IMAGINE NETWORK

Annual General Meeting
April 2023

IMAGINE | Agenda

Welcome & Introductions

EDI Moment

WHERE ARE WE NOW?
- **MAGIC Study**
- **Sub-Studies**
- **Patient Engagement**

WHERE ARE WE GOING?

IMAGINE 2.0 WORK PLAN OVERVIEW
- **Research** (FMT; AybleHealth; Nestle)
- **Patient Engagement & Capacity Building**
- **Digital Storytelling Showcase**

IMAGINE Phase 2.0 Overview of KM/IS
- **Strategies & Toolkits**
- **Three concurrent KM/IS breakout sessions**
- **Report Back**

Wrap Up & Closing

Inflammation, Microbiome & Alimentation Gastro-Intestinal & Neuropsychiatric Effects

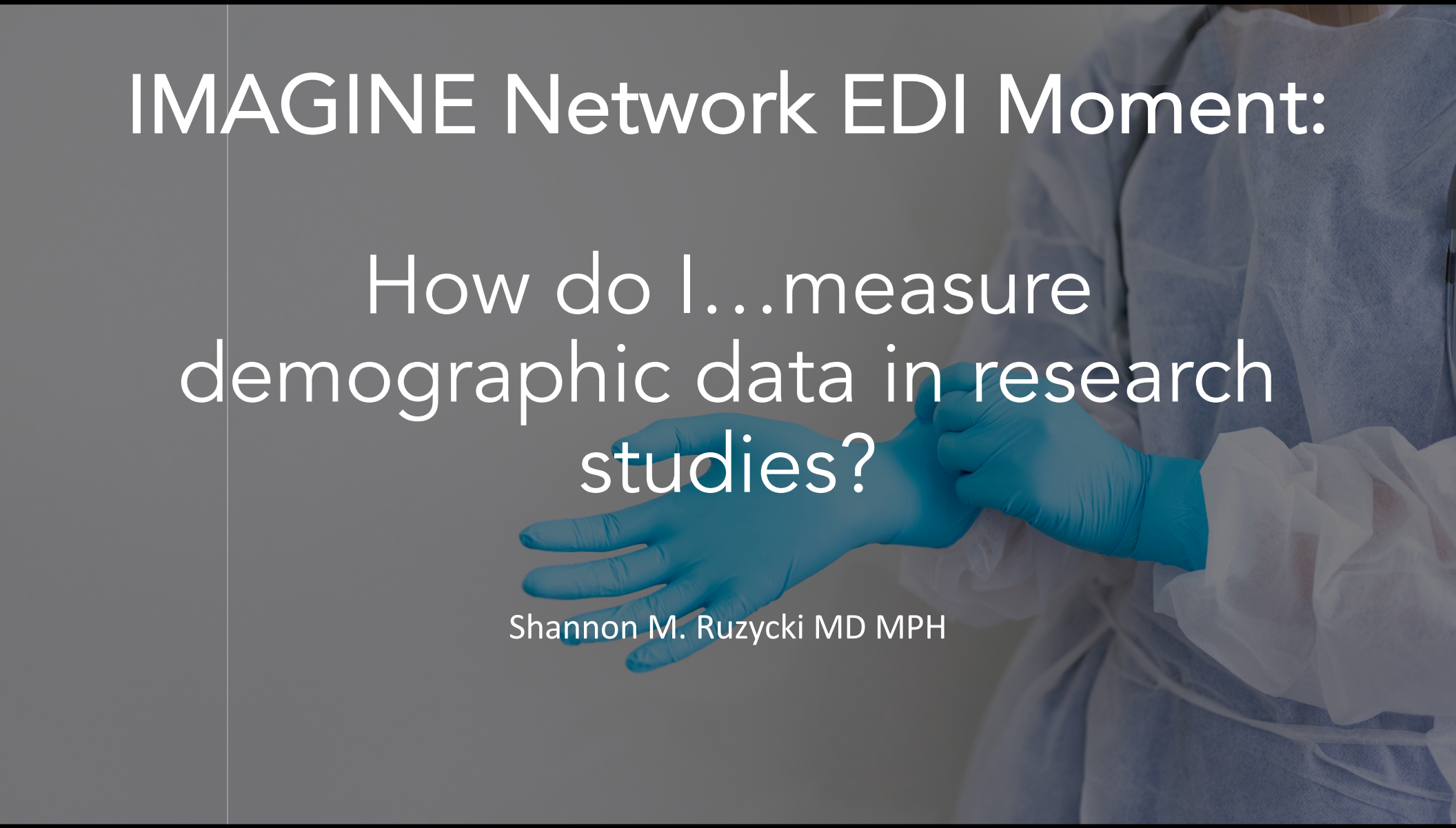
Strategy for Patient-Oriented Research
SPOR
Putting Patients First

EDI Moment

Dr. Shannon Ruzycki

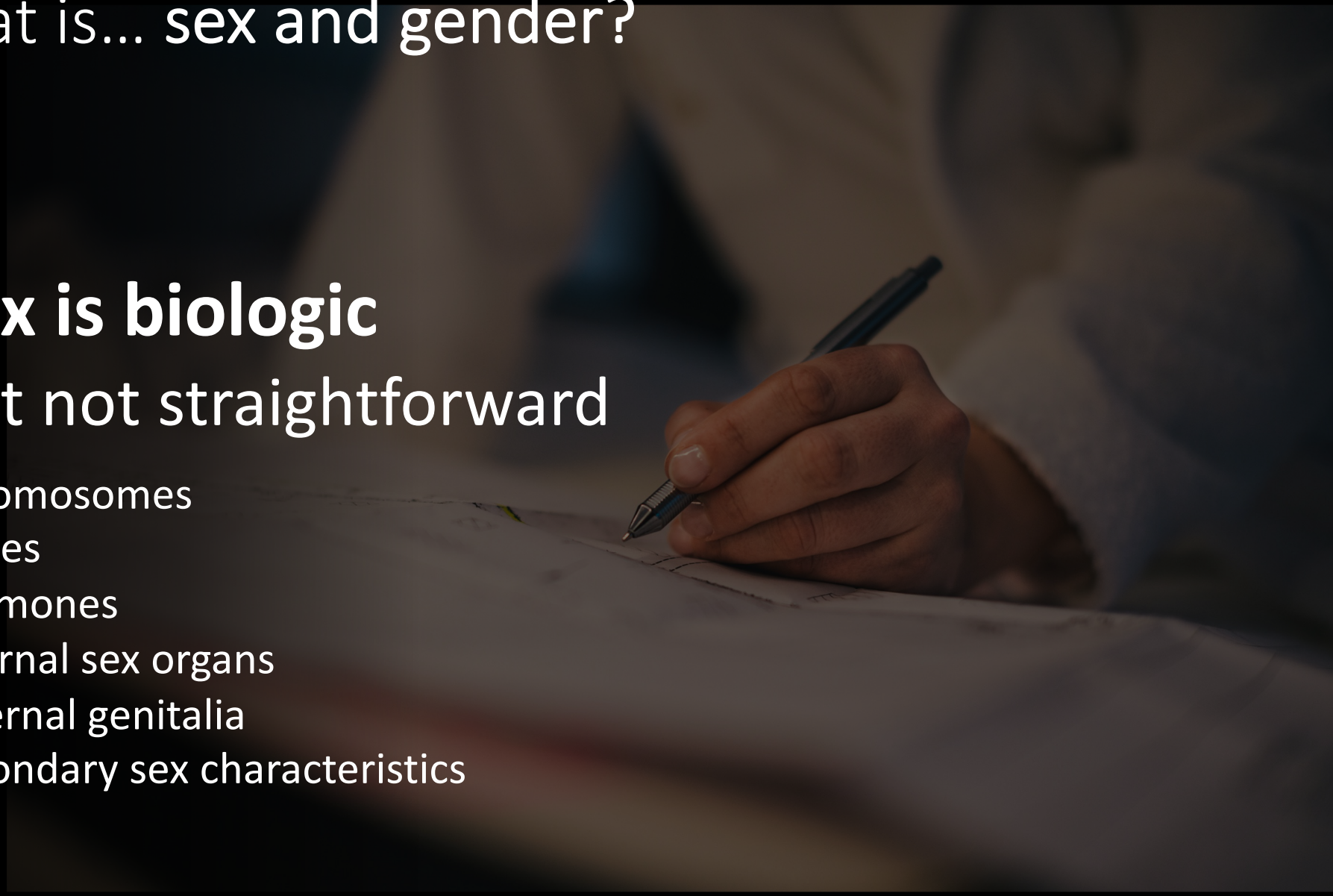
IMAGINE Network EDI Moment:

How do I…measure demographic data in research studies?



Shannon M. Ruzycki MD MPH

What is… sex and gender?



Sex is biologic

but not straightforward

Chromosomes
Genes
Hormones
Internal sex organs
External genitalia
Secondary sex characteristics

What is… sex and gender?

What is listed on our patients' medical records?

What is… sex and gender?

Gender is a social construct

Gender identity
Gender expression
Gender role

What is… sex and gender?

Gender identity

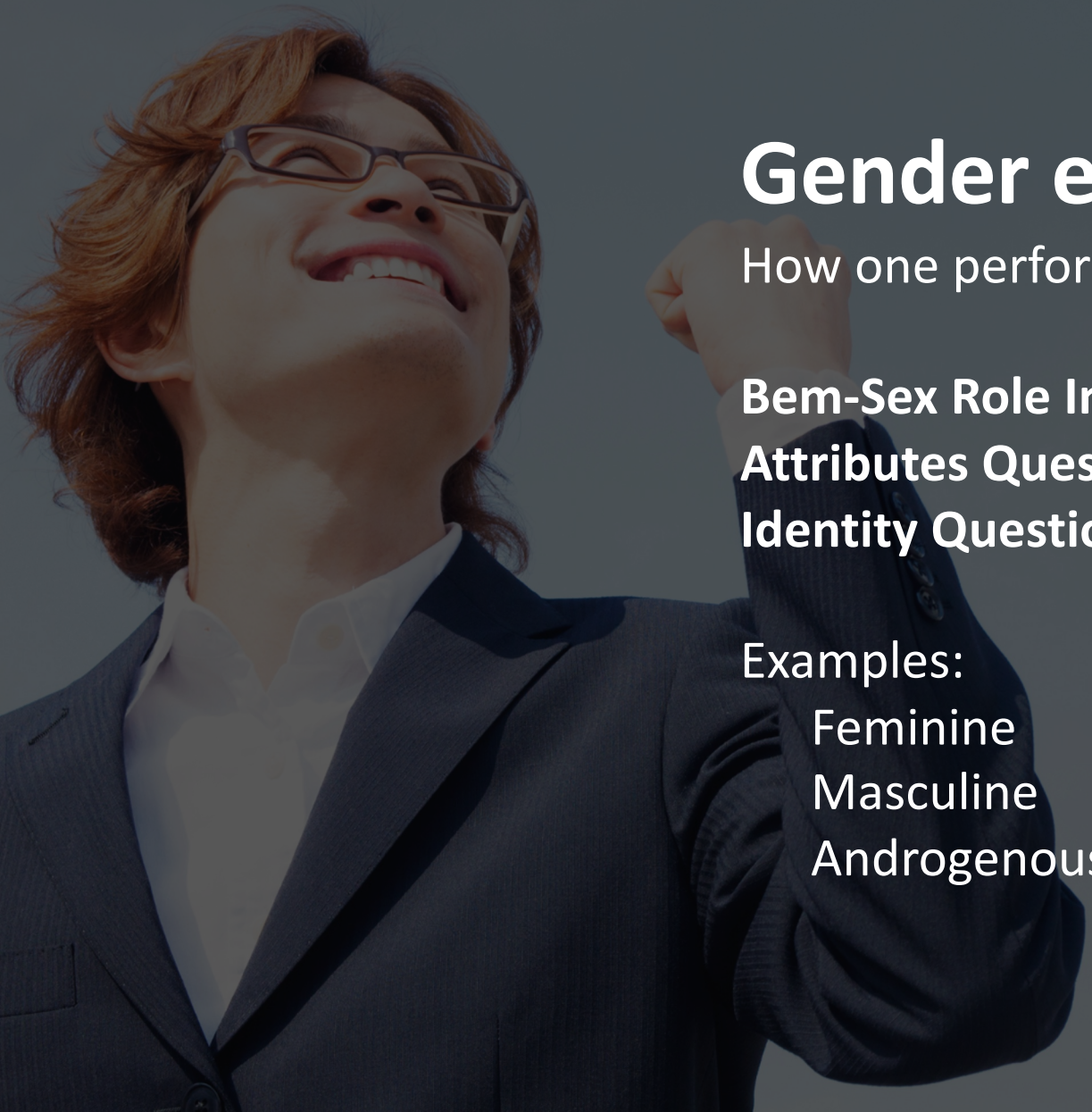
How one perceives themselves.

Self-reported.

Examples:

- Woman
- Demigender
- Non-binary

What is… sex and gender?



Gender expression

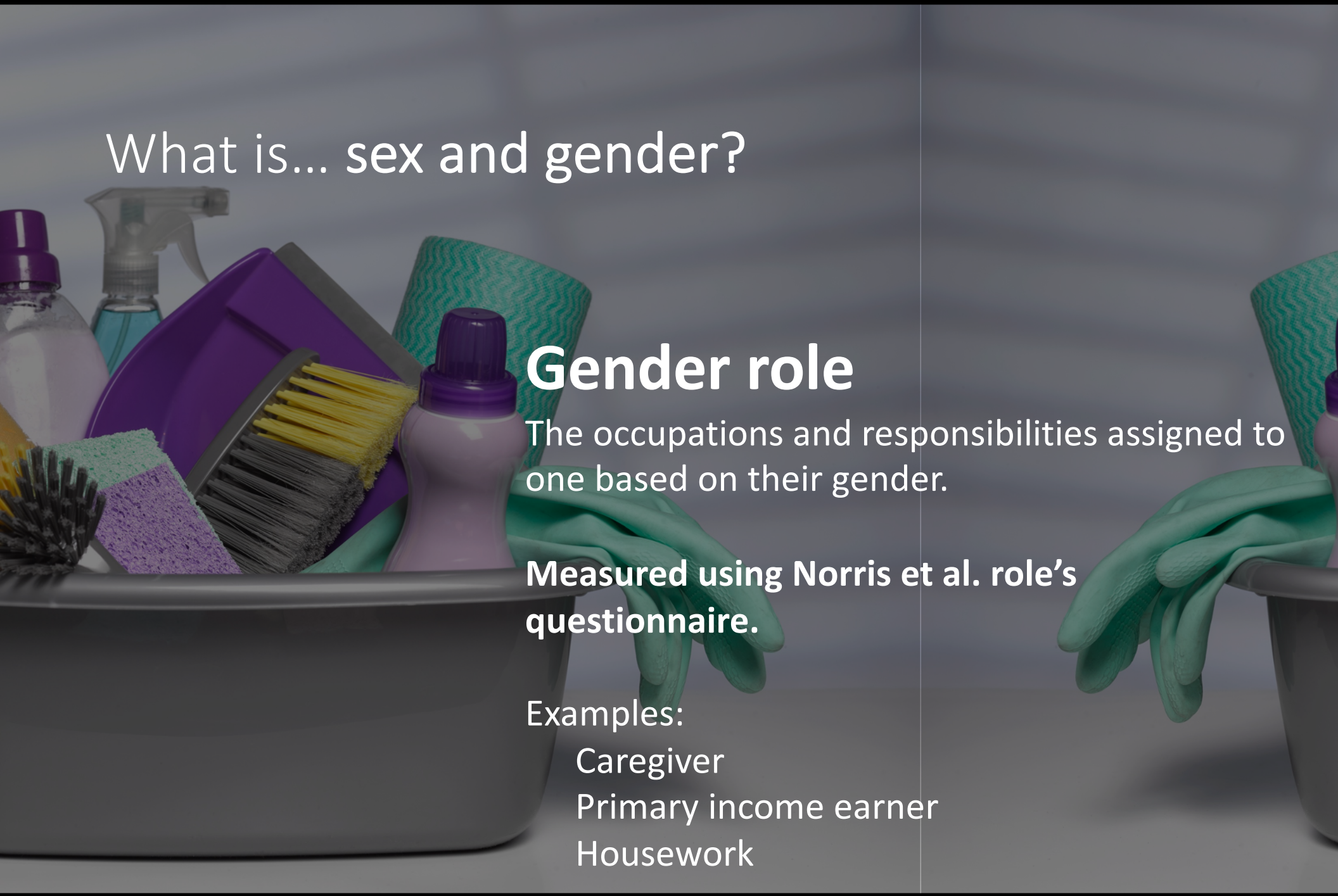
How one performs their gender.

Bem-Sex Role Inventory, extended Personality Attributes Questionnaire, the Multi-Gender Identity Questionnaire.

Examples:

- Feminine
- Masculine
- Androgenous

What is… sex and gender?



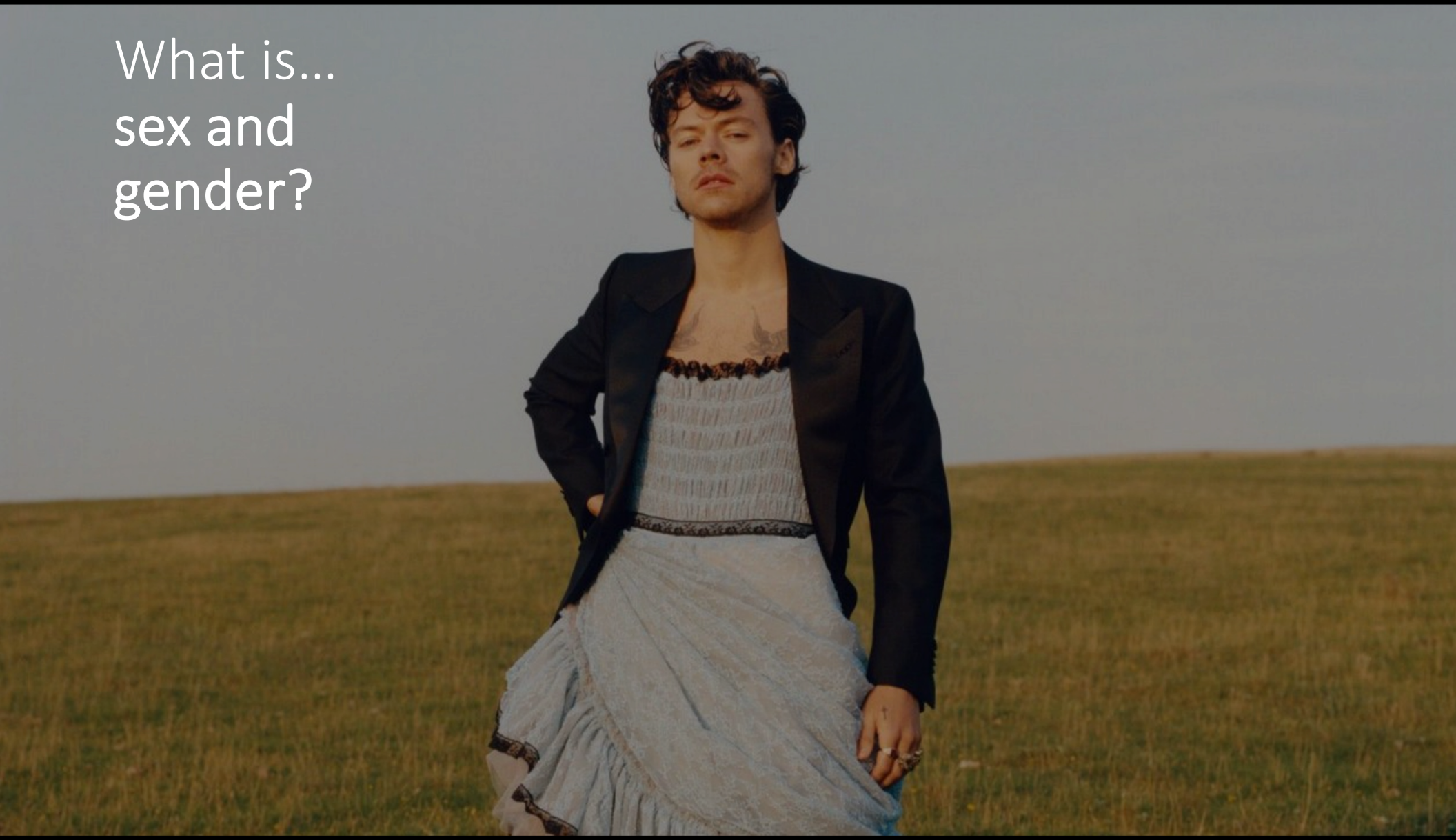
Gender role

The occupations and responsibilities assigned to one based on their gender.

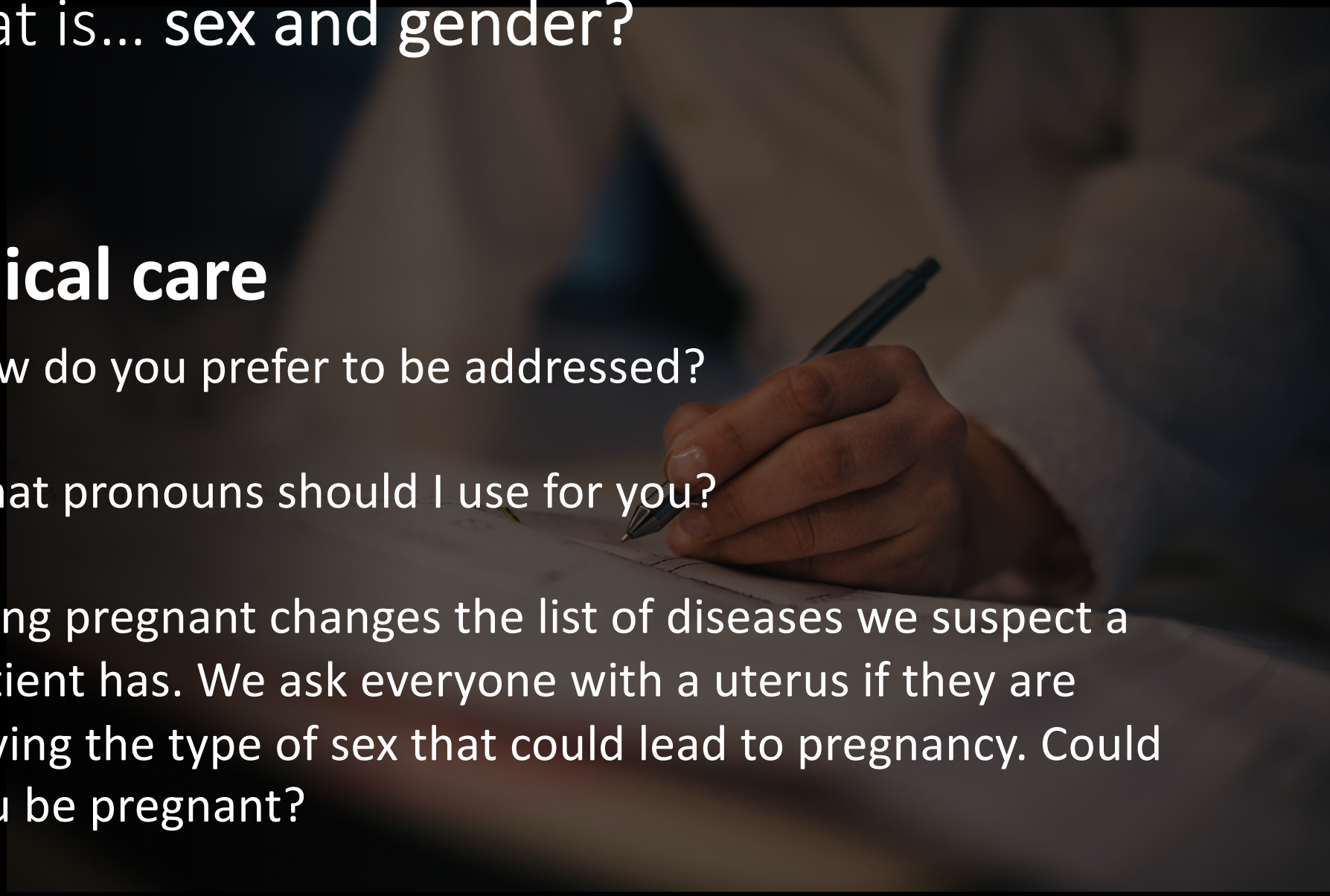
Measured using Norris et al. role's questionnaire.

Examples:

- Caregiver
- Primary income earner
- Housework


What is…
sex and
gender?

What is… sex and gender?



Clinical care

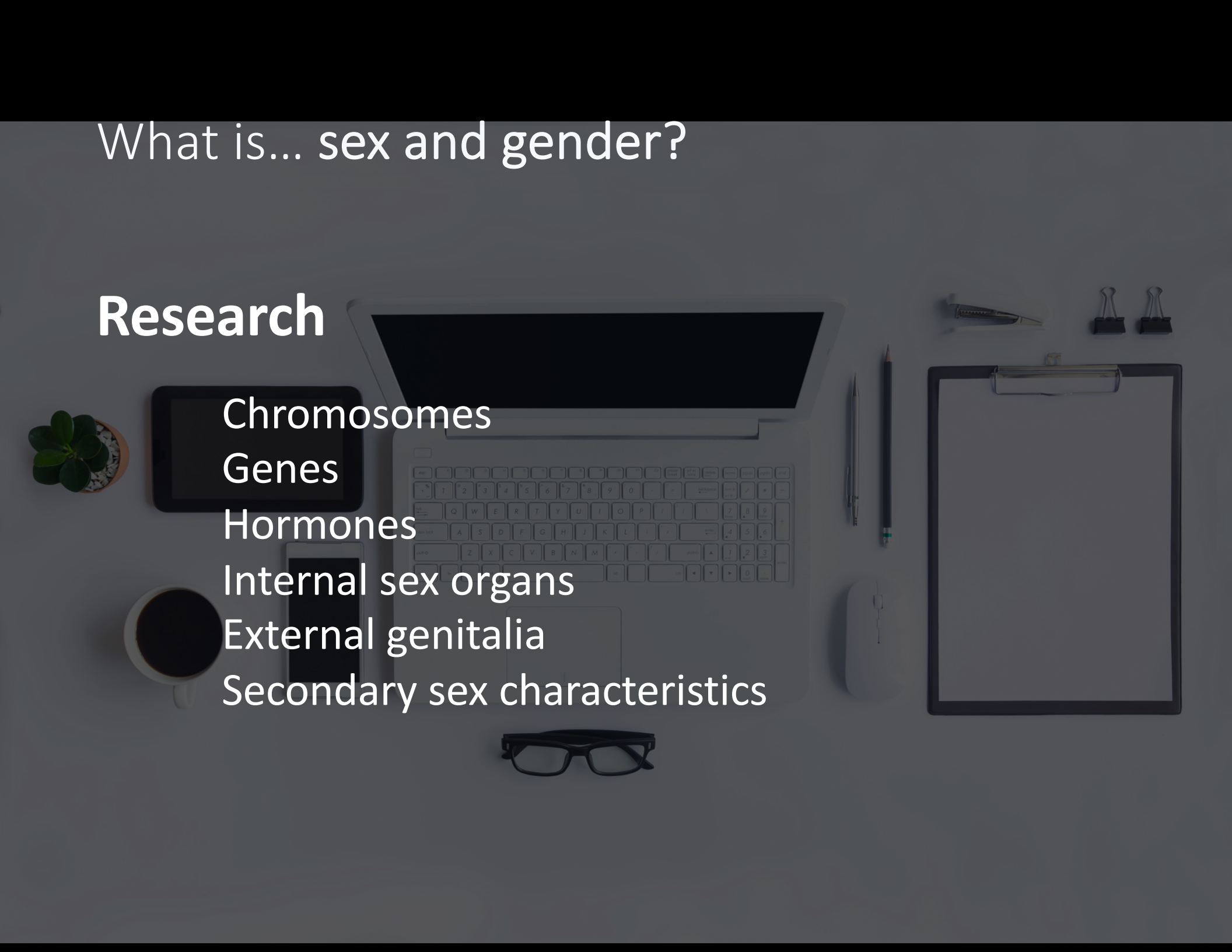
How do you prefer to be addressed?

What pronouns should I use for you?

Being pregnant changes the list of diseases we suspect a patient has. We ask everyone with a uterus if they are having the type of sex that could lead to pregnancy. Could you be pregnant?

What is… sex and gender?

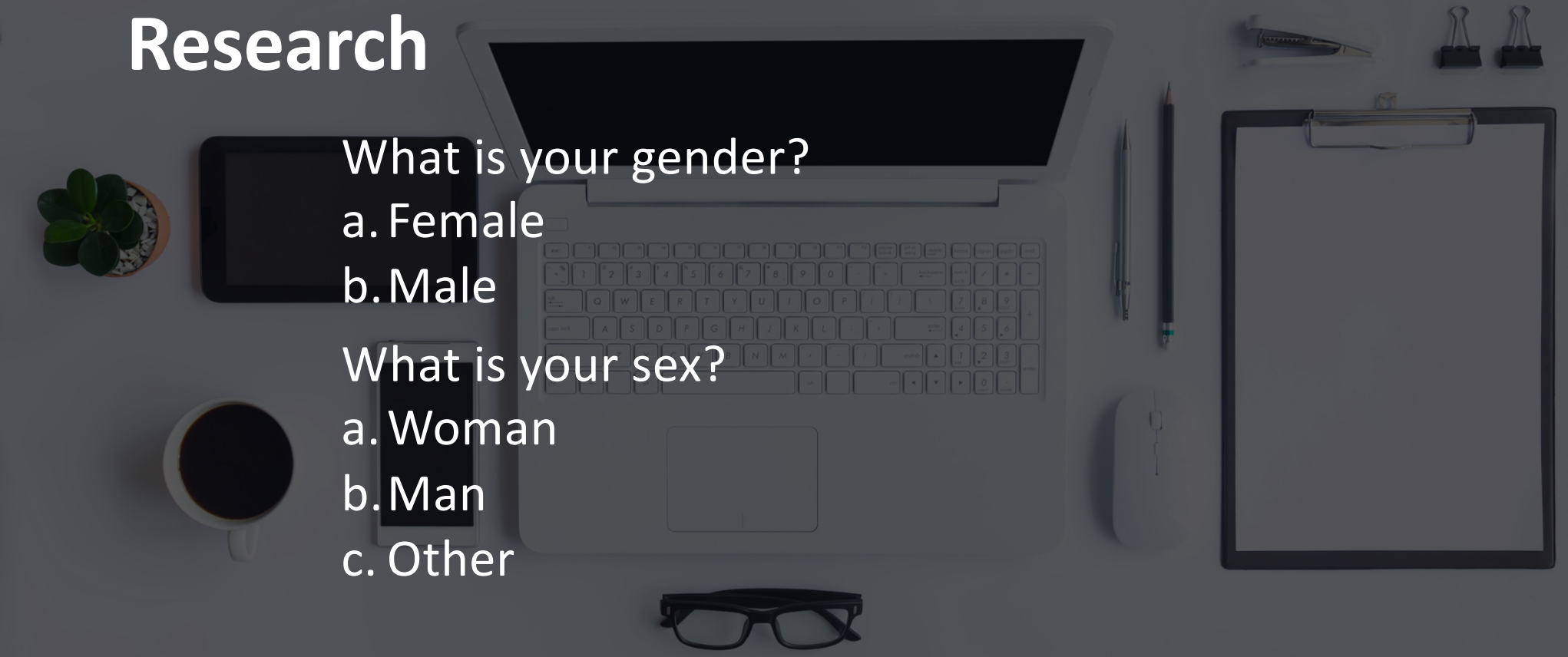
Research



- Chromosomes
- Genes
- Hormones
- Internal sex organs
- External genitalia
- Secondary sex characteristics

What is… sex and gender?

Research



What is your gender?

a. Female
b. Male

What is your sex?

a. Woman
b. Man
c. Other

What is… sex and gender?

Research

What was your **sex** assigned at birth?

a. Female
b. Male
c. Intersex

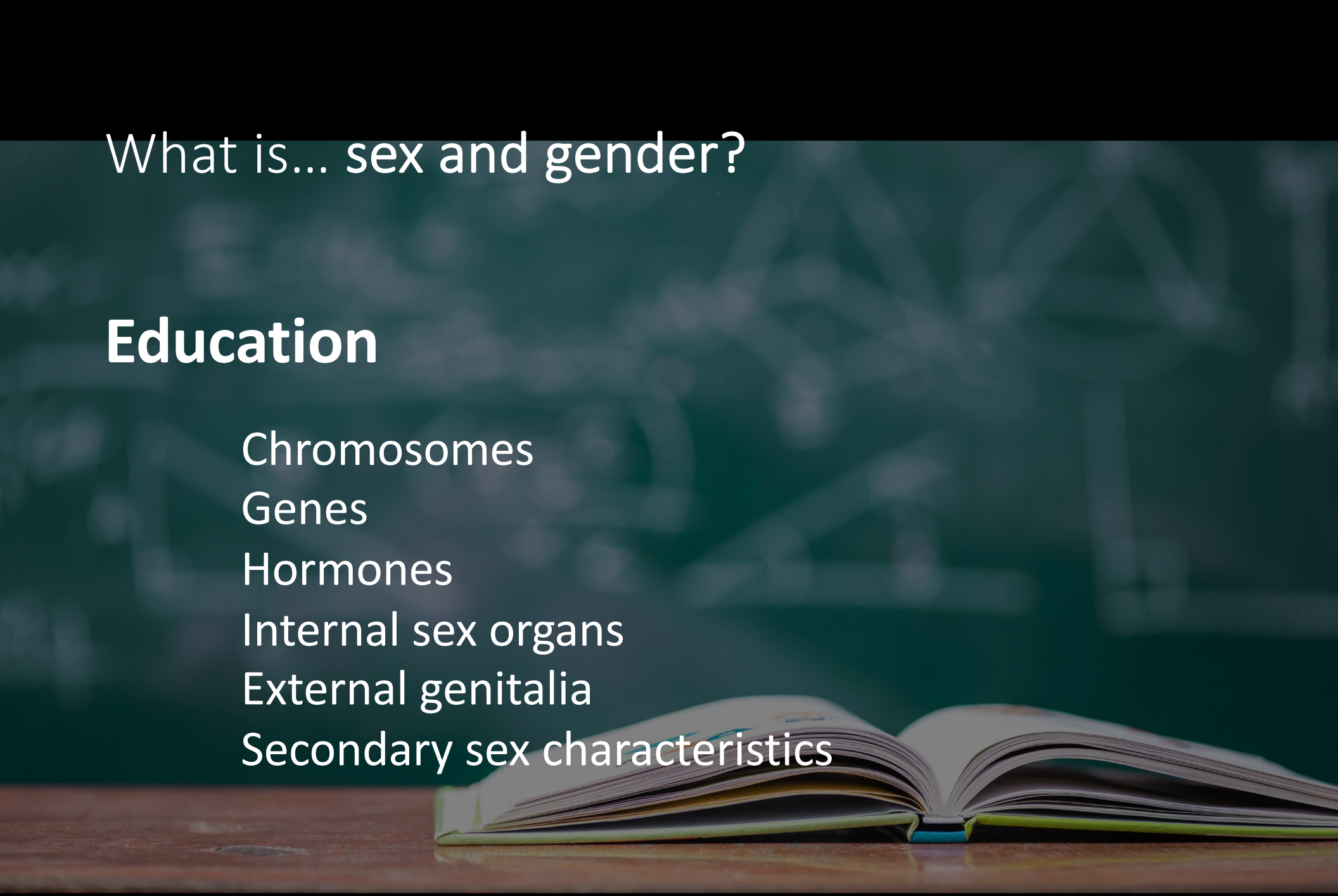
What **gender** do you identify with today?

a. Woman
b. Man
c. Non-binary gender (describe:)
d. A gender not listed (describe:)

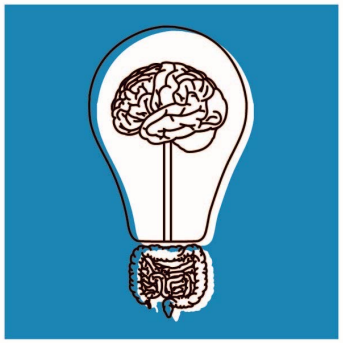
What is… sex and gender?

Education

Chromosomes
Genes
Hormones
Internal sex organs
External genitalia
Secondary sex characteristics



IMAGINE 1.0
MAGIC Study



Mind And Gut Interactions Cohort Study — IMAGINE Network

Inflammation, Microbiome & Alimentation Gastro-Intestinal & Neuropsychiatric Effects

Strategy for Patient-Oriented Research
SPOR
Putting Patients First

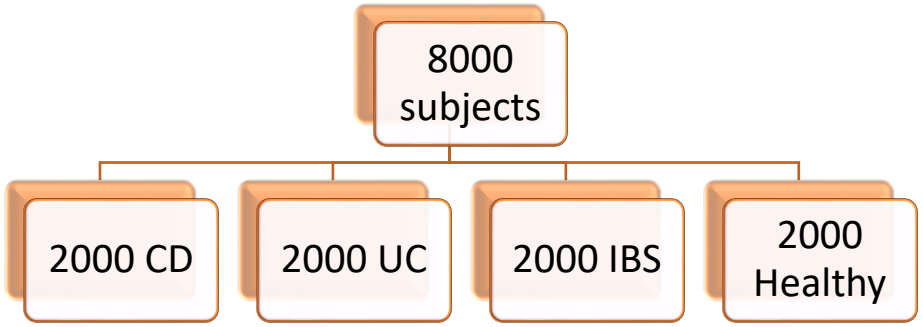
IMAGINE | MAGIC – Study Overview

Study Description:

- Multicenter longitudinal observational study looking at the relationship between inflammation, gut bacteria and diet in order to better treat IBS, IBD and their link with mental health.

Study Design:

- Subjects assessed annually for 4 years and submit blood, urine and stool samples & complete online questionnaires.

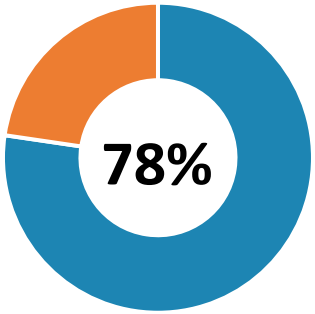


Inflammation, Microbiome & Alimentation Gastro-Intestinal & Neuropsychiatric Effects

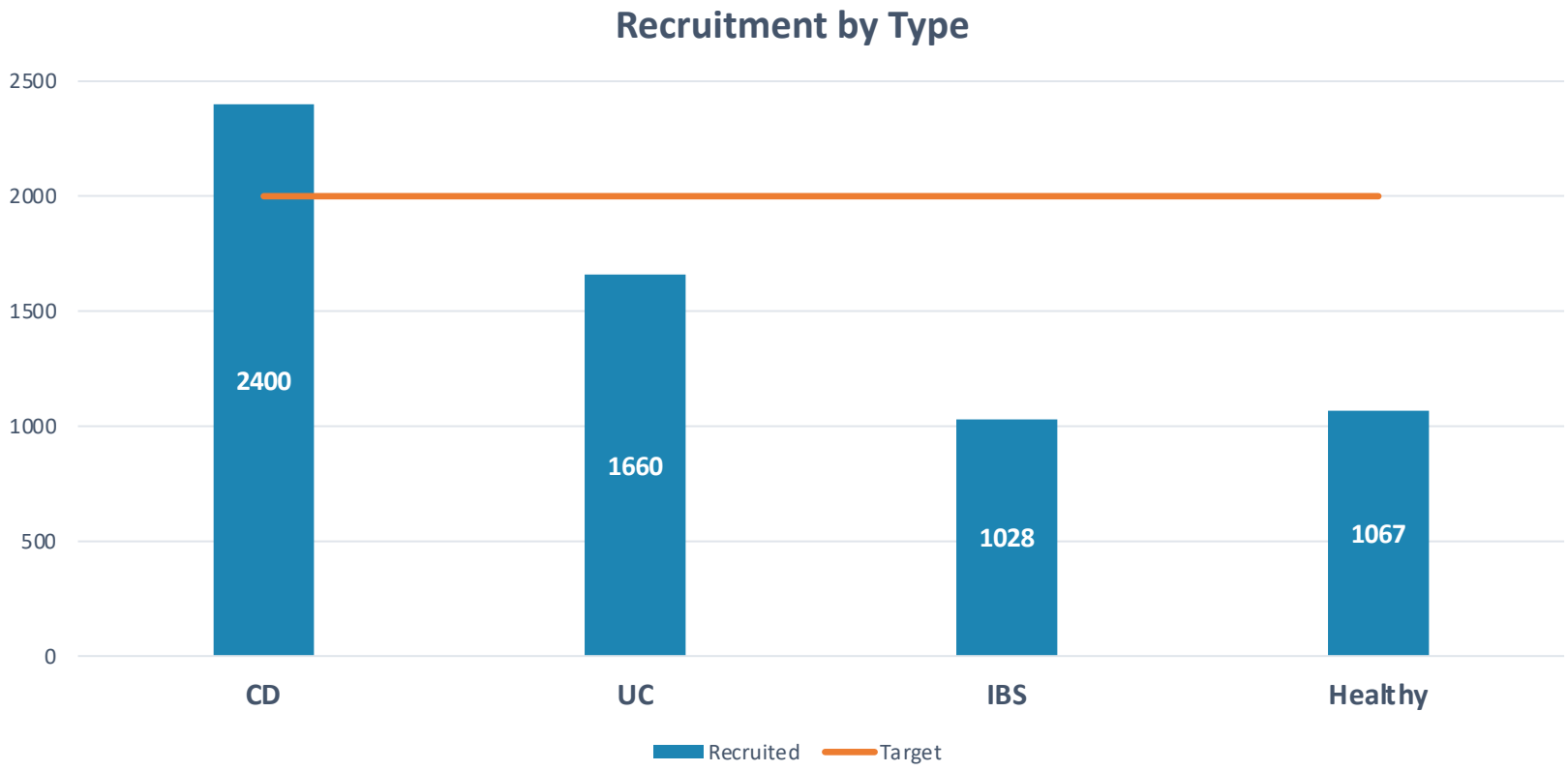
Strategy for Patient-Oriented Research SPOR Putting Patients First

IMAGINE | MAGIC Study Progress

4,426
SUBJECTS RECRUITED



Study Design | Ethics & al | Recruitment | Analysis | Dissemination



Inflammation, Microbiome & Alimentation Gastro-Intestinal & Neuropsychiatric Effects

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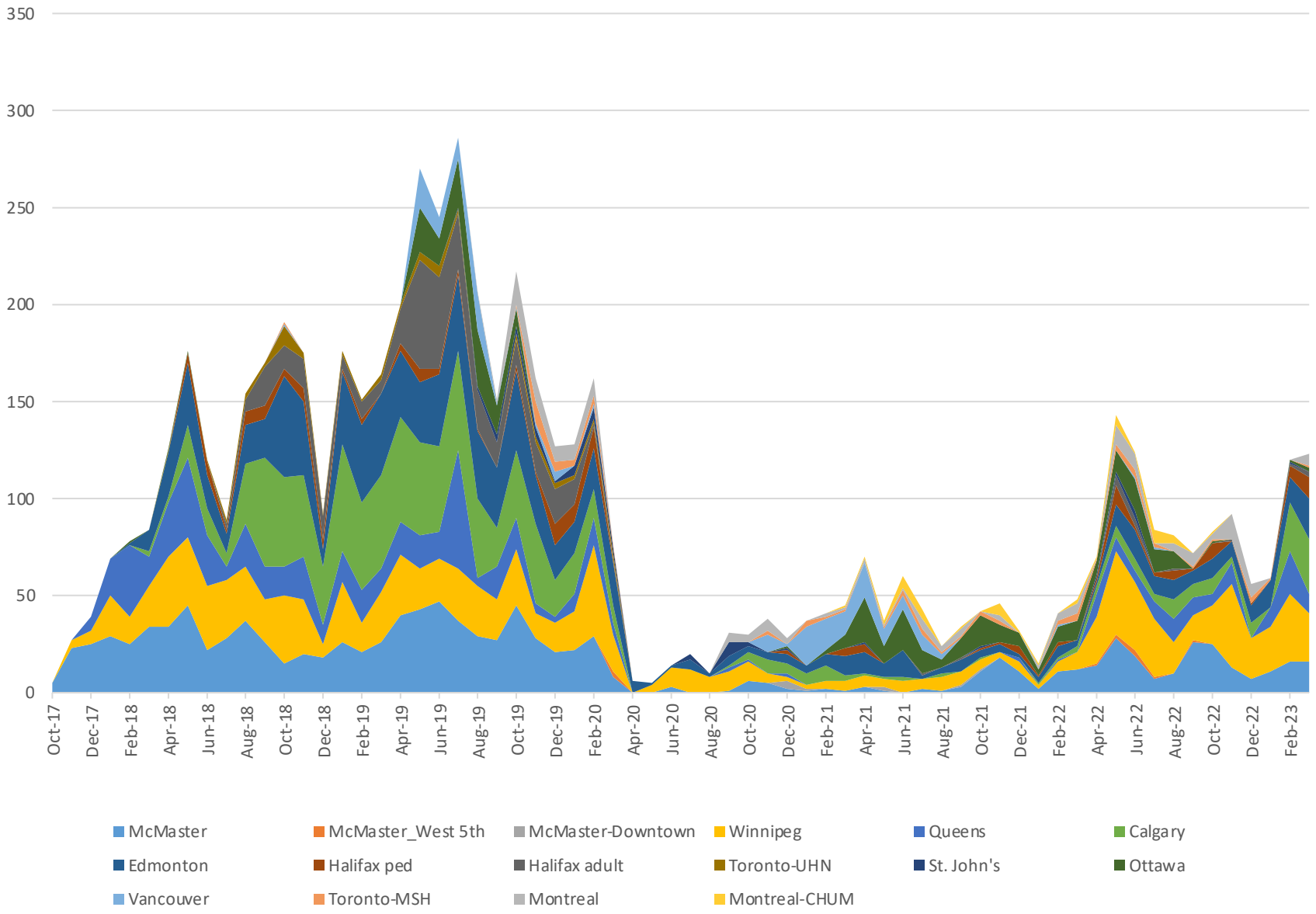
IMAGINE | MAGIC Study Monthly Recruitment



Inflammation, Microbiome & Alimentation Gastro-Intestinal & Neuropsychiatric Effects

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IMAGINE | MAGIC Visit Completeness

Inflammation, Microbiome & Alimentation Gastro-Intestinal & Neuropsychiatric Effects

Site	N	Complete CRF	Complete ALL Surveys	Blood Received at Site	Urine Received at Site	Stool Received at Site	Genetic Blood Received at Site	Complete Visit*	Complete Visit (%)
21 McMaster University Medical Centre - Hamilton	1133	979	704	1024	760	755	961	527	47%
21B St. Joseph's Healthcare, Downtown - Hamilton	17	6	13	1	8	8	1	0	.00%
22 IBD Clinical & Research Centre - Winnipeg	1152	1004	788	1010	736	734	987	578	50%
23 Hotel Dieu Hospital - Kingston	620	561	469	489	477	480	462	354	57%
24 University of Calgary - Calgary	957	880	679	669	664	663	662	596	62%
25 University of Alberta - Edmonton	945	846	576	706	682	616	729	425	45%
26 IWK Health Centre - Halifax	171	149	143	133	133	130	133	119	70%
27 NSHA, Centre for Clinical Research - Halifax	355	355	307	338	337	337	337	305	86%
28 UHN Toronto Western Hospital - Toronto	59	59	38	36	33	31	33	19	32%
29 Memorial University - St. John's	56	55	54	55	52	46	48	41	73%
30 The Ottawa Hospital - Ottawa	322	305	234	287	223	223	268	185	57%
31 GI Research Institute - Vancouver	183	163	122	164	122	121	156	84	46%
32 Mount Sinai Hospital - Toronto	70	70	49	54	52	53	53	41	59%
33 MUHC IBD Research Centre - Montreal	165	140	105	155	126	118	143	81	49%
34 Centre Hospitalier de l'Université de Montréal - Montreal	45	33	27	44	29	29	41	24	53%
TOTAL	**6250**	**5605**	**4308**	**5165**	**4434**	**4344**	**5014**	**3379**	**54%**

*CRF and surveys are complete, all specimens are collected

Strategy for Patient-Oriented Research SPOR Putting Patients First

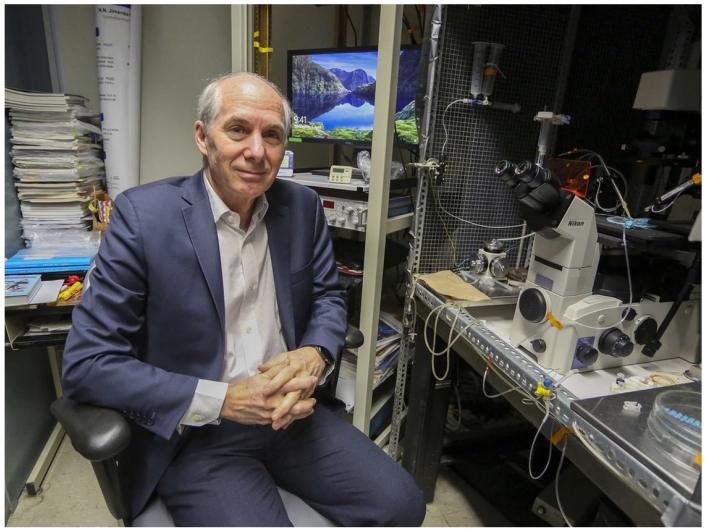
IMAGINE | MAGIC Study – Media Campaign

Queen's researchers examining gut, brain connection seek participants

Meghan Balogh

Published Apr 10, 2023 • 5 minute read

Join the conversation



CBC LISTEN | Live Radio | On Demand | CBC Podcasts | CBC Music Playlists

Ontario Morning

What's the connection between our guts and our brains?

Play Episode 7:01 | Share Episode

Dr Stephen Vanner is a Queen's University researcher leading a national study exploring the connection between the mind and your gut

Aired: April 12, 2023

More from Ontario Morning from CBC Radio

WATCH | Ontario latest province switching from biologics to biosimilars:

Ontario is the latest province to switch to cheaper, similar drug options for people with autoimmune diseases like Crohn's and arthritis. While the government expects millions in savings from the change, some patients and doctors worry the drugs won't be as effective for everyone.

Major savings for governments

Imagine SPOR
March 22 at 1:14 PM ·

Watch IMAGINE site lead, Dr. Leo Dieleman, on CTV Edmonton, talk about IBD, gut health and what IMAGINE's research is all about:

IMAGINESPOR.COM

Dr. Leo Dieleman on IBD, Gut Health, and IMAGINE's Research On CTV - IMAGINE

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

Strategy for Patient-Oriented Research SPOR Putting Patients First

Strategy for Patient-Oriented Research
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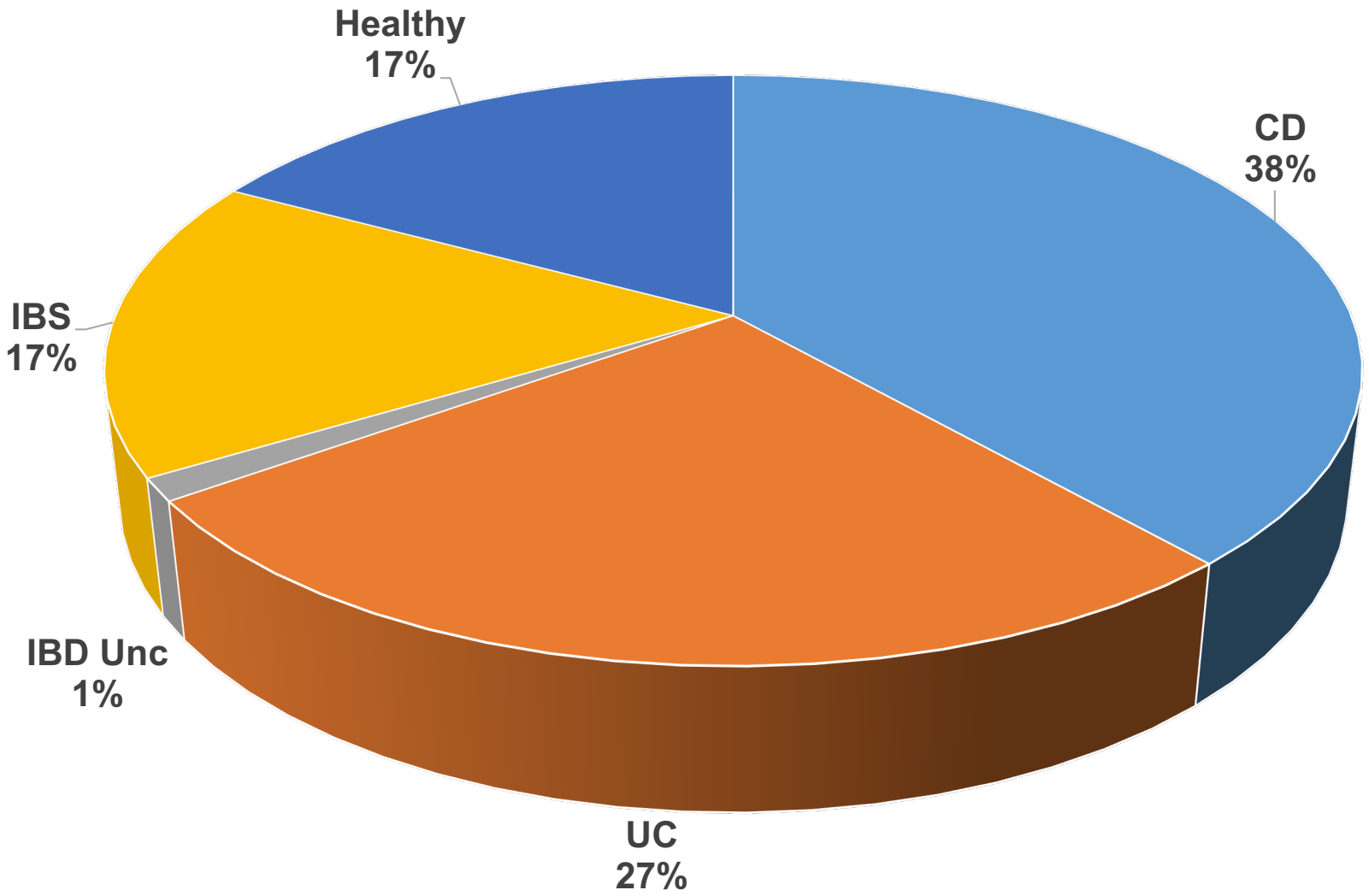
Baseline Data Summary

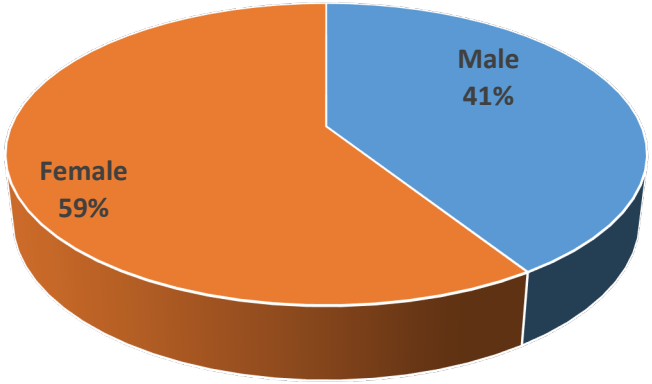
Paul Moayyedi

Participant Classification by Disease (n=6227)

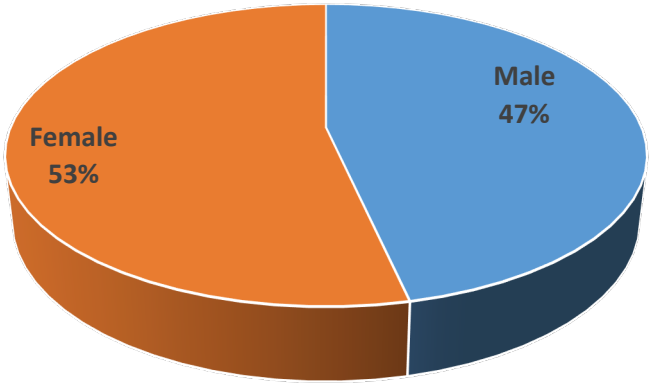


Gender by Disease Type (n=6227)

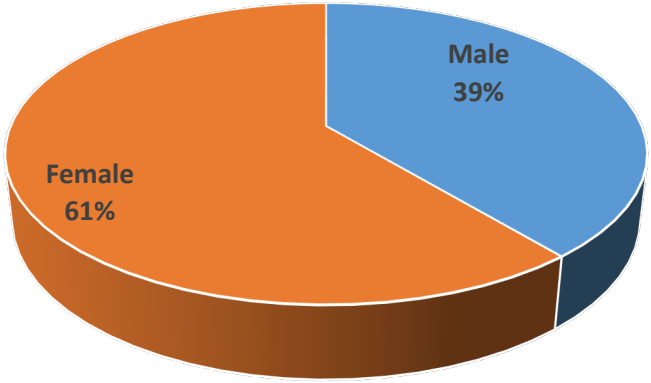
Crohn's Disease



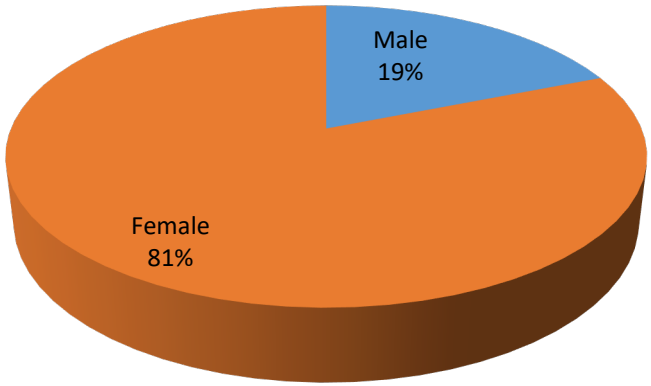
Ulcerative Colitis



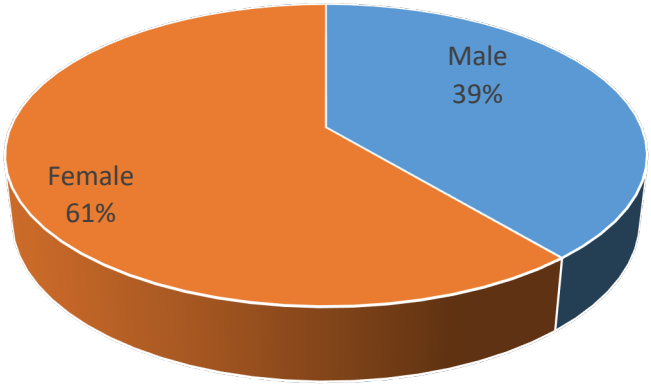
Unclassifed IBD



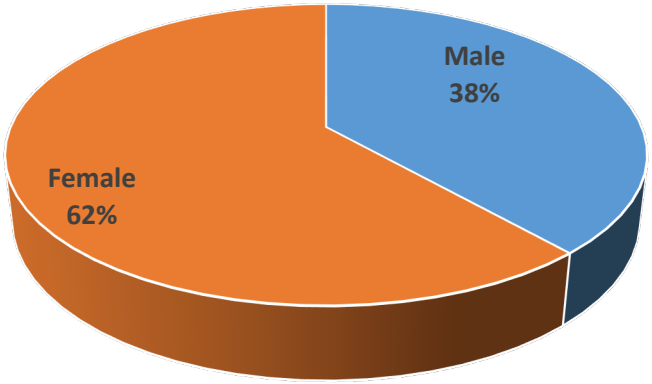
Irritable Bowel Syndrome



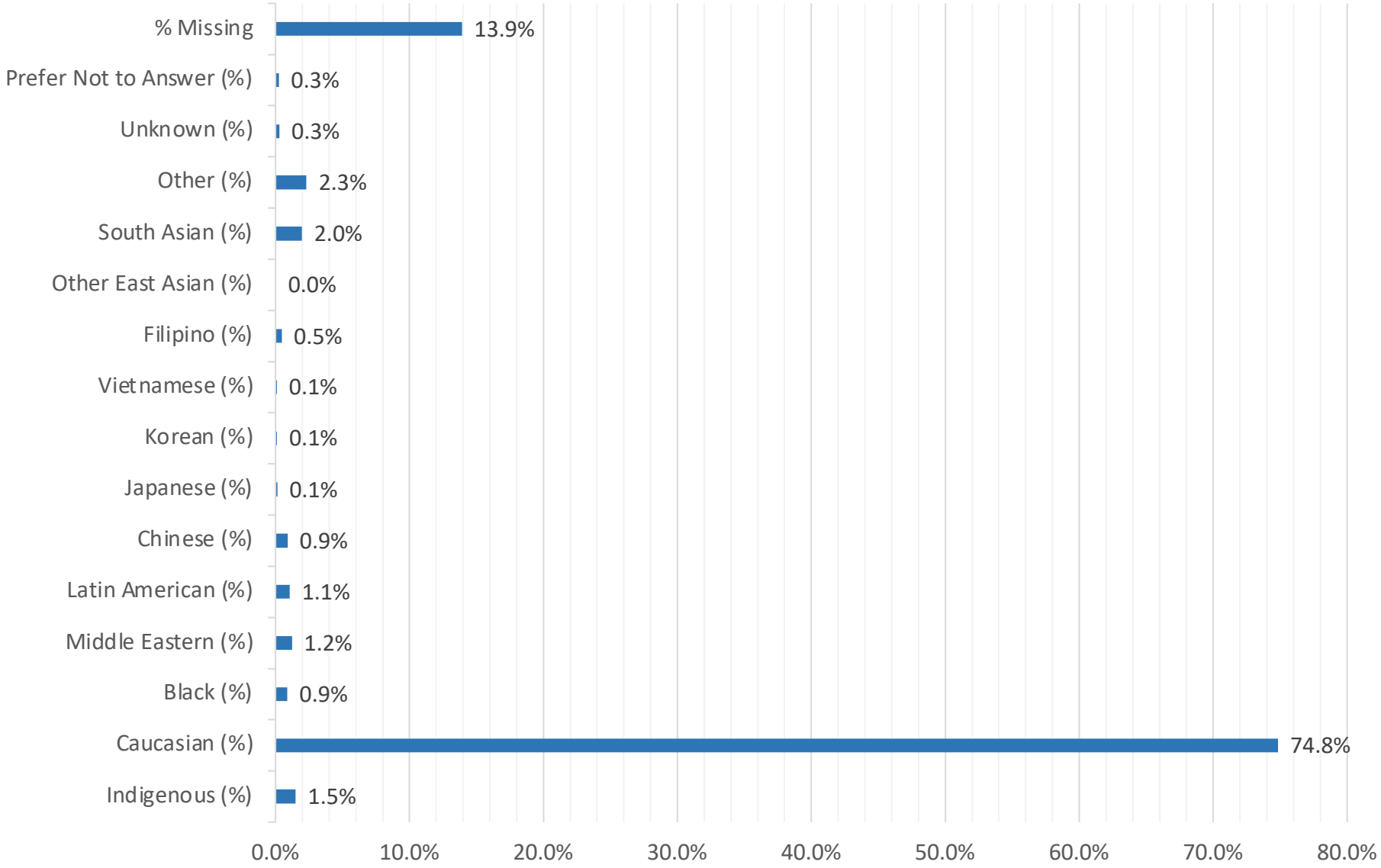
Healthy Controls



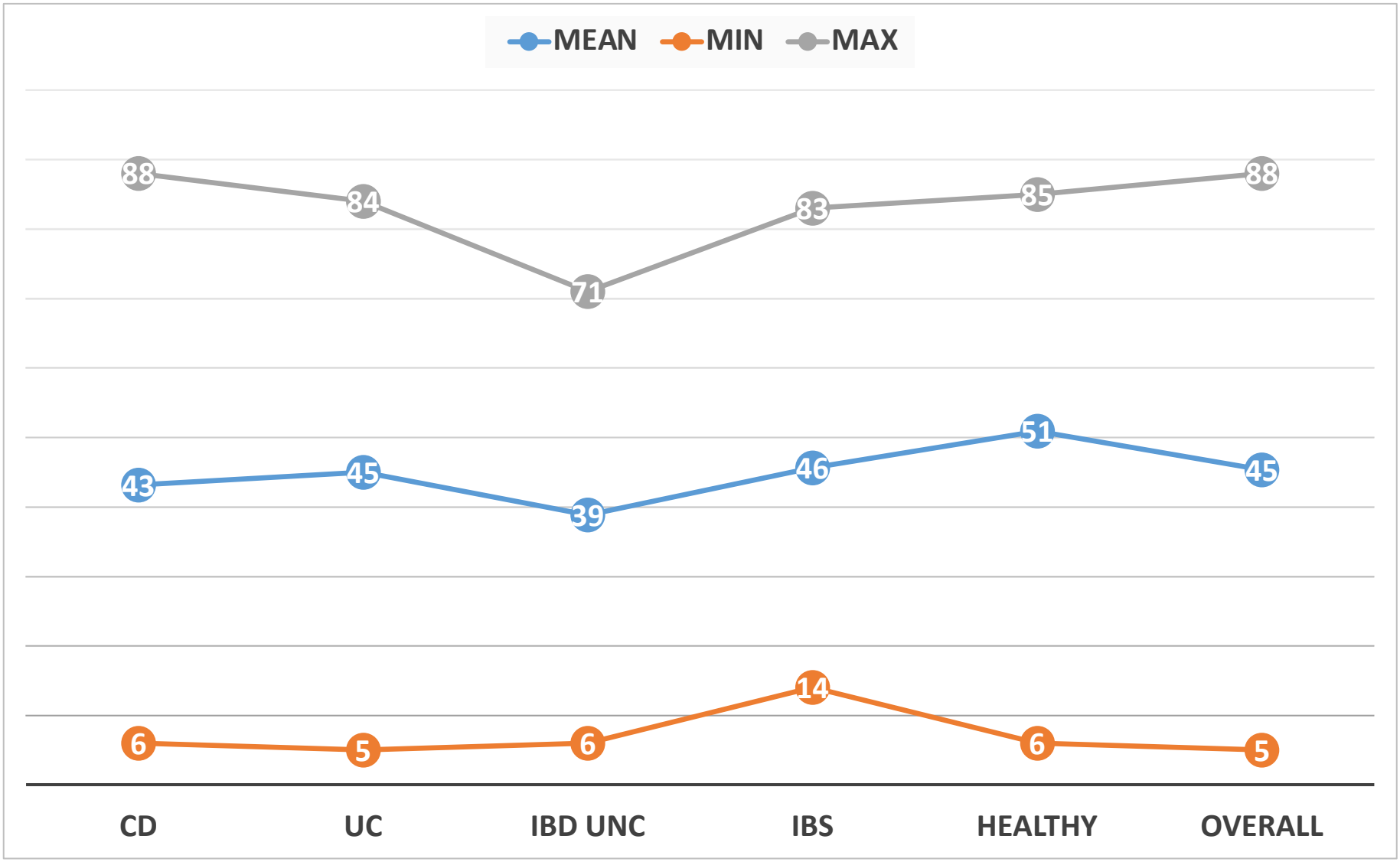
All



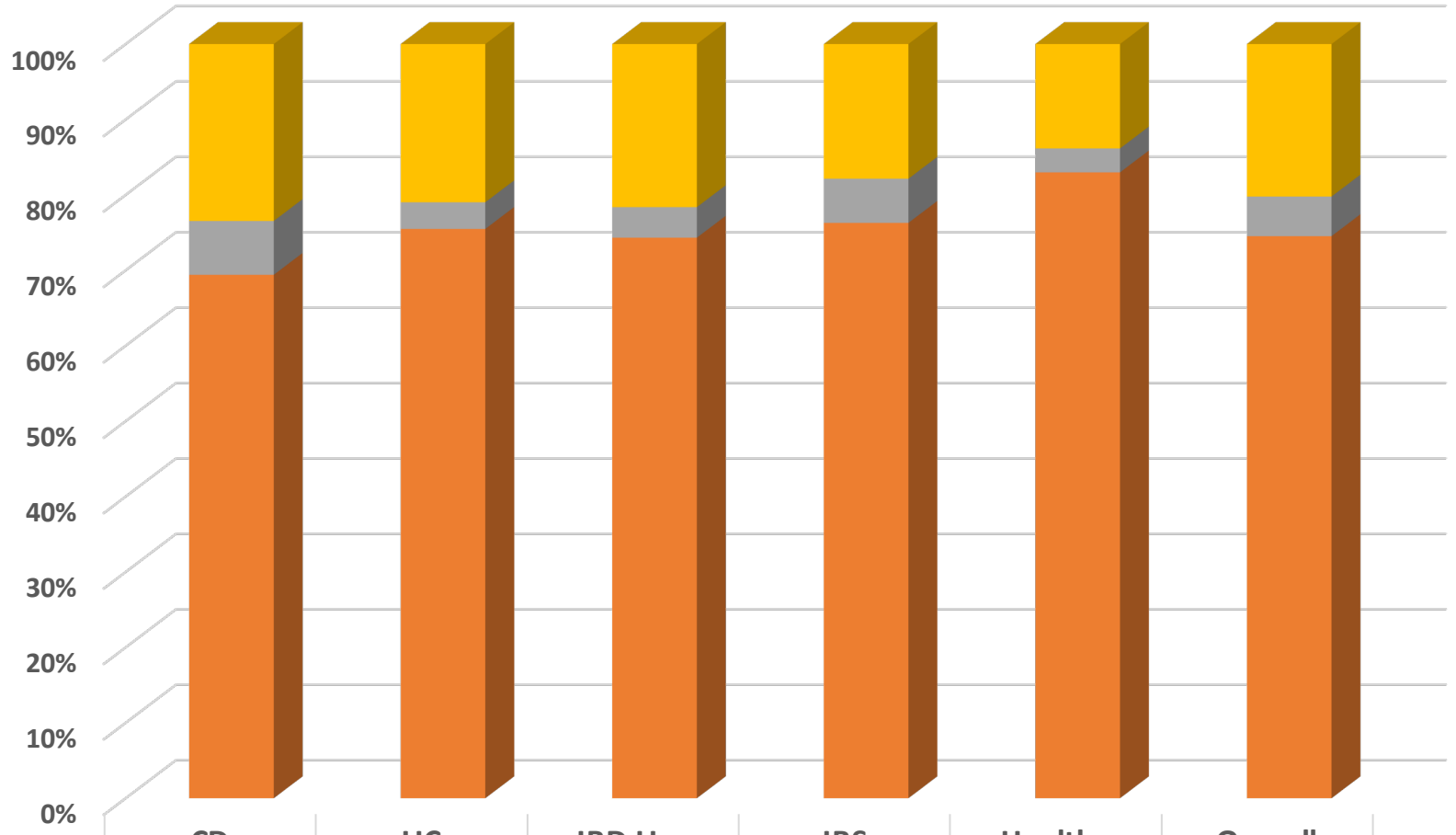
Participant Classification by Ethnicity (n=6227)



Age Distribution by Disease Group

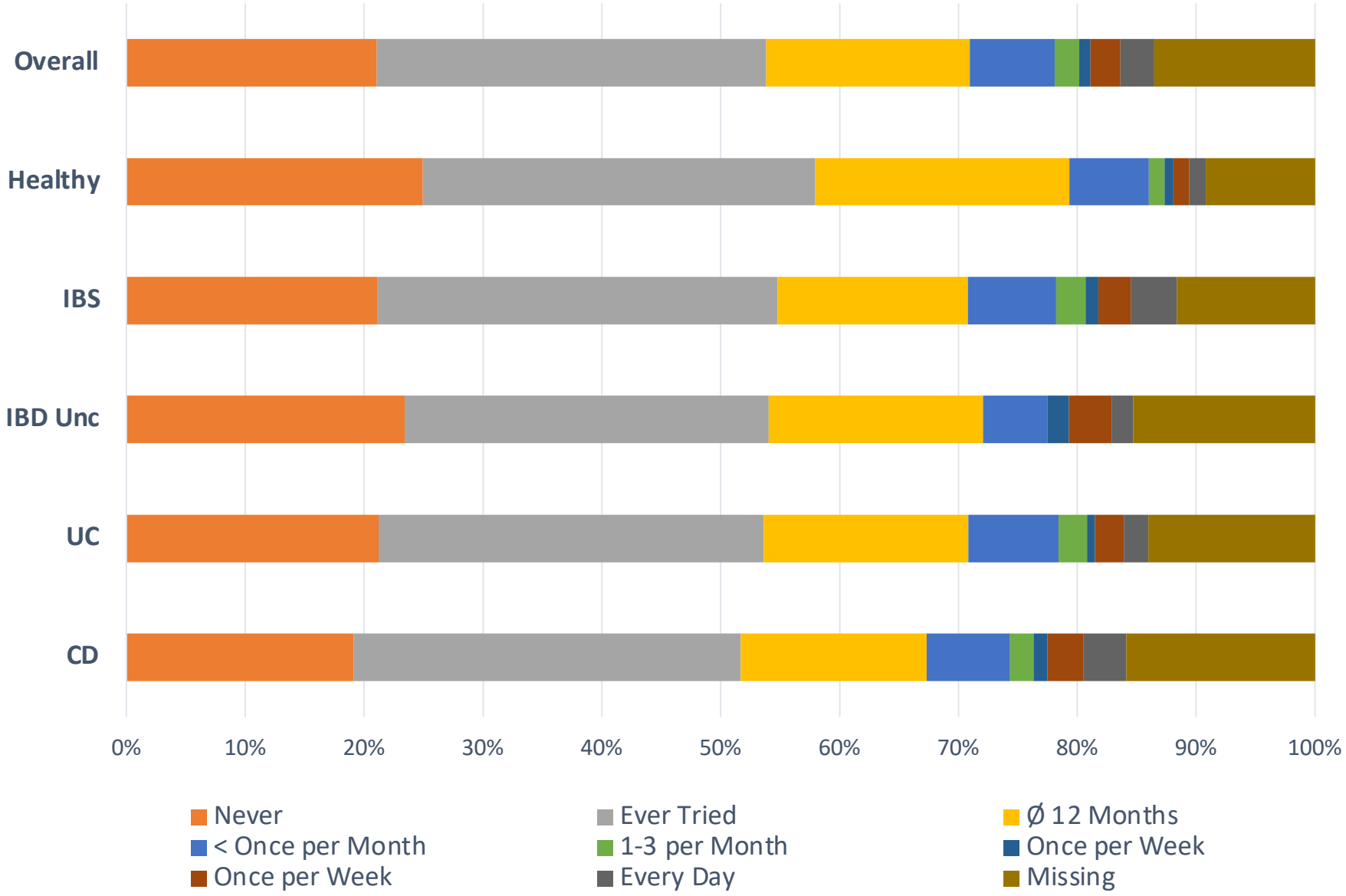


Smoking by Disease Group

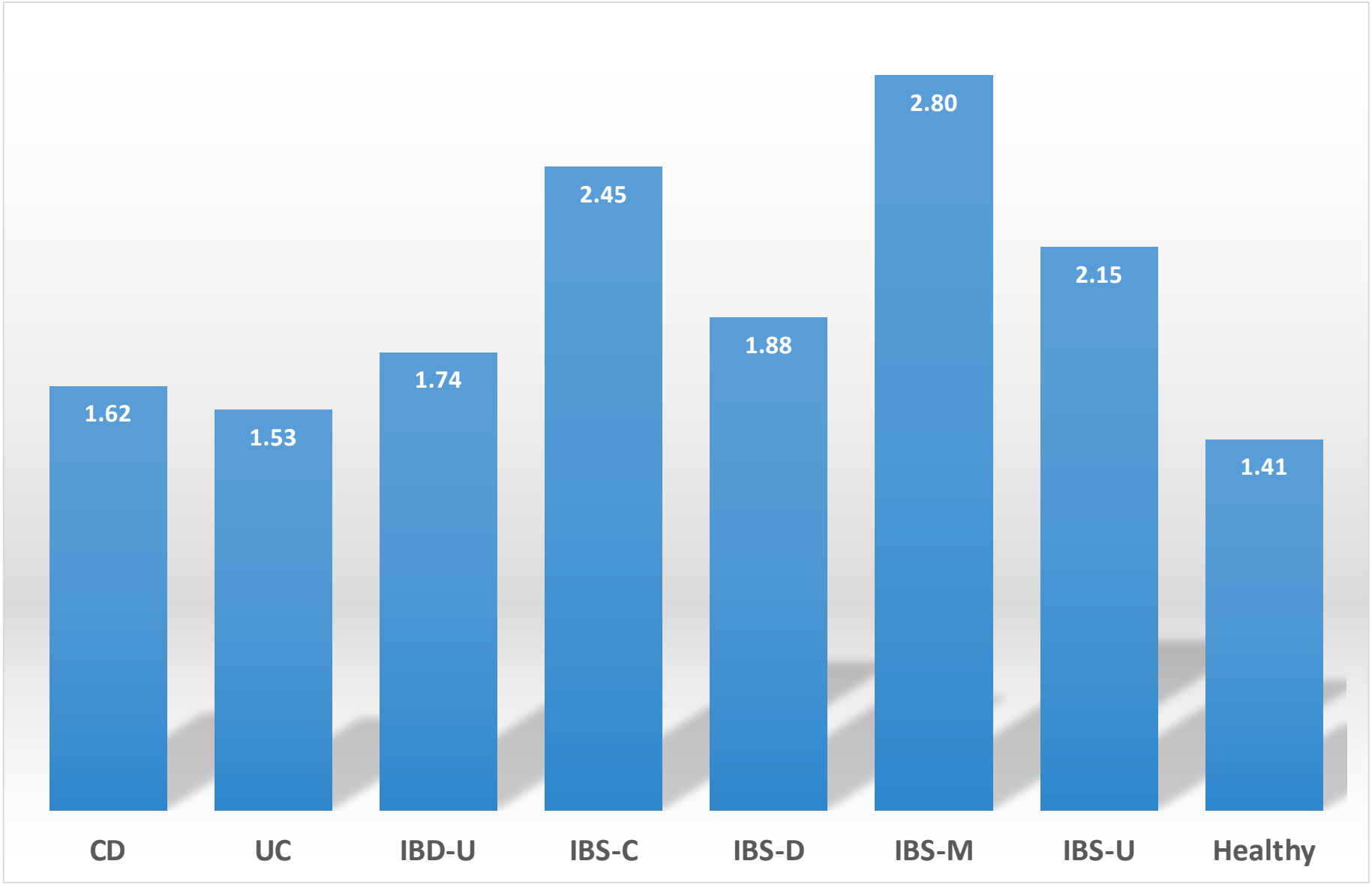


	CD	UC	IBD Unc	IBS	Healthy	Overall
# Missing	555	344	16	180	144	1239
N* Now	169	58	3	59	33	322
N* Non-Smk	1642	1238	55	769	863	4567

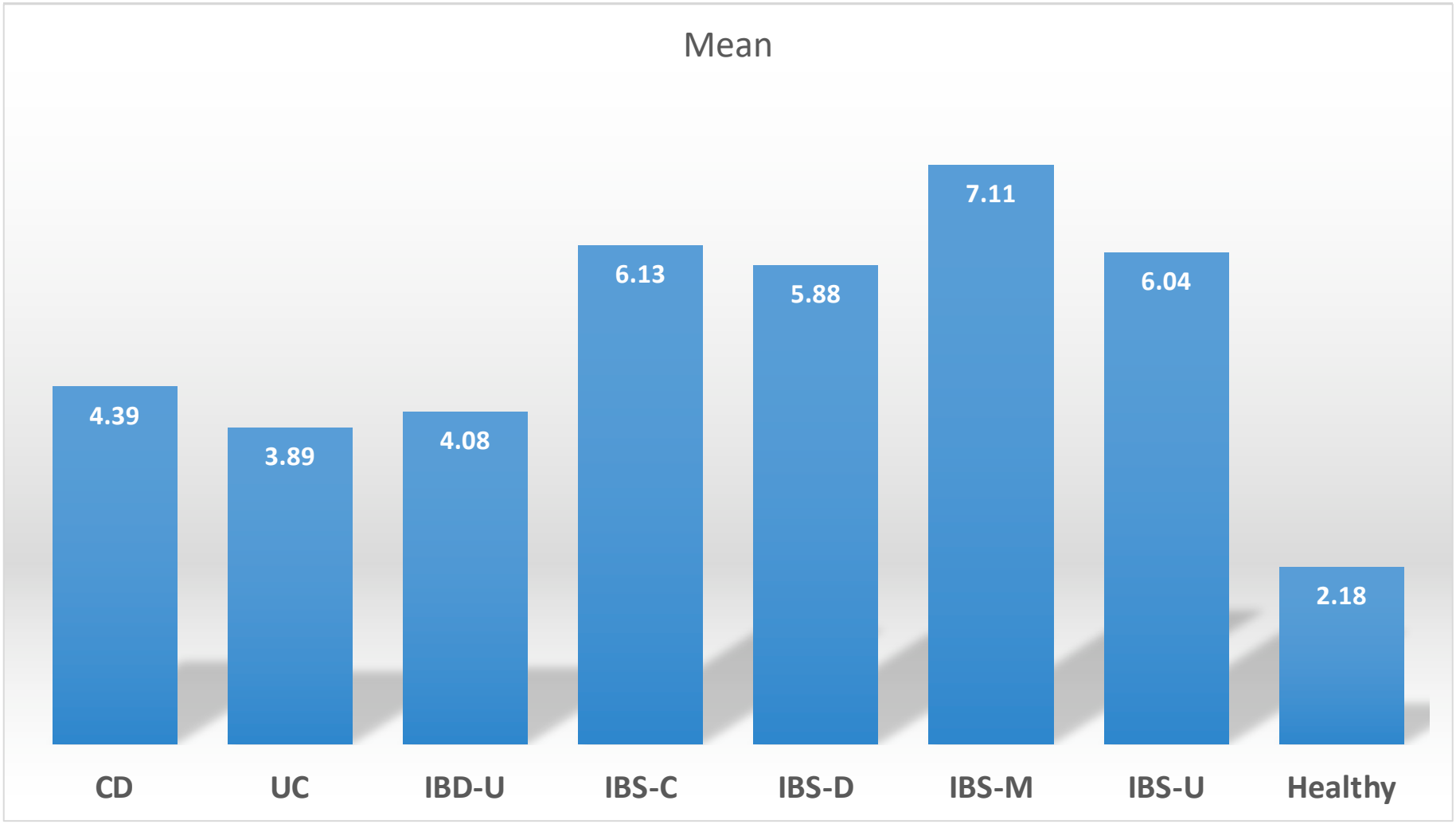
Marijuana Use by Disease Group (n=6227)



Adverse Childhood Experiences (ACE) Survey Mean Score by Disease Group (n = 4493)

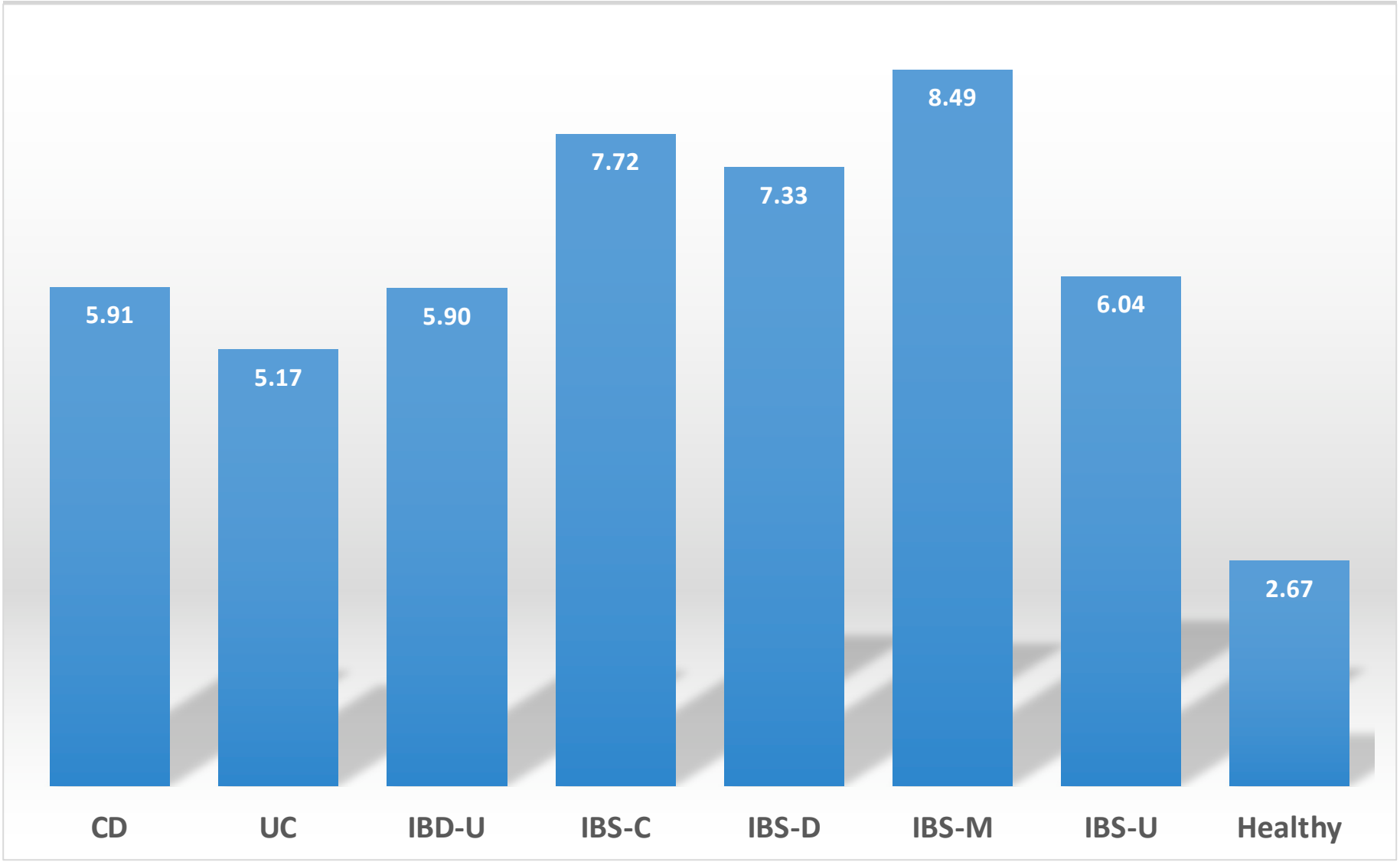


Generalized Anxiety Disorder (GAD-7) Survey Mean Score by Disease Group (n = 4568)



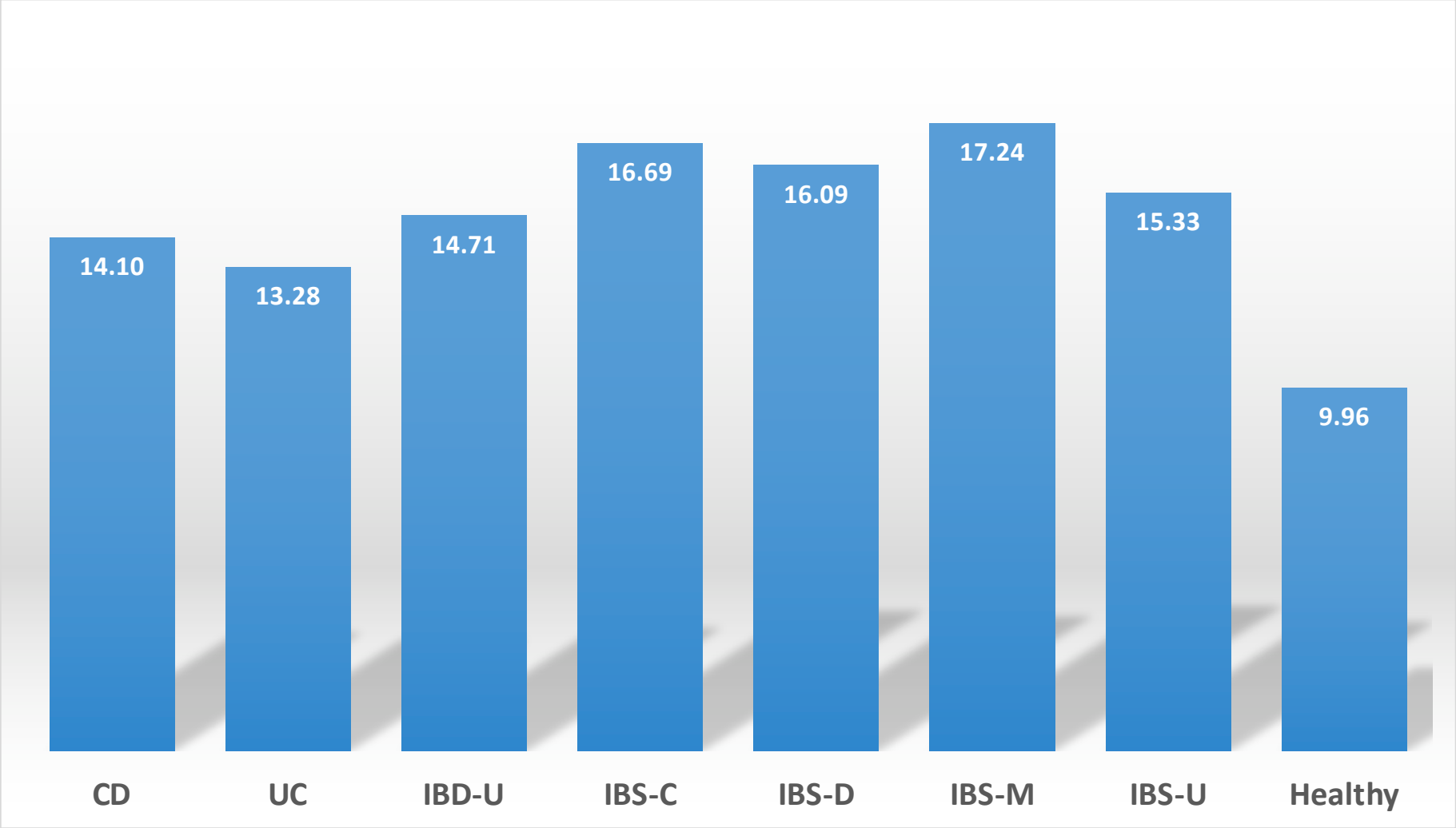
Score 0-4: Minimal Anxiety. Score 5-9: Mild Anxiety. Score 10-14: Moderate Anxiety. Score >15: Severe Anxiety

Patient Health Questionnaire (PHQ-9) Survey Mean Score by Disease Group (n = 4568)



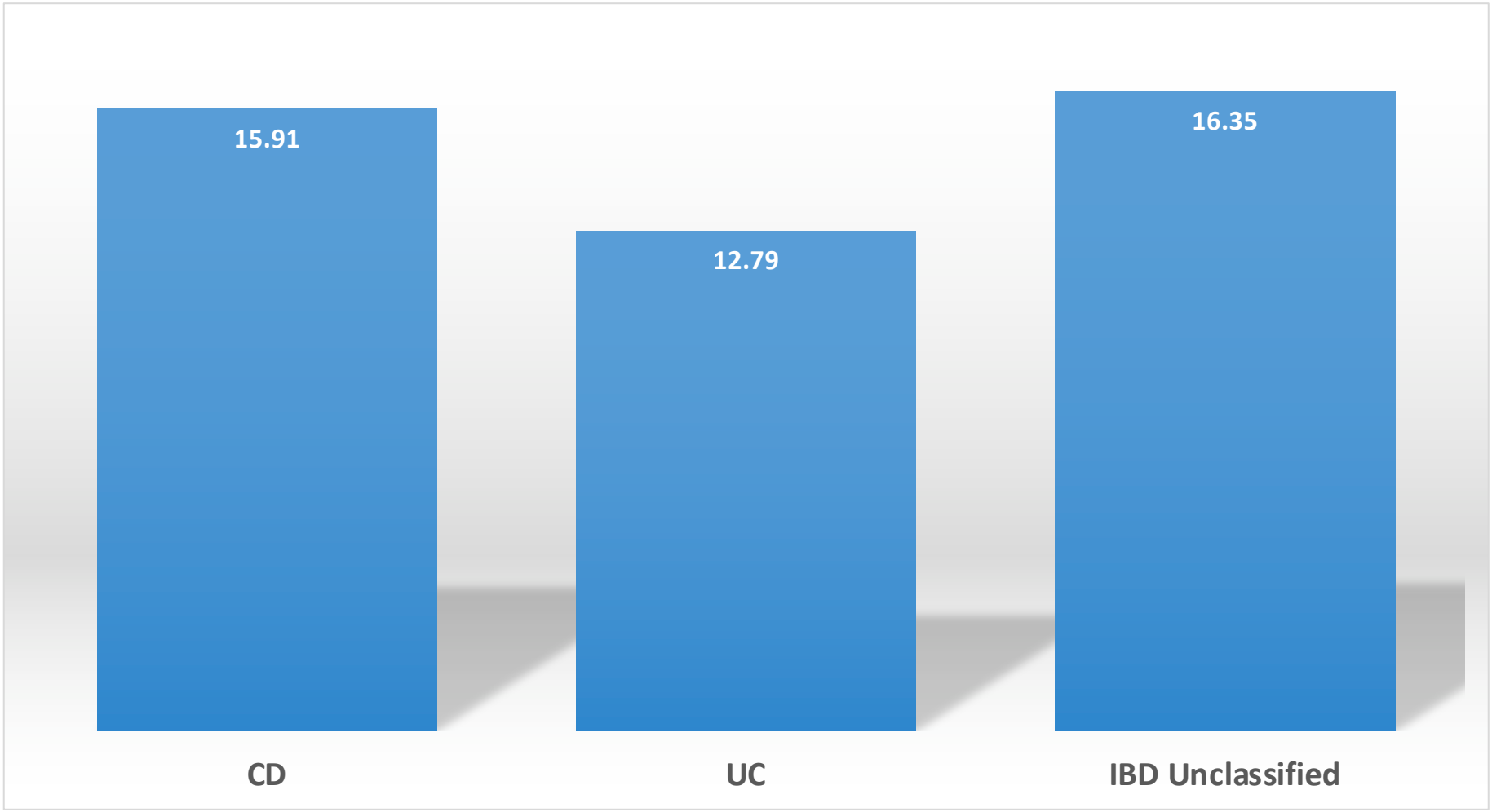
Score <5: absence of a depressive disorder; Score 5-9: mild depression;
Score 10-14: moderate depression; Score >14 major/severe depression

Perceived Stress Scale (PSS) Survey Mean Score by Disease Group (n = 4488)

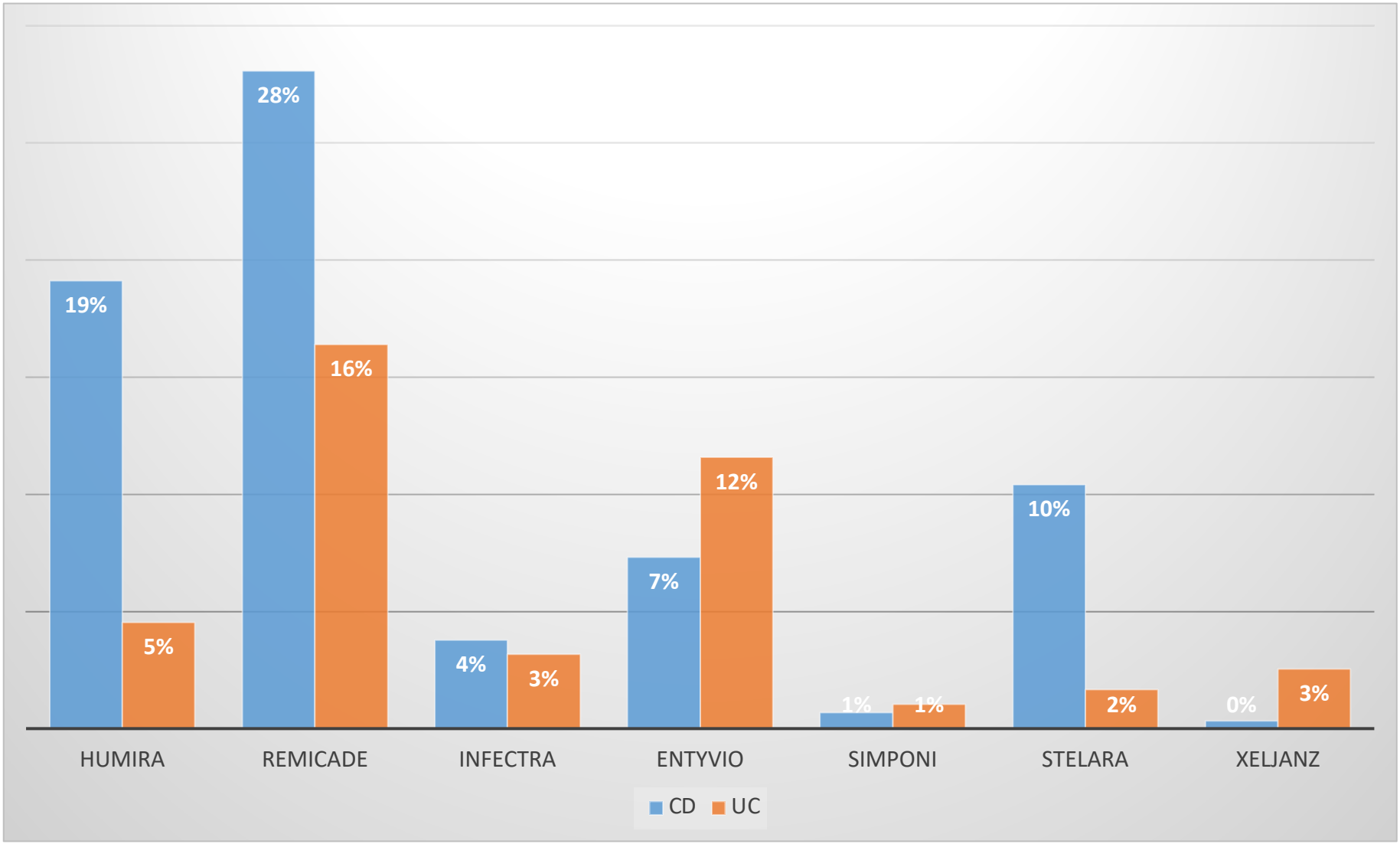


Score 0-13 – Low stress; Score 14-26 – Moderate stress; Score 27-40 – High perceived stress

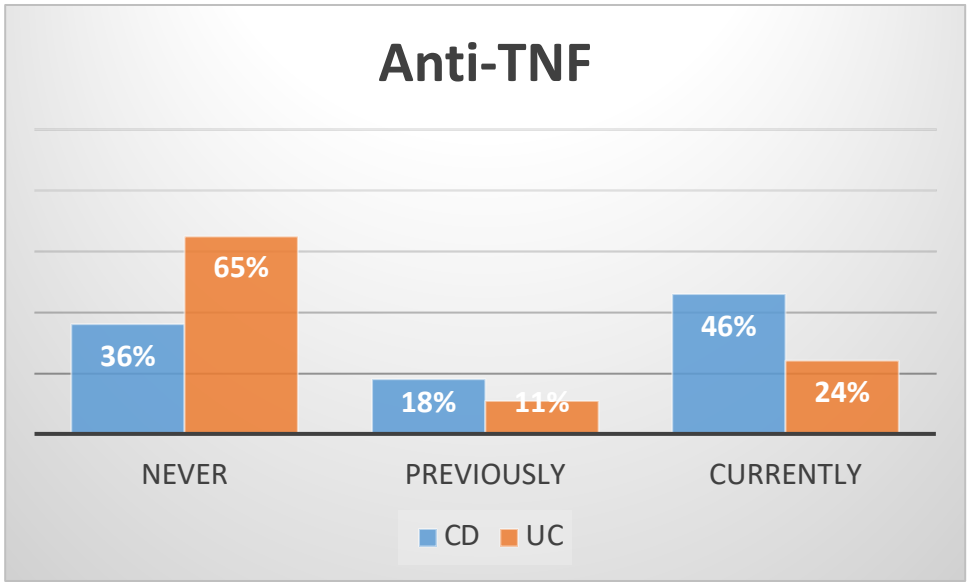
IBD Symptom Index (SIBDSI)
Mean Score by Disease Group (n = 4038)

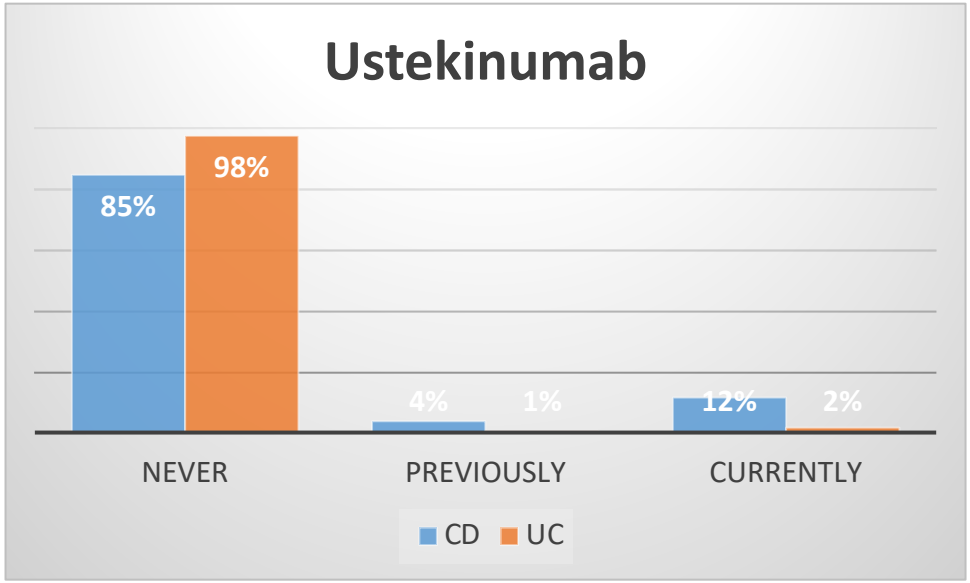


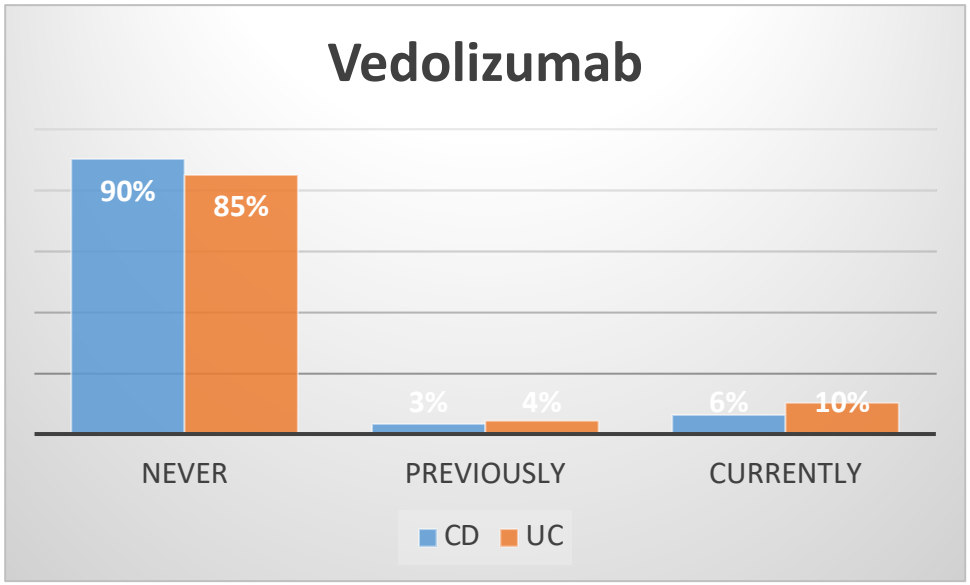
IBD Biologic Use (Patient reported, n=3054)

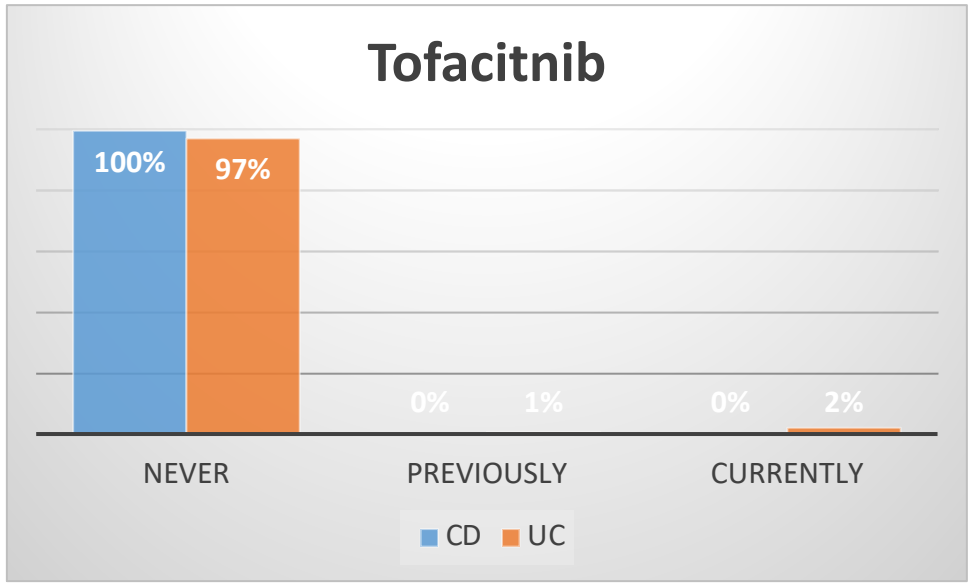


IBD Biologic Use (Site reported, n=4053)









Microbiome Profiles

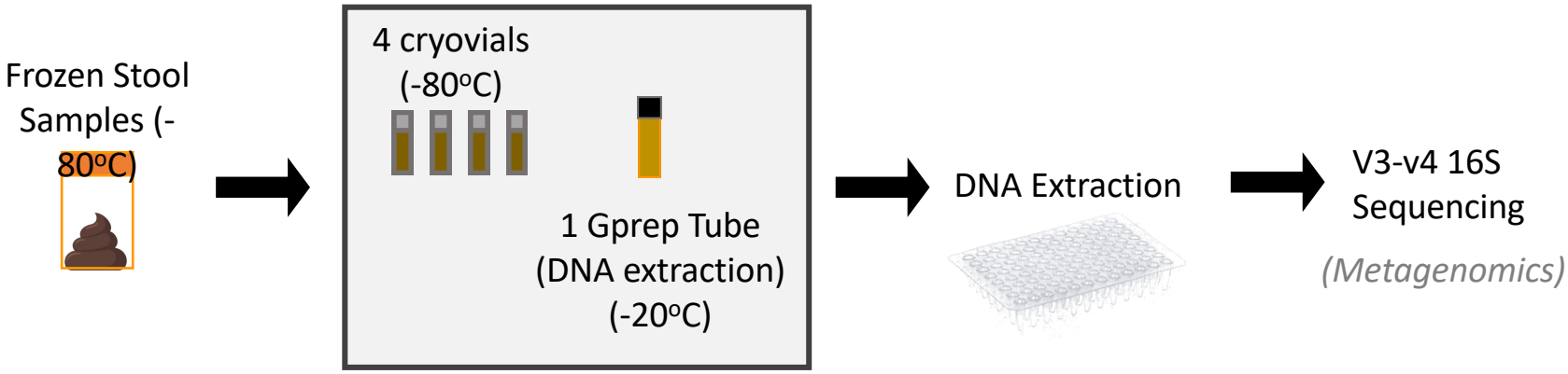
Sharok Shekkariz

MAGIC Microbiome Update

Sharok Shekarriz, Ph.D.
Postdoctoral Fellow
Surette Laboratory
Farncombe Digestive Health Research Institute
McMaster University

Michelle Shah
Laura Rossi

MAGIC Microbiome Update



Processed in Anaerobe Chamber

n = 9274 (4012 left)

n = 5267

n = 3435

Michelle Shah

Megan McCleary

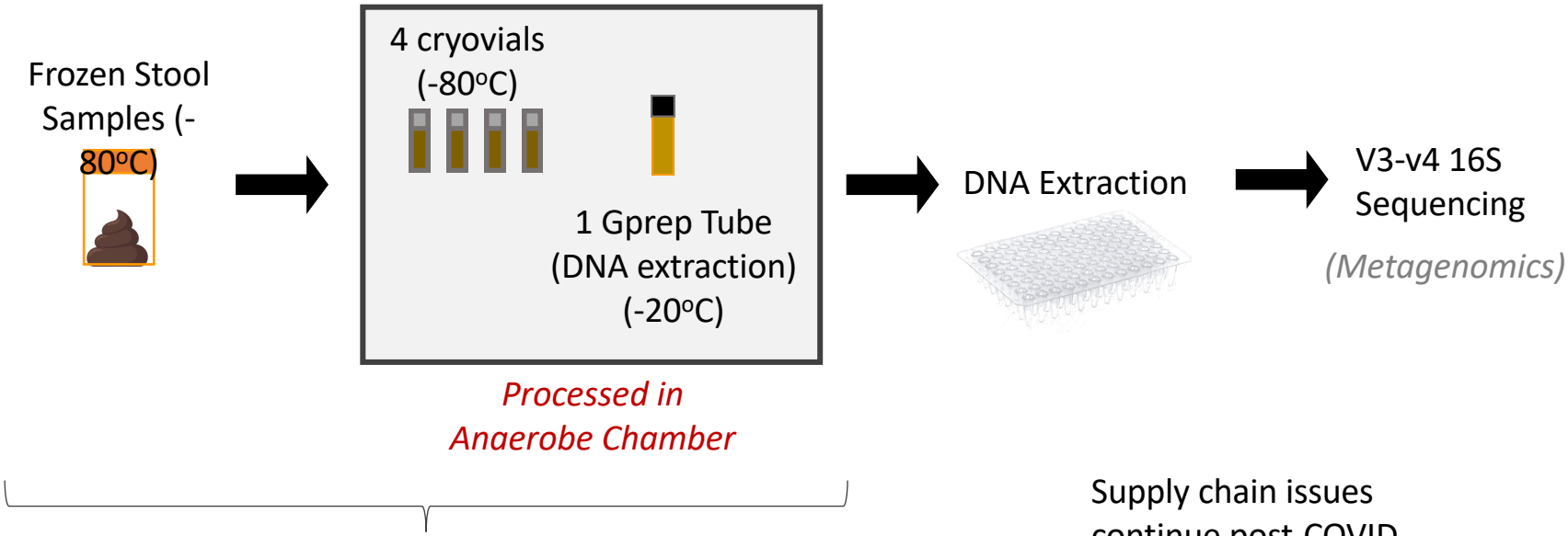
Blerina Kadiu

Michelle Shah

Laura Rossi

Laura Rossi

MAGIC Microbiome Update



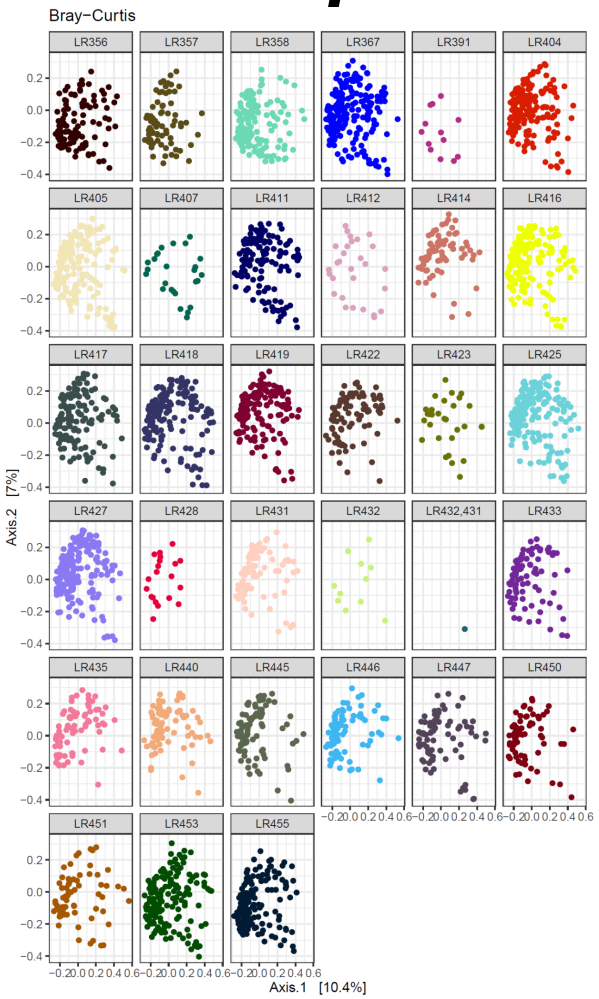
This is the bottleneck
- the work is done in anaerobe chamber
- The samples arrive not well organized

Supply chain issues continue post-COVID
-cryovials
-DNA extraction kits currently on back order

MAGIC Microbiome Update

V3-v4 16S
Sequencing
n = 3435

= 33 Sequencing runs
MiSeq (2x300nt)



So far there is no sequencing bias by run

Our experience over the last 10+ years is run bias is usually a sequencer issue
(we did have issues during covid but fortunately no MAGIC runs)

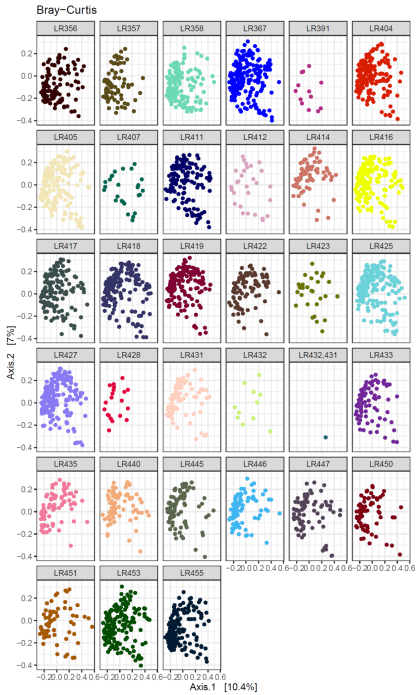
We have 2 runs with lower read depth than we like so we are re-running these (sequencer issue)

Laura Rossi

MAGIC Microbiome Update

V3-v4 16S
Sequencing
n = 3435

= 33 Sequencing runs
MiSeq (2x300nt)



This is enough data to start doing some preliminary analysis and QC on the data

*Establish reproducible informatics pipelines ***

Laura Rossi

MAGIC Microbiome Update

*Establish reproducible informatics pipelines ***

IMAGINE Study:
Assessment of Inter-Laboratory Variation in the Characterization and Analysis of the Mucosal Microbiota in Crohn's Disease and Ulcerative Colitis
Szamosi, JC … Bernstein, CN Front Microbiol. 2020; 11: 2028.

"… we find that results can be robust to the various extraction and sequencing approaches used in our study. Differences in data processing methods have a larger impact on results, making comparison among studies less reliable…" ‘

Not to exclude other analysis pipelines but have a robust pipeline where the microbiome data can be regenerated (and any other ancillary studies with additional microbiome data can be run thru the same pipeline)

MAGIC Microbiome Update

Pilot Metagenomic Study

- 120 UC
- 120 CD
- 110 IBS
- 120 Healthy Controls

In House Library construction

(Derakhshani et al BMC Genomics 2020 21(1):519)

NovaSeq S4 flow cell 2x150nt

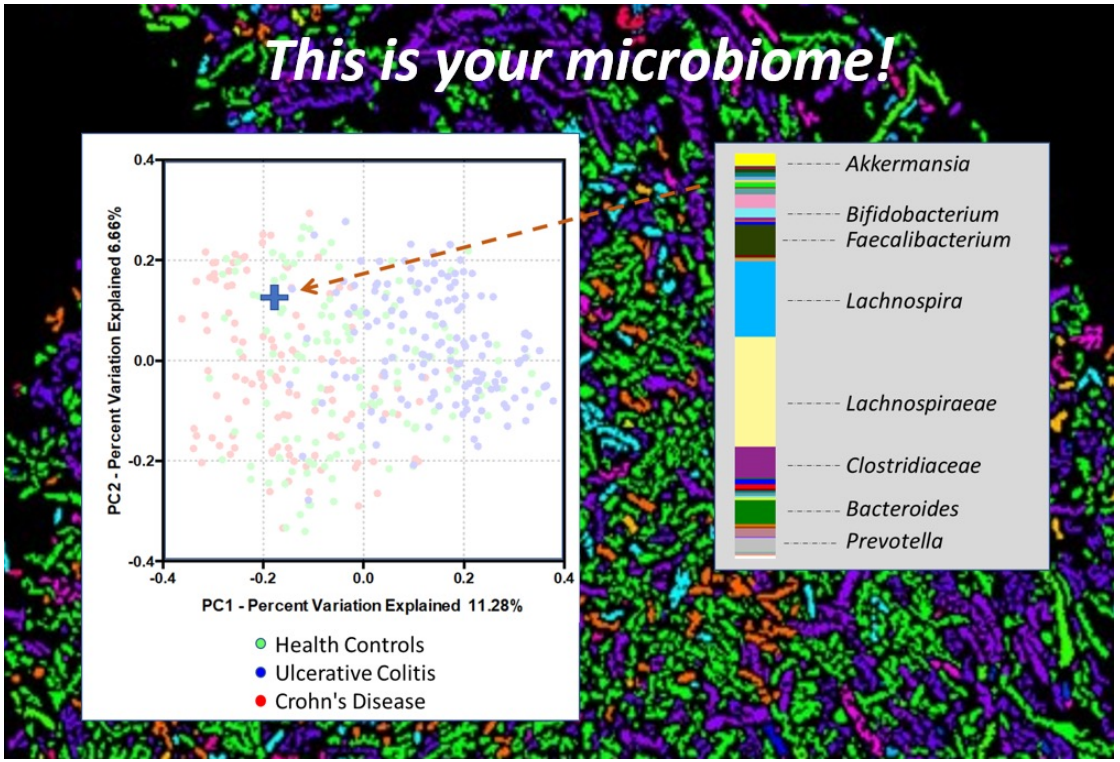
~$20x10^6$ paired reads per sample

~$70/sample (DNA already extracted)

Sharok Shekarriz / Laura Rossi

Microbiome Profile Report for Study Participants

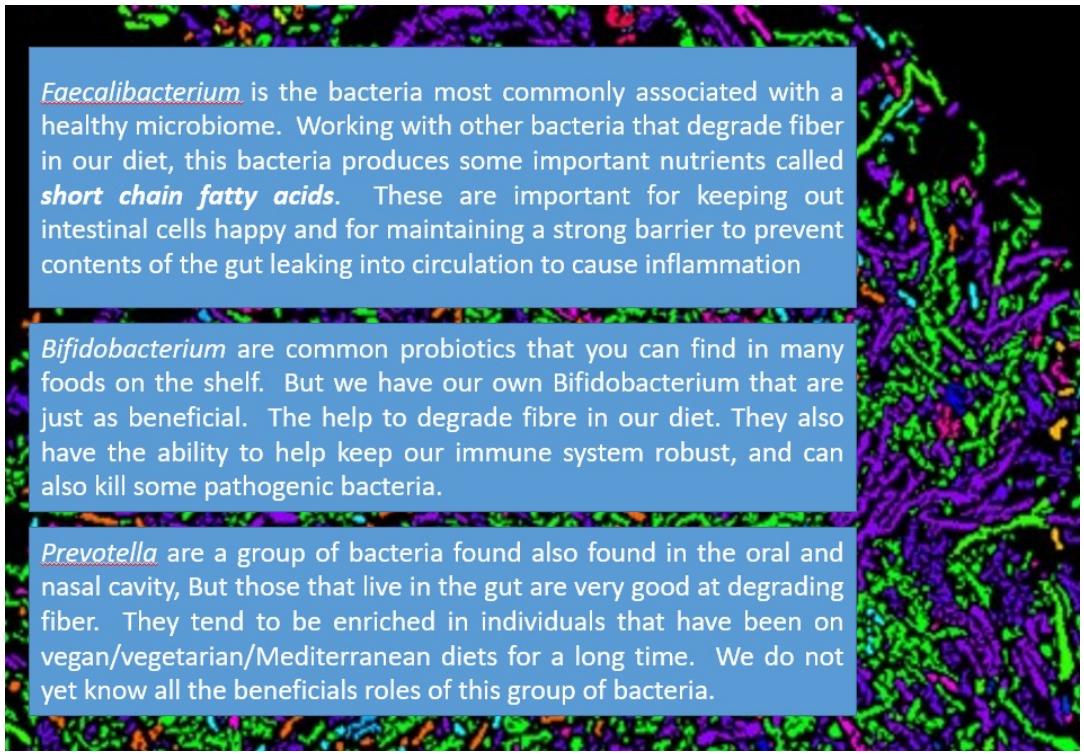
With Aida and the Patient Engagement team
and the Surette lab (led by Sharok Shekarriz)



Work in progress

Sharok Shekarriz

Microbiome Profile Report for Study Participants



Each profile will be accompanied by a lay description of specific taxa present in their sample

A lay introduction to microbiome analysis will be provided as well

Sharok Shekarriz

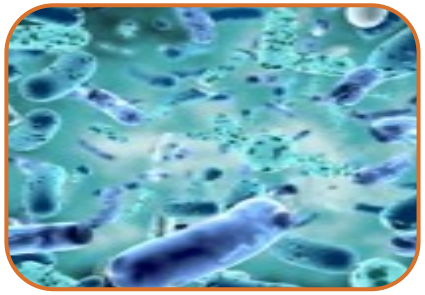
Inflammation, Microbiome & Alimentation Gastro-Intestinal & Neuropsychiatric Effects

Strategy for Patient-Oriented Research
SPOR
Putting Patients First

IMAGINE
Sub-Studies

IMAGINE 1.0 | Research Themes

33 Research Sub-Studies



Microbiome

Diet & Environment

Mental Health

Patient Engagement

Health Services & CCC's PACE

Sex & Gender

Biomarkers

Inflammation, Microbiome & Alimentation Gastro-Intestinal & Neuropsychiatric Effects

Strategy for Patient-Oriented Research SPOR Putting Patients First

IMAGINE 1.0 | SUB-STUDIES

Microbiome

- Variation of Mucosal Microbiota in IBD
- Fecal Transplantation & Antibiotics in UC
- FMT in CD (terminated early)
- FMT in IBS w/ Major Depression
- FMT in Pouchitis

Patient Engagement

- Patient Treatment Preferences
- Recruitment & Retention
- PACER: Psychosocial effects of Food
- PACER: Patient Support Tools
- Citizen-targeted website
- EP4
- DCE in Peds FMT Treatment Preferences
- Pedi & Parent Preferences for Treatment

Diet & Env.

- Gluten in IBS Pilot
- FODMAP Diet in IBS Pilot
- Diet Intervention in IBS
- Biomarkers in IBS Diet
- Diet Predicts Therapy in peds IBD
- Intermittent Fasting in IBD

Health Services/ PACE

- Telemedicine in IBD
- QI in IBD care / Global Rating Scale in IBD
- e-Clinical Care Pathways
- Patient Symptom Monitoring App
- Healthcare Utilization in IBD & IBS
- Frailty Index in IBD

Psychiatry/ Mental Health

- iCBT in IBD (pilot completed)
- Brain Imaging in IBD (terminated early)
- Stress Reduction in IBD
- Yoga in IBS Patients
- Resilience & Suicide Risk in IBD
- Mental Health Assessment in Routine IBD Care
- Neurocognitive Effects of FMT in IBS
- Pain in IBD

Sex & Gender

- Assessing MD/Patient Gender on Outcomes and Healthcare Utilization
- Patient/MD Attitudes, Experiences & Expectations of Male vs Female Patients

Biomarkers

- Epigenetic biomarkers of Anti-TNF Treatment Success in IBD
- Reduced responses to anti-inflammatory therapy
- Fecal proteolytic activity in IBD
- Immunopheno-typing in IBD
- Machine Learning

Resilience & Suicide Risk in IBD

Catastrophizing in IBD

Dean Tripp

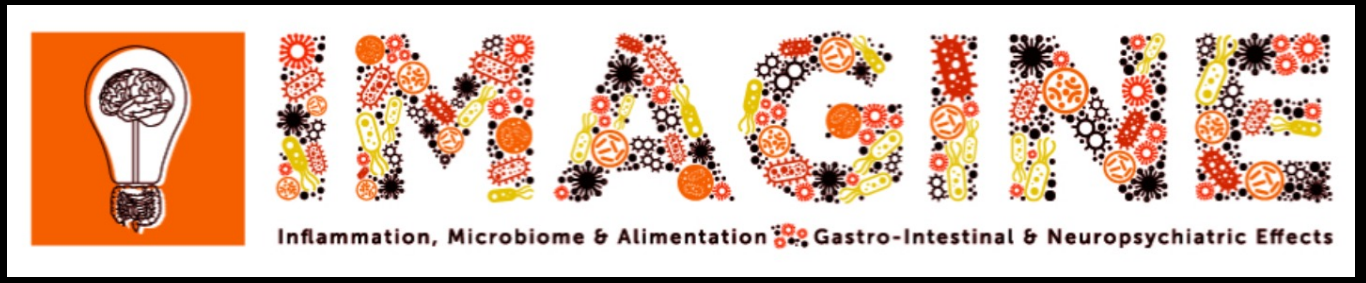
Studies to Report Update:

The IMAGINE Mental Health Working Group: Dean A Tripp, Lesley Graff, Kim Daley, Deborah Marshall, Jenna Rines, Luciano Minuzzi, Sara Kohut, Sandra Zelinsky, Paul Moayyedi, Valerie Taylor, Gail Bellissimo, Aida Fernandes, Mark Swain & Krista Jones.

- Project #1 "**UNDERSTANDING THE RELATIONSHIP BETWEEN DISEASE SEVERITY AND DEPRESSION IN INDIVIDUALS WITH INFLAMMATORY BOWEL DISEASE AND IRRITABLE BOWEL SYNDROME**"
- CPS 2023 poster

- Project #2 – "**UNDERSTANDING THE SLEEP-PAIN RELATIONSHIP IN INFLAMMATORY BOWEL DISEASE**" Jones' MSc

Project #1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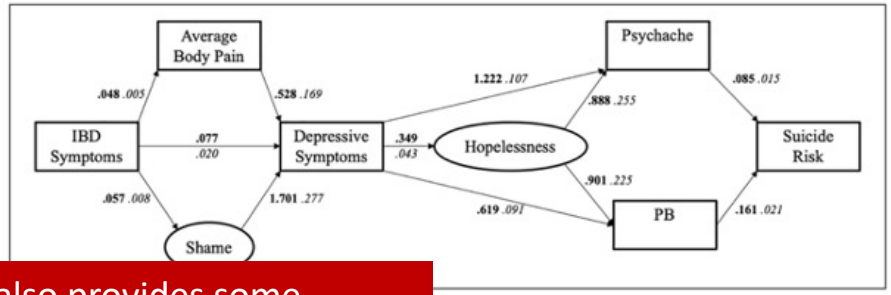
UNDERSTANDING THE RELATIONSHIP BETWEEN DISEASE SEVERITY AND DEPRESSION IN INDIVIDUALS WITH INFLAMMATORY BOWEL DISEASE AND IRRITABLE BOWEL SYNDROME

- ✓ IBD is associated with lowe
  depression compared to ge
- ✓ Depression, in turn, is asso
  severe IBD, higher pain, an
  life. Inflammation may pla
  developing depression and
  course, with depressive symptoms, further exacerbating gastrointestinal symptoms.
- ✓ Depression among patients with IBD often remains undiagnosed or undertreated.
- ✓ Patients with IBS experience a high burden of depression and anxiety (the prevalence of depression and anxiety is 37.1 and 31.4%).

Recent research in IBS also provides some interesting insights, showing that patients primarily show difficulties in tolerating affective states and differentiating affective states, which is conceptually connected to the mental process of resiliency.



gression of IBD symptoms to suicide risk.
ables are bold, *SEs* are italicized. All paths are significant. PB:

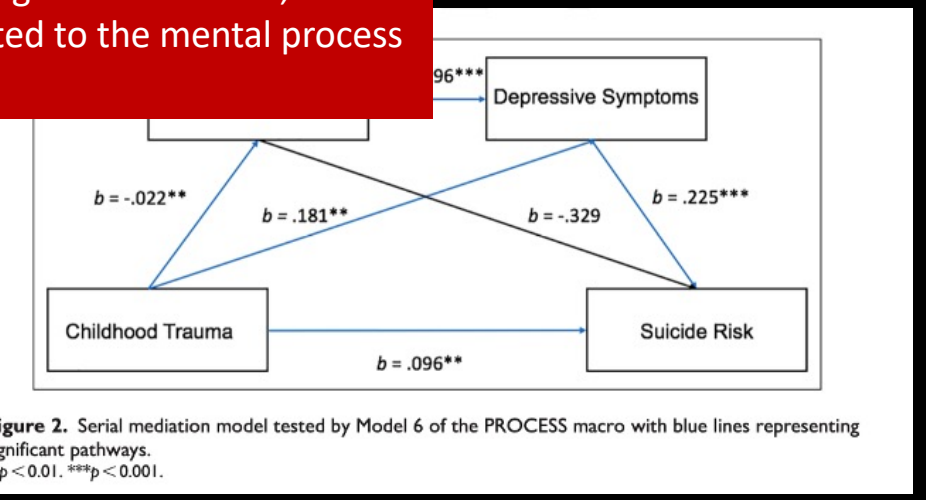
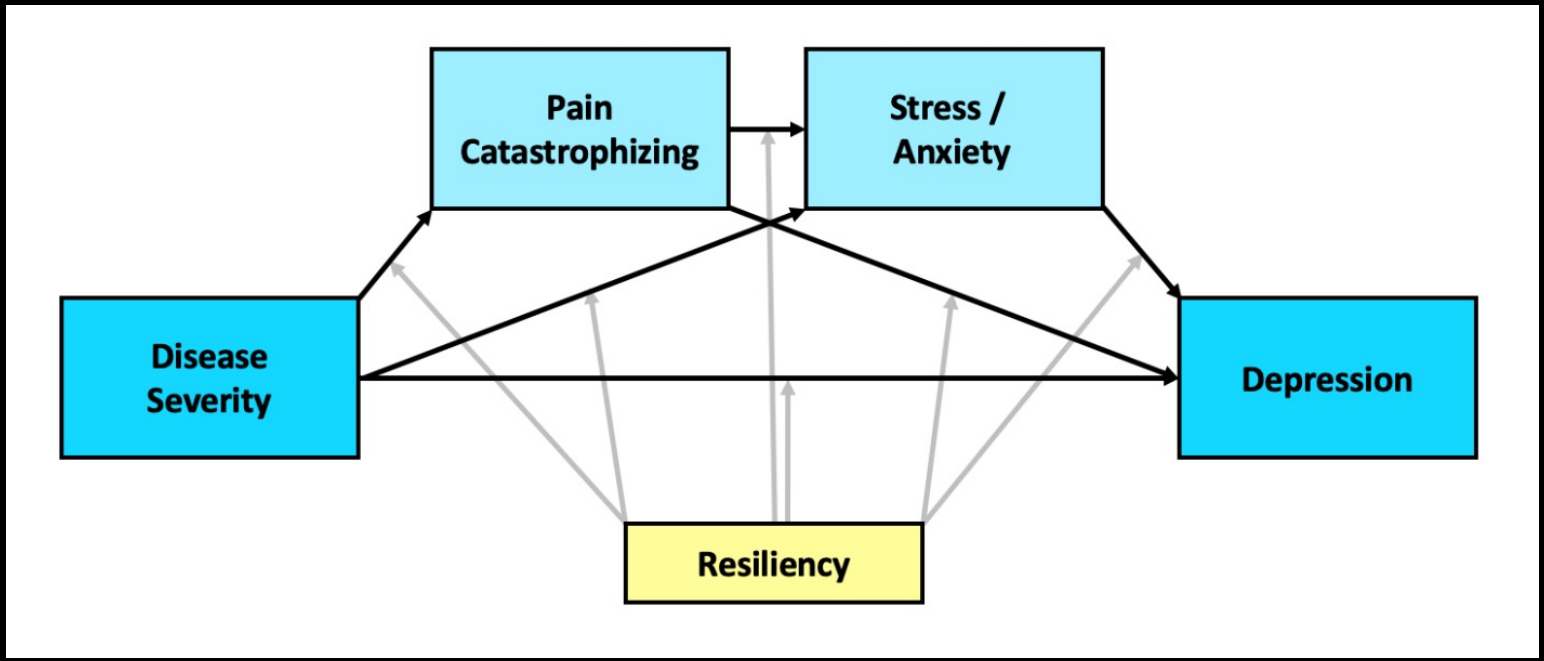


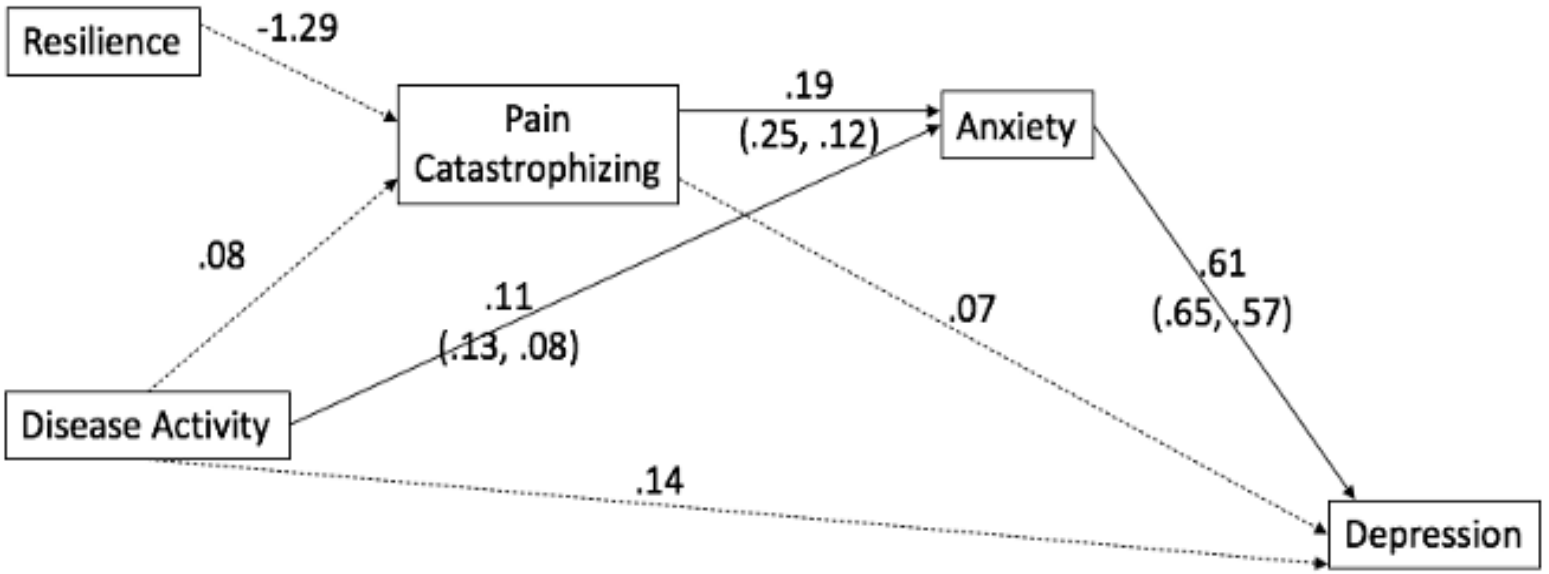
Figure 2. Serial mediation model tested by Model 6 of the PROCESS macro with blue lines representing significant pathways.
$^{**}p < 0.01$. $^{***}p < 0.001$.

This research is important because the continued identification of depression associated risk-factors in IBD and IBS populations is likely a key in reducing the high rate of patients at risk for depression and/or suicide.

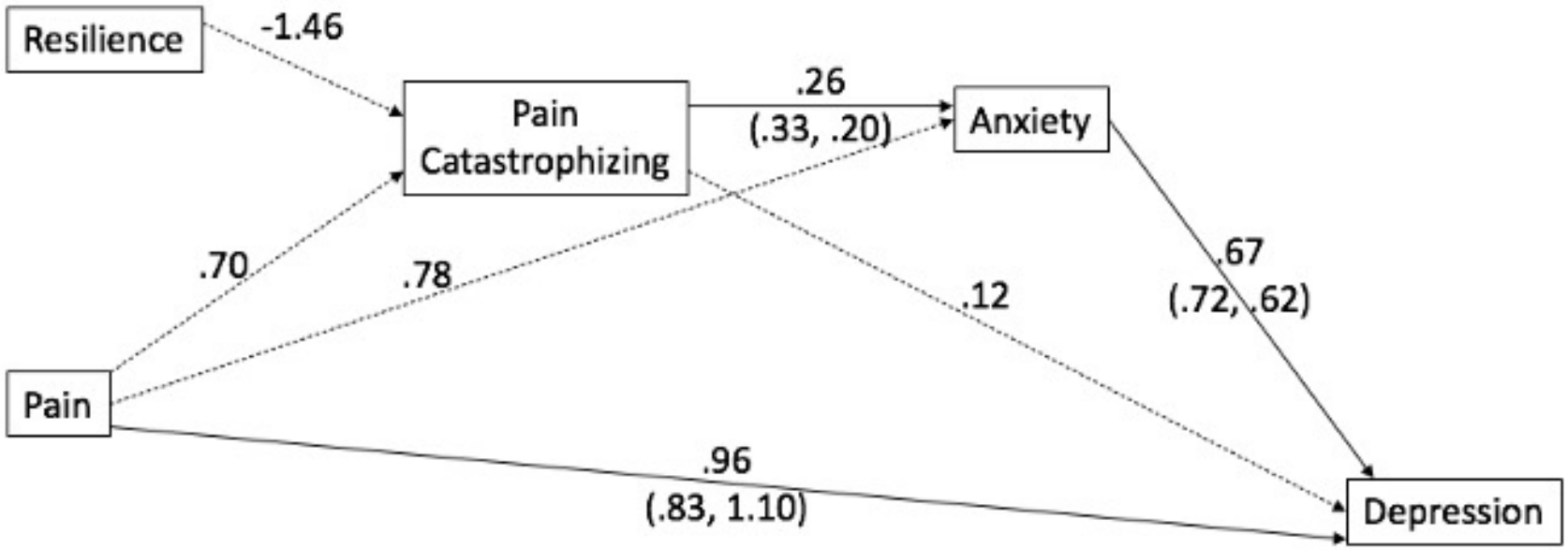
As shown below, this archival study proposes to examine a moderated serial mediation between IBD and IBS disease severity and depressive symptoms. Data are de-identified and available now in the MAGIC data at baseline.



Moderated Serial Mediation Model Including IBD Patients Only.



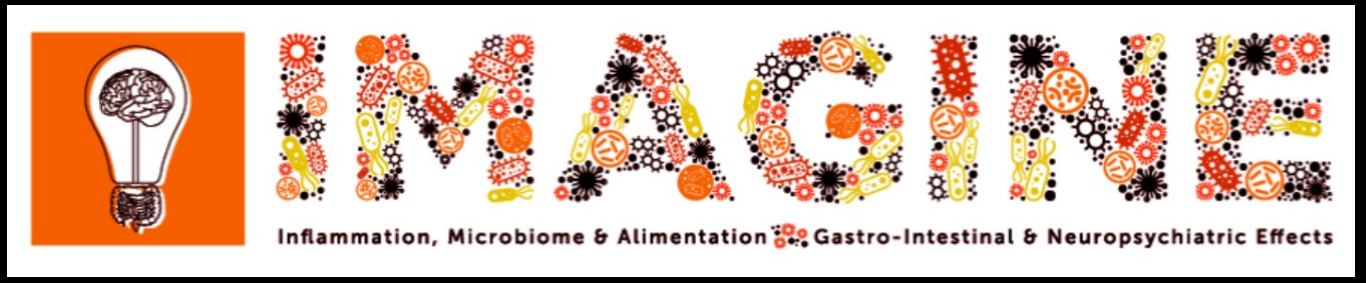
Moderated Serial Mediation Model, Including IBD and IBS Patients.



Main Discussion Points:

- Main Discussion points:
- Resiliency buffers some but not all the relationships tested in the model.
- The mechanisms of depressive symptoms are shared across IBD subtypes and disease types (IBD/IBS), suggesting that these variables are not specific to a particular disease but to painful gastrointestinal conditions more generally. These results may indicate that these mechanisms are transdiagnostic predictors of depressive symptoms in these conditions.
- Since both pain and IBD-specific symptoms were significant predictors in both models, screening for abdominal pain and pain more generally could be an efficient and helpful consideration when screening for depressive symptoms in individuals with gastroenterological conditions.

Project #2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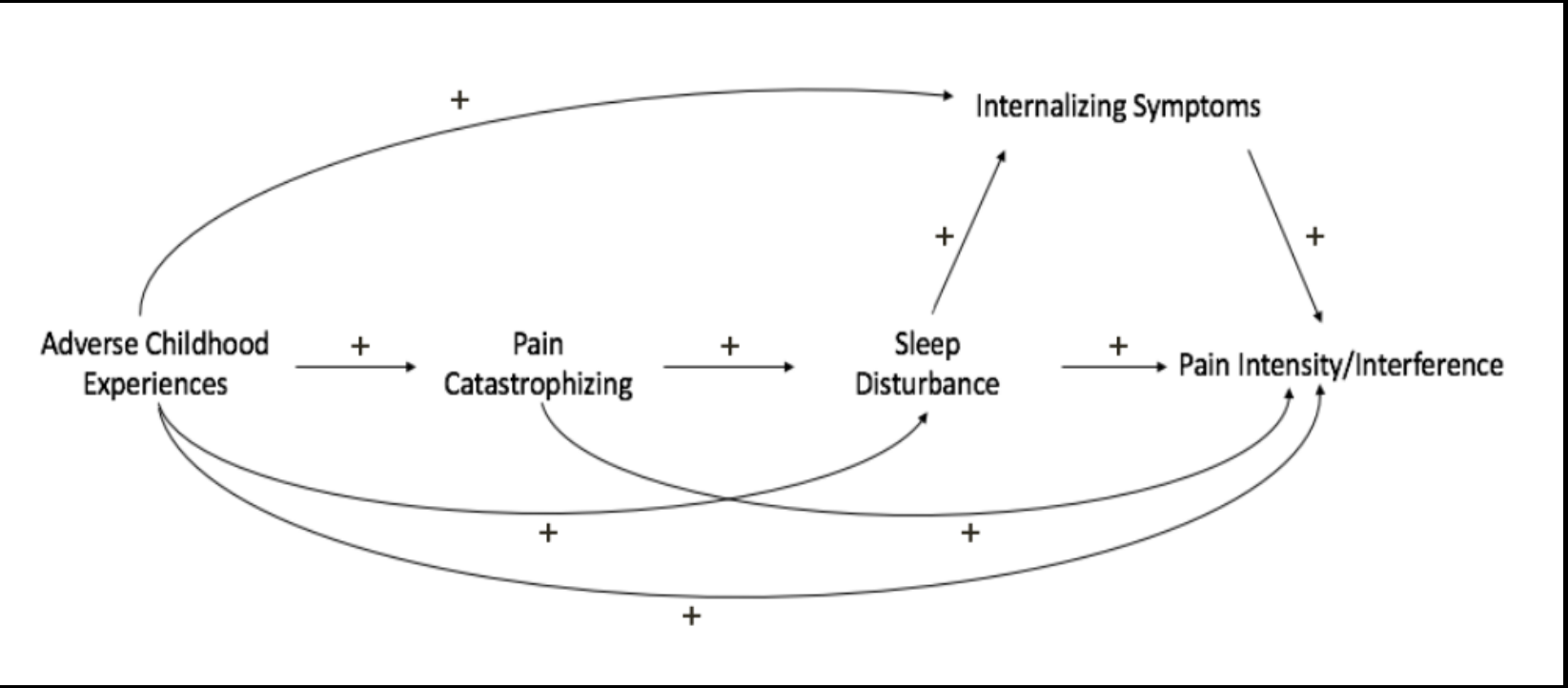
UNDERSTANDING THE SLEEP- PAIN RELATIONSHIP IN INFLAMMATORY BOWEL DISEASE

- ✓ Up to 78% of individuals with IBD experience poor sleep quality
- ✓ Poor sleep has been prospectively linked to symptom flares and subclinical inflammation
- ✓ Sleep may predict pain more reliably than pain predicts sleep

1) Examine differences in sleep and pain between individuals with IBD and healthy controls
2) Examine the relationship between sleep and pain longitudinally in individuals with IBD
3) Examine the role of shared psychosocial predisposing factors and psychological mechanisms in the sleep-pain relationship in individuals with IBD

Proposed Model:

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Diet Predicts Therapy in peds IBD

Eytan Wine

Predicting Response to Diet Therapy in Pediatric IBD: An IMAGINE Network Sub-study

Eytan Wine, MD, PhD, FRCPC

Professor of Pediatrics and Physiology
University of Alberta
Edmonton, Alberta, Canada

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

EPIC
Edmonton Pediatric IBD Clinic

IMAGINE Investigator Meeting
Toronto Airport, ON
March 11, 2023

STOLLERY CHILDREN'S HOSPITAL

CEGIIR

UNIVERSITY OF ALBERTA
QUAECUMQUE VERA

Central Hypothesis:

FFQ

Previous Diet

Clinical Data

Response to Therapy

16S rRNA

Altered Gut Microbes

Stool SCFA

Altered Gut Microenvironment

Stool Metabolomics

Overall objective: define relationship between diet, gut microbiome, and microenvironment in pediatric IBD, and how these correlate with clinical outcomes → goal of improving dietary therapy for IBD.

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Inflammation, Microbiome & Alimentation Gastro-Intestinal & Neuropsychiatric Effects

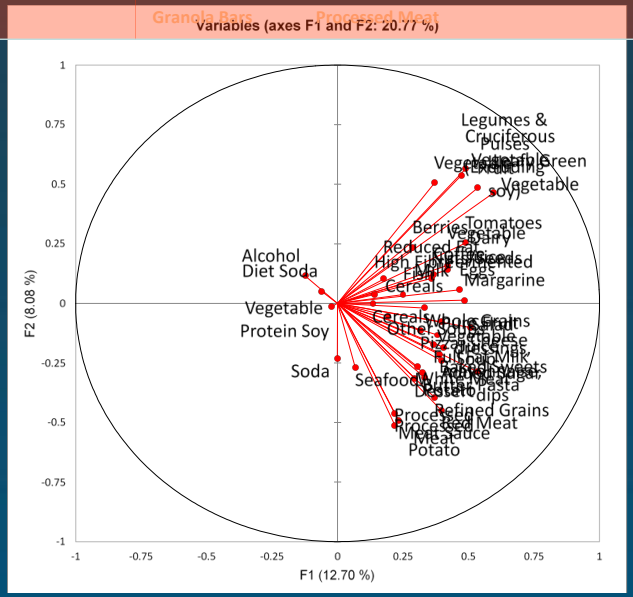
CIDsCaNN

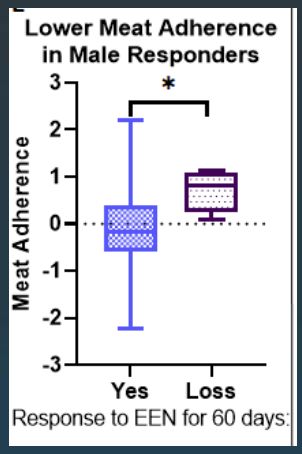
Canadian Children Inflammatory Bowel Disease Network

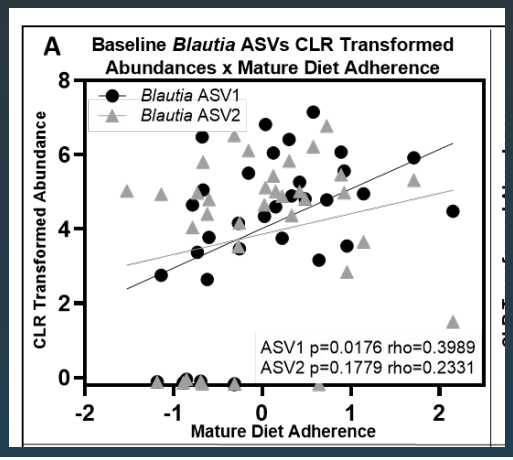
A Partnership with the CH.I.L.D Foundation

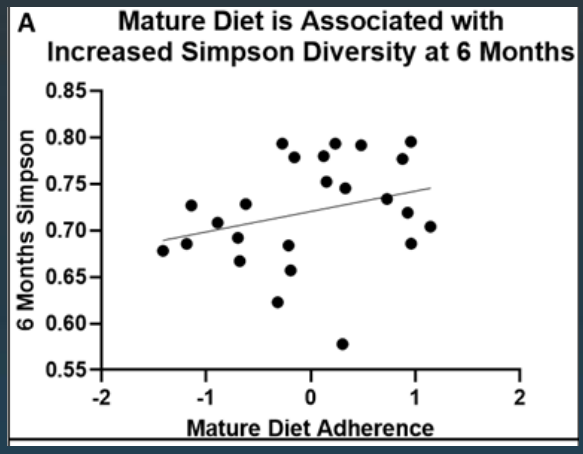
Dietary patterns are linked to microbes and treatment outcomes in pediatric Crohn disease

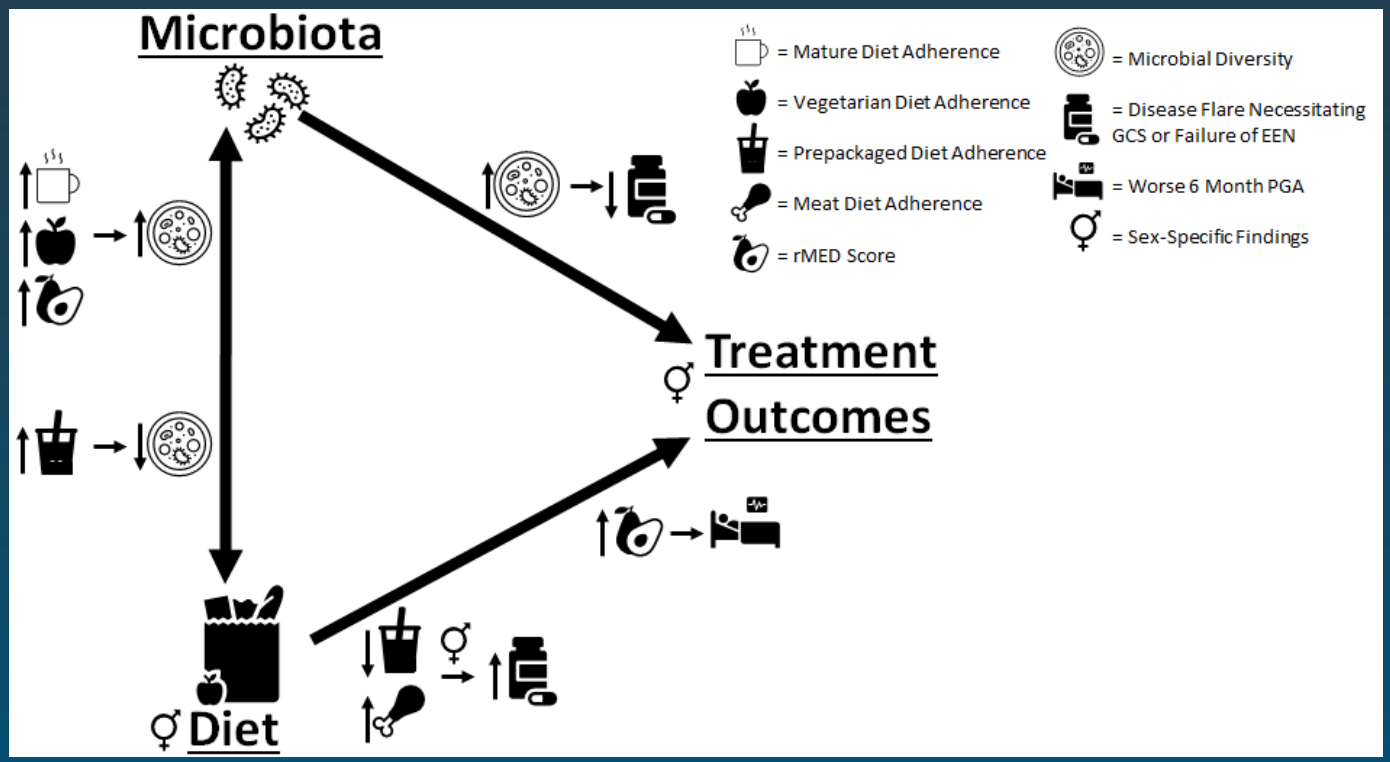
Vegetarian	Meat	Pre-Packaged	Mature
Whole Grains	Rice, Rice Noodles, Couscous	High Fiber Cereals	Chicken, Turkey without skin/fried
Vegetable Soup	Other Soups	Sugary Condiments	Fish
Soy/Tofu	RedMeat	Breaded Fish	Seafood
Salad Dressing	Pork	Diet Soda	Vegetables
Fruit	Liver Organs		Fruit
Full Fat Dairy	Chicken, Turkey with skin or fried		Coffee
Butter			Alcohol
			Milk Alternatives
Chicken, Turkey with skin/fried	Chicken, Turkey without skin	Lean Red Meat	Pizza









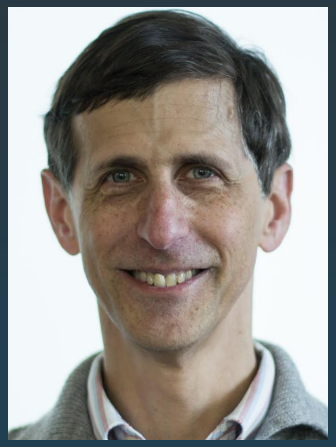


Dijk... & Wine. Paper under revisions.

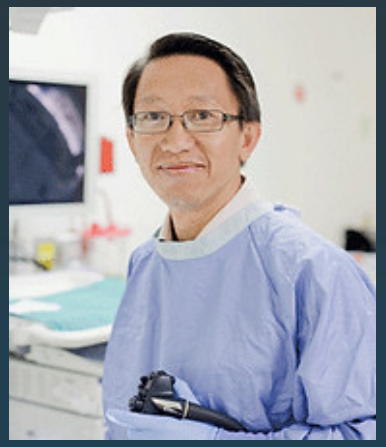
Ricardo Suarez, PhD Project:

Application of machine learning for clinical decision support in the treatment of newly diagnosed pediatric Crohn disease patients

Test concept: Predict response to EEN



Russ Grainer
(co-supervisor)



Hien Huynh

Objective: apply ML algorithms to data from 300 pCD patients, to produce a model predicting clinical and laboratory remission on EEN therapy.

1. U.ML: extract patient patterns from the dataset; correlate with clinical variables
2. S.ML: produce a trained classifier for predicting response to EEN therapy in newly diagnosed patients.
3. Evaluate classifier performance.
4. Build a ML platform for future work to identify appropriate treatments.

Aim 2 methodology: supervised ML to build a classifier

Data from historical patients

Age	CRP	FCP	BMI	……	PCDAI	Remit?
6	15	523	17.5		43	N
10	28	258	10		80	N
4	3	53	28		21	Y
15	10	300	8		50	N

Learner

Learning

Data from novel patient

Age	CRP	FCP	BMI	……	PCDAI
11	15	523	17.5		43

Classifier

Remit?
Y

Performance

Summary and Future Plans

- We have found interactions between previous diet, changes in microbes, and treatment (EEN) outcomes
- Limited by numbers…
- Plan to expand to diet RCT (using CDED)
- Hope to validate using the IMAGINE data
- Utilizing machine learning to predict response and define mechanisms

Thank you!!

FMT in IBS w/ Major Depression

Neurocognitive Effects of FMT in IBS

Valerie Taylor

Inflammation, Microbiome & Alimentation Gastro-Intestinal & Neuropsychiatric Effects

Strategy for Patient-Oriented Research
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IMAGINE | Sub-study

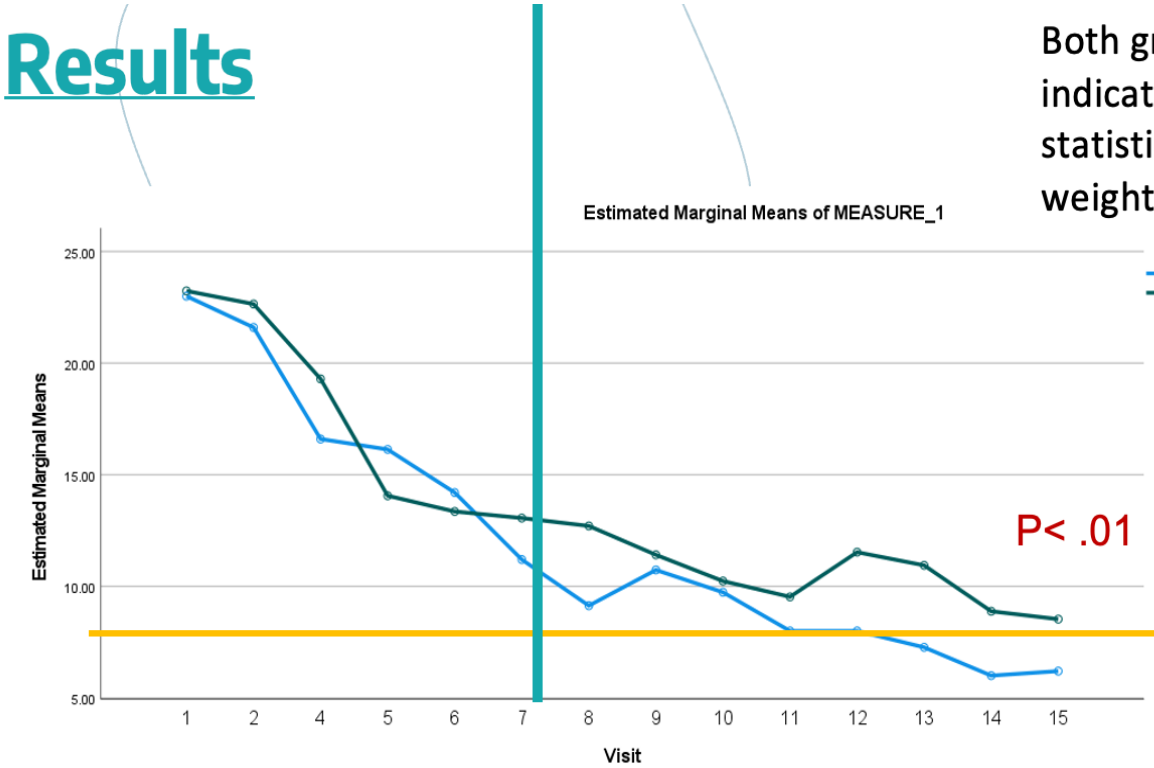
- Study Team: V Taylor, G MacQueen, H Jijon, P Beck, K McCoy
- Study Goal: **A clinical trial to evaluate the safety and efficacy of Fecal Microbiota Transplantation in a population with Major Depressive Disorder and Irritable Bowel Syndrome**
- Study Design: RCT
- Active Recruitment Sites: University of Calgary
- Recruitment Target:40

Inflammation, Microbiome & Alimentation Gastro-Intestinal & Neuropsychiatric Effects

Strategy for Patient-Oriented Research SPOR Putting Patients First

Results

Both groups' scores decreased from Visit 2 to 15, indicating that the intervention was effective, with a statistically large effect size. *There was no mania, sedation weight gain or GI related side effect.



N=17
N=16

P< .01

Remission: MADRS≤ 8

Montgomery–Asberg Depression Rating Scale (MADRS) scoring: > 34 severe depression, 20-34 moderate depression,7-19 mild depression, 0-6 normal

Both control and treatment groups had significant improvement. The mean for the intervention group drops below the control group at Visit 7 and remains lower for all final visits. At Visit 7, the intervention group (M = 11.2, SD = 7.51) is 1.86 points lower than the placebo group (M = 13.06, SD = 13.06), 95% CI [-7.76, 4.05]. The largest consistent differences in means, with the intervention group's scores being lower, occurred in the final four visits (Visit 12-Visit 15).

Eligibility Criteria

- Inclusion criteria: Age 18 – 65 years, a primary diagnosis of MDD according to the M.I.N.I. International Neuropsychiatric Interview (MINI) [15], current treatment with a first line treatment for MDD for at least 8 weeks, a MADRS score of ≥ 19. Irritable Bowel Syndrome as confirmed by Rome IV criteria.[16] We will recruit participants with the IBS-D subtype, as this group has been shown to have higher rates of depression[10], and is the sub-type used in human IBS, mice work[5]. It also represents the most common IBS subtype in the IMAGINE Network, representing almost 50% of participants and is the subtype for which FMT for symptom efficacy was recently documented[14].

- Exclusion criteria: Regular intake of non-steroidal anti-inflammatory drugs, antibiotics, or iron supplements in the 3 months prior to study entry, use of prebiotics or probiotics for medical purposes, chronic gastrointestinal diseases (excluding IBS), conditions causing immunosuppression, a significant bleeding disorder, pregnancy or breast feeding.

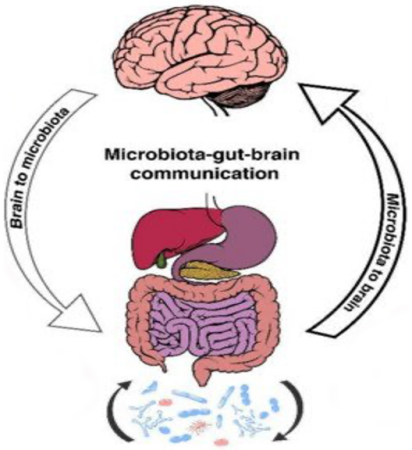
GROUPS

- Depression + treatment as usual (TAU): Complete(n=45;100%)
- Healthy controls: Complete (n=45;100%)
- Depression + FMT : 11 (n=45;24%)
- IBS + Depression + FMT : 6 (n=45;13.3%)
- IBS + Depression : 4
- IBS TAU : 6 (n=45;13.3%)

Inflammation, Microbiome & Alimentation Gastro-Intestinal & Neuropsychiatric Effects

Living with Depression and/or Irritable Bowel Syndrome?

Join a new study exploring the Gut-Brain-Axis



You are invited to participate in a clinical trial to examine the effectiveness of combining standard interventions with **Fecal Microbiota Transplantation (FMT)** in the treatment of Depression with or without Irritable Bowel Syndrome (IBS) conducted by a research team at the University of Calgary.

You are eligible to participate if you are:

- Aged 18-60
- Diagnosed with Irritable Bowel Syndrome (IBS), with or without depression
- Currently experiencing symptoms of depression
- Have tried two or more antidepressant medications

You will be reimbursed for your participation.

If you are interested in participating in this trial, or would like more information, please contact:

Vivek Kumar
Phone: 403-210-8650
Email: imafmt@ucalgary.ca

Strategy for Patient-Oriented Research SPOR Putting Patients First

This study has been approved by the University of Calgary Conjoint Health Research Ethics Board (REB 21-1358)

UNIVERSITY OF CALGARY

Comparison of Healthcare Resource Use and Costs

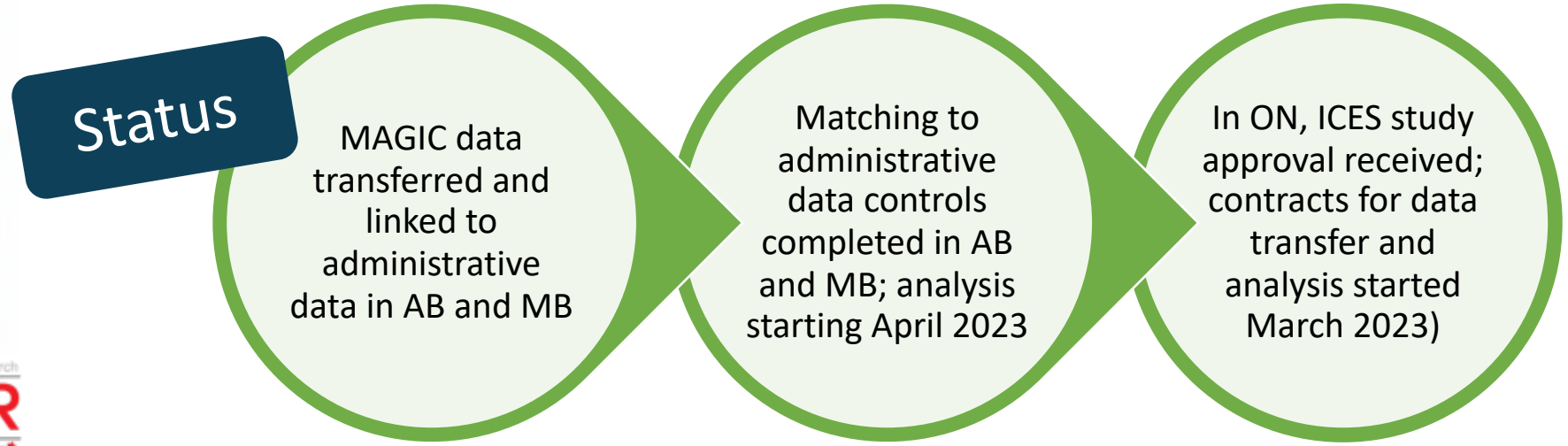
Deborah Marshall

Comparison of Healthcare Resource Use and Costs for IBD and IBS patients vs healthy controls in AB, MB, and ON

Leads: Charles Bernstein, Seth Shaffer, Sanjay Murthy, Stephen Vanner, Leslie Graff, Gil Kaplan, Eric Benchimol, Karen MacDonald, Deborah Marshall

Overview

- Estimate healthcare resource use and costs for IBD and IBS patients vs healthy controls in 3 provinces
- Linking MAGIC study data to provincial administrative health data
- Pre/post diagnosis, mental health, work/productivity impairment, menstrual cycle and quality of life



Inflammation, Microbiome & Alimentation Gastro-Intestinal & Neuropsychiatric Effects

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IMAGINE 1.0 | Other SubGrants

- Evaluation of Brain Activity and Oxygenation Using Near-infrared Spectroscopy (NIRS) in Inflammatory Bowel Disease (IBD) Patients: Correlation to gut microbiome signatures, systemic inflammation and comorbid maladaptive behavior (Swain and Ma)
- Fecal microbial transplantation (FMT) for the treatment of Crohn's disease (Jijon and Kao) - study is closed, finishing analysis and publish findings
- Understanding the neurocognitive effects of fecal microbiome transplantation in individuals with irritable bowel syndrome and depression (Taylor)
- Assessing IBD and IBS healthcare resource utilization and costs (Marshall, Bernstein, Murthy)
- Understanding child and parent preferences on treatment characteristics and targets in pediatric inflammatory bowel disease (deBruyn)
- Intermittent fasting intervention in Crohn's Disease (CD-Fast) (Raman)
- Engaging patient Partners in Designing Research on Patient Preferences (EP4) (Marshall, AB and BC SPOR SUPPORT Units)

Inflammation, Microbiome & Alimentation Gastro-Intestinal & Neuropsychiatric Effects

Strategy for Patient-Oriented Research SPOR Putting Patients First

IMAGINE 1.0

Patient Engagement Updates

Inflammation, Microbiome & Alimentation Gastro-Intestinal & Neuropsychiatric Effects

Strategy for Patient-Oriented Research
SPOR
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IMAGINE 1.0 Patient Engagement Updates

- Recruited 10 new Patient Research Partners (PRPs) in 2022
- Patient Engagement Working Group met quarterly to discuss numerous opportunities in 2022 with 30+ IMAGINE Patient Research Partners (PRPs)
- PRPs served in advisory and investigative roles:

Led, participated in Digital Storytelling Workshop

Reviewed FMT DCE research project

Advised IMAGINE investigators on recruitment strategies

Coded, analyzed focus group data for an IBD and mental health study

Participated in Patient and Public Engagement in Knowledge Synthesis Course (SPOR Evidence Alliance)

Inflammation, Microbiome & Alimentation Gastro-Intestinal & Neuropsychiatric Effects

Strategy for Patient-Oriented Research SPOR Putting Patients First

IMAGINE 1.0 Patient Engagement Updates

Inflammation, Microbiome & Alimentation Gastro-Intestinal & Neuropsychiatric Effects

2 IMAGINE-sponsored PaCER cohorts graduated

- Both cohorts presented their results at the AHS Digestive Health Strategic Clinical Network (DHSCN) Core Committee meeting in June 2022
- Some PaCER graduates served as supports for subsequent cohorts
- PaCER cohort studying psychosocial relationship between IBD & food published a paper in August 2022*

Alberta Health Services
Digestive Health Strategic Clinical Network™

Health Expect. 2022 Aug;25(4):1486-1497. doi: 10.1111/hex.13488. Epub 2022 Apr 5.

A patient-led, peer-to-peer qualitative study on the psychosocial relationship between young adults with inflammatory bowel disease and food

Jenna Rines [1 2], Kim Daley [1 2], Sunny Loo [1 2 3 4], Kwestan Safari [1 2 5 6], Deirdre Walsh [1 2], Marlyn Gill [1 2], Paul Moayyedi [7 8], Aida Fernandes [7], Nancy Marlett [1 2], Deborah Marshall [2 7]

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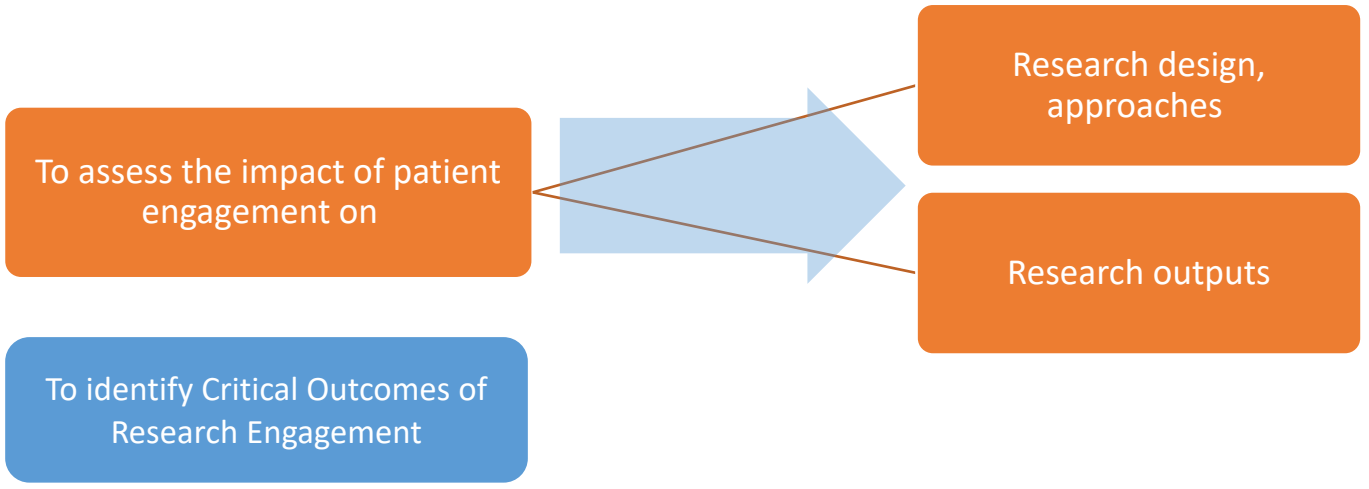
*Rines J, Daley K, Loo S, Safari K, Walsh D, Gill M, Moayyedi P, Fernandes A, Marlett N, Marshall D. A patient-led, peer-to-peer qualitative study on the psychosocial relationship between young adults with inflammatory bowel disease and food. Health Expect. 2022 Aug;25(4):1486-1497. doi: 10.1111/hex.13488. Epub 2022 Apr 5. PMID: 35383400; PMCID: PMC9327832.

Engaging Patient Partners in Designing Research on Patient Preferences (EP4): Overview

- **Study Team:** Deborah Marshall, Stirling Bryan (Co-PIs), Danielle Lavallee, Nitya Suryaprakash, Karis Barker, Aida Fernandes, Gail MacKean, Sandra Zelinsky, Tamara McCarron, Tracy Wasylak, Louise Morrin, Maria Santana

- **Objectives:** Assess and compare engagement and key research outputs between a patient-guided versus researcher-guided group undertaking a project on Discrete Choice Experiment (DCE) related to IBD
- **Method:** Surveys (PPEET2, WE-ENACT and PIERS-22) and observation at multiple timepoints



Inflammation, Microbiome & Alimentation Gastro-Intestinal & Neuropsychiatric Effects

Strategy for Patient-Oriented Research SPOR Putting Patients First

UNIVERSITY OF CALGARY

Alberta SPOR SUPPORT Unit

THE UNIVERSITY OF BRITISH COLUMBIA

Michael Smith Health Research BC BC SUPPORT UNIT

EP4: Results

	Patient-Led Group (n=7)	*Researcher-Led Group (n=7)*
Patient research partners (PRP)		
Clinicians		
Academic researchers		
PRP roles & influence: PRP in both groups were involved in many critical research tasks.	PRP had "a great deal or moderate influence" in all critical research tasks (from *getting to know the group* to *sharing final study findings*).	PRP had a "great deal or moderate influence" in some critical research tasks (*refining the question*, *reviewing literature*, *finding patients*, and *collecting data*).
Qualitative study design & approach: Both groups conducted qualitative projects to identify candidate attributes for IBD biologic tapering.	Conducted 1 focus group with 3 patients, interviews with 8 patients (n=11)	Conducted interviews with 2 patients and 3 clinicians (n=5)
Resulting attributes: Both groups identified process and outcome attributes.	11 more patient-friendly, outcome-oriented attributes	21 more clinician-friendly, process-oriented attributes
Critical Outcomes of Research Engagement: Both projects were patient-centered, collaborative, meaningful, rigorous, adaptable, ethical, legitimate, understandable, feasible, timely and sustainable.	Collaboration seemed easier in the PLG than in the RLG.	The PRPs lived experience in the RLG influenced more decisions than in the PLG.

EP4: Key Takeaways

- Collaborative and meaningful engagement of patients and researchers can impact all stages of the research process and activities including design, approach and outputs

- Both patient-led and researcher-led projects were patient-centered, collaborative, meaningful, rigorous, adaptable, ethical, legitimate, understandable, feasible, timely and sustainable (Critical Outcomes of Research Engagement (CORE))

- Differences were observed in the influence on project decisions, the number of aspects of the project influenced by the lived experience of PRPs, the roles of the project group members and the approaches taken to answer the research question.

- Dillon EC et al. Measuring the Impact of Patient-Engaged Research: How a Methods Workshop Identified Critical Outcomes of Research Engagement. J Patient Cent Res Rev. 2017;4(4):237-246

EP4: Deliverables

Project Groups:

- Each Project group prepared a report
- One of the project group members is preparing a manuscript reflecting the experiences of the group

Project Group REPORTs

- Methods
- Findings
- Potential attributes to consider for the patient preference survey
- Recommendations for sharing findings

Research Team:

- Findings presented in poster presentations:
  - 13th Meeting of the International Academy of Health Preferences Research (IAHPR)
  - 2022 Northwest SPOR Collaborative Forum
- 3 papers currently under review for publication

Inflammation, Microbiome & Alimentation Gastro-Intestinal & Neuropsychiatric Effects

Strategy for Patient-Oriented Research SPOR Putting Patients First

Patient Preferences for UC Treatments
FMT vs treatments that reflect biologics

Study Team: Charles Bernstein, Humberto Jijon, Dina Kao, Gil Kaplan, Maitreyi Raman, Yasmin Nasser; Remo Panaccione, Karen MacDonald, Glen Hazlewood, Paul Moayyedi, Deborah Marshall

Study Objectives

- Quantify preferences for fecal microbiota transplantation (FMT) vs treatments that reflect biologics
- Determine patient characteristics associated with different preference patterns

Status

- Main results manuscript submitted to J Crohn's and Colitis March 2023
- Methods manuscript drafted (submit fall 2023)

Patient Preferences for UC Treatments
FMT vs treatments that reflect biologics

Status Continued

- Survey and DCE modified for use in parent/caregiver preferences study

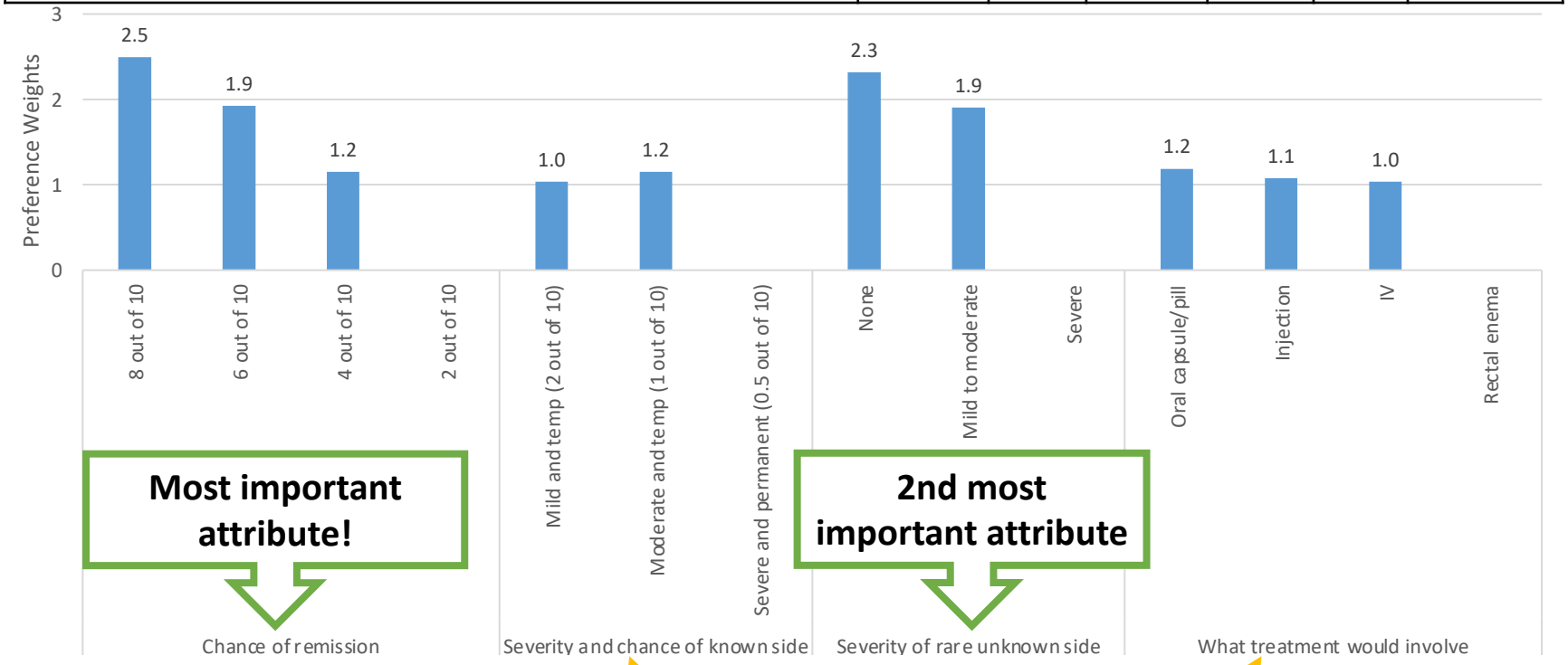
If your gastroenterologist presented the 2 treatment options below to you, which would you prefer?
Please assume your ulcerative colitis is active (flaring), if it is not active today.

	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 temporary 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 capsules or pills taken within 1 hour)
Your choice	○	●

Chance of remission most important UC treatment attribute followed by severity of rare unknown side effects

n=201 from Alberta, Manitoba, Ontario

Given what you know about FMT, would you be willing to undergo FMT as a treatment for your ulcerative colitis?	Yes		Unsure		No	
	N	%	N	%	N	%
Remission	68	34%	56	28%	19	10%
Mild ulcerative colitis	22	11%	23	11%	2	1%
Moderate ulcerative colitis	4	2%	1	0.5%	2	1%
Severe ulcerative colitis	2	1%	2	1%	0	0%
Total	**96**	**48%**	**82**	**41%**	**23**	**11%**



Most important attribute!

2nd most important attribute

Known side effects and what treatment would involve are similar and not as important as remission or rare unknown side effects

Inflammation, Microbiome & Alimentation Gastro-Intestinal & Neuropsychiatric Effects

Strategy for Patient-Oriented Research SPOR Putting Patients First

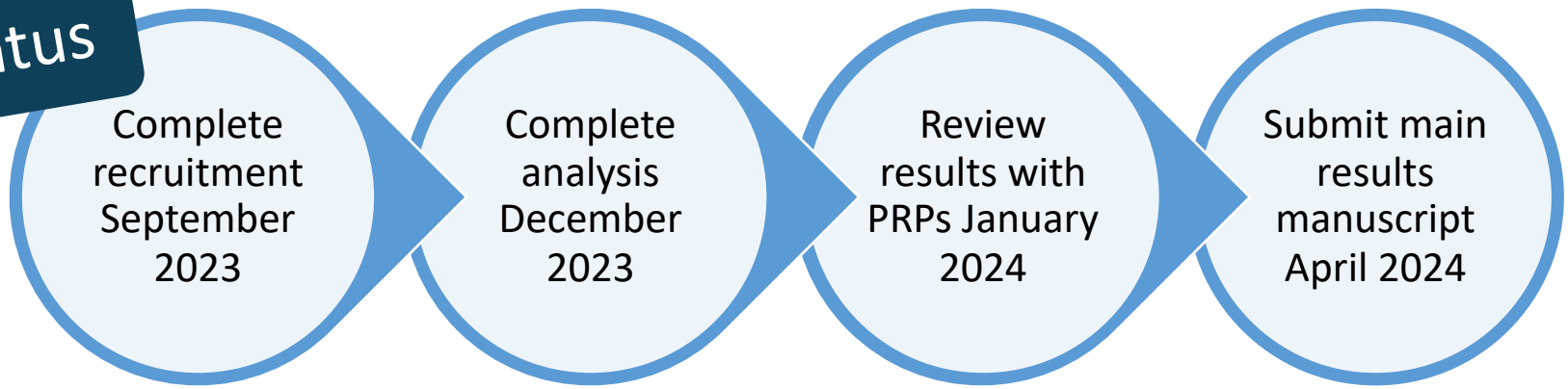
Parent/Caregiver Preferences for UC Treatment

- **Study Team:** Tony Otley, Jennifer DeBruyn, Nik Pai, Karen MacDonald, Sharlene Rozario, Carly Burow, Amy Lee Wing Ngok, Deborah Marshall
- Modified adult UC patient preferences survey for parents of children with UC
- Main survey launched September 2022 (72 consented; 65 completed surveys)

- **Pilot results** found **SEVERITY OF RARE UNKNOWN SIDE EFFECTS** most important attribute, followed by chance of remission

  - **DIFFERENT** than adult UC patient preferences (chance of remission most important)

Status



Inflammation, Microbiome & Alimentation Gastro-Intestinal & Neuropsychiatric Effects

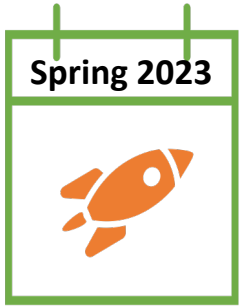
Strategy for Patient-Oriented Research SPOR Putting Patients First

Child and Parent Preferences for Treatment Characteristics and Targets in Pediatric IBD

Inflammation, Microbiome & Alimentation Gastro-Intestinal & Neuropsychiatric Effects

Study Team: Jennifer DeBruyn, Nik Pai, Tony Otley, Karen MacDonald, Amy Lee Wing Ngok, Deborah Marshall

- Examine and estimate patient and parent preferences for IBD treatments and treatment targets qualitatively and quantitatively
- Qualitative component completed
  - 19 interviews with parents (n=10) & children (age 11-18; n=9)
  - Main results manuscript drafted



- Quantitative component underway
  - Survey pre-testing completed
  - Pilot survey to launch end of April/May 2023
  - Main survey target sample size: n=300 patients and n=300 parents/caregivers

Status

Complete recruitment September 2023 → Complete analysis December 2023 → Review results with PRPs January 2024 → Submit survey results manuscript March 2024

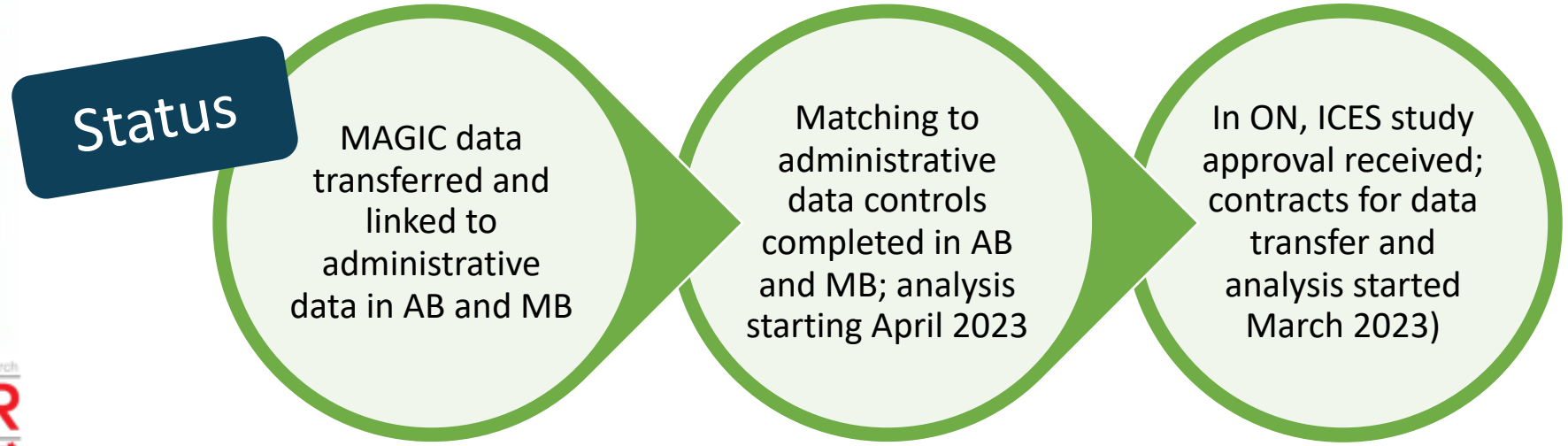
Strategy for Patient-Oriented Research SPOR Putting Patients First

Comparison of Healthcare Resource Use and Costs for IBD and IBS patients vs healthy controls in AB, MB, and ON

Leads: Charles Bernstein, Seth Shaffer, Sanjay Murthy, Stephen Vanner, Leslie Graff, Gil Kaplan, Eric Benchimol, Karen MacDonald, Deborah Marshall

Overview

- Estimate healthcare resource use and costs for IBD and IBS patients vs healthy controls in 3 provinces
- Linking MAGIC study data to provincial administrative health data
- Pre/post diagnosis, mental health, work/productivity impairment, menstrual cycle and quality of life



Inflammation, Microbiome & Alimentation Gastro-Intestinal & Neuropsychiatric Effects

Strategy for Patient-Oriented Research SPOR Putting Patients First

IMAGINE 2.0

Strategy for Patient-Oriented Research
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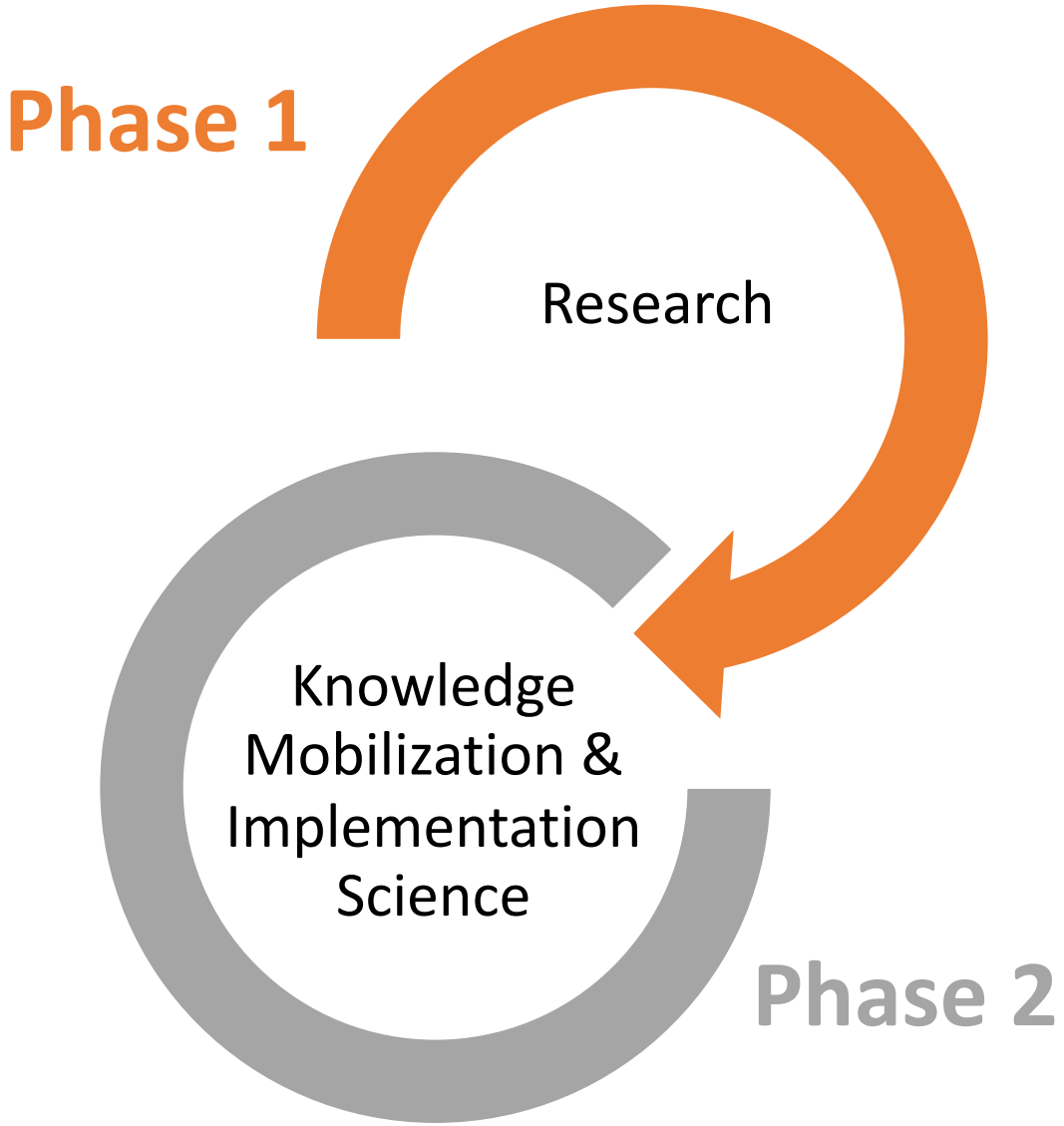
IMAGINE | Transition to Next Phase



IMAGINE 2.0 | Program Priorities

- *Scale-up FMT*
- *Microbiome biomarkers to match treatments to patients*

- *Cognitive Behaviour*
- *Mindfulness apps*
- *Psychiatry support in GI care*

- *Dietary biomarkers to match diets to patients*
- *Dietary risk factors (Food Guide)*
- *Dieticians support in GI care*

- *Telemedicine*
- *e-clinical care pathways*
- *QI self-assessment tool for GI clinics (GRS)*
- *Patient Assessment app*
- *E-clinical pathways*
- *Youth-Adult transitions*

Inflammation, Microbiome & Alimentation Gastro-Intestinal & Neuropsychiatric Effects

Strategy for Patient-Oriented Research SPOR Putting Patients First

IMAGINE 2.0 Patient Engagement & Capacity Building Plan Overview

PaCER training

- Cohort 1: IBD and mental health (in progress)
- Cohort 2: Indigenous Communities (planned for 2024)

Digital Stories

- Training workshop held (Summer 2022)
- 7 Stories Completed
- Gut Feelings Webinar (Feb 2023)

IMAGINE 2.0 Patient Engagement & Capacity Building Plan Overview

Training & Capacity Building

- Knowledge Synthesis Course
- Conference Sponsorship
- Webinar series
- Masterclass on evidence products and processes

Career Development & Mentorship

- Health System Impact Fellowship (D'Silva)
- CDDW Mentorship Cafe
- Travel Awards

Inflammation, Microbiome & Alimentation Gastro-Intestinal & Neuropsychiatric Effects

IMAGINE 2.0 RESEARCH

Strategy for Patient-Oriented Research
SPOR
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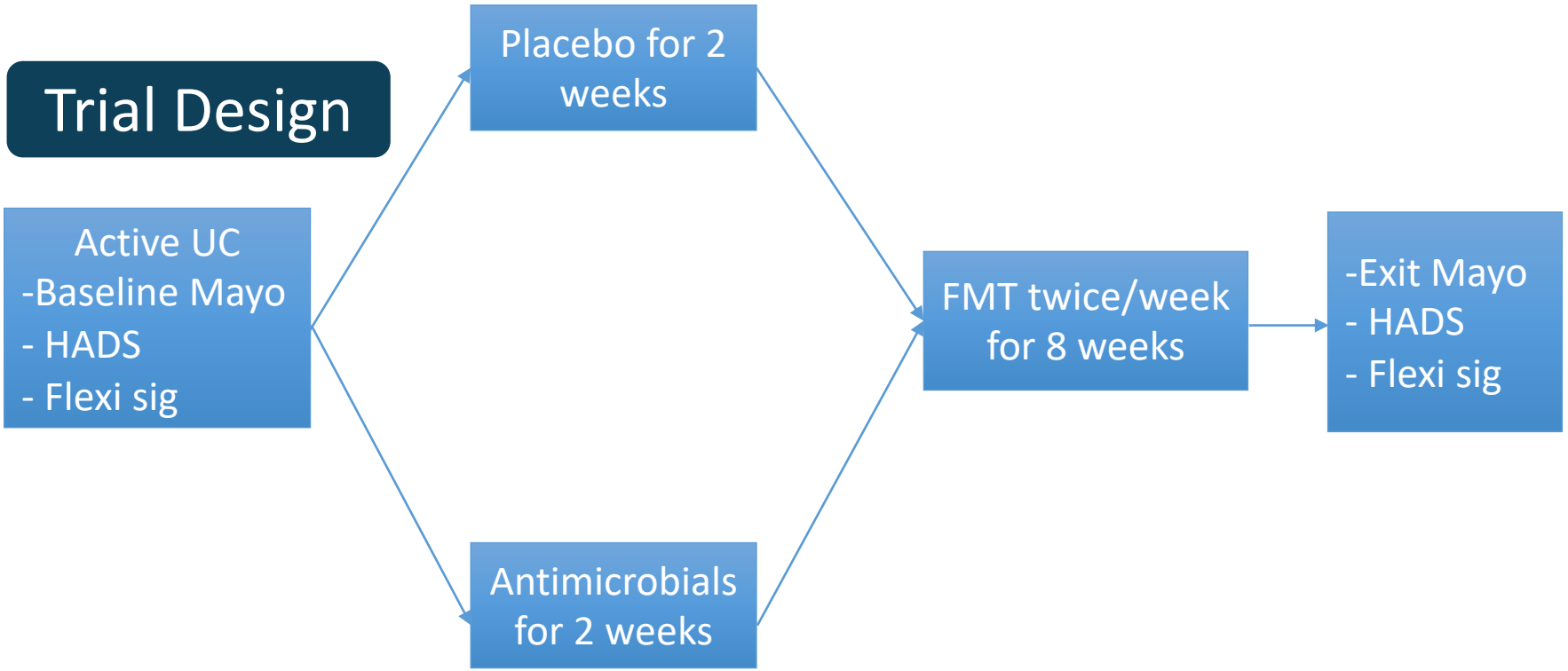
IMAGINE 2.0 | Multi-centre FMT in UC

Trial Design



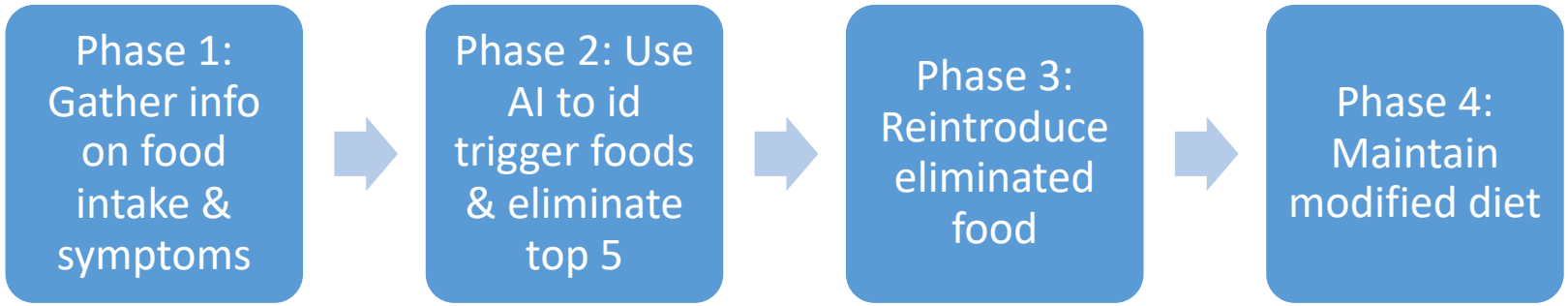
Status

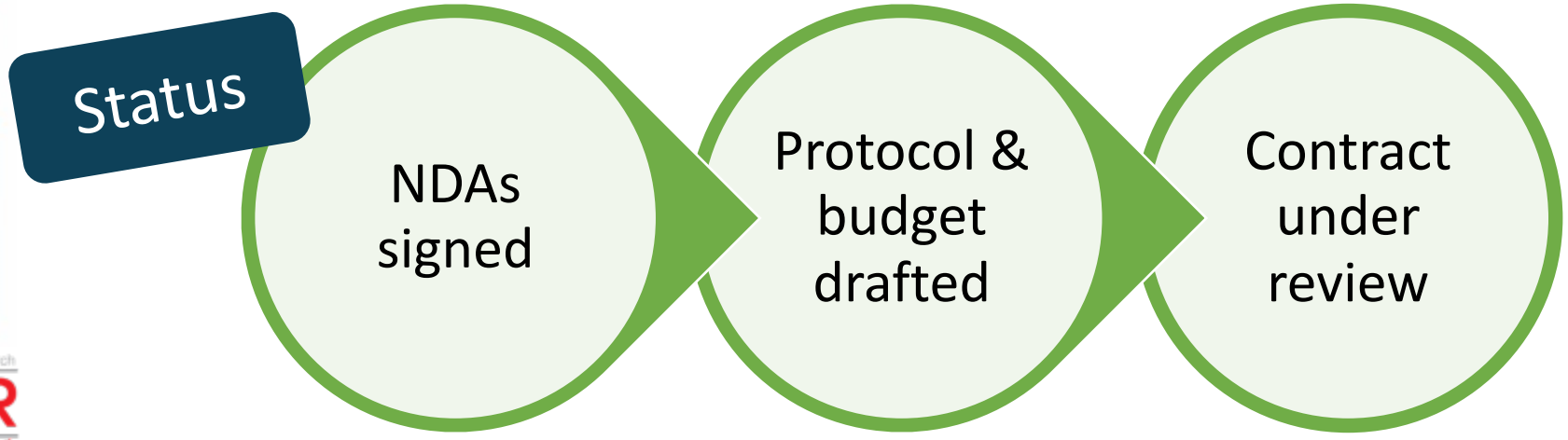
Inflammation, Microbiome & Alimentation Gastro-Intestinal & Neuropsychiatric Effects

Strategy for Patient-Oriented Research SPOR Putting Patients First

IMAGINE 2.0 | Ayble Health: AI Diet App for IBS

- **Purpose:** Personalized Trigger Food Elimination for the Amelioration of Irritable Bowel Syndrome (IBS) Symptoms
- **Study Design:** Multi-centre RCT, 12-week program & monitoring for up to 12 months





Inflammation, Microbiome & Alimentation Gastro-Intestinal & Neuropsychiatric Effects

Strategy for Patient-Oriented Research SPOR Putting Patients First

IMAGINE 2.0 | Nestle Probiotic Study (Epsilon)

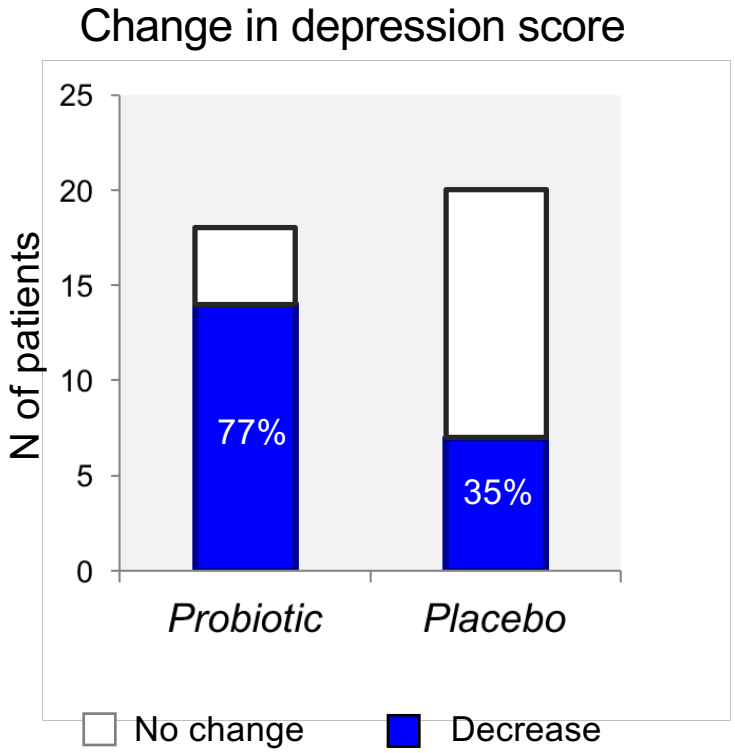
- Goal: A Randomized, Double-Blind, Placebo-Controlled Trial to Evaluate the Effects of *Bifidobacterium longum* on Intestinal and Psychological Symptoms in IBS Subjects

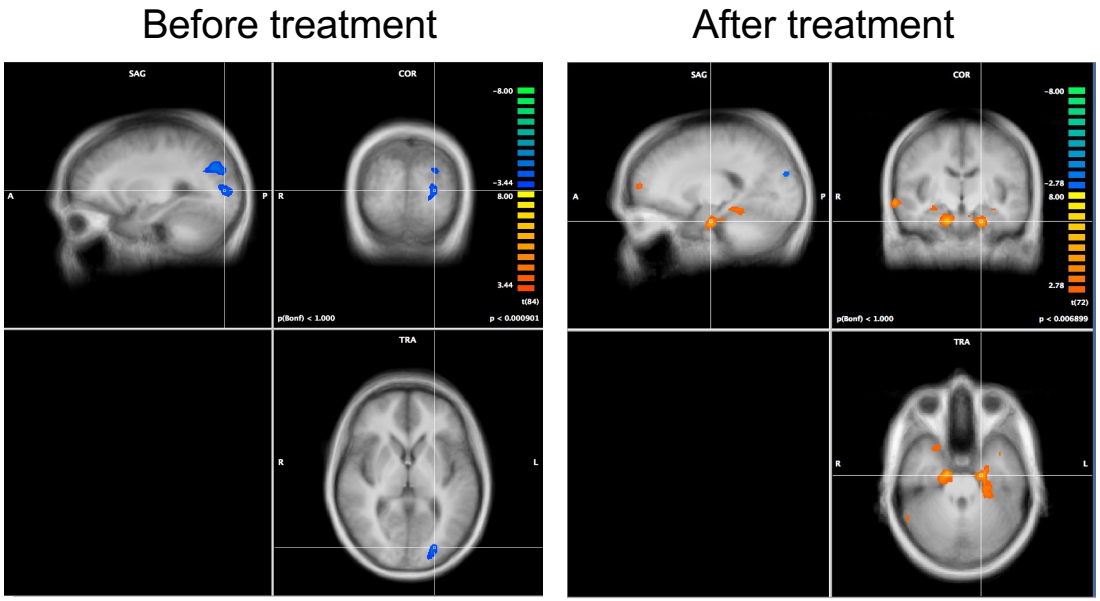
SITE	STATUS
McMaster	Currently recruiting: 13 screened, 2 completed
St. John's	Ethics approved; Site Initiation visit (SIV) completed
Winnipeg	Contract under review; SIV scheduled for May
Edmonton	Ethics resubmitted; contract under review; SIV April 12
Ottawa	Ethics application submitted; contract under review
Calgary	Ethics in progress; contract under review
Queen's	Ethics and contracts under review
Montreal	Ethics and contracts in progress

Inflammation, Microbiome & Alimentation Gastro-Intestinal & Neuropsychiatric Effects

Strategy for Patient-Oriented Research SPOR Putting Patients First

B. longum NCC3001 decreased depression and IBS scores





Pinto Sanchez *et al, Gastroenterology* 2017

Confirmatory study on effects of *B. longum* in IBS

- Multicenter RCT with184 patients with IBS (all types)
- Randomized to 6-week treatment with *B. longum* NCC3001 or placebo
- Primary outcomes: anxiety, depression, IBS symptoms
- Pragmatic study with recent changes in inclusion/exclusion criteria
- Allowed IBS medications (minimum 3 months duration)

  Allowed antidepressants/anxiolytics/psychotherapy (minimum 6 months)

Nestlé

Strategy for Patient-Oriented Research SPOR Putting Patients First

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

IMAGINE 2.0 | Nestle Probiotic Study (Epsilon)

- Goal: A Randomized, Double-Blind, Placebo-Controlled Trial to Evaluate the Effects of Bifidobacterium longum (BL) NCC3001 on Intestinal and Psychological Symptoms in IBS Subjects with Irritable Bowel Syndrome (IBS)

SITE	STATUS
McMaster	Currently Recruiting
St. John's	Ethics approved; Site Initiation visit completed
Winnipeg	Contract under review; Site initiation visit schedule May
Edmonton	Ethics resubmitted; contract under review
Ottawa	Ethics application submitted; contract under review
Calgary	Ethics in progress; contract under review
Queen's	Ethics and contracts under review
Montreal	Ethics and contracts in progress

Study progress

	Total	101 Pliamm	102 Boudreau	104 Shulman	105 Petrunia	109 Bercik	116 Paquette	117 Chouinard
Screened	**86**	27	14	8	12	13	4	8
In Screening	**2**	1	0	0	0	0	1	0
Randomized	**40**	24	5	3	4	3	0	1
Screen Failed	**43**	2	9	5	8	9	3	7
Early Terminated	**3**	0	1	1	0	1	0	0
Completed	**32**	21	4	2	4	1	0	0

IMAGINE 2.0

Patient Engagement & Capacity Building

IMAGINE 2.0 | Patient Engagement & Capacity Building Plan Overview

PaCER training

- Cohort 1: IBD and mental health (in progress)
- Cohort 2: Indigenous Communities (planned for 2024)

Digital Stories

- Training workshop held (Summer 2022)
- 7 Stories Completed
- Gut Feelings Webinar (Feb 2023)

IMAGINE 2.0 | Patient Engagement & Capacity Building Plan Overview

Training & Capacity Building

- Masterclass on evidence products and processes
- Knowledge Synthesis Course
- Conference Sponsorship
- Webinar series

Career Development & Mentorship

- Health System Impact Fellowship
- CDDW Mentorship Cafe
- Travel Awards

IMAGINE 2.0

EDI & Indigenous Engagement

IMAGINE 2.0 | EDI & Indigenous Engagement Plan Overview

Equity, Diversity & Inclusion

- Build EDI literacy among network members (EDI Moments)
- Incorporate EDI in the activities of the IMAGINE Network (EDI Champion on Res Cttee)
- Build capacity & research skills for students form underrepresented groups

Indigenous Engagement

- Provide cultural humility training opportunities (Webinar planned for May 2023)
- Engage with Indigenous Communities to co-design relevant GI health project (PaCER cohort for 2024)
- Develop appropriate KT tools to address Indigenous health disparities, food security, water quality and diet/mental health

IMAGINE 2.0

Knowledge Mobilization & Implementation Science

Inflammation, Microbiome & Alimentation Gastro-Intestinal & Neuropsychiatric Effects

Strategy for Patient-Oriented Research
SPOR
Putting Patients First

Overview of engagement & prioritization processes to date

HEALTH FORUM | McMaster University

- 2022-05-16: Network call devoted to IS/KM
- 2022-06-10: CCC
- 2022-07-08: Network AGM
- 2022-07-22: PACER call (Sunny Loo, Kim Daley, Jenna Rines)
- 2022-09-16: CCC
- 2022-10-15: Network leads
- 2022-10-19: CAG
- 2022-11-21: Network leads
- 2022-12-16: CCC
- 2022-12-19: Network leads
- 2023-01-16: Network leads
- 2023-02-13: Network leads ‘deep dive’
- 2023-03-20: Network leads
- **2023-04-14: Network AGM**

Points to be considered as we review the priorities emerging from this process (and in breakout groups)

HEALTH FORUM | McMaster University

- Examples of what's going on (or what's being planned for) in each priority area
- Insights about existing infrastructure that can be leveraged in provincial and territorial health systems that can be leveraged in each priority area
  - e.g., Alberta's strategic clinical networks
  - e.g., Ontario Health Teams
- Knowledge about patient groups that can be engaged in provincial and territorial health systems and experiences with what's worked and not in engaging such groups

1) Planning now to support the uptake and sustained use of apps and digital tools in IBD/IBS care

HEALTH FORUM

McMaster University

- **Overview of apps and digital tools connected to IMAGINE (Deborah)**
  - Keeping in mind that IMAGINE can likely best focus where IMAGINE is likely to have data that can underpin these apps and digital tools
- KM focus on supporting the uptake of apps in a policy and system environment (John)
- IS focus on supporting the sustained use of apps (Justin)

1) Planning now to support the uptake and sustained use of apps and digital tools in IBD/IBS care

HEALTH FORUM | McMaster University

- **Overview of apps and digital tools connected to IMAGINE (Deborah)**
  - **Any initial reactions to where IMAGINE can likely best focus given where IMAGINE is likely to have data that can underpin these apps and digital tools?**
- KM focus on supporting the uptake of apps in a policy and system environment (John)
- IS focus on supporting the sustained use of apps (Justin)

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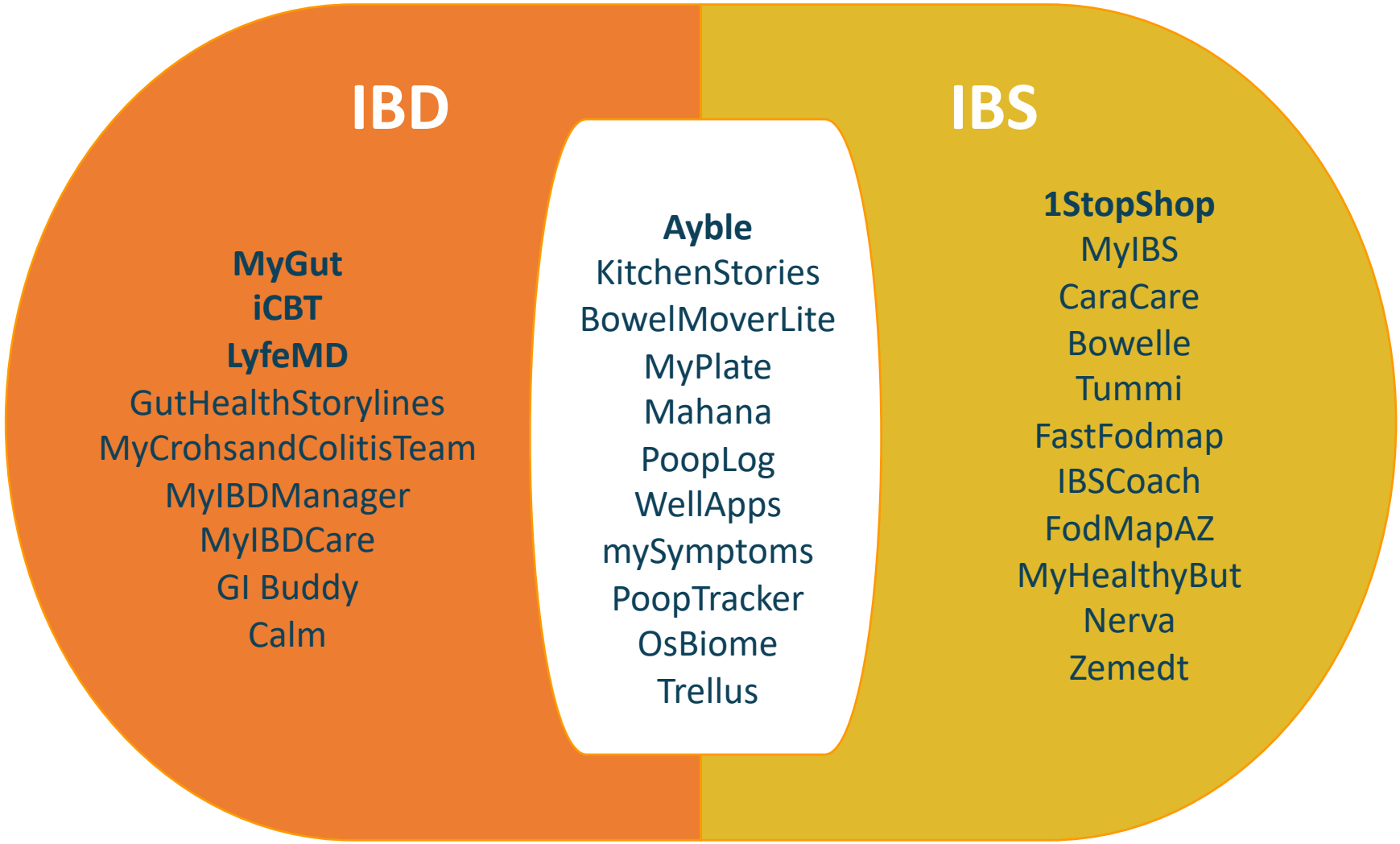
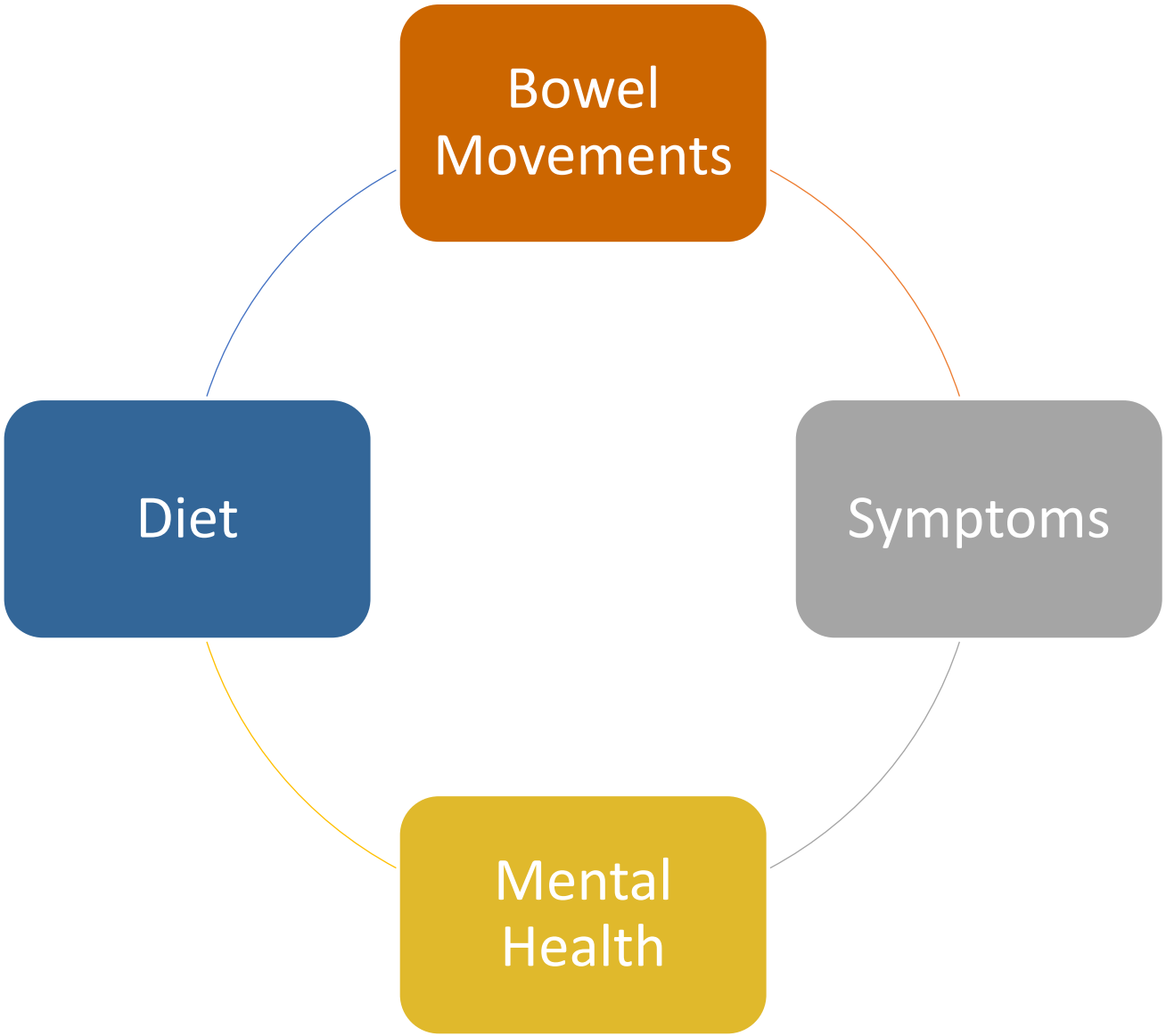
IMAGINE 2.0 KM/IS Gut Health Apps & Digital Tools



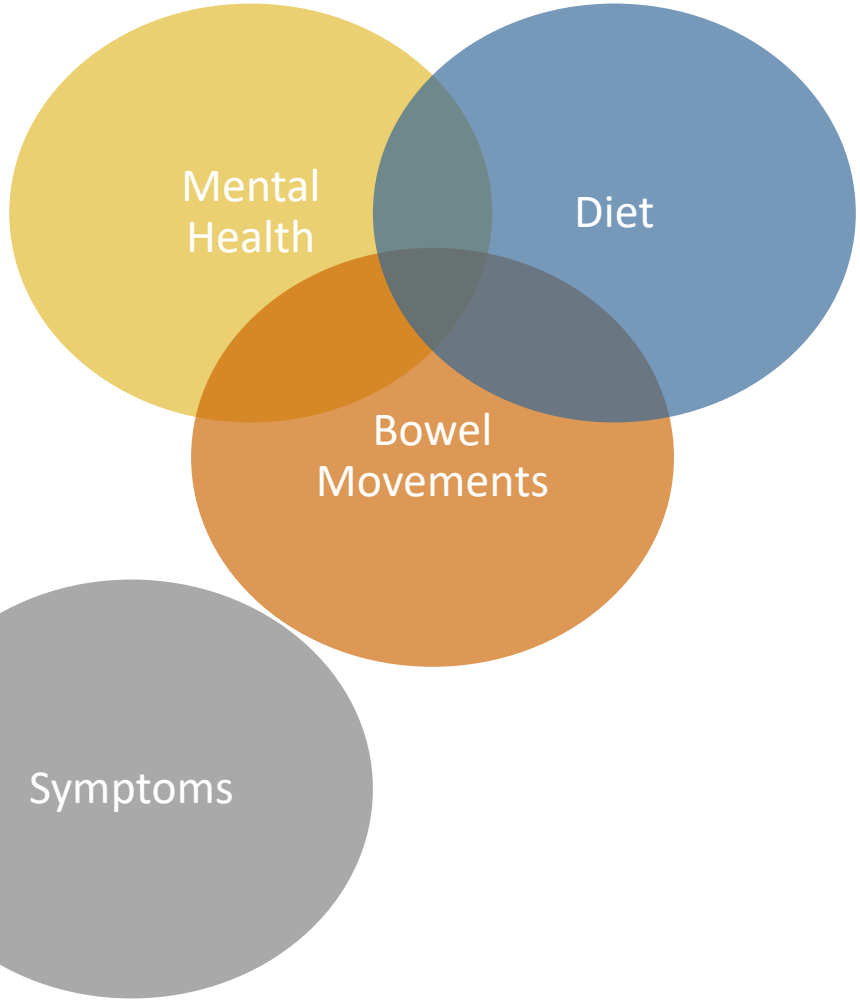
Inflammation, Microbiome & Alimentation Gastro-Intestinal & Neuropsychiatric Effects

Strategy for Patient-Oriented Research
SPOR
Putting Patients First

IMAGINE 2.0 | KM/IS Gut Health Apps & Digital Tools



IMAGINE 2.0 | KM/IS Gut Health Apps & Digital Tools



MH	iCBT Nerva Calm	Mahana GutHealthStories Trellus
BM/ MH	myIBD BowelMoverLite	
BM	PoopTracker PoopLog Osbiome	
Diet	Ayble MyPlate Tummi IBS Coach	Bowelle FastFodmap KitchenStories FodmapAZ
Diet/ MH	mySymptoms LyfeMD	
Diet/ MH/ BM	myIBS CaraCare MyHealthyGut	
Sympt	GIBuddy MyGut WellApps myIBDManager	myIBDCare IBSCoach. Zemedy MyHealthyGut

Inflammation, Microbiome & Alimentation Gastro-Intestinal & Neuropsychiatric Effects

Strategy for Patient-Oriented Research SPOR Putting Patients First

IMAGINE 2.0 | KM/IS Gut Health Apps & Digital Tools - IMAGINE Related Programs

	IMAGINE-led	Partners of IMAGINE
Mental Health	iCBT for IBD	
BM/ Mental Health		
BM		
Diet	*TBD (based on MAGIC)?*	Ayble
Diet / Mental Health	*TBD (based on MAGIC)?*	LyfeMD
Diet / Mental Health / BM / Symptoms	*TBD (based on MAGIC)?*	MyIBS – Canadian Digestive Health Foundation
Symptoms		MyGut - Crohn's and Colitis Canada
Other (Online platforms)	One-Stop Shop	PRIHS

Inflammation, Microbiome & Alimentation Gastro-Intestinal & Neuropsychiatric Effects

Strategy for Patient-Oriented Research SPOR Putting Patients First

Digital Self-management Supports for Irritable Bowel Syndrome

Adrijana D'Silva
IMAGINE CIHR Health System Impact Fellow (HSIF) Post Doctoral Associate

IMAGINE AGM
April 14, 2023

adrijana.dsilva@ucalgary.ca
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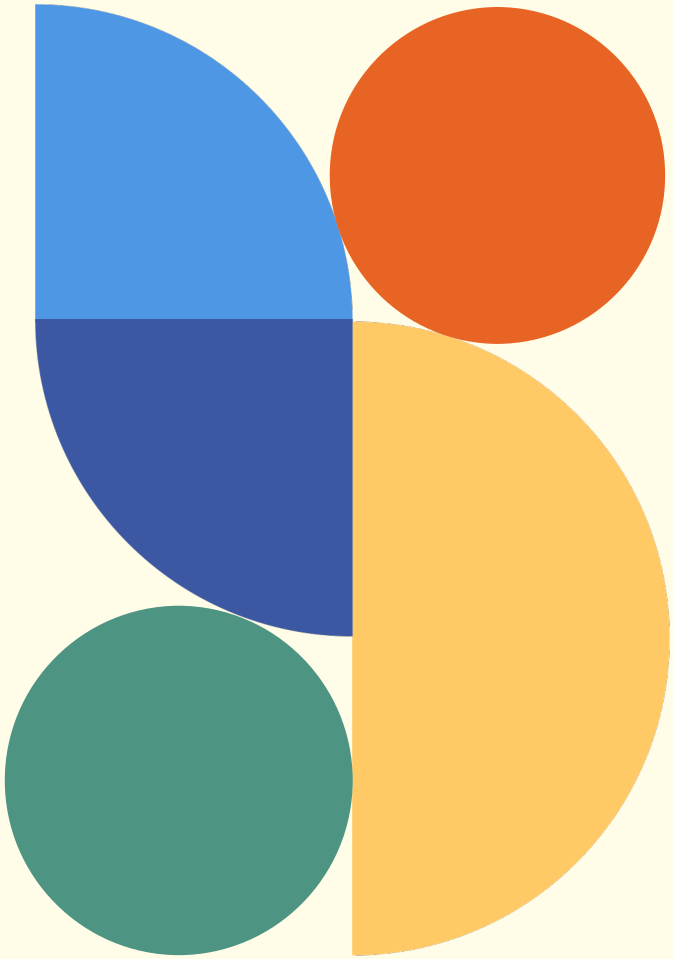
Co-Investigators

Deborah Marshall Judy Seidel Mary Modayil
Maitreyi Raman Yasmin Nasser Suzanne Downey



To better **understand** how IBS patients are self-managing in three key areas (resources, advocacy, and community) and to **co-design, develop, and evaluate** an online IBS community ("IBS One-Stop-Shop") to support evidence-based self-management

1

Determine how IBS patients are accessing online resources, what resources have been helpful, and how to support their needs using best evidence-based lay information

- *SURVEY*

2

Co-design an online resource community website with patients

- *FOCUS GROUPS*

3

Evaluate the overall usability, quality, and effectiveness of the prototype for self-management

- *PRE-POST SURVEY*

Deliverables

01

Improved access to SMS resources

02

Referral resources for healthcare professionals

03

Engaged patients

04

Enhanced patient experience

05

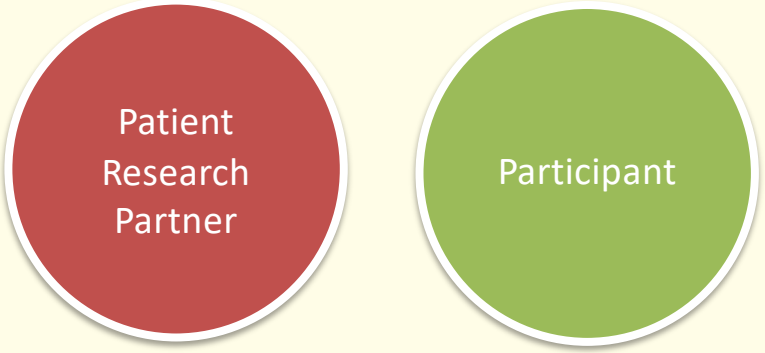
Improved management of IBS

06

Sustainability

- Committee
- Advisory Board
- Partnerships

Patient Partners



Partners & Investigators

1) Planning now to support the uptake and sustained use of apps and digital tools in IBD/IBS care

HEALTH FORUM | McMaster University

- Overview of apps and digital tools connected to IMAGINE (Deborah)

- **KM focus on supporting the uptake of apps and digital tools in a policy and system environment (John)**
  - 'Critical interpretive synthesis' plus key-informant interviews, with a focus on patient-facing digital solutions to support self-management (alone and with a provider-facing version)
  - Output will be a framework for how apps and digital tools would need to 'land' to be funded in an ongoing way by government policymakers and system leaders, which could include factors such as
    - Demonstrated pathway to at least one quadruple-aim impact
    - Ease of connection to provincial and territorial 'digital backbone' (not just a platform used by a small proportion of users)
    - Meets provincial and territorial requirements for addition to an approved apps library (e.g., aligned with evidence-based guidelines, data-sharing standards, and privacy requirements)
    - (For provider-facing ones) Supported, or at least not disincentivized, by provider-remuneration model
  - **Participation opportunities**
    - Synthesis team member (for patient partners and for providers)
      - Training available that leverages COVID-END and SPOR-EA experience
      - Meetings likely monthly in the second half of 2023

- IS focus on supporting the sustained use of apps and digital tools (Justin)
  - See Jen's slides to follow

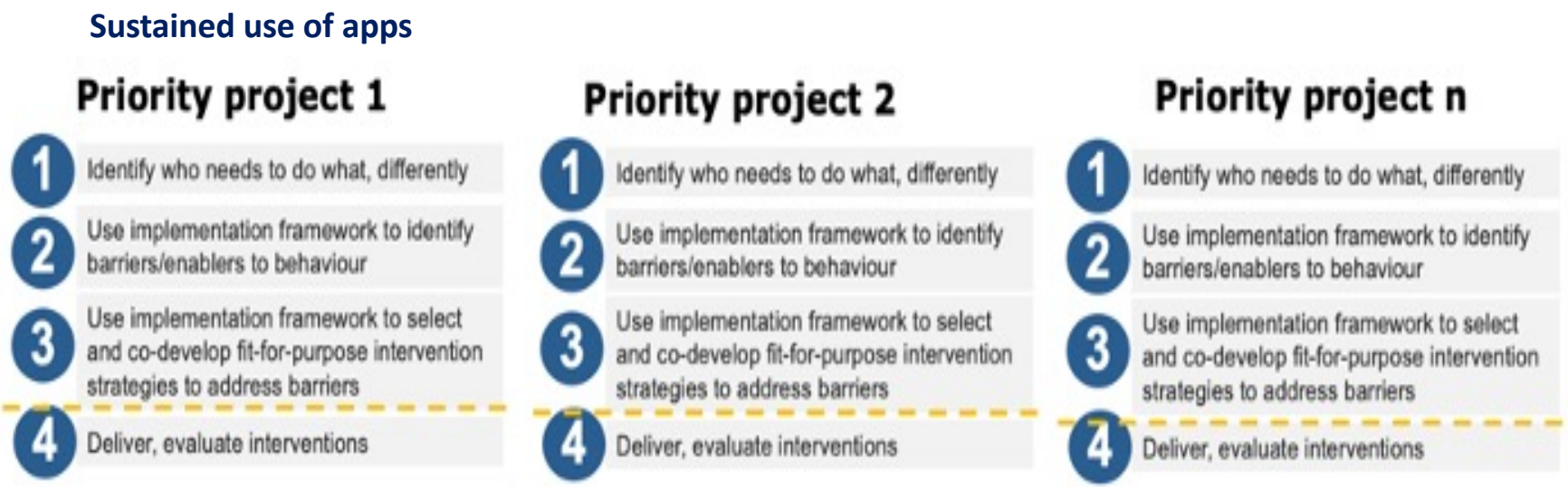
Planning now to support sustained use of apps and digital tools in IBD/IBS care

IS/KM Priority Area 1

IS focus on supporting the sustained use of apps and digital tools

IMAGINE 2.0 | Implementation Science Approach

Our programmatic ImplSci approach uses common structure of activities, contextualized to each core topic area

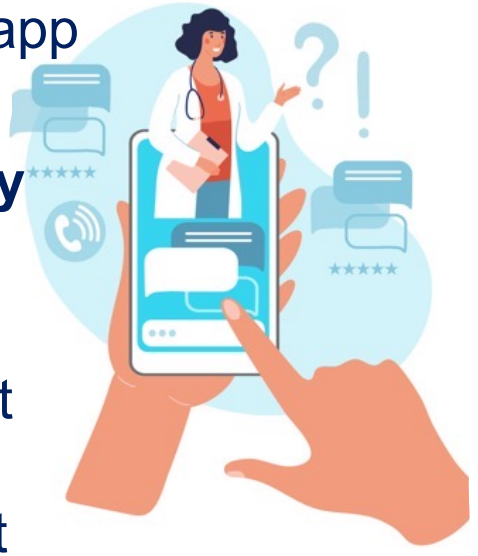


There's an app for that … if you build it, will they come (and stay)?

- Apps and digital tools provide an opportunity to support people to manage health conditions
- Sustained use over time can be a challenge
  - Only 50% of participants engage with the intervention platform as intended by the intervention developer
  - Dropout rates for trials of app-based interventions for chronic disease are high (~ 43% - but higher in real-world studies)
- Even if a promising app or digital tool is initially used and shown to work on the short-term (i.e. 'adopted'), sustained use of apps/digital tools by patients and providers

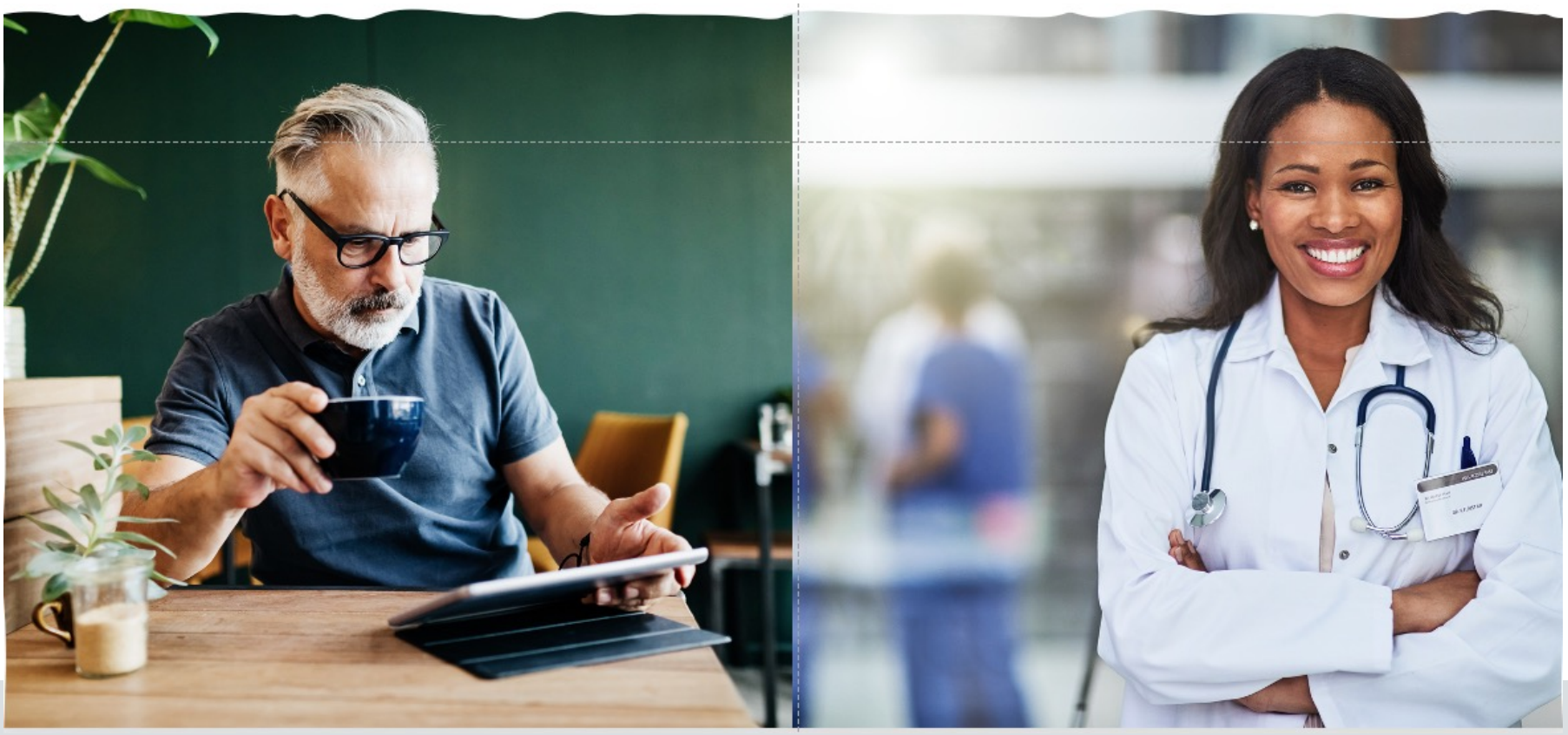
Maintenance of app use is a patient and provider behaviour change issue

- Identifying apps that are demonstrated to be effective in tracking and managing diet, mental health, bowel movements, and symptoms is a key first step (ie. does the app work)
- Assuming the app works, the next key step is to understand how best to support people to start using the app -> for the app to work, people need to start using it
- The factors that encourage patients and providers to **initially use (adoption)** an app/digital tool may not be the same as those that support **ongoing use (maintenance)** over time
  - We have an opportunity to build an understanding of what supports (and what gets in the way) of maintained use of digital tools by people with IBD/IBS and the providers that support them
- This is where we come in: developing an IMAGINE-focused evidence-base for how to support sustained used of promising apps and digital tools



How can we support the sustained use of apps and digital tools for IBS/IBD care?

- Evidence of factors known to drive maintenance of behaviour change can provide some insight
- We can draw on these insight to investigate how we can support the sustained use of apps in the context of IBD/IBS care

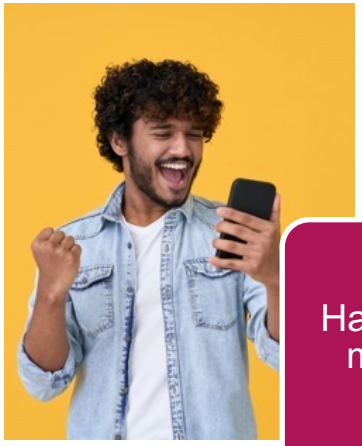


The evidence tells us people tend to maintain behaviours if they …

Build habits

Self-regulate to control their impulses and act in a goal directed manner

Can draw on physical and psychological resources to support sustained efforts



Have conducive maintenance motives

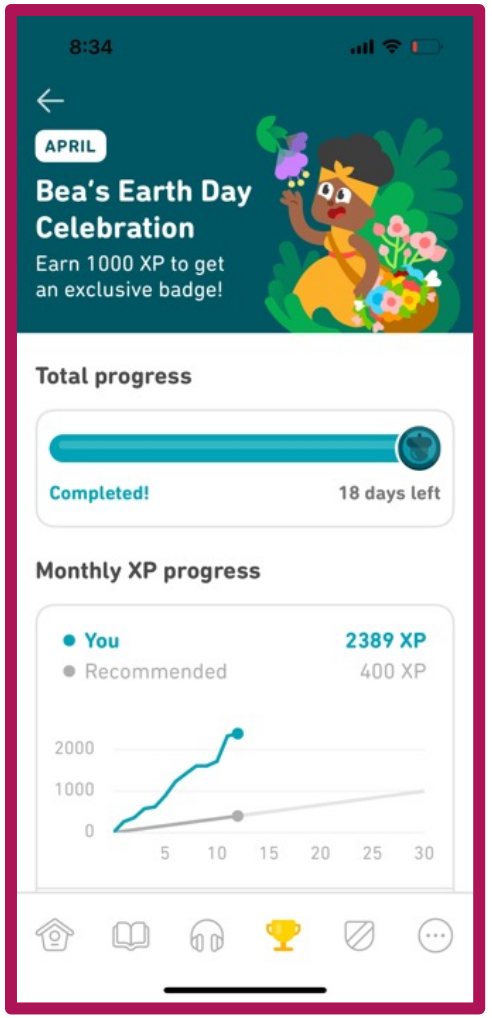
Behaviour maintenance

Have supportive physical environments and social influences

Kwasnicka et al., 2016

Maintenance Factor 1

Maintenance motives



The behaviour (app use) is:

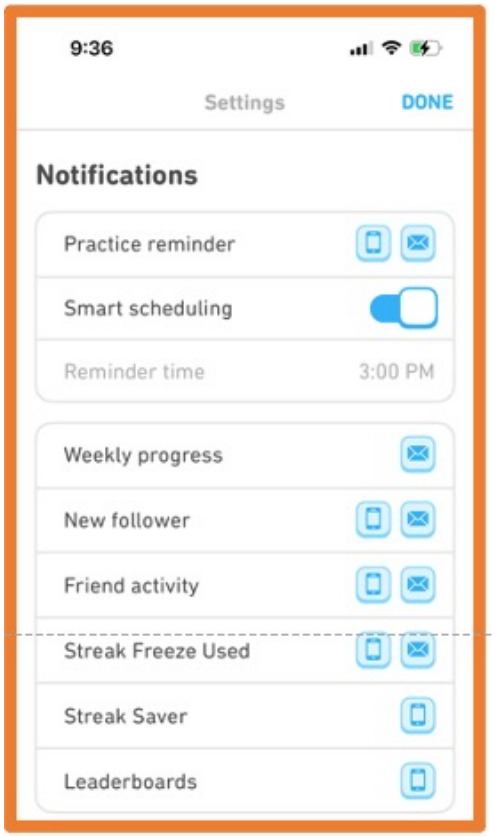
- ✓ **Enjoyable**
- ✓ **Satisfying** (seeing progress on outcomes that are important to person)
- ✓ Driven by intrinsic, rather than extrinsic motives
- ✓ Aligned with personal values and perceived to be personally relevant
- ✓ Aligned with **personal identity** and **beliefs**

Maintenance Factor 2

Self-regulation

Behaviour is more likely to be maintained when using self-regulation strategies:

- ✓For self-monitoring, self-evaluation, and self reinforcement of behaviour
- ✓To deal with temptations/impulses that conflict with long term goals
- ✓The person has self-efficacy to overcome barriers, temptations, and manage and avoid lapses/relapses
- ✓To preplan how to overcome anticipated barriers to app use (coping planning)

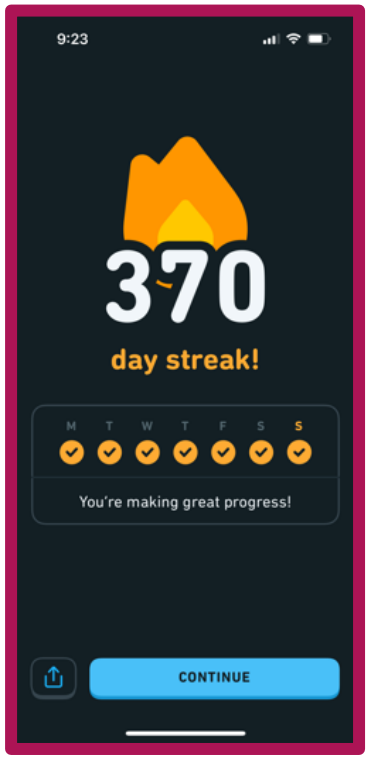


Maintenance Factor 3

Habits

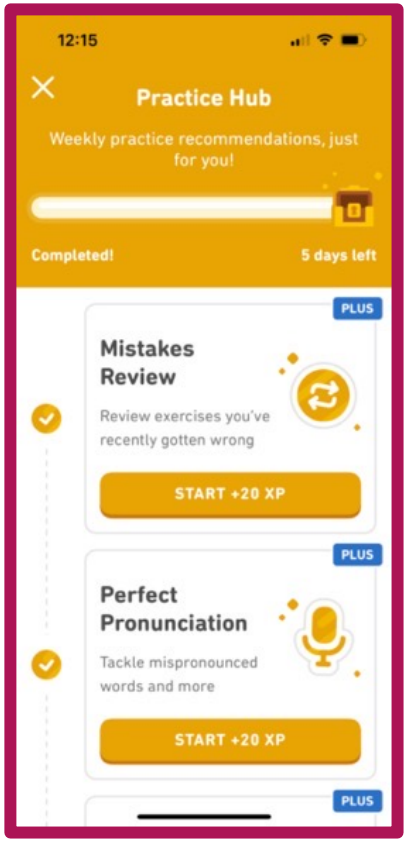
Behaviour is more likely to be maintained overtime when drawing on strategies for habit formation:

- ✓ Follows a period of successful adoption and self-regulation of the behaviour (habits take time to develop)
- ✓ Behaviour is **'automatically'** triggered by contextual cues (apps are great at this at first, but easy to start to ignore)
- ✓ Initiation and performance of the behaviour requires less conscious deliberation – is less cognitively demanding/effortful
- ✓ Developed through repetition and reinforcement (a conditioned response is evoked to a situation cue in a given context)



Maintenance Factor 4

Physical and psychological resources

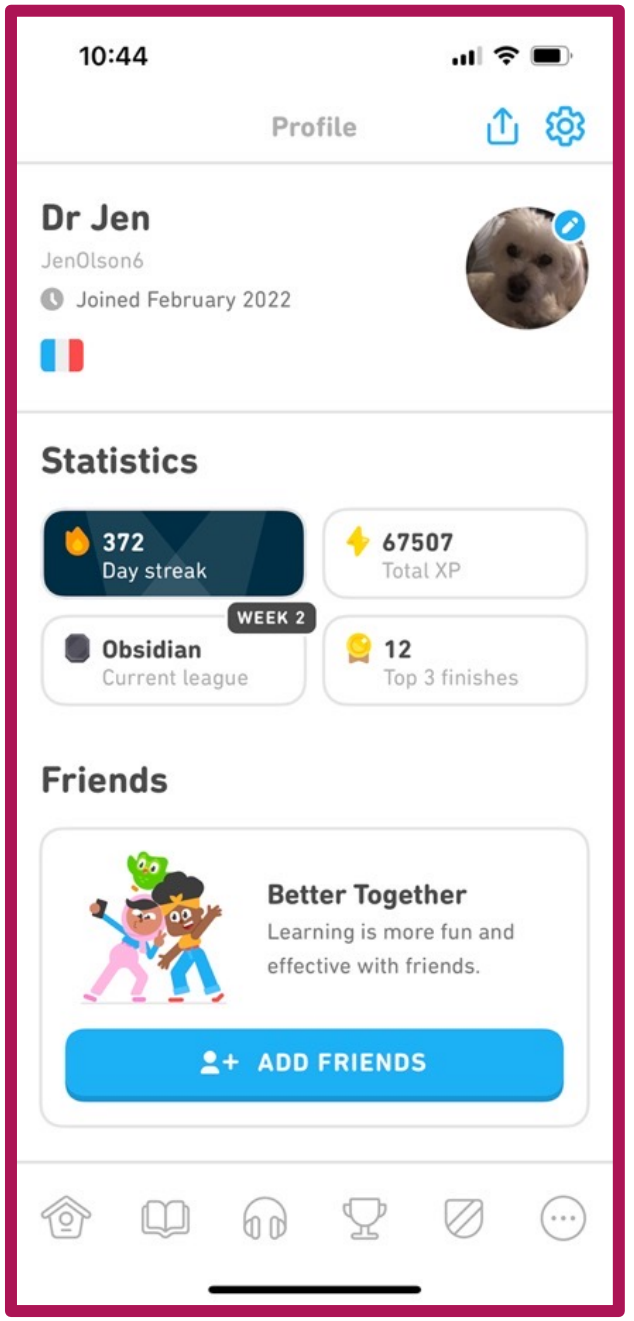


- ✓ The person has psychological and physical assets that can be drawn on to support sustained efforts to perform the behaviour
- ✓ Self-regulation drives behaviour early on, but is a limited resource, which can be depleted by tiredness, stress, exhaustion, intoxication.
- ✓ When capacity for self-regulation is low, habitual behaviours tend to take over
- ✓ Rest and positive affect can restore capacity for self-regulation

Maintenance Factor 5

Environment and social influences

- ✓A supportive environment and positive social influences
- ✓Favourable group norms/approval from group members
- ✓People more likely to follow guidance from people they trust and feel connected to
- ✓Stable contexts facilitate the development of habits



The state of our evidence-base

- Evidence of the factors associated with maintenance of behaviour ✓
- Evidence of factors associated with sustained use of m-health apps and digital tools – To be determined
- Barriers and enablers of sustained use of apps and digital tools for IBD/IBS care among people with lived experience – To be determined
- Barriers and enablers of supporting patients to use apps and digital tools for IBD/IBS care among clinicians - To be determined

A proposal for an ImplSci approach to support the sustained use of apps and digital tools in IBD/IBS care

Sustained use of IMAGINE apps & digital tools for IBD/IBS care

Identify who needs to do what, differently

Use implementation tools to identify barriers/enablers to behaviour

Use implementation tools to select and co-develop fit-for-purpose intervention strategies to address barriers

Patient/ clinician interviews

Literature review

What are the barriers and enablers that need to be addressed among people living with IBD/IBS and health professionals, to support sustained use of apps and digital tools?

Which of the factors that predict behavioural maintenance have best supported the sustained use of apps and digital tools among people living with IBS/IBD and other chronic conditions?

How have these factors been applied as strategies to support sustained use?

Synthesize evidence using implementation tools to **identify factors most likely to overcome modifiable barriers and enhance enablers**

Map factors to behaviour change techniques likely to support sustained use of IMAGINE apps and digital tools

Co-develop best practice guidelines/ checklist for incorporating techniques/ strategies to support the sustained use of IMAGINE apps and digital tools

Co-developed, evidence-informed strategy ready to be implemented and evaluated

We are seeking feedback on the proposed overall approach for this work, and on opportunities to effectively engage patients, health professionals, and investigators leading app/tool development

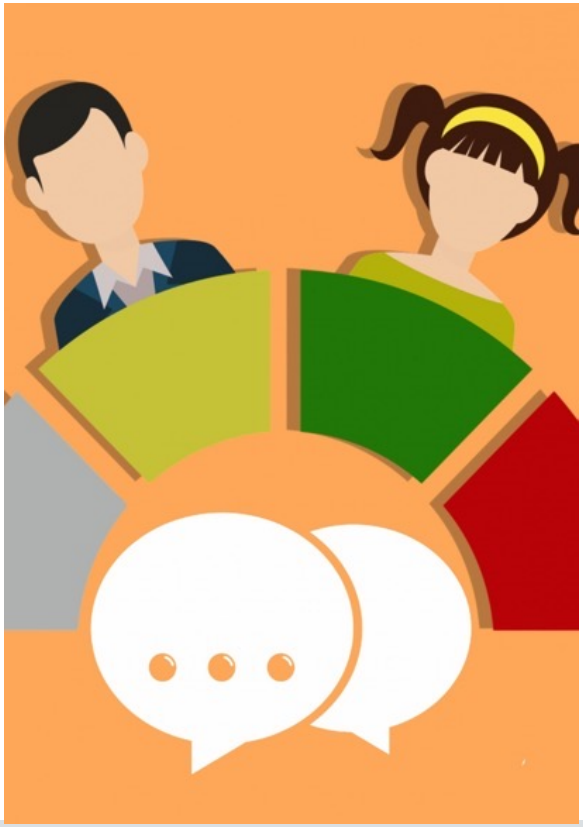
Let us know how you would like to be involved!

We are seeking partners ready to take the next steps

We have initial list of people who have opted in already
Let us know how you would like to be involved!

Our plan going forward over the coming months:

- Assess the 'lay of the land' in breakout session #1
- Assemble a working group, including a patient/citizen co-lead, to:
  - Co-develop protocol for an interview study with patients and providers to understand barriers/enablers to sustained app use in IBS/IBD
  - Ensure diversity of the sampling frame – e.g., age, gender, race and ethnicity, socio-economic, geographic
  - Co-develop protocol for an evidence synthesis of factors that support the maintained use of digital tools/apps for IBD/IBS to investigate how strategies to support sustained use of apps and digital tools need to be modified for certain contexts and populations, or



IMAGINE 2.0 | Implementation Science

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2) Optimizing the intersections between primary care & specialized lines of service (IBS, IBD, MH), directly & via virtual care

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- KM focus on a living evidence synthesis (LES) and inputs to Crohn's and Colitis Canada and other projects
  - Four 'moving parts'
    - Framework for how primary care-based population health management and specialty service lines may intersect (critical interpretive synthesis), which could include elements such as:
      - Gastroenterologists and nurse practitioners effectively functioning as primary-care providers for young patients newly diagnosed with IBD, versus as consultants for IBD care for older patients with multiple chronic conditions
      - Ways to situate the CCC work on telemedicine in a broader frame (and to help with the business case, including quadruple-aim metrics)
      - See next two slides for more detail
    - Description of the nature of the evidence in this space (scoping review)
    - Assessment of the effects of different models on quadruple-aim metrics (systematic review of effects and meta-analysis if appropriate)
    - Understanding of whether, how and why these models work and what patient partners', providers' and other stakeholders' experiences are with these models (qualitative evidence synthesis)
  - **Participation opportunities**
    - Synthesis team member (for patient partners and for providers)
      - Training available that leverages COVID-END and SPOR-EA experience
      - Meetings can start as early as May, will likely be every two months, and will ideally involve a long-term commitment given the many interconnected core products already planned and the derivative products to be developed as 'windows of opportunity emerge'

2) Optimizing the intersections between primary care & specialized lines of service (IBS, IBD, MH), directly & via virtual care

HEALTH FORUM | McMaster University

- Framework for how primary care-based population health management and specialty service lines may intersect (critical interpretive synthesis)
  - Population segments requiring specialty service lines – people requiring:
    - e.g., organ transplant, cancer care, complex cardiac and stroke care, dialysis for chronic kidney disease, care for severe and persistent mental-health conditions
    - e.g., inpatient care eating disorders, complex rehabilitation care
    - e.g., pediatric tertiary care, care for severe neurodevelopmental conditions (children/adults), care for frailty
  - Levels where specialized lines of service are currently (or could be) planned
    - Provincial
    - Regional
    - Local
  - Considerations that may shift the level at which specialty service lines are provided
    - Patient needs: acute and/or episodic versus longitudinal or life-long care
    - Organizing 'body' for population
    - Existing functions of involved provider organizations: top of PHM risk pyramid and /or supporting providers at all levels of the levels
    - Sectors from which involved provider organizations are drawn: one versus targeted versus many
    - Experience with shared care and other approaches to working with primary care and other core partners in integrated-care models (e.g., OHTs)
    - Providers of specialized lines of services are already involved as partners in integrated-care models
    - Other considerations: patient complexity

2) Optimizing the intersections between primary care & specialized lines of service (IBS, IBD, MH), directly & via virtual care

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- Living evidence synthesis (LES) update
  - Moving into sampling and data extraction for the critical interpretive synthesis (CIS)

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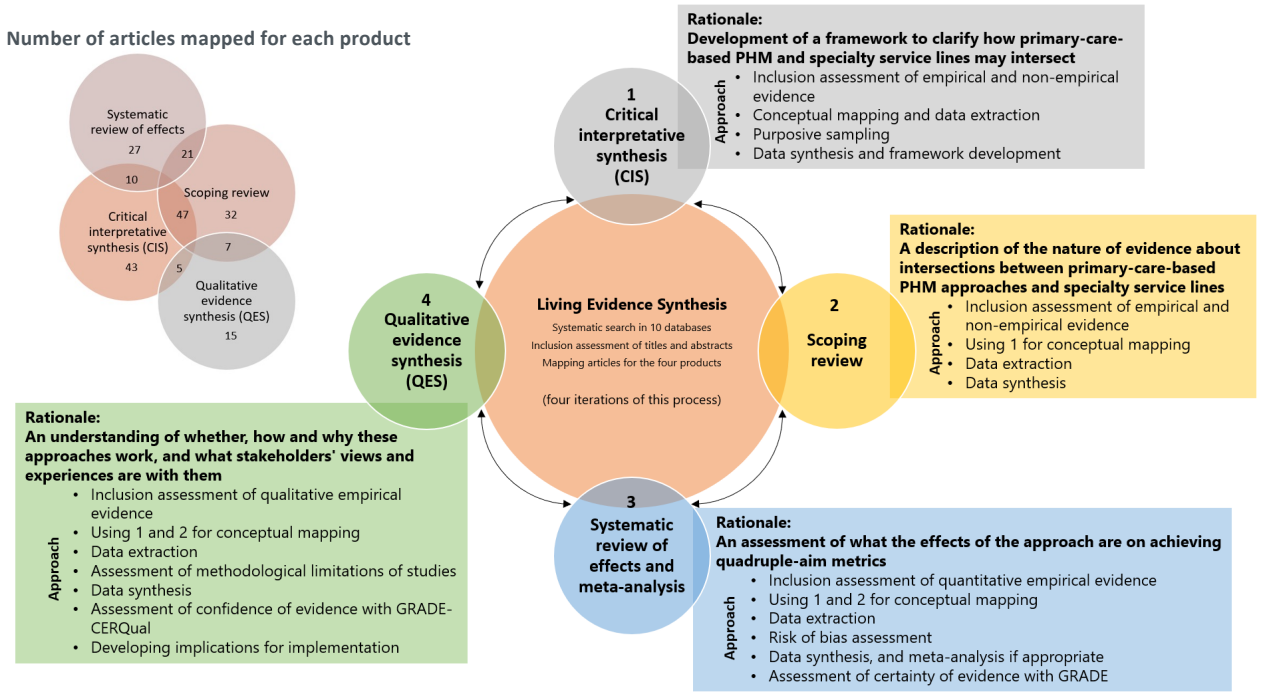
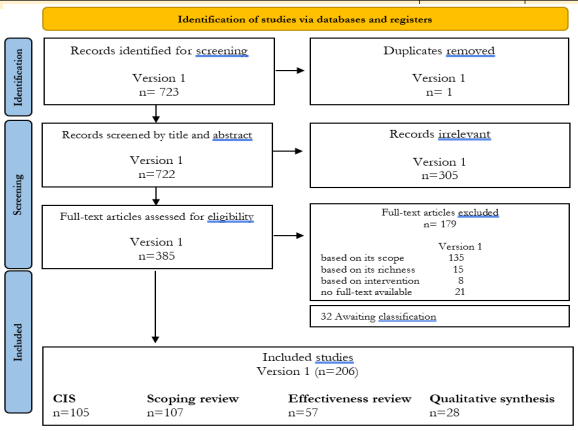


Product and task	Dec 2022-Feb 2023	Mar 2023 – May 2023
Living evidence synthesis		
Search strategy	X	
Inclusion assessment and mapping of titles and abstracts	X	
Update searching		
Writing report		X
Critical interpretative synthesis (CIS)		
Inclusion assessment	X	
Conceptual mapping and data extraction	X	
Purposive sampling		X
Data synthesis and framework development		X
Writing a draft		X



3) Enabling conversations about diet & mental health as part of IBD/IBS care (part of which grows out of a PP-led study)

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- IS focus on supporting patients and providers in these conversations (while awaiting a possible CAG guideline that does a deeper dive on diet in IBD/IBS care)
  - To be covered by Jen, including better connections between primary care and dietitians and mental-health providers for IBS and between gastroenterologists and mental health for IBD

.

Enabling conversations about diet and mental health as part of IBD/IBS care

IS/KM Priority Area 3

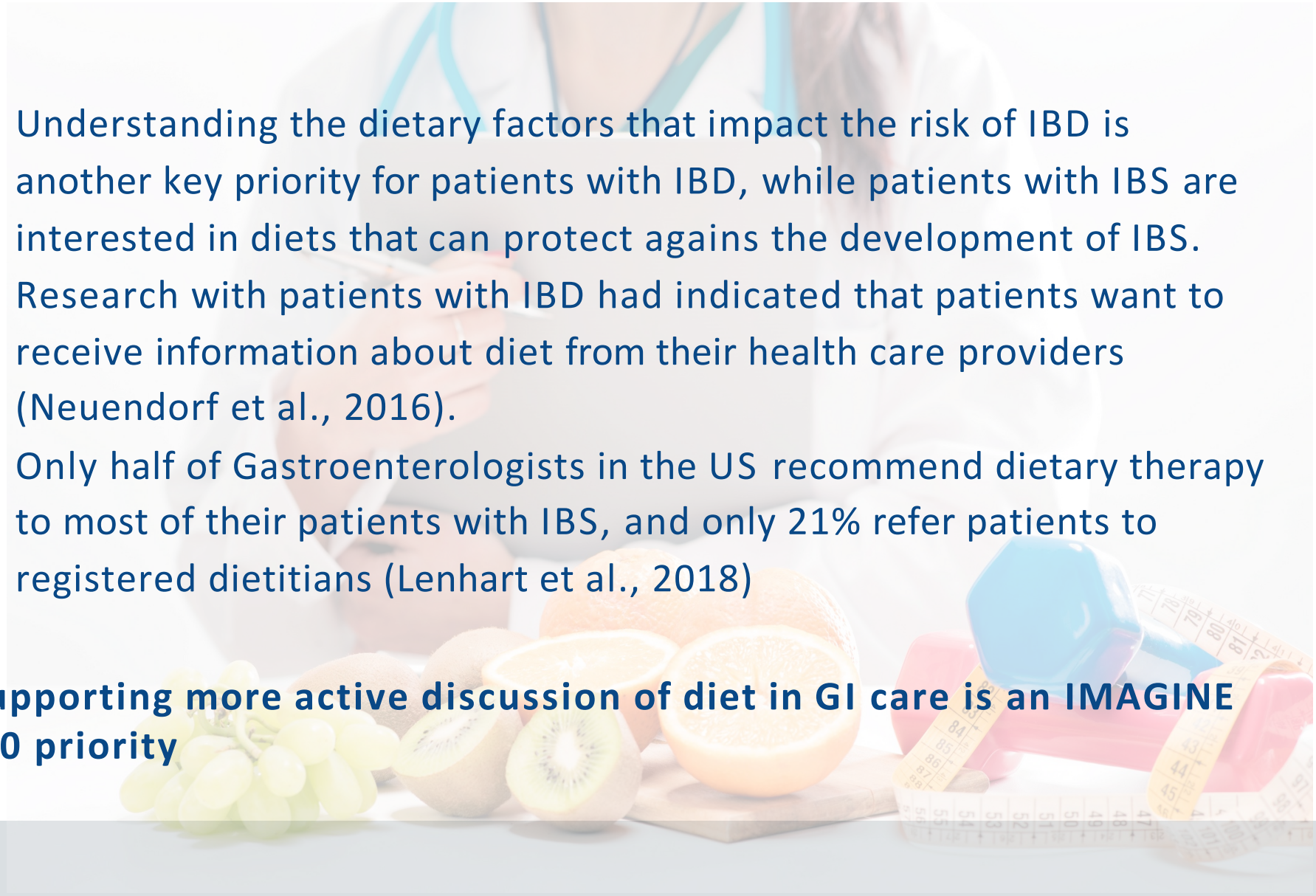
IS focus on enabling conversations about diet and mental health

Mental Health

- There is an increased prevalence of psychological comorbidity in IBS and IBD.
- Patients report that mental health is not sufficiently addressed in consultations with their gastrointestinal specialists, and are concerned about the lack of focus on mental well-being.
- Research with patients with Ulcerative Colitis suggests that around half did not feel comfortable discussing emotional concerns with their physician; and only half of physicians treating people with Ulcerative Colitis reported discussing mental health with their patients (Rubin et al. 2021).

Supporting more active discussions of mental health in GI care is an IMAGINE 2.0 priority

Diet



- Understanding the dietary factors that impact the risk of IBD is another key priority for patients with IBD, while patients with IBS are interested in diets that can protect agains the development of IBS.
- Research with patients with IBD had indicated that patients want to receive information about diet from their health care providers (Neuendorf et al., 2016).
- Only half of Gastroenterologists in the US recommend dietary therapy to most of their patients with IBS, and only 21% refer patients to registered dietitians (Lenhart et al., 2018)

Supporting more active discussion of diet in GI care is an IMAGINE 2.0 priority

IMAGINE 2.0 | Implementation Science Approach

A programmatic approach using common structure of activities, contextualized to each topic area

Sustained use of apps

Priority project 1

1. Identify who needs to do what, differently
2. Use implementation framework to identify barriers/enablers to behaviour
3. Use implementation framework to select and co-develop fit-for-purpose intervention strategies to address barriers
4. Deliver, evaluate interventions

Enabling conversations about diet

Priority project 2

1. Identify who needs to do what, differently
2. Use implementation framework to identify barriers/enablers to behaviour
3. Use implementation framework to select and co-develop fit-for-purpose intervention strategies to address barriers
4. Deliver, evaluate interventions

Enabling conversations about mental health

Priority project n

1. Identify who needs to do what, differently
2. Use implementation framework to identify barriers/enablers to behaviour
3. Use implementation framework to select and co-develop fit-for-purpose intervention strategies to address barriers
4. Deliver, evaluate interventions

1 - Who needs to do what, differently?

What do existing clinical guidelines recommend for conducting conversations on diet and mental health as part of IBD/IBS care?

Which providers are currently initiating these conversations, and when?

Which providers could/should be initiating these conversations, and when? (eg primary care; dietitians; mental health providers)

What are existing *referral* pathways and feedback/circle of care arrangements?

What evidence- and preference-informed conversations are taking place (conversation content)

With whom are patients currently having conversations about diet and mental health? How different/same for IBD/IBS?

With whom could/should/do patients want to have conversations about diet and mental health? How different/same for IBD/IBS?

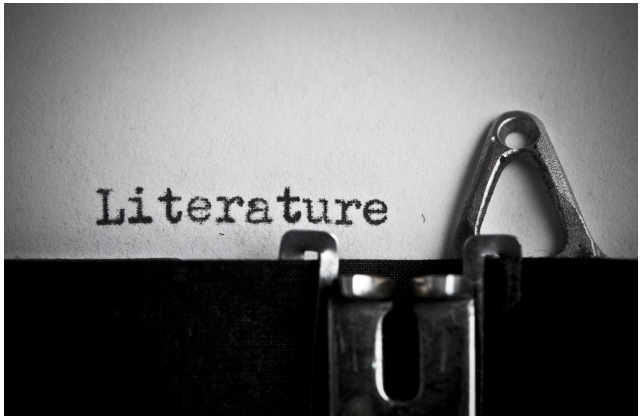
What evidence- and preference-informed conversations are/could take place (conversation content)

Breakout session #3 will help us start to map this out across Canada

2 – What are the barriers to having the conversations?

What are the barriers and enablers experienced by clinicians of having conversations about diet and mental health with patients?

What are the barriers and enablers experienced by patients of initiating conversations about diet and mental health?

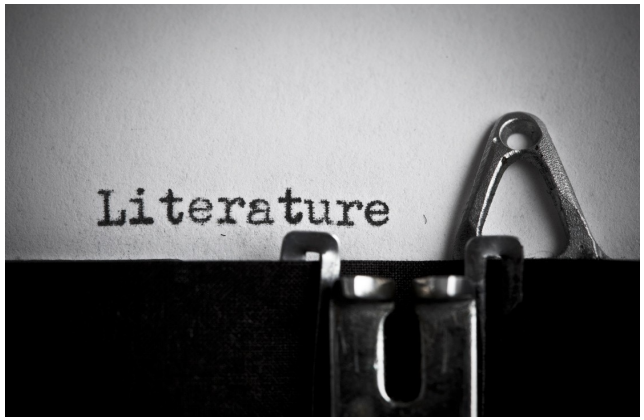


What is existing evidence of the factors associated with behaviour change among patients and clinicians to enable conversations about diet and mental health?

3 – What are the possible solutions to address identified barriers to having conversations about diet and mental health?

What **evidence-informed solutions** are best suited to address the barriers and enablers experienced by clinicians of having conversations about diet and mental health with patients?

What **evidence-informed solutions** are best suited to address barriers and enablers experienced by patients of initiating conversations about diet and mental health?



What is existing evidence of the factors associated with behaviour change among patients and clinicians to enable conversations about diet and mental health?

We are seeking partners to help us take next steps

We have initial list of those interested, but let us know how you would like to be involved!

- Our plan going forward over the coming months:
  - Assemble a working group including a patient/citizen co-lead to:
  - Clarify existing and indicated providers (the 'who') positioned to have conversations about
    - Diet
    - Mental health
    - For IBD and IBS (together or separately?)
  - Clarify range of aspects that those conversations do/should/could cover (the 'what')
  - Develop protocol for an implementation study to understand barriers/enablers from perspective of patients and providers
  - Co-develop strategies/solutions to address identified barriers

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Toolkits being used

HEALTH FORUM | McMaster University

- **IS projects: Strategies supporting changes in behaviours in patients & healthcare professionals**
  - To be covered by Jen
- KM projects: Strategies supporting changes in policy decisions by government or system decisions by organizational leaders
- IS/KM projects: ‘Learning health system’ thinking

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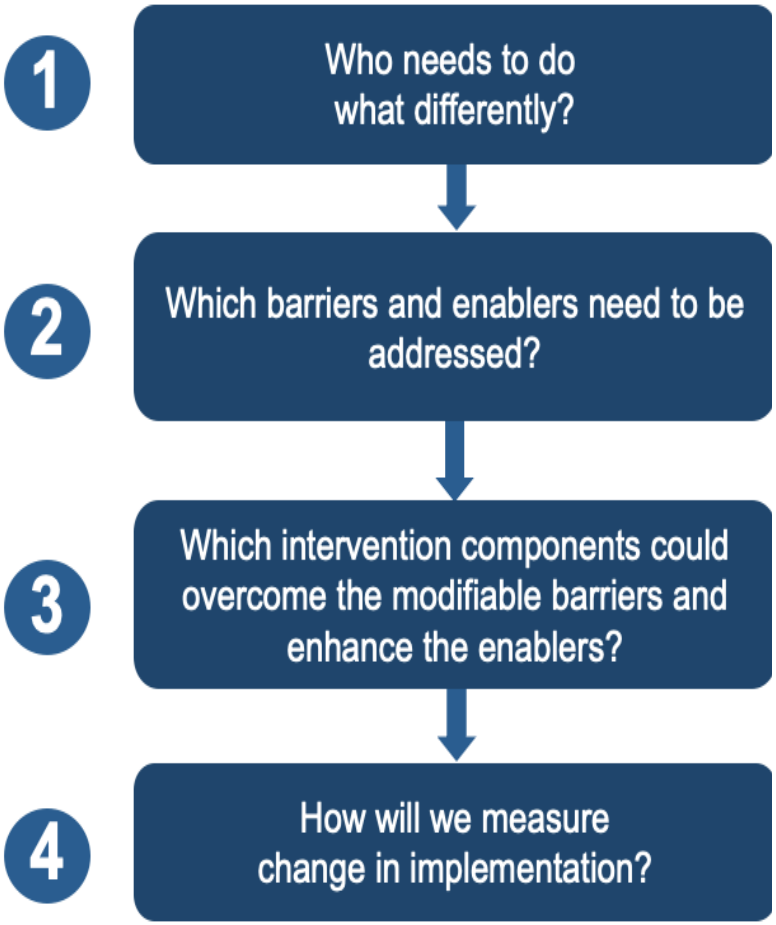
Overview of key ImplSci tools leveraged in our IMAGINE 2.0 patient and provider behaviour change projects



French et al 2012

METHODOLOGY Open Access

Action, actor, context, target, time (AACTT): a framework for specifying behaviour

Justin Presseau[1,2,3*], Nicola McCleary[1,2], Fabiana Lorencatto[4], Andrea M. Patey[1], Jeremy M. Grimshaw[1,2,5] and Jill J. Francis[6]

RESEARCH Open Access

Validation of the theoretical domains framework for use in behaviour change and implementation research

James Cane[1], Denise O'Connor[2] and Susan Michie[3*]

RESEARCH Open Access

The behaviour change wheel: A new method for characterising and designing behaviour change interventions

Susan Michie[1*], Maartje M van Stralen[2] and Robert West[3]

RESEARCH Open Access

A refined compilation of implementation strategies: results from the Expert Recommendations for Implementing Change (ERIC) project

Byron J Powell[1*], Thomas J Waltz[2], Matthew J Chinman[3,4], Laura J Damschroder[5], Jeffrey L Smith[6], Monica M Matthieu[6,7], Enola K Proctor[8] and JoAnn E Kirchner[6,9]

The Behavior Change Technique Taxonomy (v1) of 93 Hierarchically Clustered Techniques: Building an International Consensus for the Reporting of Behavior Change Interventions

Susan Michie, DPhil, CPsychol · Michelle Richardson, PhD · Marie Johnston, PhD, CPsychol · Charles Abraham, DPhil, CPsychol · Jill Francis, PhD, CPsychol · Wendy Hardeman, PhD · Martin P. Eccles, MD · James Cane, PhD · Caroline E. Wood, PhD

RESEARCH METHODS AND REPORTING

Designing and undertaking randomised implementation trials: guide for researchers

Luke Wolfenden,[1,2] Robbie Foy,[3] Justin Presseau,[4,5] Jeremy M Grimshaw,[4,6] Noah M Ivers,[7,8,9,10] Byron J Powell,[11] Monica Taljaard,[4,5] John Wiggers,[1,2] Rachel Sutherland,[1,2] Nicole Nathan,[2] Christopher M Williams,[1,2,12] Melanie Kingsland,[1,2] Andrew Milat,[12] Rebecca K Hodder,[1,2] Sze Lin Yoong[13]

A tool for clarifying who needs to do what differently

Action	Behaviour that needs to change
Actor	Person/people that do/could do the Action
Context	Physical location or social setting of Action
Target	Person/people for whom Action is performed
Time	When the Action is performed (time/date/freq)

METHODOLOGY Open Access

Action, actor, context, target, time (AACTT): a framework for specifying behaviour

Justin Presseau[1,2,3*], Nicola McCleary[1,2], Fabiana Lorencatto[4], Andrea M. Patey[1], Jeremy M. Grimshaw[1,2,5] and Jill J. Francis[6]

Tools for systematically identifying barriers/enablers

TDF Domains
Knowledge
Skills
Memory, attention and decision processes
Behavioural regulation
Environmental context and resources
Social Influences
Beliefs about capabilities
Intention
Goals
Social/professional role and identity
Beliefs about consequences
Reinforcement
Emotion
Optimism

Capability

Opportunity

Motivation

Advantages

✓Applicable to any AACTT

✓Covers breadth of factors associated with behaviour at multiple levels

✓Directly linked to strategies for addressing barriers/enablers


METHODOLOGY Open Access

A guide to using the Theoretical Domains Framework of behaviour change to investigate implementation problems

Lou Atkins[1*], Jill Francis[2,3], Rafat Islam[3], Denise O'Connor[4], Andrea Patey[3], Noah Ivers[5], Robbie Foy[6], Eilidh M. Duncan[7], Heather Colquhoun[8], Jeremy M. Grimshaw[3,9], Rebecca Lawton[10] and Susan Michie[1]


RESEARCH Open Access

The behaviour change wheel: A new method for characterising and designing behaviour change interventions

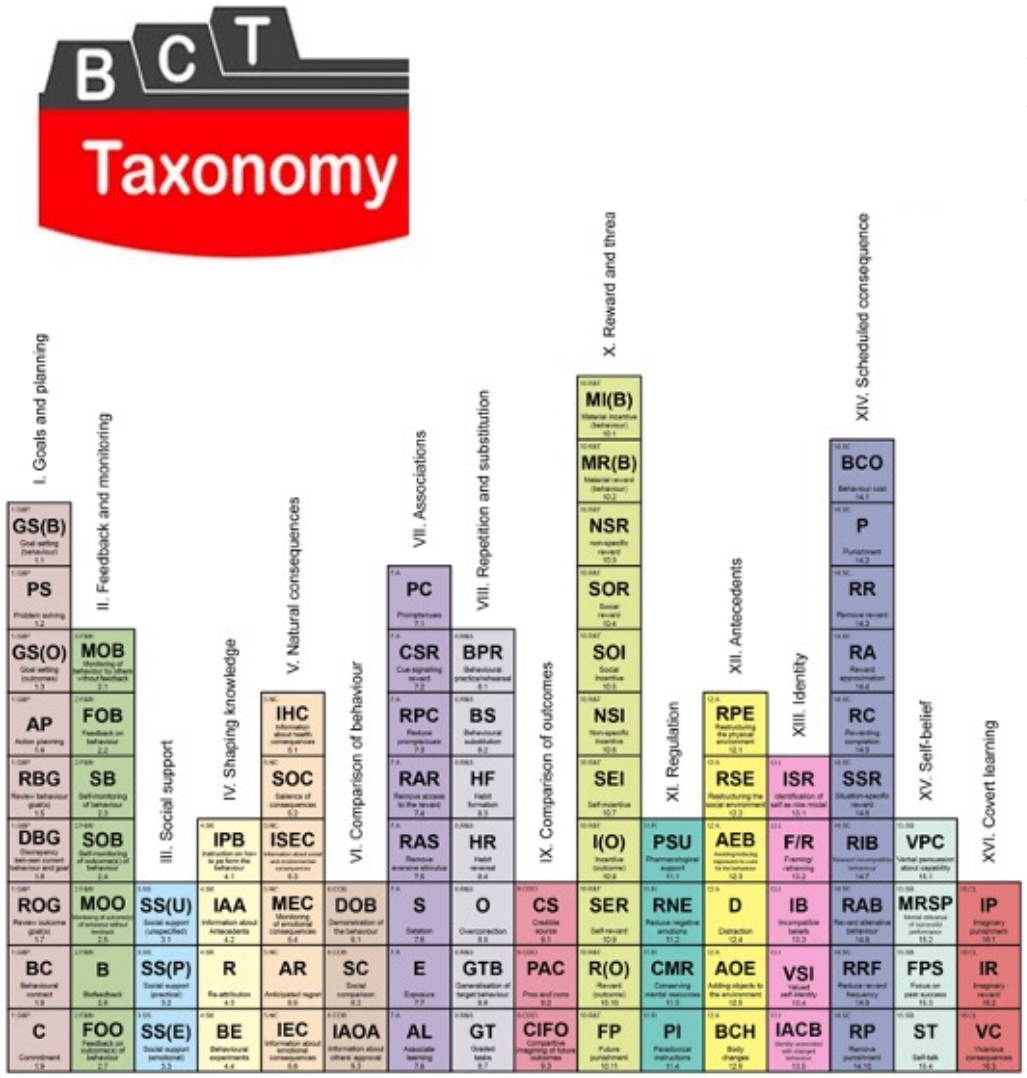
Susan Michie[1*], Maartje M van Stralen[2] and Robert West[3]


RESEARCH Open Access

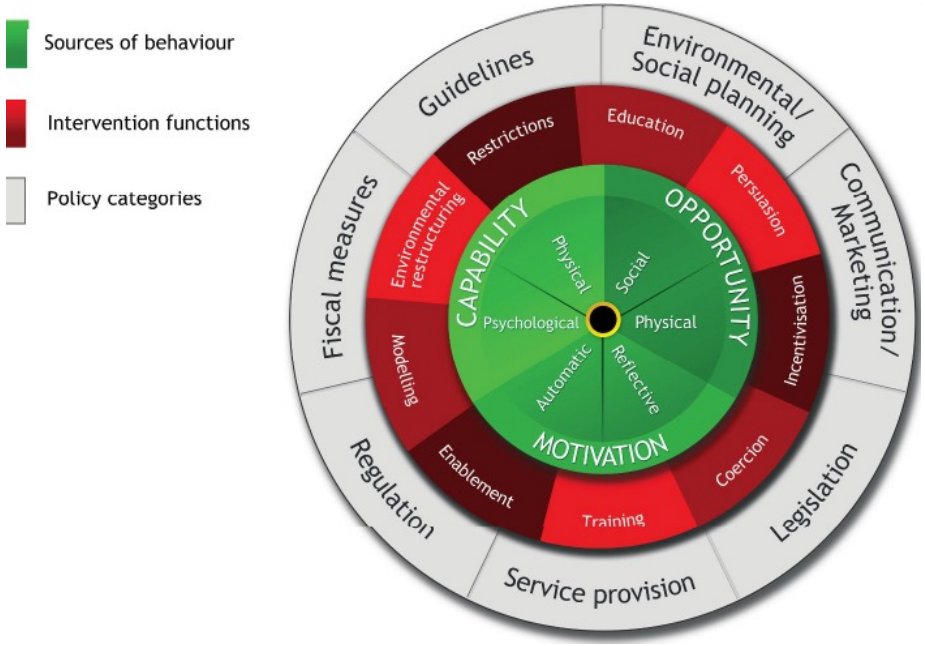
Validation of the theoretical domains framework for use in behaviour change and implementation research

James Cane[1], Denise O'Connor[2] and Susan Michie[3*]

Tools for systematically linking barriers/enablers to strategies to address them

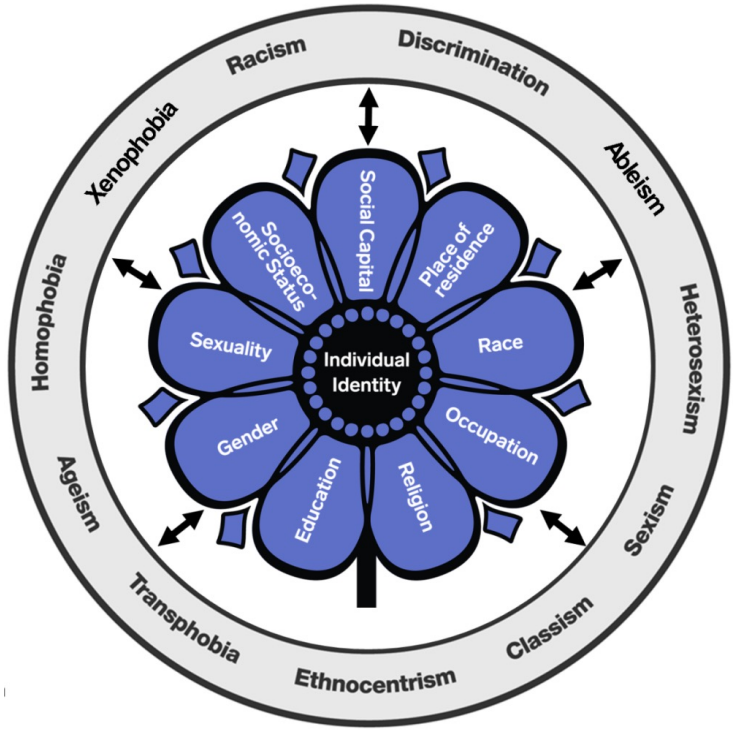


- No ‘right’ strategy for all barriers/enablers
- Best practice to select strategies and techniques best suited to address them
- There are existing tools for helping to select best strategies for each barrier/enabler



A note on equity

- Experience and identity shaped by interaction of factors
- Not only identity markers, but also their intersection with systems of power and oppression that result in social hierarchies
- People's identities and experiences are not limited to one label; rather shaped by wider intersectional factors
- We have been doing work to advance the standard tools outlined to integrate intersectionality considerations
- We will draw on these advances in our IMAGINE 2.0 projects



RESEARCH ARTICLE Open Access

Applying an intersectionality lens to the theoretical domains framework: a tool for thinking about how intersecting social identities and structures of power influence behaviour

Cole Etherington[1*], Isabel Braganca Rodrigues[2], Lora Giangregorio[2,3], Ian D. Graham[1,4], Alison M. Hoens[5,6,7], Danielle Kasperavicius[8], Christine Kelly[9], Julia E. Moore[10], Matteo Ponzano[2], Justin Presseau[1,4], Kathryn M. Sibley[9,11] and Sharon Straus[8,12]

RESEARCH Open Access

Selecting implementation models, theories, and frameworks in which to integrate intersectional approaches

Justin Presseau[1,2,3*], Danielle Kasperavicius[4], Isabel Braganca Rodrigues[5], Jessica Brairmoh[6], Andrea Chambers[7], Cole Etherington[1,8], Lora Giangregorio[9], Jenna C. Gibbs[10], Anik Giguere[11], Ian D. Graham[1,2], Olena Hankivsky[12], Alison M. Hoens[13], Jayna Holroyd-Leduc[14], Christine Kelly[15], Julia E. Moore[16], Matteo Ponzano[9], Malika Sharma[17,18], Kathryn M. Sibley[15,19] and Sharon Straus[4,18]

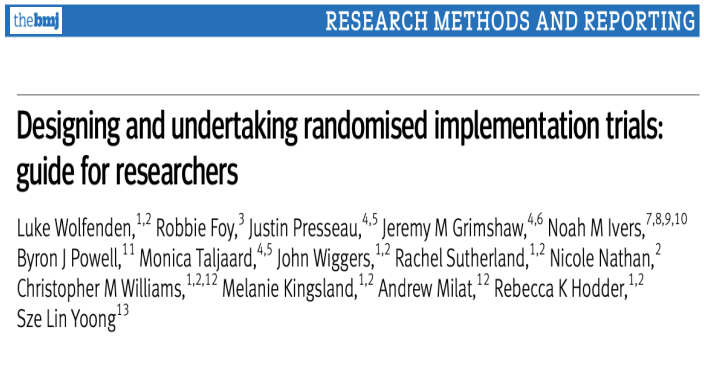
Looking towards the future: implementation evaluation

Tremendous opportunity to evaluate the implementation interventions designed to target identified barriers and enablers (requires separate funds)

- IMAGINE 2.0 provides the catalyst for the development work needed to apply for evaluation grants

Measures	Description
Acceptability	Perception among implementation stakeholders that an evidence based intervention (or implementation strategy) is agreeable, palatable, or satisfactory
Adoption	Intention, initial decision, or action to try or use an evidence based intervention (or implementation strategy). Adoption also can be referred to as "uptake"
Appropriateness	Perceived fit, relevance, or compatibility of an evidence based intervention (or implementation strategy) for a given practice setting, provider, or consumer; or perceived fit of the innovation to resolve a particular issue or problem
Feasibility	Extent to which an evidence based intervention (or implementation strategy) can be successfully used or carried out
Fidelity	Degree to which an evidence based intervention (or implementation strategy) was delivered as it was intended
Cost (incremental or implementation cost)	Cost or relative cost of the implementation of an evidence based intervention
Penetration	Integration of an evidence based intervention within a service setting and its subsystems
Sustainability	Extent to which a newly implemented evidence based intervention is maintained or institutionalised within a service setting's ongoing, stable operations

Proctor et al 2011



For example:

- **Two arm parallel randomized trial:** Individuals or groups (e.g. clinics, hospitals, primary care sites) with multiple individuals (e.g. physicians, nurses, patients) randomly assigned to receive implementation strategy or not

- **Stepped wedge randomized trials**: following baseline, implementation strategy sequentially provided to clusters in randomized order – over time, all clusters ultimately receive the intervention

Toolkits being used

HEALTH FORUM | McMaster University

- IS projects: Strategies supporting changes in behaviours in patients & healthcare professionals
- **KM projects: Strategies supporting changes in policy decisions by government or system decisions by organizational leaders**
  - **Contextualized evidence syntheses** that are prepared in a timely, demand-driven way as 'windows of opportunity' open (and that put IMAGINE evidence alongside other evidence needed for decision-making), and our current work is both an example of this and will provide the raw material for 'derivative products' that are produced as more specific 'windows of opportunity' open in provincial and territorial health systems
    - Framework for how apps and digital tools would need to 'land' to be funded in an ongoing way by government policymakers and system leaders
    - Framework for how primary care-based population health management and specialty service lines may intersect
      - Assessment of the effects of different models on quadruple-aim metrics
      - Understanding of whether, how and why these models work and what patient partners', providers' and other stakeholders' experiences are with these models
  - **Citizen panels and stakeholder dialogues** that put the available research evidence (IMAGINE and other) alongside the many other factors that will influence whether an issue moves to the decision agenda and what choices will be made → we can discuss these in more detail another time
    - E.g., strengthening health-system arrangements for FMT scale-up (if IMAGINE research supports scale-up)
- IS/KM projects: 'Learning health system' thinking

Toolkits being used

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- IS projects: Strategies supporting changes in behaviours in patients & healthcare professionals
- KM projects: Strategies supporting changes in policy decisions by government or system decisions by organizational leaders
- **IS/KM projects: 'Learning health system' thinking**

‘Layers’ involved in ‘learning and improving’ to achieve health-system goals (such as equity-centred quadruple-aim metrics)

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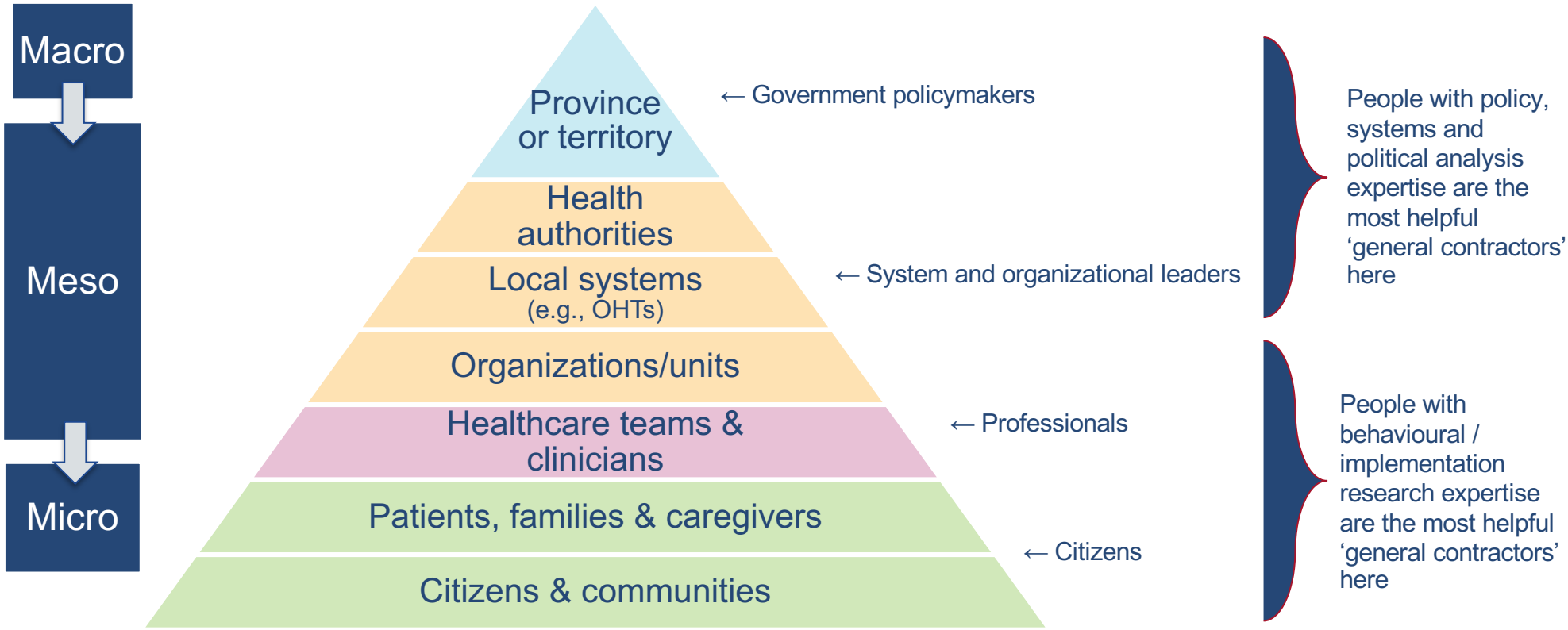

Adapted from Reid R, Wodchis W, Lee-Foon N, and Institute for Better Health-Trillium Health Partners (2022)

‘Steps’ where ‘learning and improving’ can happen (ideally supported by a ‘general contractor’ who brings in the right ‘trades’)

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Where are system gaps & what’s driving them? Where are the inequities? What priorities are we addressing (or what problems are we solving)?

Stocks of existing evidence:
1) Data analytics
2) Modeling
3) Qualitative insights
4) Evidence synthesis (global)

What evidence-informed solutions exist? How will solutions be adapted/designed with input from system users and communities?

Stocks of existing evidence:
1) Evaluation
2) Modeling
3) Qualitative insights
4) Evidence synthesis (global)
5) Technology assessments
6) Guidelines

Does this model work? How & for whom? What adaptations are needed to cement & scale?

Stocks of existing evidence:
1) Behavioural/implementation research
2) Qualitative insights
3) Evidence synthesis (global)
Flows of new evidence:
1) Data analytics
2) Evaluation

Adapted from Reid R, Wodchis W, Lee-Foon N, and Institute for Better Health-Trillium Health Partners (2022)

Evolution of research paradigm (again with a construction analogy)

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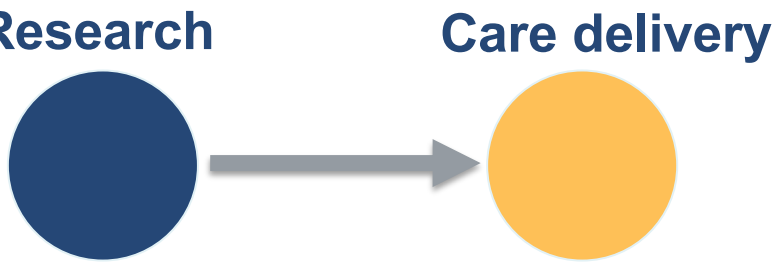
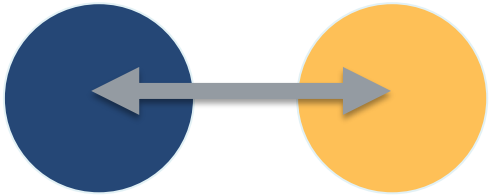
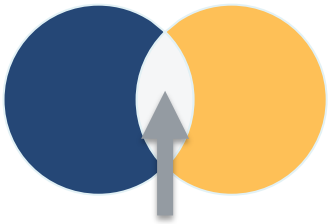


Separate & distinct enterprise



Knowledge translation & exchange



Embedded evidence-support units & applied researchers

Here we need both 'general contractors' who can leverage stocks of existing evidence and 'trades' who can contribute to flows of new evidence

Learning health system

Adapted from Reid R, Wodchis W, Lee-Foon N, and Institute for Better Health-Trillium Health Partners (2022)

A reminder

- We will be cycling through a similar process in future years as IMAGINE evidence becomes ‘ready for prime time’
  - e.g., Year 2
    - Strengthening GI care using team-based approaches
    - Strengthening health-system arrangements for FMT scale-up (to lay the groundwork for a year 4 or 5 stakeholder dialogue)
  - e.g., year 3
    - Strengthening patient self-management and clinical decision-support for GI in organizations and health systems
    - Supporting youth-to-adult care transitions for GI conditions in Canada (if there are policy- and system-level issues that Melanie Barwick won’t address)

- Also we have brief workshop-like versions of a masterclass in evidence products and processes (for teams of citizen partners, researchers and decision-makers interesting in supporting learning and improvement)

BREAKOUT SESSIONS

Breakout Group	1	2	3
Topic	Planning now to support the uptake and sustained use of digital solutions/apps in IBD/IBS care	Optimizing the intersections between primary care and specialized lines of service (IBS care, IBD care, and related mental health care), directly and via virtual care	Enabling conversations about diet and mental health as part of IBD/IBS care
Facilitators	Kaelan, Jenny and Deborah	John and Paul	Justin and Aida
Patient Partners	Shania, Shawn, Chantal	Alysia, Lisa	Gail, Kim, Sara
HCPs / Researchers	Charles, Adrijana	Stephen, Leo, Karen	Eytan, Dean, Premek
Other (Partners)	Jacqui /Siam (CCC)	Gail (BadGut); Amy Lang (CIHR)	Stuart (CAG)

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Inflammation, Microbiome & Alimentation Gastro-Intestinal & Neuropsychiatric Effects

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Strategy for Patient-Oriented Research SPOR Putting Patients First

>$2,000,000
Crohn's and Colitis Canada / Crohn et Colite Canada; McMaster University; Takeda; University of Calgary
$1,000,000 - $2,000,000
Alberta Innovates; Allergan; Queen's University; Research Manitoba; University of Alberta
<$1,000,000
Dalhousie Medical Research Foundation; Dalhousie University; IWK Health Centre; Montreal Heart Institute; Université de Montréal

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Canadian Association of Gastroenterology / L'Association Canadienne de Gastroentérologie

Canadian Digestive Health Foundation

CAN-BIND Canadian Biomarker Integration Network in Depression

CANMAT

CANGIEC Canadian Gastro-Intestinal Epidemiology Consortium

CCHCSP PCCCSE Canadian Child Health Clinician Scientist Program / Programme canadien de cliniciens-chercheurs en santé de l'enfant

Cochrane Consumer Network

PaCER innovates Patient and Community Engagement Research

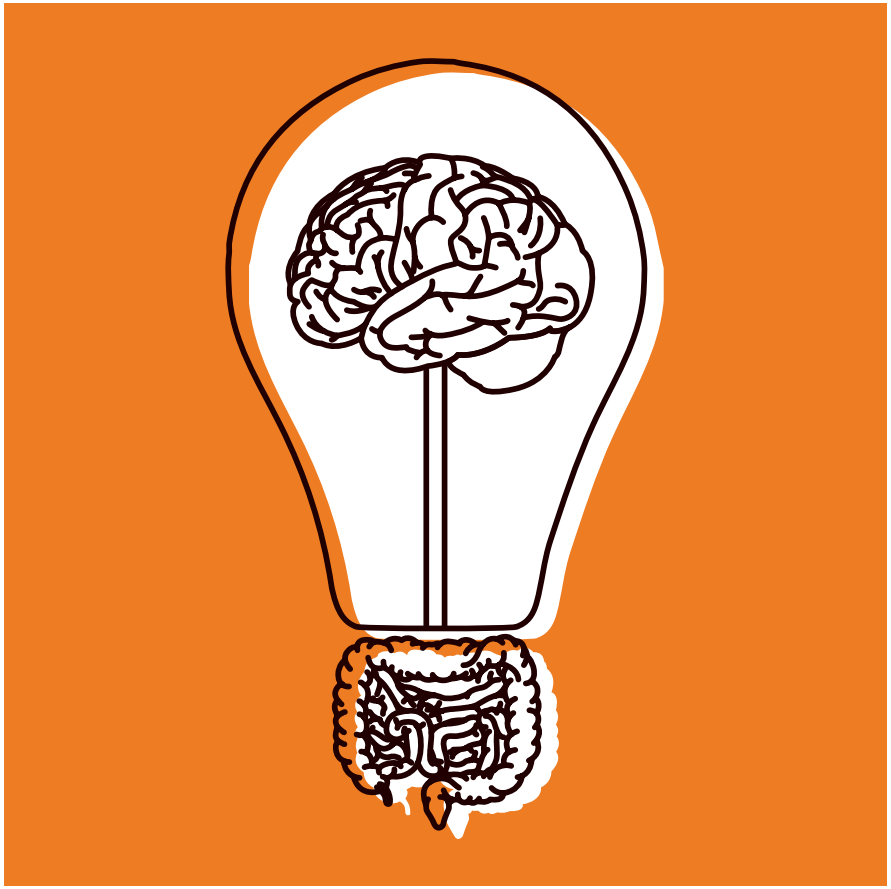
THE GEM PROJECT

Canadian Children Inflammatory Bowel Disease Network (CIDsCaNN)

IBD Genomic Medicine Consortium (iGenoMed)

James Lind Alliance Inflammatory Bowel Disease Group

Maternofetal outcomes research–Canadian Registry in IBD (MORe CaRe IBD)



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