



extensive battery of measures (Patient Health Questionnaire [PHQ-9], General Anxiety Disorder [GAD-7], Posttraumatic stress disorder [PTSD] Checklist for DSM-5 [PCL-5], Alcohol Use Disorders Identification Test [AUDIT], Drug Abuse Screening Test [DAST] and Fagerström).

In the last year, 614 women (30.5%) smoked tobacco (42.5% daily) and 9.8% were positive for both substance use and mental illness per the AC-OK. Only 11.1% of them received specific treatment in the previous three months while another 13.6% were scheduled to attend services in the following month. From the subsample assessed in depth, 62(36.5%) endorsed at least moderate depression, 35(20.6%) endorsed at least moderate anxiety, 32(18.8%) endorsed PTSD on the PCL, and 37 out of 88 alcohol users scored above the threshold in AUDIT ( $\geq 3$ ).

In conclusion, high prevalence and low treatment rates suggest that effective detection mechanisms should be integrated into usual care, allowing for early interventions.

**Keywords:** Perinatal care; perinatal mental health; dual disorders; smoking; drug use; screening.

**D**uring the first weeks of pregnancy, proper monitoring of risk factors related to fetal complications, through an adequate anamnesis, is crucial for optimal follow up. Antecedents such as previous pre-eclampsia or preterm birth are screened by almost all obstetricians in a new pregnancy in order to prevent and provide an early diagnosis of recurrences. However, despite the fact that substance use, especially tobacco use, is even more frequent (Lange, Probst, Rehm & Popova, 2018), and has a crucial impact in both the short and long term, it is usually underdiagnosed and not always part of the systematic evaluation of all obstetricians (Hankin, McCaul & Heussner, 2000). Moreover, unidentified substance use can lead to gestational complications, such as preterm birth, premature rupture of membranes or fetal growth restriction (Cnattingius, 2004; Dahlin, Gunnerbeck, Wikstrom, Cnattingius & Edstedt Bonamy, 2016; England, Benjamin & Abenhaim, 2013; Gouin, Murphy & Shah, 2011; Ko et al., 2014) and is therefore a potentially preventable cause of complications. Substance use becomes even more problematic considering that women who use substances during pregnancy usually use more than one illicit substance, multiplying the risk of fetal disease (Forray & Foster, 2015). Exposure to illicit drugs during pregnancy has also been linked to structural effects on the fetus and a range of neurobehavioral consequences during childhood and later (Holbrook & Rayburn, 2014).

When facing substance use among pregnant women, we must consider the inter-relationships between specific congenital malformations, prematurity, restriction in birth weight, stillbirth, and later fetal withdrawal syndrome or neonatal death, and other less frequent complications (Dahlin et al., 2016; Gauthier, Guidot, Kelleman, McCracken & Brown, 2016; Ko et al., 2014; Pereira, Da Mata, Figue-

Questionnaire [PHQ-9], General Anxiety Disorder [GAD-7], Post-traumatic stress disorder Checklist [PCL-5], Alcohol Use Disorders Identification Test [AUDIT], Drug Abuse Screening Test [DAST] y Fagerström). En el último año, 614 mujeres (30,5%) fumaron tabaco (42,5% diariamente) y el 9,8% fueron positivas para problemas por uso de sustancias y salud mental según la AC-OK. Solo el 11,1% había recibido tratamiento en los tres meses previos y solo un 13,6% tenía una cita en el siguiente mes. De las 170 pacientes evaluadas secundariamente, 62(36,5%) presentaron al menos depresión moderada, 35(20,6%) al menos ansiedad moderada, 32(18,8%) fueron positivas a la PCL-5, y 37 de las 88 que reconocieron uso de alcohol puntuaron por encima del umbral en AUDIT ( $\geq 3$ ). En conclusión, la combinación de una prevalencia significativa junto con bajas tasas de tratamiento, remarcan la necesidad de mecanismos de detección efectivos en la atención habitual, permitiendo una intervención temprana.

**Palabras clave:** Atención perinatal; salud mental perinatal; patología dual; tabaquismo; consumo de drogas; cribado.

iredo, de Andrade & Pereira, 2017; Pineles, Hsu, Park & Samet, 2016).

The two most relevant complications of tobacco use are prematurity and low birth weight. In both cases, first trimester cessation leads to a risk similar outcome to that of non-smokers (Blatt, Moore, Chen, Van Hook & DeFranco, 2015). These complications are dose dependent (Cnattingius, 2004). The same is known for licit substances, with studies describing physical complications (Cook et al., 2017) and behavioral and psychiatric problems related to tobacco use (Ekblad, Gissler, Lehtonen & Korkeila, 2010; Tiesler & Heinrich, 2014) and alcohol (Donald et al., 2015; Sarman, 2018).

This is of particular interest given that some women do not alter their pattern of substance use until pregnancy is confirmed (Holbrook & Rayburn, 2014). Thus smoking prevalence during pregnancy is similar to that of the general population (Cnattingius, 2004). A recent meta-analysis estimates smoking prevalence during pregnancy in Spain of 26% (Lange et al., 2018), a likely underestimate of the problem given well-known under-reporting (Garg et al., 2016). Perinatal mental health problems, bidirectionally and deleteriously related to substance use, are recognized as a major public health issue in pregnant women. Depression and anxiety prevalence studies in multiple countries described a range of between 10 to 30% in pregnant women (Austin, Priest & Sullivan, 2008; Bayrampour, Hapsari & Pavlovic, 2018; Fairbrother, Janssen, Antony, Tucker & Young, 2016; Martinez-Paredes & Jacome-Perez, 2019; Woody, Ferrari, Siskind, Whiteford & Harris, 2017). Similar to substance use, perinatal mental health problems are related to several adverse pregnancy outcomes (Kramer et al., 2009) and abnormal neurodevelopment and mental health disorders in children (Kingston, Tough & Whitfield, 2012).

Despite several initiatives revealing under-identification (Hankin et al., 2000) and recommending systematic screening, there are no universal clear guidelines, and consequently mental health conditions during pregnancy are still under-diagnosed (Bayrampour et al., 2018). Yet, few studies have analyzed the co-occurrence of mental health and substance use problems in this population. The lack of services to deal with perinatal mental health in many health care settings, highlights the need to improve detection and care of these women (Howard, Piot & Stein, 2014).

Different barriers for a proper approach to mental health during pregnancy have been identified (Bayrampour et al., 2018). One way to overcome barriers to identification and care is the development of screening questionnaires of easy use for obstetricians and midwives. The AC-OK screening tool is a useful instrument validated in Spanish and with good psychometric properties for routine screening of mental health and substance use problems in clinical settings (Chavez et al., 2017).

In this study, we use data obtained from the WOMAP (Woman Mental Health and Addictions on Pregnancy) research project, a study designed to test the feasibility, acceptability and efficacy of two different interventions for pregnant women with tobacco, benzodiazepines or other substance use problems and/or mental health disorders. Our aims were to: 1) describe the prevalence of substance use and mental health problems using the AC-OK questionnaire, including the prevalence of smoking; 2) depict whether these women received treatment or not, and 3) identify the mental illness and drug use diagnoses and severity in a subsample of women considered eligible for the WOMAP clinical trial.

## Methods

### *Setting and participants*

From July 2016 to December 2019, 2014 pregnant women were screened. Participants were selected among pregnant women under 26 weeks of pregnancy who were over 18 years of age and undergoing obstetric visits in five hospitals in the Madrid (Spain) metropolitan area: Jiménez Díaz Foundation (Madrid urban area), Infanta Leonor Hospital (Madrid urban area), Tajo University Hospital (Aranjuez), General Hospital of Villalba (Villalba) and Infanta Elena Hospital (Valdemoro). The five participating hospitals cover a health area of more than 1.300.000 inhabitants from diverse socioeconomic backgrounds.

Participants were approached in two ways: in situ, when the woman finished the obstetric visit, or by telephone, after the obstetrician in charge obtained the contact authorization from the patient. In both cases, the study was explained to the participants by research assistants, and the screening interview administered to those who accept to participate. Usual care for pregnant women in the recruitment hospi-

tals begins with a first appointment between 8-12 gestational weeks in which a detailed anamnesis and fetal ultrasound are conducted. First trimester analytical results (week 10-12) are also evaluated and chromosomal abnormalities screened. In weeks 20, 28 and 32-34 of gestation, morphological ultrasounds measuring fetal growth are performed and analytical results of each trimester are evaluated. Subsequently, at week 38-39, a static ultrasound, fetal growth and assessment of the amniotic fluid are carried out. From weeks 40-41, fetal monitoring and ultrasound controls are performed to assess the biophysical profile.

### *Assessment*

Participants were first screened to identify those considered to be at risk for co-occurring mental health/substance use problems. Those who tested positive on the screening were offered to participate in the WOMAP clinical trial and were later evaluated with a more comprehensive questionnaire. Data were collected and stored using MEmind clinician interface ([www.memind.net](http://www.memind.net)), a web-based application developed to merge different data sources, including clinician and patient data (Barrigon et al., 2017).

### *Screening assessment*

2014 women who agreed to be assessed were screened for mental health (MH), substance abuse (SA) and co-occurring mental health/substance use problems (dual disorder) with the AC-OK screen (Chavez et al., 2017; Cherry & Dillon, 2013). AC-OK is an easy-to-use questionnaire, validated in Spanish speaking populations in Spain and USA, designed to be a useful screener for mental health and substance abuse problems. The AC-OK includes 15 items, nine items related to mental health and six items related to substance abuse. The Spanish version has good psychometric properties, with good internal consistency (Mental Health Screen [ $\alpha = 0.82$ ]; Substance Abuse Screen [ $\alpha = 0.90$ ]) and excellent sensitivity and specificity. A cut-off point of 2 or more positive answers were selected for mental health subscale and one or more for substance use subscale (Chavez et al., 2017). Those women that answered "yes" to AC-OK questions 9 or 10, regarding death desire and suicidal behavior, were screened for suicide risk in the previous month with the Paykel Suicide Scale (Paykel, Myers, Lindenthal & Tanner, 1974) and referred to an immediate psychiatric evaluation as part of a safety protocol if they answer yes to Paykel questions 4 or 5 (i.e. had a suicidal plan or attempt). This questionnaire consists of five questions about suicide including life-weariness, wishes of death, suicidal ideation, suicidal plans and suicide attempts.

Furthermore, women were asked about cigarette smoking in the last 12 months (yes/no) and, among those who answered yes, how often they smoked (number of days they smoked cigarettes per week). They also were asked about mental health and/or drug/alcohol abuse services

used in the last three months and whether they had an appointment scheduled in the next month. Finally, socio-demographics characteristics were collected: age, country of origin, racial group and education level.

### **Assessment for women at risk**

Women were considered at risk (and therefore included in the clinical trial) if they had: 1) two or more positive responses to the AC-OK-Mental Health (AC-OK MH) subscale, 2) one or more positive responses to the AC-OK-Substance Abuse (AC-OK SA) subscale and/or reported smoking more than once a month, 3) no use of specialized services, defined as not having an appointment in the following month and have not seen a clinician in the past three months and 4) if the Paykel Suicide Scale was administered, they answered NO to questions 4 and 5 (Paykel et al., 1974). Exclusion criteria for entering the clinical trial were: 1) had received a diagnosis of psychotic or bipolar-related disorders or 2) lacked capacity to consent, as determined by not being able to answer questions of the study purpose or process.

Due to WOMAP study clinical trial protocols, only eligible women (n=170) were assessed with a more extensive battery of mental health and substance use questionnaires. For mental health, we used the Patient Health Questionnaire (PHQ-9) which addresses the nine DSM-IV diagnostic criteria for major depressive disorder (Kroenke, Spitzer & Williams, 2001), the General Anxiety Disorder 7-item screener (GAD-7) for anxiety (Spitzer, Kroenke, Williams & Lowe, 2006), and the Post-Traumatic Stress Disorder Checklist (PCL-5), a self-report measure for the 17 DSM-IV symptoms of PTSD (Blanchard, Jones-Alexander, Buckley & Forneris, 1996). For substance use, the questionnaires administered were the Alcohol Use Disorders Identification Test (AUDIT), a screener developed by the World Health Organization (WHO) (Bohn, Babor & Kranzler, 1995), the Drug Abuse Screening Test (DAST), a brief self-report instrument designed for drug abuse and dependence disorders detection (Yudko, Lozhkina & Fouts, 2007); and the Fagerström Test for Nicotine Dependence, a six item instrument that evaluates the amount of cigarette consumption, compulsion to smoke, and smoking dependence (Heatherton, Kozlowski, Frecker & Fagerstrom, 1991). In addition, women with a positive screen were asked about the number of days in the last month they used the following substances: alcohol, opioids, barbiturates, benzodiazepines, cocaine, amphetamines, cannabis, hallucinogens and inhalants.

### **Statistical analysis**

A descriptive study of the total sample was made regarding demographical variables with means and standard deviations or percentages as were appropriate. Rates of positive screen to the AC-OK and its subscales was calculated for

total sample and compared by educational level and racial group using chi-square tests. Smoking habit was described in the total sample using percentages. For the subsample assessed in depth scores of questionnaires were calculated.

### **Ethical considerations and data protection**

The study was carried out in compliance with the Declaration of Helsinki and approved by the Jiménez Díaz Foundation Ethics Committee for Clinical Investigation (Ref. 2015/43). After a complete description of the study, all screened participants gave informed consent.

Concerning data protection, access to the MEMind clinician user interface was restricted to researchers. Only the Principal Investigator, clinicians and researchers, using a username and password, had access to identifiable information. The data provided by the clinician were encrypted by Secure Socket Layer/Transport Layer Security (SSL/TLS) between the investigator's computer and the server. Data were stored in an external server created for research purposes. Data were encrypted using the industry-standard AES-256 algorithm. Furthermore, an external auditor guaranteed that security measures met the Organic Law for Data Protection (Spanish Government, Ley Orgánica 3/2018 de Protección de Datos Personales y garantía de los derechos digitales, 2018) standards at a high protection level.

## **Results**

### **Total sample description**

The total sample was 2014 women aged  $33.0 \pm 5.6$  years old (range 18-46). 67.6% of the women were born in Spain, 19.8% were from South or Central America, 6.2% from the rest of Europe, 2.5% from Morocco, and 3.9% from other non-European countries.

Regarding racial group identification, 75.4% (1518) of women who provided information (1965), identified themselves as white; and 14.3% (287) stated their ethnicity as Latin American. Other minority racial groups included: 1.9% (n=39) gypsy, 2.3% (n=46) Arab, 2.2% (n=45) mixed race/ethnicity, 1% (n=20) Afro-American and 0.5% (n=10) Asian. Regarding education, 880 women (43.7%) had a university degree or higher, half of the women (49.6%; n=998) completed high school or vocational-technical school, and 129 women (6.4%) only completed primary studies.

Considering mental health and substance abuse, out of the 2014 women screened, 9.8% (198) had two or more positive responses to AC-OK-MH subscale and one or more positive responses to AC-OK-SA subscale and therefore were considered at high risk of having co-occurring mental health/substance use problems, rate that increases to 17.1% (344) if smoking in the last year was added to the AC-OK as criteria for being considered at risk. For each subscale, percentages of positive items are shown in Figure 1.

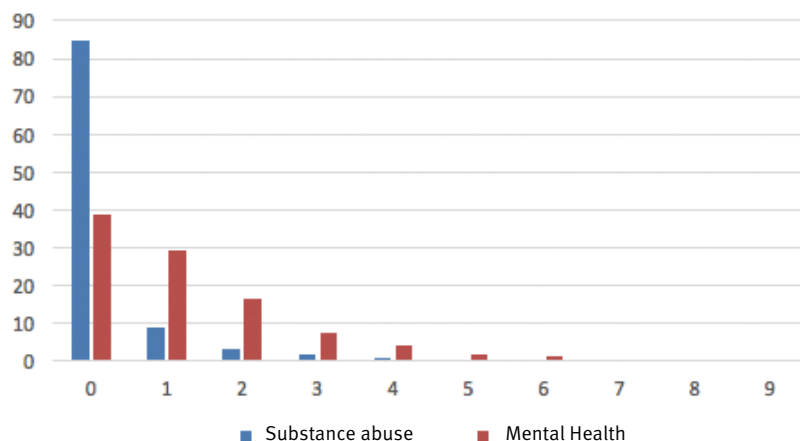


Figure 1. Percentage of women per the number of AC-OK affirmative answers in SA (6 items) and MH subscales (9 items).

Differences were observed by educational level, with 14.7% (n=19) of women considered at high risk for a co-occurring disorder in those with primary studies, compared to 11.2% (n=112) among those with high school studies and 7.5% with university studies (n=66) ( $p=0.004$ ). Differences that remain when tobacco was added to the AC-OK as a criteria for being considered at risk: 24% (n=31) with primary studies, 19.9% (n=119) with high school studies and 12.7% (n=112) with university ( $p<0.001$ ).

Regarding mental health, 32% of women (n=645) affirmatively answered two or more items, while 15% (n=302) affirmatively answered one or more items regarding substance abuse. No differences were found in the AC-OK-SA by race or educational level. A greater percentage of women with only primary studies were positive on the AC-OK-MH (43.4%; n=56) compared to 36.7% (n=366) among those with high school or vocational-technical school studies and 25% (n=220) with university studies ( $p<0.001$ ). When evaluating differences by race, those self-identifying as Asians (20%), Gipsy (20.5%), white (30.4%) or from Latin America (34.8%) had lower positive rates on the AC-OK-MH as compared to Afro-American (55.0%), those of mixed race (46.7%) or Arab (41.3%) ( $p=0.006$ ).

Among the 198 considered at risk according to the AC-OK, 22 (11.1%) received treatment at a mental health or drug abuse facility in the previous three months and 27 (13.6%) were scheduled to attend services in the following month.

Of the 99 women who answered “yes” to AC-OK questions 9 or 10, concerning death desire and suicidal behavior, they were asked about suicide risk in with Paykel Suicide Scale. Of those, two (2%) reported having made a suicide attempt, six (6.1%) had made a suicide plan, 21 (21.2%) had suicidal thoughts, 30 (30.3%) expressed death wishes, and 28 (29.3%) reported life weariness. Out of the total sample, 614 women (30.5%) had smoked tobacco during the past year (Table 1).

Table 1. Frequency of smoking (n= 614)<sup>1</sup>.

Frequency	N	Percent
Daily	261	42.5 %
5 to 6 days/week	10	1.6 %
3 to 4 days/week	13	2.1 %
1 to 2 days/week	18	2.9 %
2 to 3 days/month	10	1.6%
Less than once a month	296	48.2%

Note. <sup>1</sup> Data from six patients is missing (1%).

### Description of women at risk

One hundred and seventy women (8.4%) who fulfilled the study inclusion criteria were assessed with an in-depth questionnaire battery. Results are shown in Tables 2 and 3.

When asked about substance use in the previous month, 23 women reported alcohol use (from 12 women drinking one single day to a maximum of 1 woman drinking daily), eight used sedative drugs (five of them during the whole month, another one during 23 days, and two women more than 4 and 3 days each one), five women smoked cannabis (three in a daily basis and two twice during the month); and one woman reported cocaine use during 7 days. The rest of the drugs were not used by the 170 evaluated women.

## Discussion

Analysis of the sample of 2014 pregnant women, showed tobacco consumption figures higher than those of a recent meta-analysis that estimated a prevalence of smoking during pregnancy of 26% (Lange et al., 2018). Almost a third of our sample (30.5% of women) smoked tobacco in the last year, with 261 of smokers (42.5% of smokers) reporting daily smoking. In Spain, a recent study found a prevalence of substance use in each of the pregnancy trimesters of 21.2%, 18.5% and 13.3% respectively for tobacco use, 40.7%, 23.1%

Table 2. *Mental health and drug abuse questionnaires results (n= 170).*

	N	Percent
Depression (PHQ-9) <sup>a</sup>		
Negative (0-4)	40	23.5%
Mild depression (5-9)	68	40.0%
Moderate depression (10-14)	41	24.1%
Moderately severe depression (15-19)	16	9.4%
Severe depression (20-27)	5	2.9%
Positive (PHQ-9 ≥ 10)	62	36.5%
Generalized Anxiety (GAD-7)		
Negative (0-4)	70	41.2 %
Mild anxiety (5-9)	65	38.2%
Moderate anxiety (10-14)	22	12.9%
Severe anxiety (15-21)	13	7.6%
Positive (GAD-7 ≥ 10)	35	20.6%
PTSD (PCL) <sup>b</sup>		
Negative	138	81.2%
Positive (PCL ≥ 33)	32	18.8%
Alcohol Use (AUDIT) <sup>c</sup>		
Negative	51	58.0%
Positive (AUDIT ≥ 3)	37	42.0%
Drug Abuse (DAST) <sup>d</sup>		
Negative	37	21.8%
Positive (DAST ≥ 3)	0	0

Note. a: data not available for one woman; b: 5 women did not report traumatic events; c: 82 women did not use alcohol; d: 133 women did not use drugs.

Table 3. *Fagerström questionnaire results (only those reporting use in the last year (87) were assessed).*

	N	Percent
Very low dependence	51	58.6 %
Low dependence	21	24.1 %
Moderate dependence	10	11.5 %
High dependence	4	4.6 %
Very high dependence	1	1.1%

and 17.1% for alcohol and 4.8%, 1.9% and 1.2% for cannabis (Blasco-Alonso et al., 2015). Like this apparent progressive smoking cessation when pregnancy is confirmed, our sample revealed that, of the 614 women who claimed to have smoked in the last year at the time of evaluation, 48.2% reported smoking less than once a month.

A relevant contribution of this study to the scarce information existing in the literature regarding co-occurring problems in pregnant women, is that 9.8% (198 women) were considered at risk for a dual disorder of both mental illness and substance use disorder. In addition, 17.1% were at risk if they reported tobacco use in the last year.

While substance abuse among pregnant women has been reported in the literature (Blasco-Alonso et al., 2015;

Chang et al., 2011), dual pathology has been rarely described. From the subsample of 170 women eligible for the WOMAP trial who were evaluated in depth, 36.5 %were positive to at least moderate depression, 20.6% were positive to at least moderate anxiety, 18.8% were positive to the PTSD scale and 37 scored above the threshold in AUDIT (21.8%). These rates, again, are clinically relevant and agree with those obtained in previous studies that describe rates of up to 20% in depression and anxiety in pregnancy (Austin et al., 2008; Bayrampour et al., 2018). The significant prevalence rates of mental health, substance abuse and dual problems found in the sample of pregnant women screened positive in the AC-OK highlight the need for exploring additional efforts to treat dual disorders during initial pregnancy services, moreover when a 4.91% (99) of the women screened recognized death or suicidal thoughts.

Of note, is that only a small proportion of the patients identified as being at risk for dual disorders using the AC-OK instrument were in treatment. Only 11.1% (22 women) had received treatment in mental health or drug abuse services in the last three months and 13.6% (27 women) had scheduled an appointment in the following month. This finding highlights the significant lack of mental health and addictions care during pregnancy and suggests that new actions should be established to allow professionals involved in the care of the pregnant woman to recognize substance use and mental health disorders, and to provide proper referrals to treatment.

All pregnant women, should be asked regularly about substance use (Siu, 2015). Low treatment rates in our sample suggest that not all obstetricians, nor other professionals involved in the care of the pregnant woman, are identifying substance use and mental health problems. Considering the consequences of substance use, it should be part of usual care, not only in the first visit, but also throughout the following appointments, to evaluate and promote the cessation of consumption. Several reasons may be behind this lack of adequate recognition and identification of substance use disorder and mental illness. Among them, and added to the frequent underreport, could be the lack of knowledge of the extent of the fetal repercussion, which is probably underestimated in the short and long term. And on the other hand, as it has been described in the literature (Ebrahim & Gfroerer, 2003), the patient profile is usually more complex, being usually younger, with low socioeconomic status and higher rates of inadequate gestational control. Our findings of higher AC-OK positives on those patients with lower educational levels support this hypothesis. In addition, these patients may also deny consumption to avoid the legal repercussions that are often associated with disclosure.

Anamnesis is the essential tool for the identification of patients with mental health and substance use problems but screening tools validated for their use in pregnant

women are limited (ACOG Committee Opinion No. 524: Opioid abuse, dependence, and addiction in pregnancy, 2012). One of these tools is the CRAFFT, which has been reported to be better than medical report and the T-ACE alcohol screen for identification of prenatal substance use young patients (under 25 years old), but it has not been validated in older patients (Chang et al., 2011). It could be considered if, due to the usual lack of time in medical appointments, other additional screening tools should be applied universally or only in those patients who respond affirmatively to questions about consumption. On the other hand, the use of biological tests as screening tool could improve detection and minimize underreporting but would be less feasible to use them in routine care (Garg et al., 2016). A very simple questionnaire such as the AC-OK shows promise and could be adequate for accurate identification in the usual care of pregnant women.

There are several limitations to consider when drawing conclusions from the obtained results. First, when evaluating the prevalence results in pregnancy, it must be considered that the sample is not extracted from the entire Madrid region in which the hospitals are located. Second, a possible underestimation of prevalence, given the usual under-reporting of substance use and mental health problems, may influence the figures (Garg et al., 2016).

Despite these limitations, it can be concluded that due to the combination of significant prevalences, low rates of treatment, and the severe but preventable consequences on the mother and child, new actions, including efficient detection mechanisms should be integrated into usual clinical practice. This would allow for adequate access to treatment and promoting early cessation of substance consumption.

## Acknowledgments

This study was carried out under project PSI2016- 75854-P of the Spanish Ministry of Economy and Competitiveness.

This study received support from the Government Delegation for the National Plan on Drugs, from the Secretary of State for Social Services and Equality of the Ministry of Health and Consumer Affairs (20151073).

## Conflict of interests

The authors declare that there is no conflict of interest in any aspect of this study.

The authors declare no conflicts of interest in relation to the study, its authorship, and/or the publication of this manuscript.

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