Integration of Evidence-based Alcohol Intervention into HIV Care (ARCH-IRA)

Study Protocol

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Version 5
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STUDY OBJECTIVES

Aim 1: Examine effects of algorithm-guided alcohol treatment on alcohol consumption and alcohol use disorder (AUD) symptoms.

Hypothesis 1A: Patients who are treated using algorithm-guided alcohol treatment will decrease drinking quantity and or frequency compared to pre-algorithm levels.

Hypothesis 1B. Patients who are treated using algorithm-guided treatment will decrease current AUD symptoms compared to pre-algorithm symptoms levels.

Aim 2: Examine effects of algorithm-guided alcohol treatment on retention in HIV care and HIV-related outcomes.

Hypothesis 2A. Patients treated using algorithm-guided treatment will increase adherence to clinic visits and HIV medications compared to pre-algorithm levels.

Hypothesis 2B. Patients who receive algorithm-guided treatment will have improved HIV biomarkers (e.g., CD4 and viral load (VL)). Hypothesis 2C. There will be a positive relationship between VL and alcohol consumption measured by self-report and PeTH level.

Aim 3: Examine effects of algorithm-guided alcohol treatment on comorbid conditions (e.g., depression, anxiety, hepatitis C virus coinfection (HCV), and other drug use disorders).

Hypothesis 3A: Persons living with HIV (PLWH) with co-morbid depression and anxiety receiving algorithm–guided treatment will have better alcohol, mental health and HIV treatment outcomes compared to similar individuals in Standard of Care (SC).

Hypothesis 3B: PLWH with comorbid HCV receiving algorithm–guided treatment will have improved FIB4 results and reduced likelihood of HCV recurrence compared to persons in SC. Hypothesis 3C: Other drug use will decrease among those receiving algorithm-guided treatment vs SC.

Aim 4: Characterize provider-, staff-, patient-, and clinic-level facilitators and barriers to integration of algorithm-guided alcohol treatment. We will examine the impact of factors such as provider knowledge and confidence, geographic setting, and clinic characteristics such as size, staffing patterns (e.g., number and type of staff, providers, etc.), average number of annual visits by patients, amount of Ryan White funding, and average appointment time.

STUDY ACTIVITIES

I. Study Population

About 756 participants will be recruited from 4 participating study sites (UAB, UW, UCSD, and JHU) over a 2-year enrollment period. The approximate number of participants enrolled at UAB would be 259, UW would be 115, UCSD would be 232, and JHU would be 150. Sites may over enroll if needed.

Inclusion criteria:

1. Age 18 years or older
2. Engaged in HIV care at one of the CNICS sites and enrolled in CNICS
3. The most recent AUDIT-C score ≥3 or 4 for women / ≥4 or 5 for men and MINI ≥1, or AUDIT score ≥5 for women and ≥6 for men. For patients who identify as transgender, the female scoring cut off for AUDIT-C/AUDIT will be used.
4. English speaking
5. Able and willing to provide informed consent

Exclusion criteria:

1. Non-English speaking;
2. Suicidal ideation as measured by answering item #9 of PHQ 9 "almost every day" which triggers the CNICS suicidal ideation pager alert. This is from most recent PRO (same as AUDIT-C and AUDIT scores). Having answered PHQ9 with "almost every day" on prior PHQ-9 item #9 in the distant past does not meet exclusion criteria.
3. Unable to provide informed consent.
4. Provider refusal

II. Screening

Patients who are eligible to take the CNICS PRO on the same day as their Primary Care Provider (PCP) visit will be screened for the ARCH IRA study based on the inclusion criteria mentioned above. The CNICS PRO will indicate if the patient is eligible/ineligible for the study.

A. AUDIT and AUDIT-C Eligibility Information

The ARCH-IRA study will use the most recent AUDIT-C or AUDIT score to determine continued eligibility. A lower cutoff was selected to be more inclusive and maximize recruitment of potentially eligible participants. This choice is justified as people often under-report bad or socially undesirable behaviors such as risky sex, drug, and alcohol use.

	Women / Transgender	Men
AUDIT-C	≥3 or 4 and MINI ≥1	≥4 or 5 and MINI ≥1
AUDIT	≥5	≥6

Example of continued eligibility:

Jane scored a 4 on the AUDIT-C and a 2 on the MINI on her PRO. After a page was received (please see page XXX for more information on pages), ARCH-IRA study staff approaches Jane in clinic. Jane decided to postpone enrollment until her next clinic visit in 6 months. Jane will need to complete a new PRO at her clinic visit in 6 months.

- If she does not complete a PRO during her clinic visit, the ARCH-IRA study staff can still approach for enrollment into ARCH-IRA.
- If she does complete a PRO during her clinic visit and she her new AUDIT-C score is a 2, then Jane is no longer considered eligible for ARCH-IRA and study staff will not approach.
- If she does complete a PRO during her clinic visit and she her new AUDIT-C score is a 6 and study staff received a new Peedy page, then Jane can be approached again for enrollment.

III. Randomization

Randomization will be programmed into the CNICS PRO platform. Controls will not be approached for any study activity. Study staff will receive pages for only intervention participants. Randomization process occurs before the consenting takes place. It is a 5:1 assignment for intervention and controls. Intervention vs. control status will be tracked in the PRO platform.

IV. Peedy alerts

If a patient meets the eligibility criteria (page XXX) for ARCH-IRA, a Peedy alert is generated through the CNICS PRO platform, which is developed and run by the UW team. A Peedy alert can come through as a page and/or an email to the appropriate study staff. Each page and/or email sent will include the following: patient's ticket number (ticket generated through CNICS, valid only 48 hours); the PRO session number; and the version of Peedy the patient is eligible for (please refer to page XXX for more information on the different versions of Peedy).

A. UAB

Study staff will approach eligible patients in clinic after receiving the Peedy alert. Staff will follow the ARCH-IRA recruitment script (Appendix 3) when approaching in clinic.

B. UW

The UW will use the same script and approach as UAB and will document status including refusals and reasons in the tracking log/PRO platform. (**Note at UW: there is likely not a handoff between two staff members as described above for UAB but instead the same staff member will proceed with the consent process if the participant is willing.)

C. UCSD

TBD

D. JHU

TBD

V. Enrollment and Informed Consent

Informed consent will be obtained from the patient prior to participation in any study-related activities. Only trained study personnel with appropriate Human Subjects training will review and explain the consent form and study participation with potential enrollees. Study staff will ensure that the participant understands that their consent is voluntary to avoid coercion. Patients will be approached in private rooms or designated study space for informed consent procedures by trained study staff. ARCH-IRA study staff at all sites will follow their site's IRB guidance for obtaining informed consent.

VI. Interventions

A. Peedy video versions

i. Visit 1

For visit 1, participants can be eligible for Peedy Prime or Peedy Pharma. Peedy Prime is for participants who report heavy or binge drinking on the AUDIT-C but do not meet Alcohol Use Disorder (AUD) criteria based on the MINI. Peedy Pharmacotherapy (aka Peedy Pharma) is for participants who meet criteria for AUD at visit 1 or have a PHQ5 > 5 or PHQ9 > 10. A Peedy satisfaction survey will automatically follow all of the video versions.

ii. Visit 2

For visit 2, participants can be eligible for Peedy Prize, Peedy Problem, or Peedy Adherence. Peedy Prize is for participants who have reduced their drinking from Visit 1 to low-risk limits. Peedy Problem is for participants who received Peedy Prime on Visit 1 and continue to report risky drinking. Peedy Adherence is for participants who received Peedy Pharma during Visit 1 and are still reporting risky drinking. A Peedy satisfaction survey will automatically follow all of the video versions.

B. Text Messages

During visit 1, all participants are eligible to receive text messages that reinforce content from the intervention. Please explain that the texts do not contain any personal information and none of the content can be traced back to the participant, but the texts do suggest ways to cut down on alcohol.

For participants who opt-in to receive the text messages, study staff will refer to steps #6-10 under "Logging into Peedy" on page XX. It is critical to enter the correct phone number to ensure that participants receive the texts and guarantee that the intervention is linked to the correct cellphone.

For participants who do not opt-in to receive text messages, study staff should ask for a reason(s) as to why and document that reason in the local study log. Possible reasons for participants to refuse text messages:

I don't have a cell phone
I don't want to receive any text messages
I don't want to use my data/minutes
I am concerned text messages will be seen by others
I don't think text messages about my alcohol will help me with my drinking
I don't like to receive text messages
I don't carry my phone with me and would not get texts on time
I don't believe I need help with my drinking
Other: _____

C. CBT4CBT

i. Visit 1

During visit 1, participants who have PHQ5 ≥ 5 and/or PHQ9 ≥ 10 or have AUD on MINI would also would become eligible to receive CBT4CBT (Appendix 1 Algorithm 1). A unique CBT4CBT study ID would be assigned for each participant through CBT4CBT database. Study staff would be able to track each participant on their completion of CBT4CBT modules.

Patient care coordinator (PCC) and/or study staff will introduce CBT4CBT with participants (please see example introduction script below). The study staff and/or PCC will show the participant how to login to CB4CBT modules and provide each participant a unique username and password. The study staff or PCC will also provide a sheet with the link and login information, worksheets and some instructions to the participant (Appendix XX). The study staff and/or PCC will follow-up by phone with the participants after about a week to check in and see if they have any issues with completing the CBT4CBT modules. Study staff should use an IRB-approved (if applicable) phone script when calling participants. (*Note: please check with your site's IRB to see if you need to have an IRB-approved phone script or not.)

Example CBT4CBT introduction script:

"As part of your treatment, we are giving you access to a computerized treatment program that you can do at home: CBT4CBT. This program uses cognitive behavioral strategies to help you manage cravings to drink and provides effective strategies to reduce or quit drinking. Cognitive behavioral therapy is an effective therapy technique that allows you to examine high risk situations for drinking and by identifying your thoughts, allows you to counter that thought or develop a new way to think about the problem. Thinking about a problem differently often influences how you feel, and your subsequent behavior. CBT4CBT has 7 modules about different high risk situations and different strategies for how to think about these situations differently so that you can make the changes to your drinking. While CBT is traditionally delivered one-on-one by a trained therapist, this program uses these same strategies and techniques to teach you the skills you need, all at your own pace and in the privacy of your home. The other great thing about it is that you can go back and review as many times as you want any of the modules. It is also interactive, so the computer program will ask you questions about high risk situations and strategies along the way so you will not just be listening to someone talking; you will be learning and applying how to use these techniques. Do you have any questions?"
Answer any questions that come up, then *"Let's get you started."*

ii. Visit 2

Before visit 2, study staff/PCC should check the CBT4CBT progress of participants from the monthly email the UAB Coordinator sends out. If the participant has not logged in or made much progress despite being reminded during the phone call, the study staff/PCC should review login instructions and barriers to completion. Responses should be coded as:

Unable to access a computer
Unable to login
Did not want to do it
Did not find it helpful
Too time intensive/long
I don't think I need help with my drinking

Other, please specify

In instances where PCC cannot meet the participant in clinic, PCC will call participant and follow up on progress of CBT4CBT. PCC will make about 6 attempts in a month's time to reach participant. This will be documented in the tracking log maintained separately at each site.

iii. Generating CBT4CBT Reports

Monthly, the UAB Coordinator will download a report from CBT4CBT and share it with the ARCH-IRA team during the monthly study call.

Go to: app.cbt4cbt.com/admin
Enter user name: uabmcD0
Password: BU6007
Click Reports, select start and end date and click 'generate'.

D. Alcohol Pharmacotherapy (APT)

During visit 1, participants who have scored AUD on MINI would become eligible to receive Alcohol Pharmacotherapy (APT).

Providers/PCC/study staff can call/page Pete S. Lane/ Karen Cropsey in case they have questions on medications.

Information for Pete S. Lane:
- ✓ Pager: 205-888-6664
- ✓ phone number 205-975-3101
- ✓ Email: pslane@uabmc.edu

Information for Karen Cropsey:
- ✓ Phone: 205-975-4204
- ✓ Cell: 205-514-2025
- ✓ Email: kcropsey@uabmc.edu

In instances where you cannot reach them by phone and need to leave a VM.

VM to leave*: Hi this is 'XYZ', I have a question on ARCH IRA participant who is in the clinic/ or not in the clinic (use as appropriate). Please call back at 'phone number'.*

Paging instructions:
- Go to https://www.paging.uab.edu/
- Enter the last 4 digits of the pager number or name in the box and click search. You will see name and pager number that pops up.
- Click the pager number which is bold and green and a screen will come up saying enter your message and send button. You can only enter 80 characters for message.
- Enter message and click hit send.
- Message to send: *Question on ARCH IRA participant. Call back on 'phone number'.*

i. UAB

Study staff/PCC will use the APT algorithm (Appendix 1 Algorithm 2) and the EMR to determine which medication to recommend to the provider. Study staff/PCC will communicate with participant's provider in clinic and/or send a message through the EMR and recommend a drug from the APT list. These recommendations will be done based on APT algorithm plus consultation with PI (Karen Cropsey) of the study/addiction specialist (Dr. Pete S Lane) on case-

by-case basis via email or phone communication. Template scripts of these recommendations can be found in Appendix XX.

If APT is prescribed to the participant, study staff/PCC will communicate with participant about the side effects of the recommended drug (described in Appendix 2 under medication list) and make sure that the participant understands to call study staff/PCC and clinical care team in case s/he experiences any side effects. In addition, study staff/PCC will follow up with participants in one week to see how they are doing on their medication. Attempts will be made up to one month following receipt of medication. Study staff/PCC will call twice per week in attempting to reach the participant. If participant reports a side effect, the study staff/PCC will inform the participant's clinical care team using message center in the Cerner. The provider will determine the course of action to be taken (e.g., continue, reduce dose, and discontinue medication). Pete S. Lane/ Karen Cropsey will be available for provider to consult about medication.

ii. UW

A similar set of procedures will be used for most of these steps at the UW.

Providers will receive a notification for patients eligible for APT:

XX is participating in the ARCH-IRA study and reported at-risk alcohol use on the clinical assessment. Based on XX's risk, he is eligible and would likely benefit from Alcohol Pharmacotherapy (APT). Naltrexone is most often recommended for APT unless the patient has acute hepatitis or liver failure (LFTs>5x ULN) or is currently using prescribed or illicit opioids. The dose of naltrexone is 50 mg PO per day. We have attached an APT medication algorithm and list of medications and doses for your information. We hope this information is useful to you and that you consider whether prescribing APT would be of benefit to George.

At UW, this message can be sent through Epic with algorithm attached or printed and handed directly to provider. The assessment of appropriateness of specific APT choices based on LFTs or opiate use will be assessed by and at the discretion of the patient provider. The PCC will contact participants as above and address issues with participant regarding access, receipt of, and other issues with APT but side effects will be deferred to clinical staff.

iii. UCSD

TBD

iv. JHU

TBD

E. Dried Blood Spots

Blood spots will be done after consent on the same day the participant takes the CNICS PRO (visit 1) and at ~4-6 months (visit 2). If participant postpones blood spot on the same day of PRO, participants may not have option to come later for a blood spot. These blood spots will be created using 0.5 ml of blood and will be used to measure phosphatidylethanol (PeTH) levels.

Blood spots will be processed by USDTL (United States Drug Testing Laboratories, Inc) located in Des Plaines, IL. Sites will send the list of supplies they need to order for creating blood spot cards to UAB. Tracey Manley at UAB will assist with processing the orders (PO# 2055670). A supply order form will be completed at UAB and sent to USDTL via email (supplies@usdtl.com) or Fax (847.375.0775).

Blood spot cards will be shipped to USDTL in batches (10 or more spot cards). Sites will complete the drug sample submission form provided by USDTL and send it along with the spot card batches and save a copy for themselves at their site.

i. UAB

A 2ml plastic tube will be added to the CNICS blood draw at the UAB 1917 clinic lab. This blood will then be transported by lab staff to the vaccine clinic on 3rd floor of the 1917 clinic where the spot cards will be created and stored by the phlebotomy staff members. Spot cards will then be sent to the lab for processing in batches. Preferably, batches must be in 10 or greater and packing instructions and materials will be provided by USDLT. REPO #, ARCH study id, Date and Time will be on the labels on the samples that will be shipped to the lab. All results will be accessed using web portal with unique login credentials assigned to study staff.

ii. UW

Study staff will notify Linsday Legg (CFAR Research Nurse Coordinator) of UW PEEDY participants who complete the PRO that day. The patient will be notified that this is an opportunity to enrich the results from this study in terms of how to help patients with HIV who drink alcohol for an additional ancillary study and that they will receive $5.00 if they agree to the finger prick.

iii. UCSD

TBD

iv. JHU

TBD

F. Logging into Peedy

1. Go to: https://www.interva-online.mobi/UAB/login.jsp
2. Log-in: enter username/password and click “Login.” (If you do not have a login, please contact Heidi Hutton)
3. Under “Package” select the appropriate Peedy version to be administered using the drop-down arrow. (*Note: For Peedy Pharma, please select “2_V1 : Peedy Pharma”)
4. Once you select the package, other text fields will appear (Participant ID, First Name, Last Name, Staff Initials, etc.). The only field required is the Staff Initials.
5. Under “Type,” “Real” will be the default selection. If you are testing the system, then change this field to “Practice” using the drop down box. If the participant agrees to the text messages, please continue to #6. If the participant does not agree to the text messages, please skip #X-X. (Please refer to page XX for more information on text messages)
6. Under “Phone number” type in the participants phone number starting with 1. Do NOT include any dashes.
7. Under “Opt-In Frequency”, select the frequency of the text messages. (*Note: Frequency can only be 2, 3, or 4 times per week even though other options are listed)

8. Under “Opt-in days”, **uncheck** the boxes for the days that the participant will NOT receive text messages. Leave **checked** the days that the participant WILL receive text messages.
9. Under “Opt-in times”, **uncheck** the boxes for the times that the participant will NOT receive text messages. Leave **checked** the times that the participant WILL receive text messages.
10. Under “Your time zone”, select the appropriate time zone.
11. Click “Login.”
12. The Peedy ID (5-digit number also known as the Participant ID) will appear on the next page. Write down the Peedy ID on a piece of paper and click “Next.”
13. Under “Study ID #Entry 1”, you will enter in the Peedy ID that you just wrote down. Click “Submit.”
14. Under “Study ID #Entry 2”, you will enter in the same Peedy ID from “Study ID #Entry 1.” Click “Submit.”
15. Select the gender of the participant.
16. On the next page, select the study site you are located at.
17. On the next page, you will select if the participant is eligible for CBT or not. (For more information on CBT, please refer to page XX)
18. The program will now launch.

G. Visit 3

Visit 3 is a normal CNICS PRO during the participant’s PCP appointment at each site. No further intervention.

VII. Documenting in CNICS

After the initial Peedy alert is generated for a patient, an “ARCH-IRA Study Information” section will appear in the patient’s CNICS patient page. This section is to document that patient’s ARCH-IRA study status. Regardless of what happened with the alert, you will need to update this section for ARCH-IRA.
There are 4 events under “Protocol History” that you can choose from:

Eligible – not approached
Postponed consent
Approached refused, not okay to re-approach
Consented

After selecting the event that best fits your situation, click “Add New Event” in order for it to save.

After consenting a participant for ARCH-IRA and after updating the Protocol History to show “Consented,” a new drop-down will appear for Visit 1. After the participant either completes all or some of Visit 1 or refuses to complete Visit 1, you will update the “Protocol History” with the following options:

Visit 1 drop-down options:

Withdrawn
Viewed video 1 Peedy Prime
Viewed video 1 Peedy Pharma
Refused video 1
Refused CBT4CBT
Refused Pharmacotherapy
Completed Visit 1

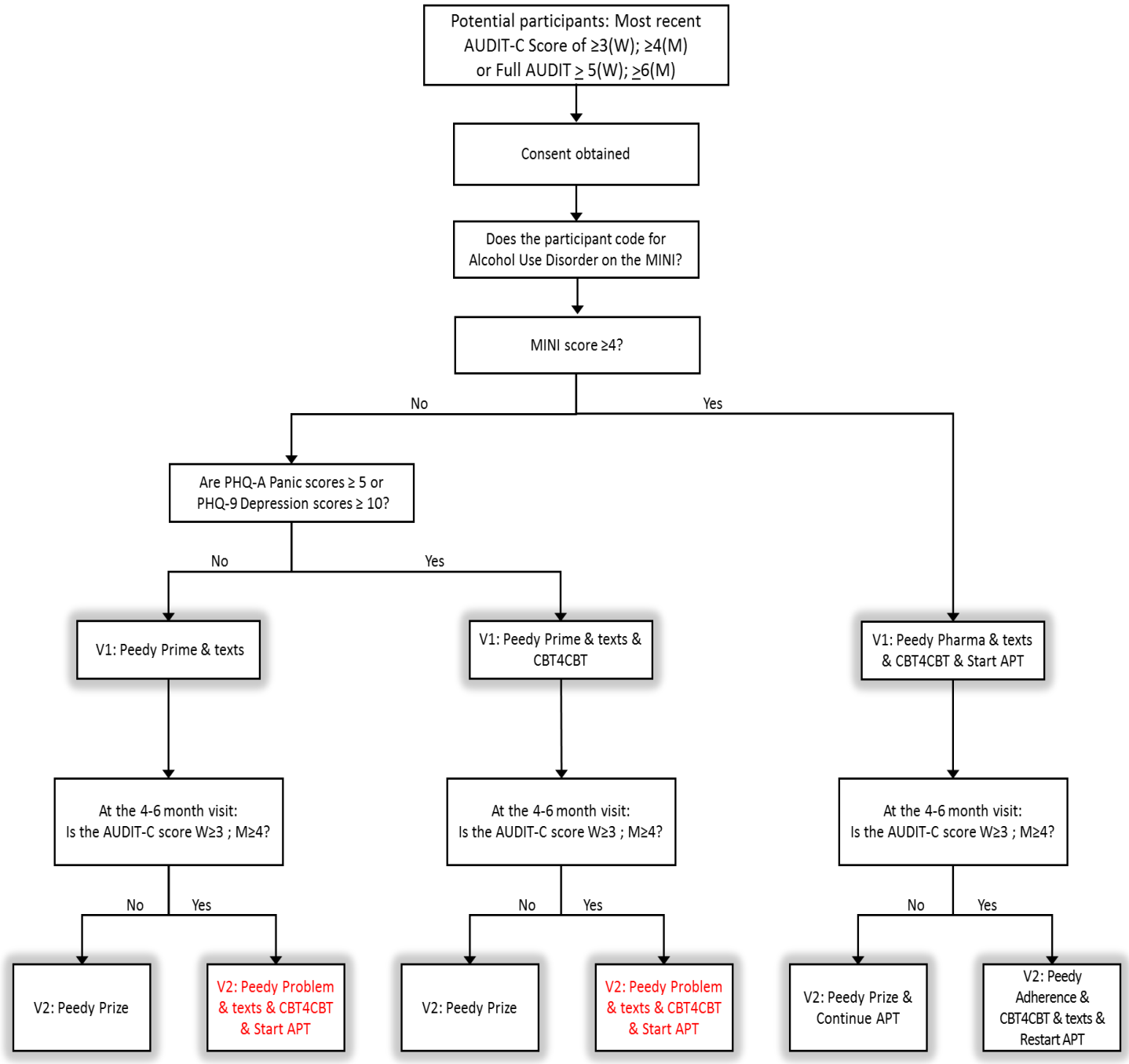
Visit 2 drop-down options:

Withdrawn
Eligible – not approached (Video 2)

Postpone Video 2
Viewed video 2 Peedy Adherence
Viewed video 2 Peedy Problem
Viewed video 2 Peedy Prize
Refused video 2
Refused CBT4CBT
Refused Pharmacotherapy
Completed Visit 2

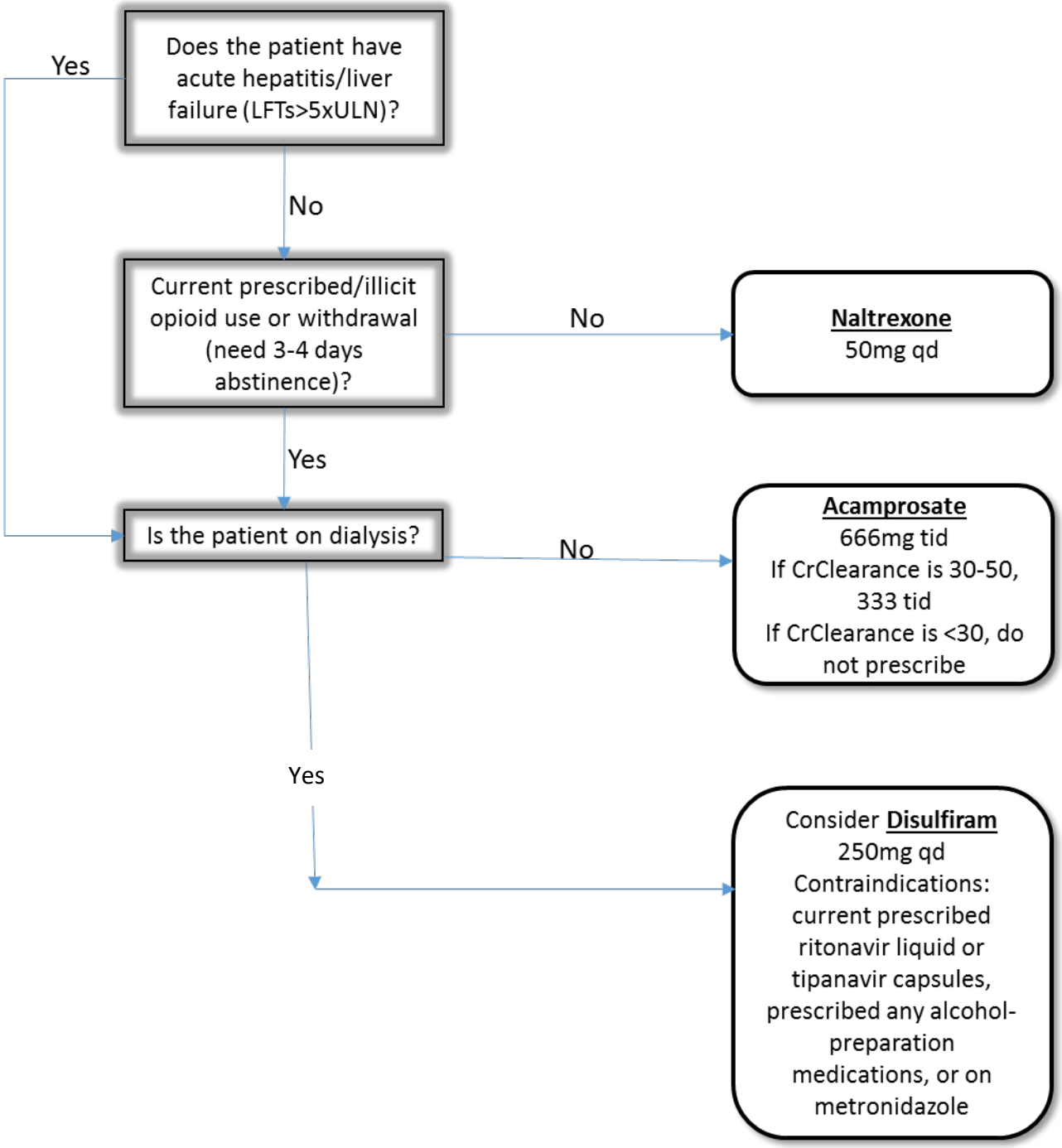
APPENDIX 1

Algorithm 1. Overall study algorithm



APT= alcohol pharmacotherapy; PHQ= Patient Health Questionnaire

Algorithm 2. APT algorithm



APPENDIX 2
APT –Medication List

Name	Method	Dosage	Side Effects
Campral (*acamprosate*)	Tablet	Two 333mg tablets 3x/day with or without food. Some patients may require a lower dose.	**Common side effects:** abdominal pain, appetite change, change in sexual desire, diarrhea, dry mouth, gas, itchy skin, nausea, nervousness, prickling or tingling sensation, skin rash, trouble sleeping, vomiting, weakness, weight gain or loss **More serious side effects:** chest pain, joint pain, pounding or fast heartbeat, symptoms of depression, and thoughts or acts of self-harm *Other: Does not help with alcohol withdrawal*
Disulfiram (antabuse)	Tablet	250mg or 500mg 2 or 3x/day	**Common side effects:** skin rash, mild headaches, metallic taste, mild weakness, dizziness, swollen tongue **More serious side effects:** allergic reactions (swelling of lips, face) and hives, shortness of breath, seizure, tiredness, yellowing of skin or eyes, dark urine, appetite changes, dizziness, vomiting, weakness, severe diarrhea *Other: Produces unpleasant effects if you drink alcohol while taking it*
Vivitrol (PO naltrexone)	Tablet	50 mg 1x/day with food	**Common side effects:** nausea, vomiting, stomach pain, diarrhea, constipation, loss of appetite, headache, dizziness, anxiety, nervousness, irritability, tearfulness, difficulty sleeping, increased or decreased energy, drowsiness, muscle or joint pain, rash **More serious side effects:** confusion, hallucinations, blurred vision, severe vomiting and/or diarrhea

Opioid list as prescribed in Cerner at UAB

Opiates
acetaminophen/butalbital/caffeine/codeine
acetaminophen-codeine
acetaminophen-HYDROcodone
acetaminophen-oxycodone
acetaminophen-tramadol
APAP/butalbital/caffeine/codeine
APAP/caffeine/dihydrocodeine
aspirin/butalbital/caffeine/codeine
aspirin-oxycodone
bupivacaine-fentanyl 200 mL
bupivacaine-fentanyl 250 mL
bupivacaine-HYDROmorphone 250 mL
buprenorphine
buprenorphine-naloxone
butorphanol
chlorpheniramine/hydrocodone/phenylephri
chlorpheniramine/hydrocodone/phenylephrine
chlorpheniramine-hydrocodone
codeine
codeine/guaifenesin/PSE
codeine/guaiFENesin/pseudoephedrine
codeine/phenylephrine/promethazine
codeine-guaifenesin
codeine-promethazine
dexbrompheniramine/hydrocodone/phenyleph
dexbrompheniramine/hydrocodone/phenylephrine
dihydrocodeine/guaiFENesin/phenylephrine
diphenhydramine/hydrocodone/phenylephrine
fentanyl
fentanyl 1
fentanyl 1,000 mcg [0.5 mcg/kg/hr] + dex
fentaNYL 2
fentaNYL 2,500 mcg [100 mcg/hr] + empty
fentaNYL 2,500 mcg [100 mcg/hr] + empty sterile container for IV fluids 50 mL
fentanyl 2,500 mcg [200 mcg/hr] + empty
fentaNYL 2,500 mcg [25 mcg/hr] + empty s
fentaNYL 2,500 mcg [25 mcg/hr] + empty sterile container for IV fluids 50 mL

fentaNYL 2,500 mcg [50 mcg/hr] + empty sterile container for IV fluids 50 mL
fentanyl 2,500 mcg [75 mcg/hr] + empty s
fentanyl 2,500 mcg [75 mcg/hr] + empty sterile container for IV fluids 50 mL
fentanyl 2500 mcg + empty sterile contai
fentaNYL 5
fentaNYL 5,000 mcg [1 mcg/hr] + empty st
fentaNYL 5,000 mcg [1 mcg/hr] + empty sterile container for IV fluids 100 mL
fentaNYL 5,000 mcg [10 mcg/hr] + empty sterile container for IV fluids 100 mL
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fentaNYL 5,000 mcg [100 mcg/hr] + empty sterile container for IV fluids 100 mL
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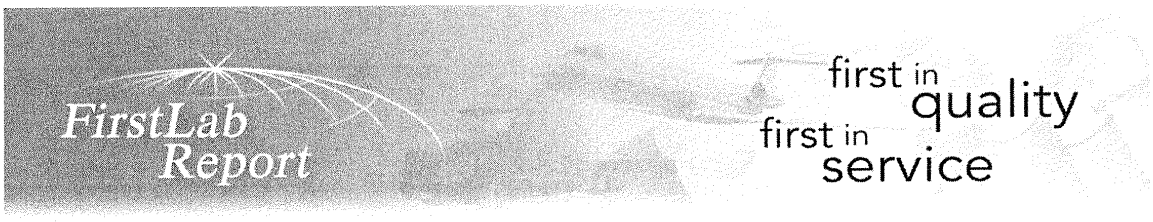
fentanyl 5,000 mcg [50 mcg/hr] + empty s
fentaNYL 5,000 mcg [50 mcg/hr] + empty sterile container for IV fluids 100 mL
fentanyl 5,000 mcg [75 mcg/hr] + empty s
fentanyl 5,000 mcg [75 mcg/hr] + empty sterile container for IV fluids 100 mL
fentanyl 5000 mcg [50 mcg/hr] + dextrose
fentanyl-ropivacaine 250 mL
guaifenesin/hydrocodone/phenylephrine
guaifenesin-hydrocodone
homatropine-hydrocodone
HYDROcodone
HYDROcodone/phenylephrine/pyrilamine
hydrocodone-ibuprofen
hydrocodone-pseudoephedrine
HYDROmorphone
ibuprofen-oxycodone
meperidine
meperidine-promethazine
methadone
morphine
morphine 250 mg [1 mg/hr] + Diluent for
morphine 250 mg [2 mg/hr] + Diluent for
morphine 30 mg [2 mg/hr] + Diluent for P
morphine-naltrexone
nalbuphine

opium
oxycodone
oxymorphone
tapentadol
traMADol
fentaNYL 5,000 mcg [100 mcg/hr] + Diluent for Premix 100 mL
fentaNYL 5,000 mcg [150 mcg/hr] + Diluent for Premix 100 mL
fentaNYL 5000 mcg [150 mcg/hr] + Diluent for Premix 100 mL
guaiFENesin/HYDROcodone/pseudoephedrine
Paregoric Liquid
Acetaminophen; Tramadol
acetaminophen-hydrocodone
buprenorphine
codeine syrup 5mg/ml
Duragesic patch
HYDROCO/APAP
hydrocodon 10/500
Hydrocodone
hydrocodone 10mg
Hydrocodone 10mg - 325 mg
loratab
Lortab
Lortab 7.5 mg
methadone
methadone 100 mg daily
morphine
morphine sulfate
ms contin 300mg every 8 h
Norco
Norco 7.5mg/325mg
Norco oral four times a
Opium Tincture
Paregoric Liquid
percocet does unknown
Suboxone Troche
tramadol 325mg-37.5mg tid
Tussionex
Tussionex tablets
Virtussin
Hydrocodone-Apap 10/500mg every 4hr prn

lortab
Morphine-sul er 60 mg 3 tabs BID
tylenol #4 taken as needed

Medications Containing Alcohol



MEDICATIONS CONTAINING ALCOHOL COMMONLY STOCKED IN MOST HOSPITALS AND PHARMACIES

Drug	% Alcohol
Actol Expectorant Syrup	12.5
Alertonic	0.45
Alurate Elixir	20.0
Ambenyl Expectorant	5.0
Anahist	0.5
Aromatic Elixir	22.0
Anaspaz-Pb Liquid	15.0
Asbron Elixir	15.0
Atarax Syrup	0.5
Bactrim Suspension	0.3
Tr. Belladonna	67.0
Benadryl Elixir	14.0
Bentyl-Pb Syrup	19.0
Benylin Expectorant	5.0
Brondecon Elixir	20.0
Bronkelixir	19.0
Butibel Elixir	7.0
Calcidrine Syrup	6.0
Cas Evac	18.0
Aromatic Cascara Sagroda	18.0
Carbrital Elixir	18.0
Cerose & Cerose DM Expectorant	2.5
Cheracol & Cheracol D	3.0
Choledyl Elixir	20.0
Chlor-Trimeton Syrup	7.0
Cologel Liquid	5.0
Citra Forte Syrup	2.0
Coldene Cough Syrup	15.0
Conar Expectorant	5.0
Coryban D	7.5
Cosanyl DM & Cosanyl Syrup	6.0
Copavin Cmpd Elixir	7.0
Darvon-N Suspension	1.0
Decadron Elixir	5.0
Dexedrine Elixir	10.0
Demazin Syrup	7.5
Dilaudid Cough Syrup	5.0
Elixir Dimetane	3.0
Dimetane Expectorant	3.5
Dimetane Expectorant-DC	3.5
Doxinate Liquid	5.0
Dimetapp Elixir	2.3
Dimacol Liquid	4.75
Donnatal Elixir	23.0
Donnagel Suspenslon	3.8
Donnagel PG Suspenslon	5.0
Dramamine Liquid	5.0
Feosol Elixir	5.0
Fer-In-Sol Syrup	5.0
Theoelixir (Elixir Theophylline)	20.0
Elixophy	20.0
Elixophylline-KL	10.0
Ephedrine Sulfate Syrup USP	3.0
Ephedrine Sulfate Syrup - Note USP	12.0
Fer-In-Sol Drops	0.2
Geriplex-FS	18.0
Gevabon Liquid	18.0
Kaon Elixir	5.0
Kaochlor	3.8
Iberet Liquid	1.0
Isuprel Comp. Elixir	19.0
Syrup Ipecac	2.0
Hydryllin Comp.	5.0
Hycotuss Expectorant & Syrup	10.0
Kay-Ciel Elixir	4.0
Lanoxin Elixir Pediatric	10.0
Liquid Lomotil	15.0
Luffyllin-GG Elixir	17.0
Marax Syrup	5.0
Mediatric Liquid	15.0
Modane Liquld	5.0
Mellaril Concentrate	3.0
Mesopin Elixir	12.5
Minocin Syrup	5.0
Nembutal Elixir	18.0
Novahistine DH	5.0
Nicol Elixir	10.0
Novahistine Expectorant	5.0
Novahistine Elixir	5.0
Novahistine DMX	10.0
Nico-Metrazol Elixir	15.0
Nyquil Cough Syrup	25.0
Mol Iron Liquid	4.75
Organidin Elixir	23.75
Ornacol Liquid	8.0
Tincture Paregoric	45.0
Parapectolin	0.69
Parelexir	18.0
Periactin Syrup	5.0
Pertussin 8 Hour Syrup	9.5
Phenergan Expectorant Plain	7.0
Phenobarbital Elixir	14.0
Phenergan Expect. w/Codeine	7.0
Phenergan Expectorant VC Plain	7.0
Phenergan Expectorant VC w/Codeine	7.0
Phenergan Expectorant Pediatric	7.0
Phenergan Syrup Fortis (25 mg)	1.5
Polaramine Expectorant	7.2
P.B.Z. Expectorant with Ephedrine	6.0
Propadrine Elixir HCl	16.0
P.B.Z. Expectorant w/Codeine & Ephedrine	6.0
Quibron Elixir	15.0
Robitussin Syrup	3.5
Robitussin AC Syrup	3.5
Robitussin PE	1.4
Robitussin DM and Robitussin CF	1.4
Rondec DM Syrup and Drops	0.6
Roniacol Elixir	8.6
Serpasil Elixir	12.0
Tedral Elixir	15.0
Temaril Syrup	5.7
Terpin Hydrate Elixir	42.0
Terpin Hydrate Elixir w/Codeine	42.0
Theo Organidin Elixir	15.0
Triaminic Expectorant	5.0
Triaminic Expectorant DH	5.0
Tussend Liquid	5.0
Tussar-2 Syrup	5.0
Tussi-Organidin Expectorant	15.0
Tussar SF Syrup	12.0
Tuss-Ornade Syrup	7.5
Tylenol Elixir	7.0
Tylenol with Codeine Elixir	7.0
Tylenol Drops	7.0
Ulo-Syrup	6.65
Valadol Llquid	9.0
Valpin-PB Elixir & Valprin	5.3
Vita Metrazol Elixir	15.0
Vlcks Formula 44	10.0
Potassium Chloride Sol. (Standard)	10.0

(a no-alcohol solution can be requested)

NOTE:

1. Mouthwashes - Scope, Listerine, Cepacol, Colgate 100, Micrin, all contain approximately 15 - 25% alcohol.

2. All elixirs contain some alcohol.

3. The following anti-tussives do *not* contain alcohol:
   - * Hycodan Syrup
   - * Hycomine Syrup
   - Triaminicol Syrup
   - * Tussionex Suspension
   - Orthoxicol Syrup
   - Actifed C Expectorant
   - Omnituss
   - Ipsatol Syrup

4. Other non-alcohol liquids:
   - Chloraseptic mouthwash/gargle
   - Liquiprin (acetaminophen)
   - Dilantin Suspension
   - Alupent Syrup
   - * Noctec Syrup
   - * Vistaril Suspension
   - Antacids
   - Kapoectate and Parget, etc.
   - Sudafed Syrup
   - * Quadrinal Suspension
   - Actifed Syrup
   - Triaminic Syrup
   - Naldecon Syrup
   - Nydrazid Syrup

*Ingestive medications may contain other addictive substances which may be considered.

Courtesy of:
Alcenas Hospital
10322 N.E. 132nd
Kirkland, Washington 98033

APPENDIX 3

In Person ARCH Recruitment Script:

After your standard introduction…

Based on your answers on the computer/iPad survey you just took, I wanted to talk to you about a research study you might be eligible for today.

The study involves watching a 15-20 minute video about alcohol and how it can affect HIV. There also are additional components of alcohol intervention that may be available during the study; you can make decisions about how much you would like to do.

For patients who watched Peedy video in round 1

While you may have seen a video in the past about your alcohol use, this is a new study that has some additional interventions that may help you with your drinking.

"Are you interested in participating in this study?

If participant responds *'Yes'* notify recruitment staff to come and proceed with consent process.

If participant responds *'No',* notify recruitment staff and provide as much detail regarding refusal as you can. Patients who refuse to participate will be informed that this is not a requirement for their care and that their relationship with the 1917 Clinic will not be affected in any way. Ask patient "may we contact you again". If you receive a definite *"NO",* communicate this to study staff and we will not approach this patient in the future. Study staff will make a note of this in the tracking logs and record reasons of decline on the tracking log. The following are the options available for decline:

Already did Peedy before
Not interested
I don't want to change
Don't have time
Unable to understand/speak English
I don't trust research studies
I don't feel well enough today to do it
I need to get my partner's permission first
Getting support from other sources
I don't have an alcohol problem
Other reason not listed

APPENDIX 4

ARCH IRA Getting Started and Troubleshooting Guide

Link: http://www.cbt4cbt.com/

User name: _____

Password: _____

Getting Started

To begin, you will log on to the link above, go to portal for clients, enter your login credentials - username and password provided to you. There will be a video for you to watch in order to check that the videos are working with your device and that sound is playing. If everything is working, click "Continue to Main Site" once. Read the next page and click "Continue to Main Site" again. From there, begin the first topic, called "Recognize the Triggers" by clicking on it from the top of the page.

The first video that plays will be a quick guide to using the program. If you have any trouble, you can return to this video to review it.

The program is made up of a combination of videos to watch and activities to complete, as well as some text messages that will be sent to your phone over the course of the program. Please pay close attention to the videos and to any instructions for the activities.

You can use the 'worksheets' provided to you for the activities listed in the modules.

Troubleshooting Guide

The video or activity is not loading. (There is a black box where the video should be.)

Try refreshing the page when something does not load. You can do this by either using your browser's refresh button or the "Restart Page" button below the video or activity. Sometimes, an entire topic will have trouble loading. If this happens, click on the "Restart Topic" button and try again.

The video looks like it has loaded, but nothing is happening.

On some devices, you have to click or tap on the video to get it to start. If it does not start afterwards, click on the "Restart Page" button and try again.

How do I go to the next page?

Within each module, you can move forwards or backwards using the small, blue arrows in the bottom left corner.

I have finished a topic. How do I go to the next one?

When you have finished a topic, click on the "Back to Topics Selection page" link at the top of the page. From there, you can choose the next topic from the middle of the page, or from the "Recommended Order" list on the left of the page.

I am not sure what to do for this activity.

For each activity, a short explanation will play before you begin. If you missed this explanation or would like to hear it again, click on the "Restart Page" button at the bottom of the page.

The program has me watch the same video several times.

While there are many videos in the program that are similar, there are small differences between each one. These differences may include changes to what people say, how they behave in different situations, or what they are thinking. Pay close attention to these differences, as they are usually there to show how changing your behaviors can change the situation.

Appendix 5
APT scripts template at UAB for these recommendations will be:
Message to Fellow/Nurse Practitioner CC Attending, Michael Mugavero, Pete S Lane, Karen Cropsey, in IMPACT Message Center: INTERVENTION PARTICIPANTS

If Naltrexone Prescription

Subject: ARCH IRA study
Pt enrolled to ARCH IRA study: U01 AA020802 - Alcohol Research Consortium on HIV – Intervention Research Consortium
Enrolled on xx/xx/xxxx, with a AUDIT/AUDIT C score of XX
Patient name scored >=4 on MINI on CNICS PRO (date xx/xx/xxxx) and is eligible for the CBT4CBT (Computer Based Training for Cognitive Therapy) and APT intervention components. Based on study algorithm and consultation with Dr. Pete S. Lane/ Dr. Karen Cropsey we recommend a prescription of tablet naltrexone 50 mg 1x/day with food. There were no chronic or current opioids listed and no LFTs >5xULN on medical record for this patient (checked on date: xx/xx/xxxx). We have also confirmed with participant about illicit opioid use since naltrexone may interact with opioids.
ARCH IRA study staff: Name

OR

Subject: ARCH IRA study
Pt enrolled to ARCH IRA study: U01 AA020802 - Alcohol Research Consortium on HIV – Intervention Research Consortium
Enrolled on xx/xx/xxxx, with a AUDIT/AUDIT C score of XX
Patient name scored >=4 on MINI on CNICS PRO (date xx/xx/xxxx) and is eligible for the CBT4CBT (Computer Based Training for Cognitive Therapy) and APT intervention components. Based on study we recommend a prescription of tablet naltrexone 50 mg 1x/day with food. There were no chronic or current opioids listed and no LFTs >5xULN on medical record for this patient (checked on date: xx/xx/xxxx). We have also confirmed with participant about illicit opioid use since naltrexone may interact with opioids.
ARCH IRA study staff: Name

If Acomprosate Prescription

Subject: ARCH IRA study
Pt enrolled to ARCH IRA study: U01 AA020802 - Alcohol Research Consortium on HIV – Intervention Research Consortium
Enrolled on xx/xx/xxxx, with a AUDIT/AUDIT C score of XX
Patient name scored >=4 on MINI on CNICS PRO (date xx/xx/xxxx) and is eligible for the CBT4CBT (Computer Based Training for Cognitive Therapy) and APT intervention components. Based on study algorithm and consultation with Dr. Pete S. Lane/ Dr. Karen Cropsey we recommend a prescription of tablet acomprosate Two 333mg tablets 3x/day with or without food. The CrClearance was not <30 on medical record for this patient (checked on date: xx/xx/xxxx).
ARCH IRA study staff: Name

OR

Subject: ARCH IRA study
Pt enrolled to ARCH IRA study: U01 AA020802 - Alcohol Research Consortium on HIV – Intervention Research Consortium
Enrolled on xx/xx/xxxx, with a AUDIT/AUDIT C score of XX
Patient name scored >=4 on MINI on CNICS PRO (date xx/xx/xxxx) and is eligible for the CBT4CBT (Computer Based Training for Cognitive Therapy) and APT intervention components. Based on study algorithm we recommend a prescription of tablet acomprosate Two 333mg tablets 3x/day with or without food. The CrClearance was not <30 on medical record for this patient (checked on date: xx/xx/xxxx).
ARCH IRA study staff: Name

If Disulfiram Prescription

Subject: ARCH IRA study
Pt enrolled to ARCH IRA study: U01 AA020802 - Alcohol Research Consortium on HIV – Intervention Research Consortium
Enrolled on xx/xx/xxxx, with a AUDIT/AUDIT C score of XX
Patient name scored >=4 on MINI on CNICS PRO (date xx/xx/xxxx) and is eligible for the CBT4CBT (Computer Based Training for Cognitive Therapy) and APT intervention components. Based on study algorithm and consultation with Dr. Pete S. Lane/ Dr. Karen Cropsey we recommend a prescription of tablet disulfiram 250mg or 500mg 2 or 3x/day. There were no active prescriptions of ritonavir, tipinavir, metronidazole or any med containing alcohol on medical record for this patient (checked on date: xx/xx/xxxx).
ARCH IRA study staff: Name

OR

Subject: ARCH IRA study
Pt enrolled to ARCH IRA study: U01 AA020802 - Alcohol Research Consortium on HIV – Intervention Research Consortium
Enrolled on xx/xx/xxxx, with a AUDIT/AUDIT C score of XX
Patient name scored >=4 on MINI on CNICS PRO (date xx/xx/xxxx) and is eligible for the CBT4CBT (Computer Based Training for Cognitive Therapy) and APT intervention components. Based on study algorithm we recommend a prescription of tablet disulfiram 250mg or 500mg 2 or 3x/day. There were no active prescriptions of ritonavir, tipinavir, metronidazole or any med containing alcohol on medical record for this patient (checked on date: xx/xx/xxxx).
ARCH IRA study staff: Name