



The APPROACH Study: Assessing Pain, Patient Reported Outcomes and Complementary and integrative Health (A VA National Demonstration Project)

VA HSR&D SDR 17-306, Taylor and Zeliadt (PIs)

PIs: Steven Zeliadt (Seattle) and Stephanie Taylor (Los Angeles)
Stephanie.Taylor8@va.gov; Steven.Zeliadt@va.gov

APPROACH
Assessing Pain, Patient Reported Outcomes and
Complementary and integrative Health



APPROACH Research Questions

1) Is combining self-care complementary and integrative health (CIH) therapies with practitioner-delivered CIH more effective at managing pain than practitioner-delivered CIH alone?

- Practitioner-delivered CIH: *Acupuncture, chiropractic care, therapeutic massage*
- Self-care CIH: *Yoga, Tai Chi/Qigong, meditation/mindfulness*

2) How effective are the individual CIH therapies?

..... For pain, depression, stress, physical health, quality of life, well-being, fatigue



Why is This Important

- Self-care therapies might be more powerful than treatments done to you, via activating a feeling of self-empowerment or control over health.



Additional APPROACH Study Details

- **Funding:** VA (\$4.6 million), the only VA-funded study in the NIH-DoD-VA Pain Management Collaboratory
- **Sites:** 18 VA “Whole Health Flagship” sites
- **Population:** 15,800 new CIH users w chronic musculoskeletal pain
- **Sample size goal:** 5,600 by April 2023 (6,841 baseline participants)
- **Pragmatic trial design:** Randomization isn’t feasible/desirable because it would mean withholding available treatments
- **Data:** VA’s OPCC&CT’s CIH Experience Survey data
- **Study results:** 2024



Key Topics Discussing Today

- **Study enrollment – through VA's CIH Experience Survey**
 - Completed 2 years of invitations to 15,800 Veterans with chronic pain newly starting CIH. Outcome data at 6 months anticipated on 6000+ Veterans
 - Discussion of sampling new users for CIH Experience Survey - Most Veterans starting CIH in the last 2 years have significant chronic pain
- **Veterans participating in lots of CIH**
 - Overview of our strategies for measuring detailed CIH use – Survey & EHR/Comm Claims
- **APPROACH Study's pragmatic/quasi-experimental design**
 - Using natural variation in patterns of combining self-care with practitioner-care as substitute for randomization
 - Sources of variation over time (including during COVID): availability, incentives, structures



APPROACH Study Team

- Barbara Bokhour, PhD
- Claire Chen, MPH
- Scott Coggeshall, PhD
- Claudia Der-Martirosian, PhD
- Jamie Douglas, MA
- Rani Elwy, PhD
- Spencer Hildie, BS
- Danna Kasom, BS
- Alexander Kloehn, MPH, RDN
- Karl Lorenz, MD, MSHS
- Briana Lott, MPH
- Michael McGowan, MA
- Melissa Medich, PhD
- Marlena Shin, JD, MPH
- Stephanie Taylor, PhD, MPH
- Joy Toyama, DrPH
- Michelle Upham, MSW
- Steven Zeliadt, PhD, MPH
- Xiaoyi Zhang, MS



APPROACH Study Advisory Board

	Researcher	VA CIH Practitioner
Meditation/ MBSR	David Kearney , MD; VA Puget Sound/ Univ. Washington	Greg Serpa , PhD; VA Los Angeles; Mindfulness Consultant OPCC&CT
Chiropractic Care	Christine Goertz , DC, PhD; Prof. Musculoskeletal Research, Vice Chair for Implementation of Spine Health Innovation, Duke University	Anthony J. Lisi , D.C.; VA National Dir. Chiropractic Service
Acupuncture	Claudia Witt , MD; Chair Complementary Med, Univ. of Zurich	Juli Olson , DC, LA; VA National Lead, Acupuncture
Yoga	Robert Saper , MD; Dir. Integrative Med.; Assoc. Prof. Family Med., Boston Univ.	Pam Pence ; VA Long Beach; Louise Mahoney , VA Palo Alto
Tai Chi	Peter Wayne , Ph.D; Harvard –Assoc. Prof. of Medicine Dir. of Research, Osher Center, Brigham and Women’s, also practitioner	Ansgar Furst , PhD; VA Palo Alto/ Stanford Psychiatry & Neurology; Also researcher
Other	Pain - Friedhelm Sandbrink MD; Dir, Nat’l Pain Mgmt. Program, VHA; Multi-site trials - Jeffery A Dusek , PhD; Dir. Research, University Hospitals Connor Whole Health; Assoc Prof., Case Western	



- 1 of 11 Trials funded by NIH-DOD-VA Pain Management Collaboratory

<https://painmanagementcollaboratory.org/>





CIH Experience Survey

- Electronic survey (web/telephone)
 - Administered by external group with invitations from VA email/VA leaders
 - 4 timepoints across 6 month period
- Asks use over last 4 weeks
- List of 6 therapies
 - Chiropractic care, acupuncture, massage therapy, yoga, Tai Chi/Qigong, meditation
 - Did you use? If used, there are additional questions



Did you do any of the following therapies or activities in the past **four weeks** or **are you about to start** doing any of them?

Chiropractic care

- Yes, I used it in the last four weeks
- Yes, I am about to start doing this
- No, I have not used it and am not just about to start using it

Next

Back

For each **Chiropractic Care** visit in the past 4 weeks, where did you get it? At the VA or in the community?

- I got visits with a VA provider
- I got visits with a provider in the community
- I'm not sure

Next

Back



For each **Tai Chi** or **Qigong** class or session you did in the **past 4 weeks**, where did you do it?

- I did classes or sessions in-person with a VA provider.
- I did classes or sessions at home guided by a VA provider
- I did classes or sessions in-person with a community provider.
- I did classes or sessions at home guided by a community provider.
- I did classes or sessions on my own using a recording, video, or app.
- I'm not sure

Next

Back



Enrollment

- Baseline responders 6,841 - 35.3% overall baseline participation rate
 - \$2 pre-incentive; email invites with simultaneously mailed letters
- 6 month completion/eligibility data are starting to be analyzed
- 94.1% 6 month retention; Survey company suggested \$10 'last chance' incentive
- Sneak Peak Results - Qualifying for APPROACH study (preliminary 6 month data)
 - 48% Practitioner-only
 - 39% Dual
 - 9% Self-care only
 - 4% Ineligible



Identify Weekly Users – Survey Sampling

- New Users
 - No CIH codes in EHR in prior 6 months
 - Over 20 weeks we identified 21,169 “new CIH users” at 18 sites



Overall Sample of Invited New CIH Users

Practitioner-Delivered	84%
Self-Care	16%

Chiro - VA	18%
Chiro -Community	31%
Acup - VA	9%
Acup - Community	18%
Massage - VA	3%
Massage - Community	5%
Tai Chi - In-person	1%
Tai Chi - Tele	3%
Yoga - In-person	1%
Yoga - Tele	3%
Meditation - In-person	3%
Meditation - Tele	5%



Community Care and Tele-CIH

Among Practitioner-Delivered CIH

VA	35%
Community	65%



EHR Identification of Chronic Pain

- 1) ICD Diagnosis of musculoskeletal disorders associated with pain
- 2) Numeric Rating Scale (0-10 Pain intensity)

Algorithm 1: Any pain in past year

≥ 1 MSK Pain ICD10 code in past year

80.4% (17,030/21,169 new CIH users)

Algorithm 2: Moderate/Severe Chronic Pain in past year

≥1 MSK Pain ICD10 code + ≥2 Numerical Rating Scale (NRS) scores ≥4 that were ≥30 days apart in past year

27.1% (5,729/21,169 new CIH users)



Cross Validation with Survey

Survey Respondents (Most sampling weeks focused on Algorithm 2;
Two sampling weeks expanded to Algorithm 1)

Algorithm 1: Any Chronic Pain in past year

91.9% Indicated Most/Every day (479/521)

Algorithm 2: Moderate/Severe Chronic Pain in past year

96.1% Indicated Most/Every day (1,741/1,811)

Zelaya CE, Dahlhamer JM, Lucas JW, Connor EM. Chronic pain and high-impact chronic pain among U.S. adults, 2019. NCHS Data Brief, no 390. Hyattsville, MD: National Center for Health Statistics. 2020.

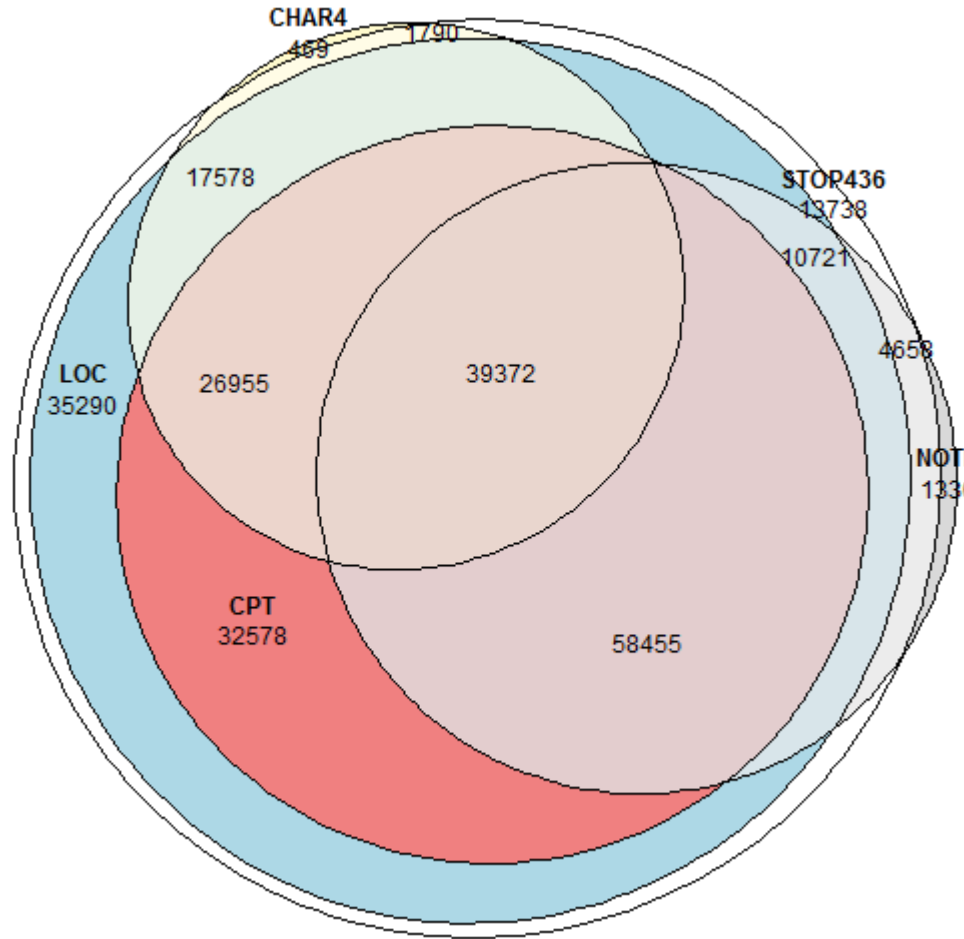


Measuring Detailed CIH Use

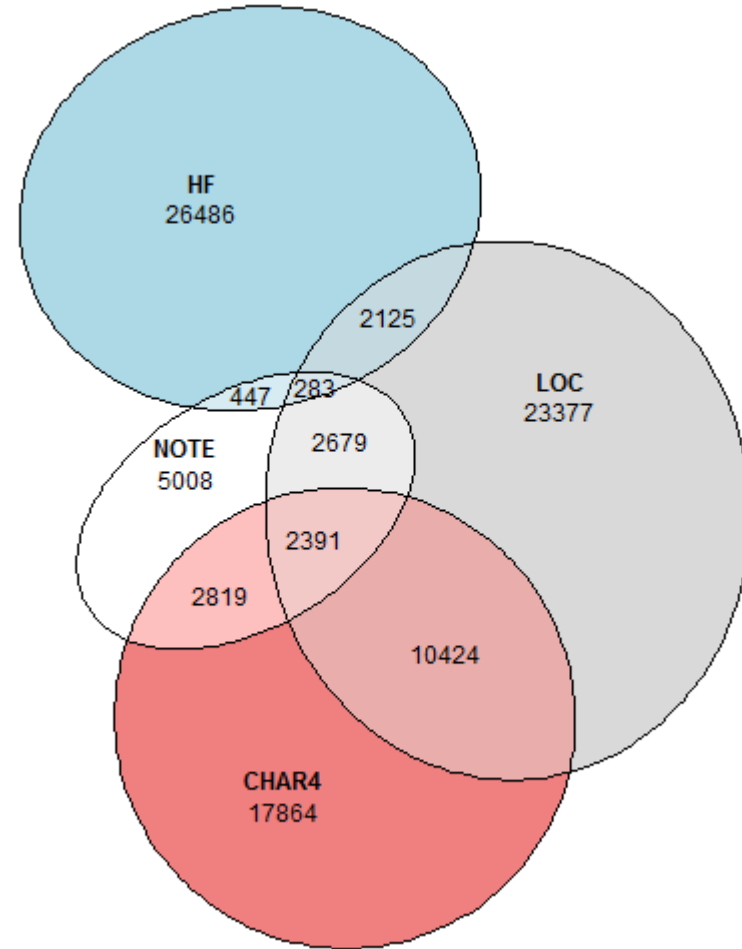
- 1) EHR/Community care claims
- 2) VA's CIH Experience Survey



Using EHR to Identify CIH



Chiropractic Care



Meditation



Did you do any of the following therapies or activities in the past **four weeks** or **are you about to start** doing any of them?

Chiropractic care

- Yes, I used it in the last four weeks
- Yes, I am about to start doing this
- No, I have not used it and am not just about to start using it

Next

Back

For each **Chiropractic Care** visit in the past 4 weeks, where did you get it? At the VA or in the community?

- I got visits with a VA provider
- I got visits with a provider in the community
- I'm not sure

Next

Back



For each **Tai Chi** or **Qigong** class or session you did in the **past 4 weeks**, where did you do it?

- I did classes or sessions in-person with a VA provider.
- I did classes or sessions at home guided by a VA provider
- I did classes or sessions in-person with a community provider.
- I did classes or sessions at home guided by a community provider.
- I did classes or sessions on my own using a recording, video, or app.
- I'm not sure

Next

Back



Acupuncture Utilization – Harmonizing Data

Survey (no self-pay or other insurance)

	<u>Yes</u>	<u>No</u>	<u>Total</u>	
EHR	Yes	94	171	265
	No	91	2235	2326
	Total	185	2406	2591 (overall concordance 89.9%)



Acupuncture Utilization – Harmonizing Data

Survey (no self-pay or other insurance)

	<u>Yes</u>	<u>No</u>	<u>Total</u>	
EHR	Yes	94	171	265
	No	91	2235	2326
	Total	185	2406	2591 (overall concordance 89.9%)

Survey (no self-pay or other insurance)

		<u>Yes</u>	<u>No</u>	<u>Total</u>
EHR	Yes	94	171	265
	No	91		
	Total	185		356

Survey (no self-pay or other insurance)

		<u>Yes</u>	<u>No</u>	<u>Total</u>
EHR	Yes	0.26	0.48	
	No	0.26		
	Total			1.00



Interviews about Survey Sampling Discordance

Among 30 interviews with discordant EHR/Baseline survey data:

- 14 patients **used** CIH, but timing was different than shown in EHR
- Visit in EHR had actually been cancelled (n=2)
 - Rescheduling/cancellations of real-time EHR sampling pulls usually corrected with future EHR pulls
 - Challenge with community referral EHR documentation + lag with actual community billing data
- Patient didn't recall participating in EHR therapy (n=10)
- Upon review with interviewer, survey info inaccurate (n=4)

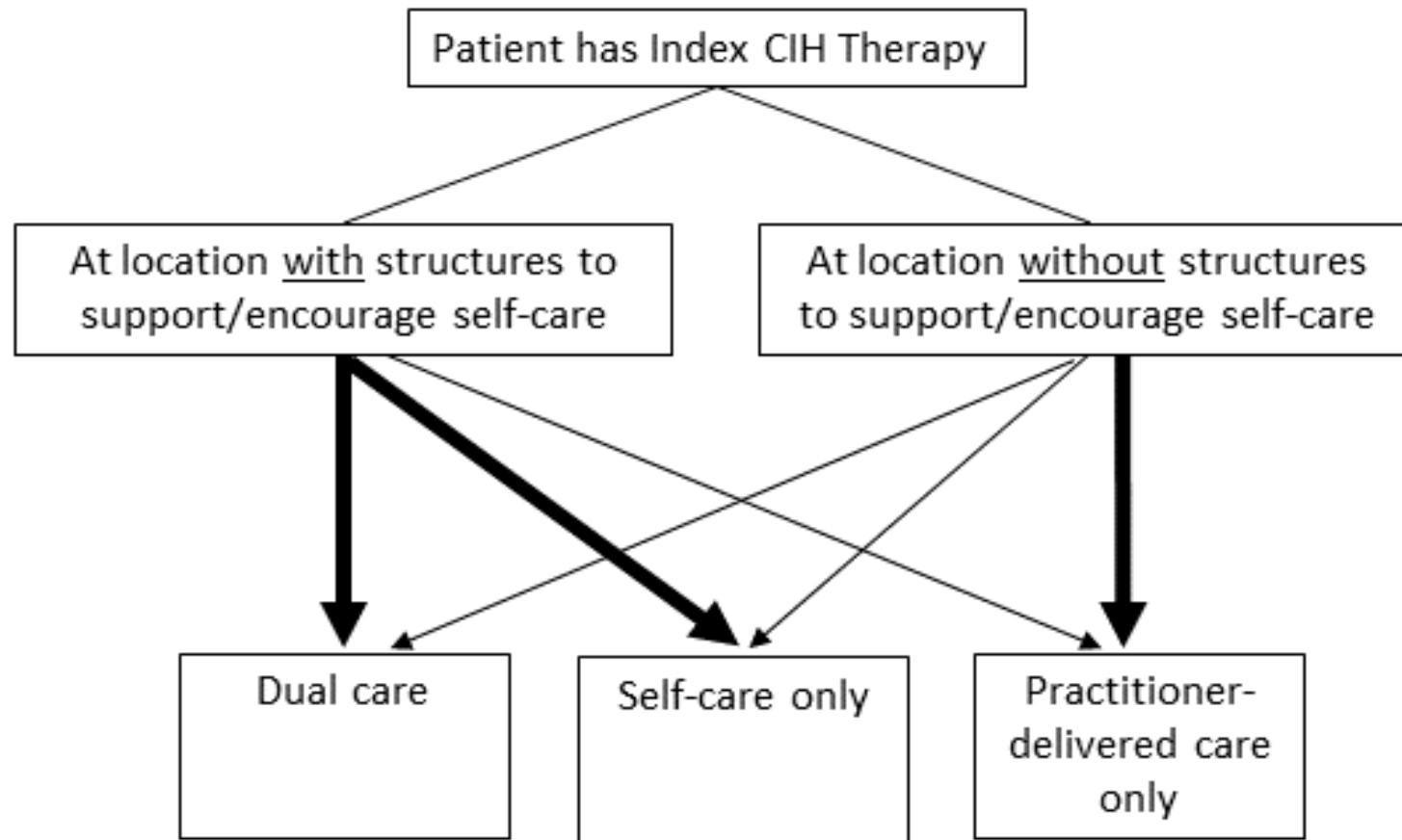


APPROACH Pragmatic Methods

- APPROACH is a 100% pragmatic trial
 - We are conducting it within a healthcare system and aren't interfering with the delivery of CIH care for this study at all.
- Although pragmatic trials are easier for healthcare systems, they bring their own methodological challenges for researchers.
- Share methodological challenges and how we are addressing them.



Quasi-Experimental Treatment Assignment



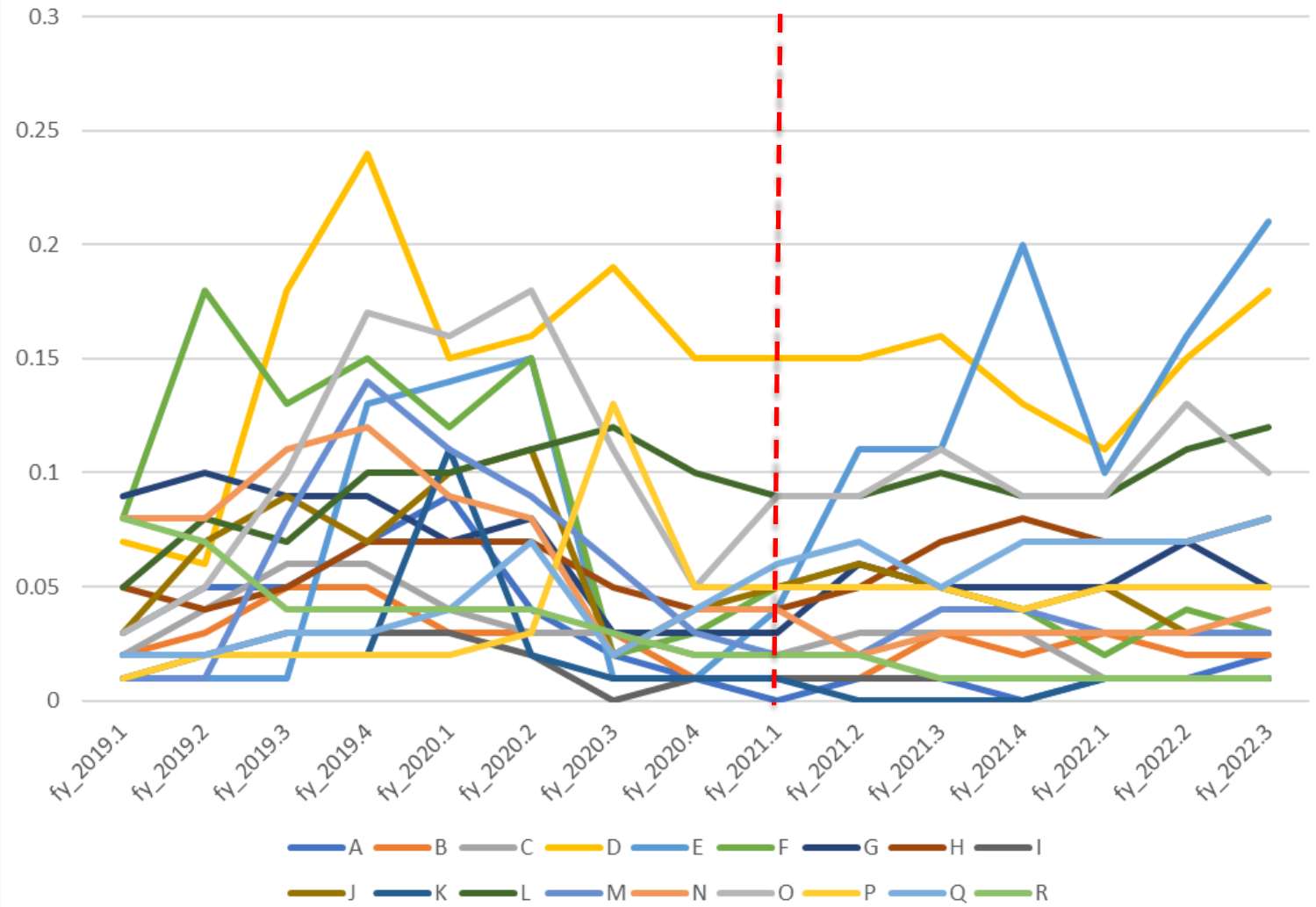


Comparing Practitioner-only CIH to Dual care

- Qualifying for APPROACH study (preliminary 6 month data)
 - 48% Practitioner-only
 - 39% Dual
 - 9% Self-care only* (Most Veterans initiating self-care CIH – 16% of invited sample – go on to use some practitioner-delivered CIH over 6-month period)
 - 4% Ineligible
- Low rates of self-care CIH only
 - Study is embedded in healthcare system offering many practitioner options
 - EHR sampling strategy

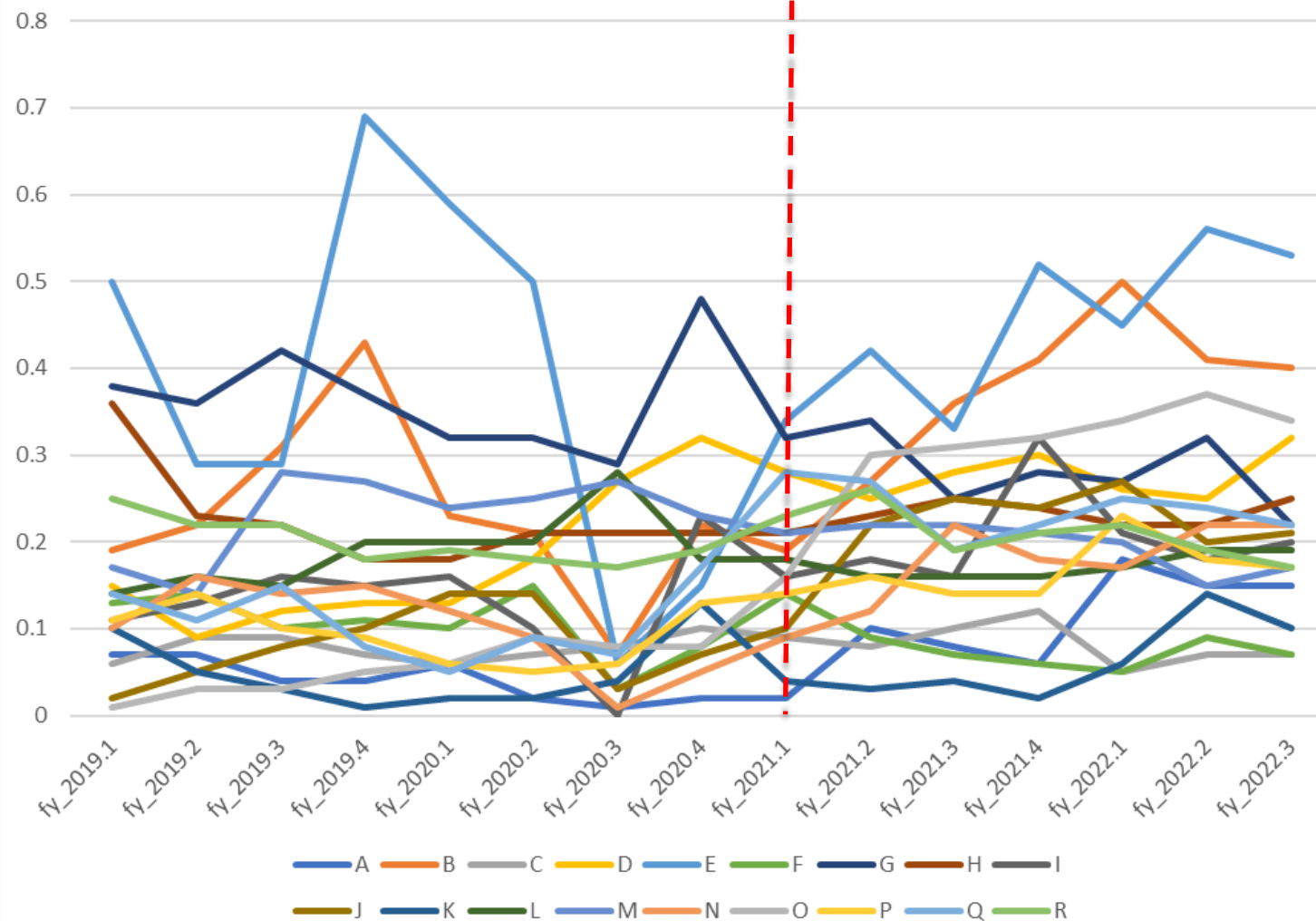


% Dual Use by Flagship Site - Initiating with Practitioner CIH



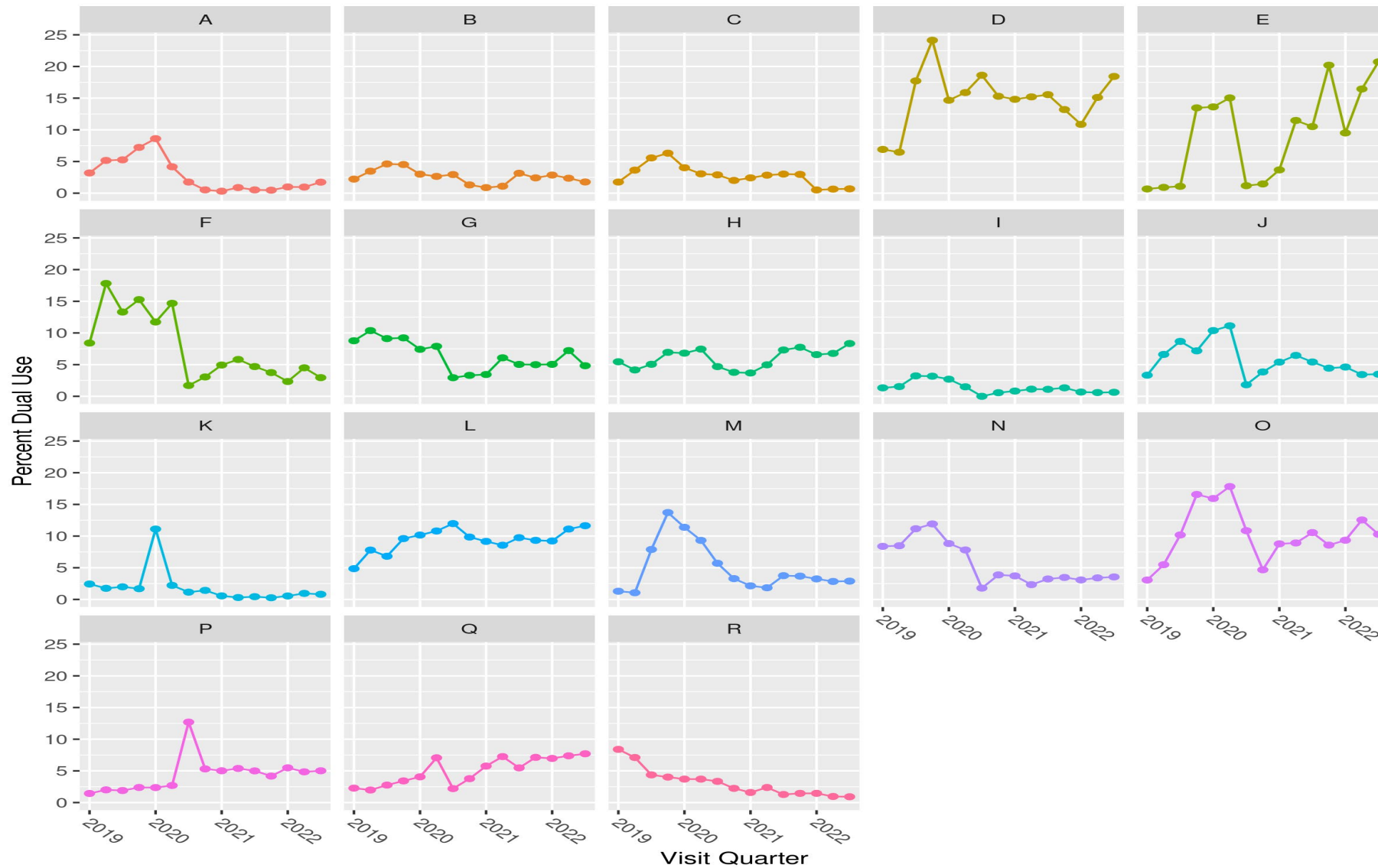


% Dual Use by Flagship Site - Initiating with Self-Care CIH





Overall Patterns of Dual Use by Site





Take Home Messages

- Evidence coming in Summer 2023 about benefits of combining self-care CIH with practitioner-delivered care
- Methods for capturing details about CIH use, especially self-care CIH/tele-CIH use, are rapidly evolving
- EHR is a potential source of data about CIH utilization but there are caveats; Survey data are important



Additional Details

- Stephanie Taylor (stephanie.taylor8@va.gov)
- Steven Zeliadt (steven.zeliadt@va.gov)
- Zeliadt SB, Coggeshall S, Thomas E, Gelman H, Taylor SL. The APPROACH trial: Assessing pain, patient-reported outcomes, and complementary and integrative health. Clin Trials. 2020 Aug;17(4):351-359
- Zeliadt SB, Gelman H, Shin MH, Elwy R, Bokhour BG, Coggeshall S, Taylor SL. Assessing the Relative Effectiveness of Self-Care and Provider-Delivered CIH Therapies to Improve Pain in a Pragmatic Trial. Pain Medicine. 2020 Dec; 21(S2): S100–S109
- Der-Martirosian C, Shin M, Upham ML, Douglas JH, Zeliadt SB, Taylor SL. Telehealth Complementary and Integrative Health Therapies During COVID-19 at the U.S. Department of Veterans Affairs. Telemed J E Health. 2022 Jul 22. doi: 10.1089/tmj.2022.0209. PMID: 35867052.