Developing Prevention: Lessons Learned From an International FASDs Prevention Study

Tatiana Balachova, PhD
and Prevent FAS Research Group

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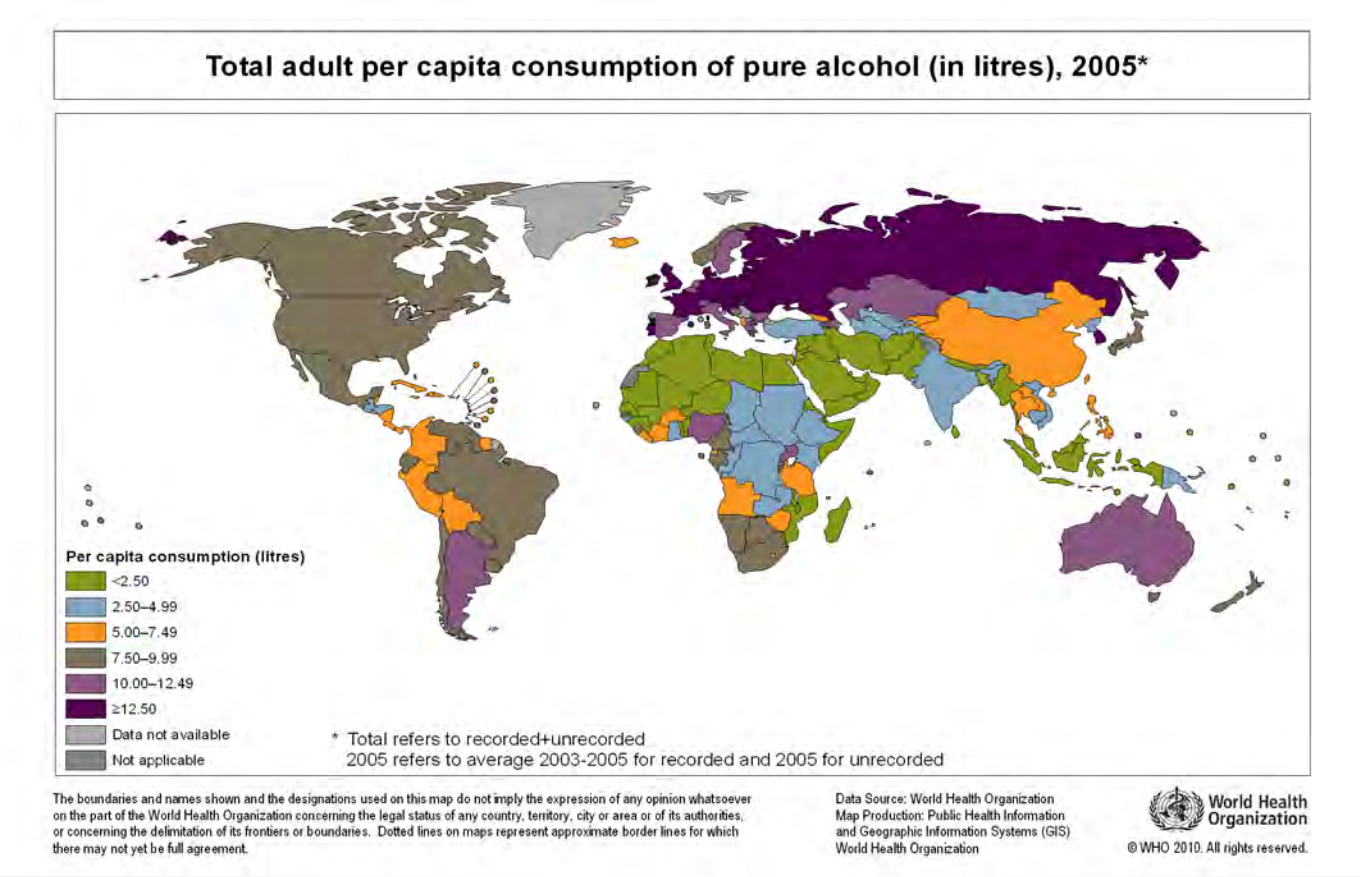
Alcohol consumption in Russia

- One of highest levels of alcohol consumption in the world (WHO, 2011)



Alcohol consumption in Russia

- Recent reports indicate increasingly hazardous drinking in young people and women (Malyutina et al., 2001; Onischenko, 2007; Perlman, 2010)
- Alcohol marketing target youth and women

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Damskaya [Ladies'] vodka: Producer states that this vodka is no more harmful than chocolate

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Prevalence of FASDs

- The highest reported prevalence of FASDs in child care settings is in Russian orphanages for children with developmental disabilities (Lange, Rehm, Popova, 2013)

- High prevalence of FASDs in children adopted from Eastern Europe (Landgren et al., 2010)

- The FAS prevalence
  - Boarding schools and orphanages for children with developmental disabilities (ages 4-18) - 7.9% (Riley et al, 2003)

    144,261 children reside at such institutions in Russia in 2008 (Rosstat, 2009)
    Estimated, 11,396 children with FAS

  - Baby's Homes (children ages 0 to 4) 13% in Murmansk and 4.6% - 9.3% in St. Petersburg (Millier et al., 2006; Palchik et al., 2010)

The University of Oklahoma
Health Sciences Center

Профилактика ФАС в России
Prevent FAS in Russia Research Group

Санкт-Петербургский
государственный университет
St. Petersburg State University
Nizhny Novgorod State Pedagogical University

Prevent FAS Research Group

St. Petersburg State University (SPSU), Russia
Larissa Tsvetkova, PhD
Alla Shaboltas, PhD
Galina Isurina, PhD
Vladimir Shapkaitz, MD, St. Petersburg Pediatric Academy
Alexander Palchick, MD, PhD, St. Petersburg Academy of Pediatrics
Nizhny Novgorod State Pedagogical University (NNSPU)
Elena Volkova, PhD
Larissa Skitnevskaya, PhD
Elena Kosych, PhD
Research coordinators and assistants at SPSU, NNSPU, and OUHSC
OB/GYN Physicians in St. Petersburg and the Nizhniy Novgorod region

University of Oklahoma Health Sciences Center (OUHSC)
Tatiana Balachova, PhD
Barbara Bonner, PhD
Mark Chaffin, PhD
Karen Beckman, MD

Statisticians: Sangeeta Agrawal, University of Nebraska
Database manager: Nicholas Knowlton, NSS

Consultants
Jacquelyn Bertrand, PhD, CDC
Oleg Erishev, MD, PhD, Bekhterev Institute, St. Petersburg
Michael Fleming, MD, MPH, Northwestern University
Edward Riley, PhD, San Diego State University
Linda Sobell, PhD, Nova Southeastern University

Advisory Board
John Mulvihill, MD, OUHSC
Kevin Rudeen, PhD, OUHSC
Mark Wolraich, MD, OUHSC
Sheldon Levy, MPH, PhD, University of Miami School of Medicine
Edward Riley, PhD, San Diego State University
Elena Varavikova, MD, PhD, MPH, Central Research Institute of Health Management and Information Systems, Russia

Developing FASDs prevention

Phase I: **Preventing FAS/ARND in Russian Children,** 2003-2007, Grant R21 TW006745 *Brain Disorders in the Developing World: Research Across the Lifespan*, NIH Fogarty International Center/NAAA, PI Bonner, OUHSC

Phase II: **Development of Education Materials for Prevention of FAS in Russia**, 2005-2008, supported by Research Grant RTOI 2005-999-01 AUCD/CDC, PI Bonner, OUHSC

Health of Children in Russia: Providing Education on FAS/FASD, 2007-2009, Research Grant RTOI 2007-999-02 AUCD/CDC, PI Balachova, OUHSC

Phase III: **Preventing FAS/ARND in Russian Children**, 2007-2013, Research Grant R01AA016234, NIAAA/Fogarty International Center, Balachova, OUHSC

Phase I: formative assessment

Objective

Assess knowledge, attitudes, drinking behaviors, and receptivity to prevention necessary for developing a FASDs primary prevention program in Russia

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Phase I: study design

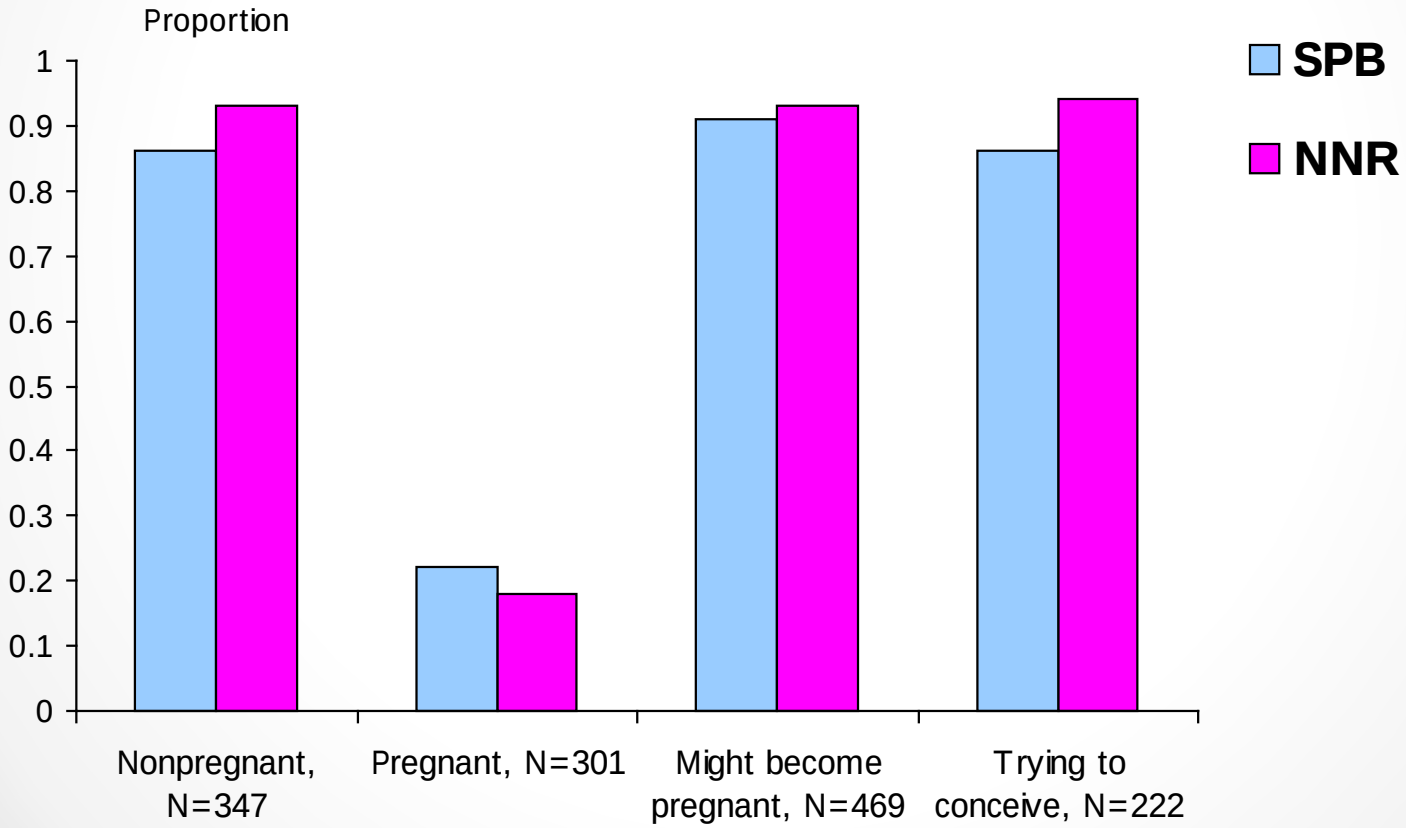
Sample

- Focus groups
  - 7 groups of women, partners, women with alcohol dependency, substance abuse treatment physicians, OB/GYN physicians, and pediatricians (N=51)

- Survey with 851 participants from St. Petersburg (SPB) and the Nizhniy Novgorod region (NNR)
  - 648 pregnant and non-pregnant childbearing age women recruited at women's clinics
  - 203 pediatricians and OB/GYNs recruited at CME courses

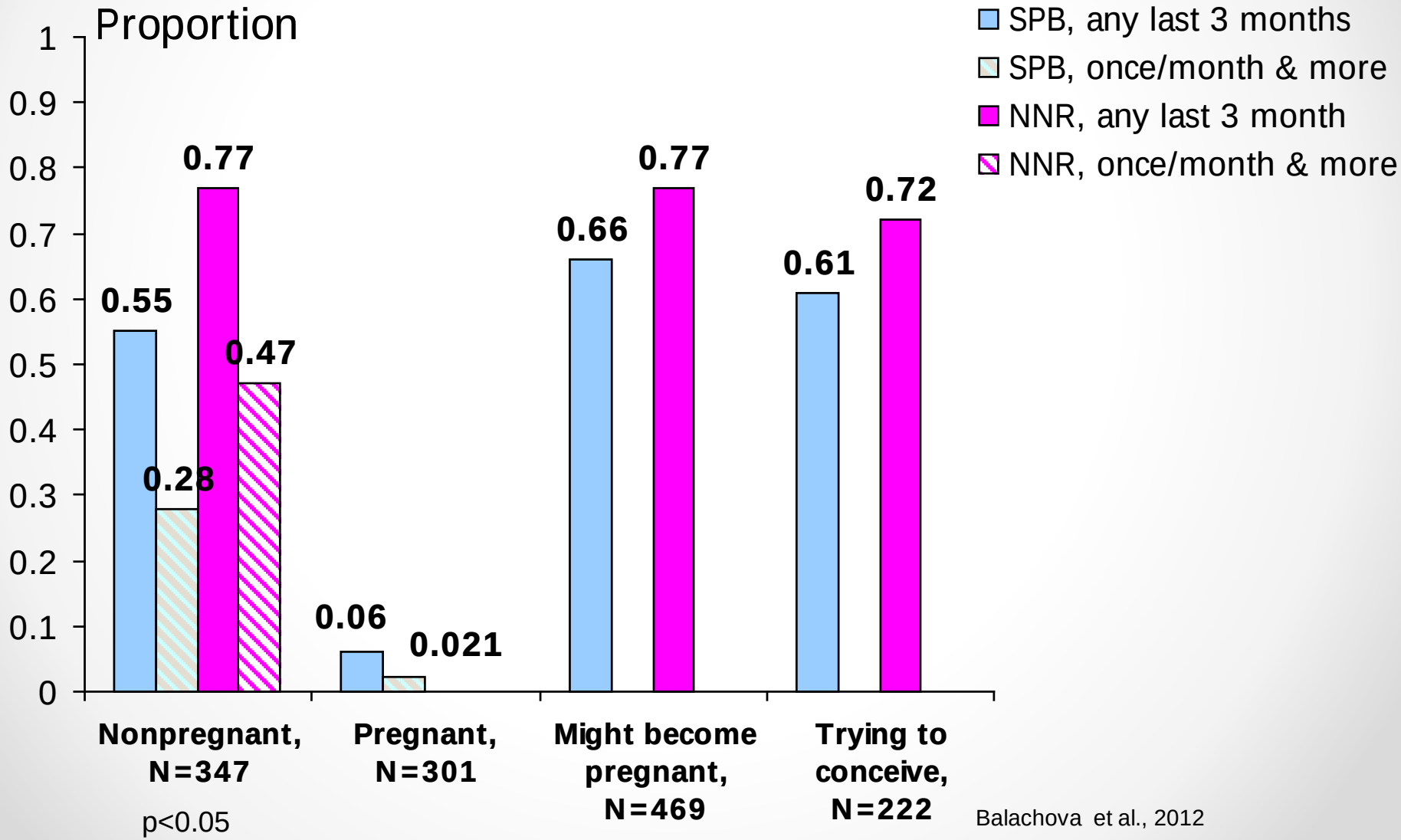



Any alcohol use



Balachova et al., 2012

Binge drinking



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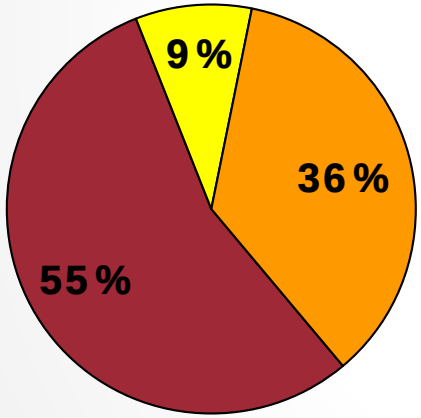
Balachova et al., 2012

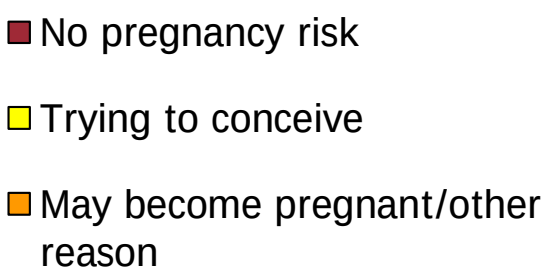
Alcohol-exposed pregnancy (AEP)

Pregnancy possibility + Risky drinking = Risk of AEP

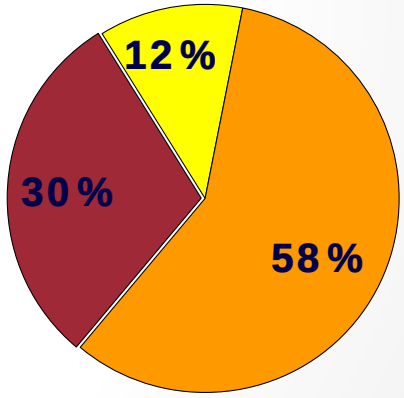
St. Petersburg



32% are at risk for AEP



The Nizhny Novgorod Region



54% are at risk for AEP

Balachova et al., 2012

Phase I: conclusions

- Pregnancy and child health are valuable
- After pregnancy recognition, a significant decline in consumption
- Alarmingly high risk of AEP among non-pregnant women

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What can influence women's decisions about alcohol use?

- Women's "own knowledge" and information from OB/GYN physicians
- OB/GYNs were willing to address the problem
- Interventions by OB/GYNs may be influential in preventing AEP
  - Both women and physicians have limited knowledge
  - Training for physicians and education materials for women were not available

Photo courtesy of Dr. Bertrand

Phase II: Developing FASDs education

Objectives

- Develop educational materials for women and training for health professionals in Russia
- Evaluate education materials and training in randomized trials

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Developing training for health professionals

Review FASD materials, medical schools, and CME curricula available in Russia

Select, translate, and modify education and training materials for women and health professionals in Russia

Train the trainers: train the Russian project faculty

Randomized educational trial

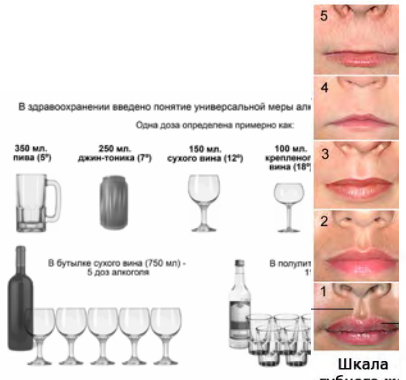
Sample

138 physicians (73 pediatricians 65 OB/GYNs) from throughout Russia were recruited at a CME program (127 completed follow-up assessments)

Procedures

- Groups of physicians (6 groups of pediatricians and 8 groups of OBGYN) were randomly assigned to intervention or control conditions
  - Control groups - a regular CME course
  - Training groups - a 3-hour training module on FASDs incorporated in a regular CME course

- The 3-hour education FASDs module included
  - 1) a presentation on FASDs foundation competencies and
  - 2) practicum in FAS diagnosis (pediatricians) or training in a brief intervention protocol (OB/GYNs) with vide modeling and role plays



S. Astley, 2004

Results: knowledge

Pediatricians N=66

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OBGs N=61

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Results

Attitudes

- OB/GYN physicians in the training group
  - were less likely to report that a pregnant woman can occasionally have one very small drink
  - strongly believed that OB/GYNs should recommend women not use alcohol during pregnancy or when they can become pregnant
- difference on other attitudes questions were not significant most likely because of the appropriate answers were given at the baseline assessment by both groups

Skills

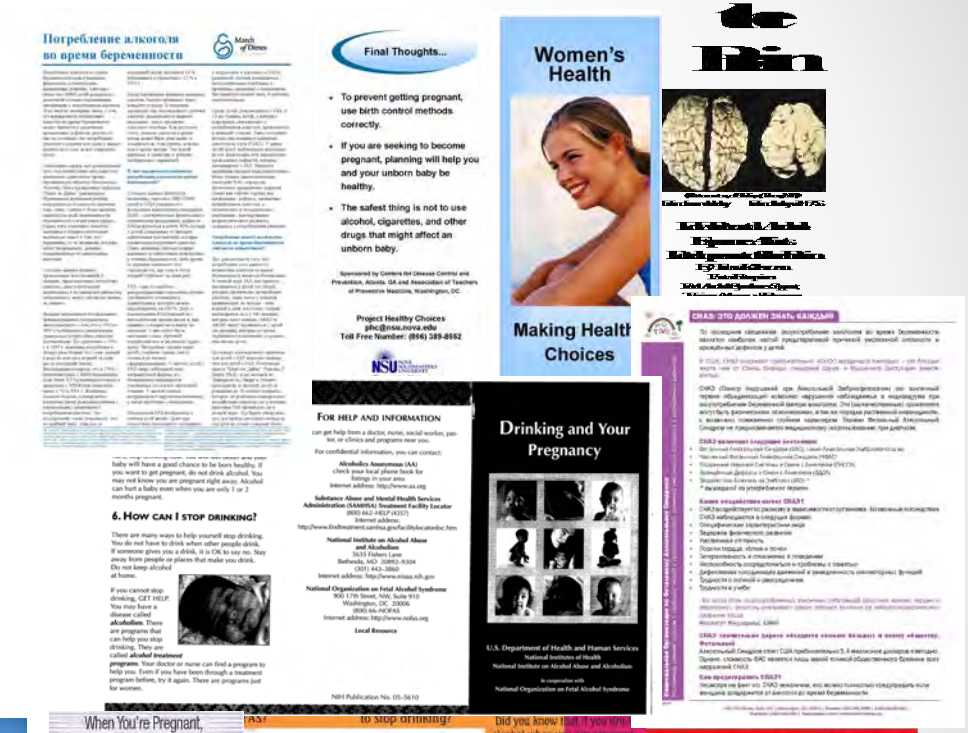
- Pediatricians improved FAS diagnostic skills
- OB/GYN physicians
  - significantly increased their competence and skills in conducting a FASD prevention intervention
  - Significantly increased competency and readiness to discuss alcohol use with women, educate women about alcohol, screen for risky alcohol use, and conduct brief interventions to prevent AEP

Developing education materials for women

Focus groups to design brochures

35 women of childbearing age were recruited from public women's clinics in two regions

Available FASD education materials were reviewed by the project expert faculty and 13 materials were selected for focus groups



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Developing education materials for women

Results

- Content
  - Specific information, research data
  - Easy to understand for everyone
  - Clear messages
  - Practical advice
- Format and design:
  - Emotional impact and attention getting
  - Question-answer format
  - Photos instead of drawings
  - Brief
  - Small size of brochures
- Positive content and images for women who are light drinkers and negative images for heavy drinkers

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Information brochures: clinical trial

Hypothesis

- Compared to the control group, women exposed to FASDs education brochures will show improved knowledge about FAS, less acceptance of any alcohol use during pregnancy, and reduced drinking at one month follow-up
- The group exposed to the negative brochure will show greater changes in the predicted directions compared to the positive brochure group at the one month follow-up





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Information brochures: clinical trial

Participants:
420 women were recruited and randomly assigned to one of three conditions: review brochures
1) FASDs prevention brochure with positive images
2) FASDs prevention brochure with negative images
3) General reproductive health material (control group)

Baseline (BL) and one month follow up (FU)

Measures

- Face-to-face structured interviews assessed knowledge, attitudes, and alcohol consumption at baseline and one-month follow-up
- A brief questionnaire assessed women's emotional responses to brochures and perceptions

Statistical analyses

McNemar's or Fishers exact test: to compare differences in prevalence proportions before and after the intervention
Linear quantile regression: to determine the relationship between the alcohol consumption at baseline and post assessment.
A linear mixed-effects model was used to compare the study conditions

Results

- Both FASDs education brochures were effective in improving women's knowledge and attitudes, were perceived as beneficial, raised concerns, and contributed to women's decision about alcohol use during pregnancy (FU)
- The positive brochure was perceived as more attractive and appropriate for women
- The negative brochure made women feel more fearful and anxious (BL) and more women remembered seeing the negative brochure, compared with control and positive brochures (FU)

Results: alcohol use

Figure removed

- Women who were drinking higher at BL are more likely to be drinking higher at FU
- Women in all three study conditions reduced the number of drinks/day between baseline and post assessment.
- The rate of change was higher among women in the positive brochure group, followed by the negative brochure and control groups

Results: alcohol use

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Positive brochure

- The proportion of women who drink at-risk reduced at FU; the change was not significant in the control and the negative brochure groups
- The proportion of at-risk drinkers decreased between baseline and post assessments by about 11%, indicating that there is an intervention effect in reducing alcohol consumption.

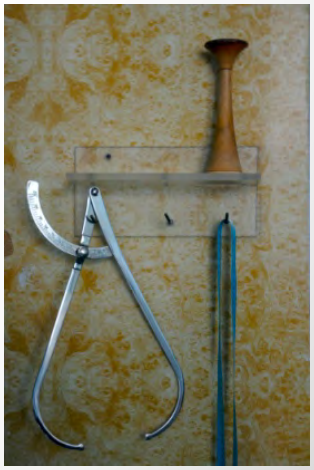
[a]McNemar exact; [$]d=difference (second column minus first one); [+]Missing data deleted on pre-post analysis

Phase II: Conclusions

- Training was effective in improving physicians' knowledge, attitudes, and targeted skills
- FASDs education brochures were effective in improving women's knowledge and attitudes
- Receiving a brochure with positively stated FASD prevention messages and positive images was associated with a significant reduction in risk drinking among childbearing age women at 1-month follow-up
- OB/GYNs significantly increased their competence and skills in conducting a FASDs prevention intervention

Phase III: Brief intervention clinical trial

Objective: Determine efficacy of the intervention in reducing the risk for alcohol-exposed pregnancies (AEP)



Intervention

Two evidence-based FASD prevention approaches adapted:

- *Healthy Moms,* brief physician intervention (BPI) (Fleming & Mundt, 2006; NIAAA 1999, 2005) and
- Project *CHOICES*, a motivational dual-focused intervention (Floyd et al., 2007)

Baby's Health is Your Choice

Use alcohol – use contraception

May get pregnant – abstain from alcohol!

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Dual-Focused Brief Physician Intervention (DFBPI)

Intervention: dual-focused BPI (DFBPI)

- Two face-to-face structured approximately 5 minutes sessions one month apart
- Incorporated into routine OB/GYN clinic visits
- Could include taking a medical history, conducting a physical exam, and/or providing/prescribing contraception

An modification of two evidence-based interventions - *Healthy Moms,* a brief physician intervention and project *CHOICES*, a motivational dual-focused intervention (Fleming & Mundt, 2006; Floyd et al., 2007; NIAAA,1999)

Methods

Study design	A two-arm, site-randomized, clinical trial
Settings	20 women's clinics in two regions in Russia , St. Petersburg (SPB) and the Nizhny Novgorod region (NNR) in Russia
Participants	Consecutively enrolled patients Inclusion criteria: childbearing age (18-44), fertile, not currently pregnant, AEP risk: in the last 3 months, 1) at-risk drinking (8 or more drinks/week or any binge - 4 or more drinks on one occasion AND 2) pregnancy possibility (at least one unprotected intercourse) in the last 3 months **1,536 women screened** **767 eligible enrolled in the study**
Measures	Baseline: A one-hour interview (in person) assessed contraception and alcohol use, attitudes to alcohol use during pregnancy, knowledge about FASDs, alcohol use, and related characteristics AUDIT, TLFB- 90 days, T-ACE Follow-up (3,6, 12 months): A 20 minutes interview (phone) on contraception and alcohol use, TLFB Intervention Fidelity: Exit Fidelity Check List completed by women and physicians independently; a subset of interventions audio recorded & coded for fidelity

Results: Daily drinking for all participants across all time points

Figure: An autoregression plot of TLFB #drinks/day, N=767 (n = 259,649 data points)

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The model was built as a piecewise version of the Autoregressive Latent Trajectory framework (Bollen & Curran, 2004) with MPlus 7.1 software using the Bayes estimator (Chaffin, 2014)

Drinking during pregnancy, including a pre-recognition period

Figure. An autoregression plot of TLFB #drinks/day, for women who reported becoming pregnant during the follow-up period (N=72)*

Date of the pregnancy recognition

Pre pregnancy recognition drinking reduced by 0.61on a given day

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*Because of FU time points and date of pregnancy recognition distributions, pre-recognition TLFB data were available for 42 of 72 women

The model was constructed with MPlus 7.1 software using the Bayes estimator

(Chaffin, 2014)

Phase III: Conclusions

- OB/GYN physicians trained in DFBPI were able to implement and maintain the skills during the trial
- The simple brief intervention can reduce at risk drinking among childbearing women and can potentially be delivered to large numbers of women who drink at risk in the general population
- The intervention is especially effective in reducing pregnant women's drinking prior to pregnancy recognition

Lessons learned

- Formative assessment is crucial
- Interdisciplinary collaboration is productive
- The high AEP risk among Russian women can be reduced with relatively small efforts
- Developed intervention can be delivered to large numbers of women at OB/GYN clinics routinely

“FAS is our life and a tragedy of our society”

A focus group participant, 2004

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