CHOICES: Reducing the Risk of Alcohol-Exposed Pregnancy in Women of Childbearing Age

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Karen Ingersoll Ph.D.
Disclosure

- Nothing to disclose
Objectives

- Identify key features of evidence-based prevention interventions for alcohol-exposed pregnancy risk
- Use a 2 question screening tool to identify AEP risk
- List 3 different population subgroups for whom AEP interventions are indicated.
Goal: Prevent FAS and FASDs

- Brain damage
- Low IQ
- SGA with no catch up growth
- Organ and tissue damage
- Neurological deficits
- Neurocognitive deficits
Scope of the Issue

Women and Alcohol

• Over 50% of U.S. women age 18 - 44 use alcohol.
• Nearly 33% binge drink.
  • National Center for Health Statistics, 2008

• Women who binge drink are at increased risk of an unintended pregnancy and an alcohol exposed-pregnancy.
• About 10% of pregnant women report using alcohol, 2% drink excessively— heavy drinking, binge drinking, or both.
  • Tsai and Floyd, 2004
Weighted Prevalence Estimates of Binge Drinking* Among Women Aged 18 – 44 Years — BRFSS, 2012

*Four or more drinks on any one occasion during the last 30 days
Alcohol Use and Binge Drinking among Women of Childbearing Age – United States, 2006-2010

• 7.6% of pregnant women (or 1 in 13) and 51.5% of non-pregnant women (or 1 in 2) reported drinking alcohol in the past 30 days
• Among pregnant women, the highest estimates of alcohol use were among those who were:
  • Aged 35-44 years (14.3%)
  • White (8.3%)
  • College graduates (10.0%)
  • Employed (9.6%)
Alcohol Use and Binge Drinking among Women of Childbearing Age - United States, 2006-2010

- 1.4% of pregnant women (or 1 in 71) and 15.0% of non-pregnant women (or 1 in 7) reported **binge drinking** in the past 30 days.
- Binge drinkers binged about three times per month, approximately six drinks on an occasion whether pregnant or not.
- Among non-pregnant binge drinkers, prevalence, frequency, and intensity were highest among those aged 18-24 years.
Risk for AEP

- Risk for pregnancy
- Risky drinking:
  - More than 8 Standard drinks/week
  - More than 3 Standard drinks/occasion
Estimated number and percentage of women at risk for AEP: 1 in 30

| Table 1 | Number and percentage of U.S. women at risk of an alcohol-exposed pregnancy (AEP) during the last month according to drinking pattern, where AEP risk was defined as drinking (daily, binge, or any use) combined with not using contraception while having sex with a male |

<table>
<thead>
<tr>
<th>Drinking pattern during month</th>
<th>Number and percentage of women at AEP risk among all non-pregnant women (weighted denominator = 7,236(^a), weighted denominator = 58,486,902)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unweighted numerator</td>
<td>Weighted numerator</td>
</tr>
<tr>
<td>Daily</td>
<td>38</td>
</tr>
<tr>
<td>Binge</td>
<td>91</td>
</tr>
<tr>
<td>Any use</td>
<td>264</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Drinking pattern during month</th>
<th>Number and percentage of women at AEP risk among non-pregnant women who were not sterile and whose partner was not known to be sterile (unweighted denominator = 3,173(^b), weighted denominator = 24,934,732)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unweighted numerator</td>
<td>Weighted numerator</td>
</tr>
<tr>
<td>Daily</td>
<td>32</td>
</tr>
<tr>
<td>Binge</td>
<td>80</td>
</tr>
<tr>
<td>Any use</td>
<td>227</td>
</tr>
</tbody>
</table>

Michael J. Cannon · Jing Guo · Clark H. Denny · Patricia P. Green · Heidi Miracle · Joseph E. Sniezek · R. Louise Floyd

FAS: From Surveillance to Prevention

- Fetal Alcohol Syndrome (FAS) identified in 1967
- FAS is caused by alcohol consumption during pregnancy
- 30 years of research on FAS focused on diagnosis, epidemiology, surveillance, and treatment of affected children
- Prevention was an afterthought--provide pregnant women with alcoholism treatment
Economic Costs of FAS

One case of FAS costs
- $130,000 first 5 years
- $360,000 10 years
- $587,000 in 15 years
- Over $1M in 30 years
  - Lupton, Burd, & Harwood, 2004
Prevention of Alcohol-Exposed Pregnancies

- Address risky drinking among women at risk for pregnancy
- Address any drinking among pregnant women
Screening for drinking while pregnant

- The CDC reports that 1 in 6 (17%) of adults (includes pregnant women subgroup) are asked by their doctor about drinking.
- In a study of over 12,000 women who drank alcohol during their third trimester, 30% reported that their health care provider did not discuss the effects of alcohol use on the child.
- US Preventative Service Task Force recommends 3 screening tools specifically for pregnant women are T-ACE, TWEAK, and 4-Ps (pregnancy, past, partner, parent); T-ACE was effective in randomized trials.
Brief Intervention with Pregnant Women

- Significant reductions in alcohol use
  - Chang et al., 2005; O’Connor and Whaley, 2007
- Higher birth weights
- Lower fetal mortality rates
  - O’Connor and Whaley, 2007
Computerized SBI for alcohol and sugary drink use in pregnancy (Nayak, Korcha, Kaskustas & Avalos, 2014)

- English and Spanish modules on demographics, health, beverage use with tailored pathway based on risk
- Tested in public health clinic with 290 pregnant women
- 87% completed program on stand-alone unmonitored kiosk
- Program completion took average of 10-15 minutes
- Alcohol use in pregnancy identified among 21% by program vs. 13% by staff screening
- No data on intervention impact yet
Primary prevention of alcohol-exposed pregnancies

- Paradigm shift to true prevention with a new pre-conception strategy: find drinkers who were not pregnant, but who were at risk for AEP, and help them change drinking and contraception habits

- 1997: CDC funded a multisite research team to determine settings and develop and test an intervention for women at risk of AEP
Epidemiological study of 2672 women in 6 diverse settings found high rates of women at risk for AEP.

Recent drug use, hx of smoking, inpatient substance abuse tx, inpatient mh tx, and recent physical abuse, all increased risk of AEP risk.
Single Item Screener for AEP risk

- Johnson, Sobell, & Sobell (2010) and Balachova et al., (in press) assessed U.S. and Russian samples of women at risk for AEP.
- At baseline, both studies had asked: **How often did you have 4 or more drinks on one occasion?**
- In both samples, this single binge drinking question **would have identified** over 98% of those at risk for an AEP.
- Single Binge Drinking Question should be tested as a screener in general samples of women.
Help them change with Intervention

- MI selected as the foundational intervention for “CHOICES”
- MI style evokes person’s hopes, values, and goals
- Motivational Activities included:
  - Providing Information
  - Feedback
  - Self-Monitoring
  - Decisional Balance
  - Goal Setting
  - Planning
# CHOICES Intervention

<table>
<thead>
<tr>
<th>Relationship Building, Exploring Drinking and Contraception</th>
<th>Personalized Feedback of Risk for AEP</th>
<th>Setting Goals</th>
<th>Change Planning</th>
</tr>
</thead>
<tbody>
<tr>
<td>MI Relationship Skills: Reflective Listening, Emphasizing choice and control</td>
<td>MI Elicit-Provide- Elicit Strategy, Reflective Listening, Explore Ambivalence</td>
<td>MI Technical Skills: Eliciting Change Talk, Resolving Ambivalence</td>
<td>MI Relational and Technical Skills</td>
</tr>
</tbody>
</table>
CHOICES Study Design

- RCT with 830 women ages 18-44 from 6 sites in 3 states
- Proactive recruitment, non-treatment seeking sample
- At baseline, 100% were at risk for AEP due to **risk drinking AND ineffective/ inconsistent contraception**
- Women were randomized to CHOICES (Experimental) or Informational Control conditions
- CHOICES intervention was 4 sessions plus a gynecology informational visit
- Assessments occurred at baseline, 3M (post intervention), 6M, and 9M
CHOICES Outcomes

- The intervention group was twice as likely to have reduced risk for an AEP after 3, 6, and 9 months, compared with the information-only control group.
- More women in the intervention group changed both drinking and birth control behaviors.

**Reduced risk (9M):**

<table>
<thead>
<tr>
<th></th>
<th>Experimental</th>
<th>Control</th>
</tr>
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<tbody>
<tr>
<td>AEP</td>
<td>69%</td>
<td>54%</td>
</tr>
<tr>
<td>Alcohol</td>
<td>49%</td>
<td>40%</td>
</tr>
<tr>
<td>BC</td>
<td>56%</td>
<td>39%</td>
</tr>
</tbody>
</table>
What did women change to reduce AEP risk?

- Contraception only: 33%
- Contraception and Drinking: 47%
- Drinking only: 20%
Impact of CHOICES Study

- CHOICES intervention was efficacious
- Outcomes were robust across settings
- CHOICES could reduce the rate of AEP and FASDs if disseminated
- Adaptations began: College women, Native American women, Briefer, Telephone, Internet
College women and AEP risk

Funded by AAMC/CDC Collaborative Agreement
Epi study: risks among college women n=2012

**Drinking**
- 8 or more per week: 23%
- 5 or more per time: 63%
- Risky drinking: 64%

**Pregnancy**
- Of sexually active (80%):
  - Use contraception ineffectively: 21%
  - No contraception: 6%

**AEP Risk** 17%
BALANCE Intervention Study

- Modified CHOICES to fit college population
  - One motivational session versus brochure
  - Feedback on risk behavior and personality variables
  - Conducted in student health center
  - Briefer follow-ups (1- and 4-months)
- Mailed or emailed follow-ups
Only independent predictor of AEP risk at four-month follow-up was assignment to the control group (OR 2.2, 95% CI 1.2-4.1).
What about Briefer?

- Can CHOICES or BALANCE be made practical?
- Can it work in a single session?
- Can it work with community women?
- What if you don’t provide contraception?
How low can you go?

- RCT of single 90-minute session interventions EARLY (MI + FB, FASD information, assessment)
- Video Information (FASD information, assessment)
- Assessment Control (assessment only)
- 258 women randomly assigned
- Follow-ups at 3 & 6M

NIAAA R01 AA14356
EARLY Intervention

- MI Techniques: evocation, collaboration, autonomy support and OARS
- Personalized feedback
  - drinks/week, drinks/day, binging, BAC
  - $ Costs of drinking
  - Pregnancy risk
  - Efficacy of different contraception methods
- 10 minute video
- Activity to explore ambivalence, readiness, tempting situations, or change planning
- Encourage a gyn visit if none in past yr
EARLY Outcomes: AEP Risk

Baseline 3M 6M

Video

Info

EARLY

* * *
EARLY Conclusions

- All conditions decreased Risk Drinking, Ineffective Contraception, and AEP Risk
- MI had larger effects than Video or Info on Ineffective Contraception and AEP risk
- Overall rate of women still at risk for AEP in EARLY condition was 62.1%; (36.4% in CHOICES and 31.3% in BALANCE)
- Single session intervention for AEP risk has weaker effects than CHOICES
EARLY Remote

- Adaptation of the EARLY MI condition for mail and telephone delivery
- Recruitment via Craigslist ads; screened 673 interested women
- Reduced barriers to access by offering remote alternative to face to face counseling
- Single arm prospective pilot study; n=46

Funded by NIAAA 3R01AA14356
## EARLY Remote Rates at Risk

<table>
<thead>
<tr>
<th></th>
<th>BASELINE</th>
<th>6M</th>
<th>Effect Size¹ (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean</td>
<td>Mean</td>
<td></td>
</tr>
<tr>
<td>Ineffective Contraception Rate</td>
<td>84.5% (n=44)</td>
<td>64.3% (n=32)</td>
<td>d=.57 (.07, 1.07)</td>
</tr>
<tr>
<td>Risk Drinking</td>
<td>n=44/44</td>
<td>n=28/32</td>
<td>% 87.5%</td>
</tr>
<tr>
<td>At risk for AEP</td>
<td>n=44/44</td>
<td>n=22/32</td>
<td>% 68.8%</td>
</tr>
</tbody>
</table>

Conclusion: Remote delivery is feasible. Pilot results are comparable to face to face EARLY intervention.
Healthy CHOICES (Wilton et al., JSAT 2014)

- 2 session brief intervention modelled on CHOICES using MI + Personalized FB
- BI delivered in person vs. on telephone
- 6M Follow-up; 68% retention in study
- No differences between conditions
- Significant reductions in pregnancy risk to 56%, risky drinking to 89%, and AEP risk to 52%
The OST CHOICES Program was made culturally appropriate for American Indian women and implemented with three communities, two on the Pine Ridge reservation and one off.

Data on drinking, sexual activity, and contraception use were collected at baseline and 3- and 6-months post-intervention.

Data were analyzed using descriptive statistics, one-way ANOVA, and a random intercept generalized estimating equation (GEE) model.
Oglala Sioux CHOICES Results

- 193 non-pregnant American Indian women enrolled in the OST CHOICES Program, and all were at-risk for AEP because of binge drinking and being at-risk for an unintended pregnancy.
- Fifty-one percent of participants completed both 3- and 6-month follow-up.
- Models showed a significant decrease in AEP risk from baseline at both 3- and 6-month follow-ups, indicating the significant impact of the OST CHOICES intervention.
- Women in the OST CHOICES Program were more likely to reduce their risk for AEP by utilizing contraception, rather than decreasing binge drinking.
Began as a tribally-run program using a 2-session MI plus Feedback individual intervention based on CHOICES with cultural adaptations for Native American women

Needs assessment identified preference for Group mode

OST CHOICES Group Activities modified due to low literacy and numeracy. Ex: some women do not “get” counting drinks, so Group includes drink pouring to aid in learning by doing

OST CHOICES Group emphasizes LARC rather than barrier methods
Oglala Sioux Tribe CHOICES Group

- 2-session CHOICES Group model launched 2014
- Follow-up data of OST CHOICES (both individual and group combined) show that at 3M, 79% of women are classified as no longer at risk for AEP; at 6M, this drops to 73.9%
  - Most women are getting on depo-provera or implants for contraception
  - Some drinking reductions, but most remain at risky levels

CHOICES Dissemination

- CDC projects in STD clinics yielded 2 session model
- CDC projects at 2 Hospitals integrated AEP risk screening into EMRs
- CDC-HIS, NIAAA funding for the Oglala Sioux Tribe
  CHOICES and CHOICES Group for OST
- SAMHSA funded public substance abuse treatment programs to add the CHOICES intervention
- Provinces of Manitoba and British Columbia have adapted it for Youth and Family settings
.choices dissemination

- Free counselor manuals, client workbooks, & training materials are available through CDC website at:
  http://www.cdc.gov/ncbddd/fasd/freematerials.html

- CHOICES is cited in
New Directions: eHealth

- Can CHOICES be delivered using the Internet?
- R34 Feasibility Pilot Study-- NIAAA
- Adapted CHOICES into a highly interactive Internet Intervention that is personalized, tailored to the user, and uses MI counseling style in all language and interactivity elements
Welcome to CARRII. To begin, click the “How to Use” link in the information panel. After you complete the How To Use Tutorial, you will be able to access the first Core in the program.
Cores

These are the six Core units for CARRII. During the first week, please complete the Overview Core. A new Core becomes available one week after the previous Core is completed. This gives you time to practice the techniques learned in each Core before moving to the next one. Completed Cores can be reviewed at any time.
Click scenarios to rate your temptation and confidence levels. Then click Risk Summary to learn more.
DRINKING TEMPTATION & CONFIDENCE

Click scenarios to rate your temptation and confidence levels. Then click Risk Summary to learn more.
We had plans!

Why are you changing them?

You don’t care about my feelings!

Go do whatever you want. I don’t want to argue.

But don’t expect me to stay home by myself!

WHAT WOULD YOU DO?
Scenario: Conflict with others.

Risky Drinking Levels
4 or more standard drinks at 1 time.
8 or more standard drinks in 1 week.

How **tempted** are you to drink at risky levels when you are upset by conflict with others?

**Temptation Rating**
Low | Medium | High

How **confident** are you that you can avoid drinking at risky levels when you are upset by conflict with others?

**Confidence Rating**
Low | Medium | High

Risk Assessment

You’re in a high risk situation. When you experience conflict and disagreement, you lose your head. Even though you wanted to drink below risky levels, you want to go out and party hard to forget about this stress.

When your temptation is higher than your confidence to handle it, you might take chances and drink at risky levels.
CARRII RCT

- Pilot tested (n=74) CARRII in a small RCT against an educational website
- Participants recruited mostly via Craigslist ads for volunteers placed in 15 top binge drinking cities in U.S.
- Similar measures to previous CHOICES-like studies and added daily diaries via Internet
- Participants were 57% White, 19% Black, 8% Biracial, 5% Asian, 8% Other, with 16% reporting Hispanic ethnicity
- Educational levels: Less than High School, 5.4%, High School 30%, College 35%, Advanced Degrees 14%
CARRII Pregnancy Risk Outcomes

- Baseline: CARRII 88.6%, PatientEd 74.3%
- Post Treatment: CARRII 69.7%, PatientEd 77.4%
- 6M FU: CARRII 50%, PatientEd 61.3%

Significance levels:
- Baseline: p<.04
- Post Treatment: p<.001
CARRII Risk Drinking Outcomes

Baseline: 77.1%
Post Treatment: 82.9%
6M FU: 59.4%, 61.3%

CARRII vs PatientEd

Significance:
- p < 0.02
- P < 0.09
CARRII AEP Risk Outcomes

- Baseline: 68.6%
- Post Treatment: 58.1%
- 6M FU: 45.2%

Significance:
- Post Treatment vs Baseline: p<.001
- 6M FU vs Baseline: p<.005

Legend:
- CARRII
- PatientEd
Conclusions: Preventing Alcohol-exposed pregnancies

- AEP risk can be decreased with motivational interventions
- 4 session CHOICES and single session college-focused BALANCE interventions are most efficacious
- 2 sessions less efficacious than CHOICES
- Single session may be too brief for community women
- eHealth and group approaches show promise
- mHealth being tested
- Most women change both behaviors, AND more women change contraception than drinking
The Future of Screening for AEP prevention

- **Risk screening** must be adopted across educational, medical, and community settings.

- **Single Binge Drinking Question** (How often do you have 4 or more drinks on one occasion) can identify many women at risk for AEP. If answer is $>0$, ask a second question:

  - How often do you use a method of birth control exactly as directed when having vaginal sex? If answer is $<100\%$, consider her at risk for AEP.
The Future of Brief Intervention for AEP prevention

- Efficacious brief interventions should be disseminated more widely
- Culturally competent adaptations should be tested
- A continuum of interventions is needed:
  - Highest risk women should get the most potent, relatively longer interventions
  - Less intensive brief interventions should be distributed broadly, including use of technology to increase intervention reach
Thank you

- **Key collaborators**: Drs. Velasquez, Floyd, Sobell, Ceperich, Sobell, Farrell-Carnahan, Hanson, Ritterband, Nettleman
- Research team members at University of Virginia, Virginia Commonwealth University, and Sanford Research
- Funding from CDC, AAMC, NIAAA
Questions?

Karen Ingersoll Ph.D.
kareningersoll@virginia.edu