



REPRIEVE

Randomized Trial to Prevent Vascular Events in HIV

REPRIEVE (A5332) RETENTION TOOLKIT

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REPRIEVE Retention Champions

The REPRIEVE Retention Toolkit contains information, ideas, and materials you can use in your efforts to connect with and retain participants at your site. Retention is a vital aspect of the REPRIEVE Trial; the materials enclosed are designed to help REPRIEVE sites maintain participant engagement in the trial over the follow-up years. Thank you to the REPRIEVE Sites who took part in the REPRIEVE Retention Champion Initiative and shared retention practices that contributed to the development of the Retention Toolkit, we could not have developed this toolkit without your expertise.

If you have not already done so, please work with your local IRB to obtain any necessary approvals prior to using participant directed materials.

If you have questions about any of the material enclosed or would like to share retention practices from your site, please contact Marissa Diggs at mdiggs@mgh.harvard.edu.

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SECTION 1.0. ON-SITE STRATEGIES TO PROMOTE RETENTION IN REPRIEVE

We strongly encourage REPRIEVE sites to implement some of these simple on-site practices that may increase participant retention at study sites.

1.1. Team Meetings to Discuss Participants at Risk of Loss to Follow-Up

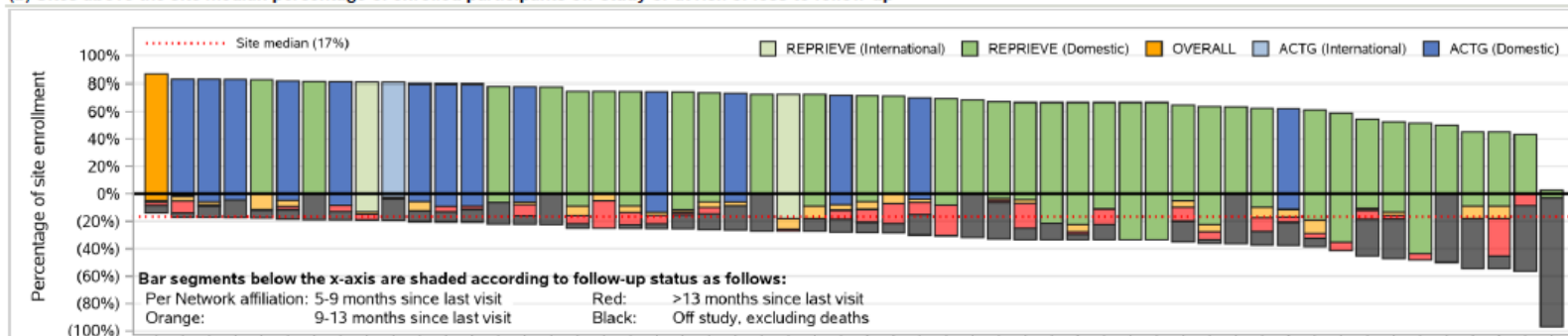
Retention Strategy: Hold monthly meetings with all relevant REPRIEVE site staff to discuss any participants who may be at risk for loss to follow-up.

It is extremely important to identify any participants who are at risk of loss to follow-up (LTFU) (i.e. have not been in for a visit in >1 missed visit). Once an at-risk participant is identified, sites should have a common practice in place (perhaps from the site's own LTFU SOP or the REPRIEVE MOPs section on LTFU) to try and make contact with the participant. Through conversations with the REPRIEVE sites, including international sites, we learned of various approaches sites use to locate a participant who has missed visits. Section 5.0 of this document outlines some of these strategies. We encourage you to implement them at your site, if appropriate.

Tools:

To help sites keep track of their participants who may be at risk of LTFU, the REPRIEVE Data Coordinating Center (DCC) generates a figure that indicates whether your site has any participants LTFU or at risk of LTFU. **Figure 0.4: Site Summaries of Participants Off-Study or at Risk for Loss to Follow-Up** is included in the Monthly Site Scorecard and is an important tool to help identify if your site has any participants at risk of LTFU. An example of Figure 0.4 is included below. **We recommend site teams review this figure monthly and keep an eye on the proportion of orange/red at your site.** If your site's bar has a red section this indicates a participant, or number of participants, has gone >13 months since their last visit. You can then work as a team to try and identify the participant(s) and then take measures to try and contact them.

(b) Sites above the site median percentage of enrolled participants off-study or at risk of loss to follow-up



1.2. Visit Scheduling Flexibility and Coordination

Retention Strategy: Be flexible when scheduling REPRIEVE study visits. If possible allow early morning or evening appointments and coordinator study visits with the participants clinic visits, if they occur at or near the study site.

The majority of REPRIEVE sites that took part in the Retention Champion Initiative already identified visit scheduling flexibility and coordinating study visits with clinic visits and current on-site retention

strategies, and data shows that these strategies are effective. Study participants are volunteering their time to the REPRIEVE study in addition to working full-time jobs and managing day-to-day tasks and additional visits with health care providers. While being cognizant of both the CRS Coordinator and Investigator time and schedules, it goes a long way with participants when sites make an effort to coordinate REPRIEVE visits with already scheduled clinic visits. This helps minimize travel time and costs, and time away from work for participants. Additionally, in an effort to minimize time away from work, many sites offer early morning or evening study appointments and find this practice very well received among participants. ***Please note we recognize not all sites have the ability to offer early morning or evening appointments, or coordinate study and clinic visits.***

Tools:

- Log onto the Protocol Specific Web Page to access the **Visit Schedule Template** and **Visit Calendar**.
- In the most recent Protocol Amendment, the REPRIEVE Team lengthened the visit windows from 21 days to **30 days** to allow for more flexibility when trying to schedule participants within the allotted visit window.

1.3 Between Visit Monthly Check-In Calls

Results from the Retention Champion Initiative indicated that sites performing a monthly between visit phone call had a significantly lower number of participants off-study and off-treatment compared to sites that did not do between visit check-in calls. **This is an easy, cost effective way to ensure participant retention.**

1.4. Develop Standard Agreed Upon Language to Discuss REPRIEVE and Review Goals of REPRIEVE at Every Visit

REPRIEVE is a long trial, so it can be helpful to remind participants about the importance of the trial, why the study is being conducted and what the goals of the study are. It may be helpful to sites to develop standard agreed upon language to use when discussing REPRIEVE with participants. To help you develop this language, refer to section 3.0 to review the key messages of REPRIEVE.

SECTION 2.0. REPRIEVE KEY MESSAGES

These key messages on REPRIEVE both clarify basic facts about the study and articulate ideas that will resonate with your audience. Share these messages with trial site spokespeople before media interviews and with event leaders who will engage with members of the public. These pages can serve as a helpful guide for discussions on REPRIEVE. Reminding participants about the importance of the trial and research being conducted is a good way to keep them engaged in the study.

Top Messages:

- People with HIV are living longer thanks to lifesaving treatments, but as they age, they can face new complications like HIV-related heart disease.
- The REPRIEVE trial confronts this emerging challenge to learn how people with HIV can live in good health even longer.

- REPRIEVE is the largest HIV randomized clinical trial and the largest ACTG study to date.

HIV treatment can prevent AIDS and prolong life, but we don't yet have treatments to prevent HIV-related heart disease.

- Longer lives are a victory, but people living with HIV have other important needs, too.
- Over the past two decades, cardiovascular disease (stroke and heart attack), cancer and diabetes have emerged as major causes of death worldwide for people living with HIV, even surpassing AIDS-related deaths in many countries.
- Studies show people living with HIV are 50 to 100 percent more likely to develop cardiovascular disease even while taking effective treatment.
- Data suggest that women living with HIV are up to three times more likely to have a heart attack than women without HIV.
- Researchers believe that the chronic inflammation associated with HIV may play a role in increasing the risk of cardiovascular disease in people living with HIV.
- Early and uninterrupted antiretroviral therapy (ART) is still the best way to extend life and prevent death in people living with HIV.
- Another contributor to increased cardiovascular disease risk may be the effect of certain lifesaving anti-HIV medications that can raise lipid levels.

Scientists are working on a solution around the world, and this community can help.

- REPRIEVE (Randomized Trial to Prevent Vascular Events in HIV) is a large, randomized clinical trial to test a strategy for heart disease prevention in people living with HIV.
- REPRIEVE will test whether a daily statin (a drug used to treat high cholesterol) can reduce the risk of heart disease among people living with HIV. Early data indicate that statins may provide a protective benefit.
- The trial launched in April 2015 in the United States and seeks to enroll 7,500 participants. Trial sites have been established in 11 countries across the globe, including the US, Canada, Brazil, Thailand, and South Africa, to name a few.

REPRIEVE offers an opportunity to learn more about aging with HIV. This research could pay dividends now and may transform care for future generations.

- Clinical trials have yielded groundbreaking advancements in HIV prevention and treatment. REPRIEVE is poised to transform the fight against HIV-related heart disease.
- REPRIEVE is an opportunity to get ahead of the growing HIV-related heart disease problem and find much-needed solutions to keep people healthy and living longer.
- We don't yet know whether a statin will help prevent HIV-related heart disease. We also do not know how effectively statins work in women living with HIV, specifically. REPRIEVE seeks to answer both of these questions.
- No matter the study's outcome, REPRIEVE will expand our knowledge of how HIV and heart disease are related, and how this connection may impact men and women from New York to Rio to Bangkok to Johannesburg.

SECTION 3.0. SOCIAL MEDIA TOOLS & TIPS

Retention Strategy: Keep your participants informed of important/exciting trial updates via social media platforms (Facebook, Twitter, or Instagram).

Tools:

- Follow the main REPRIEVE Trial social media accounts at @reprivetrials on Twitter and Facebook and share/like/retweet any messages shared from the REPRIEVE Clinical Coordinating Center.

- Use the generic REPRIEVE messages below as templates to create your own messages and post on your site's social media's platform (**pending local IRB approval**). *Please note all messages have been approved for release by the study/sponsor/collaborators/partners. Participating sites can share/like the messages or revise and post on their own pending local IRB approval.*

General Messaging	
Twitter	Facebook
People with #HIV are up to 2x as likely to develop #HeartDisease, including #HeartAttack and #stroke, as people without HIV. Learn more about how @NIH and @retrievetrial hope to reverse this trend: http://bit.ly/NIAIDHeartMonth	People with HIV are up to twice as likely to develop heart disease, including heart attack and stroke, compared to people without HIV. Learn more about how @NIH and @retrievetrial hope to reverse this trend: https://www.niaid.nih.gov/news-events/happy-heart-month-what-people-living-hiv-should-know
DYK people with #HIV are up to 2x more likely to have a heart attack? Learn more at retrievetrial.org #HeartHealth	Did you know that people living with #HIV are 50-100% more likely to have a heart attack or another form of cardiovascular disease? Learn more about this HIV-CVD connection by visiting www.retrievetrial.org . #HeartHealth
#HIV raises your risk of heart disease--but researchers are testing if statins can help. @retrievetrial #HeartHealth	If you are #HIV positive, you may be at an increased risk of developing heart disease. But researchers are currently asking if statins may be able to help lower this risk. Learn more at www.retrievetrial.org . #HeartHealth
#DYK there's a link between #HIV & #HeartDisease? The @retrievetrial is looking to get ahead of the problem by using statins to prevent heart disease and is the largest #RCT in #HIV to date!	Did you know there's a link between HIV and Heart Disease? The @retrievetrial is looking to get ahead of the problem by testing the use of statins to prevent heart disease in people with HIV – and they are well on their way! REPRIEVE is the largest randomized clinical trial and ACTG study to date with over 7500 volunteers enrolled!
National Black HIV/AIDS Awareness Day	
Today is #NBHAAD: DYK #HIV increases the risk of #heartdisease? See how #NIH is addressing this problem bit.ly/1RRqL7y	Today is National Black HIV/AIDS Awareness Day. Heart disease is a health issue that disproportionately affects African Americans. But did you know that #HIV can increase the risk of developing heart disease as well? See how #NIH is addressing this problem with the REPRIEVE clinical trial. #NBHAAD
National Women & Girls HIV/AIDS Awareness Day	
Today is #NWGHAAD: DYK #HIV increases the risk of #heartdisease? See how #NIH is addressing this problem bit.ly/1RRqL7y	Today is National Women & Girls HIV/AIDS Awareness Day. Heart disease is the leading cause of death in American women. But did you know that #HIV can further increase your risk? See how #NIH is addressing this problem with the REPRIEVE clinical trial. #NWGHAAD
HIV Long-Term Survivors Awareness Day	

<p>June 5th, 201X marks XX [insert relevant date and years] years since the first published report of what would become commonly known as #HIV. Today is about bringing awareness to the millions of #HIV long-term survivors. #ItsStillNotOver</p>	<p>June 5th, 201X marks XX [insert relevant date and years] years since the first published report of what would become commonly known as HIV. Since then, much medical progress has been made to improve the lives of people living with HIV/AIDS, but there are still millions of people surviving with HIV. Today is about bringing awareness to the million HIV long-term survivors.</p>
<p>National HIV/AIDS and Aging Awareness Day</p>	
<p>Aging with #HIV? Learn more about how you might be at risk of #heartdisease: reprieve.org #NHAAAD</p>	<p>Today is National HIV/AIDS and Aging Awareness Day. Thanks to improved therapies, people with #HIV are living longer, healthier lives. But while cardiovascular disease is a concern for many older people, having #HIV may put you at a higher risk of experiencing a heart attack or stroke. Learn more about the CVD-HIV connection at www.reprieve.org. #NHAAAD</p>
<p>National Latinx AIDS Awareness Day</p>	
<p>Today is #NLAAD: DYK #HIV increases the risk of #heartdisease? See how #NIH is addressing this problem http://bit.ly/1RkNQd8</p>	<p>Today is National Latino AIDS Awareness Day. Did you know that living with #HIV can increase your risk of developing heart disease? See how #NIH is addressing this problem with the REPRIEVE clinical trial. #NLAAD</p>
<p>#DYK the #Latinx community accounts for nearly 1/4 of all #HIV diagnoses in the US? Today, on #NLAAD, we want to educate the #Latinx community about the increased risk of #heartdisease among #PLWH. Visit www.reprieve.org to learn about how #NIH is addressing this problem.</p>	<p>Did you know the Latinx community accounts for nearly ¼ of all HIV diagnoses in the US? Today, on National Latinx AIDS Awareness Day, we want to educate the Latinx community about the increased risk of heart disease among people with HIV. Visit www.reprieve.org to learn about how the NIH is addressing this problem.</p>
<p>World AIDS Day</p>	
<p>#DYK as AIDS-related deaths decrease in the US, #heartdisease deaths among those w/#HIV increase? Learn more: http://bit.ly/1RkNQd8 #WorldAIDSDay</p>	<p>Today, we observe #WorldAIDSDay. Did you know that even though deaths from AIDS-related morbidities are decreasing in the United States, heart disease deaths among those living with #HIV are increasing? People living with HIV are 50-100% more likely than the general population to develop cardiovascular disease. Learn more about the CVD-HIV connection at www.reprieve.org and see how #NIH is addressing this serious problem: http://www.youtube.com/watch?v=MNDKfsAkNDQ</p>
<p>#WorldAIDSDay reminds us how important it is to participate in research. People with #HIV ages 40-75 may be eligible for the @reprieve</p>	<p>#WorldAIDSDay reminds us how critical clinical trial research has been to advancing medical science on HIV/AIDS, but more research is still needed! If you are #HIV positive and between the ages of 40 and 75, you may be eligible to participate in a trial studying the connection between HIV and heart disease. Learn more at www.reprieve.org.</p>

SECTION 4.0. COMMUNITY EVENTS AND HIV/AIDS AWARENESS DAYS

Retention Strategy: Stay engaged with REPRIEVE participants by participating in local community HIV/AIDS awareness events and recognizing HIV/AIDS Awareness Days in your clinic and/or on your social media platforms.

4.1. HIV/AIDS Awareness Days

Complete List of HIV/AIDS Awareness Days*		
Awareness Day	Hashtag	Date
National Black HIV/AIDS Awareness Day	#NBHAAD	February 7
National Women and Girls HIV/AIDS Awareness Day	#NWGHAAD	March 10
National Native HIV/AIDS Awareness Day	#NNHAAD	March 20
National Youth HIV & AIDS Awareness Day	#NYHAAD	April 10
National Transgender HIV Testing Day	#TransHIV	April 18
HIV Vaccine Awareness Day	#HVAD	May 18
National Asian & Pacific Islander HIV/AIDS Awareness Day	#APIMay19	May 19
HIV Long-Term Survivors Day	#HLTSAD	June 5
National HIV Testing Day	#HIVTestingDay	June 27
National HIV/AIDS and Aging Awareness Day	#HIVandAging	September 18
National Gay Men's HIV/AIDS Awareness Day	#NGMHAAD	September 27
National Latinx AIDS Awareness Day	#NLAAD	October 15
World AIDS Day	#WAD	December 1

**These awareness days typically happen on or around the dates listed, we suggest confirming dates beforehand as they may change year to year.*

4.2. Community Events

Participating in community events can be a great way to not only raise awareness about HIV/AIDS, but they also provide a unique opportunity to bond with REPRIEVE participants. We encourage REPRIEVE sites/clinics to organize teams for AIDS Walks/Runs! The REPRIEVE CCC is happy to provide REPRIEVE Swag for these events. And if your site does participant in an AIDS Walk, take a picture of your team and share it with the REPRIEVE CCC!

Tools:

- See section 4.1 for a complete list of HIV/AIDS Awareness Days
- See section 3.0: Social Media for REPRIEVE related social media messages you can share on specific HIV/AIDS awareness days.
- Contact mdiggs@mgh.harvard.edu for REPRIEVE Swag if participating in community events!

SECTION 5.0. RETENTION AND LOST TO FOLLOW-UP SOP

Retention Strategy: Develop site-specific retention and/or loss-to-follow-up SOP.

Although section 12.3 of the REPRIEVE MOPS outlines a detailed procedure for participants who are lost to follow-up (LTFU), we encourage sites to use the tips below to develop their own SOP with procedures that work best at their site. A handful of REPRIEVE sites already implement this practice and graciously shared their Retention/LTFU SOPs with the CCC team who then extracted the most useful tips and strategies, outlined below. The information below was developed based off of *Never Say Lost: A Practical Guide for Maintaining Participant Follow-Up in Clinical Trials* (NSABP, 2004), AIDS Research and Treatment Center of the Treasure Coast (Matthew Gaskill), and a site-developed communication tracking document.

5.1. Establishing a Rapport with REPRIEVE Participants

- Develop a rapport with the study participant early on, this will ensure open communication between study staff and the participant throughout the trial.
- All study and clinic staff should make every participant feel welcomed and included. Study staff should make every effort to thoroughly answer any questions the participant may have about REPRIEVE.
- At every visit, review a schedule of upcoming study visits and accommodate dates/times (within the protocol window) that works best for the participant for their next required study visit.
- Consider giving the participant business cards of the study coordinator and/or principle investigator to the participant's study contacts. The participant can then distribute these cards to their identified study contacts so they are familiar and cooperative should the study staff need to get in touch with them.

5.2. Tips for Making Contact or Locating REPRIEVE Participants

- Try to reach the participant by **phone** at least 3 times.
- If study staff is unsuccessful in reaching the participant directly, contact the participant's primary contacts. Depending on the nature of the relationship of the individual who is contacted with the study participant, study staff should use appropriate discretion when speaking to an individual other than the study participant.
- If the contact via phone is unsuccessful, try to reach the participant in **writing**.
- Prepare a letter from study staff stating that other attempts to reach the participant have been unsuccessful.
- **When sending a letter to a participant, include a self-addressed, stamped, prepaid envelope and a worksheet for the participant to complete with updated contact information and basic health status.**
- **Hospitals** can be a useful resource for locating missing participants. Hospital chart/patient notes/medical records should contain the participants most recent information, including: home address, telephone number, place of employment, spouse's name, and an emergency contact's name.
- **Check schedules** in the surgery, medical, cardiology, and other hospital outpatient clinics where the participant may have had a recent appointment.
- The **hospital pharmacy** can be another source if the participant has recently obtained a prescription.
- **Newspaper obituary columns** – names of deceased residents are usually published in local newspapers.

5.3. Documenting Attempted Contact

- Study staff should make every effort to maintain accurate and up-to-date contact information on the participant. Contact information should be verified and/or updated at every visit.
- Create a standard document to track all attempted contact with the study participant. This will help in organizing efforts to reach the participant and prevent re-approaching unsuccessful contacts. Below is an example of a standard document used to track attempted contact.

EXAMPLE Standard Procedures for Documenting Attempted Contact with Study Participants

1. Telephone participant *at least* 3 times over the course of 1 – 2 weeks

Attempt 1:

Date: _____

Number (i.e. cell, work, home): _____

Result: _____

Attempt 2:

Date: _____

Number (i.e. cell, work, home): _____

Result: _____

Attempt 3:

Date: _____

Number (i.e. cell, work, home): _____

Result: _____

2. Call primary/alternative contacts

Date: _____

Contact: _____

Result: _____

Date: _____

Contact: _____

Result: _____

3. Call Primary Care Provider for assistance in locating participant

Date: _____

Contact: _____

Result: _____

4. Send written communication with return envelope

Date: _____

Mailing Address: _____

Result: _____

Final Outcome: _____

DATE: _____ SIGNATURE: _____

SECTION 6.0. REPRIEVE Website Resources

The REPRIEVE website has a new look! The website has been redesigned to focus more on participant retention. Sites are encouraged to direct participants to the REPRIEVE website to stay up-to-date on trial news, read informative blogs and REPRIEVE participant newsletters. New additions to the REPRIEVE website and how sites and participants can use them are outlined below.

6.1. Meet REPRIEVE Participants/Share Your REPRIEVE Story

The REPRIEVE Website features profiles on REPRIEVE participants from around the globe. Sharing these with participants may help them feel a sense of community within the trial. If any participants would like to share their story or what REPRIEVE/being part of research means to them, they will be able to submit comments directly on the website! These comments will be reviewed before being posted.

6.2. 'Our Story' and 'In the News' Pages

Under the 'Our Story' page, participants and sites can take a walk down memory lane with this detailed timeline of REPRIEVE, dating back to 2013. Additionally, the 'In The News' blog features all media coverage of REPRIEVE and links to corresponding articles.

6.3. REPRIEVE Community Advisory Board Page

Participants and sites can view profiles of the REPRIEVE Community Advisory Board members to learn more about what REPRIEVE participants are doing in the trial and community at large. Additionally, participants can express interest in joining the REPRIEVE CAB by clicking the "Interested in Joining? Click Here" button!

6.4. Follow YOUR Heart Blog

The REPRIEVE Follow YOUR Heart campaign publishes monthly *My Heart Matters* blogs designed to break down the key points about hot-topic issues in a way that makes the topic simple and quick to understand. Though many of the blogs are women focused, some topics apply to all REPRIEVE participants. Some of the most recent and popular blog posts are hyperlinked below.

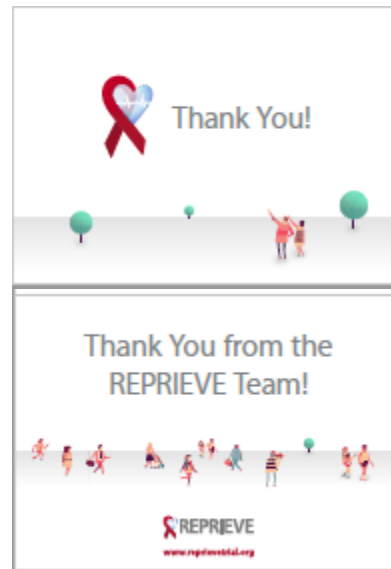
[Vaping and E-Cigarettes: How do they affect my heart health?](#) - By Diana Cagliero, MA

[Nutrition Information Labels & Heart Healthy Diets: Things You Should Know](#) - By Diana Cagliero, MA

[A Midlife \[Symptom\] Crisis](#) - By Sara E. Looby, PhD

SECTION 7.0. REPRIEVE Tokens of Appreciation

Sites identified 'Providing Tokens of Appreciation' as a potential strategy to help retain participants in REPRIEVE. The REPRIEVE CCC has developed tokens of appreciation for sites to hand out to their participants at their discretion. To request tokens for your site, please contact Marissa Diggs at mdiggs@mgh.harvard.edu.

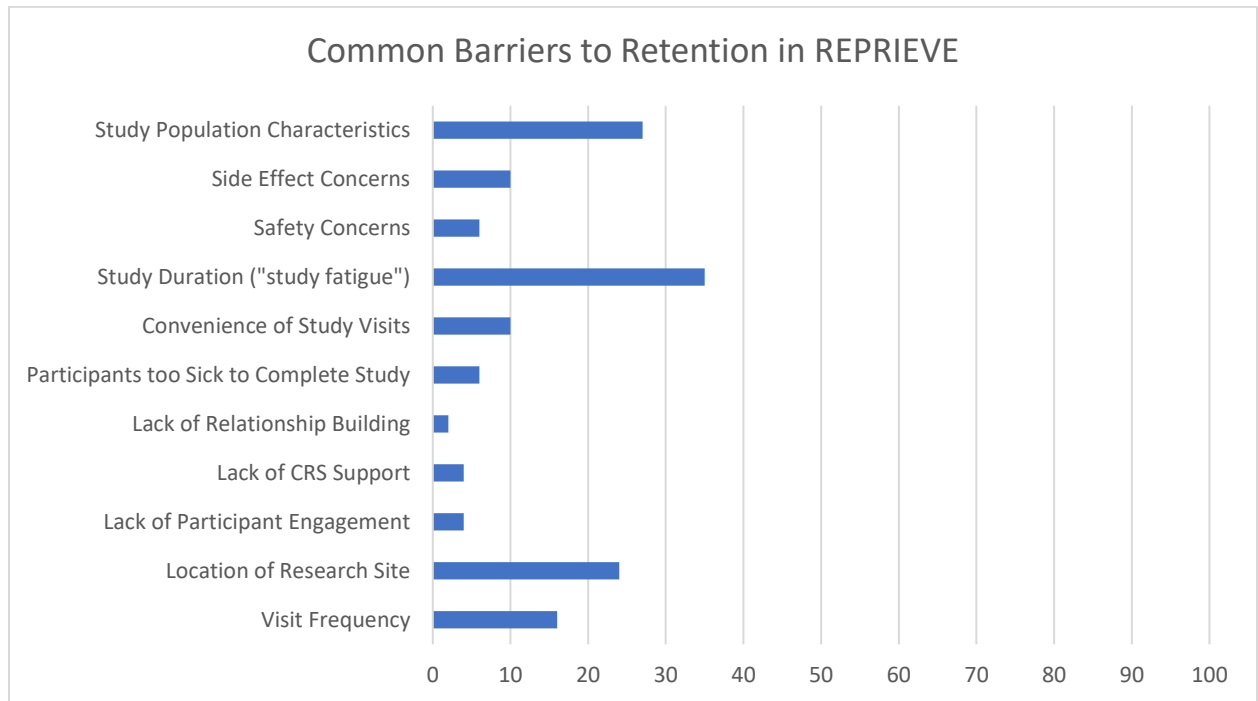


APPENDIX A: RETENTION CHAMPION INITIATIVE RESULTS

Members of the REPRIEVE Clinical Coordinating Center (CCC) spoke with over 50 REPRIEVE sites about common barriers to retention, current on-site strategies to promote retention in REPRIEVE, and what retention strategies sites feel would be helpful to implement.

A.1. Common Barriers to Retention in REPRIEVE

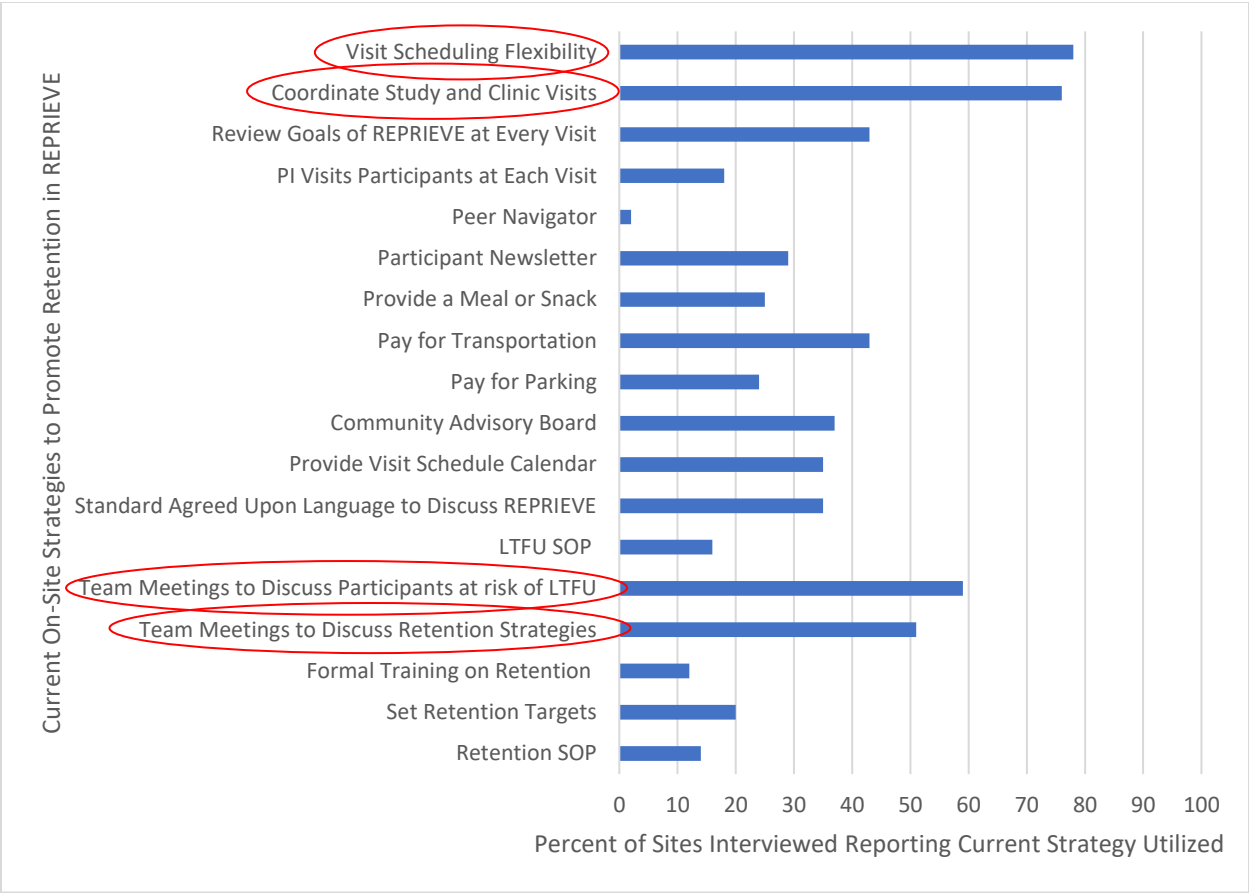
'Study Duration ("study fatigue")' was identified as the most frequently cited barrier to retention in REPRIEVE. To address this barrier, many of the retention strategies enclosed in this toolkit are to help the participant continue to feel engaged, so as not to experience "study fatigue".



A.2. Current On-Site Strategies to Promote Retention in REPRIEVE

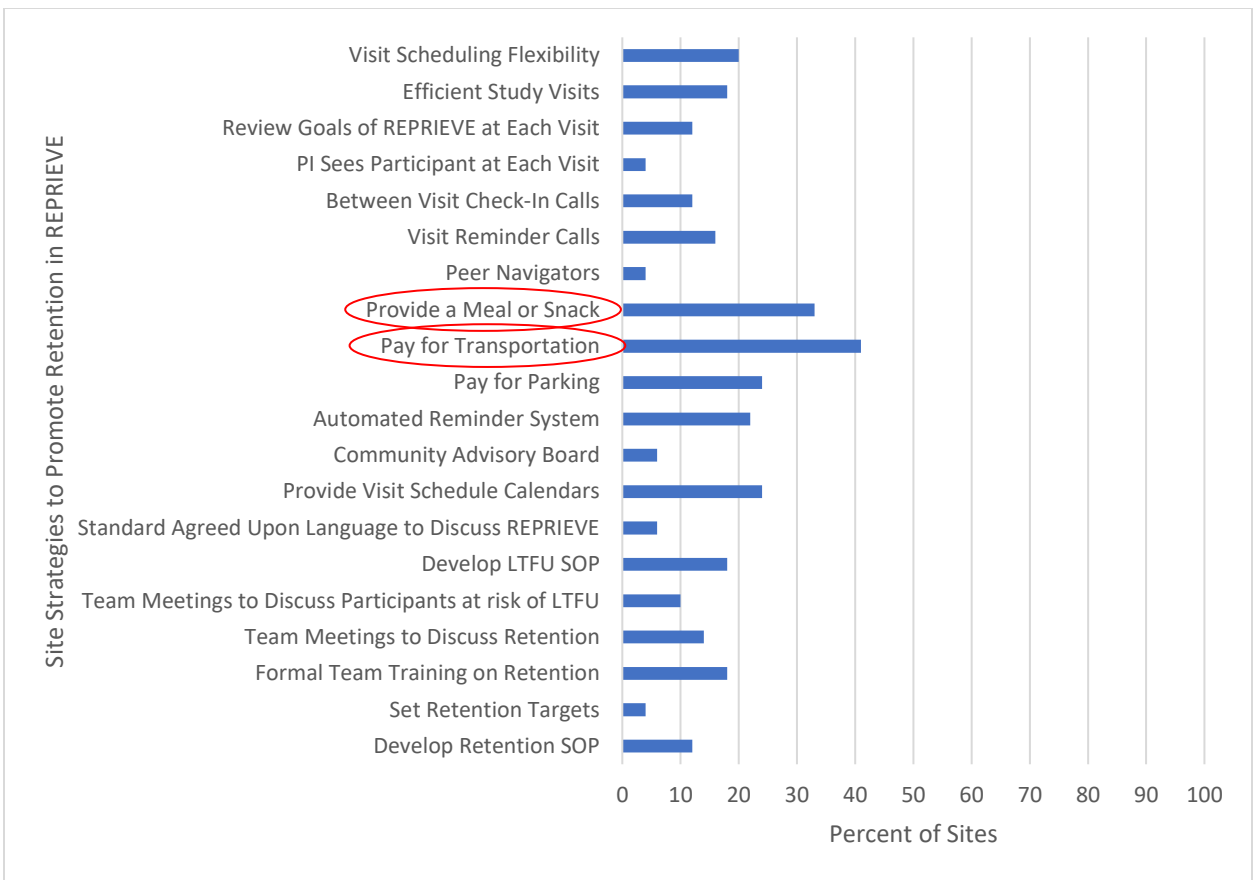
Over 70% of REPRIEVE sites interviewed reported flexible visit scheduling (i.e. early morning, evening, or weekend visits) and make an effort to coordinate study visits and clinic visits. Results of a Chi-square analysis indicate that the relationship between coordinating study visits and clinic visits and percent of participants off-study is statistically significant at an alpha level of 0.95 ($p=0.024$); **indicating that the percent of participants off-study at sites who coordinate clinic visits and study visits is significantly less than at sites who do not make an effort to coordinate clinic and study visits.**

Similarly, though fewer than 50% of sites interviewed currently implement this practice, results of a Chi-square analysis indicate that the relationship between paying for transportation and percent of participants off-study is statistically significant ($p=0.021$). The percent of participants off-study at sites who provide transportation is significantly less than at sites who do not provide transportation.



A.3 Strategies That Should be Implemented at Sites to Promote Retention in REPRIEVE

When speaking with sites, members of the REPRIEVE CCC Team asked, “In addition to the current retention practices at your site, which of the strategies listed do you think would be helpful in retaining participants in the REPRIEVE Trial?”. Sites identified ‘Pay for Transportation’ and ‘Provide a Meal or Snack’ (particularly on fasting visits) as two strategies that would be helpful in promoting retention in REPRIEVE.



A.4. Materials to Promote Retention in REPRIEVE

Sites interviewed were asked what materials they thought would be helpful to promote retention in REPRIEVE. Nearly 50% of sites identified a ‘pen or similar gift’ would be helpful in promoting retention, as well as thank you and birthday cards, and the participant newsletter. As a result, the REPRIEVE CCC has designed REPRIEVE pens, magnet calendars, and thank you/birthday cards. Additionally, Participant Newsletters are created annually in the Spring and hard copies are provided to sites in their desired language(s) at request. Newsletters and tokens of appreciation are available to all sites, to request tokens for your site please contact Marissa Diggs at mdiggs@mgh.harvard.edu.

