Folic acid and antiseizure medication
Maternal-Fetal Medicine perspective

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ENTIS Sep 1st 2023 Dublin

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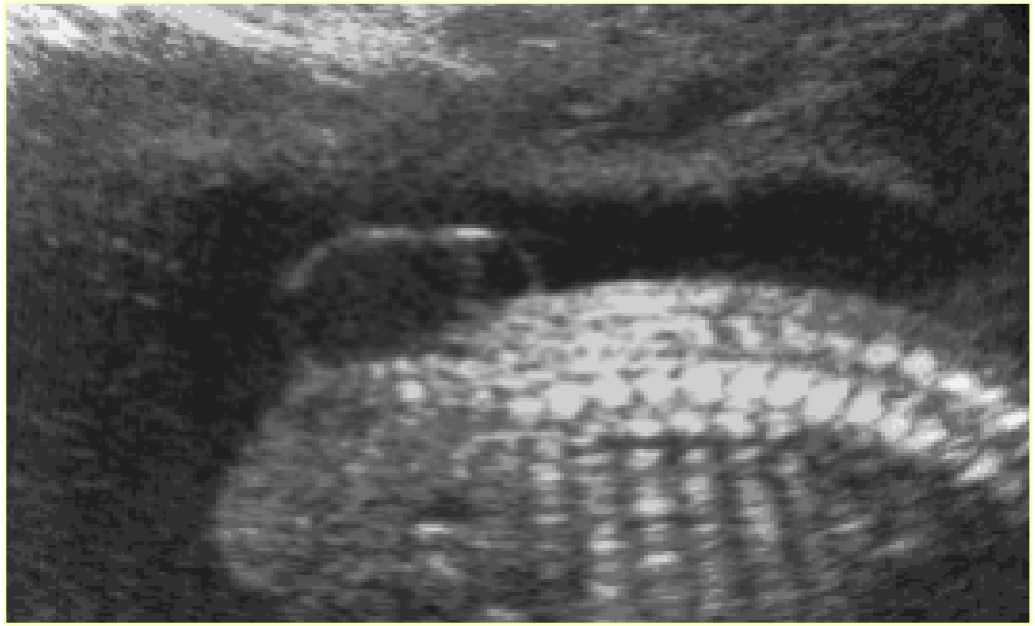
MFM perspective



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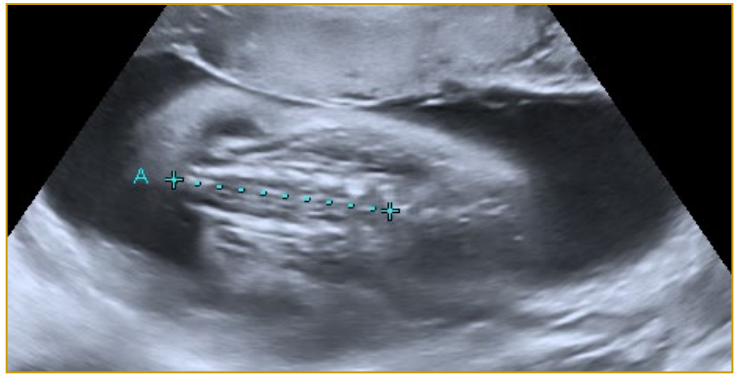

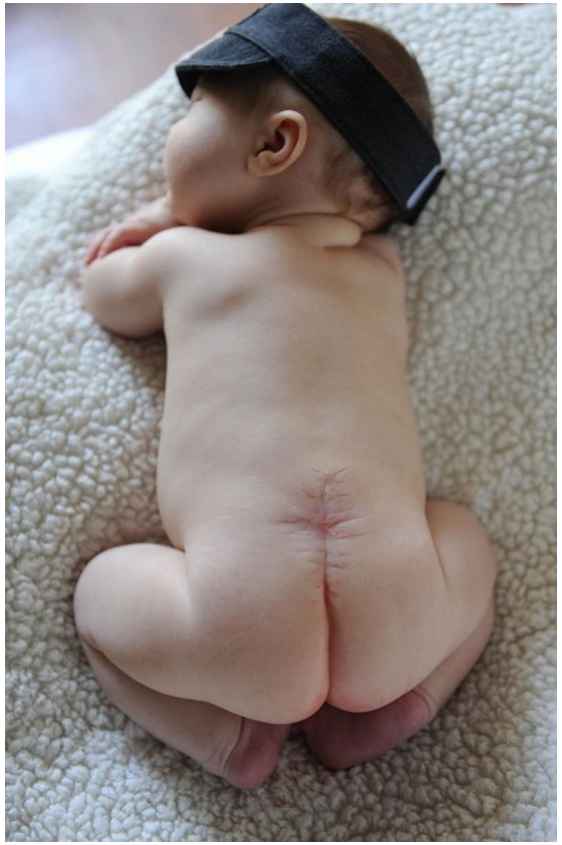

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Neural Tube Defects

- Over 4,500 pregnancies per year are affected by NTDs in the European Union (EU) (Busby 2005).
- The average prevalence of NTDs for EU countries is 0.91 per 1,000, based on EUROCAT registry data, and this has not decreased in the last 3 decades (Khosnood 2015, Morris 2021)

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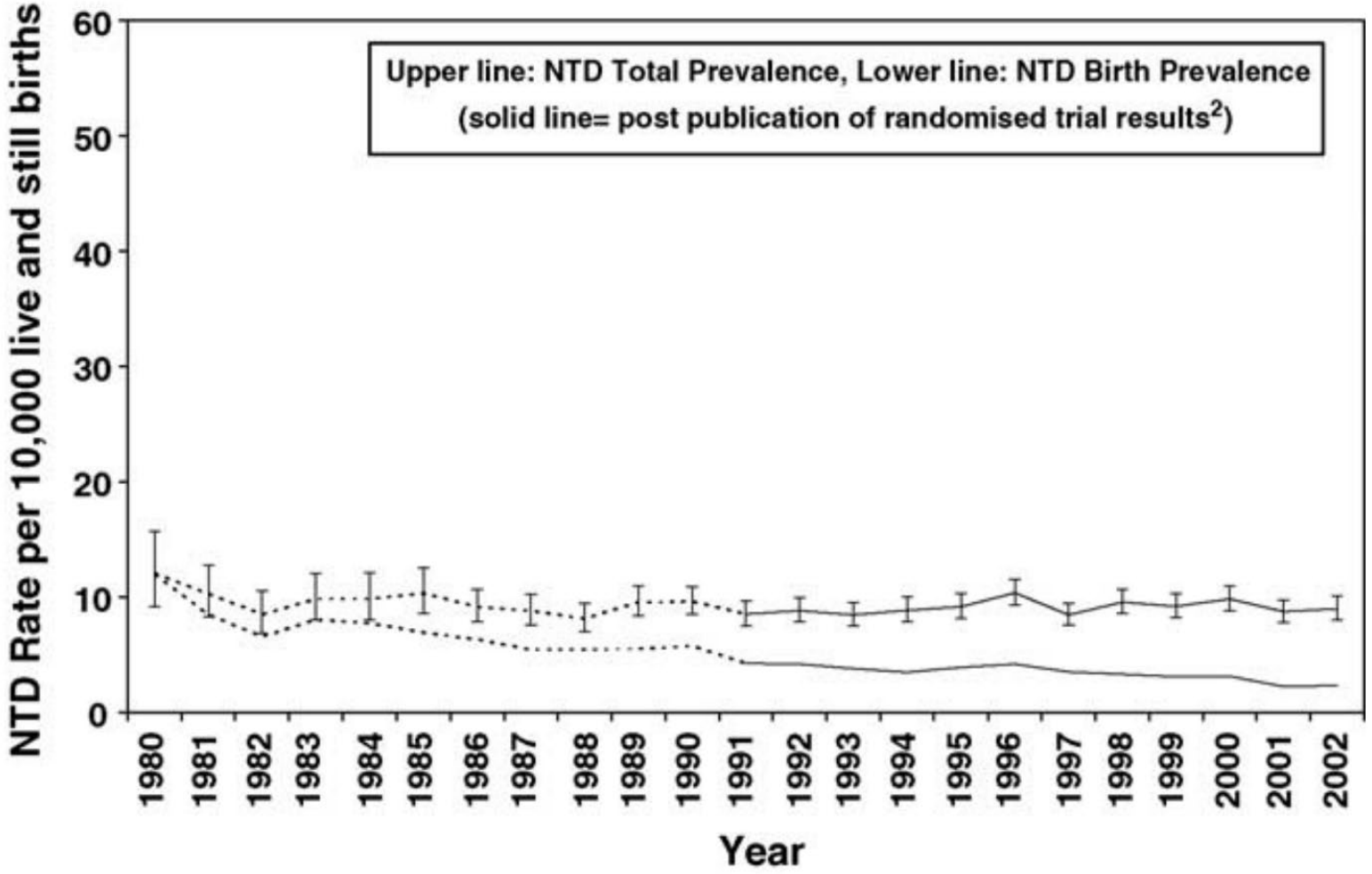

Fig. 2. Total prevalence rate per 10,000 births and birth prevalence rate (excluding terminations) of neural tube defects in Europe-exclUKI, 1980–2002, adjusted for registry.

Busby 2005

Neural Tube Defects

- Since 1991 it has been known that folic acid supplementation prevents NTDs (MRC vitamin Study group Lancet RCT).

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MRC Vitamin Research Group

- Lancet 1991
- Multicentred study: 33 centres, 7 countries
- 1,817 women with **prior NTD**
- Randomised:

1. Folic acid 4mg od
2. Other vitamins
3. Both
4. Neither

- 1,195 completed pregnancies
- 27 NTD
  - 6 in Folic Acid arm
  - 21 in the other two groups
- 4mg folic acid od reduced NTD by 72% in high risk group (RR 0.28, 95%, CI 0.12-0.7)

Wald et al Lancet 1991

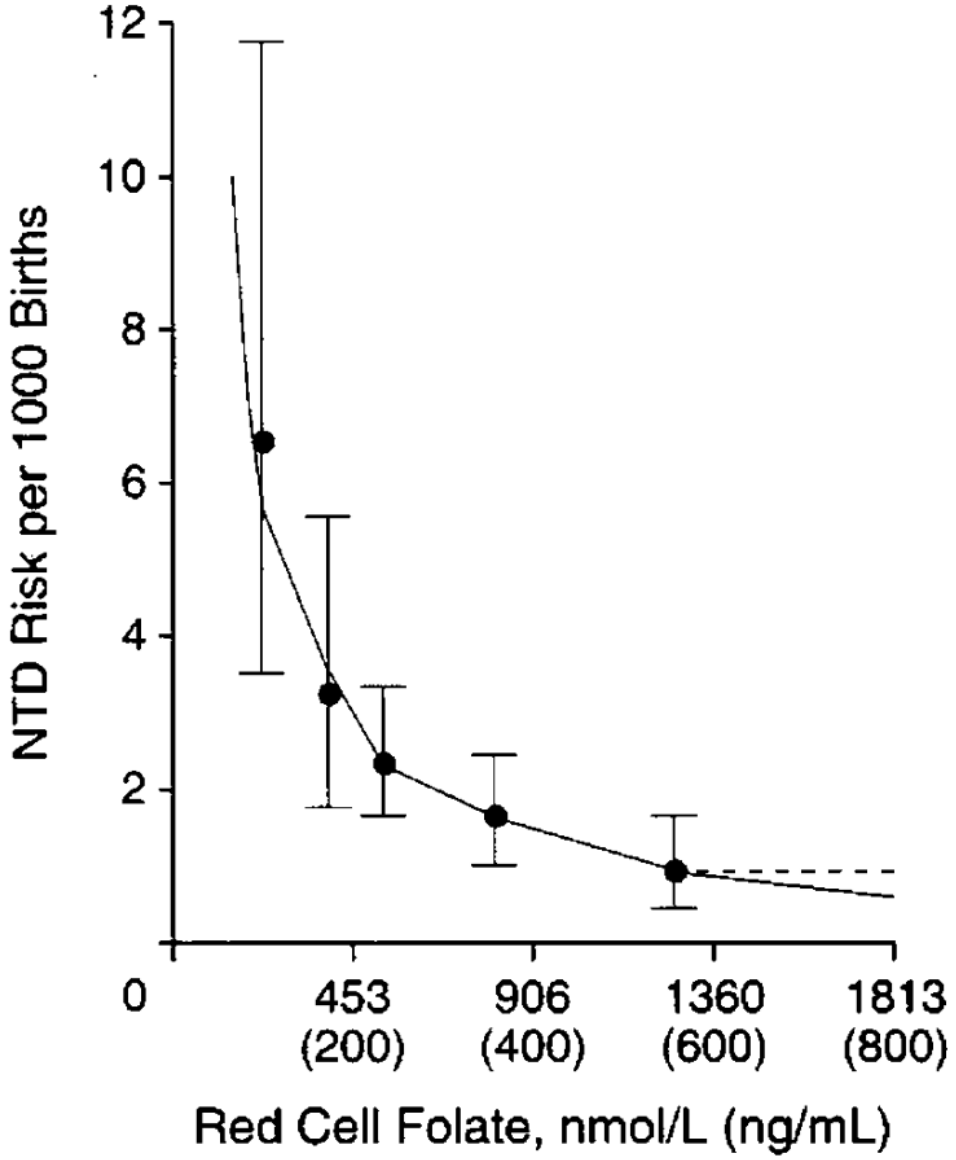
Plasma Folate related to NTD risk

Table 1.—Distribution of Cases and Controls and Risk of Neural Tube Defect (NTD) by Plasma Folate Level*

Plasma Folate, nmol/L (ng/mL)	No. (%) of Cases	No. (%) of Controls	Risk of NTD per 1000 Births	95% Confidence Interval
0-4.4 (0-1.9)	17 (21.0)	27 (10.9)	3.7	2.1 to 5.9
4.5-6.7 (2.0-2.9)	20 (24.7)	45 (18.2)	2.6	1.6 to 4.0
6.8-11.2 (3.0-4.9)	21 (25.9)	63 (25.5)	1.9	1.2 to 3.0
11.3-15.8 (5.0-6.9)	13 (16.0)	50 (20.3)	1.5	0.8 to 2.6
≥15.9 (7.0)	10 (12.4)	62 (25.1)	0.9	0.5 to 1.7
Total	**81 (100.0)**	**247 (100.0)**	1.9	1.5 to 2.3

Daly JAMA 1995, n=56,049

Plasma Folate related to NTD risk



Daly JAMA 1995, n=56,049

Folic Acid and NTD

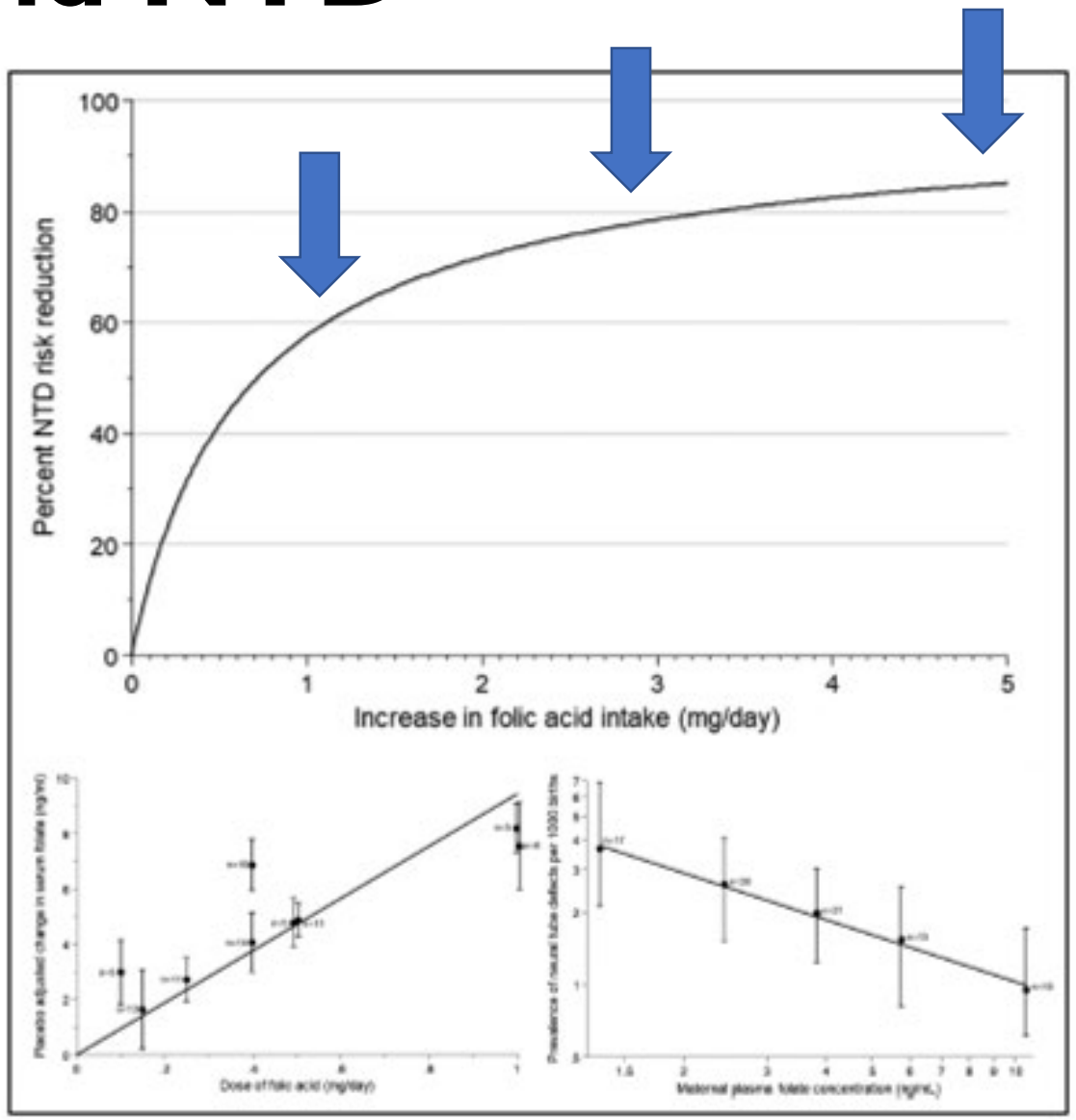


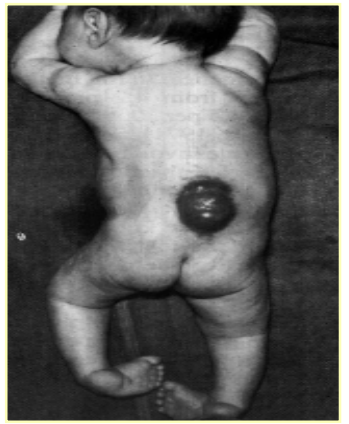
Figure. Main graph: percentage neural tube defect (NTD) risk reduction according to increase in folic acid intake per day for people aged 20–35 with a starting folate level of 5ng/ml. This is based on the equation: Percent NTD risk reduction = 100 × [1-[[9.4 × increase in folic acid intake (mg/day) + 5]/5]$^{-0.81}$]] derived from the data in the lower graphs, reproduced from Wald et al.[10]

Folic acid 5mg od recommended

?is 5mg the best dose
?3mg
?1mg

Wald 2022

Neural Tube Defects



- Women are unlikely to achieve the circulating levels of folic acid needed to prevent NTDs (red blood cell folate > 906 nmol/L) through a healthy diet alone (Daly 1995),

- Approximately-two thirds of cases of NTDs are preventable with adequate FA supplementation (Botto 1999).

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Neural Tube Defects

- Public health advice in Europe- 400 mcg of FA for at least 4 weeks prior to pregnancy and during the first trimester to prevent NTDs (Daly 1995).

- 40 % of pregnancies are unplanned - proportion of women taking FA to prevent NTDs is circa 10 and 35 % (Cawley 2016, Johnson 2012).

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Folic acid fortification of flour

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Full length article

Folic acid fortification of flour to prevent neural tube defects in Europe – A position statement by the European Board and college of obstetrics and gynaecology (EBCOG)

Sarah Petch [a,*], Fionnuala McAuliffe [b,*], Sharleen O'Reilly [c], Cliona Murphy [d], Sam Coulter-Smith [e], Diogo Ayes de Campos [f], Hajra Khattak [g], Tahir Mahmood [h,i,1]

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2022

Folic acid fortification of flour

- 1998: The USA and Canada - FA fortification of flour
- Canada - a decrease in NTD prevalence from 1.58 to 0.86 per 1,000 within 4 years of FA fortification (Bearak 2022).
- USA - Reduction spina bifida and anencephaly 0.76 to 0.56 per 1,000 in the first year of flour fortification (DeWals 2017).
- Chile - 50 % reduction in NTD over a 10 year period after wheat flour FA fortification in 2000 (Williams 2002)
- **No increases in adult nor childhood cancer reported (Grupp 2011)**

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Other benefits of Folic Acid in Pregnancy

- Unconfirmed reduced risk of:
- Child brain tumours / leukemia (Milne 2010, 2012, Thompson 2021)
- Congenital heart defects / other congenital defects
- Preterm delivery (4 studies vs 1)
- Low infant birth weight
- Improved neurodevelopmental outcomes
- Reduced CP (MOBAND-CP 2022, 9-12/40 folic acid 0.4mg)

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Silva 2017

FASSTT

- RCT folic acid second and third trimesters
- 400 mcg/day of folic acid or placebo from 14 weeks until the end of pregnancy (McNulty 2013).
- A follow up study of children born to mothers receiving folic acid showed significantly higher cognitive scores at 3 and 7 and 11 years (McNulty 2019, Caffrey 2021).

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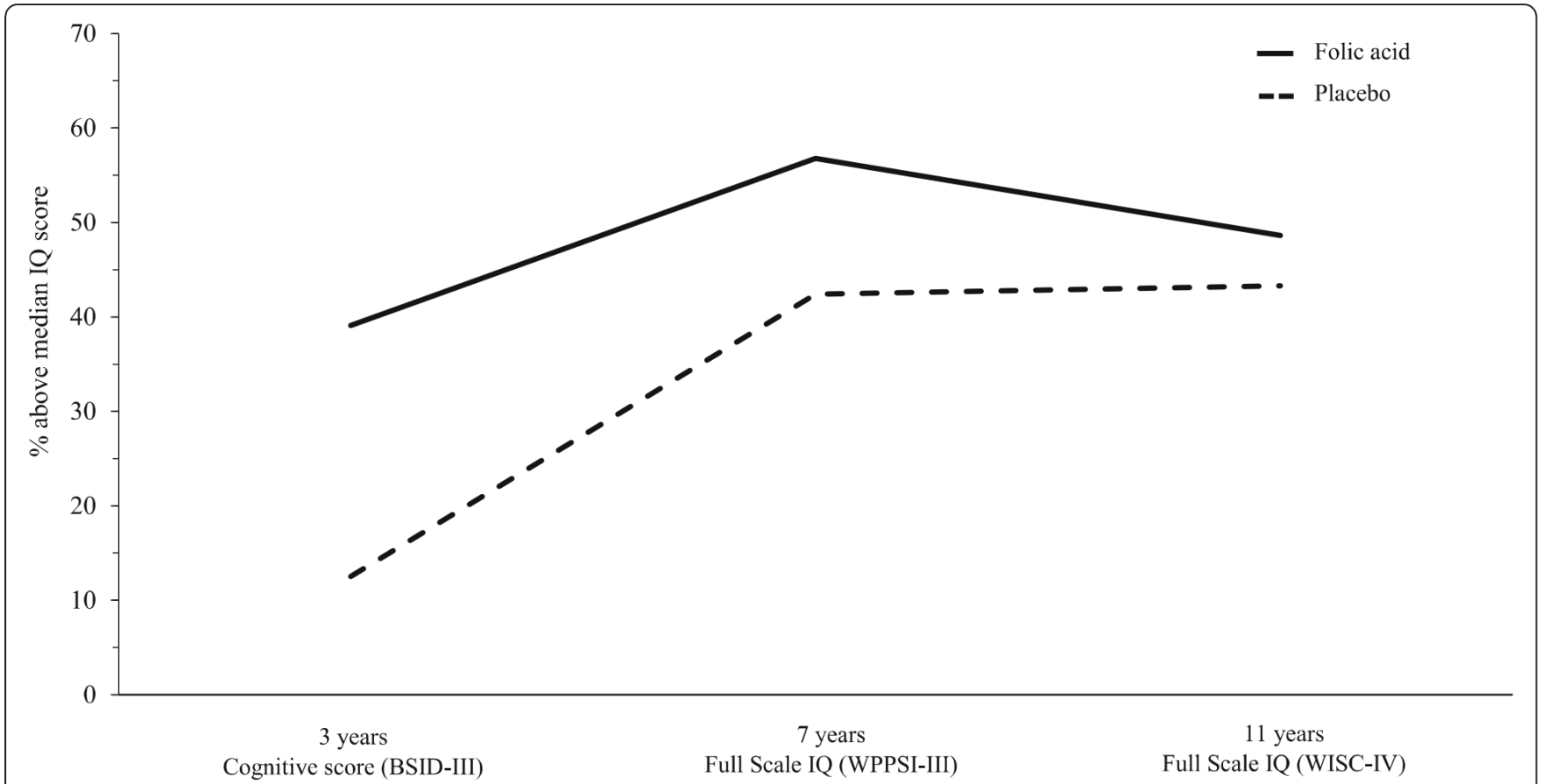

Fig. 2 Percentage of FASSTT Offspring participants at 3, 7 and 11 years achieving above average cognitive performance by treatment allocation of the mother during pregnancy. In children at 3 years, cognitive performance was assessed by the BSITD-III test, at 7 years by the WPPSI-III test and at 11 years by the WISC-IV test. Values are percentage of children at 3, 7 or 11 years, by treatment group of the mother, who achieved above the median cognitive score for children at that age (relative to those who scored at and below the median score); median scores are 10.0 in the BSITD-III test, 23.0 in the WPPSI-III test and 102.5 in the WISC-IV test. Total participants numbers at each age are 3 years, $n = 39$; 7 years, $n = 70$; and 11 years, $n = 68$. 71.4% of the children from FA-treated mothers who had cognitive scores above the median at 11 years also scored above the median at 7 years and Full Scale IQ scores at these time points were significantly correlated ($r = 0.463$; $p < 0.0001$)

Caffrey 2021 (placebo vs 0.4mg folic acid from 14 wks to birth)

Epilepsy in Pregnancy - Mother

MBRRACE Maternal Deaths Inquiry (2020) Showing a doubling of epilepsy deaths among pregnant women with epilepsy

Key report findings:

- **Twice as many women with epilepsy (twenty-two) died** during or up to a year after the end of pregnancy (UK & Ireland) in 2016-18 from causes related to epilepsy, compared to 13 women in 2013-15
- **SUDEP was the main cause of death** for these women (15), though 2 drowned and 2 died due to status epilepticus (prolonged seizures). Exact cause of death was not available for 3 women though they were known to have epilepsy
- **4 women were not taking epilepsy medications** and very few women had documented pre-pregnancy counselling
- The majority had uncontrolled epilepsy pre-pregnancy, less than half had specialist review during pregnancy

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Epilepsy in Pregnancy - Baby

- Increased congenital defects (Valproate, topiramate) Cohen 2023
- Increased risk of adverse neurodevelopmental outcomes (autism spectrum disorder and intellectual disability (valproate 2.5x, topiramate 3x) Dreier 2023
- Increased risk of adverse psychiatric outcomes (all outcomes valproate (1.8x), topiramate (ADHD 2x), levetiracetam (anxiety 2x) Bjork 2022

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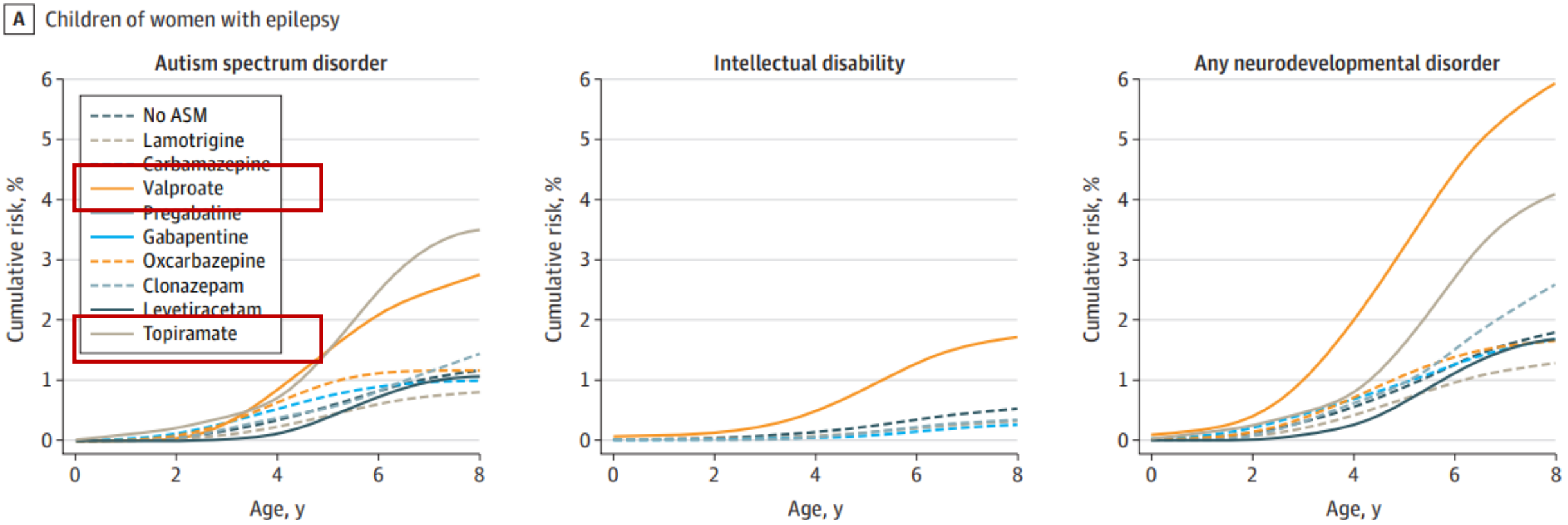
Incidence of Autism and intellectual disability after Prenatal Exposure to Antiseizure Medication

Figure 1. Cumulative Incidence of Neurodevelopmental Disorders After Prenatal Exposure to Antiseizure Medication (ASM)



Bjork 2022

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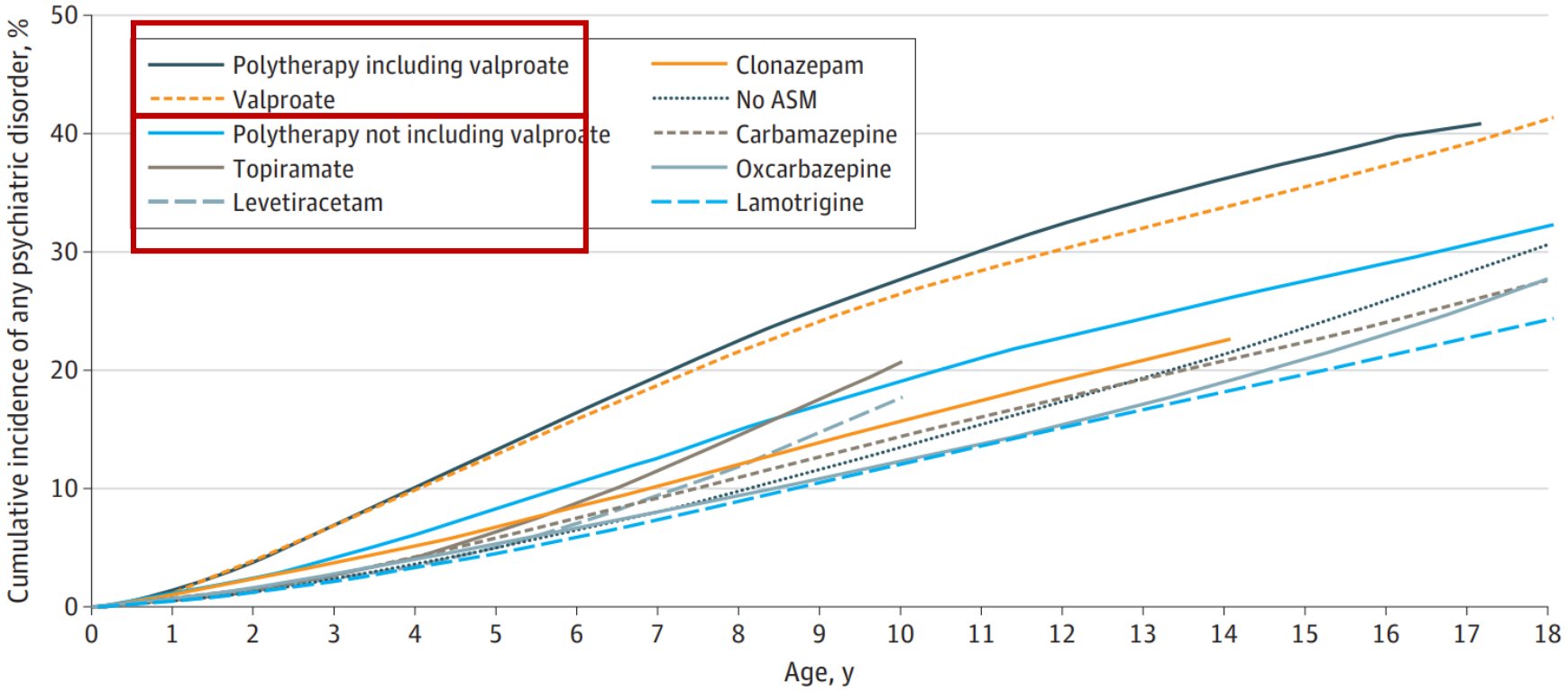
Incidence of the Combined Psychiatric End Point with Prenatal Antiseizure Medication (ASM)

Figure 1. Cumulative Incidence of the Combined Psychiatric End Point According to Prenatal Antiseizure Medication (ASM) Exposure



Dreier 2023

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Epilepsy in Pregnancy - Baby

- Increased congenital defects (Valproate, topiramate) Cohen 2023
- Increased risk of adverse neurodevelopmental outcomes (valproate, topiramate, levetiracetam) Dreier 2023, Bjork 2022
- *Generally considered related to antiseizure medication (ASM)*

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Epilepsy in Pregnancy - Baby

- Folic acid known to reduce risk of NTD (Wald et al 1991)
- Evidence that folic acid in WWE on ASM may reduce risk of child autistic traits (Bjork 2018)
- Folic acid may also ameliorate language delay in same children (Synnove 2018)

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Is there benefit of using folate in pregnancy?

Risks

Benefits

Folate requirements increase 5- to 10-fold during pregnancy (with peak maternal requirement at around five months gestation)

Periconceptual use is known to decrease the risk of NTDs

<u>Unconfirmed</u> reduced risk of:

- Child brain tumours / leukemia
- congenital heart defects / other congenital defects
- preterm delivery (4 studies vs 1)
- low infant birth weight
- improved neurodevelopmental outcomes
- Reduced CP (MOBAND-CP 2022, 9-12/40)

Silva 2017

> 1mg folic acid

JAMA Neurology | Original Investigation Nov 2022

Cancer Risk in Children of Mothers With Epilepsy and High-Dose Folic Acid Use During Pregnancy

Håkon Magne Vegrim, MD; Julie Werenberg Dreier, PhD; Silje Alvestad, MD, PhD; Nils Erik Gilhus, MD, PhD; Mika Gissler, PhD; Jannicke Igland, PhD; Maarit K. Leinonen, MD, PhD; Torbjörn Tomson, MD, PhD; Yuelian Sun, MD, PhD; Helga Zoega, MA, PhD; Jakob Christensen, MD, PhD, DrMedSci; Marte-Helene Bjørk, MD,

Received: 6 June 2023 | Accepted: 9 June 2023

DOI: 10.1111/epi.17680

Epilepsia™

COMMENTARY June 2023

Unjustified allegation on cancer risks in children of mothers with epilepsy taking high-dose folic acid during pregnancy—No proof of a causal relationship

Received: 6 July 2023 | Accepted: 12 July 2023

DOI: 10.1111/epi.17717

Epilepsia™

COMMENTARY July 2023

High-dose folic acid and cancer risk; unjustified concerns by von Wrede and colleagues regarding our paper

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Vegrim *et al.* 2022 study details

Key findings

Table 2. Association Between Maternal Epilepsy, Filled Prescription of High-Dose Folic Acid, and Risk of Childhood Cancer in the Offspring[a]

Maternal epilepsy	High-dose folic acid	Live births	Childhood cancer cases	Incidence rate per 100 000 person-years (95% CI)	Cumulative incidence at 20 y (95% CI)[b]	Crude HR (95% CI)	aHR 1 (95% CI)[c]	aHR 2 (95% CI)[d]	aHR 3 (95% CI)[e]
Yes	Yes	5934	18	42.5 (26.8-67.5)	1.5 (0.5-3.6)	2.4 (1.3-4.5)	2.4 (1.3-4.4)	2.5 (1.1-5.8)	2.7 (1.2-6.3)
	No	21 850	29	18.4 (12.8-26.5)	0.6 (0.3-1.1)	1 [Reference]	1 [Reference]	1 [Reference]	1 [Reference]
No	Yes	46 646	69	20.0 (15.8-25.4)	0.4 (0.3-0.5)	1.1 (0.9-1.4)	1.1 (0.9-1.4)	1.1 (0.9-1.4)	1.1 (0.9-1.4)
	No	3 304 741	4927	18.9 (18.4-19.5)	0.4 (0.4-0.4)	1 [Reference]	1 [Reference]	1 [Reference]	1 [Reference]

- 2.5-fold ↑risk among WWE with high dose folic acid (> 1mg) use
- No evidence of increased risk among children of women without epilepsy that used high dose folate

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Vegrim *et al.* 2022 study details

Key findings

Table 3. Association Between Maternal Epilepsy, Maternal Prescription Fill for Antiseizure Medication (ASM), High-Dose Folic Acid, and Risk of Childhood Cancer in the Offspring[a]

Maternal epilepsy	Maternal ASM	High-dose folic acid	Live births	Incidence rate per 100 000 person-years (95% CI)	Cumulative incidence at 20 y (95% CI)[b]	Crude HR (95% CI)	aHR 1 (95% CI)[c]	aHR 2 (95% CI)[d]
Yes	Yes	Yes	5531	43.0 (26.8-69.2)	1.4 (0.5-3.1)	2.9 (1.1-7.5)	2.9 (1.1-7.7)	3.0 (1.1-7.9)
		No	5195	19.1 (9.5-38.1)	0.6 (0.2-0.13)	1 [Reference]	1 [Reference]	1 [Reference]
	No	Yes	403	NA	NA	NA	NA	NA
		No	16 655	18.2 (11.8-27.9)	0.6 (0.3-1.1)	1 [Reference]	1 [Reference]	1 [Reference]
No	Yes	Yes	819	NA	NA	NA	NA	NA
		No	6045	23.0 (11.5-46.0)	0.4 (0.1-1.0)	1 [Reference]	1 [Reference]	1 [Reference]
	No	Yes	45 827	19.7 (15.4-25.1)	0.4 (0.3-0.5)	1.1 (0.8-1.4)	1.1 (0.8-1.4)	1.1 (0.8-1.4)
		No	3 298 696	18.9 (18.4-19.5)	0.4 (0.4-0.4)	1 [Reference]	1 [Reference]	1 [Reference]

- Increased risk among WWE using ASMs with high dose folic acid use
- Unable to assess risk among WWE without ASM use who used high dose folate
- Unable to assess risk among women without epilepsy who used ASM and high dose folate
- No increased risk among women without epilepsy who did not use ASM, but did use high dose folate

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Vegrim *et al.* 2022 study details

Other key findings

- **Dose response relationship**
  Higher risks among those born to WWE
  - ≥4mg daily (aHR 3.4, 95% CI; 1.1 to 10.7)
  - <4mg daily (aHR 2.9, 95% CI; 1.2 to 7.2)
  - Not statistically significant, thus no dose-response (but a trend towards…)

- **Antiseizure Medication**
  Cancer risk increased among children exposed to ASM in utero for any indication (aHR 1.5, 95% CI, 1.1 to 2.1) compared with that of children unexposed to any ASM (regardless of folic acid exposure)

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Summary of Findings

- ASMs were used by almost the entire cohort of WWE filling prescriptions for high-dose folic acid (n=5,531/5,934, 93.2%)
- Could ASM use (or factors related to it) be explanatory?
  - ASM use risk =aHR 1.5 (95% CI, 1.1 to 2); vs
  - ASM and high dose folate together = aHR 2.9 (95% CI 1.1 to 7.7) **?synergy**
- Most of the cancer events appeared **>10 years**
  - This long lag time may introduce the risk of unmeasured confounding
- Childhood cancer is a heterogenous outcome, with multiple risk factors
- Some findings are based on small numbers of exposed and affected individuals, which produced wide-confidence limits (inaccurate risk estimates)

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Summary of Findings

Factors negatively impacting on the conclusions:

1. Risk of bias – possible impacts from confounding
2. Imprecision
   - wide confidence limits
   - risk estimates were not possible for some stratifications

Factors positively impacting on the conclusions:

1. Magnitude of the effect is high – possible that confounding factors would not completely explain the increased risk
2. Possible dose response effect described
3. Sensitivity analyses supported the primary findings

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Conclusion

- Women on high dose folic acid without epilepsy - same risk of childhood cancer as the background population
- Take home message is **not** that high dose folic acid causes childhood cancer

- An **association** seen in **one study** in women with **epilepsy on ASM**
- Confounding may well be an issue
- Association does not = causation
- Evidence regarding benefit of high dose folic acid in WWE lacking – but extrapolated data taken from women with prior NTD show ~ 72% reduction in NTD

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Is there benefit of using folate in pregnancy?

Risks

Vegrim study - possible association with increased risk of childhood cancer with high dose

Lack of clear evidence that high dose folate is of definite benefit beyond decreasing the risk of NTD

Lack of clear evidence that high-dose folate is superior to standard dose folate (although theoretically possible for known folate antagonists, eg ASM)

Benefits

Folate requirements increase 5- to 10-fold during pregnancy (with peak maternal requirement at around five months gestation)

Periconceptual use is known to decrease the risk of NTDs

Unconfirmed reduced risk of:

- Child brain tumours / leukemia
- congenital heart defects / other congenital defects
- preterm delivery (4 studies vs 1)
- low infant birth weight
- improved neurodevelopmental outcomes
- Reduced CP (MOBAND-CP 2022, 9-12/40)

Silva 2017

What does International Guidance say?

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Pre 2022

- 2017: **American College of Obstetricians** and Gynecologists (ACOG) recommends folic acid 4 mg daily for women at high risk of having offspring with neural tube defects, but does not recommend doses above **0.4 mg** daily for women taking ASMs.
- 2009 **American Academy of Neurology (AAN)** recommends preconceptional folate supplementation to reduce the risk of major congenital malformations (MCM) in WWE. They **do not comment on folate dosage**.
- 2019 **International League Against Epilepsy** Task Force on Women and Pregnancy: "Evidence for the best periconceptional dose of folate in women with epilepsy taking AEDs remains inadequate. Recommendations vary from 0.4 to 4-5 mg/d. Given the incidence of unplanned pregnancies, women of childbearing potential taking AEDs should be on **at least 0.4 mg/d** of folate."
- **2022 RCOG** All WWE should be advised to take **5 mg/day** of folic acid prior to conception and to continue the intake until at least the end of the first trimester to reduce the incidence of major congenital malformation.

Pre 2022

- **2022 Epilepsy Ireland** "You are advised to take folic acid prior to becoming pregnant. This should ideally be taken at least 3 months before you become pregnant and continued until you are 14 weeks pregnant. Although folic acid is recommended for all women who are pregnant, please check the **best dose suitable** to you with your epilepsy specialist"

- **2018 Public Health Agency of Canada** : All women who could become pregnant need to take a multivitamin with 0.4 mg of folic acid in it every day. Women with certain medical conditions and on certain drugs may also need **a higher dose** of folic acid.

- **2009 Italian Consensus Conference on Epilepsy** and Pregnancy, Labor and Puerperium: All women of childbearing potential should receive folic acid supplements. The optimal dose of folic acid is unclear. Some authors recommend **0.4–0.5mg/day**, and **5mg/day for women taking valproic acid or carbamazepine**.

Benedetta Soldati, Senior Pharmacist, National Maternity Hospital

Post 2022

- **UKTIS** (2023): Although the clinical benefits of high-dose FA are assumed rather than confirmed in some groups where use in pregnancy is advised, based on the findings of the Vegrim et al. study alone, UKTIS do not currently plan to alter their guidance about **high-dose FA** use among women using antiseizure medications (ASMs) in pregnancy.

- **Swiss League Against Epilepsy** (Aug 23): women of child-bearing age who are on anti-seizure medication should continue to take folic acid regularly and prior to conception. The Epilepsy League now recommends a dose of **1-3 mg** per day. Higher doses can be considered on an individual basis, depending on the **mother's folate blood level** or ethrocyte test results. This could be the case for expectant mothers who are on powerful enzyme-inducing medicines.

Comments from fellow MFMs

‘From now I am using 0.8mg for newer ASM that do no interfere with FA metabolism eg LTG’

‘I continue with FA 5mg for valproate, carbamazepine and phenytoin’

‘I always use 5 mg for first trimester and then revert to usual pregnancy dose 0.4mg, for women at high risk for NTD including those on ASM’

What is **your** recommendation for WWE on ASM?

Stratify by ASM

Option A

Continue current recommendations, up to 5mg

Possible increased cancer risk (absolute risk 0.6 to 1.4%)

Effect on NTD known

Option B

Recommend WWE usual dose folate (0.4mg)

Effect on NTD uncertain

Option C

Recommend WWE on ASM receive

> 1mg folic acid if higher risk (e.g. Valproate, carbamazepine)

Effect on NTD uncertain

Option D

Recommend WWE on newer ASM receive

< 1mg folic acid

Effect on NTD uncertain

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If higher dose (> 1mg) for how long in pregnancy?

Option A

Up to14 weeks gestation, then reduce to usual 0.4mg dose

Option B

Continue high dose for entire pregnancy

Option C

Continue high dose

> 14 weeks only for women on valproate/

carbamazepine/

phenytoin

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Conclusion

General population

- Folic acid prevents NTD in total population and in those with previous NTD

- Beneficial effects on child neurodevelopment

- **Food fortification of folic acid proven to reduce NTD at population level with no increased rates of adult or childhood cancer**

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Conclusion

Women with Epilepsy on ASM

- Increased risk of congenital malformation and children with intellectual disorders - folic acid may ameliorate risks
- Evidence regarding benefit of high dose folic acid in WWE lacking – but extrapolated data taken from women with prior NTD show ~ 72% reduction in NTD
- Association with folic acid > 1mg and childhood cancer reported– requires support from other observation and scientific studies on causation
- Consider personalised dosing of folic acid for WWE on ASM?

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SEVENTH FRAMEWORK PROGRAMME

HRB Health Research Board

NATIONAL CHILDREN'S RESEARCH CENTRE

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