Antiseizure Medication and Fetal Neurodevelopmental Outcomes

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INTRODUCTION

Managing epilepsy during pregnancy requires careful weighing of the neurodevelopmental risks that antiseizure medications (ASMs) may pose to the developing fetus. This evidence-based table, developed and reviewed by leading epilepsy specialists, summarizes current research on prenatal ASM exposure across key developmental domains — including autism spectrum disorder risk, IQ, verbal development, adaptive functioning, executive function, and behavioral outcomes. Risk levels range from low (lamotrigine, levetiracetam) to high (valproate, phenobarbital), and are intended to support informed, shared decision-making between patients and their healthcare providers.

RISK OF ADVERSE NEURODEVELOPMENTAL OUTCOMES

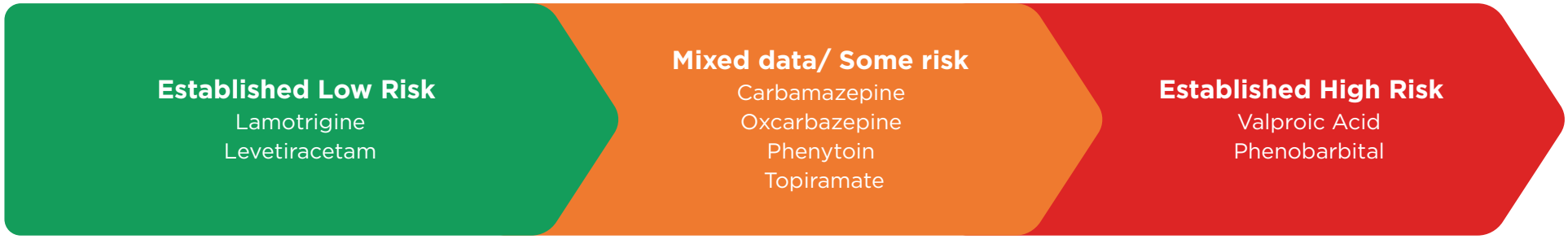

TABLE OF CONTENTS:

Lamotrigine							Risk: Low
Summary Based on current and scope of evidence, prenatal exposure to lamotrigine has the best safety profile. IQ and other cognitive and behavioral outcomes were unaffected by increased doses and cognitive outcomes at age 6 for children born to women with epilepsy are similar to those of children without epilepsy.							
Autism Features	**Verbal Development**	**IQ**	**Adaptive Scores**	**Executive Functioning**	**Behavioral Outcomes**	**Other**	
Two small studies show elevated rates of autistic traits in lamotrigine-exposed offspring, and a larger population study for risk but it was mitigated by folate in the first trimester. However, other large prospective cohort and population-based studies found no increased risk of ASD.	Cognitive outcomes in 6 year old children of women with epilepsy did not differ from children of women without epilepsy.	IQ was not affected by increased ASM doses or blood concentrations.	Adaptive functioning of children of women with epilepsy did not significantly differ from that of children of women without epilepsy. Decreasing adaptive functioning among children of women with epilepsy by 4.5 years of age was associated with increasing third-trimester ASM blood concentrations of lamotrigine exposure (but to a lesser degree than levetiracetam.	A significant decrease in functioning (specifically social skills and personal or health related self skills) was also observed with increased third trimester dosing when children were 4.5 years of age, but was not present at age 6 years in the same cohort.	There are multiple studies showing a lack of adverse behavioral outcomes.	N/A	
References: 1-3, 5-7,13,15,16,19, 20, 24, 25, 34, 35							

Levetiracetam

Risk: Low

Summary
Based on current and scope of evidence, prenatal exposure to leveitractetam is safe. Leveitracetam may be associated with some nuanced effects of children's verbal development, adaptive development, and executive functioning, especially at high doses. However, the risks appear low.

Autism Features	Verbal Development	IQ	Adaptive Scores	Executive Functioning	Behavioral Outcomes	Other
Three large population based studies did not show an increased risk of autism spectrum disorder in offspring exposed to levetiracetam.	Cognitive outcomes in 6-year-old children of women with epilepsy did not differ from children of women without epilepsy. Higher 3rd trimester maternal levetiracetam concentration was associated with worse verbal index scores at the age of 3 and 6 but this appeared to be at concentrations higher than 24.0 (this was not significant after removal of outliers and high levetiracetam levels suggesting that replication would be needed to interpret this result).	IQ was not affected by increased ASM doses or blood concentrations.	Adaptive functioning of children of women with epilepsy did not significantly differ from that of children of women without epilepsy. One study showed that decreasing adaptive functioning among children of women with epilepsy by 4.5 years of age was associated with increasing third-trimester ASM blood concentrations for levetiracetam (n=78 on monotherapy). However another study showed that there was no difference in adaptive functioning for kids exposed to levetriactetam (n=42)	A significant decrease in functioning (specifically social skills and personal or health related self skills) was observed with increased third trimester dosing when children were 4.5 years of age but was not present at age 6 years in the same cohort.	One study showed that 14% (n=33) of offspring had parent reported behavioral problems. However, a seconds study (n=42), showed no parent reported problems for their offspring.	LEV-exposed children had lower scores in delayed memory for names.

References: 1-5, 7, 11,13, 34

Oxcarbazepine	Risk: Limited Data/Mixed Data/Unclear Risk

Summary
Current evidence is quite limited, but indicates that oxcarbazepine exposure in utero is not associated with a significant increase in risk for ASD, IQ, ADHD or other neurodevelopmental outcomes.

Autism Features	Verbal Development	IQ	Adaptive Scores	Executive Functioning	Behavioral Outcomes	Other
Limited data, but larger population based studies with no increased of ASD.	No evidence	Limited data. 1 study that reported increased risk of intellectual disability but this was not found in other studies.	Limited evidence with some studies with n=1 children exposed to OXC showing no increased risk.	Limited evidence with some studies with n=1 children exposed to OXC showing no increased risk.	Population based studies showing no increased of ADHD.	No evidence

References: 14, 29

Phenytoin

Risk: Evidence regarding neurodevelopmental outcomes after prenatal phenytoin exposure is limited and low-certainty. Available data do not demonstrate a clear or consistent adverse neurodevelopmental signal, though the evidence base is substantially smaller than for valproic acid or newer ASMs.

Summary
There is insufficient high-quality evidence to conclude that phenytoin meaningfully worsens global neurodevelopmental outcomes. For full-scale IQ, results suggest possibly no difference compared with valproic acid, based on limited Class I data.

Autism Features	Verbal Development	IQ	Adaptive Scores	Executive Functioning	Behavioral Outcomes	Other
Population-level registry data do not show an increased risk of autism spectrum disorder with prenatal phenytoin monotherapy. Observed prevalence estimates are comparable to children of mothers with epilepsy not exposed to valproic acid.	Evidence regarding expressive or receptive language outcomes after phenytoin exposure is inconclusive. Older cohort studies report variable findings, but these are limited by small sample sizes and confounding and are not sufficient to establish a consistent association.	Mean full-scale IQ estimates in phenytoin-exposed children fall within the average range, and confidence intervals cross zero when compared with valproic acid. Verbal IQ differences observed in some analyses reflect better performance than valproic acid.	Data on adaptive behavior are sparse and non-specific. While some ASM-exposed cohorts show slightly lower adaptive scores overall, phenytoin-specific effects are not clearly delineated.	There is insufficient evidence to determine whether prenatal phenytoin exposure affects executive functioning. No robust phenytoin-specific signal has been demonstrated.	Behavioral findings are mixed and inconsistent, with no reproducible pattern of internalizing or externalizing disorders attributable specifically to phenytoin exposure after adjustment for confounders.	Phenytoin's most well-established risk remains structural teratogenicity (fetal hydantoin syndrome). In contrast, neurodevelopmental risks remain uncertain, with current evidence suggesting no clear excess risk, but limited by small sample sizes and heterogeneity.

References: 5-7, 9, 10, 13,14,16, 37-39

Topiramate

Risk: Mixed Data/Some Risk

Summary
Current evidence indicates that topiramate exposure in utero may be associated with increased autism spectrum disorder risk, impaired verbal development, impaired adaptive functioning, and behavioral outcomes such as ADHD. However, the evidence is mixed or limited in many cases due to sample size, comparator groups or study methods.

Autism Features	Verbal Development	IQ	Adaptive Scores	Executive Functioning	Behavioral Outcomes	Other
Although the SCAN-AED study found an adjusted hazard ratio of 2.8 [95% CI 1.4–5.7] for children exposed to Topiramate, other studies found no definite increased association between children exposed to Topiramate (during second half of pregnancy) compared to those unexposed to any antiseizure medication during pregnancy (propensity-score adjusted hazard ratio).	There may be increased risk associated with Topiramate exposure. There is limited evidence.	No definite association. Possible increased risk of intellectual disability (ID) for children exposed to Topiramate with adjusted hazard ratio (aHRs) of 3.5 [95% CI 1.4–8.6]. However, study used prevalence in the general population of children as a comparator group.	Limited evidence. An observational, cross-sectional study found poorer adaptive behavior in women with epilepsy and their children. Compared to normative samples, children exposed to topiramate had poorer levels of adaptive behavior with significantly lower mean scores in global adaptive behavior scale (p = .023), daily living skills (p = .003),socialization (p = .028). A similar pattern was observed for communication skills (M = 94.90, p =0.252) but this difference did not reach significance. Frequency analyses revealed that 42.9% of the topiramate-exposed cohort fell beneath the 'average' range (M = ≤ 85) for global ABC, with up to a third of children also falling beneath the 'average' range on communication skills (23.80%), daily living skills (33.33%) and socialization skills (23.80)	No data found	Some evidence of increased risk of ADHD (aHR, 2.38; 95% CI, 1.40-4.06) but the number of children with prenatal exposure to topiramate was relatively low (n = 290; mean [SD] follow-up, 7.0 [3.7] years)	No evidence

References: 6,10-13

Carbamazepine

Risk: Mixed Data/Some Risk

Summary
Current evidence indicates that Carbamazepine exposure in utero is not associated with large increases in risk for neurodevelopmental outcomes but the evidence is mixed with some studies showing increased risk in particular in ASD, and behavioral outcomes.

Autism Features	Verbal Development	IQ	Adaptive Scores	Executive Functioning	Behavioral Outcomes	Other
Large population-based studies and smaller studies have occasional found, small but not statistically significantly increased risk of ASD with prenatal carbamazepine exposure.	Evidence is mixed with some studies showing no difference from controls and other showing a decrease in verbal abilities for children exposed to CBZ in utero.	There are several small studies showing suggesting that CBZ is not associated with lower IQ than controls, or is associated with better IQ than children exposed to VPA in utero. Population based studies have found mixed results with some showing an increased risk of intellectual disability but others showing no significant risk.	Small number of studies with small CBZ sample sizes suggest that adaptive behavior is not affected by in utero exposure to CBZ.	Small number of studies with small sample sizes suggest that executive function is not affected by in utero exposure to CBZ.	Adverse behavioral outcomes have been associated with CBZ exposed children as compared to unexposed offspring including a higher prevalence of behavioral regulation problems, a single study described an increased risk of tic disorder.	In utero exposure to carbamazepine was associated with poorer academic performance in adolescence (class II evidence).

References: 3,5,7,14-16,19-29

Phenobarbital

Risk: High

Summary
Current evidence on phenobarbital exposure in utero indicates no human study evidence to support increased risk of autism spectrum disorder. There is evidence (albeit more limited than the other listed ASMs) of intellectual disability, impaired verbal IQ, and worsened behavioral outcomes. There is no human data on executive function and adaptive scores for phenobarbital use.

Autism Features	Verbal Development	IQ	Adaptive Scores	Executive Functioning	Behavioral Outcomes	Other
Despite evidence of decreased play behavior in rodents, there is no definitive increased association between children exposed to Phenobarbital and autism.	There are several studies that have indicated a reduced verbal IQ (mostly not adjusted for maternal IQ). In a study of 34 children, there was a 8.32 adjusted difference in verbal IQ, when maternal IQ was also included (95% CI 2.13-14.50)	There are several small scale studies showing lower IQ. In a study of 34 children, there was a 6.72 adjusted difference in IQ. 95%, when maternal IQ was also included CI (0.42; 13.02). Some additional studies reported similar or a higher IQ difference IQ.	Data is lacking in humans, but there is evidence in rodents of an increased risk of low adaptive behavior.	Animal models suggest frontal-cortex injury from phenobarbital that could impair executive function, but there is no human data.	Some data suggest an increased risk of behavioral and emotional disorders following in utero exposure to phenobarbital, but findings are based on limited sample sizes, and no specific hazard ratios have been reported	In a study of 34 children, there was a 3.74 difference in performance IQ when maternal IQ was adjusted with a 95% CI of −3.41; 10.90

References: 30-32,34

Valproate

Risk: High

Summary
Current evidence indicates that valproate exposure in utero is associated with an increase in risk for autism and autism spectrum disorders, lower mean intelligence quotient (IQ) scores at 3 and 6 years old and lower verbal and nonverbal abilities, memory and executive function. (1-4)Additionally, exposed valproate exposed children are at higher risk of intellectual disability with delayed childhood milestones.

Autism Features	Verbal Development	IQ	Adaptive Scores	Executive Functioning	Behavioral Outcomes	Other
Increased risk of autism disorders and autism spectrum disorders with 2-4-fold increased risk compared to children exposed to other ASMS .Reported with dosages < 750 mg and even higher risk at dosages > 750 mg.	Lower scores on verbal and nonverbal abilities and expressive language abilities. Dose dependent (>800 mg/day)	2-5-fold increased risk of intellectual disability. Low IQ by nearly 10 points. Dose dependent.	Increased risk of low adaptive behavior skills. Dose dependent.	Impaired executive function. Dose dependent.	2-4-fold increased risk of emotional and behavioral disorders. 1.5- fold increased risk of ADHD. ncreased risk of attachment disorders and tic disorders.	Reduced learning and memory abilities.

References: 2,4,5-9,40-41

Abbreviations

ASM: Anti-seizure Medications; ASD: autism spectrum disorders; IQ: Intelligence quotient;

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