



The HOPE Trial Consortium

Engagement and Participation of Patient Advisors with Lived Experiences in the HOPE Consortium Clinical trial to reduce Pain and Opioid Use in Hemodialysis– from inception through dissemination

DISCLOSURE

- No relevant disclosures



- **Denise Esserman, PhD** – Discussion Moderator
- **Michael Fischer, MD** – Overview of HOPE Trial Design
- **Paul Kimmel, MD** – NIDDK Advocacy of Patient Engagement
- **Dave M. White** – Patient Advisor Perspective
- **Sagar Nigwekar, MD** – Patient Advisor Involvement in HOPE Committees & Impact of Patient Engagement on the MGH Clinical Center
- **Sarah Schrauben, MD** – Clinical Investigator Perspective on Patient Engagement
- **Svetlana Vassilieva, MD** – Study Coordinator Perspective of Patient Advisor Engagement on Recruitment & Retention
- **Heather B Howell, MSW**- Coaches Partnering with HOPE Trial Participants to Prioritize Patient Goals
- **Leah Bernardo** – Logistics & Coordination of Involving Patient Advisors in Research



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Hemodialysis Opioid Prescription Effort (HOPE) Consortium Trial to Reduce Pain and Opioid Use in Hemodialysis

- Slides adapted from HOPE DSMB presentation by Laura Dember, MD

Pain and Opioid Use in Hemodialysis



- 60% of hemodialysis patients report pain
- Patients have identified symptom relief as a top research priority and recommended pain as a core outcome for hemodialysis clinical trials
- Management is particularly challenging due to:
 - Pharmacologic properties / medication toxicities
 - Concurrent depression, anxiety, and frailty
 - Lack of expertise by nephrologists in pain management
 - Limited access for patients to non-nephrologist care providers
- Analyses of data from the United States Renal Data System (2006 – 2010) found:
 - 60% of dialysis patients had 1 or more opioid prescriptions during any 12-month period, and 20% had prescriptions for ≥ 90 days per 12 months
 - Opioid use was associated with increased risk of falls, fractures, hospitalizations, and death

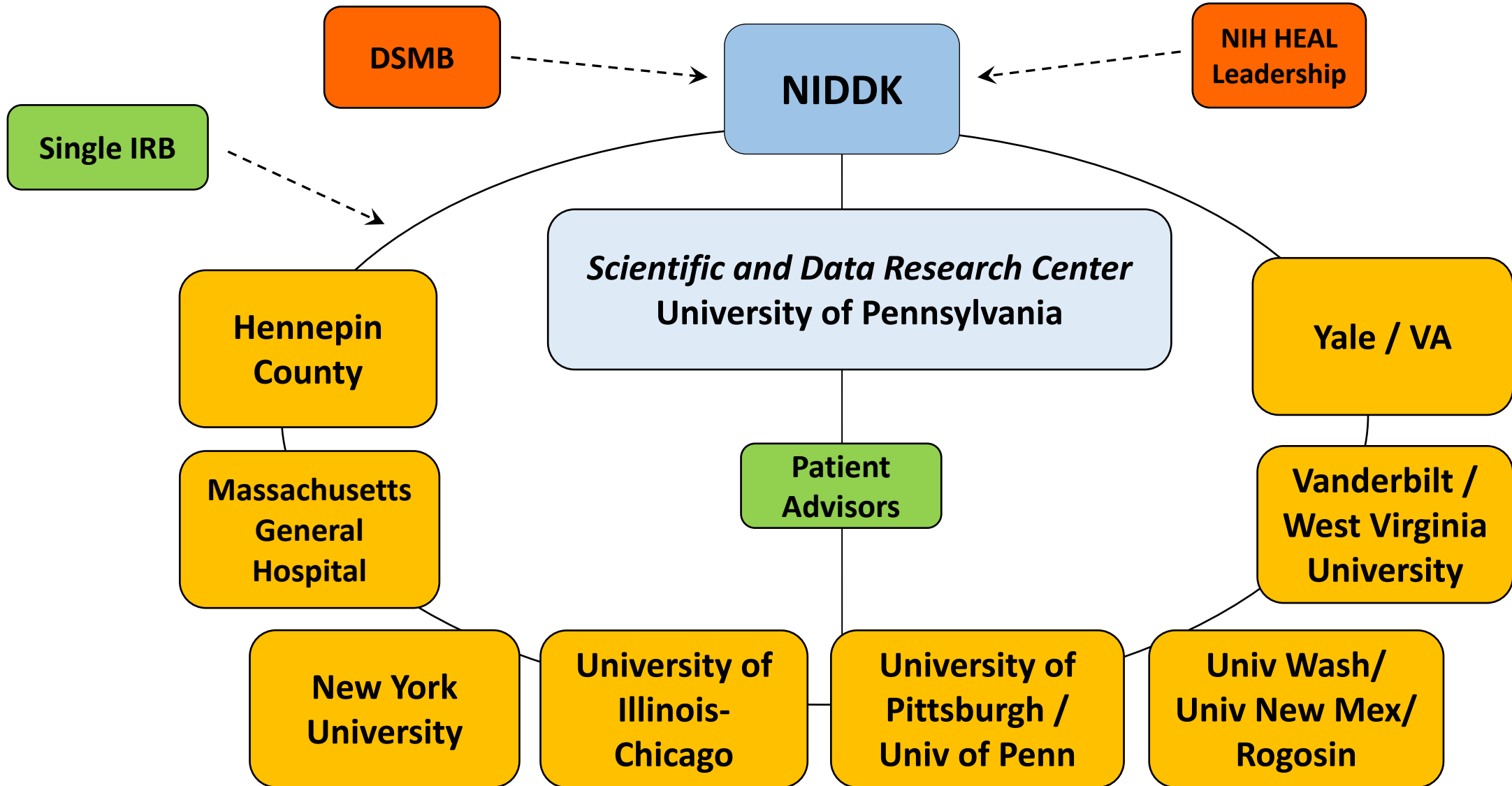
HEAL and NIDDK Charge

(RFA 18-030 and 18-031)



- Multicenter randomized trial evaluating both non-pharmacologic and pharmacologic approaches for reducing pain and opioid use in maintenance hemodialysis
- Clinical Center and SDRC applications
 - Trial proposal
 - Multiple-PI structure that includes expertise in nephrology, pain, opioid use, medication assisted therapy, and biostatistics
 - Patient advisors
- Design trial collaboratively post-award by full group of grant recipients, including patient advisors

Consortium Structure



Trial Questions



Primary Question

- Does pain coping skills training reduce pain interference?

Secondary (Exploratory)

- Is buprenorphine acceptable, well tolerated, and efficacious as an alternative to full agonist opioids for patients taking opioids for pain?

Additional Questions

- Does pain coping skills training improve other patient-reported outcomes?

Secondary Outcomes



1. Pain and Opioid Use*

Domain	Instrument or Data Source	Look-Back Period	Time-Points for Assessment
Pain intensity	Brief Pain Inventory (BPI) Severity	7 days	Weeks 0, 12, 24, 36
Pain catastrophizing	Pain Catastrophizing Scale – SF 6	None	Weeks 0, 12, 24, 36
Opioid use	Timeline <u>Followback</u>	30 days	Weeks 0, 12, 24, 36
Composite of pain and opioid use	BPI Interference / Timeline <u>Followback</u>	7 days/30 days	Weeks 0, 12, 24, 36

2. Conditions or Symptoms Associated with Pain or Opioid Use*

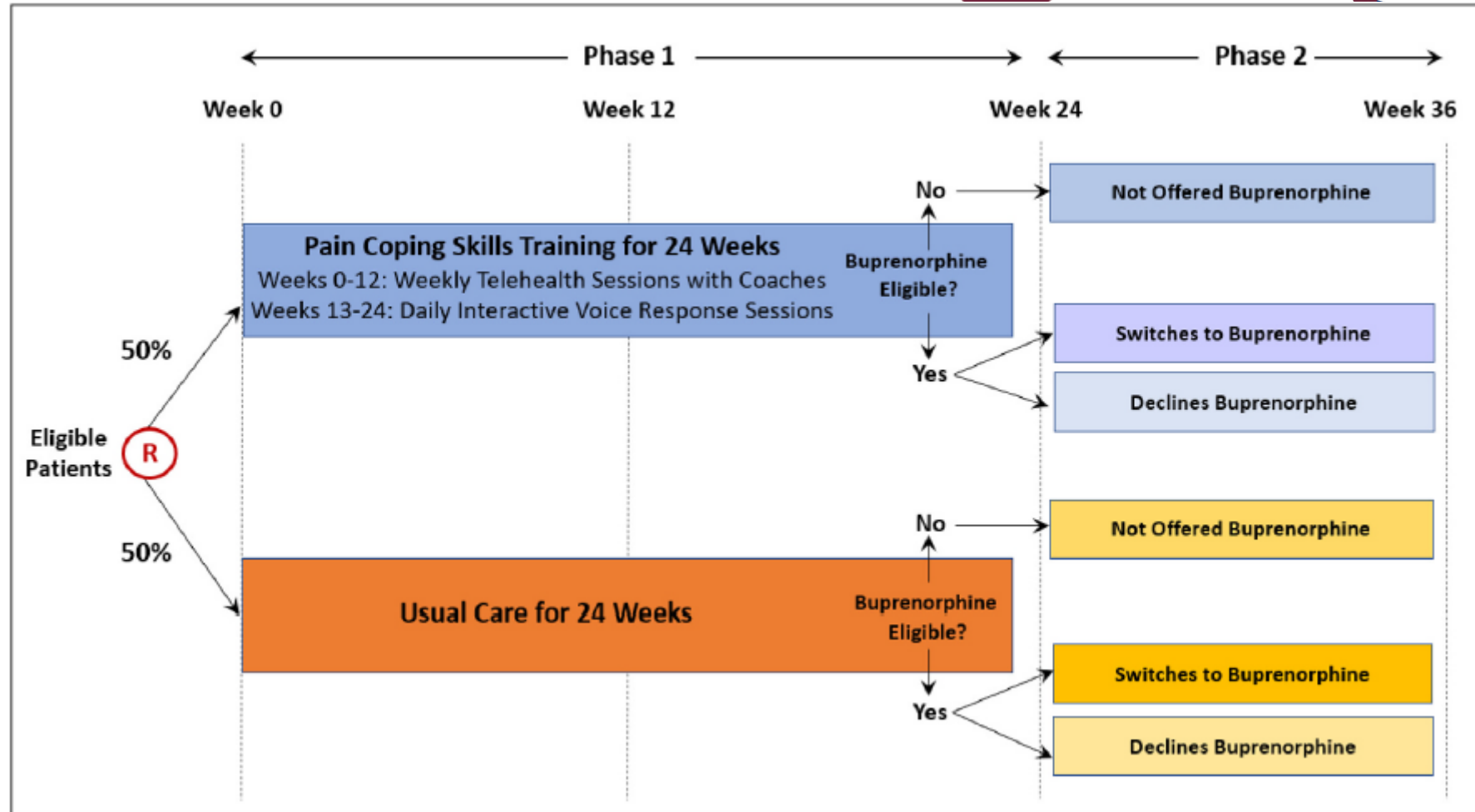
Domain	Instrument or Data Source	Time-Points for Assessment
Depression	Patient Health Questionnaire (PHQ)-9	Weeks 0, 12, 24, 36
Anxiety	Generalized Anxiety Disorder (GAD)-7	Weeks 0, 12, 24, 36
Sleep quality	PROMIS Sleep Disturbance 6a + Sleep Duration Question	Weeks 0, 12, 24, 36
Fatigue	PROMIS Fatigue SF 6a	Weeks 0, 12, 24, 36
Other symptoms	Dialysis Symptom Index	Weeks 0, 12, 24, 36
Physical functioning	PROMIS Physical Functioning SF 6b	Weeks 0, 12, 24, 36
Coping	Coping Strategies Questionnaire: 1-item version	Weeks 0, 12, 24, 36
Quality of Life	Single Item Quality of Life Measure	Weeks 0, 12, 24, 36
Self-efficacy	Chronic Pain Self-Efficacy Scale (CPSS)	Weeks 0, 12, 24, 36
Discrimination	Everyday Discrimination Scale	Weeks 0, 36
Satisfaction	Patient Global Impression of Change	Weeks 0, 12, 24, 36
Family intrusion	PROMIS Satisfaction with Social Roles and Activities	Weeks 0, 12, 24, 36
Social support	Multidimensional Scale of Perceived Social Support (MSPSS)	Weeks 0, 12, 24, 36

*All ascertained using centralized computer assisted telephone interviewing (CATI)

The results of the CATI questionnaires will not be provided to research teams

3. Clinical Events: falls, hospitalizations, deaths (ascertained by Clinical Center research coordinators)

Trial Design



Eligibility Criteria



Inclusion	Exclusion
Age ≥ 18 years	Moderate or severe opioid use disorder
English- or Spanish-speaking	On methadone, buprenorphine, or naltrexone for OUD
Undergoing in-center maintenance hemodialysis for ≥90 days	Current heroin use
Chronic pain defined as a response of “Most days” or “Every day” to the following question: “In the past 3 months, how often have you had pain?” Answer options: Never, Some days, Most days, Every day	Moderate or severe non-opioid substance use disorder with exception of tobacco use disorder
	Severe cognitive impairment on the Mini-COG administered before dialysis or on a non-dialysis day
Current PEG score ≥ 4	Unstable bipolar disorder, schizophrenia, post-traumatic stress disorder, other psychotic disorder or active suicidal intent
In subset of at least 300: Prescription opioid use during at least 3 of the past 6 months	Hospice care or life expectancy < 6 months
	Anticipated kidney transplant, transfer to another dialysis facility, or change to home dialysis within 6 months

Pain Coping Skills Training (PCST)



- Psycho-educational approach that incorporates:
 - Cognitive behavioral pain coping skills - the most studied non-pharmacologic treatment for chronic pain, endorsed by the CDC and American College of Physicians
 - Motivational Interviewing - widely used to reduce opioid use
 - These approaches have been used by HOPE investigators in previous trials for pain* and in patients treated with dialysis#
- Goal is to help patients develop skills to manage pain-associated disability and emotional distress, and to reduce opioid use
- Trial will use a central pool of coaches with standardized training and ongoing oversight

*Keefe F et al. Pain coping skills training in the management of osteoarthritic knee pain: a comparative study; *Behavior Therapy* 1990; 21: 49-62

Heapy A, et al. Interactive voice response-based self-management for chronic back pain; *JAMA Internal Medicine* 2017; 177 765-773

#Mehrotra R, Cukor D, et al. Comparative efficacy of therapies for treatment of depression for patients undergoing maintenance hemodialysis: a randomized clinical trial. *Ann Internal Med* 2019; 170:369-379

Pain Coping Skills Training



Baseline

Week 12

Week 24

Weekly Telehealth Sessions

Daily Assessment Calls

Pain Coping Skills Training Telehealth Sessions
(Cognitive Behavioral Therapy + Motivational Interviewing)

Weekly 45 minute sessions
Telehealth 1 on 1 with live coach



Interactive Voice Response (IVR) Booster Sessions
(Touchtone phone and voice messages with coach)

Customized Messages +
Asynchronous Weekly Coach Feedback +
Self-Paced Skill Review



Usual Care



- Participants receive written educational materials about chronic pain, opioid medications, and available resources
- Treating clinicians will be provided with information about the trial and participant's randomized assignment

Monitoring and Maintaining Safety



- SAEs and Adverse Events of Interest ascertained through participant contacts every 4 weeks
- AEs of Interest
 - Withdrawal symptoms (via SOWS)
 - Suicidality
 - Development of opioid or other substance use disorder
 - AE from any medication started during the trial to address pain, depression, or anxiety
- All Clinical Centers have investigators with expertise in opioid use, pain management, buprenorphine administration, mental health, and nephrology
- Specific plan for suicidality identified by CATI team (PHQ-9, question 9) or research teams
 - Research team notified, Columbia Suicide Severity Scale administered, arrangements for care made
- Specific plan for substance use disorder that develops or becomes evident during the trial
 - Referral to non-study clinicians for evidenced-based SUD care

Alignment with Dialysis Providers



- Anticipated benefits of PCST are highly consonant with goals of dialysis providers. If effective, patients should:
 - Feel better
 - Have less depression and anxiety
 - Be more engaged in care
 - Be more satisfied with care
 - Be more adherent with treatment
 - Have better quality of life
 - Have fewer hospitalizations
- Buprenorphine may have many of the same benefits as PCST, plus reduction in morbidity and mortality; all are consistent with dialysis provider goals
- Addressing the opioid epidemic should be viewed as positive by dialysis providers

Where did study activities occur?



- This trial began in 2020 = onset of COVID-19 pandemic
- Face-to-face: pre-screening, screening, and consent
- CATI: most data collection activities occurred via CATI
- Pain coping skills training intervention
 - Generally during dialysis (using facility wifi) – preferred by participants
 - Devices for use in the dialysis unit provided with cleaning protocols and secure storage
 - Head-set so other patients cannot hear coach and highly sensitive microphones allowed patients to speak quietly while also not detecting extraneous noise

Sample Size



- Total goal participant sample for consortium: **640 participants**
- Timeline was to complete sample randomization by **6/1/23**

Enrollment



- Prescreening began: **12/28/20**
- First randomized participant: **1/22/21**
- **640** participants randomized: **3/29/23**
 - 3 additional participants randomized by 4/7/23 before study closed
- **Total: 643 participants**

HOPE Consortium Trial

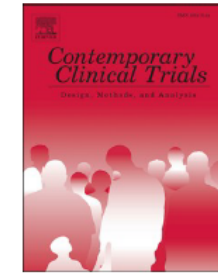


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The design and baseline characteristics for the HOPE Consortium Trial to reduce pain and opioid use in hemodialysis



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HOPE Baseline Characteristics



Demographic characteristics

Age, years	60.2 (12.8)
Female	288 (44.8%)
American Indian or Alaskan Native	22 (3.4%)
Asian	6 (0.9%)
Black	308 (47.9%)
Native Hawaiian or Other Pacific Islander	6 (0.9%)
White	209 (32.5%)
Multiple Races	11 (1.7%)
Race not reported	81 (12.6%)
Hispanic or Latino	119 (18.5%)
Ethnicity not reported	7 (1.1%)

HOPE Baseline Characteristics



Clinical Characteristics

Post-dialysis BMI, kg/m ²	31.3 (12.7)
Pre-dialysis systolic BP, mm Hg	144.2 (25.4)
Pre-dialysis diastolic BP, mm Hg	76.8 (15.7)
Duration of dialysis treatment, years	4.5 (4.7)

HOPE Baseline Characteristics



Comorbidities

Diabetes mellitus	380 (59.1%)
Coronary artery disease	175 (27.2%)
Heart failure	169 (26.3%)
Atrial fibrillation or flutter	113 (17.6%)
Ventricular arrhythmia	33 (5.1%)
Heart valve replacement or repair	35 (5.4%)
Stroke or transient ischemic attack	128 (19.9%)
Peripheral vascular disease	102 (15.9%)
Cancer	106 (16.5%)

HOPE Baseline Characteristics



Substance Use

Opioid use during 3 of the last 6 months	144 (22.4%)
Opioid use during the last 14 days	161 (25.0%)
Average MME/day for those with opioid use during the last 14 days	6.4 (0.0–22.5)
Current or former tobacco use	321 (49.9%)
Current alcohol use	64 (10.0%)

HOPE Baseline Characteristics



Laboratory Values

Blood urea nitrogen, mg/dL	54.0 (22.5)
Creatinine, mg/dL	9.3 (3.9)
Albumin, g/dL	3.9 (0.4)
Hemoglobin, g/dL	10.9 (1.7)
Bicarbonate, mEq/L	24.3 (4.1)
Kt/V	1.6 (0.3)

HOPE Baseline Characteristics



Pain

BPI Interference¹

6.57
(5.14–7.86)

BPI Severity¹

6.00
(4.50–7.50)

Possible range is 0–10 with higher scores indicating more pain interference or more severe pain, respectively.

Summary



- Large diverse population of maintenance hemodialysis patients enrolled who reflect the overall US dialysis population
- Substantial pain interference and intensity among the enrolled cohort
- Enrollment targets met ahead of schedule for many reasons
 - Trial addressed something important to patients
 - Highly engaged patient advisors who informed recruitment materials
 - Supportive dialysis partners



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NIDDK Perspectives



- The Kidney Urologic and Hematologic (KUH) Division of NIDDK included requirements for Patient Advisors in RFAs for the Kidney Precision Medicine project (KPMP) and APOL1 Long-term Outcomes studies (2017).
- Participation of Patient Advisors was required of each of the Clinical Centers and the Coordinating Center by the foundational RFAs for the HOPE trial.
- KUH has made a commitment to include the patient voice in all stages of research development and conduct, from workshops, to research applications, to the conduct and internal and external oversight of studies and the reporting and dissemination of research results to the scientific and patient communities.
- Kimmel PL, Jefferson N, Norton JM, Star RAL CJASN 14:768-770, 2019

NIDDK and Patient Engagement in HOPE



- Patient Advisors participated in all Steering Committee meetings.
- Patient Advisors participated on the Recruitment Committee, and on the Patient Advisor Committee, as well as the Quality Assurance and other study Committees.
- Patient Advisors were included as authors on study publications
- Additional Patient Advisors (independent of study Patient Advisors) were included in the external Data and Safety Monitoring Board.
- Patient Advisors consulted on and appeared in a recruitment video which was fundamental to the recruitment success of the HOPE Consortium.



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HOPE Trial Patient Advisors



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Punta Gorda, FL

Scientific and Data
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Robert Grindstaff, MD

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Dave White

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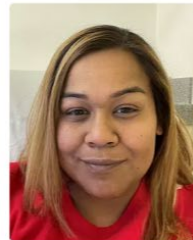
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PATIENT VOICE

Appropriate Use of Opioids in Patients with Kidney Diseases

White, David M.

[Author Information](#)

Clinical Journal of the American Society of Nephrology 13(5):p 675-676, May 2018. | DOI: 10.2215/CJN.03540318

OPEN

Metrics

In this issue of the *Clinical Journal of the American Society of Nephrology*, Ishida *et al.* report on an investigation using data from the US Renal Data System to investigate the effects of opioids on patients on hemodialysis (1). The timely findings of Dr. Julie Ishida and her colleagues regarding the effects of opioid use on patients on hemodialysis confirm a need for more nephrology-related pain management research. Dr. Ishida's team concluded that there is a correlation between higher opioid dosages and the likelihood of a patient on hemodialysis suffering an adverse event, and that



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HOPE Consortium:

Participant Recruitment and Retention

Massachusetts General Hospital approach developed with inputs from patient advisors



- Participant identification
 - Multiple dialysis organizations as partners- Fresenius, DaVita and Dialysis Clinic Inc.
 - Collaboration with facility nurse manager, nurses, technicians, and social worker
 - Feedback from the attending nephrologist regarding patient candidacy for research
 - Concurrent recruitment activities at >1 dialysis facility
 - Periodically revisiting dialysis facility census due to turnover, hospitalization issues
- Approaching potential participants for clinical trial participation
 - In-person
 - Video outlining study activities
- Dialysis facility staff engagement to bolster retention and recruitment
 - Lunch and learn sessions at dialysis facilities



HOPE Consortium-

Quality Control Committee:

Example of patient representation in Consortium committees

- Quality Control Committee
 - Responsible for ensuring adherence to the best research practices during the conduct of trial and providing assurance that the data and reported results are credible and accurate, and that the rights, integrity, and confidentiality of the trial participants are protected.
 - In addition to clinical and research experts, patient advisor was included as a committee member and the advisor actively participated in monthly meetings of the committee
- Patient advisor input applied to all quality indicators monitored by the committee, for example
 - Timeliness of survey questionnaire completion
 - Comprehensive quality assessment of the behavioral therapy intervention
 - Uncertainty around the thresholds that define quality



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HOPE Consortium:



- Participant feedback from a recruitment center with an urban population on the East Coast while study underway
- Recruitment facilitators
 - Participants appreciated topic of study – a patient- oriented outcome that impacted their quality of life
 - Buprenorphine was optional - based on patient advisors during the design stage; key factor in enrollment
 - Racial concordance of patients and recruitment study team members

HOPE Consortium: Participant Feedback



- Facilitators of study conduct
 - iPad stands – aid in conduct of PCST sessions as most participants limited to one hand, and many suffer from weakness
 - Flexibility of location and mode for PCST sessions – driven by patient preference
 - phone or with iPad
 - dialysis unit or at home
- Suicidality protocol – participants appreciated being connected with dialysis center social worker and outside resources



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Clinical Research Coordinator Perspective - Barriers



- Patient Advisors participated on the Recruitment and Retention Committee
 - Patient Advisors joined Clinical Coordinators' meetings
 - Helped us to resolve challenges: Operational, Emotional and Cultural
- Operational: Study pens for pre-screening for patients to keep
- Cultural: Patient advisors helped develop study Brochure and Flyers showing diversity, advised on terminology and better words to use
- Emotional: Provided tips on how to establish rapport with a dialysis patient

Study Recruitment & Retention – Lessons learned










- Best time to approach dialysis patients
- Have dialysis staff (nurses, social workers, treating nephrologists) to make first introduction
- Education about Chronic Pain for successful pre-screening
- Study teams' diversity helped with trust and language barriers
- Flexibility in means of compensation and timely payments as an incentive for enrollment and retention (use of ClinCards very helpful)
- Future clinical trials should keep a patient Advisory committee
- Recruitment video was a success and could be beneficial in future studies

Recruitment Materials



HOPE

HEMODIALYSIS PAIN REDUCTION EFFORT

Do you suffer from chronic pain that interferes with your usual activities?

Have you felt that your pain was ignored by others?

Have you had bad experiences with pain medication?


HOPE is a research study that is testing ways to improve pain management for patients on dialysis with pain for more than 3 months.

Pain Coping Skills Training involves 12 one-on-one video sessions with a trained coach who will help you learn skills to manage pain.


Later, you might be offered a medication called buprenorphine that may treat your pain with

fewer side effects than traditional opioid medications.

You do not need to be on pain medication in order to participate, and you will not be required to change any pain medication you are currently using.



Helping People on Dialysis Manage Pain



To see if the **HOPE** study might be a good fit for you, complete our survey by going to www.HOPEHDSurvey.org or use your smartphone camera to scan the QR code.

The HOPE study is funded by the National Institute of Diabetes and Digestive and Kidney Diseases



What will I be asked to do?

Other Important Details

Phase 1

During **Phase 1** of the **HOPE** study, you will be randomly assigned (like tossing a coin) into one of two groups: Pain Coping Skills Training (PCST) or Usual Care.


If you are assigned to the PCST group, you will:

-  Attend video-based sessions with a trained coach to help you learn skills to manage your pain (Weeks 1-12)
-  Complete brief, automated, booster phone sessions during which you will be asked to answer questions about your pain (Weeks 13-24)

If you are assigned to the Usual Care group, you will:

Receive information about pain, pain medications, and ways to manage pain. You will continue to work with your usual doctors to manage your pain.

Phase 2

 If you take opioid medication for your pain, at week 24 you may be randomly assigned to one of two groups: buprenorphine or no

Your participation will last 8-10 months

- Participation is voluntary, you can stop at any time
- You will be paid for completing activities

What is the HOPE study?

HOPE is a clinical trial testing two different approaches to help people reduce or manage their pain.

If you regularly experience pain, **HOPE** might be a good fit for you. You do not have to be on pain medication to be in this study.

The study includes two phases, and participants will be in the study for 8-10 months. All study activities will happen during dialysis, over the phone, or over video chat sessions during a time that works best for your schedule.

You can use a tablet or a smart phone to attend video sessions with the research team. If you do not have a tablet or a smart phone, the study will provide one for you to use. You do not need any experience using a tablet or video chat. We are more than happy to teach you!

HOPE

HEMODIALYSIS PAIN REDUCTION EFFORT

Are you a dialysis patient?

The knowledge gained by your participation in the **HOPE** study could help other dialysis patients with pain.

If you are interested in learning more about the **HOPE** study, go to www.HOPEHDSurvey.org





Do you have pain?

If the answer is yes then you may be eligible for a research study that is helping people on dialysis manage pain.



Helping People on Dialysis Manage Pain

The **HOPE** study is funded by the National Institute of Diabetes and Digestive and Kidney Diseases, and is a National Institutes of Health HEAL Initiative trial.



Helping People on Dialysis Manage Pain



Helping People
on Dialysis
Manage Pain

The HOPE Study

Information about a research study
that might be of interest to you

As presented by

The HOPE Patient Advisors



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Pain Coping Skills Training (PCST)



- Coaches provided up to 12-sessions of skills training for hemodialysis patients who reported clinically significant chronic pain.
- Skills training and associated support from health coaches aimed to help individuals reduce pain interference on their day to day quality of life
- Sessions conducted via telehealth (not in person) and either during hemodialysis sessions (in clinic) or outside of session, patient preference
- This clinical trial seems like a magnificent “of course”, “no problem” idea to scientists, but verging on impossible to anyone actually working or receiving healthcare in a community dialysis clinic.
- Patient Advisor Wisdom/lived experience = clinical trial success

Patient advisors made success possible



- Research assistants embedded within clinic
- Consistent coach assignment
- Participant choices in their care-
 - How many sessions?
 - Session format?
 - Session location, date, time, etc?
 - Topics, sequence and depth of coaching themes
 - Extensive training in motivational interviewing spirit
- Trial enrollment goals met ahead of schedule
- Retention outcomes beat study goals

Patient lens guided all conversations



- Sessions aligned with patient **values**
 - Health, Independence, Relationships, Faith, Career/Education, Hobbies/Leisure & Personal qualities
- Patients set their own health **goals**
 - Physical activity, Health behavior, Social/relationships, outings, etc
- Patients helped the care team to better understand barriers (what got in the way)
 - Structural barriers, Physical health, Emotional health, Interpersonal
- Patients empowered themselves to build facilitators
 - Structural, Social/relational, Personal characteristics
- None of these were prescribed by the team as a way to cope with chronic pain; these strategies were designed and implemented by patient advisors/participants



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- **Leah Bernardo** – Logistics & Coordination of Involving Patient Advisors in Research

Logistical Considerations For Including Patient Advisors in Research



When reflecting on the success of Patient Advisor contributions to the HOPE Trial, there are four main areas that stand out as being particularly important for coordinating and maintaining those relationships:

- Communication
- Flexibility
- Opportunity
- Financial Considerations



Communication

- Patient Advisor communication preferences (not all Patient Advisors use email)
- Keep Patient Advisors up to date with study progress
- Include Patient Advisors in the same communications that are sent to other members of the study team
- **Action Items:** add Patient Advisors to listservs and calendar invitations, send meeting reminders, use preferred methods of communication



Opportunity

- In HOPE, Patient Advisors were offered the opportunity to participate in a wide variety of study activities, not just stakeholder meetings
- **Action Items:** Involve Patient Advisors in all study-wide committees, development of important study documents, manuscript writing groups, etc.



Flexibility

- Some Patient Advisors may need help with technology
- Scheduling can sometimes be difficult due to medical appointments/treatments
- If travel is required for important study meetings, some Patient Advisors may need help booking travel
- Patient Advisors may miss meetings or calls due to health concerns
- **Action Items:** Offer assistance with technology (e.g., joining zoom calls, opening & editing documents), be open to rescheduling if needed, be understanding that the amount of time/effort Patient Advisors can contribute may fluctuate



Financial Considerations

- Patient Advisors should be paid for their time
 - Annual stipend, stipend for longer multi-hour meetings or in-person meetings
- Paying for travel and hotel accommodations (if applicable)
- **Action Items:** Budget for Patient Advisor-related costs like annual stipends, stipends for longer in-person meetings and travel costs

Thank you!

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- **Denise Esserman, PhD** – Discussion Moderator
- **Michael Fischer, MD** – Overview of HOPE Trial Design
- **Paul Kimmel, MD** – NIDDK Advocacy of Patient Engagement
- **Dave M. White** – Patient Advisor Perspective
- **Sagar Nigwekar, MD** – Patient Advisor Involvement in HOPE Committees & Impact of Patient Engagement on the MGH Clinical Center
- **Sarah Schrauben, MD** – Clinical Investigator Perspective on Patient Engagement
- **Svetlana Vassilieva, MD** – Research Coordinator Perspective of Patient Engagement on Recruitment & Retention
- **Heather B Howell, MSW**- Coaches Partnering with HOPE Trial Participants to Prioritize Patient Goals
- **Leah Bernardo** – Logistics & Coordination of Involving Patient Advisors in Research

Buprenorphine Eligibility Criteria (Phase 2)



Inclusion	Exclusion
Daily prescription opioid use with average of ≥ 20 MME/day	Known allergy or prior intolerance to buprenorphine
	Current use of buprenorphine
For participants of childbearing potential, a negative serum pregnancy test and willingness to use an effective form of contraception during the buprenorphine administration period.	Moderate-severe substance use disorder

Buprenorphine Intervention (Phase 2)



- Partial opioid agonist, similar analgesic properties to full agonists but safer due to less respiratory depression, lower risk of overdose
- In hemodialysis setting, safety is established and no need to modify the dose
- Use in HOPE will be limited to those who remain on opioids (≥ 20 MME/day) after Phase 1 intervention (PCST or Usual Care)
- In-person or video visit with study buprenorphine prescriber and written informed consent will be required prior to initiation of buprenorphine
- Drug will be shipped from central pharmacy to participant
- Initiation at home will be the default approach; initiation in a clinical setting is allowed
- Plan for post-trial approach for each participant will be developed during the trial and a transition period for 1 – 3 months after Week 36 visit will be incorporated