

Issue 4, December 2016

The National Register of Antipsychotic Medication in Pregnancy (NRAMP)

Welcome to the Christmas Issue of our NRAMP Newsletter for Clinicians

Welcome to the December issue of our NRAMP Newsletter for Clinicians. We offer our most sincere thanks for your continued support throughout the year and hope that you will remain connected to our service with your ongoing patient referrals, queries and comments.

Recruitment update

This year has been extremely busy, achieving our former target of 300 consented participants and moving on to our new target of 500 consented participants. However, although requests for antipsychotic medication safety information have continued, the second half of 2016 has seen referrals and recruitment slow down, bringing our current total to 308.

Recruitment drive

To improve this we will be launching a recruitment drive next year, which will include increased telephone and email contact with our main recruiting centres around Australia, and presentations to clinicians and consumers, to increase awareness of, and interest in the project. Presentations can be conducted in-person, by Skype or teleconference to meet the needs of audiences, particularly those who are interstate, as NRAMP is based in Victoria. If you or your Team would like to learn more about this opportunity or would like to book a presentation for 2017, please contact the NRAMP Team to discuss your requirements. Contact details are at the end of page 2.

What is the benefit to participants?

This is a very good question, and one which is asked of the NRAMP Team on an ongoing basis. Women generally take part in NRAMP for different reasons, for example, to learn more about antipsychotic medication use in pregnancy and breast feeding, or for the opportunity to help other women like themselves. These are excellent reasons, but one of the most recorded reasons, by participant self-report, would have to be the opportunity to seek support from someone with mental health knowledge who is outside their immediate milieu, that is, a person who is not a family member or friend, or part of their healthcare team. Women also unanimously report their appreciation for the anonymity of telephone

calls, even though face-to-face meetings are an option, particularly for women who live within a 2 hour radius of NRAMP home base, the Alfred Hospital in Melbourne. Women also call the NRAMP Team when they have further questions, or want to share some news of themselves, their pregnancy or growing infant, whether they are part of the study or their participation has concluded. In addition, many participants who have taken part in NRAMP will return with a subsequent pregnancy; there are currently more than 25 women in this group. It is clear from these observations that participants place a level of importance on personal interaction, which can develop over time, between themselves and researchers. Participant anecdotal reports tell us that apart from anything else NRAMP may represent, this interaction is central to their wellbeing. Although the NRAMP Team are not participants' healthcare providers, we do appear to be playing an important role in the support, advise and education of women in this vulnerable population group.

Your referrals are important

As you can see, your referrals are extremely important. We urge you to consider your patients with a view to referring them to the NRAMP Team. <u>Inclusion criteria</u> include women who take antipsychotics during pregnancy, are pregnant or have had a baby in the last 12 months and can provide informed consent. The Referral Form can be found in the Clinicians' Portal of the NRAMP website, at: www.maprc.org.au/nramp

NRAMP Snapshot

The last NRAMP Snapshot for this year will present a summary of maternal and infant outcomes where mothers took aripiprazole during pregnancy. To begin, we provide an overall ranking of the most prescribed antipsychotic medications recorded in NRAMP. The top five, from most prescribed to least prescribed, include quetiapine, olanzapine, **aripiprazole**, risperidone and clozapine.

To date we have recorded 39/308 (13%) participants who took, or are taking, aripiprazole during pregnancy. Of this number, 31 have completed their involvement in NRAMP, four (4) were lost to follow up and four (4) have yet to complete. Dose range was between 2.5mg and 30mg per day. Antipsychotic medication changes were noted at the time points of pre-pregnancy and in each trimester. For example, 27 women were taking aripiprazole before and leading up to pregnancy, 22 were taking aripiprazole at 13 weeks gestation, 10 at 26 weeks gestation and 8 at the time of birth (approximately 40 weeks gestation). This compares with the 18 participants who were also taking concomitant antipsychotic medications, predominantly quetiapine, while some women ceased aripiprazole all together. Fourteen (14) women were also taking concomitant antidepressants and to a lesser degree, mood stabilisers (5) during pregnancy.

Pregnancy Outcomes

Pregnancy outcomes include 34 live births to date, including two sets of twins, who were born at 36 weeks and 37 weeks gestation. The remainder are made up of the following: one (1) ectopic; three (3) lost to follow up before the birth; and two (2) have yet to birth. Of the live births, one infant died at 10 days old (ketoacidosis, cerebral haemorrhage).

Maternal Outcomes

Eight (8/39; 21%) women were diagnosed with gestational diabetes mellitus (GDM) during pregnancy, five (5) of whom required insulin, one (1) took metformin and two (2) were diet-controlled. Known family history of diabetes was recorded for five (5) women, with two (2) women reporting ongoing issues with diabetes following the birth. These outcomes, along with outcomes for the other typical and atypical antipsychotic medication use reported in NRAMP, help us to build a GDM picture in the NRAMP cohort overall. Although there is a known link between antipsychotic medication use, weight gain and the development of GDM (A & B) there also appears to be a strong link with family history of diabetes, including GDM in previous pregnancies.

Infant Outcomes

Respiratory distress was recorded in 8/34 (24%) infants at birth, compared with 22% in the general Australian population (*C*).

Medication withdrawal symptoms were recorded in 6/34 (18%) infants at birth. There is currently no available AIHW data to compare with this outcome.

NICU and SCN admissions: Admissions to either NICU or SCN or both were recorded for 13/24 (38%) infants, compared with 16% of the Australian general population (C).

Outcomes at 12 months

Maternal outcomes at 12 months postnatal are very encouraging, with 26/39 (67%) reported to be managing well, both physically and mentally, at this time. Others not accounted for here were: lost to follow up, to complete NRAMP involvement, ectopic and following infant death.

Infant outcomes at 12 months of age are also very encouraging, with 31/34 (91%) achieving all developmental milestones across the five major domains at this time. The remainder were still to complete NRAMP involvement, and one infant death.

Conclusion

These outcomes are just a sample of the wealth of information being collected in the NRAMP database, and provide insight in to antipsychotic medication safety guideline development and subsequent patient care and management in the future.

References

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B. Boden, R, et al (2012). Antipsychotics in Pregnancy: Relation to Fetal and Maternal Metabolic Effects. *Archives of General Psychiatry*. 69 (7),715-721

C. Australian Institute of Health and Welfare (AIHW) 2013

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