Current gaps in global IBD management

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Learning Objectives

- To consider where we are currently in IBD management
- To review the complexity of IBD management
- To discuss the gaps in getting the best treatments to patients with IBD
- To review a new model of IBD healthcare delivery

We can do so much better for IBD care

25 years since infliximab was approved for Crohn's disease

Professional Affairs and Public Policy

Infliximab Approved for Use in Crohn's Disease: A Report on the FDA GI Advisory Committee Conference

Asher Kornbluth, M.D.

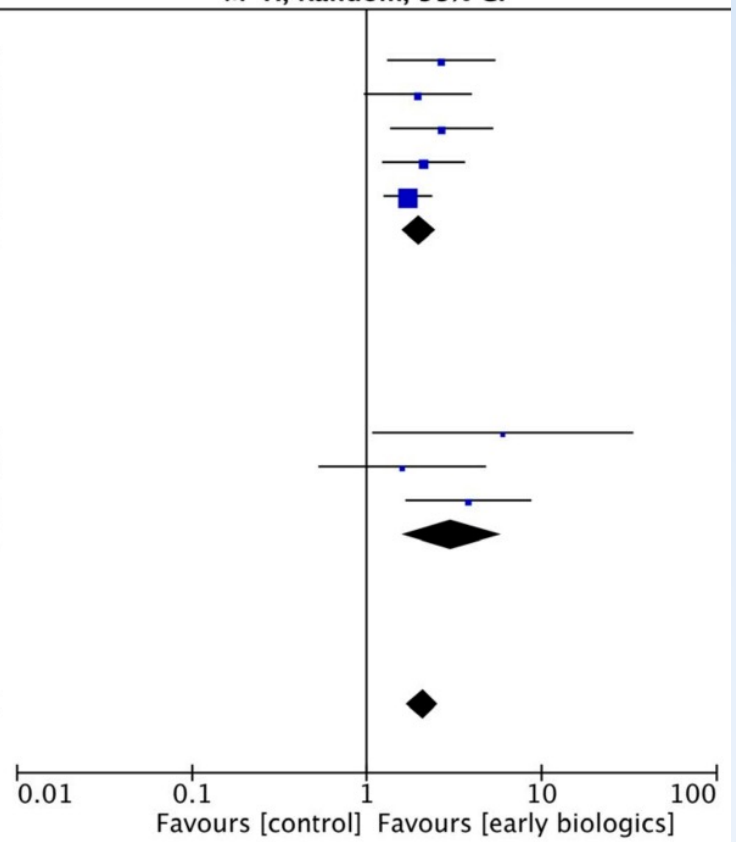
The Mt. Sinai Medical Center, New York, New York, U.S.A.

August 24, 1998

July 1, 1998

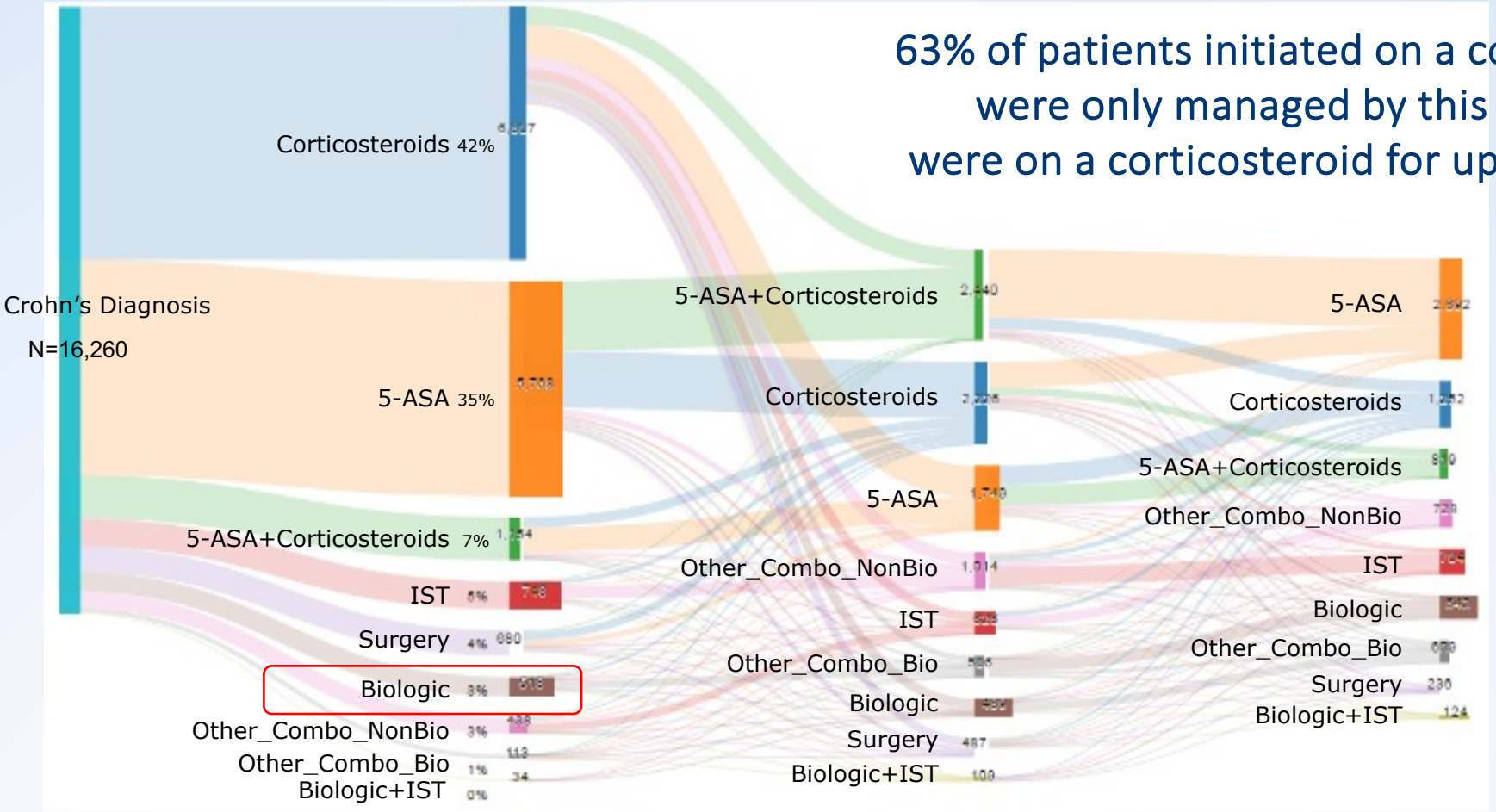
Early biologics (within 2 years) are more effective than typical “step-up therapy”

Study or Subgroup	Early Treatment Biologics Events	Total	Control Events	Total	Weight	Odds Ratio M-H, Random, 95% CI
1.1.1 Adult						
D'Haens 2008	39	65	23	64	9.0%	2.67 [1.31, 5.45]
Schreiber 2010	24	39	79	176	9.1%	1.96 [0.97, 4.00]
Colombel 2015	105	134	31	54	9.9%	2.69 [1.36, 5.29]
Faleck 2019	24	62	135	588	15.4%	2.12 [1.23, 3.66]
Panaccione 2016	84	174	418	1190	44.6%	1.72 [1.25, 2.37]
Subtotal (95% CI)		**474**		**2072**	**88.0%**	**1.99 [1.59, 2.50]**
Total events	276		686			
Heterogeneity: $Tau^2 = 0.00$; $Chi^2 = 2.24$, $df = 4$ ($P = .69$); $I^2 = 0\%$						
Test for overall effect: $Z = 5.92$ ($P < .00001$)						
1.1.2 Pediatric						
Kim 2011	15	18	5	11	1.6%	6.00 [1.08, 33.38]
Hyams 2009	16	26	13	26	3.8%	1.60 [0.53, 4.82]
Walters 2014	58	68	41	68	6.7%	3.82 [1.67, 8.75]
Subtotal (95% CI)		**112**		**105**	**12.0%**	**3.07 [1.59, 5.94]**
Total events	89		59			
Heterogeneity: $Tau^2 = 0.03$; $Chi^2 = 2.20$, $df = 2$ ($P = .33$); $I^2 = 9\%$						
Test for overall effect: $Z = 3.33$ ($P = .0009$)						
Total (95% CI)		**586**		**2177**	**100.0%**	**2.10 [1.69, 2.60]**
Total events	365		745			
Heterogeneity: $Tau^2 = 0.00$; $Chi^2 = 6.12$, $df = 7$ ($P = .53$); $I^2 = 0\%$						
Test for overall effect: $Z = 6.79$ ($P < .00001$)						
Test for subgroup differences: $Chi^2 = 1.48$, $df = 1$ ($P = .22$), $I^2 = 32.3\%$						



Ungaro R, et al. Aliment Pharmacol Ther. 2020.

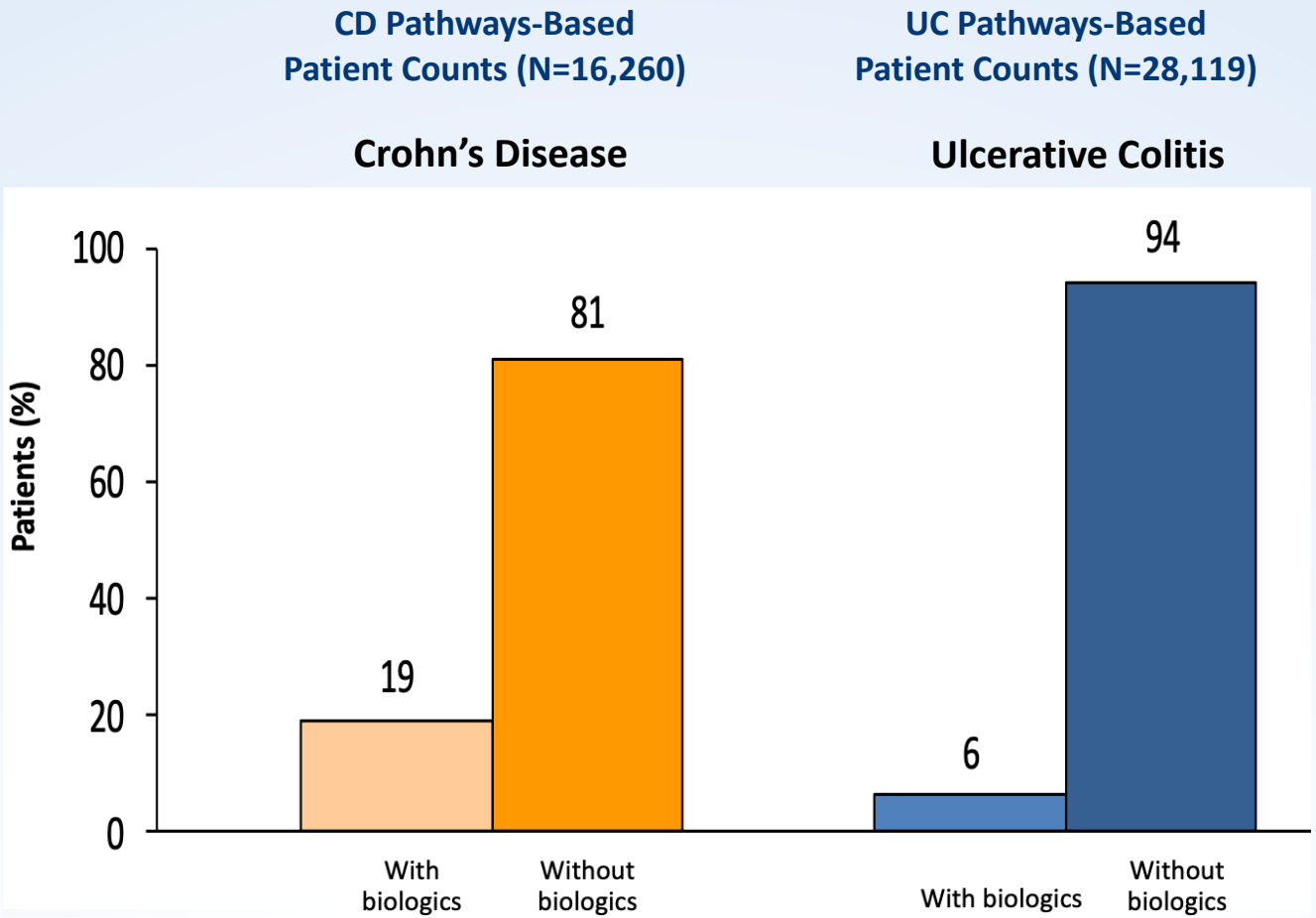
But we are not taking advantage of the progress!



63% of patients initiated on a corticosteroid were only managed by this agent; some were on a corticosteroid for up to 10 cycles

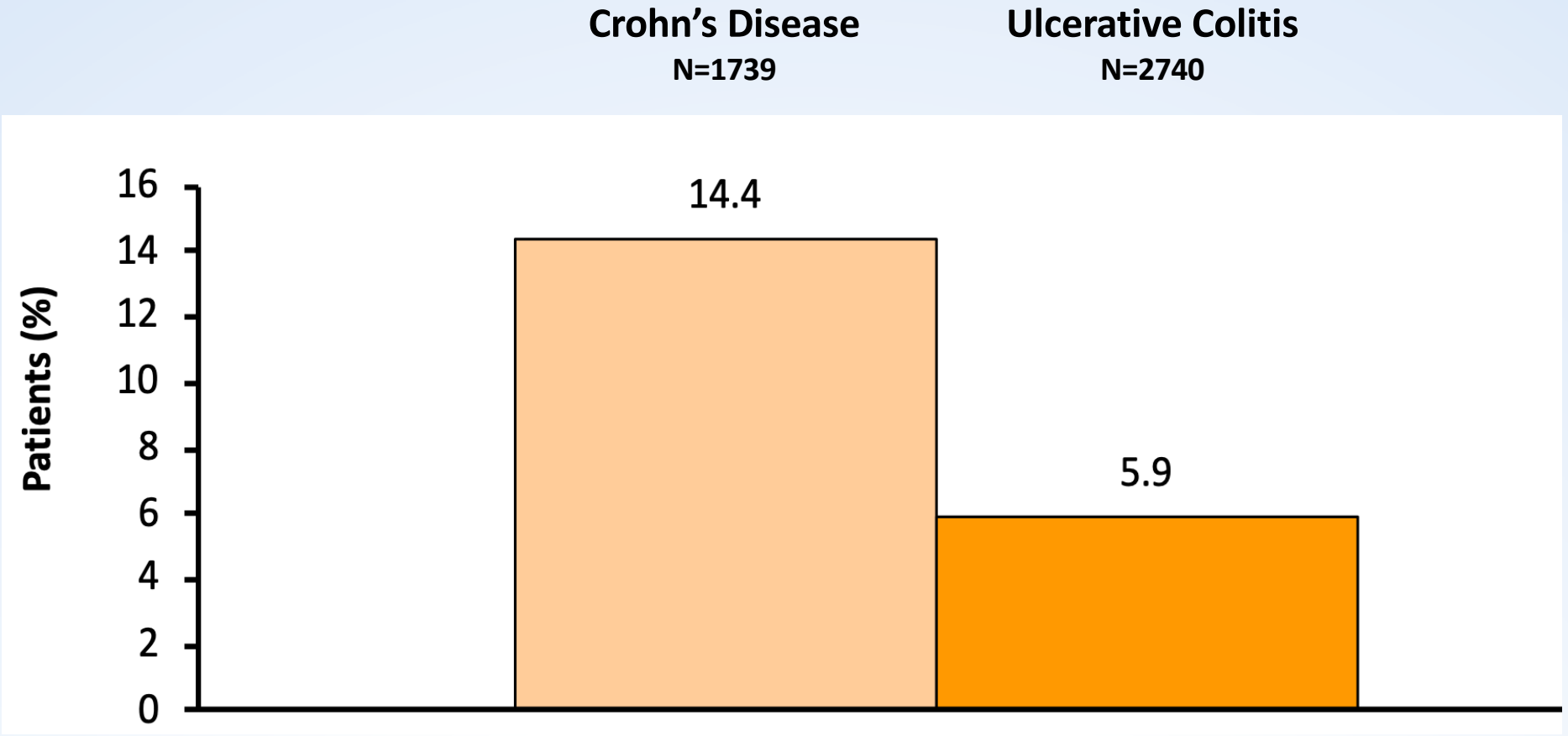
Siegel CA, et al. Clin Transl Gastroenterol. 2020.

Overall use of biologics at any time point ("ever use") from 2008-2016



Siegel CA, et al. Clin Transl Gastroenterol. 2020.

Use of any advanced therapy in newly diagnosed IBD patients over 2 years from 2017-2021



Siegel CA, et al. Presented at DDW 2023.

What is the real issue here?

- Insurance companies/government payers?
- Patients and parents are scared and don't want to use "scary" drugs before they are super sick?
- Providers
  - IBD is a rapidly evolving sub-specialty within GI
  - IBD care is about the provider team, well beyond the 1:1 patient and provider relationship
  - Practice incentives ($$) are not aligned towards more time in the clinic

IBD care is getting significantly more complex

- **2000**
  - 5-ASAs
  - Corticosteroids
  - 6MP, azathioprine
  - Methotrexate
  - Infliximab

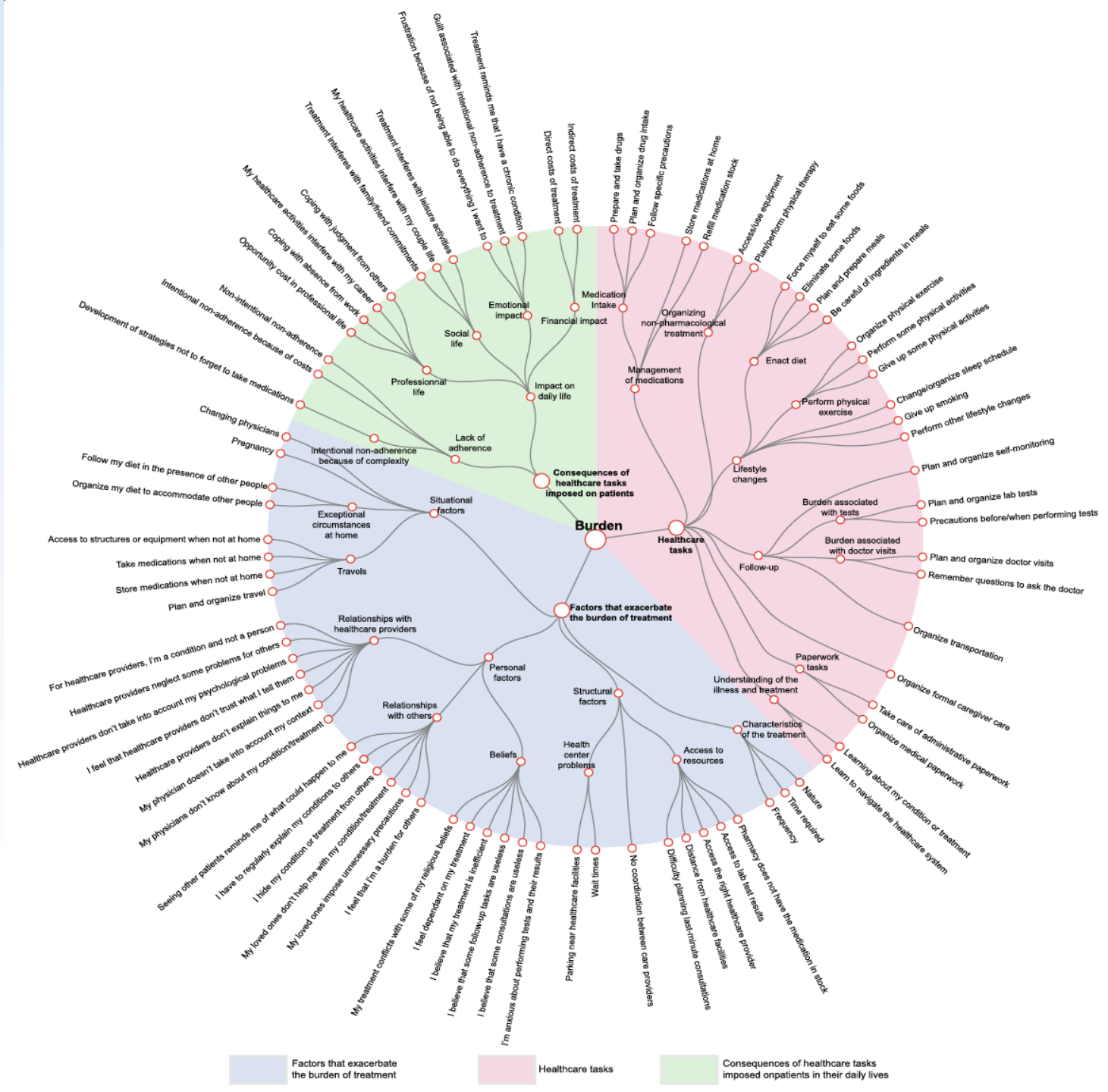
- **2022**

We need to consider proactive versus reactive treatment for Crohn's Disease

The burden of chronic disease on patients

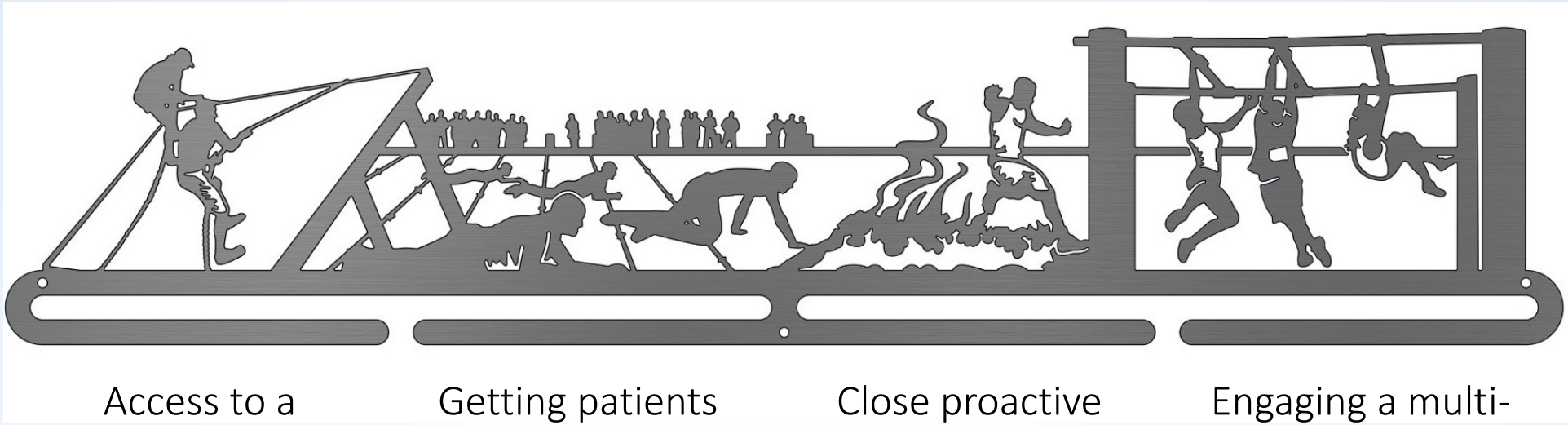
This takes a team!

- Blue – factors that exacerbate the burden of treatment
- Purple – healthcare tasks
- Green – consequences of these tasks on daily lives



Tran et al. BMC Medicine 2015.13:115

The obstacles of giving excellent care to all patients with IBD



Access to a specialist

Getting patients started on the right medications

Close proactive follow-up

Engaging a multi-disciplinary team

Real world gaps for getting patients what they need

- Barriers that delay (or prevent) access to the best treatment
- Increasing complexity of IBD management
- Access to a multidisciplinary team
- Proactive versus reactive care
- Distinguishing disease activity versus disease severity

Distinguish disease *activity* versus disease *severity*

Activity

Reflects cross-sectional assessment of biologic inflammatory impact on symptoms, signs, endoscopy, histology, and biomarkers

Severity

Includes longitudinal (disease course) and historical factors that provide a more complete picture of the prognosis and overall “burden” of disease

Distinguish disease *activity* versus disease *severity*

Activity

How is your patient TODAY?

Severity

What has your patient's disease course been over their history since diagnosis?

Real world gaps for getting patients what they need

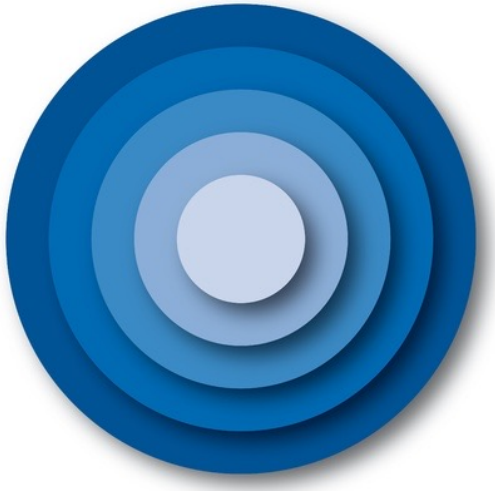
- Barriers that delay (or prevent) access to the best treatment
- Increasing complexity of IBD management
- Access to a multidisciplinary team
- Proactive versus reactive care
- Distinguishing disease activity versus disease severity

- We need to reconsider our current model for delivery IBD care.
- As children → adults and the growing number of adults with IBD increases, how are we going to give them all great care?
- We need to be innovative and creative to improve and sustain high quality care in the future!

Dartmouth Health

Introducing RADIUS

Rural **A**PP/MDs **D**elivering **I**BD Care in the **U**nited **S**tates



Current Supporters

THE LEONA M. AND HARRY B. HELMSLEY CHARITABLE TRUST

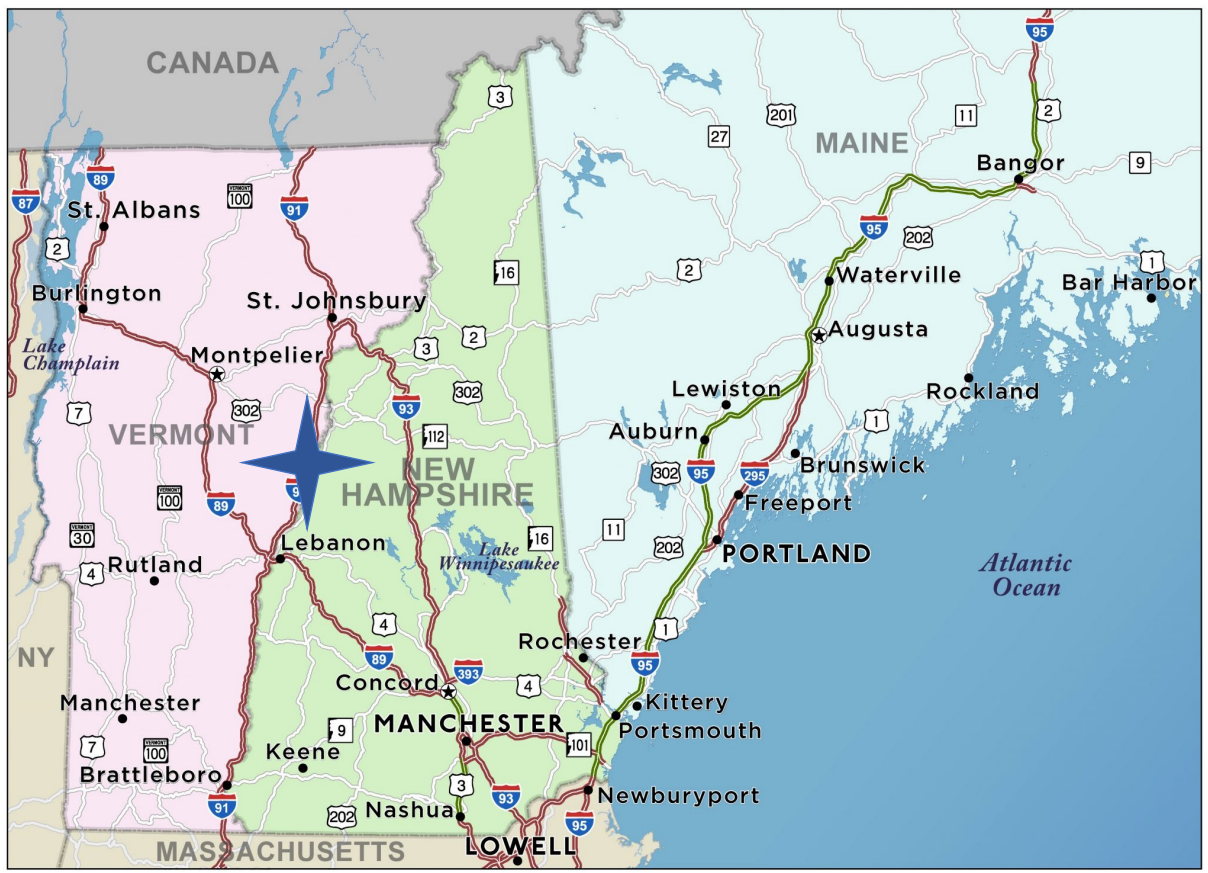
Pfizer

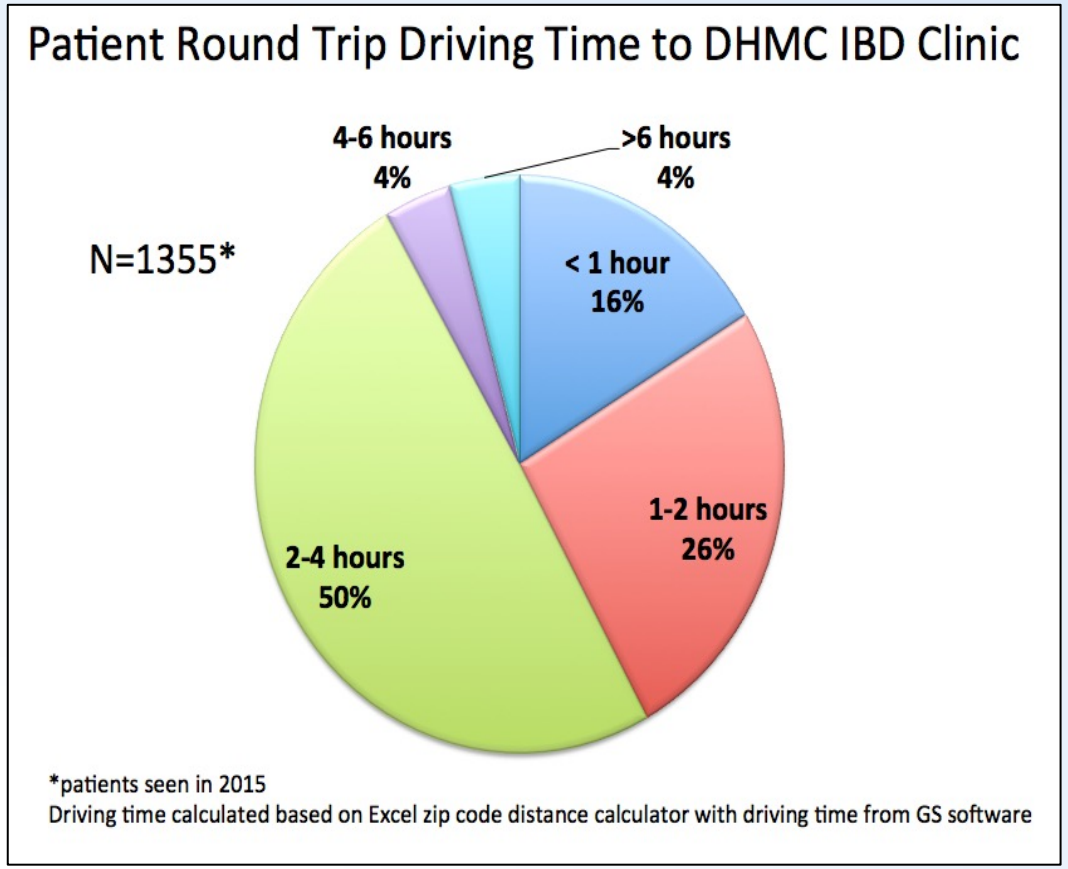
janssen

It is very rural in Northern New England!

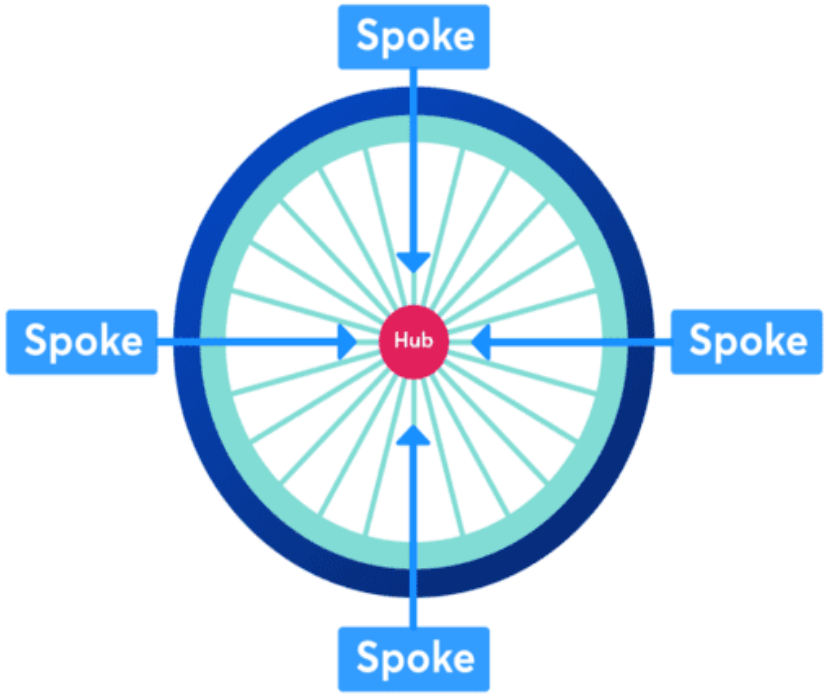
Patient travel time to Dartmouth

“you can’t get there from here”





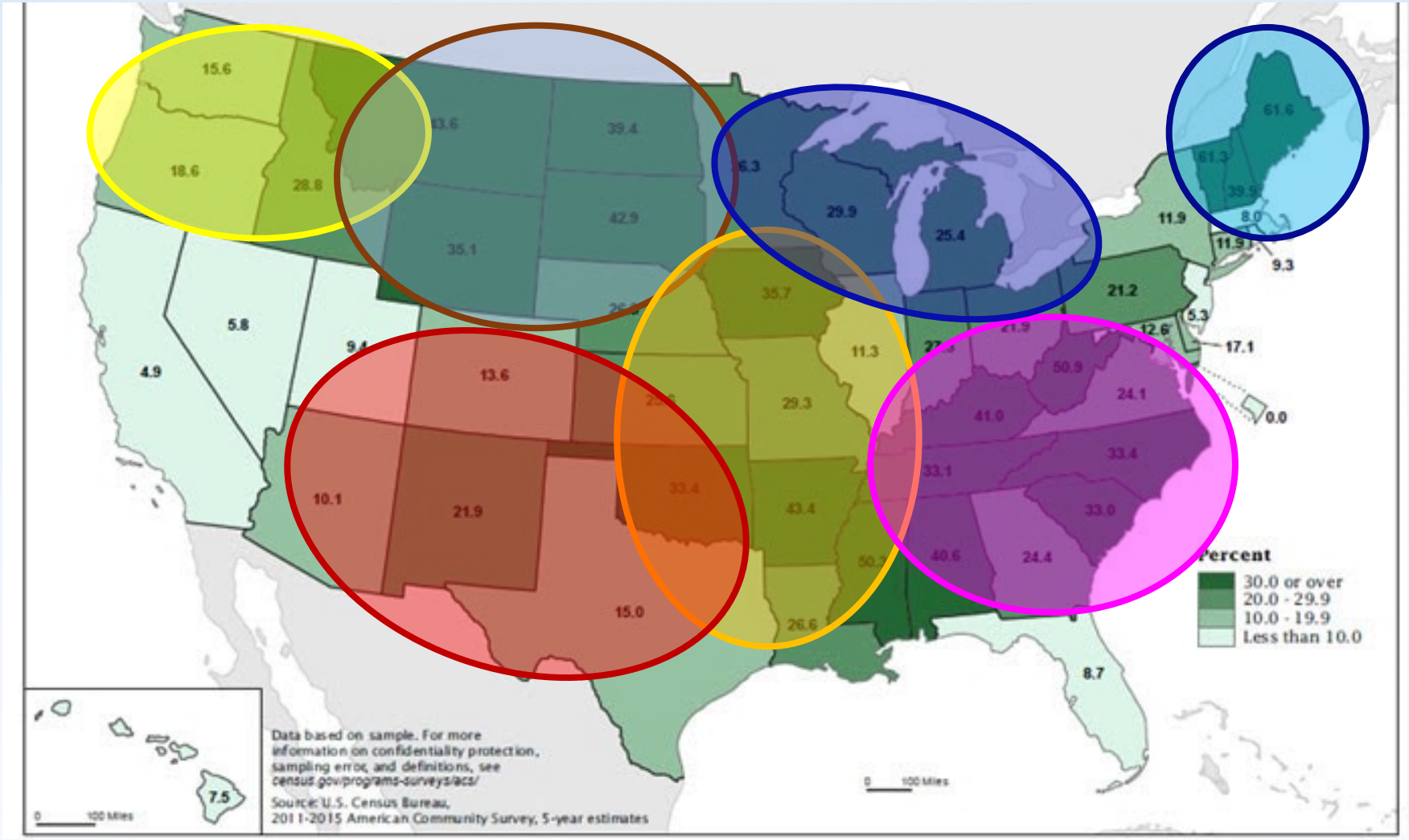
“Spoke and Hub” model for RADIUS telemedicine program



RADIUS - this is how we do it (patient care and mentoring)

- These are one-time visits with the patient, otherwise access becomes a big problem
- The patients follow-up routinely with their referring advanced practice providers (APP) “spoke” provider
- My coordinator and I meet with the APPs on a regular basis (every 1-2 months) to run through their list of patients and give 1:1 mentoring
- If big decisions need to be made, we can see the patients again, but almost always the patients are happy to work directly with their APP in their local community
- Quarterly webinars - didactic teaching and case reviews (all hubs and spokes)
- Annual in person RADIUS symposium

Ultimate Goal of RADIUS



Can the RADIUS model help all adult and pediatric patients with IBD?

- Probably **not just for rural** locations…why not for everywhere?
- All patients with IBD have at minimum a **one-time comprehensive visit** with an IBD specialist TEAM
- **Local "community" providers** managing their patients and specialists used to guide early disease management, identify patients needing extra support, and to be creative with advanced and complicated disease
- Patients (and family) are able to **stay in their community** for care
- IBD specialist team **mentors the local teams** (MD, APP, psychologist, pharmacists, social works, dietitians)
- **If this one of many options to change the current model of IBD care?**

Summary

- We have many great treatments available, but we need to work on how to get the right treatments, to the right patients, at the right time
- We have significant gaps in our current IBD care, many of which are related to barriers preventing progress
- We need to work to close these gaps by:
  - **Optimizing the medications and system that we currently have**
  - **Adding new therapies**
  - **Improving the way that we deliver care to patients with IBD**