

Issue 1, March 2016

The National Register of Antipsychotic Medication in Pregnancy (NRAMP)

Welcome to Issue 1 of our NRAMP Newsletter for Clinicians, 2016

The New Year has begun

We offer a very warm welcome to the first issue of our NRAMP Newsletter for Clinicians, in 2016. What better way to commence our first communique than to applaud you, our wonderful clinicians, allied healthcare workers, participants and their families. Indeed without your loyal and ongoing support we would not have achieved our current number of 295 consented participants. Nor would we be able to collect, collate and analyse such essential perinatal data, attend conferences, publish articles and compile and disseminate this Newsletter. This latter form of communication, in particular, has enormous potential in that it consistently brings new referrals and queries from pregnant women and new mothers with mental illness as well as from clinicians across many different health disciplines. Such wonderful support, in turn, encourages us here in the 'NRAMP engine room' to forge ahead, completing the cycle of patient, knowledge, management plan and optimal health outcomes.

The final 'push' to reach our recruitment target

We continue to strive for our current recruitment target of 300 consented participants, which will be achieved this year, with 5 more successful consents sought. To reach this important milestone in NRAMP's history, we require your continued support, by whatever means that works best for you, be that via email, telephone call, fax or face-to-face discussion. Please be assured of our most grateful thanks in the important part you play. The outcomes from this world-first research study will lead the way in perinatal mental health research and guide us in the management and care of pregnant women and new mothers with mental illness, both now and in the future.

What will happen then?

Once we have achieved the 300 consented participants, the work of NRAMP will continue in various ways. While some participants will be involved with ongoing interviews until they reach 12 months postpartum, we will also focus on file reconciliation, data compilation and analysis, paper preparation and publication and Perinatal Antipsychotic Medication Guideline development, all of which is expected to take another 12 to 24 months approximately. Please be assured that we will continue to encourage you to seek advice and support regarding the care and management of your patients, just as you have done in the past. NRAMP personnel will remain available to answer your queries.

Where will NRAMP be in the future?



At this stage, the future of NRAMP depends largely on available resources and future funding opportunities. However moving forward, we envisage a variety of different options, including a focus on specific antipsychotic groups (first and second generation) and individual antipsychotic medications; possible collaborations on the local, national and international scene; specific areas of focus which relate to maternal and infant outcomes, both as separate and combined groupings; projects which involve sample collection and analysis, as well as observational data gathering; individual population group studies, for example, indigenous Australians. These examples represent the tip of the iceberg only,

but do give a good indication of many opportunities for further world class research in this totally under-researched area of women's mental health, and the repercussions this can have on family mental health. NRAMP is preparing for the next generation of families. The work already undertaken plays a vital role in underpinning whatever eventuates in the next 100 years, in terms of education, prevention and treatment options for future population health and wellbeing.

NRAMP Snapshot

Our first Snapshot for 2016 will look at infant outcomes for the first 220 pregnancies and 211 one year old infants, compared with data presented in the NRAMP paper 'A Prospective Cohort Study of Antipsychotic Medications in Pregnancy: The First 147 Pregnancies and 100 One Year old Babies', which was published in PLOS ONE in May 2014 (1). Outcomes for this paper were collated from NRAMP data collected between 2005 and 2012. The primary message from this paper reports that, apart from the ongoing need for safety data surrounding the use of antipsychotic medication in pregnancy, live births and healthy infants at 12 months of age were by far the most common outcome. The paper also emphasised that clinicians must be aware of neonatal complications at the time of birth, particularly respiratory distress (1). Looking now at the 2014 data for 220 pregnancies and the subsequent 211 one year old infant outcomes, which was collected between 2005 and 2014, the

Summary Comparison between Infant NRAMP Data in 2012 and 2014		
Date	2012 (PLOS ONE paper published in 2014) (1)	2014 outcome data
Pregnancies	147	220 (a difference of 73 pregnancies)
One year old infants	100	211 (a difference of 111 one year old infants)
Gestation at birth	37.6 (n=142)	37.7 (n=211)
Birth weight: < 2.5kg	11 (8.4%)	19 (9%)
> 4.5kg	7 (5.3%)	10 (5%)
APGAR at 5 mins < 7	4 (3%) (n=127)	20 (9%) (n=211)
Respiratory distress	48 (37%) (n=129)	80 (38%) (n=211)
Neonatal abstinence syndrome	20 (15%) <i>(n=131)</i>	53 (25%) (n=211)
NICU or SCN admission	56 (43%) <i>(n=131)</i>	87 (41%) (n=211)

data continue to follow the same pattern as previously reported, confirming the need for further indepth research and strengthening our argument to support and educate pregnant women and new mothers with mental illness, as well as the clinicians who manage their care.

Neonatal respiratory distress, of any degree, was reported in 37% (48) of neonates in the PLOS ONE paper, compared with 38% (80) neonates in the 2014 data. In the two years between these groups, NRAMP reports a further 32 infants who have experienced neonatal respiratory distress of any degree. By comparison, the Australian Institute of Health and Welfare (AIHW 2012) reports neonatal respiratory distress, of any degree, in the general population at 20% (2). This confirms the significance of NRAMP data, regardless of timeframe or year of data collection. Although there may be several other well known causative factors involved, such as transient tachypnoea of the newborn, respiratory distress syndrome, persistent pulmonary hypertension, meconium aspiration, congenital

anomalies or prematurity, neonatal respiratory distress is an important finding in the NRAMP cohort, and represents a significant health issue for infants of mothers who take antipsychotic medication during pregnancy.

Neonatal abstinence syndrome (NAS) data also provides insight in to medication use during pregnancy. Although NRAMPs main focus is the perinatal use of first and second generation antipsychotics, some participants also take concomitant medications such as mood stabilisers, antidepressants and/or benzodiazepines, the combination of which will need to be explored in future research. NRAMP data presented in the PLOS ONE paper reports 15%, or 20 instances of NAS, compared with a highly significant 25%, or 53 instances in the 2014 data. This represents a further 33 infants with reported NAS symptoms in the two years between data collection points and indicates the importance of such findings in our cohort. Also of note is that the NAS outcomes are not maternal medication dose-dependent, in both mono and polypharmacy. Even so, some participants took antipsychotics only, and still reported NAS symptoms for their infants at birth. Interestingly, the AlHW does not report neonatal abstinence syndrome in the general Australian population, so there is nothing to compare our data with at this time. In addition, the risks and benefits of breast feeding while taking antipsychotics is another area requiring further research, and is frequently among the many questions asked by participants, who need to make their own informed decisions based on the advice they receive from all sources. NRAMP outcomes continue to report that mothers successfully breast feed their infants while continuing to take their antipsychotic medications, with minimal infant sedation and no known residual effects noticed at 12 months of age.

References:

- (1) Kulkarni, J et al, 2014. A Prospective Cohort Study of Antipsychotic Medication in Pregnancy: The First 147 Pregnancies and 100 One Year Old Babies, *PLOS ONE*, 9 (5)
- (2) Australian Institute of Health and Welfare (AIHW), 2012

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