DRUG & ALCOHOL FINDINGS Research analysis

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▶ Preventing alcohol and tobacco exposed pregnancies: CHOICES Plus in primary care.

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Compared to brief advice, the CHOICES Plus intervention significantly lowered the risk of alcohol- and tobacco-exposed pregnancies among women in a low-income primary care population. This US-based trial illustrates the efficacy of a bundle of 'pre-conception' services for risky drinking, smoking, and ineffective contraception.

SUMMARY Drinking and smoking during pregnancy present significant and preventable risks to prenatal health (the period before birth) and perinatal health (around the time of birth). However, many pregnancies are unplanned, and women may continue drinking and smoking into their first and sometimes second trimesters unaware that they are pregnant.

Interventions designed to minimise or prevent harms have tended to focus on cessation of substance use during pregnancy. Project **CHOICES** was different; focusing instead on the period before conception, it aimed to increase participants' motivation and commitment to change risky drinking and ineffective contraception in order to prevent an alcohol-exposed pregnancy from occurring in the first place. The featured study tested an amended version called **CHOICES Plus**, which offered a bundle of services in primary care settings addressing drinking and ineffective contraception plus smoking, in half the number of sessions.

Key points
From summary and commentary

The CHOICES Plus trial tested a bundle of services in predominantly low income primary care settings, addressing risky drinking, smoking, and ineffective contraception among 'at risk' women.

After nine months, women assigned to the intervention had a significantly lower risk of alcohol- and tobacco-exposed pregnancies than women assigned to brief advice.

Targeting interventions at women before they become pregnant could shift the focus in clinical practice from treatment of substance-exposed pregnancies to prevention of a major (and costly) public health concern.

The trial compared two CHOICES Plus sessions and a contraceptive visit (131) with brief advice and referral to community resources (130).

The two 40-minute CHOICES Plus sessions were manualised and delivered by professionals with a specific postgraduate qualification in behavioural health. Discussions were tailored to each participant's self-rated readiness to change. Smokers were referred to one or two evidence-based smoking-cessation programmes that provide self-help materials and optional counselling (the American Cancer Society's Texas Quitline programme and Fresh Start programme offered by the Harris Health System). The contraceptive counselling visit was separate from the counselling sessions and provided by a family doctor or nurse practitioner. This included taking a medical history, discussing options for contraception, doing a physical exam and pregnancy test if requested, and providing contraception. In the comparison group, brief advice (also delivered by behavioural health professionals) involved brief advice about drinking and smoking, a 'healthy lifestyle' brochure

addressing diet, exercise, and illicit drug use, a referral brochure to community services, and referrals to health services covering contraception, smoking, alcohol, and other drug services.

Participants were recruited using a brief screening instrument completed either in the clinics (60%) or by telephone (40%) in response to posters placed in clinic and hospital waiting rooms. Eligible participants were risky drinking women, under 45 years of age, whose recent sexual activity and contraceptive use meant they might become pregnant. They were considered at risk of an alcohol-exposed pregnancy if there was evidence of risky drinking and a risk of an unplanned pregnancy, whereas their risk of a tobacco-exposed pregnancy was determined by a combination of any current smoking and a risk of an unplanned pregnancy.

Everyone assigned to CHOICES Plus received the first session, 88% completed both sessions, 53% attended the contraceptive visit, and 71% of the 61 smokers in the CHOICES Plus intervention accepted a referral for Quitline (37) or Fresh Start (6). Of those accepting a Quitline referral, 57% received services; 50% received Fresh Start services. Everyone in the brief advice group received brief advice and referral.

The average age of participants was 31. Most were from low-income households (70% under $20,000) and identified as Hispanic (47%) or non-Hispanic black (42%). Nearly half (45%) were current smokers at risk of both alcohol- and tobacco-exposed pregnancies, and according to their AUDIT questionnaire scores, the average participant was drinking at hazardous or harmful levels. Just under half the women who qualified for the trial agreed to join it and all but 13 of the 261 women who joined it were followed up nine months later.

Main findings

At the end of each follow-up period (three, six, and nine months), women's risk of alcohol- and tobacco-exposed pregnancies was significantly lower in the CHOICES Plus group than the brief advice group. It was estimated that CHOICES Plus participants were more than twice as likely to reduce their risk of both alcohol- and tobacco-exposed pregnancies than brief advice participants, were more likely to reduce individual behaviours associated with their risk of an alcohol-exposed pregnancy, and were more likely to increase self-reported smoking cessation at nine months.

Describing the routes to reduced risk, more women (40%) in the CHOICES Plus group reduced both of the risk factors for alcohol-exposed pregnancies after nine months than either risk behaviour alone (24% risky drinking and 36% ineffective contraception). Although there was a significant change in smoking cessation at nine months in the CHOICES Plus group, reduced risk of tobacco-exposed pregnancy was reached primarily through the use of effective contraception (54%).

Additional analyses sought to assess the degree to which participant dropout might have influenced these findings:
- The optimistic scenario for alcohol-exposed pregnancies was that women in the CHOICES Plus group who could not be followed-up at nine months were at reduced risk of an alcohol-exposed pregnancy while women in the brief advice group were at risk. When this was tested it produced a significant treatment effect. This was also the case for tobacco-exposed pregnancies.
- The pessimistic scenario was that women in CHOICES Plus who could not be followed-up were at risk and all women in brief advice were at reduced risk. This still produced a reliable treatment effect. When this scenario was tested for tobacco-exposed pregnancies, on the other hand, there was no treatment effect.

The authors' conclusions

The featured study found that CHOICES Plus significantly reduced the risk of alcohol- and tobacco-exposed pregnancies, demonstrating that addressing both issues in a single programme was both feasible and efficacious in a low-income primary care population.

These findings are important as many women of 'childbearing age' who drink and smoke may continue to do so before realising they are pregnant, and unknowingly risk an alcohol-exposed or tobacco-exposed pregnancy during a critical time for foetal development.

The generalisability of the study may be limited by the low (47%) consent rate. The time participants were required to commit to was the most frequent reason given for declining participation, making it difficult to separate interest in participating in the intervention from interest in participating in the study with its multiple follow-up sessions. However, among the women who did participate, the retention rate was high across all time points, and CHOICES Plus was consistently more effective than brief advice.

Reductions in the risk of drinking and increases in effective contraception for the CHOICES Plus women were comparable to those found in the original CHOICES efficacy trial. Future research could expand CHOICES Plus to include prevention of cannabis-exposed pregnancies, as nearly half (45%) of enrolled women were also using cannabis.

In contrast with the majority of interventions that focus on stopping substance use during pregnancy, CHOICES Plus focused on the period before conception, aiming to prevent both alcohol and smoking-exposed pregnancies in one bundle of services. Targeting interventions at women before they become pregnant could shift the focus in clinical practice from treatment of substance-exposed pregnancies to prevention of a major (and costly) public health concern.

FINDINGS **COMMENTARY** CHOICES Plus reduced the risk of alcohol- and tobacco-exposed pregnancies, indicating that the intervention from which it hailed (CHOICES) could be amended to target more than one risky behaviour, and in half the number of sessions.

Drinking and smoking during pregnancy are independently associated with poor outcomes, and when they occur concurrently, magnify the potential adverse effects – for example, further increasing the risk of early labour, low birth weight, and restricted child growth. While CHOICES Plus was specifically designed to address both risky drinking and smoking, smoking was not required for participation in the study. Among those randomised, less than half (45%) were current smokers at risk of both alcohol- and tobacco-exposed pregnancies, which limited the sample on which all primary outcomes could be assessed to 118 out of 261 people.

Interventions that can prevent alcohol- and tobacco-exposed pregnancies from occurring (or at least reduce their likelihood) have clear benefits over interventions that seek to mitigate the harms among women already pregnant; however, less clear is what criteria should be used to capture the pool of women at risk.

CHOICES Plus was an example of 'indicated prevention', aimed at those identified as high risk as opposed to the whole population. Of the 11,470 women screened (a big task in itself), 5% were considered eligible, and nearly half (47% or 261) consented to be included in the study. In 2016, the US Centers for Disease Control and Prevention cast the net wider than this for its preventive work, advising all women to stop drinking alcohol if they were "trying to get pregnant or could get pregnant", or "not using birth control with sex". This recommendation was not received warmly; the goal was laudable, but the wording was seen as paternalistic, giving the impression that women were "incapable of making responsible choices about their reproductive health".

In the United States, these 'responsible choices' are arguably constrained to a greater degree than in the UK due to the lack of free or affordable healthcare – including the lack of free or affordable contraception. In October 2017, for example, the Trump administration issued a ruling that allowed employers to decline the provision of free birth control to employees through their company insurance on religious grounds. This context may give interventions like CHOICES Plus, which specifically seek out 'at risk' women in low-income populations, an even deeper significance. In the UK, contraception can be accessed free of charge on prescription via the National Health Service, though women can still experience barriers to finding suitable (and therefore effective) methods of preventing unplanned pregnancies (1 2).

Building capacity to prevent and manage 'foetal alcohol spectrum disorders' – lifelong physical, behavioural, and cognitive disabilities caused by alcohol consumption during pregnancy – is a critical issue for the British Medical Association. In the UK, their recommendation for women who are pregnant, or considering a pregnancy, is that "the safest option is not to consume any alcohol". Similarly, the Royal College of Obstetricians and Gynaecologists advises that "The safest approach is not to drink alcohol at all if you are pregnant, if you think you could become pregnant or if you are breastfeeding".

Guidelines from the Chief Medical Officer also state that "If you are pregnant or planning a pregnancy, the safest approach is not to drink alcohol at all, to keep risks to your baby to a minimum". However, "The risk of harm to the baby is likely to be low if a woman has drunk only small amounts of alcohol before she knew she was pregnant or during pregnancy". A report commissioned by Alcohol Concern (which merged with Alcohol Research UK in 2017) found that key stakeholder groups including policy makers, health service practitioners, antenatal educators, and parents perceived the precautionary principle underpinning the advice above about drinking during/before pregnancy to be inconsistent with "the informed-choice approach that underpins alcohol advice for the general population". Some stakeholders concluded for themselves (ie, it was not explicit in the guidelines) that the guidance was intended to "provide an extra layer of protection to the foetus", and others that "it is intended to protect more vulnerable and less educated women who lack the capacity to interpret the evidence wisely". There was also a perception that this was "an example of over-reach, legitimising social

surveillance of pregnant women" and "congruent with a normalised directive approach to communicating with women in pregnancy".

There are many reasons why women may continue to drink during pregnancy – for example, not knowing they are pregnant, not being aware of the risks of drinking during pregnancy, and having problems with alcohol dependence. They may also, in the absence of evidence that light drinking can cause serious lasting effects, want to continue to have 'a glass every now and again' for the same reasons why people who are not pregnant enjoy doing the same.

Emphasising the importance of removing the stigma from women who drink during pregnancy, or who enter pregnancy with existing drinking problems, the British Medical Association have advised that:
• Healthcare professionals should reassure pregnant patients that, while there is no definitive evidence, the risks associated with drinking *small quantities* of alcohol are likely to be low.
• Healthcare professionals should be given sufficient time and resources to ensure that any woman who is pregnant, or who is planning a pregnancy, and who is identified as drinking at low-to-moderate levels, is offered brief intervention counselling. This should occur at the earliest possible stage and be considered part of routine antenatal care.
• Where high levels of consumption are identified, and with this a high-risk of prenatal alcohol exposure, pregnant women should be offered referral to specialist alcohol services for appropriate treatment.
• Healthcare professionals should avoid blame, and create an environment where patients can disclose their drinking without feeling threatened or judged.
• There should be a deeper understanding of the many reasons why women may drink during pregnancy, and a deeper appreciation for the fact that "alcohol consumption during pregnancy does not occur in isolation [and…] must be viewed in the context of society's relationship with alcohol".

In this field (and indeed this paper), the term 'pre-conception' is used to identify where interventions are delivered *before* pregnancy, as opposed to *during* pregnancy. Depending on how it is used, this terminology can be problematic because it assumes a state of 'pre-pregnancy' among women of so-called childbearing age (who may not want to become pregnant or may not be able to become pregnant), and may not make sense where part of the goal of the intervention is to prevent pregnancy from occurring. However, the vernacular appears to come from a life-course view of alcohol harm prevention that reflects a primary focus on mitigating the harms to the foetus/child, but involves interventions delivered to the mother – hence why a phase of 'pre-conception' is assumed in the first place, and is followed by 'pregnancy', which is followed by 'childhood' (when the children are aged 0–18 years), and finally 'adulthood' (over 18 years).

With evidence across a range of settings that CHOICES can significantly reduce the risk of alcohol-exposed pregnancies, the original programme has already been embraced in the US, and implemented with funding from the Substance Abuse and Mental Health Services Administration and the Centers for Disease Control and Prevention. The next step for CHOICES Plus is to be tested in relatively real-world conditions, showing, for example, how effective the manualised intervention would be when delivered by 'typical' practitioners.

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