Innovations in Tele-Behavioral Health and Research

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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

Racial Disparities in Maternal Mortality

White 2021: 26.6 per 100,000 live births

Black 2021: 69.9 per 100,000 live births

American Indian 2021: 49.2 per 100,000 live births

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

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

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


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


Barriers to Successful Screening & Effective Referral to Treatment

<table>
<thead>
<tr>
<th>Patient</th>
<th>Provider</th>
<th>Healthcare System</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stigma</td>
<td>Insufficient time</td>
<td>Cost: Time &amp; Re/Training</td>
</tr>
<tr>
<td>Fear of social/legal consequences</td>
<td>Lack of MH/SUD knowledge</td>
<td>Separation of MH/SUD care</td>
</tr>
<tr>
<td>Lack of available or accessible *MH/SUD treatment providers</td>
<td>Lack of available or accessible *MH/SUD treatment providers</td>
<td>Lack of available or accessible *MH/SUD treatment providers</td>
</tr>
</tbody>
</table>

*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

97% of patients have a cell phone

Text Message Based Screening

Brief Intervention
Remote Care Coordinator (MSW)

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

Referral to Treatment
Telemedicine/ Office or Home
Follow up

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

Communicate with Ob/Peds Team
Screening information
Referral and Tx Progress
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
In-Person Screening & Referral

- **SOC**
  - Black: 14.6%
  - White: 21.4%
  - p = <0.023

- **LTW**
  - Black: 83.0%
  - White: 85.9%
  - p = 0.689

Listening to Women and Pregnant & Postpartum People
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
Funding: HRSA, NIH, PCORI

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Telehealth Outreach Program for Traumatic Stress

Regan Stewart, PhD
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
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)

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

- 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

*Keeping resources local (within PR)*
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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Thank you!

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Remote Trial Methods for Evaluating Tele-behavioral Health Interventions

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Remote Trials
Remote Trials

Charleston, SC  Charleston, SC  Charleston, SC
Remote Trials

Florence, SC  Barnwell, SC  Pickens, SC
Remote Trials

Houston, TX  Seattle, WA  Buffalo, NY
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

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

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
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.
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.
Compliance with Remote CO Capture via COast
Remote Home Spirometry

(MUSC HRSA-Funded Telehealth COE)

Setting Up Your Remote Lung Monitor

Please take out your remote lung monitor and insert the included mouthpiece into the circular slot above the screen.

Tap continue to begin syncing the device to your phone.
MyTrials (NCATS Phase I STTR)

This platform can be expanded to incorporate additional remote patient monitoring devices.
MyTrials (NCATS Phase I STTR)

This platform can be expanded to incorporate additional remote patient monitoring devices.
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
### Configure Module: CheatBlocker

**Project:** New lCo Study Screener

**Settings**

<table>
<thead>
<tr>
<th>Setting</th>
<th>Values</th>
</tr>
</thead>
<tbody>
<tr>
<td>Popup title:</td>
<td>* must provide value</td>
</tr>
<tr>
<td>Acceptance Message:</td>
<td>* must provide value</td>
</tr>
<tr>
<td>Rejection Message:</td>
<td>* must provide value</td>
</tr>
<tr>
<td>Eligibility message:</td>
<td>* must provide value</td>
</tr>
<tr>
<td>Potential duplicate message:</td>
<td>* must provide value</td>
</tr>
<tr>
<td>Automatic Duplicate Check:</td>
<td>* must provide value</td>
</tr>
</tbody>
</table>

**Compare Dates By:** 6

**Time Period:** Months

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Field</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>first_name - First Name</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>last_name - Last Name</td>
<td>-</td>
</tr>
<tr>
<td>2.</td>
<td>email - E-Mail</td>
<td>+</td>
</tr>
<tr>
<td>3.</td>
<td>telephone - Phone num1</td>
<td>+</td>
</tr>
</tbody>
</table>
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

<table>
<thead>
<tr>
<th></th>
<th>STARS</th>
<th>COast</th>
<th>VapeX</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Total Screenings Completed</strong></td>
<td>468</td>
<td>464</td>
<td>166</td>
</tr>
<tr>
<td><strong>Original Duplicates (#, %)</strong></td>
<td>36 (8%)</td>
<td>25 (5%)</td>
<td>21 (13%)</td>
</tr>
<tr>
<td><strong>Duplicate Entries (#, %)</strong></td>
<td>64 (14%)</td>
<td>50 (11%)</td>
<td>36 (22%)</td>
</tr>
<tr>
<td><strong>Total Duplicates (#, %)</strong></td>
<td>100 (21%)</td>
<td>75 (16%)</td>
<td>57 (34%)</td>
</tr>
<tr>
<td><strong>Range (duplicates per original)</strong></td>
<td>1-33</td>
<td>1-5</td>
<td>1-6</td>
</tr>
</tbody>
</table>

### Duplicated fields

<table>
<thead>
<tr>
<th>Duplicate fields</th>
<th>STARS</th>
<th>COast</th>
<th>VapeX</th>
</tr>
</thead>
<tbody>
<tr>
<td>First name, last name, e-mail, and phone number</td>
<td>48</td>
<td>62</td>
<td>27</td>
</tr>
<tr>
<td>E-mail and phone number</td>
<td>8</td>
<td>3</td>
<td>6</td>
</tr>
<tr>
<td>First name, last name, and phone number</td>
<td>2</td>
<td>6</td>
<td>1</td>
</tr>
<tr>
<td>First name, last name</td>
<td>2</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>First name, last name, e-mail</td>
<td>1</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Phone number</td>
<td>3</td>
<td>3</td>
<td>1</td>
</tr>
<tr>
<td>E-mail</td>
<td>0</td>
<td>1</td>
<td>1</td>
</tr>
</tbody>
</table>
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?
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  • Zachary Gavin
  • Chuck Olczak
  • Yehuda Brickman
  • Rob Sandridge
Thank you!

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