Telehealth Centers of Excellence

MUSC Health
Medical University of South Carolina

National Telehealth Center of Excellence

Innovations in Tele-Behavioral Health and Research

Connie Guille, MD – Professor, Departments of Psychiatry and Ob/Gyn
Regan Stewart, PhD – Associate Professor, Department of Psychiatry
Jen Dahne, PhD – Associate Professor, Department of Psychiatry

Objectives

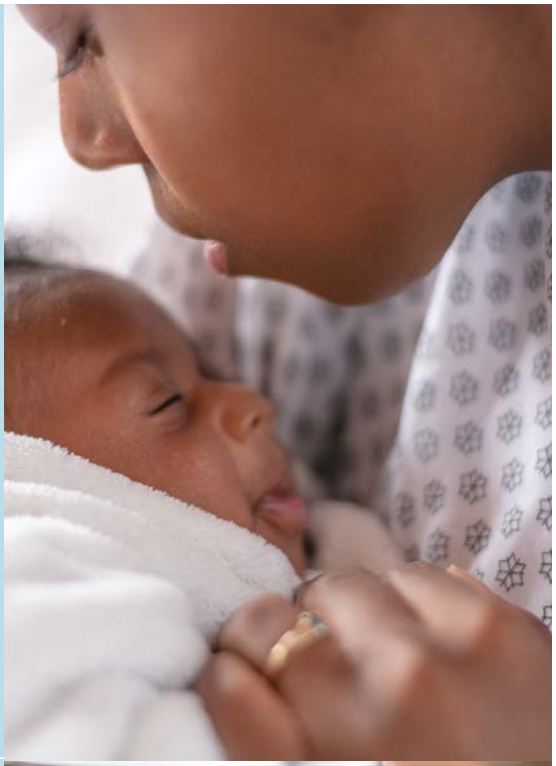
- Describe the role telehealth can play in supporting screening, referral, and treatment of perinatal mental health.
- Describe models for dissemination and training of evidence-based telehealth treatments (e.g., trauma-focused CBT)
- Identify opportunities for use of decentralized/remote clinical trial methods for evaluation of tele-behavioral health.

Leveraging Technology to Improve Maternal Health and Substance Use Disorder and Screening and Treatment

Connie Guille MD
Professor, Depts. Of Psychiatry & Ob/Gyn

Objectives

1) Appreciate the prevalence and impact of unrecognized and untreated maternal mental and substance use disorders.
2) Understand the importance of screening, identification, and treatment of maternal mental and substance use disorders.
3) Appreciate the role of technology in improving the screening and referral to treatment for maternal mental and substance use disorders.



Maternal Mortality in the US is higher than any other developed country

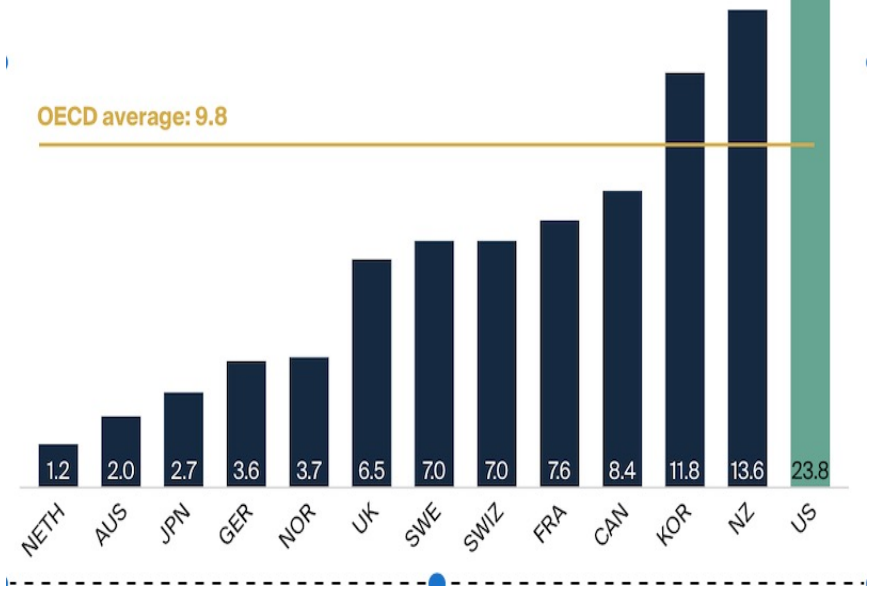
High Income Countries 2020:
12 per 100,000 live births

United States 2020:
23.8 per 100,000 live births

United States 2021:
32.9 per 100,000 live births

Maternal mortality, deaths per 100,000 live births

32.9 deaths per 100,000 live births (2021)
1,205 maternal deaths in 2021
3 maternal deaths per day



Source: Munira Z. Gunja, Evan D. Gumas, and Reginald D. Williams II, *U.S. Health Care from a Global Perspective, 2022: Accelerating Spending, Worsening Outcomes* (Commonwealth Fund, Jan. 2023). https://doi.org/10.26099/8ejy-yc74

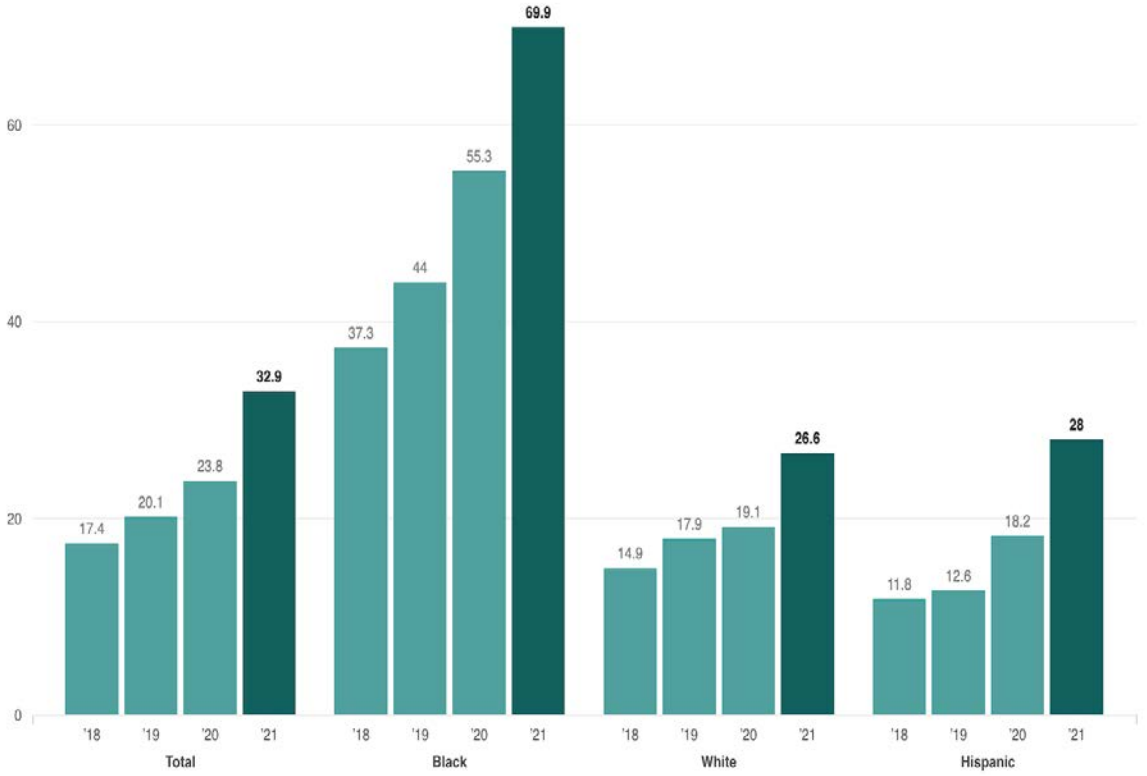
Racial Disparities in Maternal Mortality

White 2021:
26.6 per 100,000 live births

Black 2021:
69.9 per 100,00 live birth

American Indian 2021:
49.2 per 100,000 live births

Maternal Mortality By Race 2018-2021



Notes

The World Health Organization defines a maternal death as the death of a woman "from any cause related to or aggravated by pregnancy or its management (excluding accidental or incidental causes) during pregnancy and childbirth or within 42 days of termination of pregnancy."

Source: National Center for Health Statistics, Centers for Disease Control and Prevention

Pregnancy-Related Deaths: Data from Maternal Mortality Review Committees in 36 US States, 2017–2019

Most frequent underlying causes of pregnancy-related death:

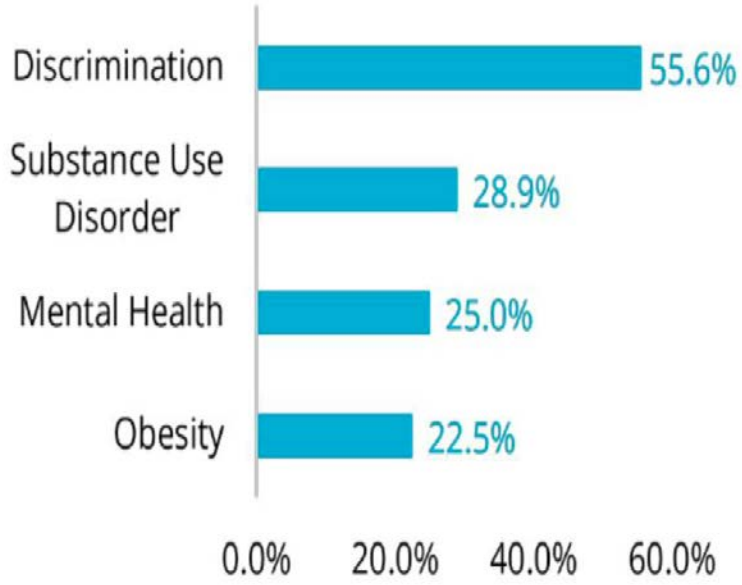
- Mental health conditions (22.7%)
- Hemorrhage (13.7%)
- Cardiac and coronary conditions (12.8%)
- Infection (9.2%)
- Thrombotic embolism (8.7%)
- Cardiomyopathy (8.5%)

84.2% deaths determined to be preventable

Trost SL, Beauregard J, Njie F, et al. Pregnancy-Related Deaths: Data from Maternal Mortality Review Committees in 36 US States, 2017-2019. Atlanta, GA: Centers for Disease Control and Prevention, US Department of Health and Human Services; 2022.

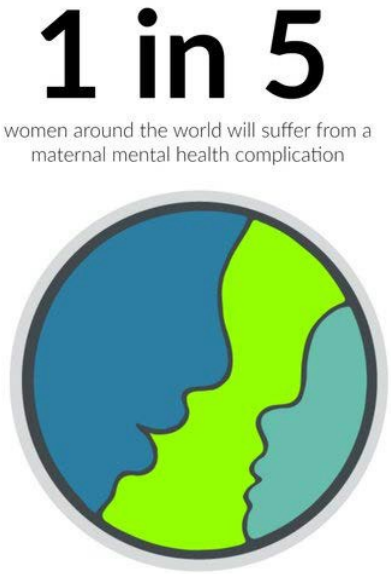
Maternal Maternal Mental Health and Substance Use Disorders are…

…Most Common Contributor to Other Causes of Maternal Death



Maternal Maternal Mental Health and Substance Use Disorders are…

…the Most Common Complication of Pregnancy & Childbirth



Maternal Mental Health Affects Women, Children and Families

Low Birth Weight
Preterm Birth
NICU Admissions
C-sections

Cognitive, Motor, Growth Delays.
Behavioral, Academic, Mental
Health Problems

Poor Prenatal Care
Smoking
Substance Use

Difficulty Bonding
Less Breastfeeding
More Divorce

Many Maternal Deaths due to Mental Health Conditions are Preventable

MATERNAL HEALTH

By Susanna L. Trost, Jennifer L. Beauregard, Ashley N. Smoots, Jean Y. Ko, Sarah C. Haight, Tiffany A. Moore Simas, Nancy Byatt, Sabrina A. Madni, and David Goodman

Preventing Pregnancy-Related Mental Health Deaths: Insights From 14 US Maternal Mortality Review Committees, 2008–17

Trost, SL, Beaurard, JL, Smoots, AN, Ko, JY, Haight SC, Moore Simas AS, Byatt N, Madni SA, Goodman, D. Preventing Pregnancy-Related Mental Health Deaths: Insights From 14 US Maternal Mortality Review Committees, 2008–17. Health Affairs Vo. 40, No. 10.

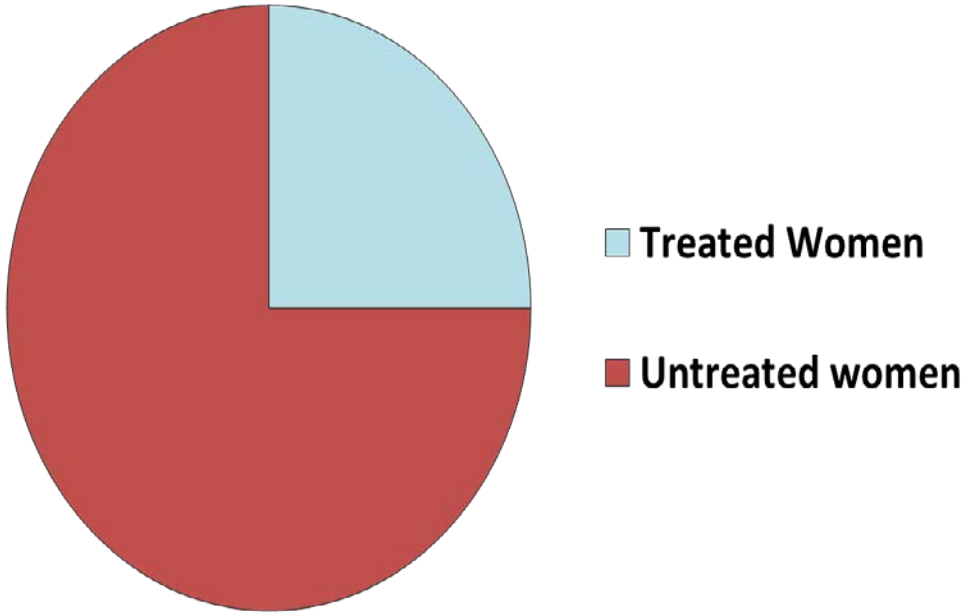
Screen & Referral to Treatment [Standard of Care]

1 in 8 women will be screened

The majority of mental health problems are unrecognized and untreated.

1 in 4 women receive treatment

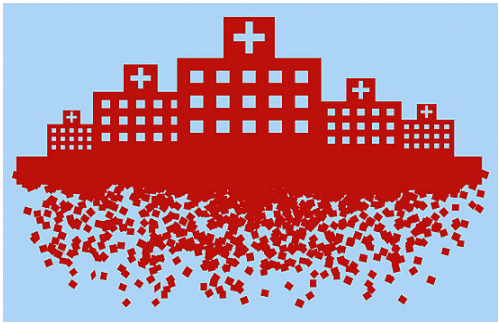
Black women < receive treatment compared to White women



Haight SC, Byatt N, Moore Simas TA, Robbins CL, Ko JY. Recorded Diagnoses of Depression During Delivery Hospitalizations in the United States, 2000-2015. Obstet Gynecol. 2019 Jun; 133(6):1216-1223.

Bauman BL, Ko JY, Cox S, et al. *Vital Signs:* Postpartum Depressive Symptoms and Provider Discussions About Perinatal Depression — United States, 2018. MMWR Morb Mortal Wkly Rep 2020;69:575–581.

Barriers to Successful Screening & Effective Referral to Treatment



Patient	Provider	Healthcare System
Stigma	Insufficient time	Cost: Time & Re/Training
Fear of social/legal consequences	Lack of MH/SUD knowledge	Separation of MH/SUD care
Lack of available or accessible *MH/SUD treatment providers	Lack of available or accessible *MH/SUD treatment providers	Lack of available or accessible *MH/SUD treatment providers

*MH: Mental Health; SUD: Substance Use Disorder

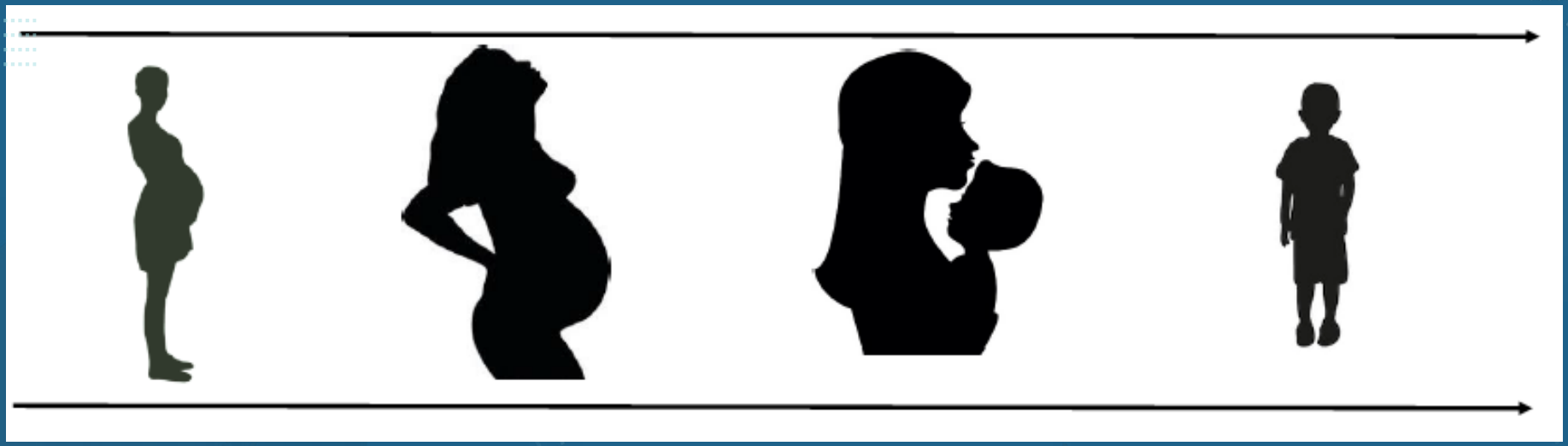
Listening to Women & Pregnant & Postpartum People

Text Message Based Screening

Brief Intervention
Remote Care Coordinator (MSW)

Referral to Treatment
Telemedicine/ Office or Home Follow up

Communicate with Ob/Peds Team
Screening information
Referral and Tx Progress



Screening During Pregnancy and the Year Postpartum

- Pregnancy Screens:
  - 1st Prenatal Care Visit or Anytime After
  - Each Trimester of Pregnancy
- Postpartum Screens:
  - 1 Month Postpartum
  - Every 3 Months After Delivery Until 12 Months Postpartum

Design for Dissemination

LTWP

Text Message Based Screening

Brief Intervention
Remote Care Coordinator (MSW)

Referral to Treatment
Telemedicine/ Office or Home Follow up

Communicate with Ob/Peds Team
Screening information
Referral and Tx Progress

97% of patients have a cell phone

Clinical Efficiency
- Enrollment Existing Staff
- Automated feedback
- Prioritize patients in need

Care Coordinator, MSW
- Least expensive, most qualified
- Bill for screening, case management
- Work remotely with multiple practices

Pilot:
Routine Prenatal Care

Listening to Women (LTW)
Vs.
Standard of Care (SOC) [In-Person Screening & Referral]

RNs Enrolled Peripartum Women in Listening to Women (LTW)

- N = 98.9% [547/553]
- Jan. 2020-April, 2021

In-Person Screening & Referral (SOC)

- N=2,988
- Jan, 2017- Dec. 2019

Determined Rates of Women:

- Screened
- Screened positive
- Referred to treatment
- Received treatment

Guille C., et. al. (2021) A Non-Randomized Trial of In-Person Vs. Text/Telephone Screening, Brief Intervention and Referral to Treatment for Pregnant and Postpartum Women. Psychiatric Research and Clinical Practice. 3(4):172-183.

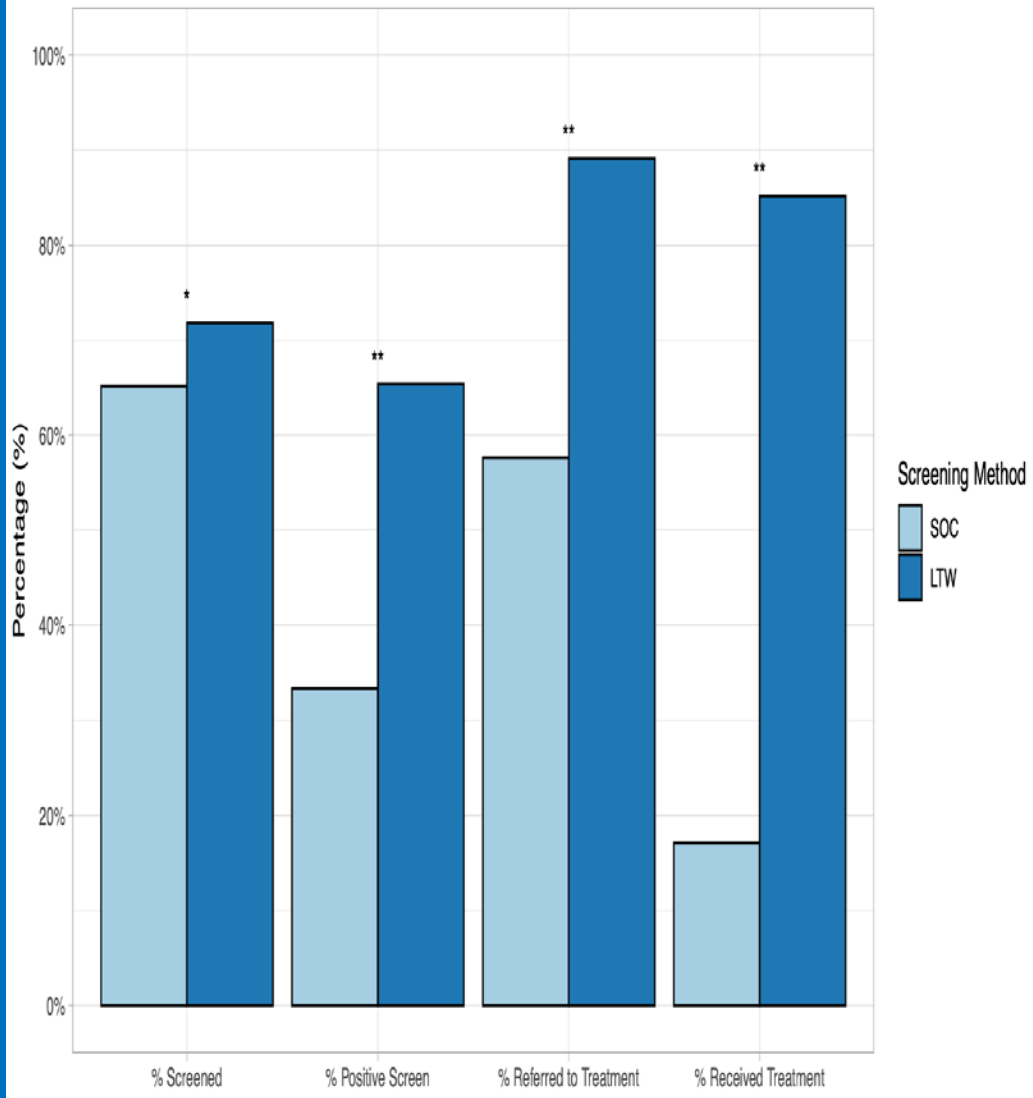
Compared to SOC, LTW were significantly more likely:

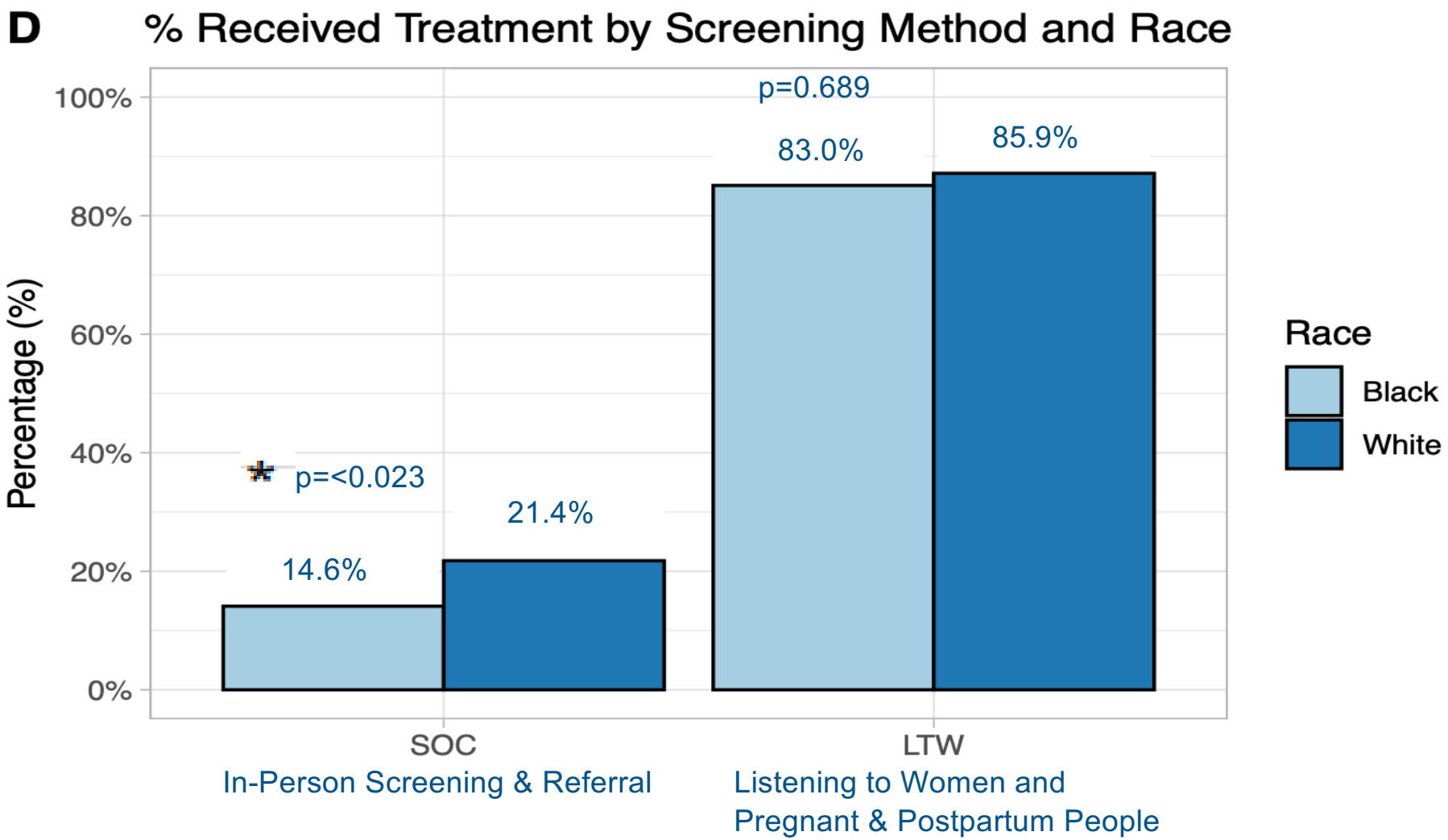
1) Screened
[71.8% vs. 65.2%, p<0.0024*]
RR 1.09 (95% CI 1.0287, 1.1608) p=0.004

2) Screened Positive
[65.4% vs. 33.3%, p<0.0001]**
RR 1.89 (95% CI 1.7137, 2.1007) p=<0.0001

3) Referred to Treatment
[89.1% vs. 57.6%, p<0.0001]**
RR 1.55 (95% CI 1.4264, 1.6932) p=<0.0001

4) Received Treatment
[85.2% vs. 17.1%, p<0.0001]**
RR 5.00 (95% CI 3.9806, 6.3027) p=<0.0001




D
% Received Treatment by Screening Method and Race
Percentage (%)
100%
80%
60%
40%
20%
0%
p=<0.023
14.6%
21.4%
p=0.689
83.0%
85.9%
SOC
In-Person Screening & Referral
LTW
Listening to Women and
Pregnant & Postpartum People
Race
Black
White

Next Steps

Goal: Conduct a Large Step-Wedge Randomized Controlled Trail in “13” Ob/Gyn Practices

Study Aims: Compare LTWP Vs. In-person screening & referral to determine differences in rates

- Treatment attendance and treatment retention [Primary Outcomes]
- Patient Reported Outcomes (PROs) (e.g., depression, substance use, maternal functioning)

Mixed Methods Evaluation

- Implementation processes and outcomes in trial and non-trial clinics

Exploratory Analyses

- Determine sub-group characteristics and mediators of effectiveness on primary outcomes

Acknowledgments

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MUSC Telehealth Center of Excellence
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Telehealth Outreach Program for Traumatic Stress

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Medical University of South Carolina

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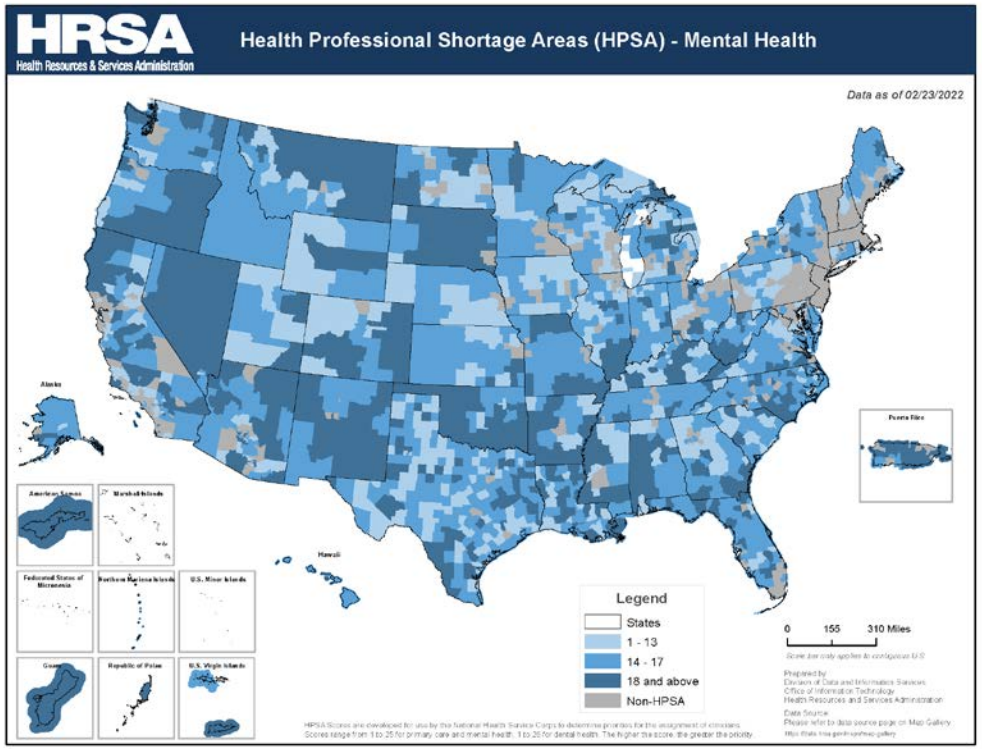


Very few receive services

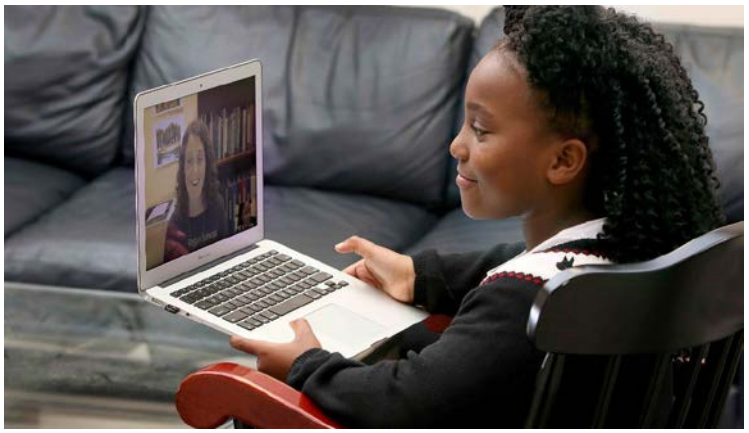
- People don't get the services they need: Less than 1/2 of individuals with mental health problems are estimated to receive needed services (NAMI, 2021)
- Significant disparities exist for mental health access for ethnic minorities and rural populations

Even fewer complete services

- High premature termination in community treatment
  - 28%-75% depending on the study (de Haan et al., 2013)
- Hispanic and African American children are at greater risk for treatment dropout (Pellerin et al., 2010)

MUSC Telehealth Outreach Program for Traumatic Stress

- Established 2015
- Evidence-based trauma-focused treatment via telehealth for children across SC
- Goal of increasing access to care for populations that are underserved by office-based mental healthcare programs
    - Especially, rural populations, and racial/ethnic minorities
- School-based & home-based



Program Evaluation/Outcome Data

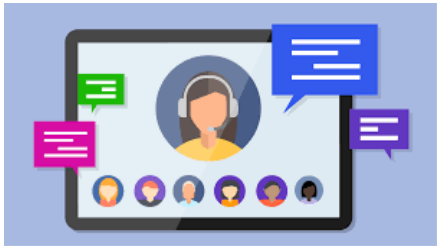
- Over **3,700 visits** with over **400 patients** in **14 counties** to date (30% of all counties in SC)
- 70% school-based, 30% home-based
- 80% treatment completion rate
- The **first ever papers documenting the feasibility, safety, and effectiveness of telehealth delivery of child trauma treatment** are published by our team at MUSC

Bottom line: Telehealth for child trauma treatment is feasible and it works!

Help, I'm New to Telehealth! – Requests for Training

- Calls & emails from across the country

- Telehealth webinars & presentations



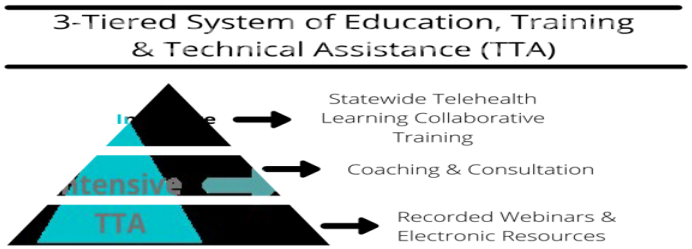
Expansion of the TOP-TS Program

- AND THEN….we received several other grants and additional funding to expand the program

SAMHSA
Substance Abuse and Mental Health Services Administration

HRSA
Health Resources & Services Administration

Telehealth Outreach Program for Traumatic Stress



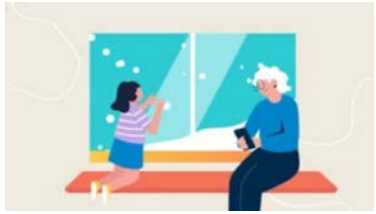
- The TOP-TS team has trained over 7,500 individuals in telehealth delivery of evidence-based trauma-informed practices in 23 U.S. states/territories and 3 countries since 2019.

Videos & Fact Sheets for Caregivers & Therapists

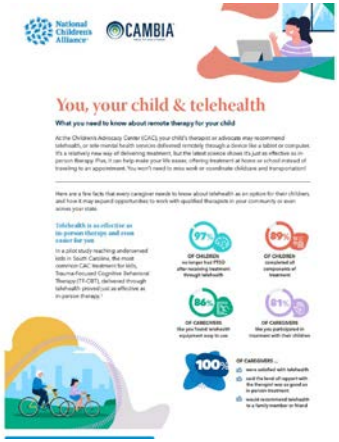
- Worked with National Children's Alliance to create fact sheets & brief animated videos about benefits of telemental health (English & Spanish)

For Caregivers

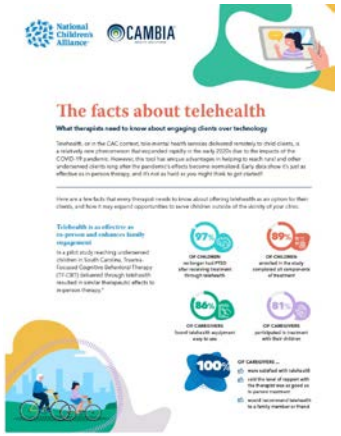
For Therapists



For Caregivers



For Therapists



https://learn.nationalchildrensalliance.org/telehealth

TOP-TS in Puerto Rico

- Collaboration between MUSC, Puerto Rico Department of Education, University of Puerto Rico Medical Sciences Campus, Albizu University-Mayagüez Campus
- Created the first school-based telepsychiatry consultation program in Puerto Rico
- 5 under-served schools in the Mayagüez region of Puerto Rico

School-Based Telepsychiatry in Culebra, PR

*Keeping resources local (within PR)

- First school-based telehealth site in Puerto Rico
- Connecting to psychiatrists in San Juan, PR to Culebra, PR
- Inclusion of Community Health Worker
- Collaboration- MUSC, UPR, Escuela Ecológica, PR Public Health Trust

Recent MUSC HRSA Telehealth COE & Southeastern Telehealth Resource Center Collaboration for Puerto Rico

- MUSC review/revision of SETRC Spanish language documents
- Puerto Rico Department of Health
- Puerto Rico Primary Care Association (FQHCs)
- Puerto Rico Public Health Trust
- Telehealth Conference in Puerto Rico (January 2024)

Future Directions: Need for Telehealth Research for Child Traumatic Stress

- Currently no RCT examining child traumatic stress treated via telehealth
  - Open pilot feasibility trials (MUSC team conducted)
  - Lots of research published for adult trauma treatment via telehealth
- Tx outcome study w/2 conditions: (1) Telehealth TF-CBT vs (2) TAU In-Person TF-CBT (Randomized Effectiveness-Implementation Trial: Hybrid Type 1)
- Feasibility, acceptability & effectiveness of telehealth delivery of TF-CBT within community-based settings for underserved youth
- Puerto Rico community mental health centers

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Puerto Rico Department of Education
Escuela Ecológica Culebra
Puerto Rico Public Health Trust

Thank you!

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Remote Trial Methods for Evaluating Tele-behavioral Health Interventions

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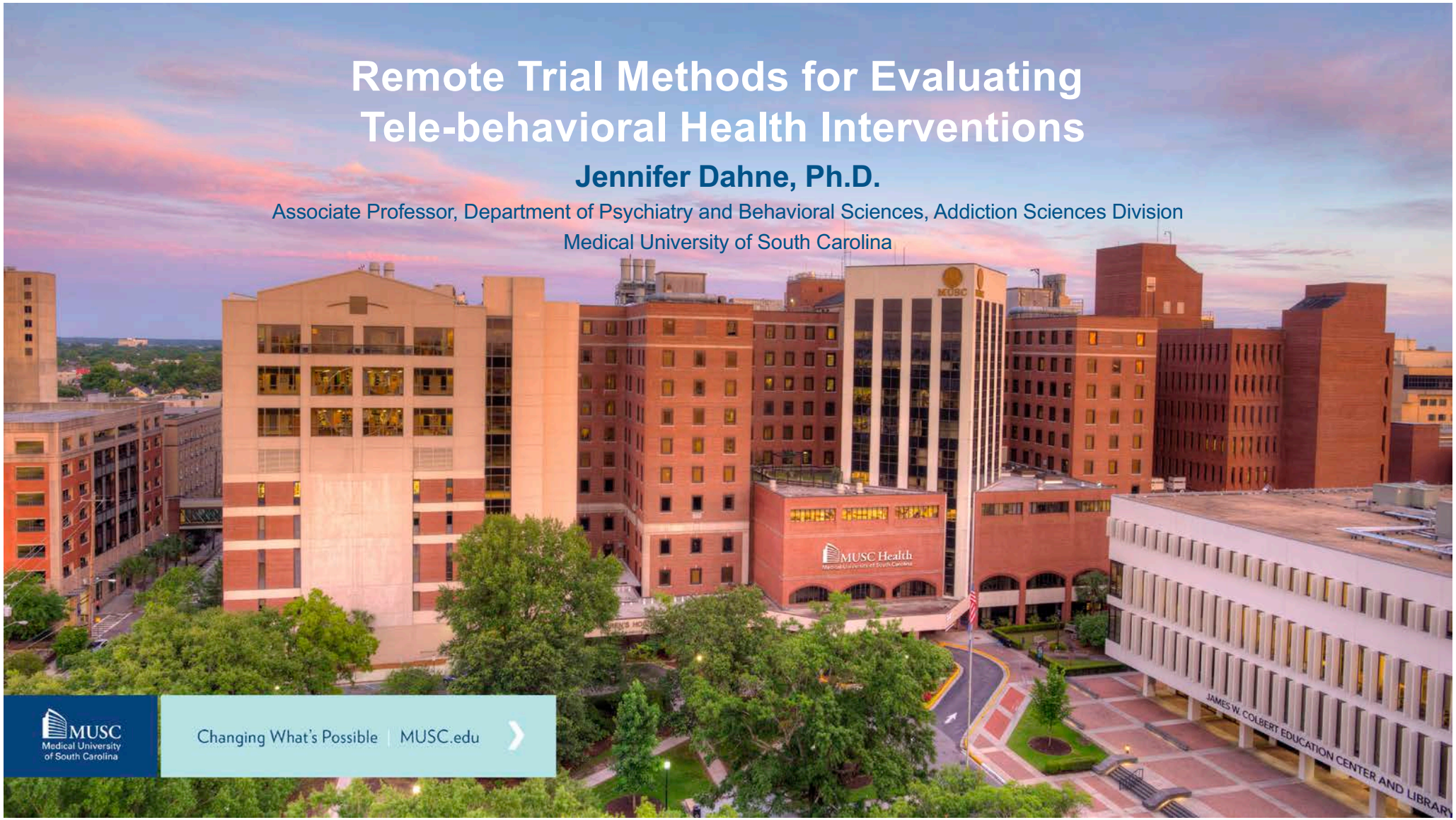
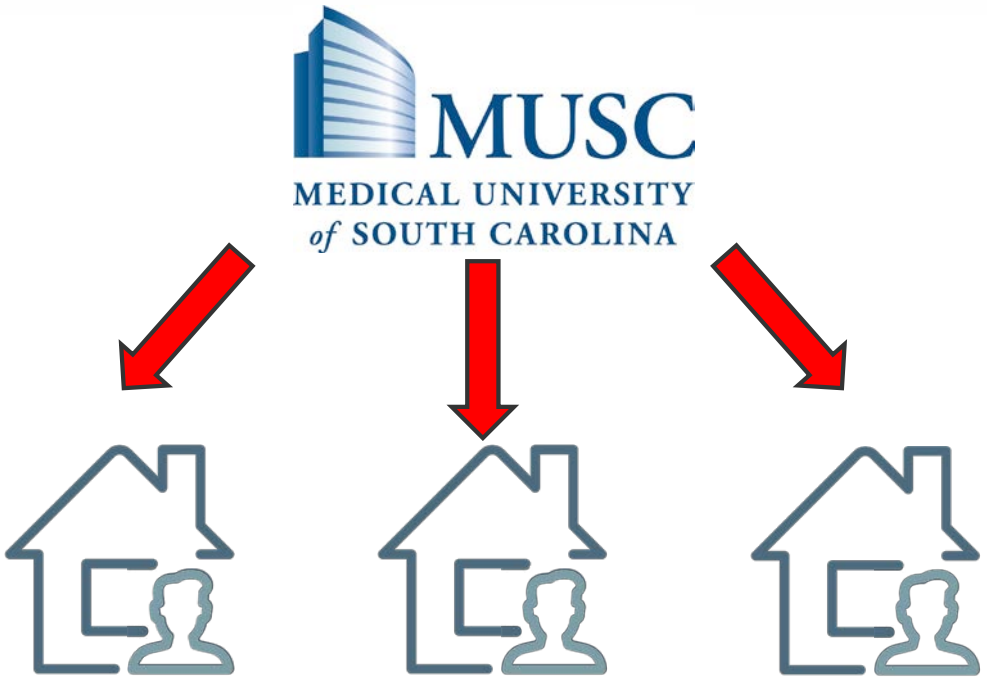


Remote Trials



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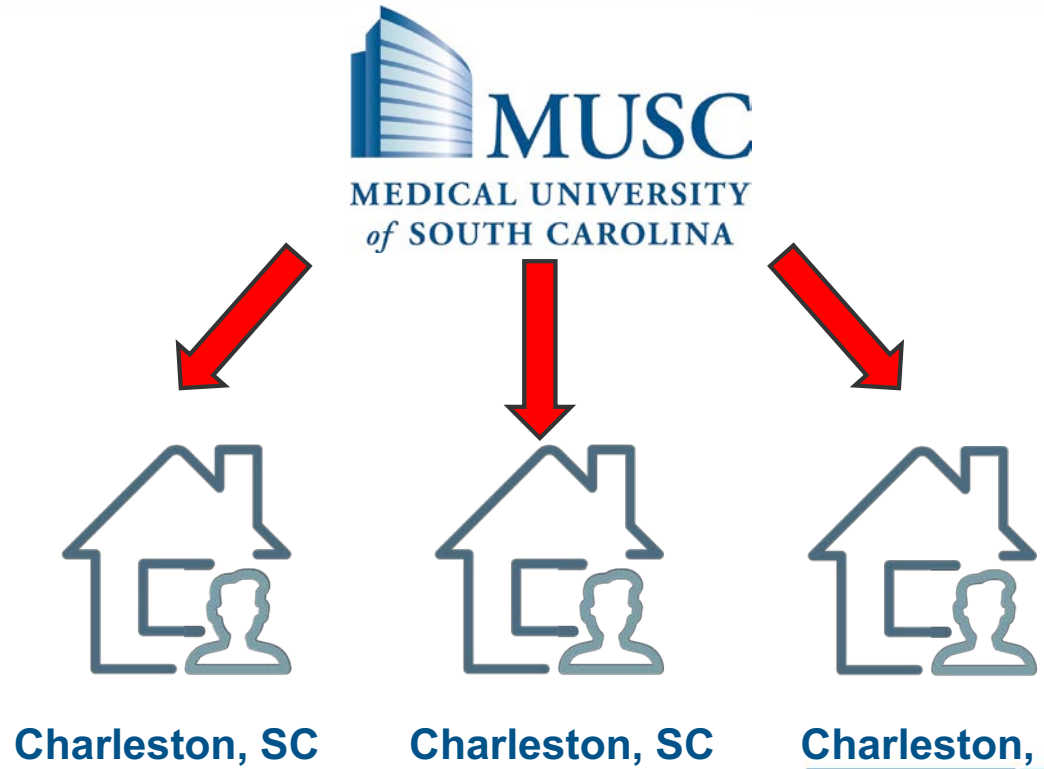
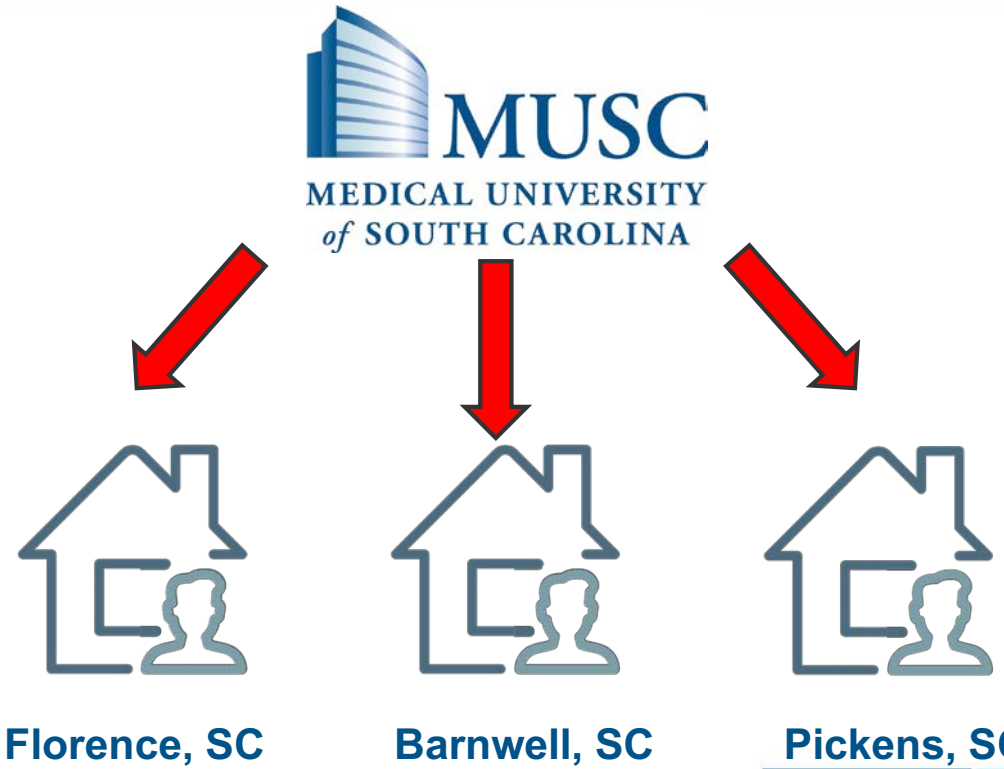
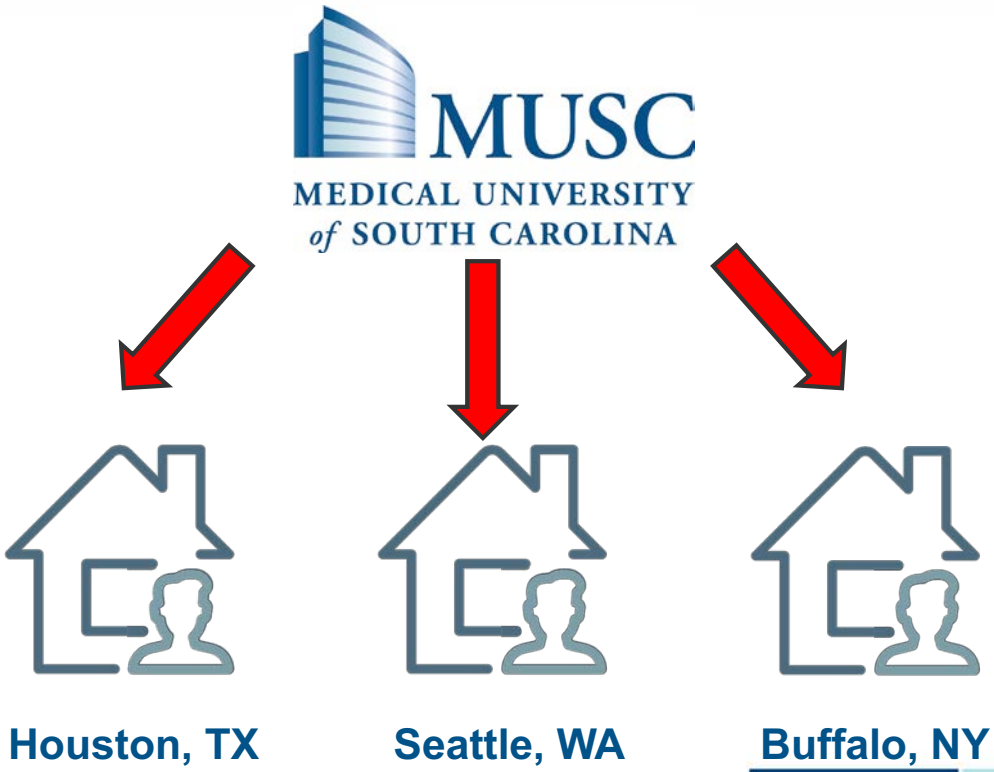


Remote Trials



Remote Trials



The Promise of Remote Trials

- **Remote trials offer several advantages over traditional in person trials:**
  - Wider participant pool, increased results generalizability
  - Reduced regulatory hurdles (e.g., vs. multisite clinical trial)
  - Reduced participant burden, critically important for ill patients
- **Heightened relevance during COVID-19, but not *only* relevant during COVID-19**
- **Remote trials are particularly relevant for evaluation of tele-behavioral health interventions**
  - Telehealth interventions can reduce barriers to care, extending intervention reach
  - They must be evaluated within remote contexts while maintaining the rigor of traditional in person trials

Dahne J, Tomko RL, McClure EA, Obeid JS, Carpenter MJ. Remote Methods for Conducting Tobacco-Focused Clinical Trials. *Nicotine Tob Res.* 2020;22(12):2134-2140. PMC7454765

The Perils of Remote Trials: Addressing the Potential for Fraud

- **Fraud**: Providing false data that misrepresents critical information about eligibility criteria or study outcomes.
- Fraud is not unique to remote trials.
- Because participants are not seen in person, remote trials *may* be more susceptible to fraud.
  - Important literature gap: Prevalence of fraud in remote vs. in person trials
- Fraud mitigation strategies *may* decrease fraud prevalence.
  - Important literature gap: Effectiveness of different fraud mitigation strategies

Dahne J, Tomko RL, McClure EA, Obeid JS, Carpenter MJ. Remote Methods for Conducting Tobacco-Focused Clinical Trials. *Nicotine Tob Res.* 2020;22(12):2134-2140. PMC7454765

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Why Should We Care About Fraud?

- The case of "**Destined to Succeed**"
  - Does not have the condition (e.g., does not smoke in a cessation trial)
  - Regardless of treatment allocation, participant **will** appear to respond
  - 40% of participants (>1 research study per year) admit to exaggerating or feigning symptoms
  - Increased risk when trials do not include biomarker confirmation
    - Biomarker confirmation may be more difficult in remote vs. in person trials

Devine et al., 2013; McCann et al., 2015; Slide credit: Dr. Rachel Tomko

Who You Think You're Enrolling

Who You Think You're Enrolling

Who You Actually Enroll

Who You Think You're Enrolling

Who You Actually Enroll

Even if treatment does not truly work at all, 50% will appear to have quit, which is better than all first line FDA-approved pharmacotherapies for cessation.

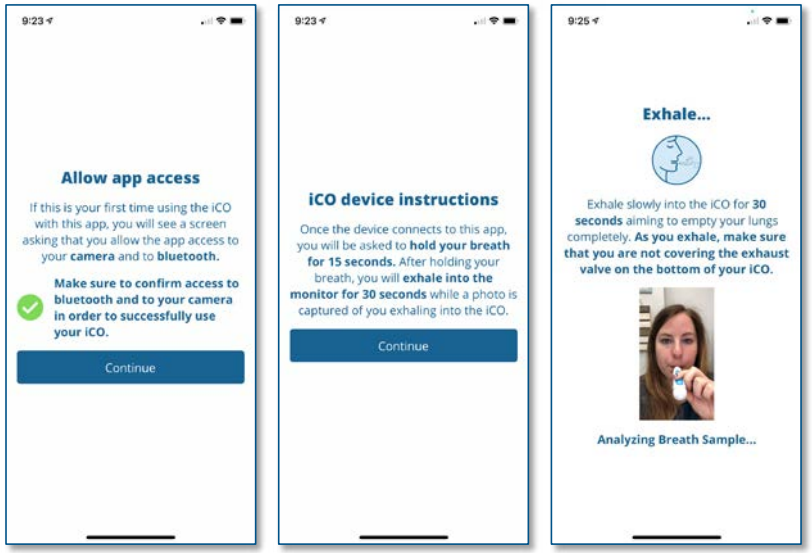
Who You Think You're Enrolling

Ineffective treatments will appear efficacious and will be disseminated, negatively impacting public health.

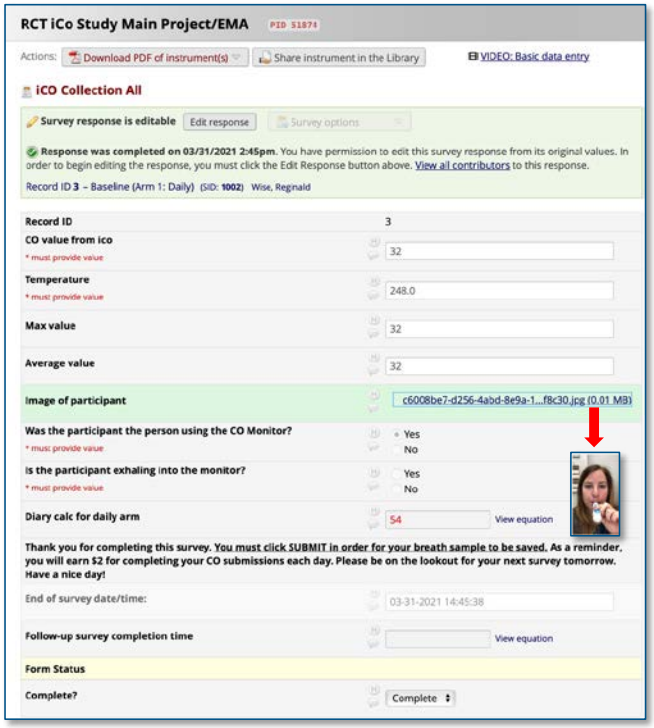
Even if treatment does not truly work at all, 50% will appear to have quit, which is better than all first line FDA-approved pharmacotherapies for cessation.

Improving Rigor with Remote Biomarker Capture: COast (NCI R21)

Participant View



Investigator View



Dahne J, Tomko RL, McClure EA, Obeid JS, Carpenter MJ. Remote Methods for Conducting Tobacco-Focused Clinical Trials. *Nicotine Tob Res.* 2020;22(12):2134-2140. PMC7454765

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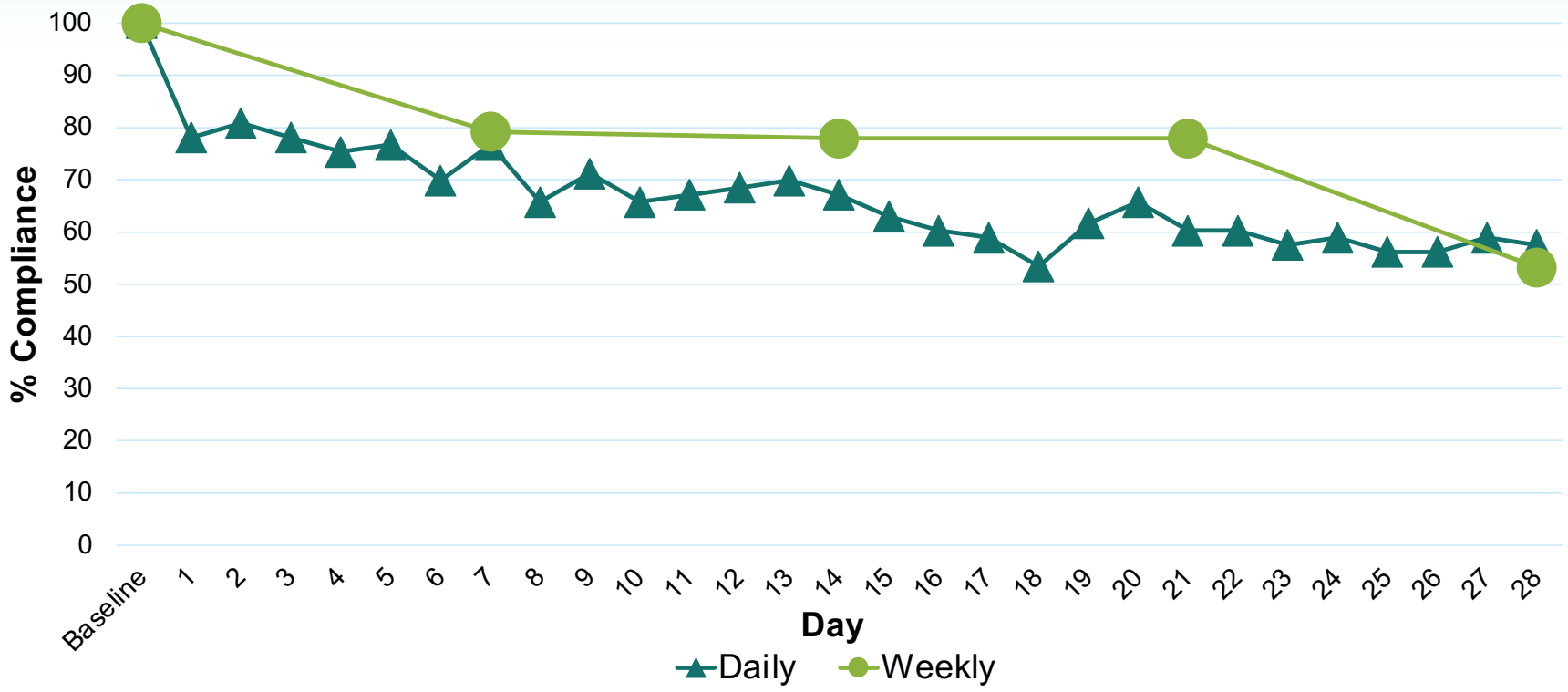
Compliance with Remote CO Capture via COast



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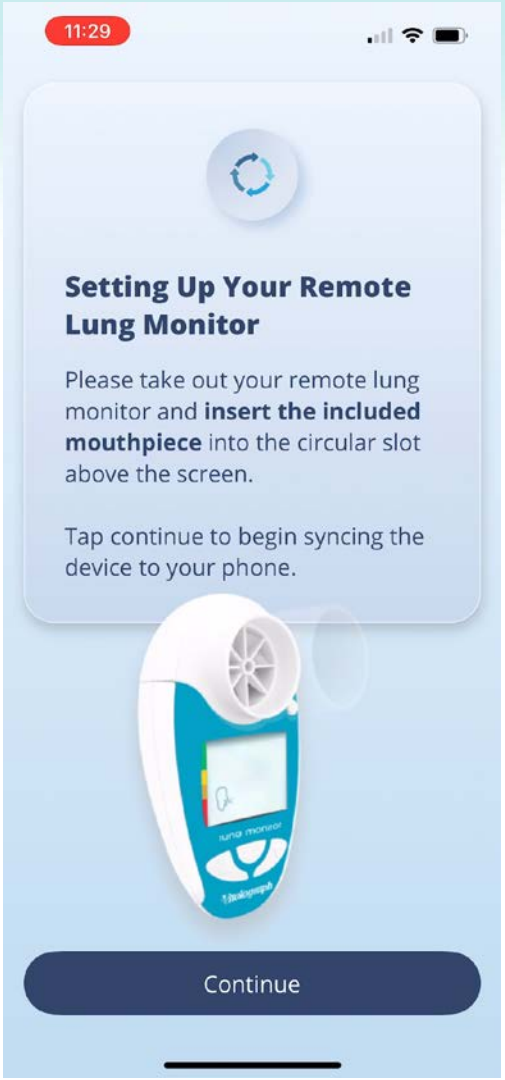
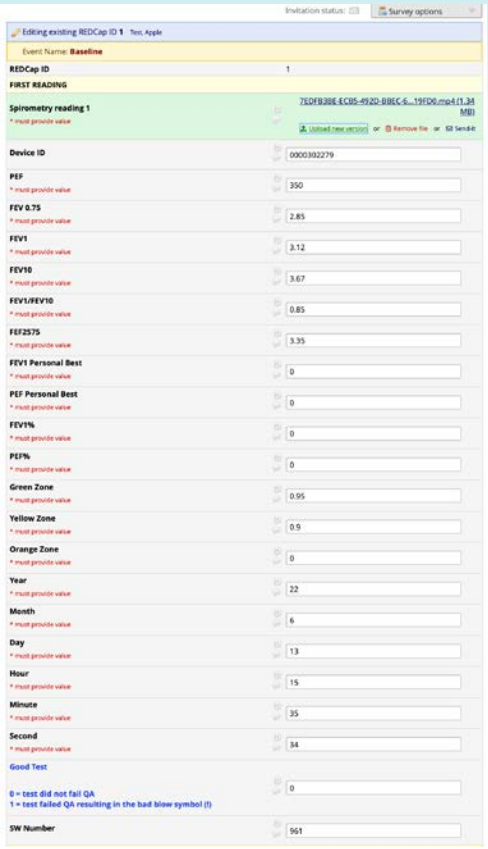
Remote Home Spirometry

(MUSC HRSA-Funded Telehealth COE)





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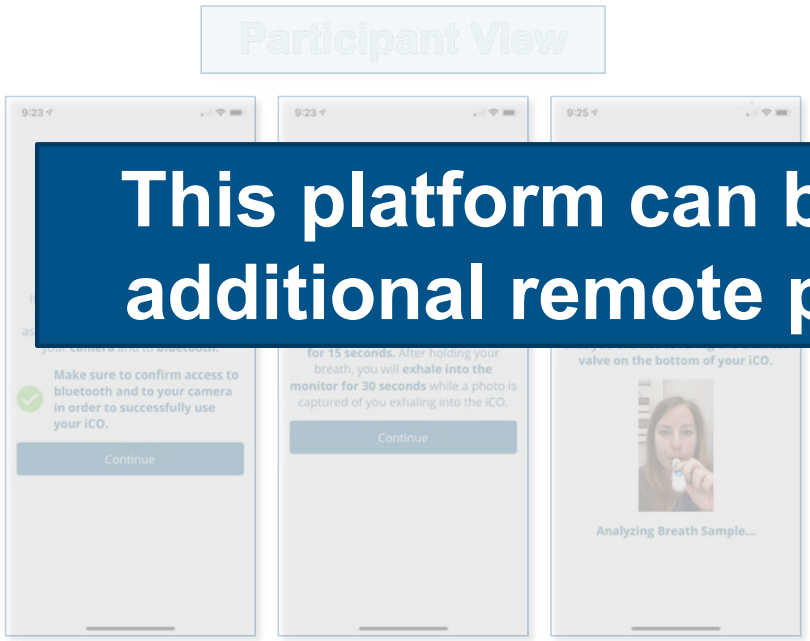
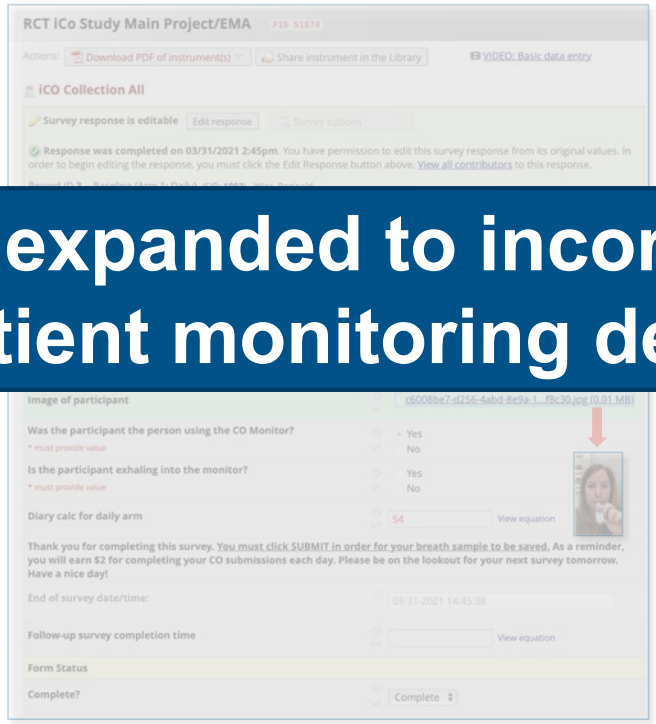
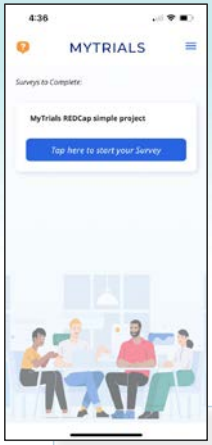
MyTrials (NCATS Phase I STTR)





This platform can be expanded to incorporate additional remote patient monitoring devices.

MyTrials (NCATS Phase I STTR)



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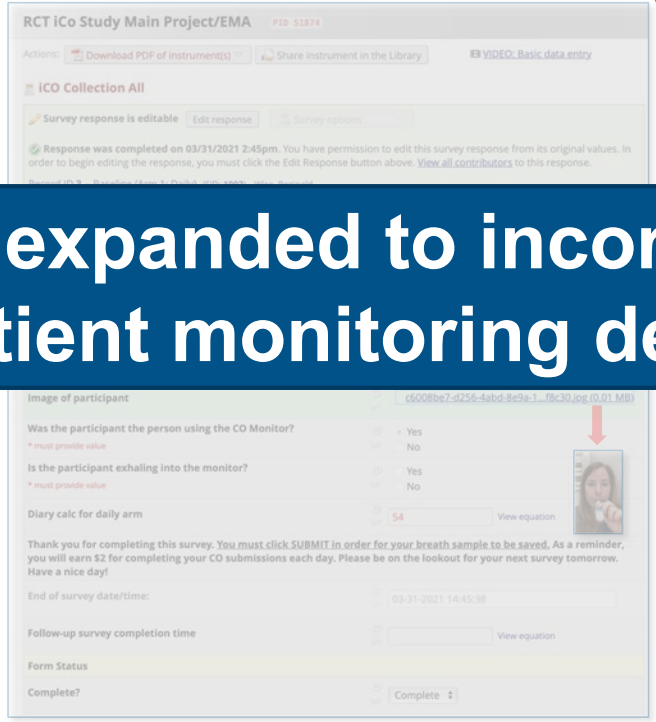

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Further Preventing Fraudulent Study Entry: Cheatblocker

- Focus is on identifying and preventing one form of fraud: repeatedly completing study screening in an attempt to falsely gain study entry
- A REDCap module that can be installed to your institution's instance of REDCap by your REDCap administrator and then deployed within any REDCap project
- Offers investigators flexibility in how they would like to define repeat entries
  - You can use any field or combination of fields in your dataset for defining duplicates
- Initial release February 2021, currently in use at 80 different REDCap institutions

Dahne J, Tomko RL, McClure EA, Obeid JS, Carpenter MJ. Remote Methods for Conducting Tobacco-Focused Clinical Trials. *Nicotine Tob Res.* 2020;22(12):2134-2140. PMC7454765

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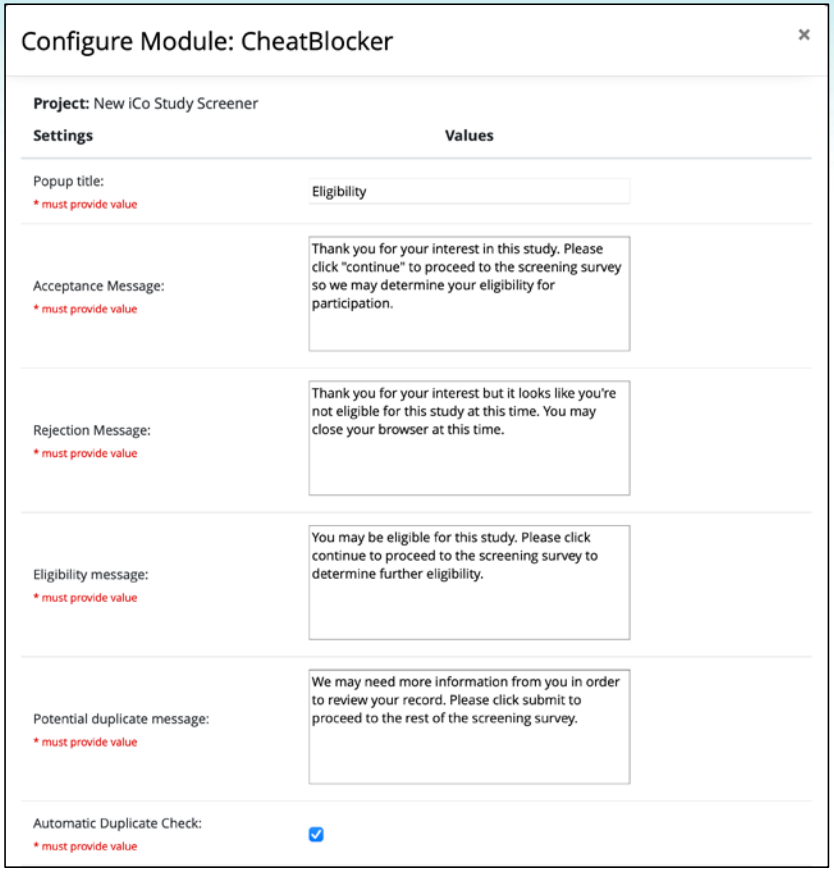
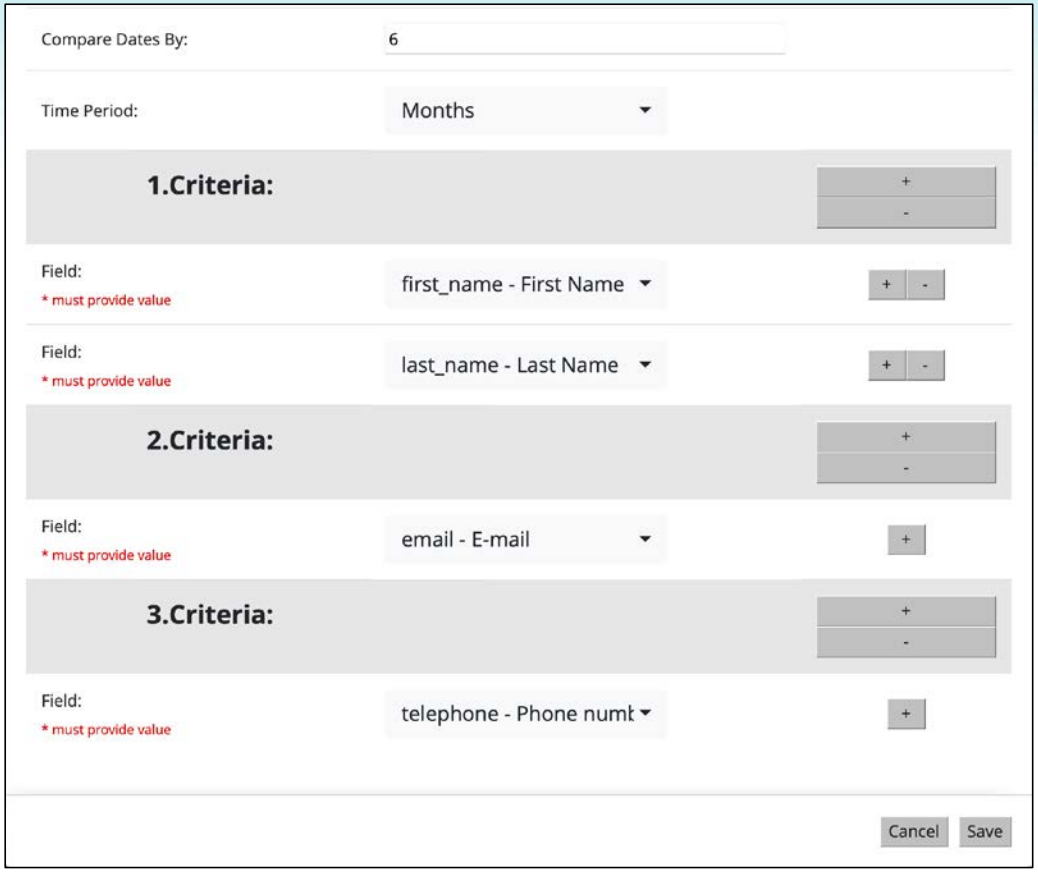

Configure Module: CheatBlocker
Project: New iCo Study Screener
Settings
Values
Popup title:
* must provide value
Eligibility
Acceptance Message:
* must provide value
Thank you for your interest in this study. Please click "continue" to proceed to the screening survey so we may determine your eligibility for participation.
Rejection Message:
* must provide value
Thank you for your interest but it looks like you're not eligible for this study at this time. You may close your browser at this time.
Eligibility message:
* must provide value
You may be eligible for this study. Please click continue to proceed to the screening survey to determine further eligibility.
Potential duplicate message:
* must provide value
We may need more information from you in order to review your record. Please click submit to proceed to the rest of the screening survey.
Automatic Duplicate Check:
* must provide value


Compare Dates By:
6
Time Period:
Months
1.Criteria:
Field:
* must provide value
first_name - First Name
Field:
* must provide value
last_name - Last Name
2.Criteria:
Field:
* must provide value
email - E-mail
3.Criteria:
Field:
* must provide value
telephone - Phone numb
Cancel
Save

In this project, duplicate entry defined as:

- Identical first name AND last name

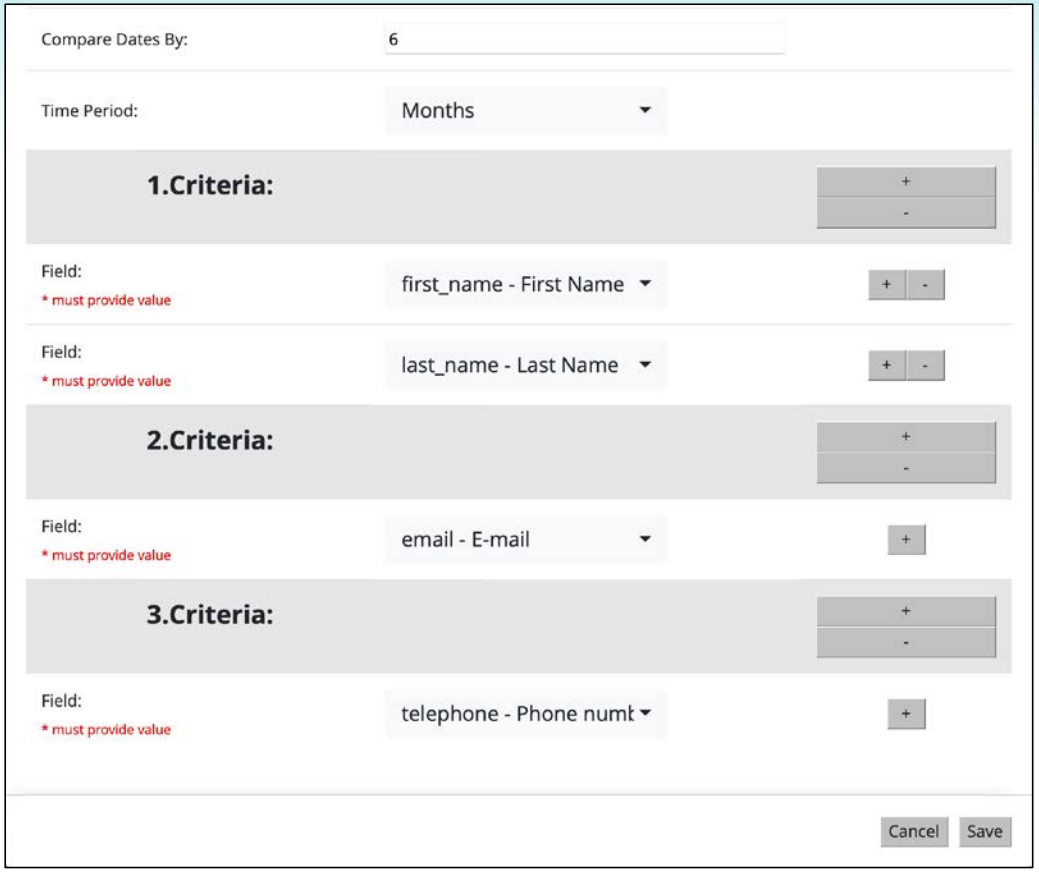
OR

- Identical e-mail address

OR

- Identical telephone number

Between entries within 6 months of one another



Data from 3 Studies Using Cheatblocker

	STARS	COast	VapeX
Total Screenings Completed	468	464	166
Original Duplicates (#, %)	36 (8%)	25 (5%)	21 (13%)
Duplicate Entries (#, %)	64 (14%)	50 (11%)	36 (22%)
Total Duplicates (#, %)	100 (21%)	75 (16%)	57 (34%)
Range (duplicates per original)	1-33	1-5	1-6
Duplicated fields			
First name, last name, e-mail, and phone number	48	62	27
E-mail and phone number	8	3	6
First name, last name, and phone number	2	6	1
First name, last name	2	0	0
First name, last name, e-mail	1	0	0
Phone number	3	3	1
E-mail	0	1	1

Something was changed between entries

Future Thinking

- What fraud prevention strategies work best, in what contexts (studies), and for which participants (types of fraud)?
  - What fields are the best to use for detecting fraud? Does fraud look different within tele-behavioral health intervention studies vs. other types of studies?
- Means of committing fraud keep advancing (masking IP addresses, sharing inclusion criteria online) and our methods of detection need to advance at a faster pace.
- Studies should include and publish (clinicaltrials.gov, manuscripts) plans for preventing/addressing fraud along with outcomes related to fraud detection.
- There are good reasons why participants may provide fraudulent responses (marginalized groups, sensitive clinical topics). How do we address fraud in those circumstances?

Acknowledgements

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Collaborators

- Matthew Carpenter, PhD
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- Kenneth Ruggiero, PhD
- Marty Player, MD MSCR
- Dee Ford, MD MSCR

Research Team

- Noelle Natale
- Louise Freeman
- Olivia Levins
- Sarah Reilly
- Amy Wahlquist, MS

"OK, but if we work *together*... Whammo! Depth perception!"

BMIC Development Teams

- Paul Powers
- Buck Rogers
- John Clark
- Andrew Cates
- Bernard Jansen
- Jihad Obeid, MD FAMIA

App Development Team

- MountainPass Technology
  - Jack Kustanowitz
  - Zachary Gavin
  - Chuck Olczak
  - Yehuda Brickman
  - Rob Sandridge

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If you're interested in using CheatBlocker or our device integrations with REDCap, feel free to contact me!

Thank you!

dahne@musc.edu