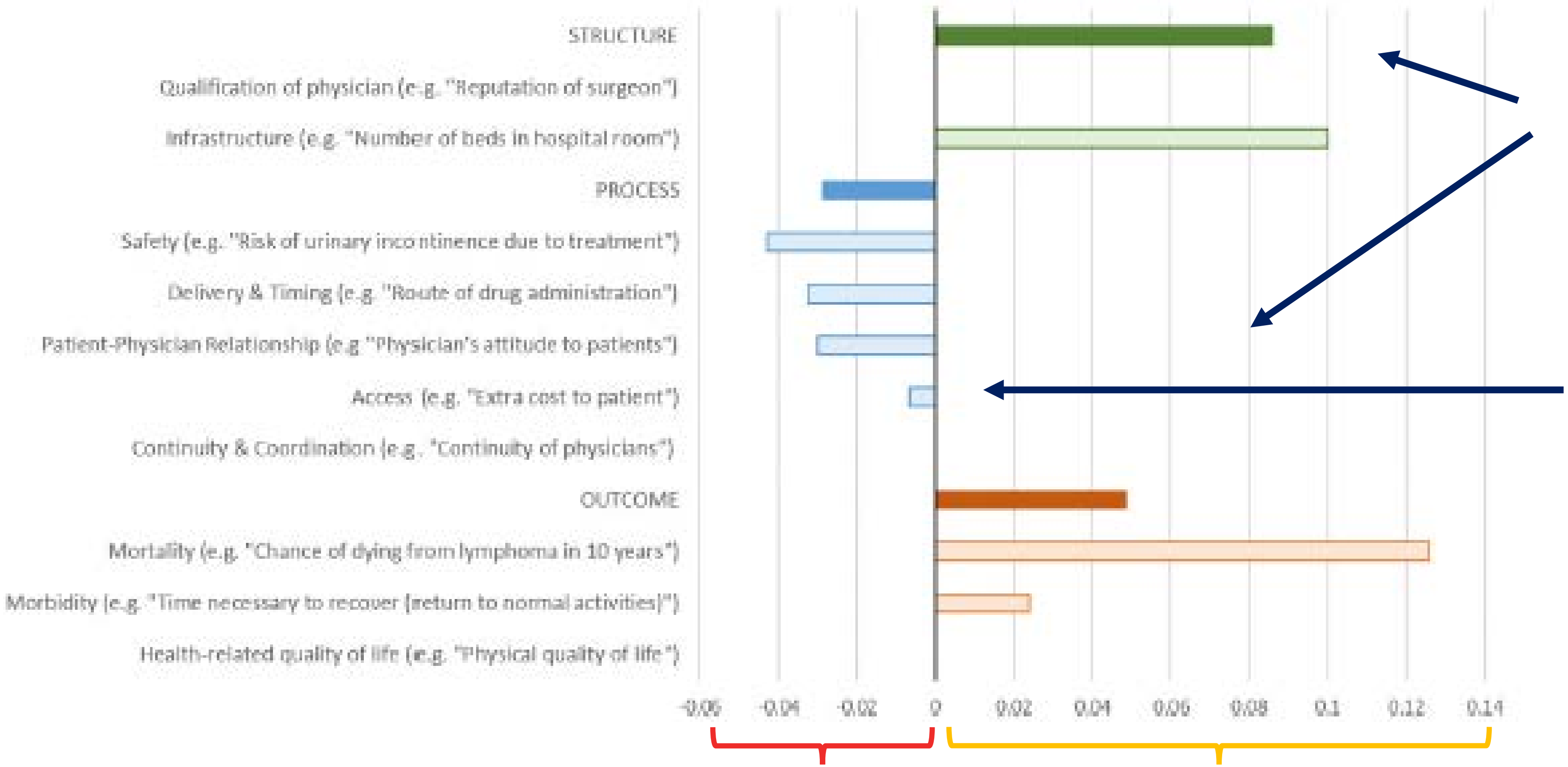
ISPOR Preferences Task Force (in progress):

A Framework for Measuring Patient Preferences to Inform Decision Making in Health.

Co-chairs: John Bridges, Deborah Marshall, Esther de Bekker-Grob

Patient and Provider Preferences Differ

(Systematic Review: n=38 papers, n=16 interventions, n=26 conditions)



Providers rank **<u>structure and outcome attributes</u>** more highly than patients

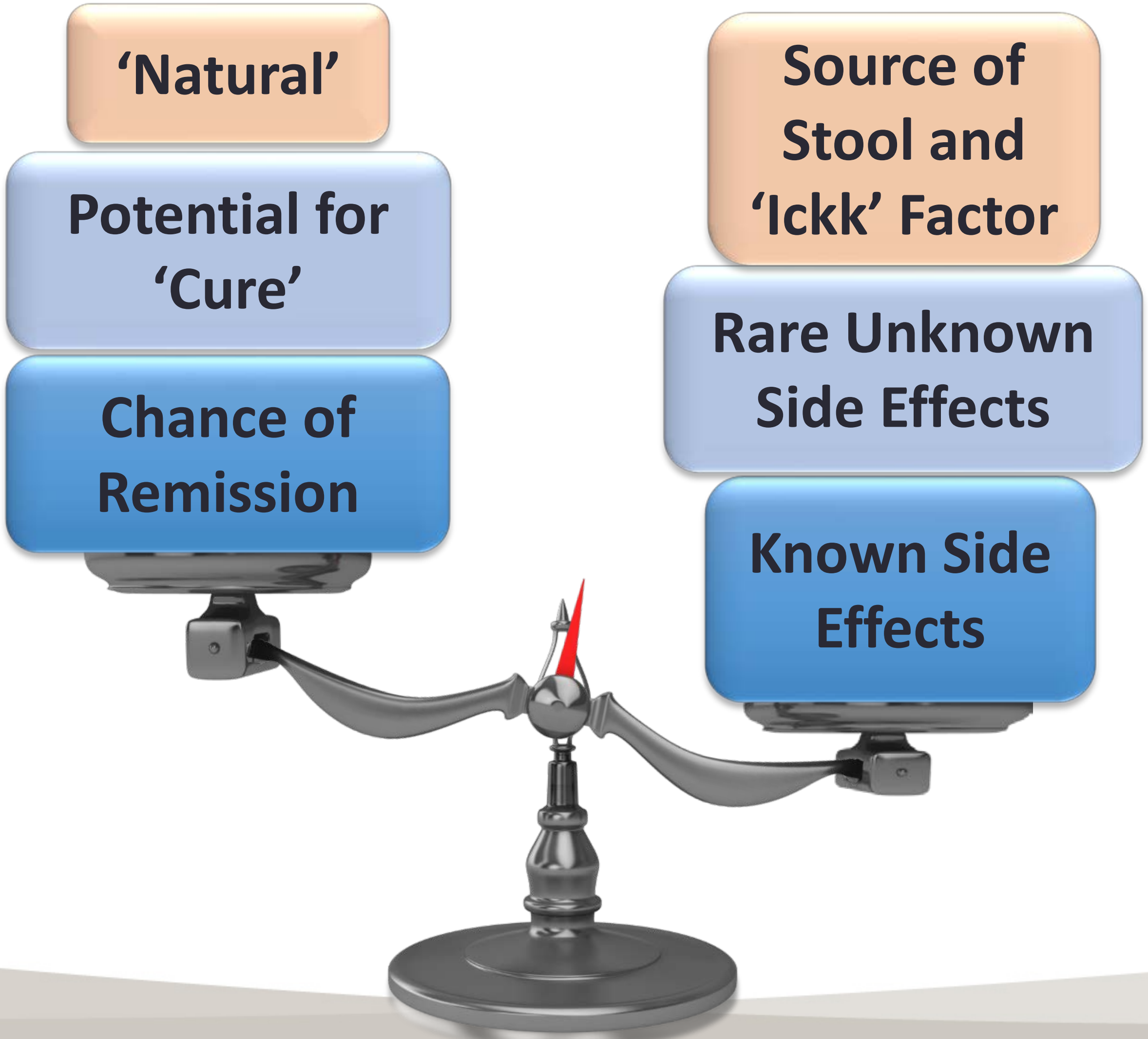
Patients rank **<u>process attributes</u>** more highly than providers

Patients rank attribute higher than physicians

Physicians rank attribute higher than patient

- Muhlbacher A and Juhnke C Appl Health Econ Health Policy, 2013; Donabedian A. JAMA 1988; Harrison M et al. BMJ Open, 2017

Assessing Value of Alternative Therapies for IBD Considerations of Fecal Microbial Transplant



‘Natural’

Potential for ‘Cure’

Chance of Remission

Benefits of FMT

Source of Stool and ‘Ickk’ Factor

Rare Unknown Side Effects

Known Side Effects

Risks / Aversions to FMT

Example of Preferences Choice Task

If your gastroenterologist presented the 2 treatment options below to you, which would you prefer?

	Treatment A	**Treatment B**
Chance of remission	2 out of 10 	6 out of 10 
Severity and chance of known side effects	Mild and temporary 2 out of 10 chance 	Moderate and temporar 1 out of 10 chance 
Severity of rare unknown side effects	Mild to moderate	None
What treatment would involve	• Rectal enema • Once weekly for 6 weeks (up to 30 minutes per treatment)	• Oral capsule or pill • One time treatment (up to 40 or pills taken within 1 hour)
Your choice	○	●

- Patients are asked to choose between different profiles
- Each profile is defined by treatment features
- Pattern of choices to the series reflects:

What are the most important features to patients?

What is the trade-off between features (risks and benefits)?

POLL
#2

Do you currently use a shared decision-making tool when discussing treatment options with your IBD patients?

☐ Yes

☐ No

Shared Decision-Making (SDM)

A structured process to incorporated evidence as well as patient values & preferences into HC decisions

A trade-off between harms and benefits that could be altered by patients' values and preferences

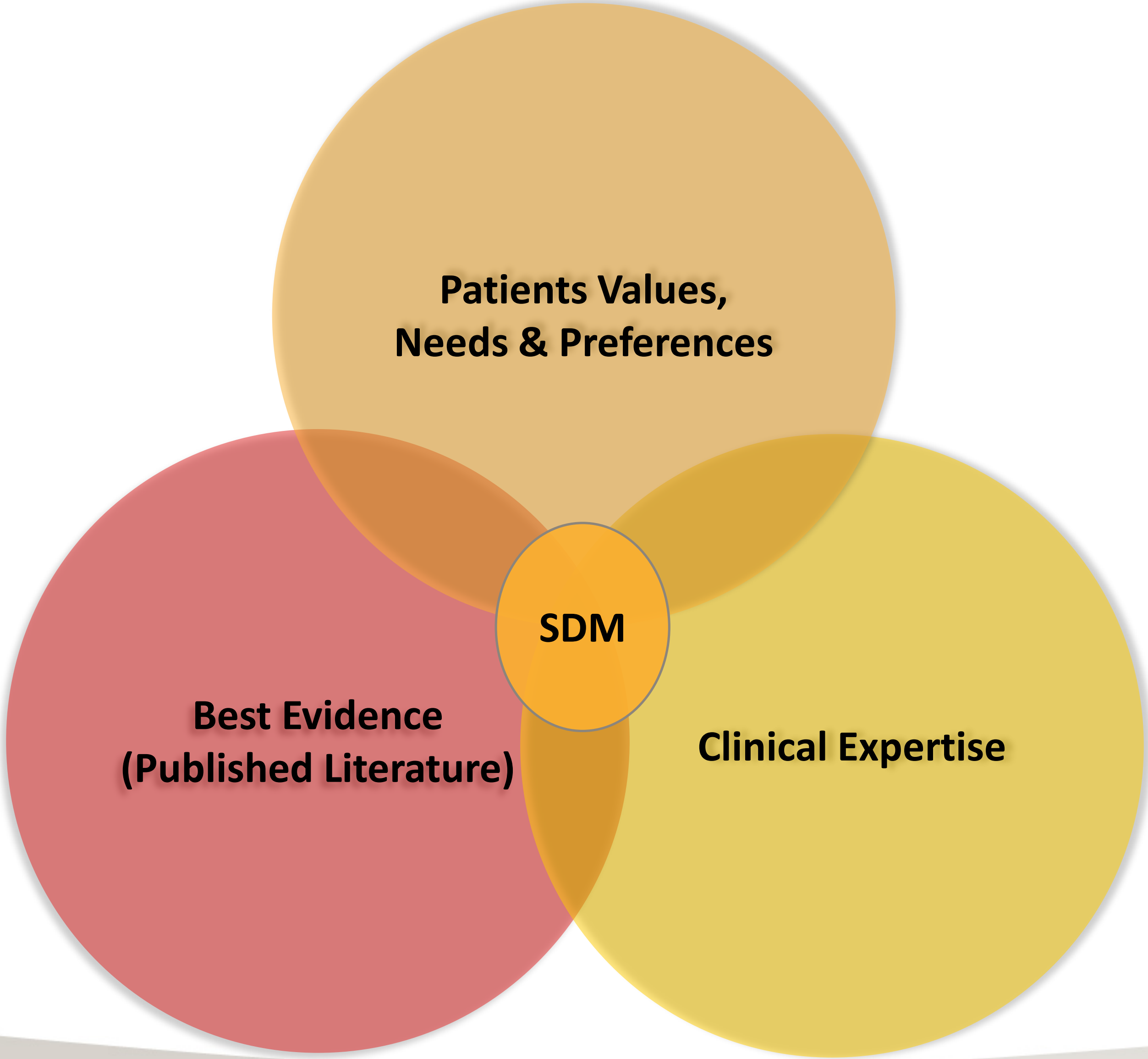
The core elements of SDM are risk communication & values clarification (VC). VC considers patient values & preferences

Patient decision aids
are KT tools that facilitate SDM, but individuals might require more than one office visit to make a decision

Grad R, Légaré F, Bell NR, et al. Shared decision making in preventive health care: What it is; what it is not. *Can Fam Physician*. 2017;63(9):682-684.

Légaré F, Witteman HO. Shared decision making: examining key elements and barriers to adoption into routine clinical practice. Health Aff (Millwood). 2013 Feb;32(2):276-84. doi: 10.1377/hlthaff.2012.1078. PMID: 23381520.

Patient-HCP Partnership in Treatment Decision-Making



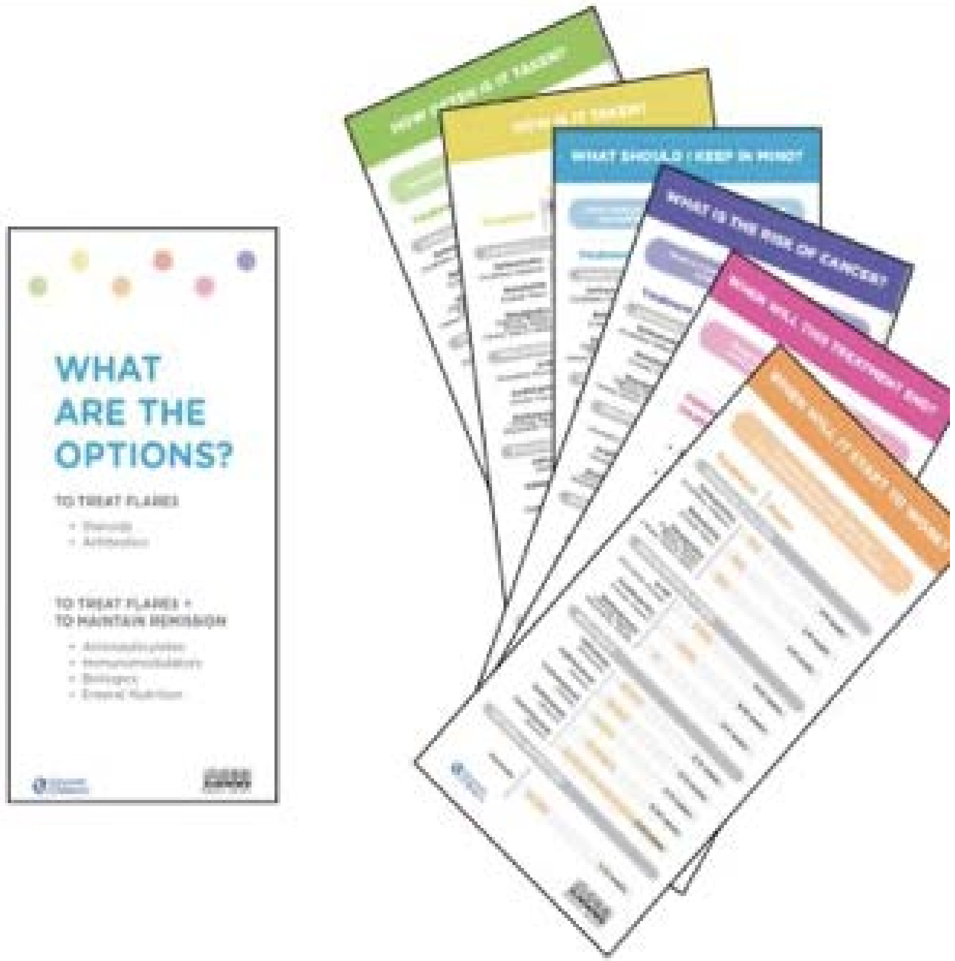
Patients Values,
Needs & Preferences

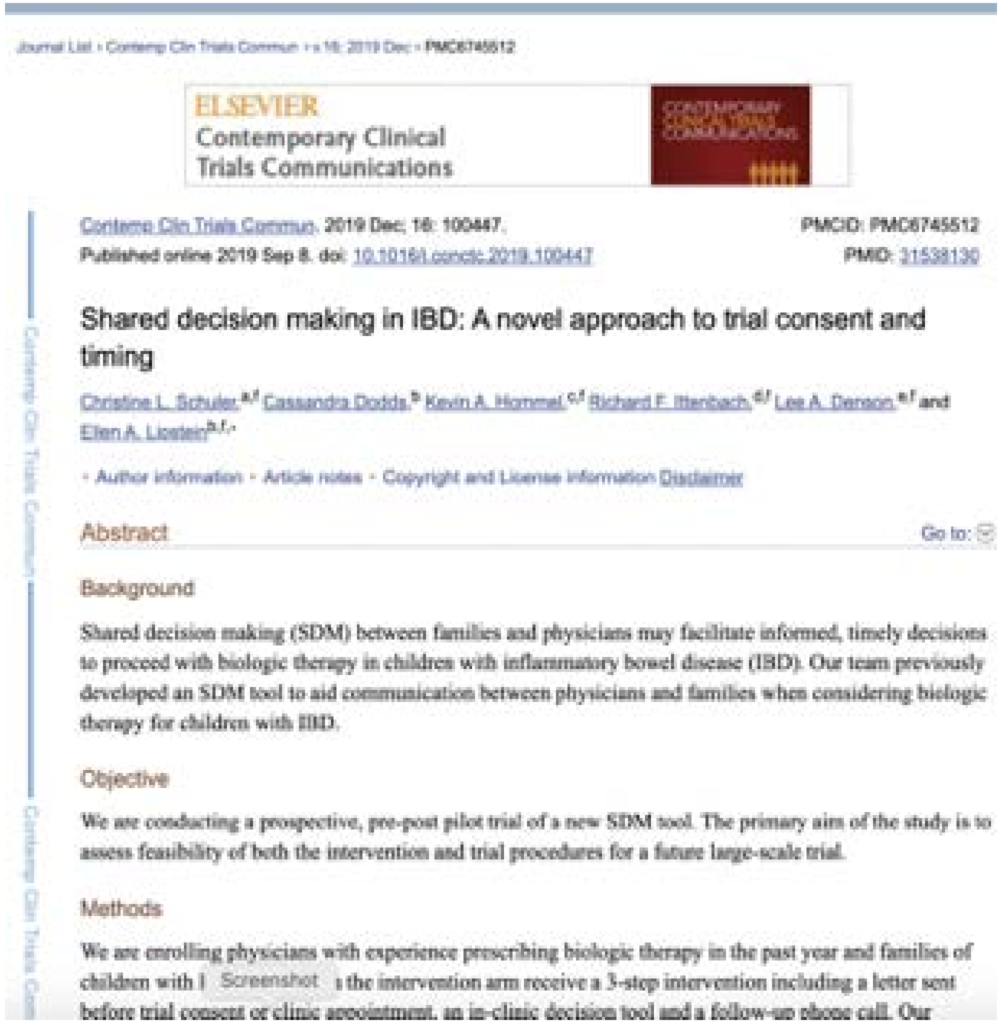
SDM

Best Evidence
(Published Literature)

Clinical Expertise

IBD Shared Decision-Making Tools





Contemp Clin Trials Commun. 2019 Dec; 16: 100447.
Published online 2019 Sep 8. doi: 10.1016/j.conctc.2019.100447

PMCID: PMC6745512
PMID: 31538130

Shared decision making in IBD: A novel approach to trial consent and timing

Christine L. Schuler,[a,f] Cassandra Dodds,[b] Kevin A. Hommel,[c,f] Richard F. Ittenbach,[d,f] Lee A. Denson,[e,f] and Ellen A. Lipstein[b,f,*]

Abstract

Background

Shared decision making (SDM) between families and physicians may facilitate informed, timely decisions to proceed with biologic therapy in children with inflammatory bowel disease (IBD). Our team previously developed an SDM tool to aid communication between physicians and families when considering biologic therapy for children with IBD.

Objective

We are conducting a prospective, pre-post pilot trial of a new SDM tool. The primary aim of the study is to assess feasibility of both the intervention and trial procedures for a future large-scale trial.

Methods

We are enrolling physicians with experience prescribing biologic therapy in the past year and families of children with I Screenshot s the intervention arm receive a 3-step intervention including a letter sent before trial consent or clinic appointment, an in-clinic decision tool and a follow-up phone call. Our

Potential Benefits of Shared Decision-Making

- Leads to better patient satisfaction and outcomes
- Patient-centric
- Takes into consideration the needs, preferences, values and lifestyle of patients
- Can lead to improved health literacy and medication adherence
- Potential cost savings to the healthcare system

Conclusions

1. Both patients and clinicians have specific responsibilities in shared decision-making and bring their own unique perspectives and expertise to the discussion

2. Shared decision-making and goal setting is a process in which clinicians and patients work together

3. Sharing of information and resources, have conversations that help you come to a mutual agreement and common goals

Questions?

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Thank you for attending! Any further questions, please connect with us!

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