United in Care: A Modified Delphi Journey to Determine Meaningful Reporting Measures in Specialty Pharmacy

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Learning Objectives

1. Explain the current state of outcome measurement and reporting in specialty pharmacy.
2. Describe the process and lessons learned from designing and executing the modified Delphi methodology to determine consensus on meaningful measures to be used in specialty pharmacy practice.
3. Review case studies of how the modified Delphi methodology has been used to reach consensus by a national multistakeholder panel including results in rheumatoid arthritis, ongoing efforts in inflammatory bowel diseases, and future plans across specialty areas.

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- ✓ Submit by Monday, April 28, 2025

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Faculty/Reviewer/Planner	Reported Relevant Financial Relationships
Autumn Zuckerman, PharmD, BCPS, CSP *Faculty*	*Research support unrelated to this presentation:* AstraZeneca, Sanofi, Beigene, UCB
Karen Thomas, PharmD, PhD, MBA *Faculty*	Disclosed no relevant financial relationships.
Casey Butrus, PharmD *Reviewer*	Disclosed no relevant financial relationships.
Brittany V. Henry, PharmD, MBA *Planner*	Disclosed no relevant financial relationships.

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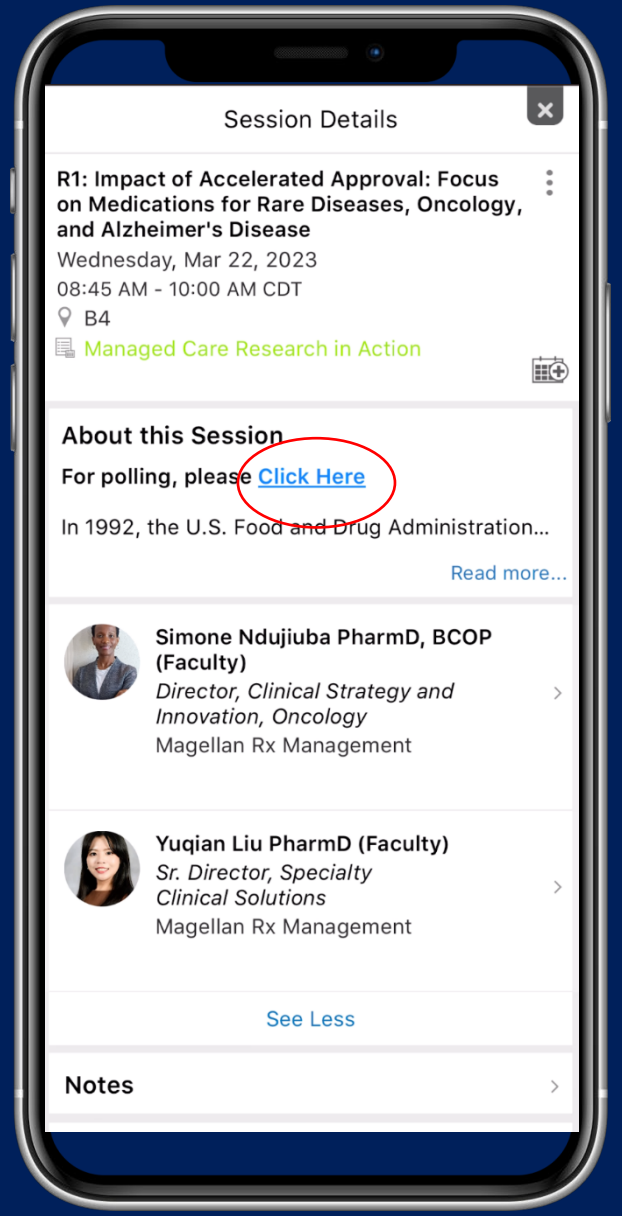

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Pre-Test

Polling Question

LQ1: Which of the following best describes the current state of outcome measurement and reporting in specialty pharmacy?

a) Primarily focuses on operational metrics

b) Efficiently performed structured data from one source

c) Measures are rarely measured or reported, and there is little emphasis on improving this area

d) Limited to accreditation measures only

Polling Question

LQ2: Which of the following is a key lesson learned from using the modified Delphi methodology to determine consensus on meaningful measures in specialty pharmacy practice?

a) It is ineffective in achieving consensus among experts

b) There are clear guidelines for how to determine consensus

c) Engaging a diverse panel of experts makes consensus easier to achieve.

d) It is helpful to determine the specificity of planned measures prior to engaging experts.

Polling Question

LQ3: Which of the following measures were excluded as a result of the first survey round in the modified Delphi study to identify outcome measures for specialty pharmacists in rheumatoid arthritis?

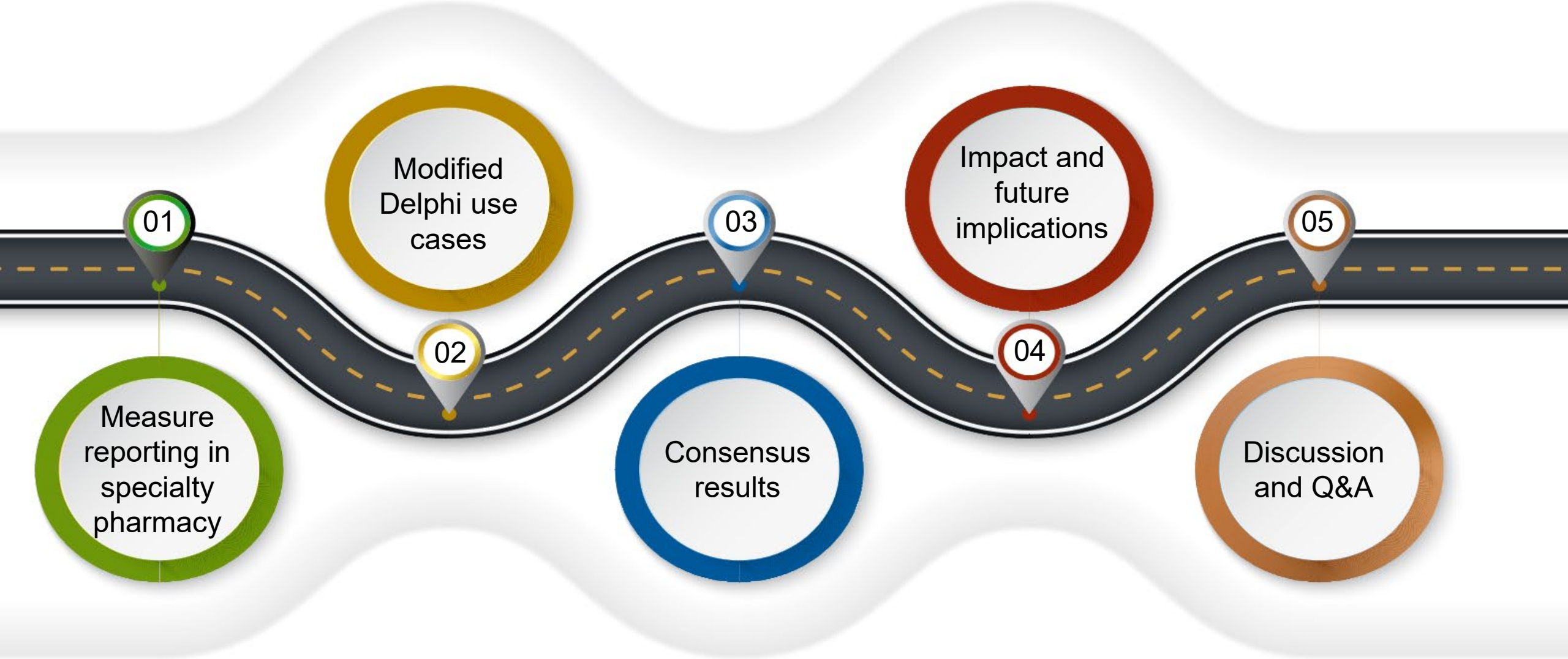
a) Adherence

b) Medication outcomes

c) Unplanned healthcare utilization

d) Safety screening

Presentation Roadmap

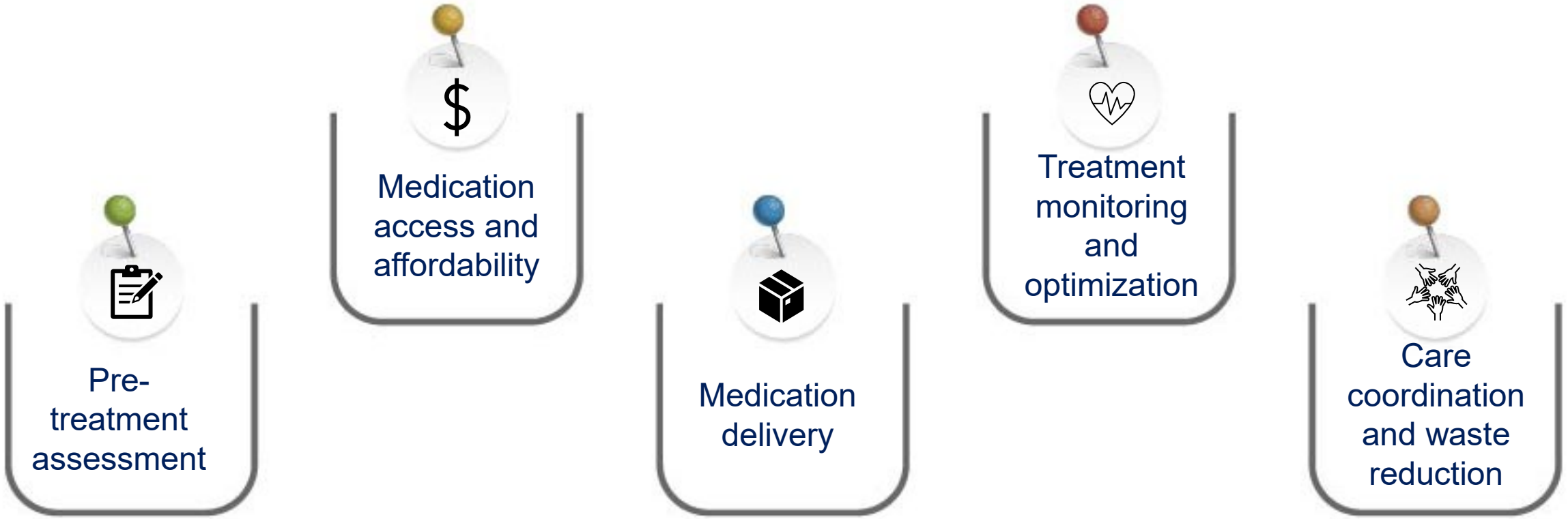


“Specialty Medications”

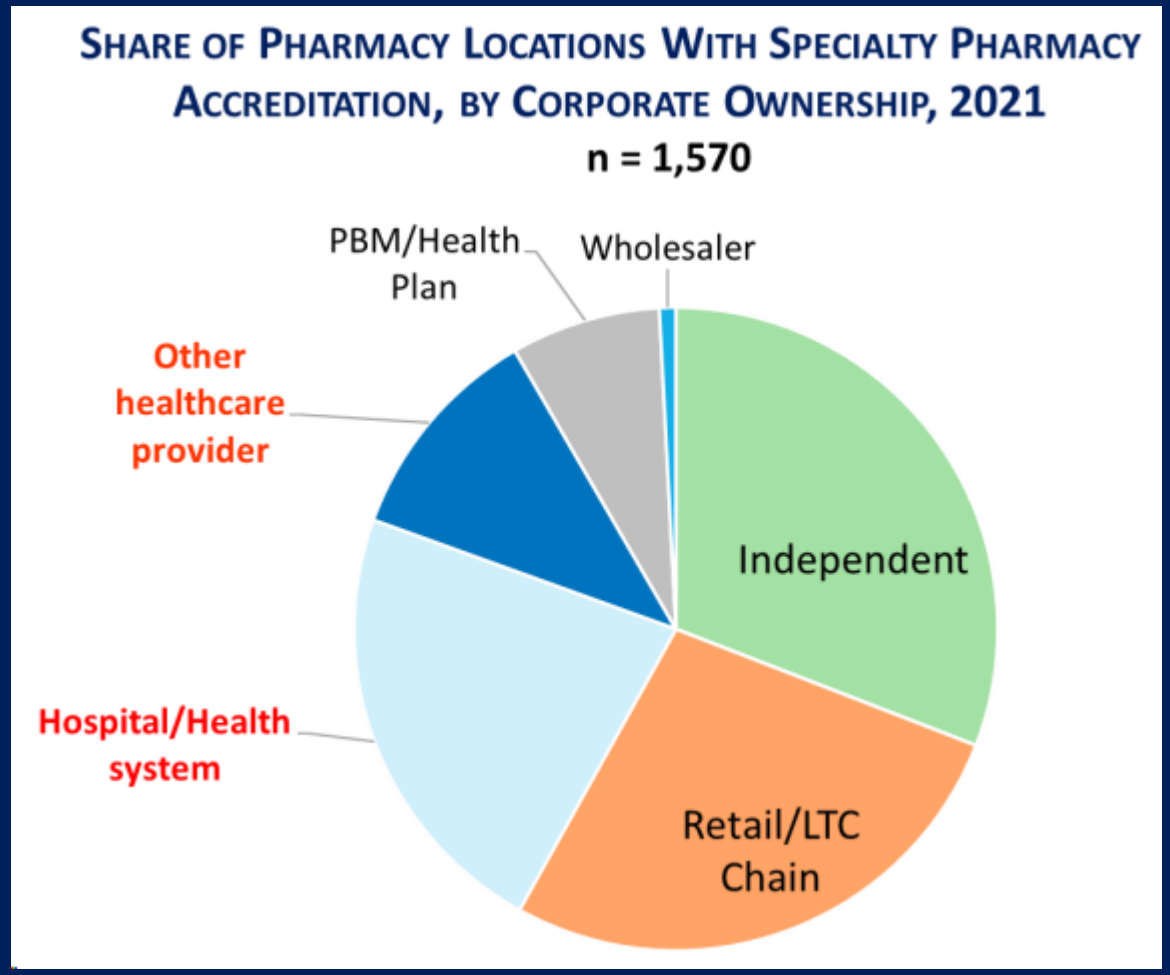
- A specialty drug is **more complex** than most prescription medications and can be a **biologic or traditional** drug.

What is Specialty Pharmacy? NASP. Available at: https://naspnet.org/wp-content/uploads/2019/08/What-Is-Specialty-Pharmacy-090718.pdf

Specialty Medications Need a Different Pharmacy Model



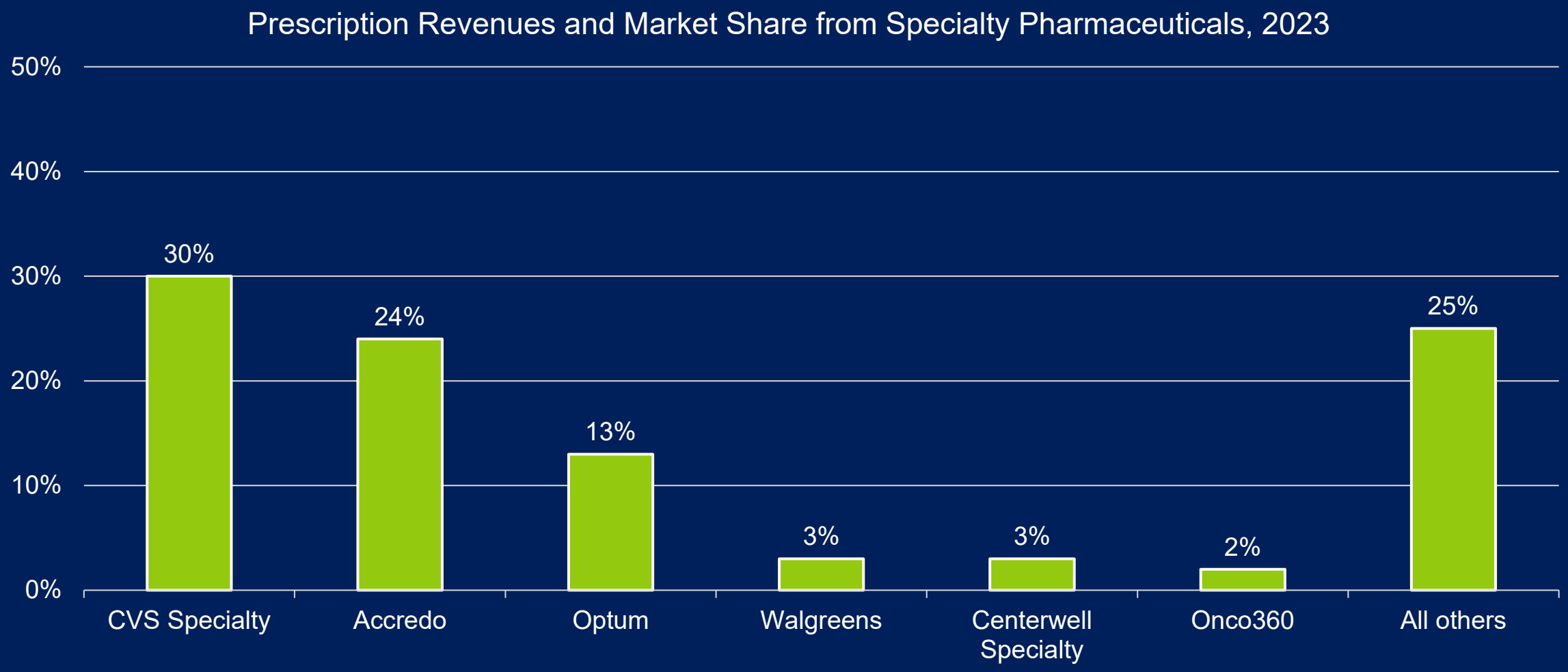
Specialty Pharmacy Models



- Diversity in pharmacy models
- Specialty medication distribution channels determination:
  - PBM network restrictions
  - Manufacturer distribution restrictions
  - Patient choice

Adapted from: Fein, Adam J. "The Top 15 Specialty Pharmacies of 2023: Market Shares and Revenues at the Biggest PBMs, Health Plans, and Independents." *Drug Channels*, 16 Apr. 2024. Available at: https://www.drugchannels.net/2024/04/the-top-15-specialty-pharmacies-of-2023.html. Permission received.

Specialty Pharmacy Models



Fein, Adam J. "The Top 15 Specialty Pharmacies of 2023: Market Shares and Revenues at the Biggest PBMs, Health Plans, and Independents." *Drug Channels*, 16 Apr. 2024. Available at: https://www.drugchannels.net/2024/04/the-top-15-specialty-pharmacies-of-2023.html.

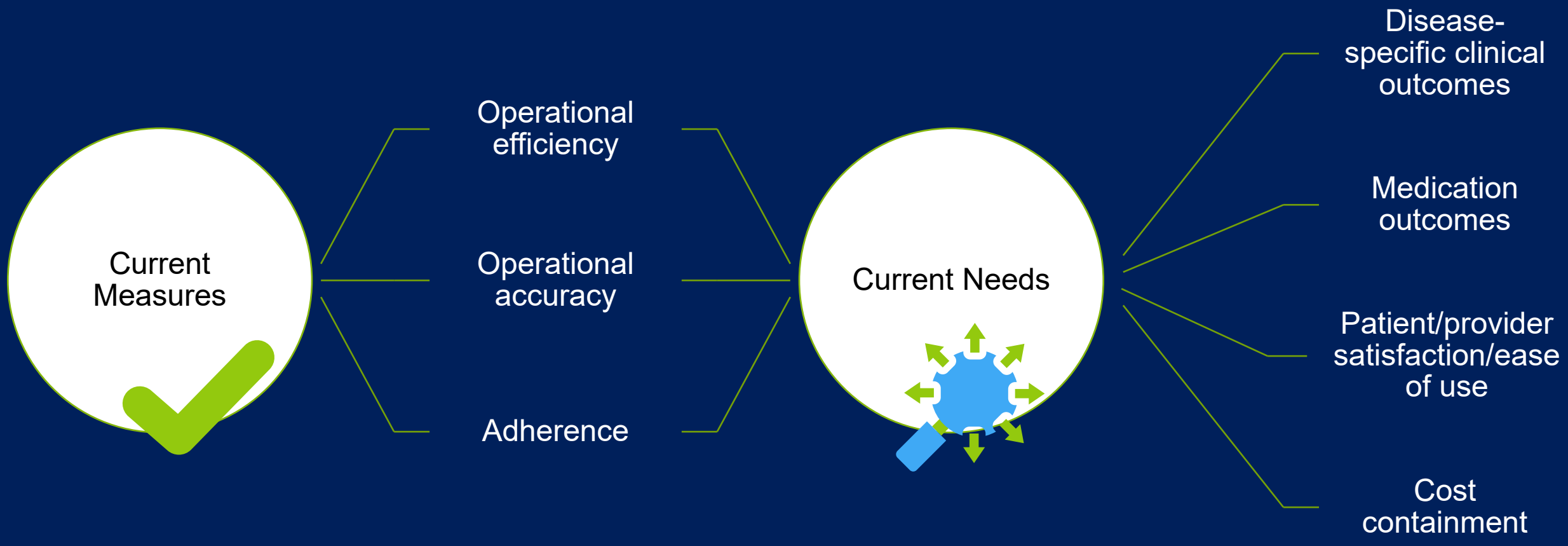
Measures are Used to Set a Standard in Specialty Pharmacy

- Accreditation Measures
  - URAC
  - ACHC
- PQA Quality Specialty Measures set

Pharmacy Quality Alliance. *PQA Specialty Measure Core Set*. PQA, 2024. Available at: www.pqaalliance.org/assets/Measures/PQA_Specialty_Measure_Core_Set.pdf.

Specialty Pharmacy Impact on Outcomes

Current State of Measure Reporting in Specialty Pharmacy



Specialty Pharmacies Report a Lot of Data

Internal Reporting
Productivity Metrics
Rx Volumes

Mandatory Measures
Hepatitis C Completion Rate
Rx Turnaround Time
Adherence Rates

Contractual Reporting
Payor Measures Reports
Manufacturer Distribution Reports

Slide courtesy of Thom Platt, PharmD (University of Kentucky Health System)

Varying Data Sources and Structure

Unstructured

Structured

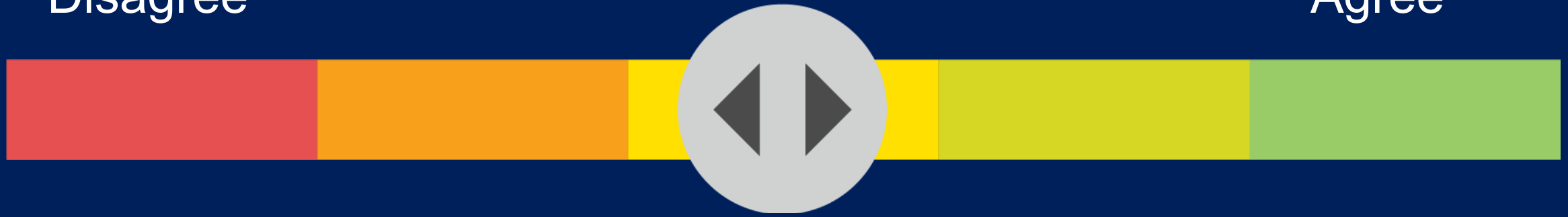
How COULD measures be used?

- Improved patient care
- Standardization
- Value assessment
- Network distribution design

Interactive Question

Agreement Likert Scale

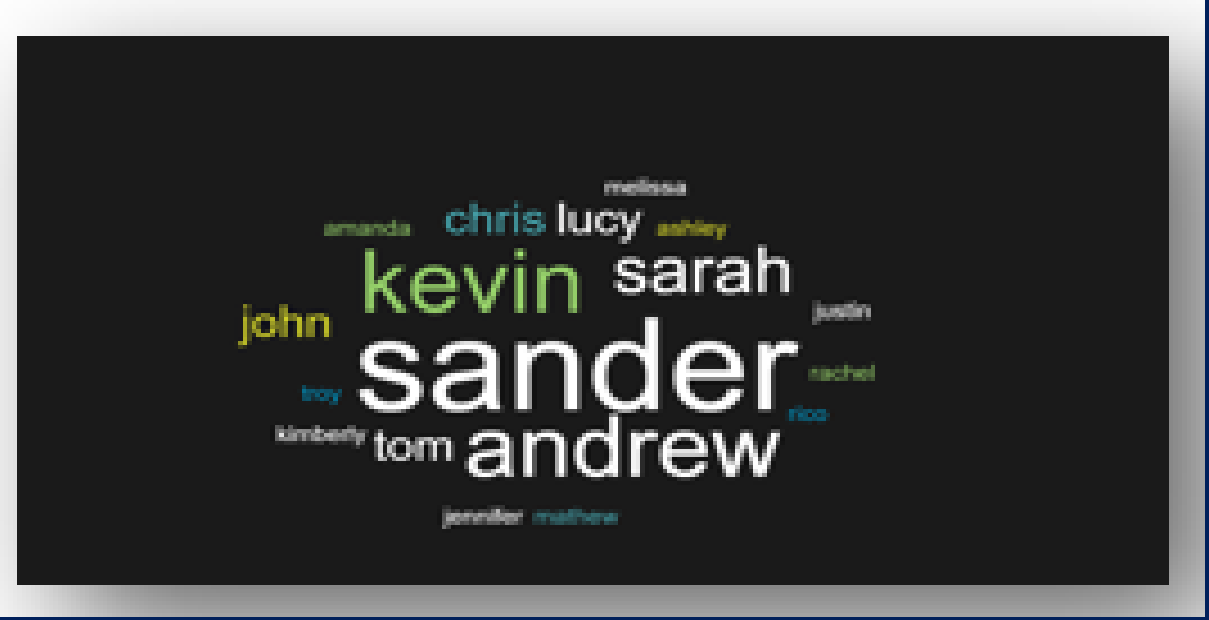
Standardized measures for specialty pharmacies to collect and report are needed.



AMCP

Word Cloud

What is needed to enable standardized measure development?



Reaching Consensus

- Stakeholder consensus is key to implementation
- Aim: reach an agreement or a **convergence of opinion**
- Methods for reaching consensus
  - [Modified] Delphi method
  - Nominal Group Technique

Sarah Drumm, Catriona Bradley, Frank Moriarty, 'More of an art than a science'? The development, design and mechanics of the Delphi Technique, Research in Social and Administrative Pharmacy, Volume 18, Issue 1, 2022, Pages 2230-2236, ISSN 1551-7411, https://doi.org/10.1016/j.sapharm.2021.06.027.

Modified Delphi Method

- Iterative process of completing questionnaires over several rounds
- Typically uses a Likert scale for respondents to indicate agreement/scoring
- Respondent feedback is circulated anonymously prior to each round

Contents lists available at ScienceDirect

Research in Social and Administrative Pharmacy

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

‘More of an art than a science’? The development, design and mechanics of the Delphi Technique

Sarah Drumm [a,*], Catriona Bradley [a], Frank Moriarty [b]

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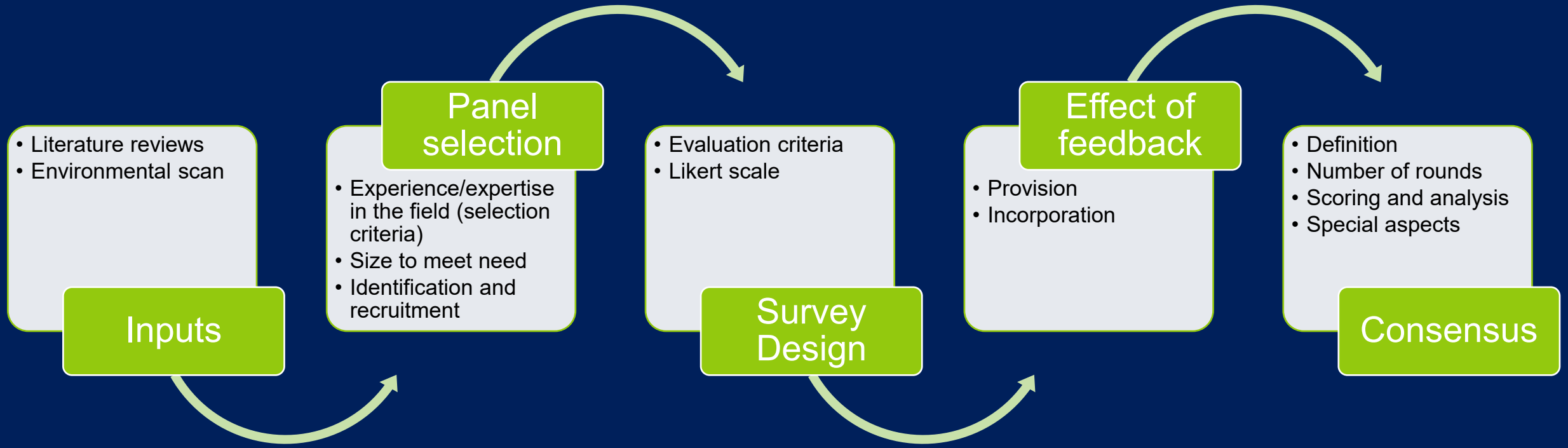
Sarah Drumm, Catriona Bradley, Frank Moriarty, ‘More of an art than a science’? The development, design and mechanics of the Delphi Technique, Research in Social and Administrative Pharmacy, Volume 18, Issue 1, 2022, Pages 2230-2236, ISSN 1551-7411, https://doi.org/10.1016/j.sapharm.2021.06.027.

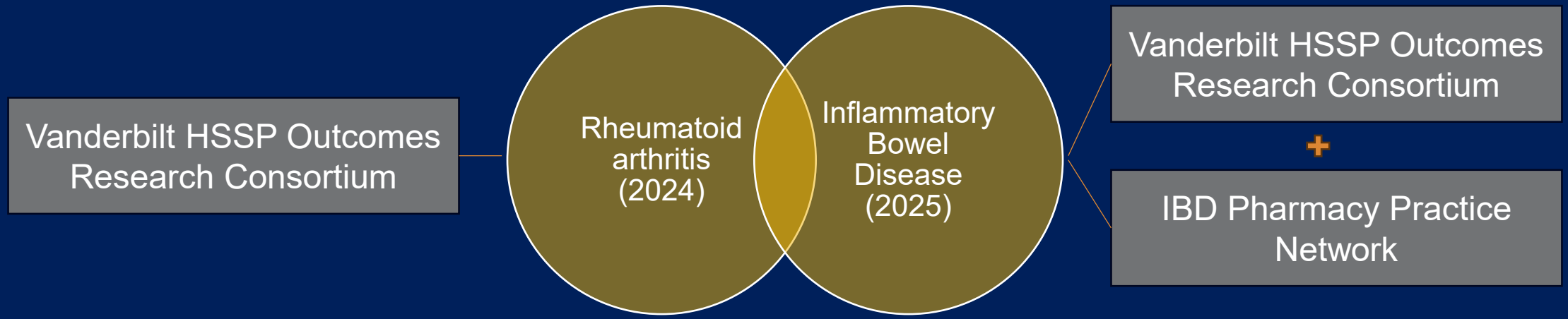
Elements of the Modified Delphi



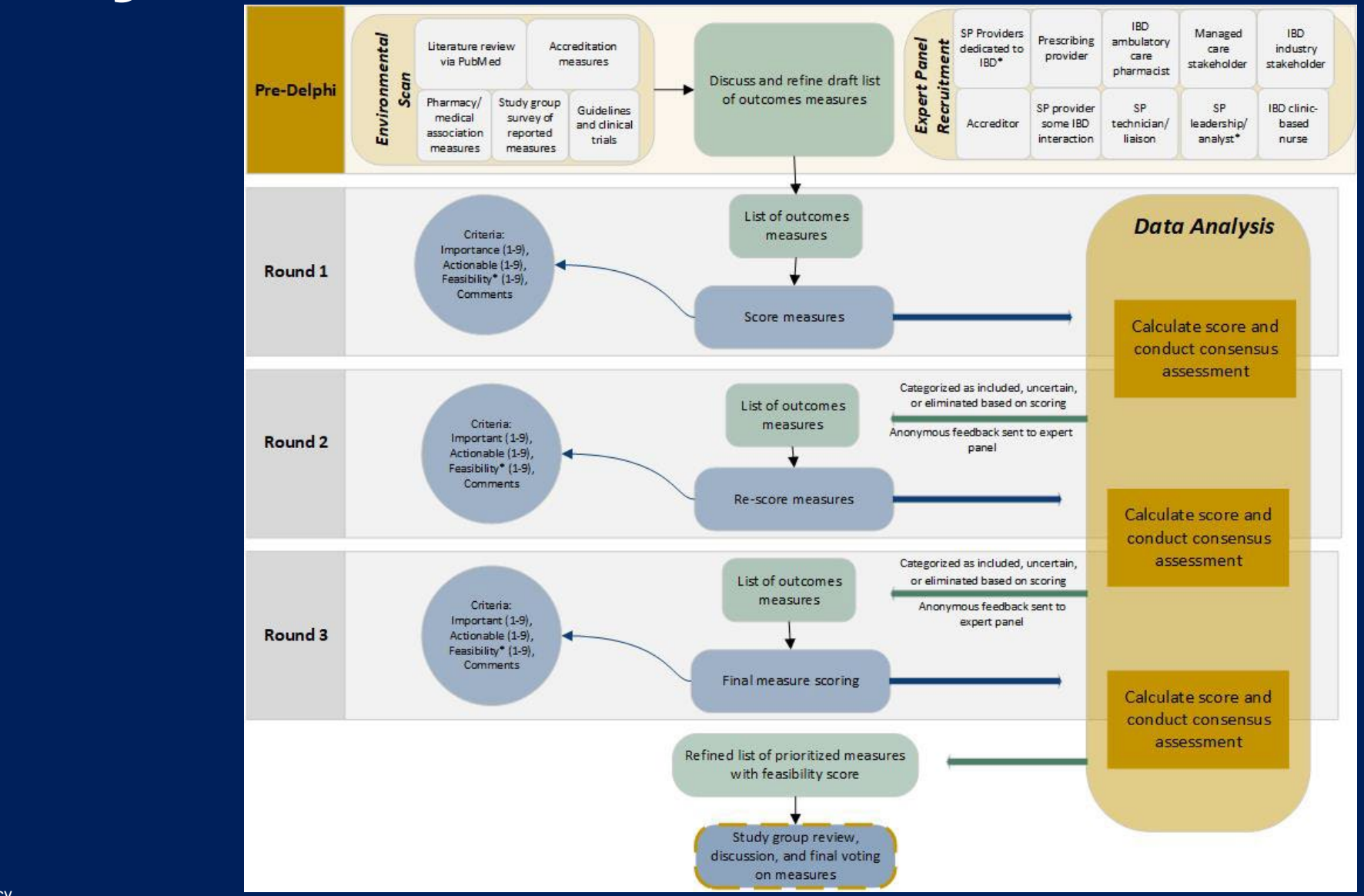
Niederberger M, Schifano J, Deckert S, et al. Delphi studies in social and health sciences—Recommendations for an interdisciplinary standardized reporting (DELPHISTAR). Results of a Delphi study. PLOS ONE. 2024;19(8):e0304651. doi:10.1371/journal.pone.0304651
Sarah Drumm, Catriona Bradley, Frank Moriarty, 'More of an art than a science'? The development, design and mechanics of the Delphi Technique, Research in Social and Administrative Pharmacy, Volume 18, Issue 1, 2022, Pages 2230-2236, ISSN 1551-7411, https://doi.org/10.1016/j.sapharm.2021.06.027.

Project Development

- Vanderbilt Health System Specialty Pharmacy (HSSP) Outcomes Research Consortium (n=70 sites)
- Purpose: Identify important and actionable measures to be used in specialty pharmacy practice
- Study group engagement- listserv used to recruit interested sites within the Consortium

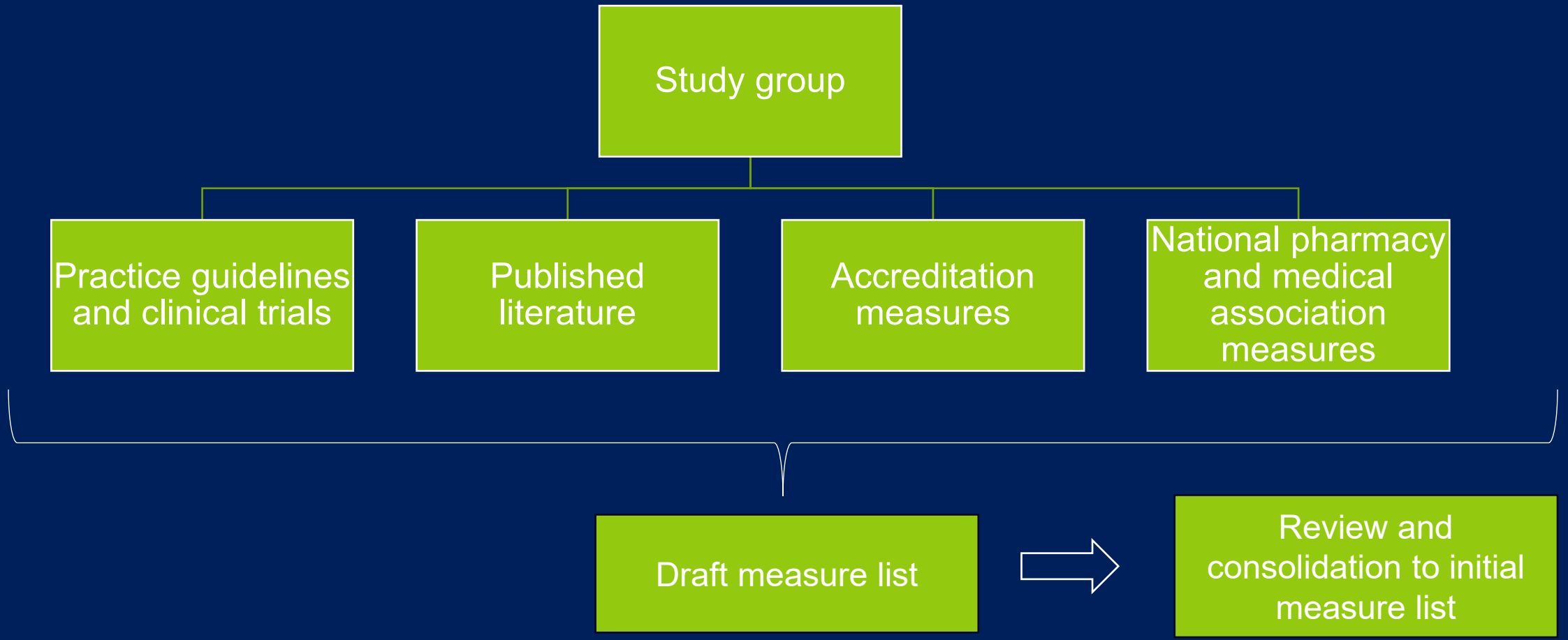


Study Procedures



SP = specialty pharmacy

Environmental Scan



Environmental Scan Procedures

Review Matrix on Identifying Outcome Measures for Specialty Pharmacists in IBD Using the Delphi Method

		REFERENCE & PURPOSE				SUBJECTS				DATA				
Reviewer 1 Initials	Reviewer 2 Initials	Title, Journal, citation information	DOI	Year Published	Purpose	#	Population Tested/ Population of Interest	Study Design	HSSP Study - yes/no	Year(s) Data Collected	Control	Intervention	Measure(s)	Name of the Measure *(i.e. primary outcome - please specify)*
CE	CED	J Clin Gastroenterol. 2011 Nov-Dec;45(10):878-82. doi: 10.1097/MCG.0b0	10.1097/MCG.0b013e3182192207	2011	ractices and beliefs of medication adhere	395	Gastroenterologists treating IBD	Survey	no		na	na	na	na
CE	CM	J Crohns Colitis. 2008 Jun;2(2):181-8. doi: 10.1016/j.crohns.2008.02.001.	10.1016/j.crohns.2008.02.001	2008	Define quality of health care	na	na-commentary	Review article/Delphi method	no	na	na	na	na	na
CE	EO	Inflamm Bowel Dis. 2004 Jul;10(4):444-50; discussion 451. doi: 10.1097/0	10.1097/00054725-200407000-00020	2004	ts of communication for health care profe	na	na-commentary	Review article	no	na	na	na	na	na
CED	JL	Crohns Colitis 360. 2024 Oct 10;6(4):otae055. doi: 10.1093/crocol/otae05	10.1093/crocol/otae055	2024	s in IBD (STRIDE-II) - establishing these in	55	GI physicians (40) 62% specialists,	anonymous survey, lit review, IBD expert	no	2024	Not RCT,	Not RCT, qualitative	of disability, mucosal healing,	QoL scores (no specific units/
CED	JN	J Am Pharm Assoc (2023). 2023 Nov-Dec;63(6):1776-1784.e3. doi: 10.101	10.1016/j.japh.2023.08.023	2023	r interactions with pharmacists, value on t		patients, 9 IBD	Patients with chronic diseases (CVD/ IBD)	Survey/ group sessions - quantitative and	Oct-21	Not RCT,	Not RCT, qualitative	Patient perceptions on	X
CED	JS	J Crohns Colitis. 2022 Sep 8;16(9):1436-1446. doi: 10.1093/ecco-jcc/jjac0	10.1093/ecco-jcc/jjac053	2022	Q CT-P13 (biosimilar) - looking at persister	178	Patients with IBD	Multicenter cohort study	no	mentioned, but mentions COVID disrupting the	Baseline	SC infliximab (biosimilar)	Harvey Bradshaw Index (HBI), simple clinical colitis activity index (SCCAI), C reactive protein (CRP), fecal calprotectin (FC)	Harvey Bradshaw Index (HBI), simp activity index (SCCAI), C reactive pro calprotectin (FC)
CED	KR	J Adv Nurs. 2021 May;77(5):2248-2266. doi: 10.1111/jan.14744. Epub 202	10.1111/jan.14744	2021	atic lit review (SLR) on nursing outcomes	Variable	IBD - UC and CD - adult 18 and over, with	Systematic Literature Review	yes	2000-2020 (SLR)	X	X	X	Bowel Disease Quality of Life Que
CED	MO	Gastroenterol Hepatol. 2020 Mar;43(3):126-132. doi: 10.1016/j.gastrohep	10.1016/j.gastrohep.2019.09.011	2020	ients refractory to biological treatments. A	69	disease evolution (>5 years), complex	Observational, retrospective	no	reported,	Baseline	Weeks 16, 24, 32, 48	HBI	Harvey Bradshaw Index (pr
CED	TD	Clin Gastroenterol Hepatol. 2018 Nov;16(11):1777-1785. doi: 10.1016/j.c	10.1016/j.cgh.2018.04.007	2018	designed for individuals with IBD. It atter	322 (198 Crohn's, 124 UC)	Patients in the Total Care-IBD program - CD/UC, 16-60 years, member of University of Pittsburgh Medical Center (UPMC) Plan	Retrospective analysis	yes	June 2015-July 2016	patients were disproportionally enrolled into program, making non-enrolled	includes interventions such as medication changes, behavioral care integration,	SIBDQ, HBI, UCAI (IBD/GI Metrics), PHQ9 (Depression), GAD-7 (Generalized Anxiety Disorder)	Secondary: Short Inflammatory B Questionnaire, Harvey Bradshaw In Index, Patient Health Questionnair Anxiety Disorder
CED	DS	Eur J Gastroenterol Hepatol. 2017 Jun;29(6):646-650. doi: 10.1097/MEG.0	10.1097/MEG.0000000000000839	2017	of introducing special IBD nurse position	(72% CD,	Patients with IBD who had contact with	Prospective observational study	no	9/2014-8/2015	outcomes of	integration into a	interventions: ER admissions,	X
CED	AS	World J Gastroenterol. 2016 Sep 14;22(34):7625-44. doi: 10.3748/wjg.v22	10.3748/wjg.v22.i34.7625	2016	ntify/ manage medication non-adherence	X (review)	pregnant patients with IBD	Review/ synthesis	no		X	X	QoL, including SF 36	From review: SF36, Quality of life in
CED	AZ	Obstet Gynecol. 2015 Aug;126(2):401-412. doi: 10.1097/AOG.000000000	10.1097/AOG.0000000000000978	2015	ical guidance on management of IBD dur		Patients with "digestive diseases" also	Synthesis of data/ clinical guidance	no		X	X	X	Medication Adherence
CED	CM												IBD-specific quality indicators	X
CED	EO													X
CM	JS													X
CM	KR													1-year rate of sustained
CM	MO													Primary
CM	GP													N/A
														N/A

Revised Metric	Revised Category	Clarifications needed
ACR20	Disease activity	none
ACR20, 50	Disease activity	none
ACR50, ACR70, Eular Response	Disease activity	what is the eular response?
activity limitation via FFI	?Functional status	need more detail
anti-CCP	Disease activity (lab)	need more detail
Beck Depression Inventory	QOL	need more detail
BRAF-NRS	unk	need more detail
CDAI	Disease activity	none
CDAI	Disease activity	none
CDAI	Disease activity	none
CDAI	Disease activity	none
CDAI, DAS28, SDAI, RAPID3, PAS-II	Disease activity	none
CDAI, DAS28, CRP, SDAI, RAPID3, PAS-II; PROMIS PF10a, HAQ-II, MD HAQ	Disease activity, functional status	none
Cervical X Ray	Changed to disease activity	need more detail
Consider how your rheumatic disease has affected you during the last week. If you remain in th ecomin	QOL	need more detail
CQR-19	unk	need more detail

Setting Measure Specifications

Measure		1st level	2nd level	3rd level	4th level
A *measure (collect, track)* of **patient disease activity** (a measure that informs treat to target or achievement of remission, e.g., morning joint stiffness, disease burden, fatigue, pain)	Yes/No/Unsure	Yes	What should be captured related to disease activity?	1. Documentation that disease activity has been assessed 2. Outcomes of disease activity assessment 3. Actions taken by the pharmacy to address disease activity	
		Yes	What methods should specialty pharmacies use to assess disease activity?	Validated clinical assessment requiring clinical assessment (CDAI, DAS, DAS28-ESR/CRP, SDAI, MBDA, RADAI, RADAI-5) Validated clinical assessment using patient-reported outcome (RAPID3, RAPID5, PAS-II, RADAI, RADAI-5) A single question posed to the patient evaluating their own disease activity (patient-reported outcome question)? Laboratory Indicators Other	What is your prefered clinical assessment tool? Do you have a recommended question?
		Yes	How soon should patient disease activity be measured by specialty pharmacies after treatment initiation	Within 3 months Within 6 months Within 1 year Other	
		Yes	How often should patient disease activity be measured by specialty pharmacies once the patient is considered stabilized on therapy	Monthly Every 3 months Every 6 months Annually Other	

Environmental Scan Lessons Learned

- Determine the specificity of planned measures and build review procedures around that
- Err on the side of inclusion
- It takes a village!
  - 2 reviewers for each item
  - Timing and deadlines are important

Stakeholder Selection

- Goal: Incorporate all stakeholders involved in specialty medication management and reporting

Specialty pharmacy

- Specialty pharmacist with *some* clinic involvement
- Specialty pharmacist *dedicated* to clinic
- Pharmacy technician
- Pharmacy analyst
- Pharmacy leader

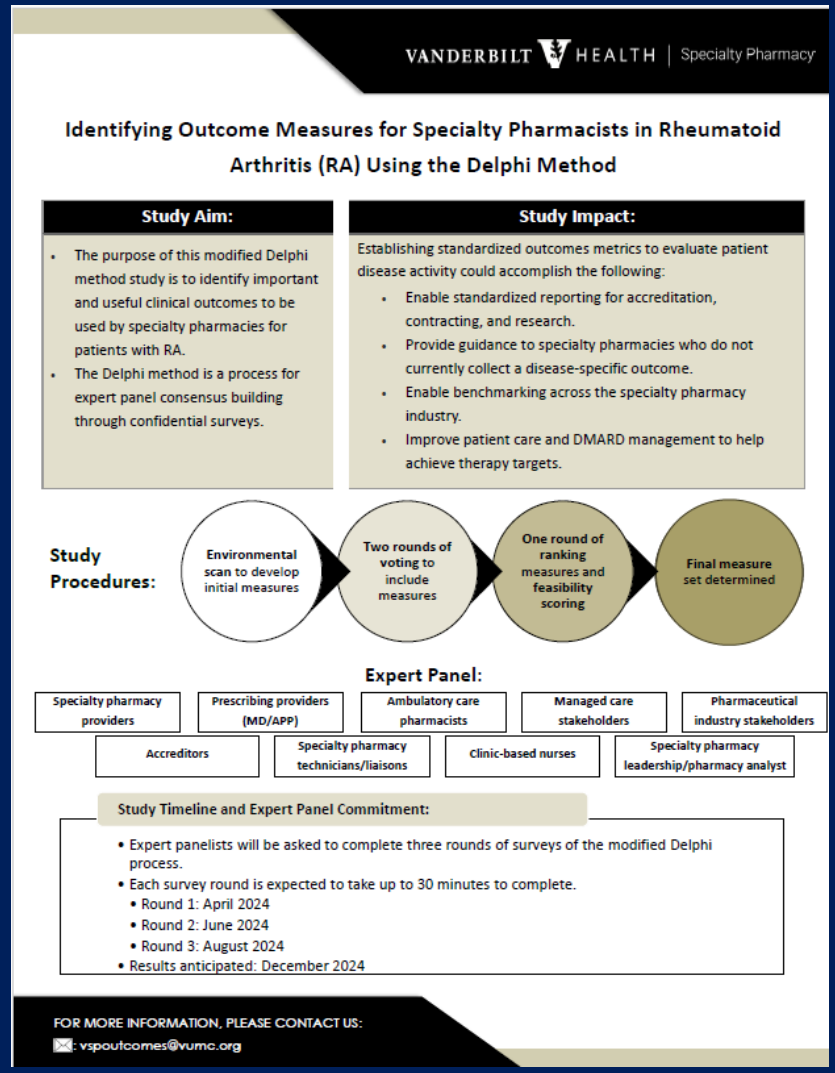
Stakeholder Selection

- Define selection criteria
- Consider weighting

Expert Panel Role	Selection criteria
Specialty pharmacy providers (PharmD/RN) **dedicated to RA**	Specialty pharmacy staff member (PharmD or RN) whose primary role is dedicated to educating, managing, and monitoring (including completing reassessments) patients with rheumatologic conditions.
Specialty pharmacy providers (PharmD/RN) **with some RA involvement**	Specialty pharmacy staff member (PharmD or RN) who assists with educating, managing, and monitoring patients with rheumatologic conditions, but it is not their primary or sole practice area.
Specialty pharmacy technician/liaison	Certified pharmacy technician whose primary role is to assist patients with rheumatologic conditions including assisting with medication access (prior authorizations, insurance appeals and denials), and completing and scheduling refill calls.
Prescribing provider (MD, Advanced Practice Provider [NP/PA])	Provider who routinely treats and prescribes therapy for rheumatoid arthritis. This does not include pharmacists practicing under a collaborative practice agreement.
Ambulatory care pharmacist	Ambulatory care pharmacist whose primary practice site (≥30hours per week) is spent in patient care (education, care coordination, conducts/completes follow-up assessments, etc.) for patients with rheumatologic conditions.
Managed care stakeholder	Healthcare professional who practices in a managed care role involving benefits design, population health management, or reporting/analytics for a health plan. Experts may be employed by an insurer, pharmacy benefits manager, or population health department. The key criterion for this stakeholder is that they are aware of or involved in designing metrics of interest to the managed care organization when evaluating a population of patients with rheumatologic conditions.
Pharmaceutical industry stakeholder	Healthcare professional employed by a pharmaceutical manufacturer which manufactures and distributes specialty medications for RA. The stakeholder should be involved in designing metrics that will be used in contract reporting or whose primary role is in health economics and research (HEOR) at the pharmaceutical manufacturer company.
Accreditor	Healthcare professional employed by an accrediting body for specialty pharmacy that routinely designs or reviews accreditation measures for patients with rheumatologic conditions.
Clinic-based nurse	Nurse whose primary practice site (≥30hours per week) is spent in patient care (education, care coordination, etc.) for patients with rheumatologic conditions. Not affiliated with the specialty pharmacy.
Pharmacy analyst/ Specialty pharmacy leadership	Healthcare professional (most often a pharmacist or pharmacy technician) who manages the collection, aggregation, and reporting of data in patients with rheumatologic conditions to external stakeholders (e.g., accreditors, manufacturers, payers).

Stakeholder Recruitment

- Study group submitted at least 1 contact per stakeholder type
- Vanderbilt team reached out to each contact
- Stakeholders consented to participate
- Provided acknowledgement opportunity



VANDERBILT HEALTH | Specialty Pharmacy

Identifying Outcome Measures for Specialty Pharmacists in Rheumatoid Arthritis (RA) Using the Delphi Method

Study Aim:

- The purpose of this modified Delphi method study is to identify important and useful clinical outcomes to be used by specialty pharmacies for patients with RA.
- The Delphi method is a process for expert panel consensus building through confidential surveys.

Study Impact:

Establishing standardized outcomes metrics to evaluate patient disease activity could accomplish the following:

- Enable standardized reporting for accreditation, contracting, and research.
- Provide guidance to specialty pharmacies who do not currently collect a disease-specific outcome.
- Enable benchmarking across the specialty pharmacy industry.
- Improve patient care and DMARD management to help achieve therapy targets.

Study Procedures:

Environmental scan to develop initial measures → Two rounds of voting to include measures → One round of ranking measures and feasibility scoring → Final measure set determined

Expert Panel:

- Specialty pharmacy providers
- Prescribing providers (MD/APP)
- Ambulatory care pharmacists
- Managed care stakeholders
- Pharmaceutical industry stakeholders
- Accreditors
- Specialty pharmacy technicians/liaisons
- Clinic-based nurses
- Specialty pharmacy leadership/pharmacy analyst

Study Timeline and Expert Panel Commitment:

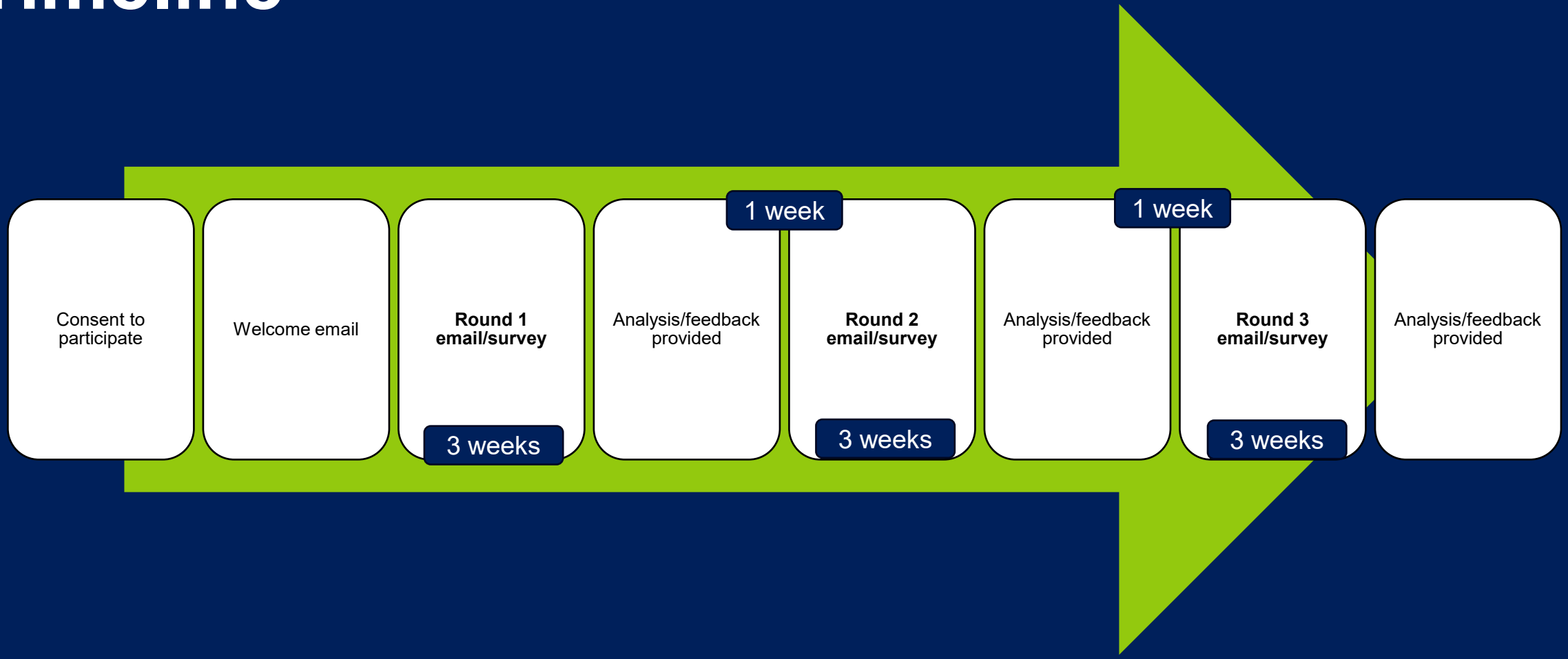
- Expert panelists will be asked to complete three rounds of surveys of the modified Delphi process.
- Each survey round is expected to take up to 30 minutes to complete.
  - Round 1: April 2024
  - Round 2: June 2024
  - Round 3: August 2024
- Results anticipated: December 2024

FOR MORE INFORMATION, PLEASE CONTACT US:
: vspoutcomes@vumc.org

Stakeholder Selection and Recruitment Lessons Learned

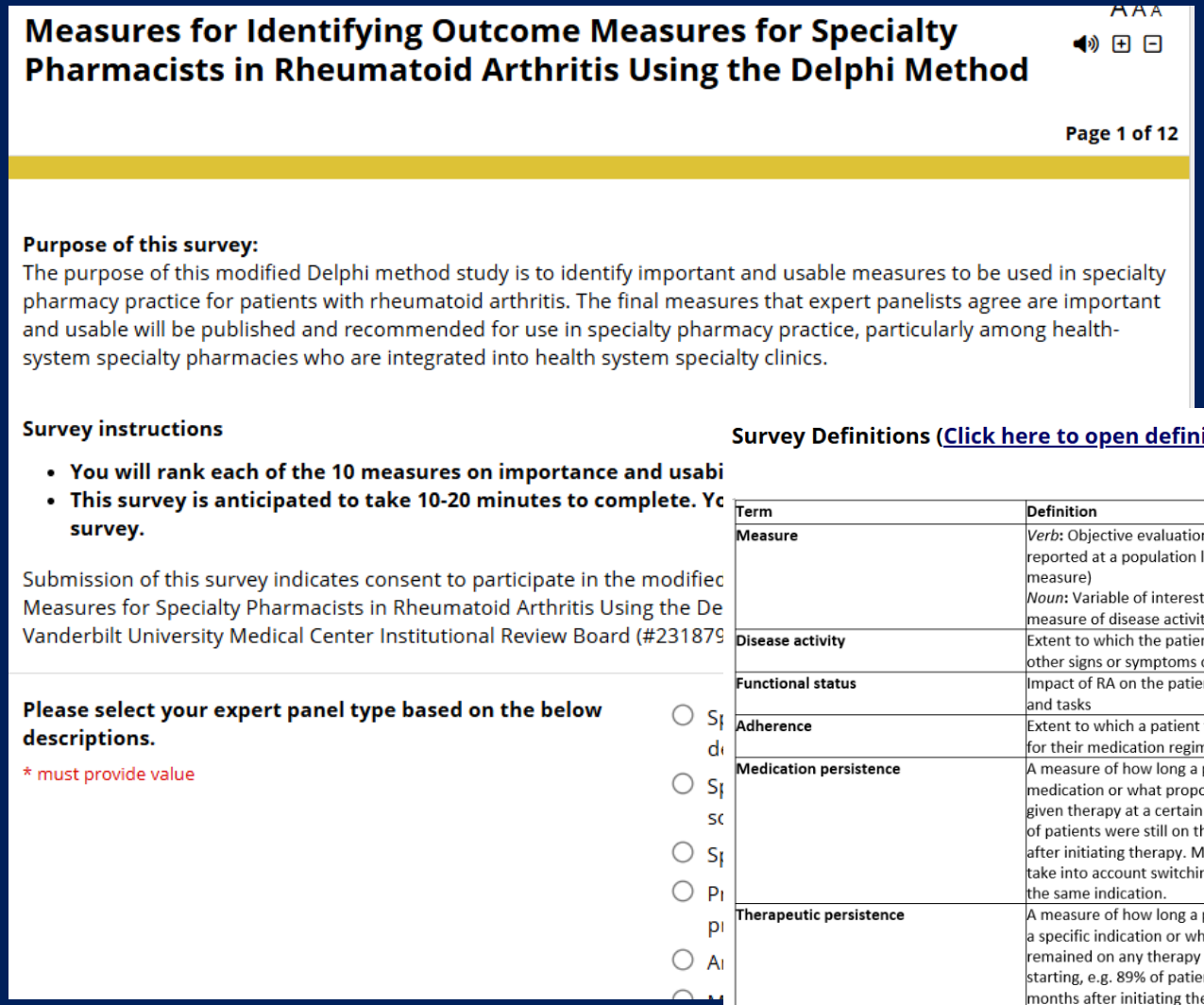
- Definitions are important (and debated)
- Some stakeholders need lengthy approval times for participation
- Likely beneficial to expand beyond study group contacts

Stakeholder Communication Timeline



Survey Design

- REDCap
- Anonymous
- Easy to use
- Clear definitions and directions provided



Measures for Identifying Outcome Measures for Specialty Pharmacists in Rheumatoid Arthritis Using the Delphi Method

A A A

Page 1 of 12

Purpose of this survey:
The purpose of this modified Delphi method study is to identify important and usable measures to be used in specialty pharmacy practice for patients with rheumatoid arthritis. The final measures that expert panelists agree are important and usable will be published and recommended for use in specialty pharmacy practice, particularly among health-system specialty pharmacies who are integrated into health system specialty clinics.

Survey instructions

- **You will rank each of the 10 measures on importance and usabi**
- **This survey is anticipated to take 10-20 minutes to complete. Yo survey.**

Submission of this survey indicates consent to participate in the modifiec Measures for Specialty Pharmacists in Rheumatoid Arthritis Using the De Vanderbilt University Medical Center Institutional Review Board (#231879

Please select your expert panel type based on the below descriptions.

* must provide value

Survey Definitions (Click here to open definitions in a new tab)

Term	Definition
Measure	*Verb*: Objective evaluation that can be monitored and reported at a population level e.g., specialty pharmacies measure) *Noun*: Variable of interest to be evaluated (noun- e.g., a measure of disease activity)
Disease activity	Extent to which the patient is experiencing inflammation or other signs or symptoms of immune system activity
Functional status	Impact of RA on the patient's ability to perform daily activities and tasks
Adherence	Extent to which a patient follows the prescribed instructions for their medication regimen
Medication persistence	A measure of how long a patient has been on a specific medication or what proportion of patients has remained on a given therapy at a certain time point after starting, e.g. 89% of patients were still on the same medication X 12 months after initiating therapy. Medication persistence does NOT take into account switching between medications used for the same indication.
Therapeutic persistence	A measure of how long a patient has been on any therapy for a specific indication or what proportion of patients has remained on any therapy at a certain time point after starting, e.g. 89% of patients were still on therapy X 12 months after initiating therapy. Therapeutic persistence DOES take into account switching between medications used for the same indication.
Medication switching	A measure of the number or frequency of patients changing from one medication to another.

Survey Feedback/Lessons Learned

- Difficulty to complete:

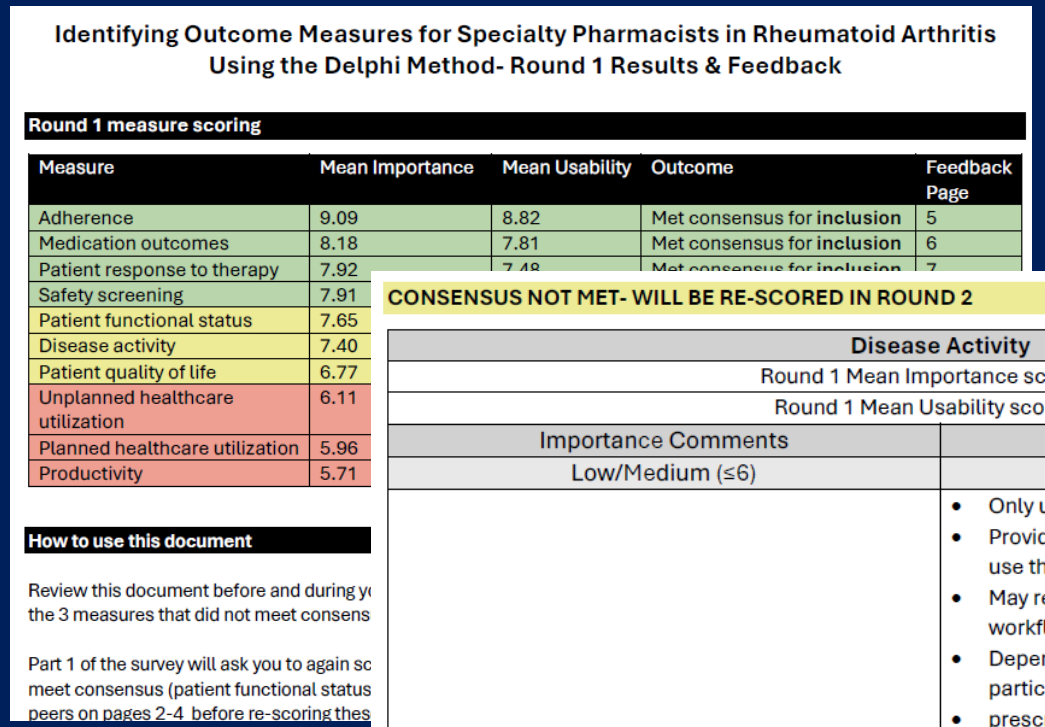
  - Definitions are useful, but potentially add complexity
    - *No difficulty, just needed to pay close attention to the wording….*
    - *I felt there were a lot of nuances within the survey with the wording.*

- Difficulty to Understand:

  - Ensure clear flow and explain context of questions
    - *May have been good to understand the flow of questions earlier.*
    - *Better context and perspective could have been helpful.*

Expert Panelist Feedback

- Provided at least 1 week prior to most recent round
- Encouraged panelists to review prior to scoring in the subsequent round
- Usefulness of feedback sent to panel : 4.28/5



Identifying Outcome Measures for Specialty Pharmacists in Rheumatoid Arthritis Using the Delphi Method- Round 1 Results & Feedback

Round 1 measure scoring

Measure	Mean Importance	Mean Usability	Outcome	Feedback Page
Adherence	9.09	8.82	Met consensus for **inclusion**	5
Medication outcomes	8.18	7.81	Met consensus for **inclusion**	6
Patient response to therapy	7.92	7.48	Met consensus for **inclusion**	7
Safety screening	7.91			
Patient functional status	7.65			
Disease activity	7.40			
Patient quality of life	6.77			
Unplanned healthcare utilization	6.11			
Planned healthcare utilization	5.96			
Productivity	5.71			

How to use this document

Review this document before and during y
the 3 measures that did not meet consens

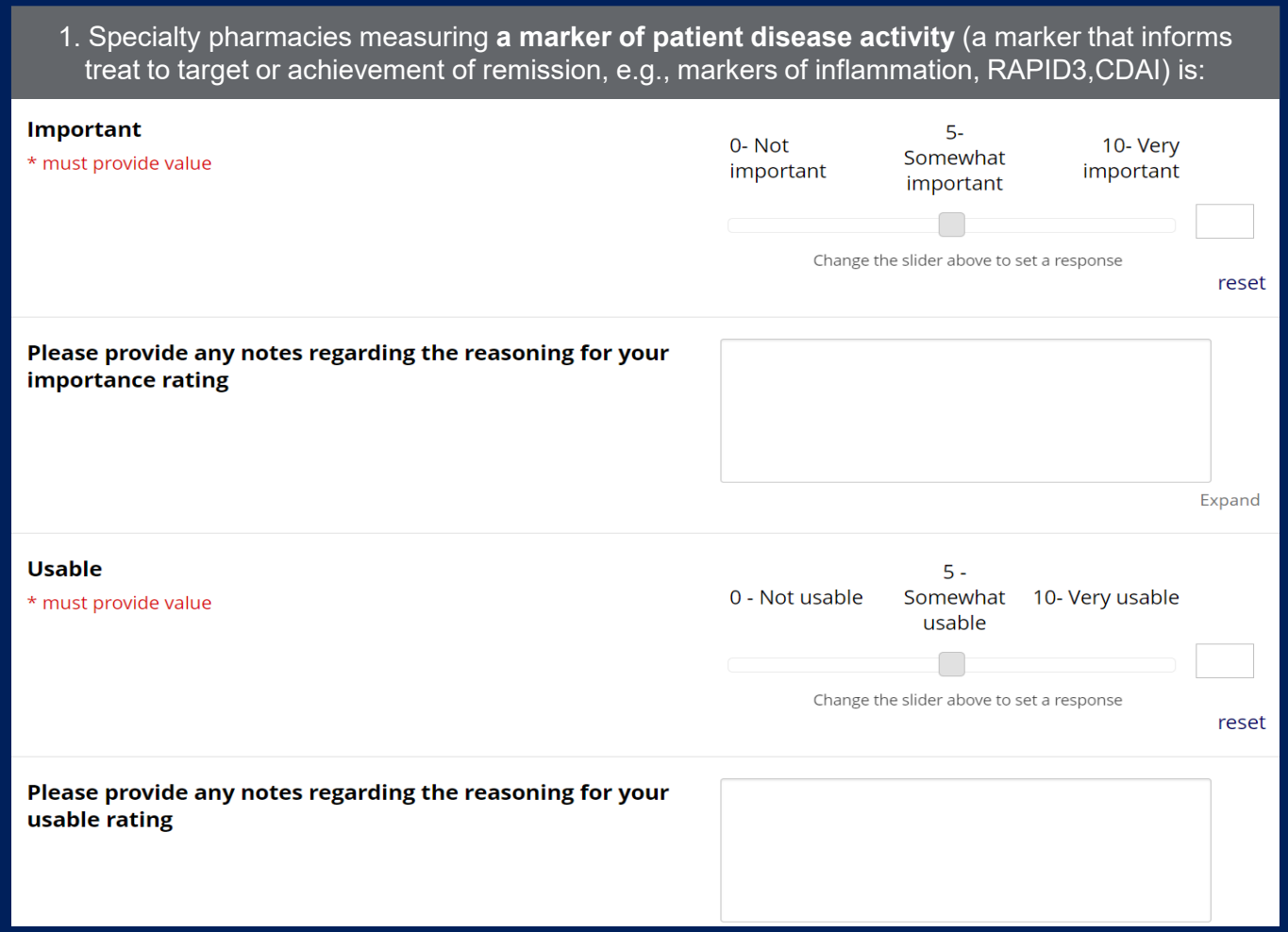
Part 1 of the survey will ask you to again sc
meet consensus (patient functional status
peers on pages 2-4 before re-scoring thes

CONSENSUS NOT MET- WILL BE RE-SCORED IN ROUND 2

Disease Activity	
Round 1 Mean Importance score: 7.4	
Round 1 Mean Usability score: 7.3	
Importance Comments	Usability Comments
Low/Medium (≤6)	Low/Medium (≤6)
	• Only usable if it triggers some kind of action. • Provider input varies, variability on the ability to use this data to direct patient care • May require additional staff time and training, new workflows, and modifications to software. • Dependent on the consistency of patients' participation. • prescriber/physician team primarily driving changes to therapy based on markers of disease
High (≥7)	High (≥7)
• SPs well positioned to capture and monitor • Can be used for research to improve RA care • Important if a threshold or change or in absolute scoring that triggers some kind of action • Increasingly important for Prior-Authorizations and Accreditation Requirements. • Essential to assess treatment efficacy. • More frequent touches with SP make the SP measurement much better from a timing standpoint. • Need to be able to measure response systematically.	• Data from marker of pt disease activity is not always helpful for pharmacist tx plan/rec. EX: it is a known progressive disease. • Ideally, measures of disease activity are succinct. • Patients not able to distinguish between RA and other comorbidities • Well-positioned to measure this, but not always in clinic or able to order labs if needed • Feedback from several providers that RAPID3 is less indicative of disease activity than other measures.

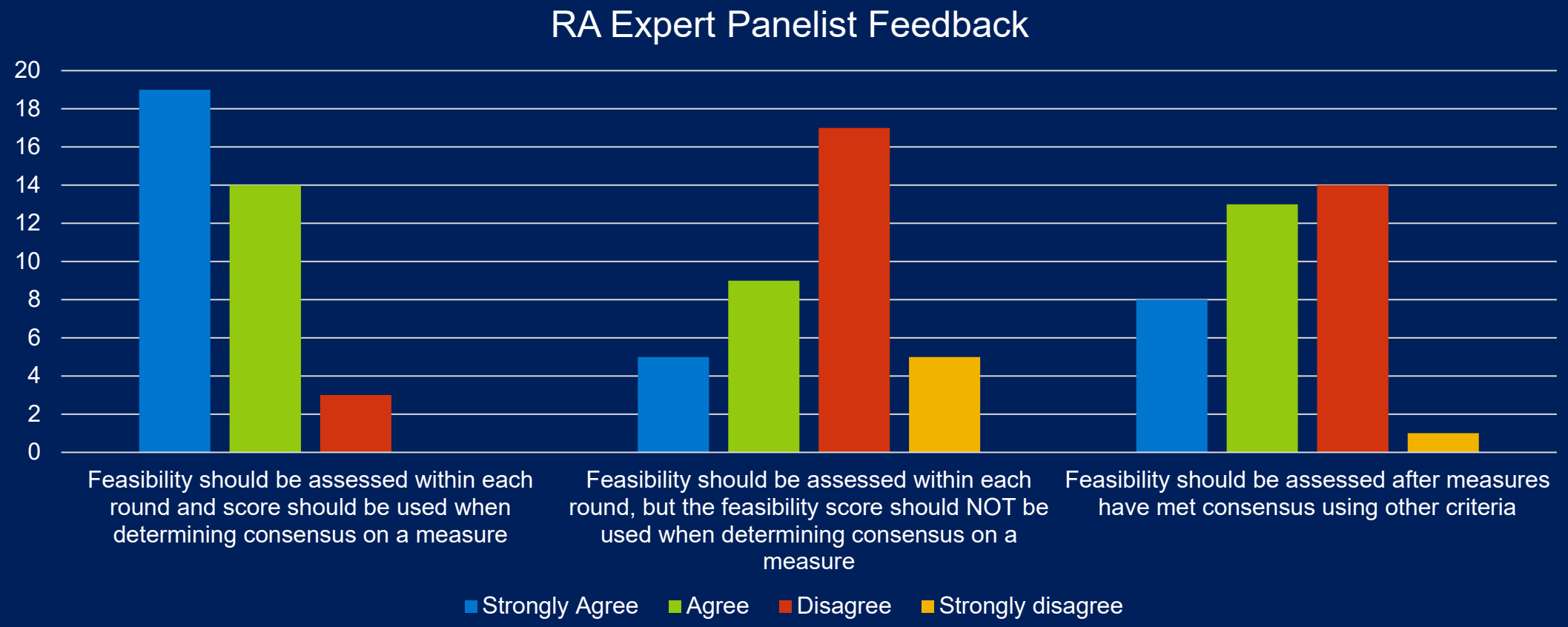
Measure Evaluation

- Likert scale- 3, 5, 9, 10
- Scoring is typically based on “agreement”
- Chose to rank measures on two factors:
  - **Important**/meaningful
    - Defined as how meaningful the expert panel deems the measure to be for patient care
  - **Usable**/actionable
    - Defined by the National Quality Forum as the “extent to which potential audiences are using or could use performance results for both accountability and performance improvement to achieve the goal of high-quality, efficient healthcare for individuals or populations”



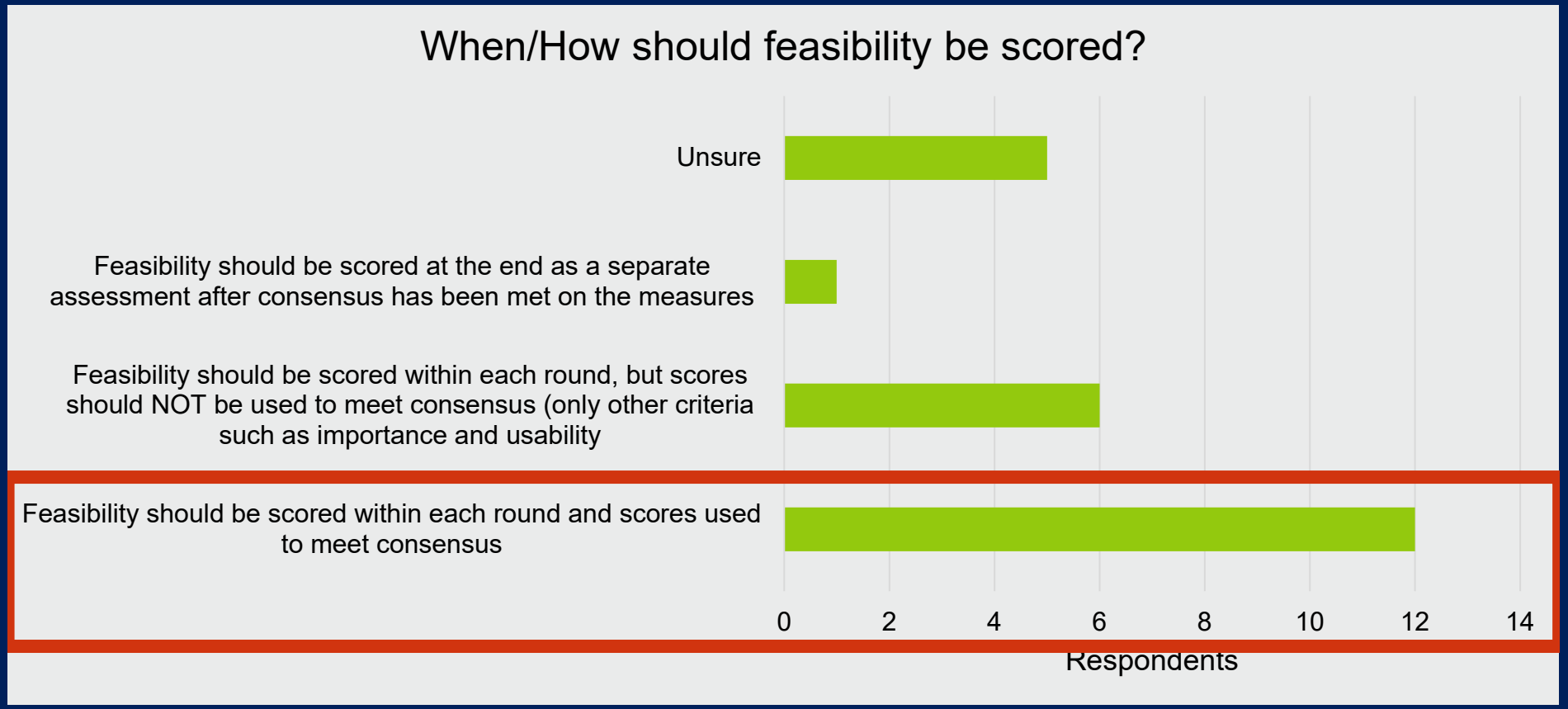
Feasibility…

- Key aspect for implementation/uptake
- Considerations for contributing to consensus



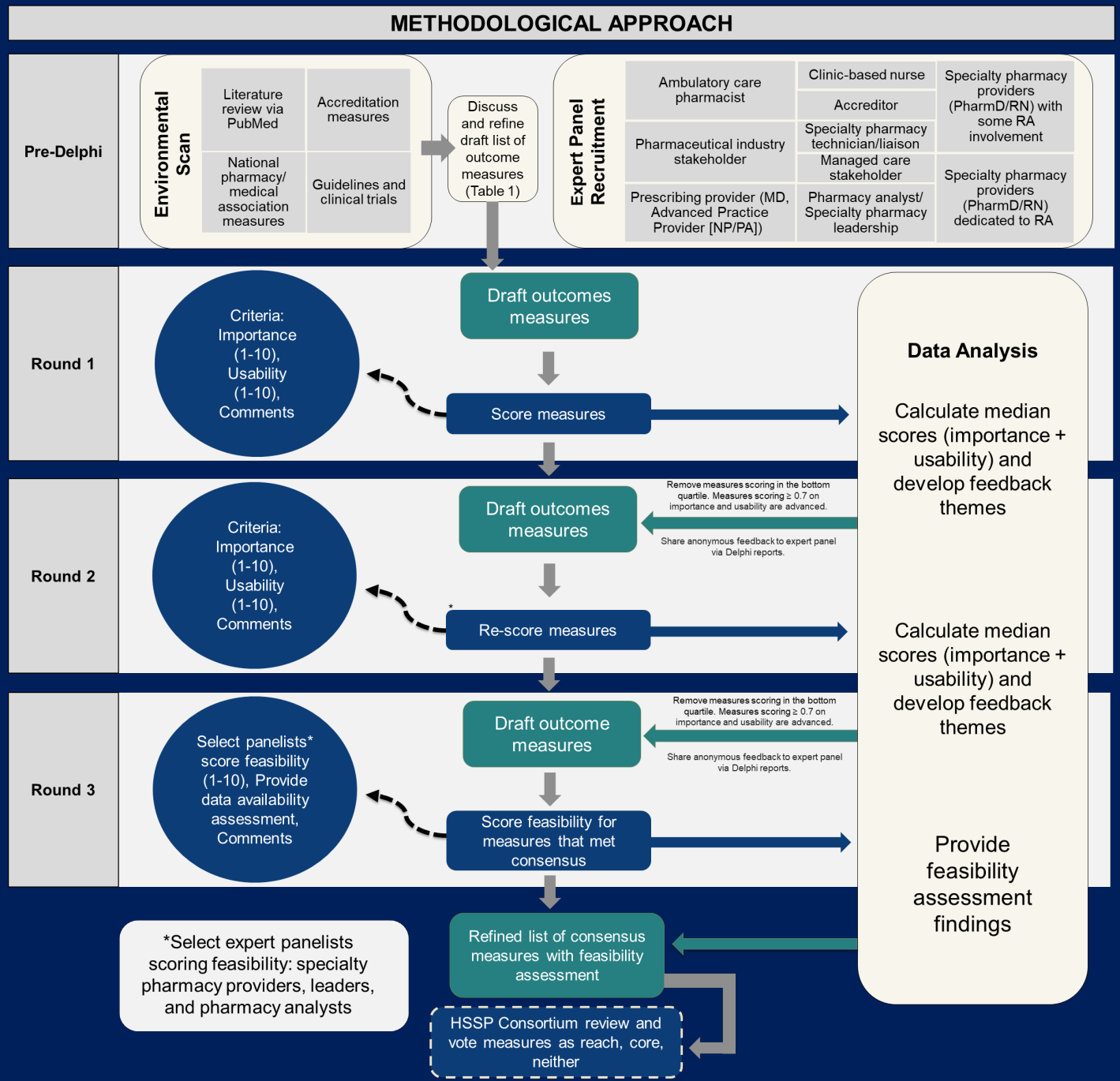
Feasibility…

- IBD Study Group Voting

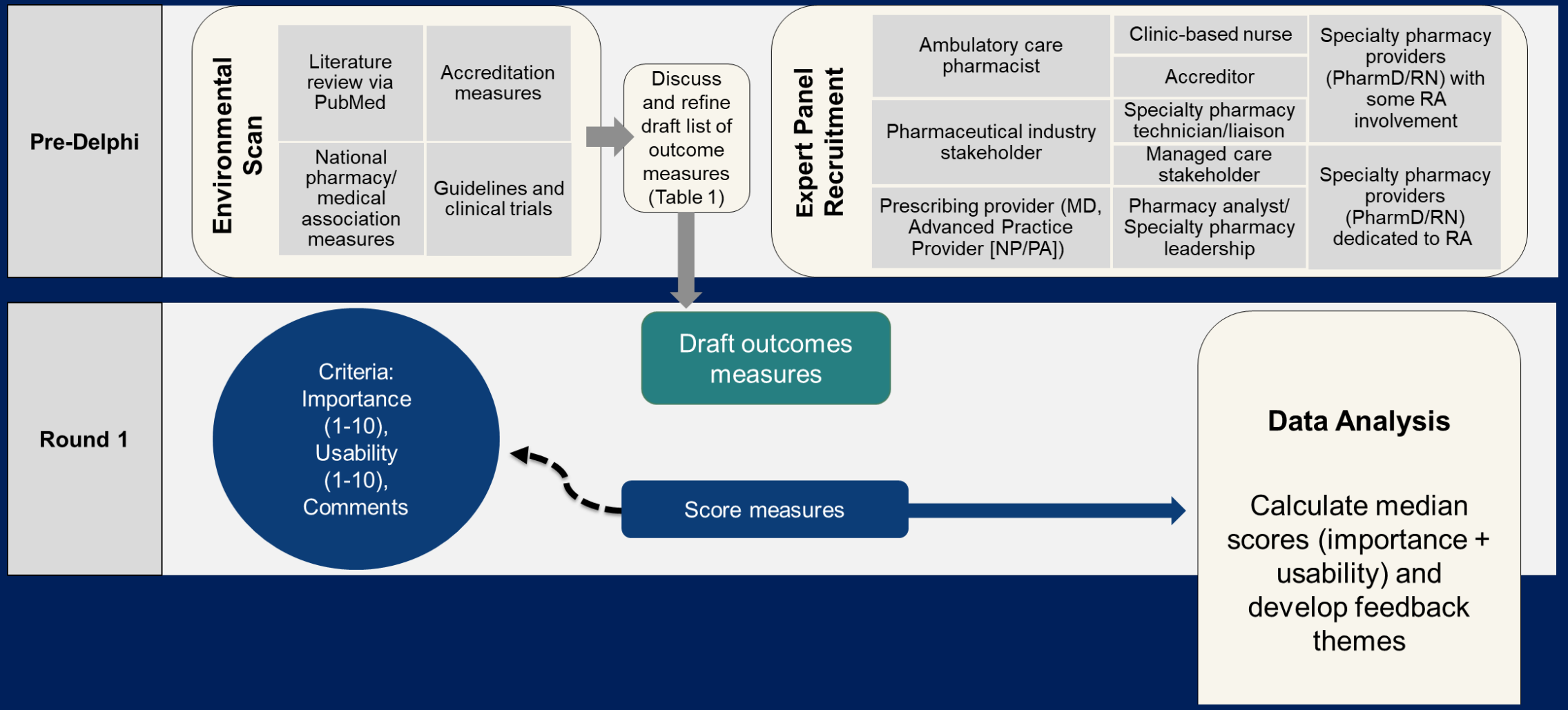


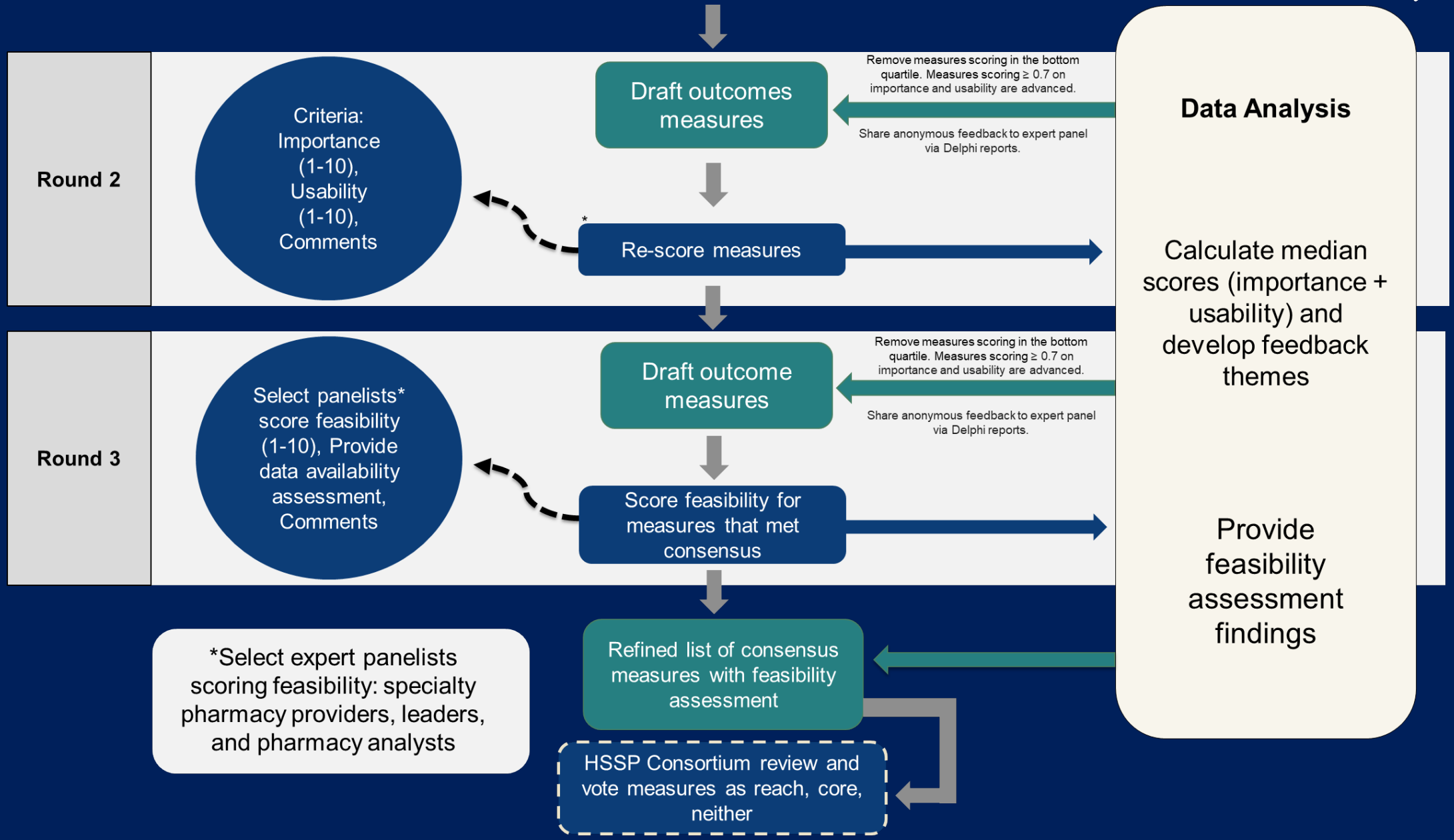
Identifying Outcome Measures for Specialty Pharmacists in Rheumatoid Arthritis Using the Delphi Method

2024 - Results


METHODOLOGICAL APPROACH
Pre-Delphi
Environmental Scan
Literature review via PubMed
Accreditation measures
National pharmacy/ medical association measures
Guidelines and clinical trials
Discuss and refine draft list of outcome measures (Table 1)
Expert Panel Recruitment
Ambulatory care pharmacist
Clinic-based nurse
Accreditor
Specialty pharmacy providers (PharmD/RN) with some RA involvement
Pharmaceutical industry stakeholder
Specialty pharmacy technician/liaison
Managed care stakeholder
Specialty pharmacy providers (PharmD/RN) dedicated to RA
Prescribing provider (MD, Advanced Practice Provider [NP/PA])
Pharmacy analyst/ Specialty pharmacy leadership
Round 1
Criteria: Importance (1-10), Usability (1-10), Comments
Draft outcomes measures
Score measures
Round 2
Criteria: Importance (1-10), Usability (1-10), Comments
Draft outcomes measures
Remove measures scoring in the bottom quartile. Measures scoring ≥ 0.7 on importance and usability are advanced.
Share anonymous feedback to expert panel via Delphi reports.
Re-score measures
Round 3
Select panelists* score feasibility (1-10), Provide data availability assessment, Comments
Draft outcome measures
Remove measures scoring in the bottom quartile. Measures scoring ≥ 0.7 on importance and usability are advanced.
Share anonymous feedback to expert panel via Delphi reports.
Score feasibility for measures that met consensus
Data Analysis
Calculate median scores (importance + usability) and develop feedback themes
Calculate median scores (importance + usability) and develop feedback themes
Provide feasibility assessment findings
*Select expert panelists scoring feasibility: specialty pharmacy providers, leaders, and pharmacy analysts
Refined list of consensus measures with feasibility assessment
HSSP Consortium review and vote measures as reach, core, neither

METHODOLOGICAL APPROACH




Round 2
Criteria: Importance (1-10), Usability (1-10), Comments
Draft outcomes measures
Remove measures scoring in the bottom quartile. Measures scoring ≥ 0.7 on importance and usability are advanced.
Share anonymous feedback to expert panel via Delphi reports.
*
Re-score measures
Round 3
Select panelists* score feasibility (1-10), Provide data availability assessment, Comments
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Remove measures scoring in the bottom quartile. Measures scoring ≥ 0.7 on importance and usability are advanced.
Share anonymous feedback to expert panel via Delphi reports.
Score feasibility for measures that met consensus
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Calculate median scores (importance + usability) and develop feedback themes
Provide feasibility assessment findings
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Refined list of consensus measures with feasibility assessment
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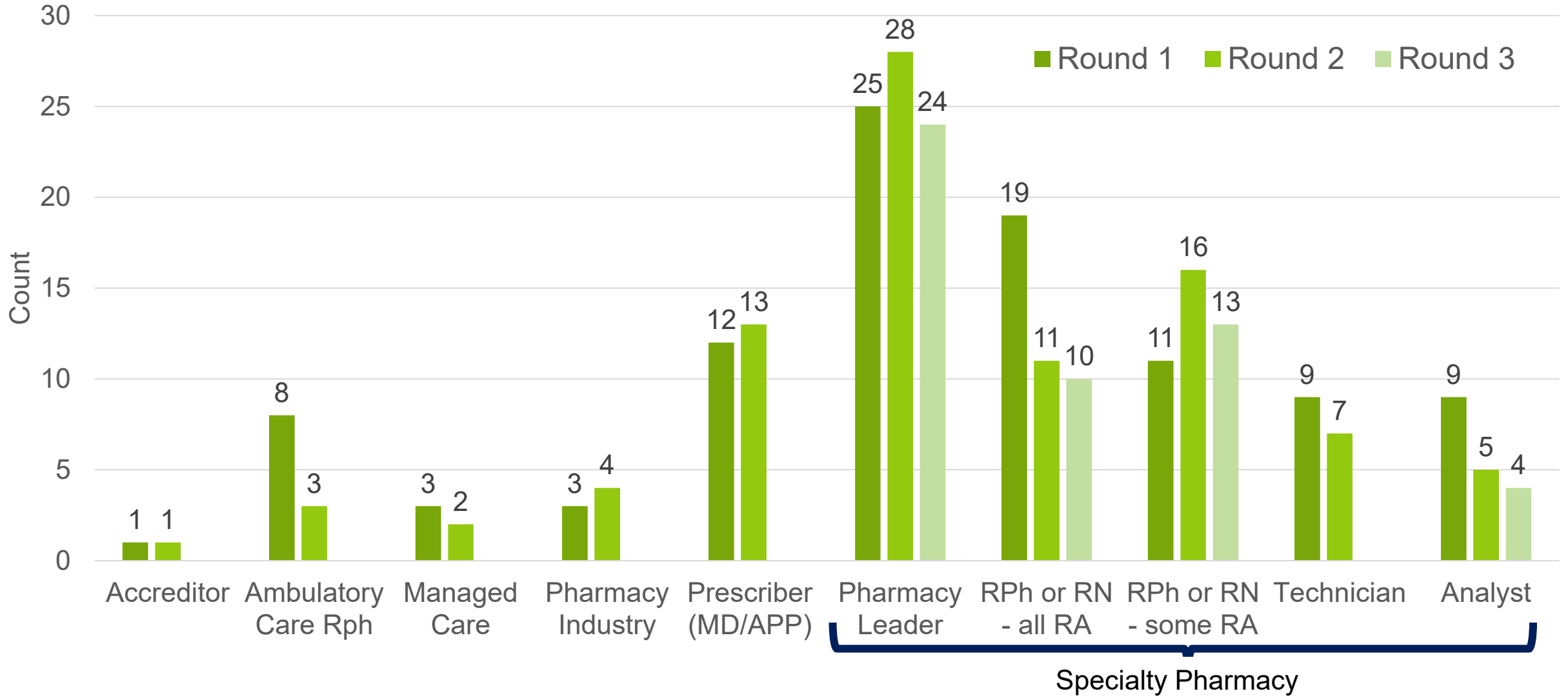
Stakeholder Survey Responses



Round 1 - Importance & Usability

Measures
Adherence
Disease activity
Medication outcomes
Patient functional status
Patient quality of life
Patient response to therapy
Planned healthcare utilization
Productivity
Safety screening
Unplanned healthcare utilization

Survey to evaluate consensus

Remove measures scoring in the bottom quartile.

Measures scoring ≥ 0.7 on importance and usability are advanced.

Included
Adherence
Medication outcomes
Patient response to therapy
Safety screening

Uncertain
Patient functional status
Disease activity
Patient quality of life

Excluded
Unplanned healthcare utilization
Planned healthcare utilization
Productivity

Round 2 - Importance & Usability

Uncertain
Patient functional status
Disease activity
Patient quality of life

Survey to evaluate consensus

Included
Patient functional status
Disease activity

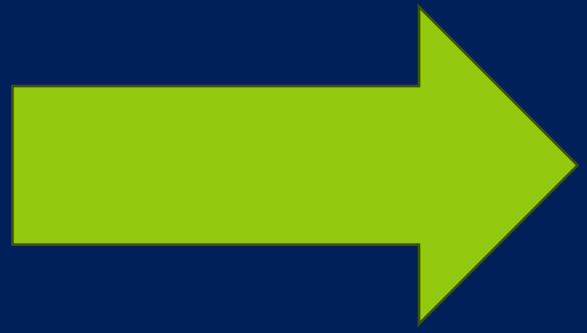
Remove measures scoring in the bottom quartile.

Measures scoring ≥ 0.7 on importance and usability are advanced.

Excluded
Patient quality of life

Overall Importance & Usability

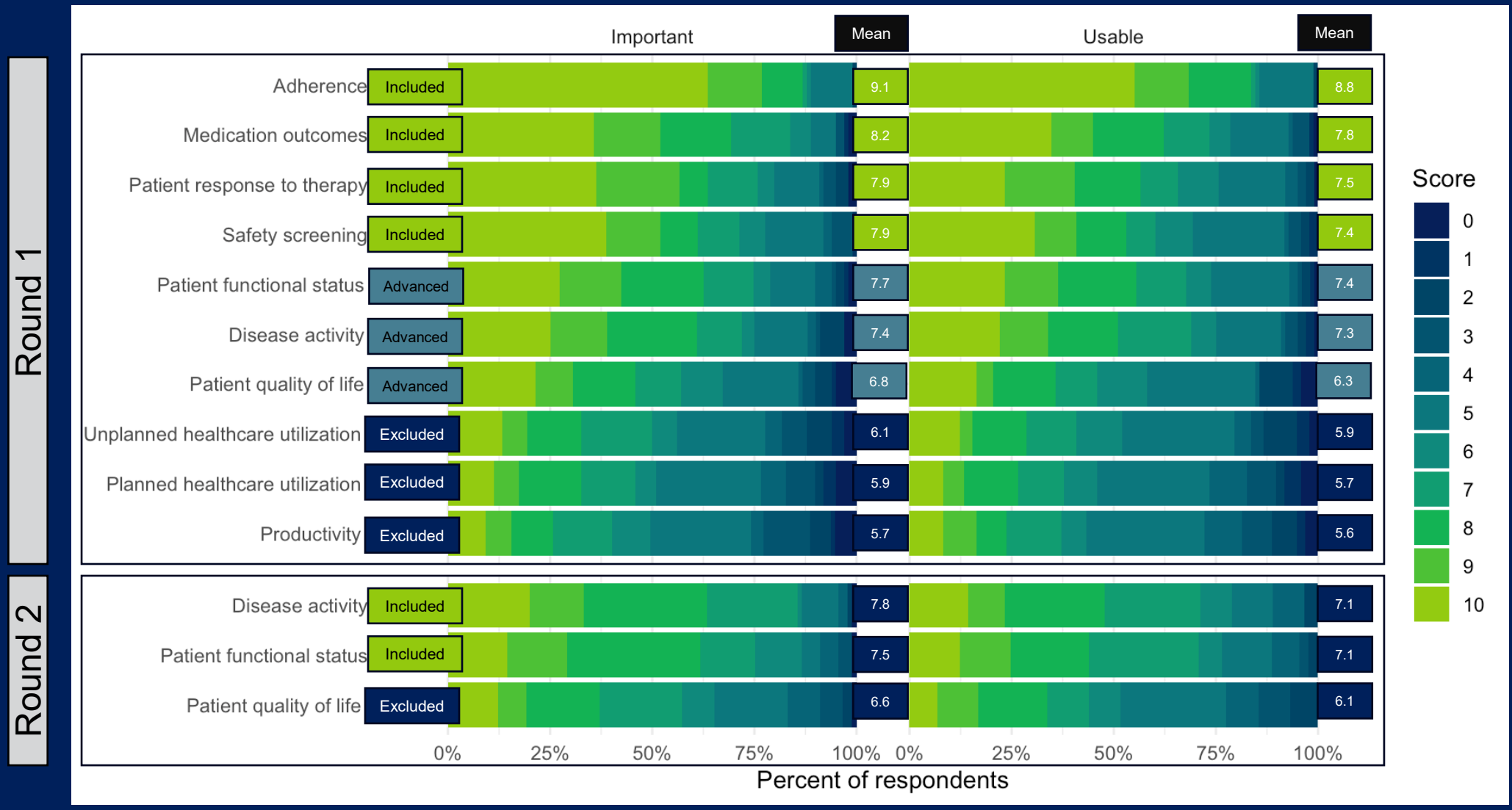
Measures
Adherence
Disease activity
Medication outcomes
Patient functional status
Patient quality of life
Patient response to therapy
Planned healthcare utilization
Productivity
Safety screening
Unplanned healthcare utilization



Included
Adherence
Medication outcomes
Patient response to therapy
Safety screening
Patient functional status
Disease activity

Excluded
Unplanned healthcare utilization
Planned healthcare utilization
Productivity
Patient quality of life

Importance & Usability



Round 2 – Measure Specifications

3. Patient response to therapy measures

What should be captured related to patient response to therapy? (select all that apply)

* must provide value

- [ ] Documentation that patient response has been assessed
- [ ] Outcomes of patient response assessment
- [ ] Actions taken by the pharmacy to address patient response
- [ ] N/A- should not be measured by specialty pharmacies

How should response to therapy be assessed? (select all that apply)

* must provide value

- [ ] Disease activity measure (e.g., clinical assessment [RAPID3], patient-reported question)
- [ ] Functional status measure (e.g., PGA, visual analog scale, patient reported question)
- [ ] Single patient question evaluating disease status (e.g., stable, better, worse)
- [ ] Treat to target progression based on patient goals (e.g., stable, better, worse)
- [ ] Persistence to medication/stopping or changing treatment
- [ ] Flare occurrence/frequency
- [ ] Unsure
- [ ] Other
- [ ] N/A- should not be measured by specialty pharmacies

HOW SOON should response to therapy be measured by specialty pharmacies after treatment initiation (baseline)?

* must provide value

- ○ Within 1 month
- ○ Within 3 months
- ○ Within 6 months
- ○ Within 1 year
- ○ Other
- ○ Unsure
- ○ N/A- should not be measured by specialty pharmacies

reset

How often should response to therapy be measured by specialty pharmacies?

* must provide value

- ○ Monthly
- ○ Quarterly
- ○ Every 6 months
- ○ Annually
- ○ Other
- ○ Unsure
- ○ N/A- should not be measured by specialty pharmacies

reset

Round 2 – Measure Specifications

Adherence	
Specification	Preference
Documentation	• **Actions taken by the pharmacy to address adherence (90%)** • **Adherence scores (87%)** • Documentation that adherence has been assessed (71%)
Methods	• **Patient-reported missed doses (83%)** captured monthly (60%) • PDC (77%) captured quarterly (51%)

Medication outcomes	
Specification	Preference
Elements to capture / monitoring frequency	• **Serious adverse events (90%)** measured/aggregated monthly (43%) • **Medication discontinuation (82%)** measured/aggregated quarterly (35%) • **Medication switching (75%)** measured/aggregated quarterly (28%) • Common Adverse Events (66%) measured/aggregated monthly (44%) • Specific medication persistence (64%) measured/aggregated either quarterly (32%) or every 6 months (30%)

Safety screening measures	
Specification	Preference
Elements to capture	• **Documentation that safety screening has been assessed (87%-96% for all elements)**
Screening to be captured / monitoring frequency	• **TB screening (83%)** prior to initiation only (33%) or based on PI (35%) • **Drug-specific lab monitoring (77%)** based on package insert (57%) • **HBV screening (76%)** prior to initiation only (39%) or based on package insert (35%) • **Immunization screening (76%)** annually (49%)

Round 3 - Feasibility

Measure	Feasibility of COLLECTION % Moderate/very feasible	Feasibility of REPORTING % Moderate/very feasible	Current Elements Collected and/or Reported
Adherence	**Patient-reported: 98%** Any measure: 88% PDC: 82%	**Any measure: 92%** **Patient-reported: 88%** **PDC: 86%**	**Patient-reported: 86%** PDC: 77%
Medication outcomes	**Discontinuations: 92%** **Serious AEs: 86%** Switching: 82% Common AEs: 71% Medication Persistence: 71%	**Discontinuations: 84%** **Serious AEs: 78%** Switching: 75% Medication Persistence: 65% Common AEs: 63%	**Serious AEs: 86%** **Discontinuations: 73%** Switching: 63% Common adverse events: 63% Medication persistence: 39%
Safety screening	**TB screening: 90%** **HBV screening: 88%** **Drug-specific labs: 80%** Immunization screening: 78%	**TB screening: 82%** **HBV screening: 78%** Drug-specific labs: 67% Immunization screening: 65%	**TB screening: 88%** **HBV screening: 80%** Drug-specific labs: 67% Pregnancy: 55% Infection risk assessment: 51% Immunization screening: 49% HCV screening: 47% Cardiovascular risk: 31%

Final Measures

Adherence (any measure)	Safety screening
Medication outcomes	TB screening
Discontinuations	HBV screening
Serious adverse events	Immunization screening
Common adverse events	Drug-specific lab screening
Medication switches	Patient functional status
Medication persistence	Disease activity
Patient response to therapy	

Determining Consensus

- Scoring measures
  - Importance score
  - Usability score
  - Feasibility score
  - Composite score
- Consider use
- Optimal number of rounds 2-3[1]

RA Procedures

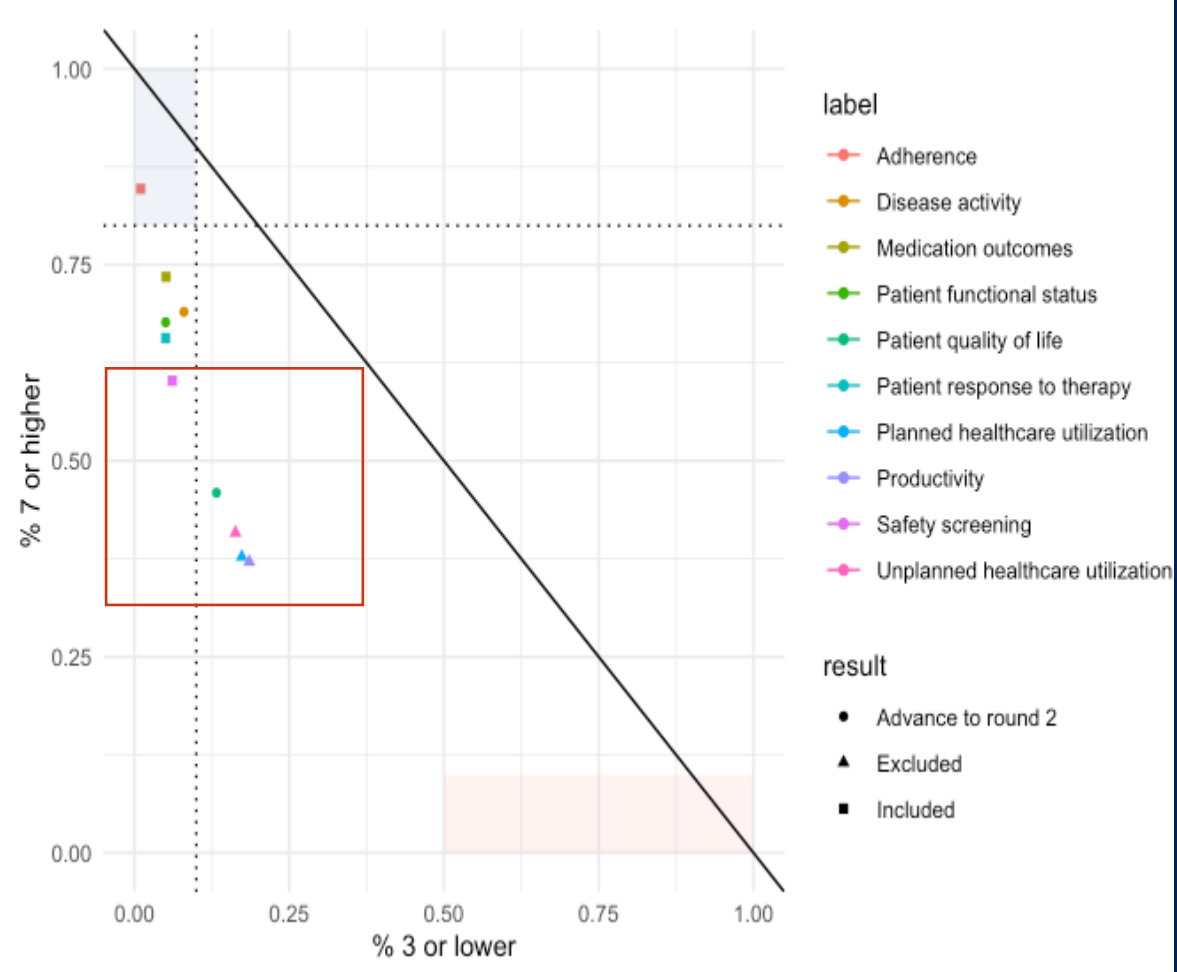
10-point Likert scale	**Round 1:** Mean importance and usability score <6.25 removed	**Round 2:** Mean importance and usability score <7 removed	**Round 3:** Feasibility score	**General to specific measure breakdown**	**Measure categorization:** Reach, core

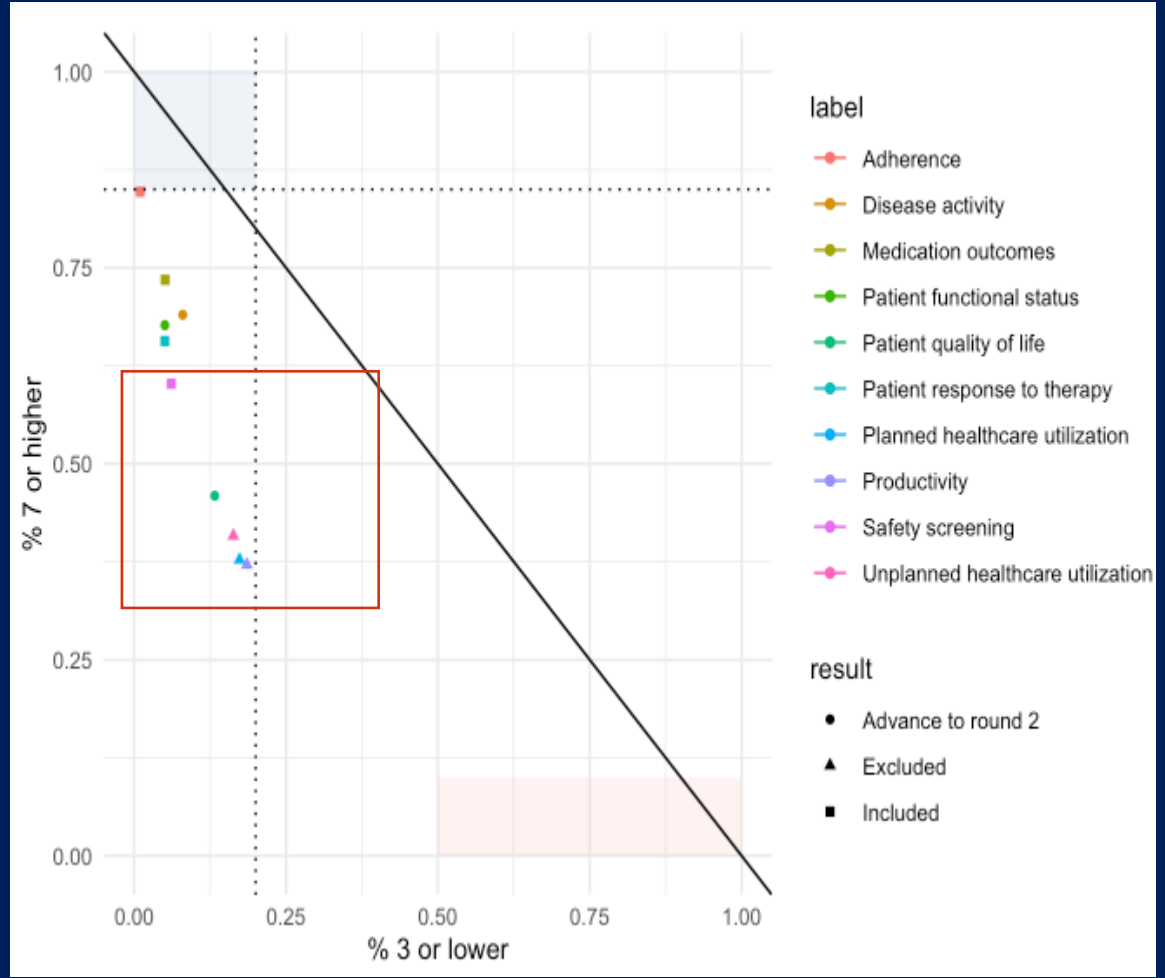
IBD Procedures

9-point Likert scale	**Rounds 1 and 2:** Composite score + feasibility score	**Round 3**: Median composite values visualized to determine consensus	**Measure categorization**: Reach, core

1. Sarah Drumm, Catriona Bradley, Frank Moriarty, 'More of an art than a science'? The development, design and mechanics of the Delphi Technique, Research in Social and Administrative Pharmacy, Volume 18, Issue 1, 2022, Pages 2230-2236, ISSN 1551-7411, https://doi.org/10.1016/j.sapharm.2021.06.027.

More of an Art





Determining Consensus- Planned IBD Analysis

Round 1

	Composite score (lowest of importance and usability)	Feasibility
Included- no further scoring	Median score ≥7	At least 90% score ≥4
Uncertain- included for voting in Round 2	Median score 4-6	At least 50% score ≥4
Eliminated- no further scoring	Median score 1-3	More than 50% score <4

Round 2

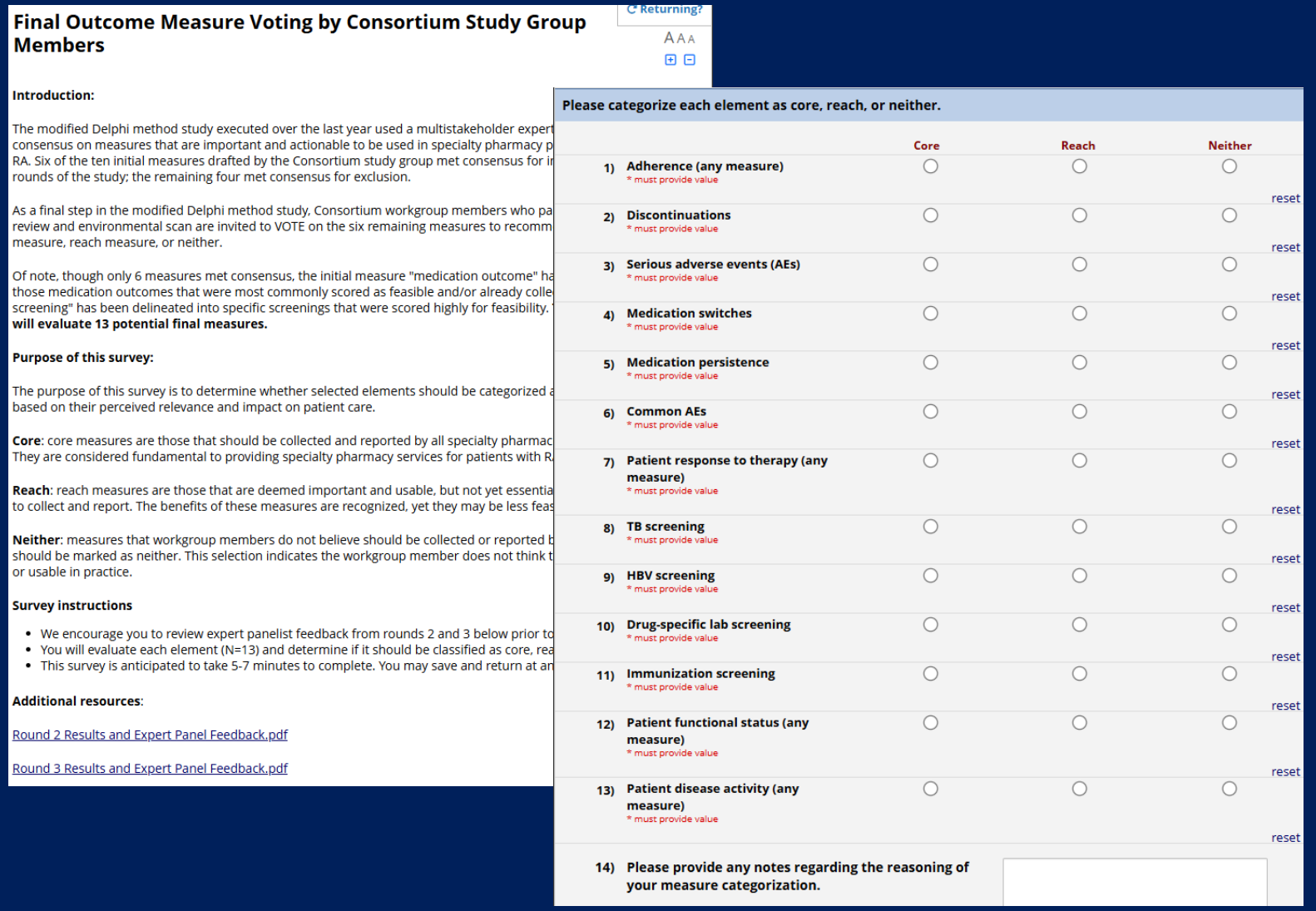
	Composite score (lowest of importance and usability)	Feasibility
Included- no further scoring	Median score ≥6.5	At least 80% score ≥4
Uncertain- included for voting in Round 3	Median score 4-6.5	At least 50% score ≥4
Eliminated- no further scoring	Median score 1-3	More than 50% score <4

Round 3

After scoring from round 3, **median composite values will be visualized** to determine an appropriate level of consensus based on results. Measures must have at least a median feasibility score of 5 to be considered for inclusion.

Final Determination

- Study group voting
- Core
  - Defined as measures that should be collected and reported by all specialty pharmacies **without exception**
- Reach
  - Deemed important and actionable but **not yet essential** for specialty pharmacies to collect and report



Final Outcome Measure Voting by Consortium Study Group Members

Returning?

Introduction:

The modified Delphi method study executed over the last year used a multistakeholder expert consensus on measures that are important and actionable to be used in specialty pharmacy p RA. Six of the ten initial measures drafted by the Consortium study group met consensus for i rounds of the study; the remaining four met consensus for exclusion.

As a final step in the modified Delphi method study, Consortium workgroup members who pa review and environmental scan are invited to VOTE on the six remaining measures to recomm measure, reach measure, or neither.

Of note, though only 6 measures met consensus, the initial measure "medication outcome" ha those medication outcomes that were most commonly scored as feasible and/or already colle screening" has been delineated into specific screenings that were scored highly for feasibility. **will evaluate 13 potential final measures.**

Purpose of this survey:

The purpose of this survey is to determine whether selected elements should be categorized a based on their perceived relevance and impact on patient care.

Core: core measures are those that should be collected and reported by all specialty pharmac They are considered fundamental to providing specialty pharmacy services for patients with R

Reach: reach measures are those that are deemed important and usable, but not yet essentia to collect and report. The benefits of these measures are recognized, yet they may be less feas

Neither: measures that workgroup members do not believe should be collected or reported b should be marked as neither. This selection indicates the workgroup member does not think t or usable in practice.

Survey instructions

- We encourage you to review expert panelist feedback from rounds 2 and 3 below prior to
- You will evaluate each element (N=13) and determine if it should be classified as core, rea
- This survey is anticipated to take 5-7 minutes to complete. You may save and return at an

Additional resources:

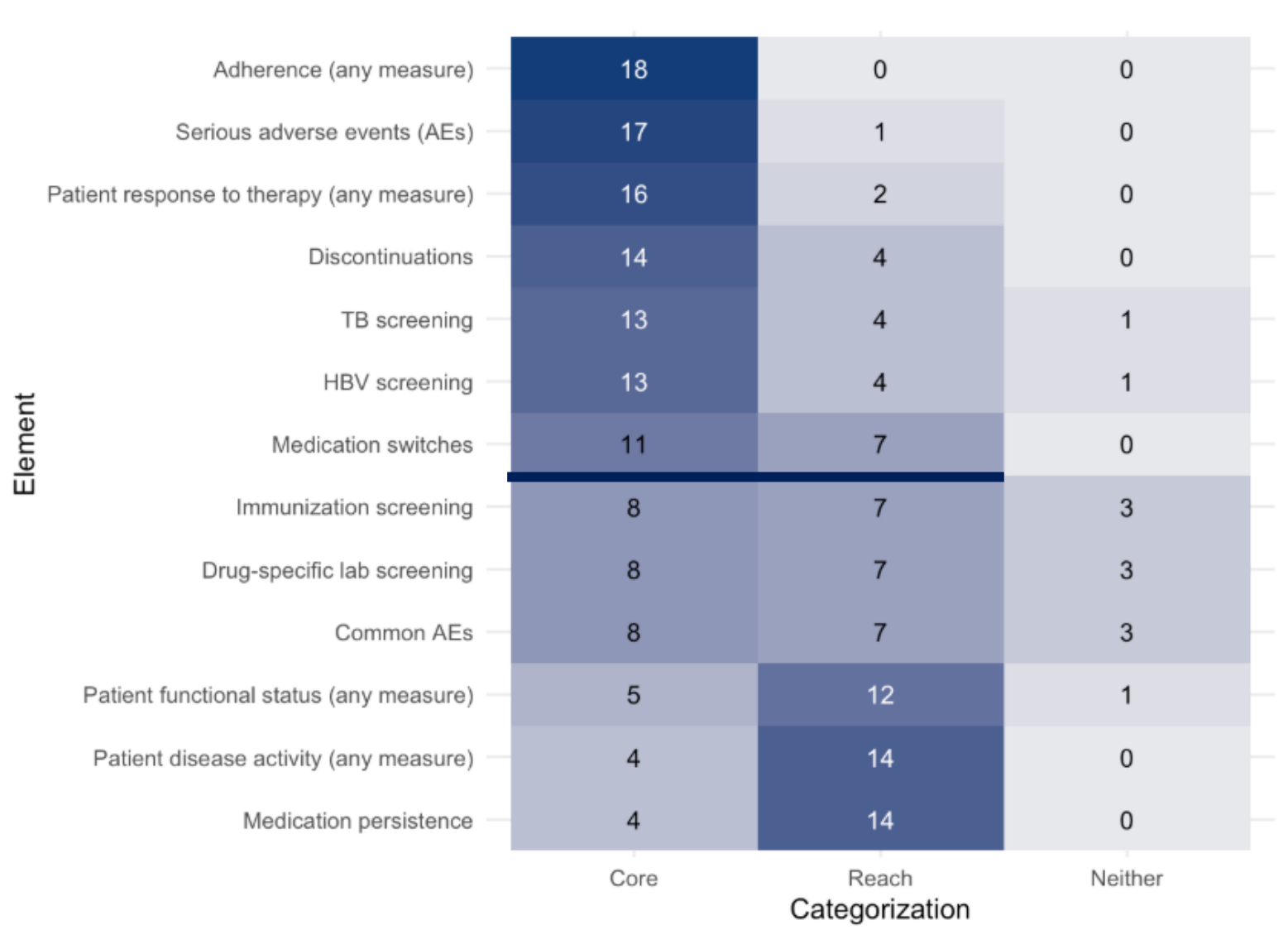
Round 2 Results and Expert Panel Feedback.pdf

Round 3 Results and Expert Panel Feedback.pdf

Please categorize each element as core, reach, or neither.

	Core	Reach	Neither
1) **Adherence (any measure)** * must provide value	○	○	○ reset
2) **Discontinuations** * must provide value	○	○	○ reset
3) **Serious adverse events (AEs)** * must provide value	○	○	○ reset
4) **Medication switches** * must provide value	○	○	○ reset
5) **Medication persistence** * must provide value	○	○	○ reset
6) **Common AEs** * must provide value	○	○	○ reset
7) **Patient response to therapy (any measure)** * must provide value	○	○	○ reset
8) **TB screening** * must provide value	○	○	○ reset
9) **HBV screening** * must provide value	○	○	○ reset
10) **Drug-specific lab screening** * must provide value	○	○	○ reset
11) **Immunization screening** * must provide value	○	○	○ reset
12) **Patient functional status (any measure)** * must provide value	○	○	○ reset
13) **Patient disease activity (any measure)** * must provide value	○	○	○ reset
14) **Please provide any notes regarding the reasoning of your measure categorization.**			

Core or Reach Measures



Stakeholder Feedback

General agreement on importance / usability of metrics

- Exception: prescribers commenting on elements that are less traditionally roles of pharmacists
  - “Not the pharmacy’s role”
  - “This seems intrusive”

36 comments about elements being useful or important for prior authorizations or insurance coverage

- None from managed care stakeholders

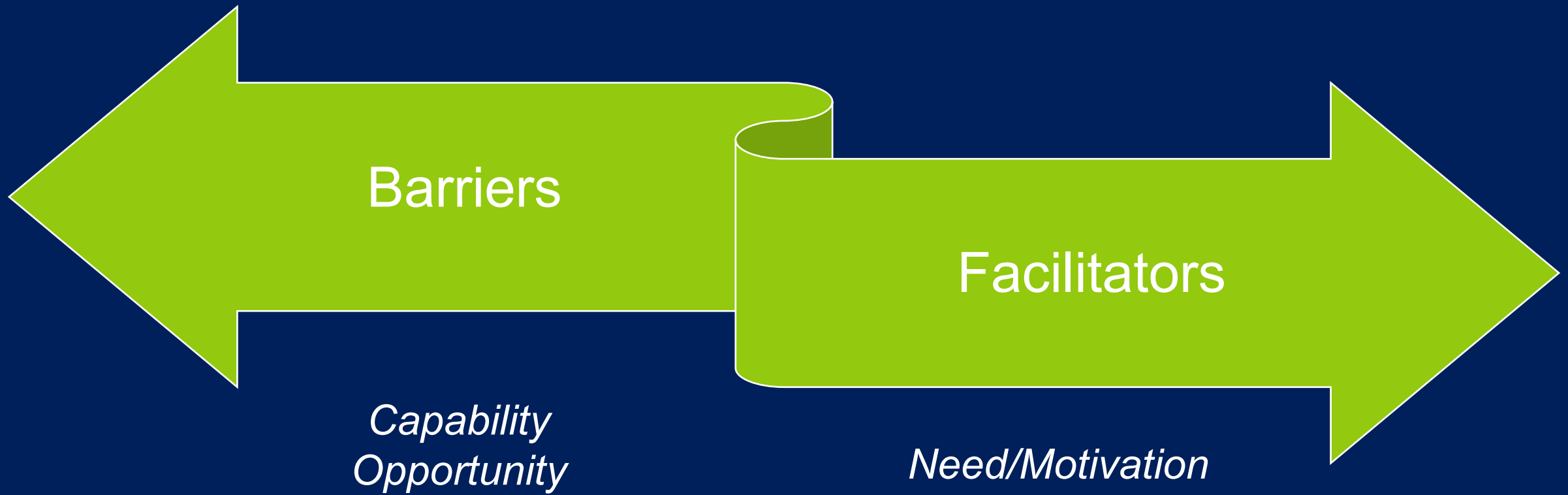
Determining Consensus Lessons Learned

- Guidelines for determining consensus are vague
  - Modeling can help
  - Consider study purpose
- Feasibility is essential (for this work)
- If scoring expands beyond agreement, fewer variables are easier
- Additional specifications should be based on expert panelist role (potentially)
- Stakeholder feedback themes are useful

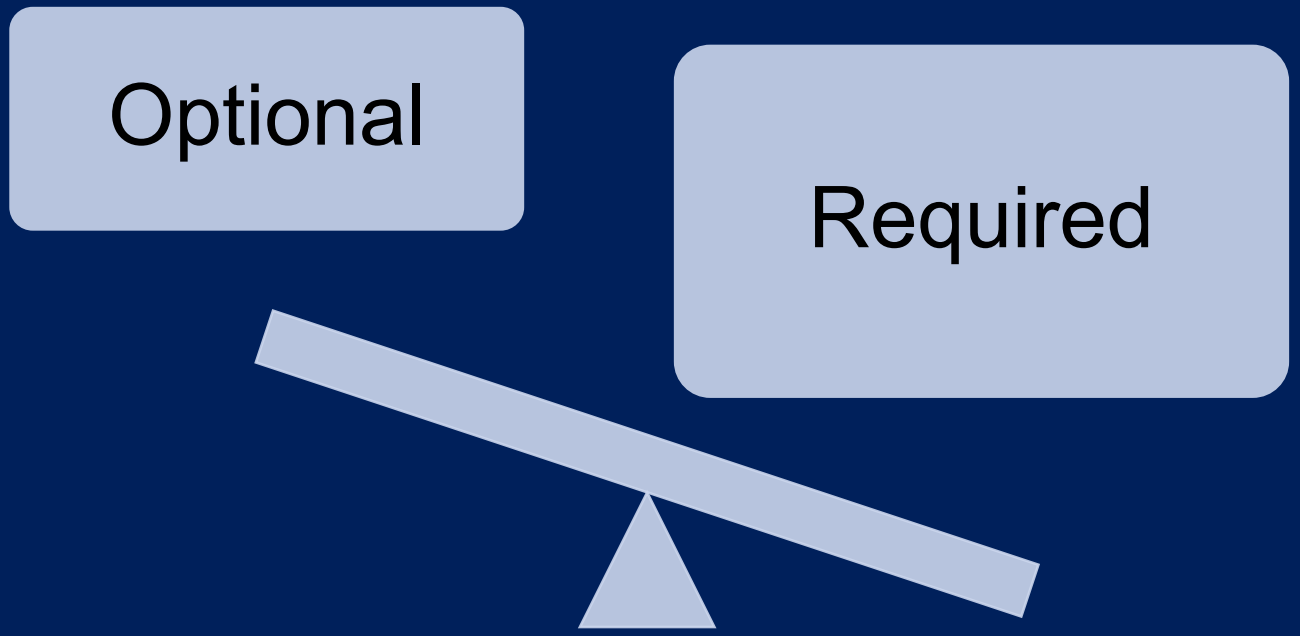
Implementation Challenges

Measures	Collected discretely	Collected- limited or non-discrete	Not collected
Adherence	14	1	0
Serious AEs	9	6	0
Patient response to therapy	8	7	0
Medication discontinuations	10	4	1
TB screening	11	3	1
HBV screening	9	5	1
Medication switches	2	11	2
Medication persistence	6	3	6
Common AEs	5	9	1
Drug-specific lab screening	9	3	3
Immunization screening	8	6	1
Patient functional status	4	7	4
Patient disease activity	8	4	3

Implementation Challenges



Implementation Challenges



Pharmacies prioritize required reporting elements over optional elements

Opportunities:

- Partnerships
- Meaningful data contracts
- Elevate practice and patient care

What's next?

RA Study

- Sharing Results
- Encourage Implementation

IBD Study

- Environmental scan is underway
- Surveys later this year

Other disease states?

Key Takeaways

- Specialty pharmacies are capable and willing to report measures that are important and meaningful to manage specialty pharmacies, but implementation barriers exist.
- The modified Delphi method can be used to reach consensus about what measures should be collected and reported by specialty pharmacies and can help steer the field of specialty pharmacy.
- Managed care stakeholders should participate in developing consensus on meaningful measures in specialty pharmacies and use these measures to evaluate specialty pharmacy performance and selection.

Open Discussion

- Feedback on use cases presented?
  - Stakeholders
  - Measure evaluation
  - Rounds
- Delphi Method- use cases and ideas for future use?

Post-Test

Polling Question

LQ1: Which of the following best describes the current state of outcome measurement and reporting in specialty pharmacy?

a) Primarily focuses on operational metrics

b) Efficiently performed structured data from one source

c) Measures are rarely measured or reported, and there is little emphasis on improving this area

d) Limited to accreditation measures only

Polling Question

LQ1: Which of the following best describes the current state of outcome measurement and reporting in specialty pharmacy?

a) **Primarily focuses on operational metrics**

b) Efficiently performed structured data from one source

c) Measures are rarely measured or reported, and there is little emphasis on improving this area

d) Limited to accreditation measures only

CORRECT RESPONSE: **A**
BRIEF EXPLANATION: **B- data is often structured and unstructured and from multiple sources; C- Specialty pharmacies have a large amount of outcomes reporting and want to improve; D- Measures are reported to multiple stakeholders**

Polling Question

LQ2: Which of the following is a key lesson learned from using the modified Delphi methodology to determine consensus on meaningful measures in specialty pharmacy practice?

a) It is ineffective in achieving consensus among experts

b) There are clear guidelines for how to determine consensus

c) Engaging a diverse panel of experts makes consensus easier to achieve.

d) It is helpful to determine the specificity of planned measures prior to engaging experts.

Polling Question

LQ2: Which of the following is a key lesson learned from using the modified Delphi methodology to determine consensus on meaningful measures in specialty pharmacy practice?

a) It is ineffective in achieving consensus among experts

b) There are clear guidelines for how to determine consensus

c) Engaging a diverse panel of experts makes consensus easier to achieve.

d) It is helpful to determine the specificity of planned measures prior to engaging experts.

CORRECT RESPONSE: **D**
BRIEF EXPLANATION: **A- this method can successfully lead to consensus; B- clear guidelines are not available and approaches should be based on purpose; C- consensus may be harder with a more diverse panel**

Polling Question

LQ3: Which of the following measures were excluded as a result of the first survey round in the modified Delphi study to identify outcome measures for specialty pharmacists in rheumatoid arthritis?

a) Adherence

b) Medication outcomes

c) Unplanned healthcare utilization

d) Safety screening

Polling Question

LQ3: Which of the following measures were excluded as a result of the first survey round in the modified Delphi study to identify outcome measures for specialty pharmacists in rheumatoid arthritis?

a) Adherence

b) Medication outcomes

c) Unplanned healthcare utilization

d) Safety screening

CORRECT RESPONSE: **C**
BRIEF EXPLANATION: **Adherence, medication outcomes, and safety screening were identified for *inclusion* after the first round of surveys. Unplanned healthcare utilization, planned healthcare utilization, and productivity met consensus for exclusion during the first round.**

Questions

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