Trump, Paracetamol, and Autism

Causal Lessons from Pregnancy Drug Safety Research

AARHUS UNIVERSITY
DEPARTMENT OF BIOMEDICINE

VIKTOR H. AHLQVIST
POSTDOCTORAL FELLOW IN STATISTICAL GENETICS AND PRECISION PSYCHIATRY

24 NOVEMBER 2025

Karolinska Institutet

DRUG SAFETY IN PREGNANCY

Pregnant individuals are often excluded from drug trials.

When a drug comes to market, it is often unclear if the drug is safe during pregnancy.

- However, many pregnant individuals require medication (>60% in Nordics).

Pregnant individuals and clinicians often must balance multiple risks.

- Both maternal and fetal health must be considered.

PREGNANCY PHARMACOEPIDEMIOLOGY

Safety data typically comes from observational studies, where individuals using a drug are followed up and compared to those who do not use the drug.

- This discipline is sometimes referred to as **pregnancy pharmacoepidemiology**.

To claim that a drug has a **causal effect** (either negative or positive), there should be no other explanation for a difference in outcomes between users and non-users.

- Drug users are often very different from non-users.

TRUMP: PARACETAMOL IN PREGNANCY CAUSES AUTISM

PARACETAMOL ('ACETAMINOPHEN')

Original Investigation

April 9, 2024

Acetaminophen Use During Pregnancy and Children's Risk of Autism, ADHD, and Intellectual Disability

Viktor H. Ahlqvist, PhD[1]; Hugo Sjöqvist, MSc[1]; Christina Dalman, MD, PhD[1]; Håkan Karlsson, PhD[2]; Olof Stephansson, MD, PhD[3,4]; Stefan Johansson, MD, PhD[3,5]; Cecilia Magnusson, MD, PhD[1,6]; Renee M. Gardner, PhD[1]; Brian K. Lee, PhD[1,7,8]

» Author Affiliations

JAMA. 2024;331(14):1205-1214. doi:10.1001/jama.2024.3172

”THE TRUMP EFFECT”

THE BARBRA STREISAND EFFECT OF SCIENCE

ALL RESEARCH OUTPUTS	OUTPUTS FROM JAMA: JOURNAL OF THE AMERICAN MEDICAL ASSOCIATION	OUTPUTS OF SIMILAR AGE
#92	#2	#1
of 29,626,222 outputs	of 38,834 outputs	of 361,729 outputs

LET'S TAKE A STEP BACK

CONTEXT

Acetaminophen (paracetamol) is commonly used to manage pain and fever during pregnancy.

Considered to pose minimal risk during pregnancy.

- EMA; FDA; ENTIS; ACOG, SFOG, NHS, etc.

Other therapeutics are typically not an option.

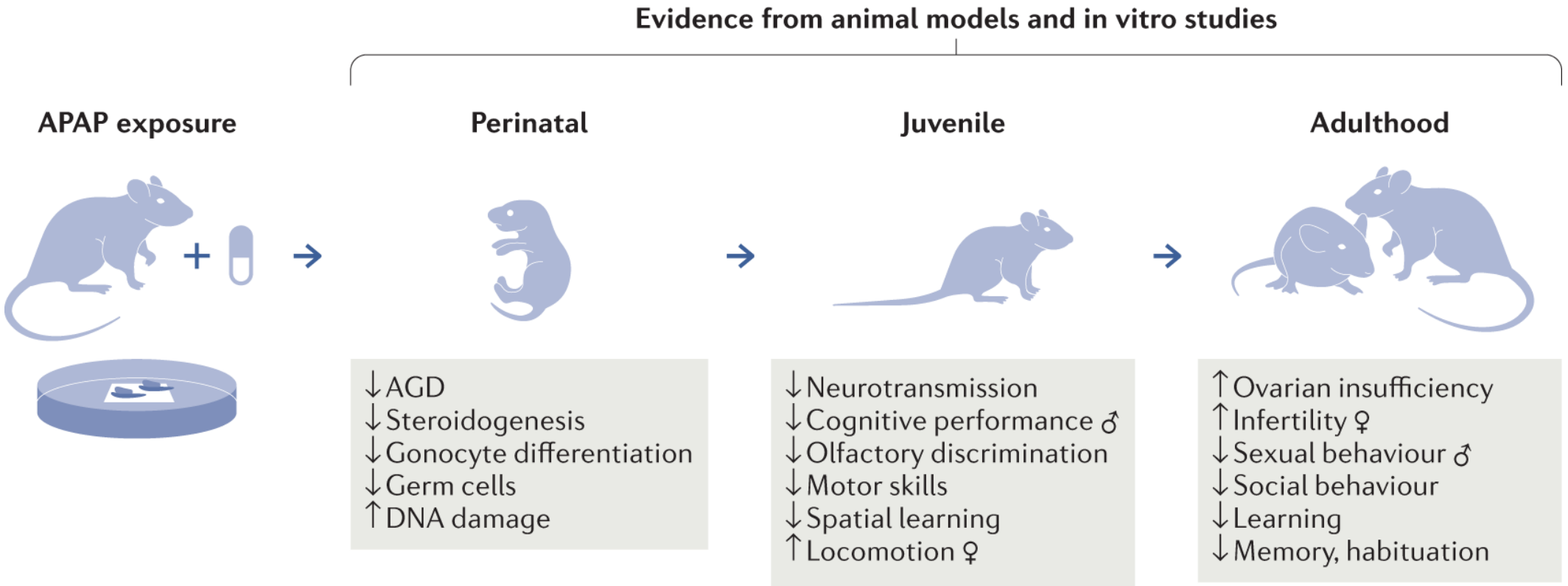
- (High dose) aspirin/NSAIDs contraindicated due to bleeding & kidney development.
- Opiates are known to be teratogenic.

Consensus Statement | Open access | Published: 23 September 2021

Paracetamol use during pregnancy – a call for precautionary action

Ann Z. Bauer, Shanna H. Swan, David Kriebel, Zeyan Liew, Hugh S. Taylor, Carl-Gustaf Bornehag, Anderson M. Andrade, Jørn Olsen, Rigmor H. Jensen, Rod T. Mitchell, Niels E. Skakkebaek, Bernard Jégou & David M. Kristensen

Nature Reviews Endocrinology **17**, 757–766 (2021) | Cite this article

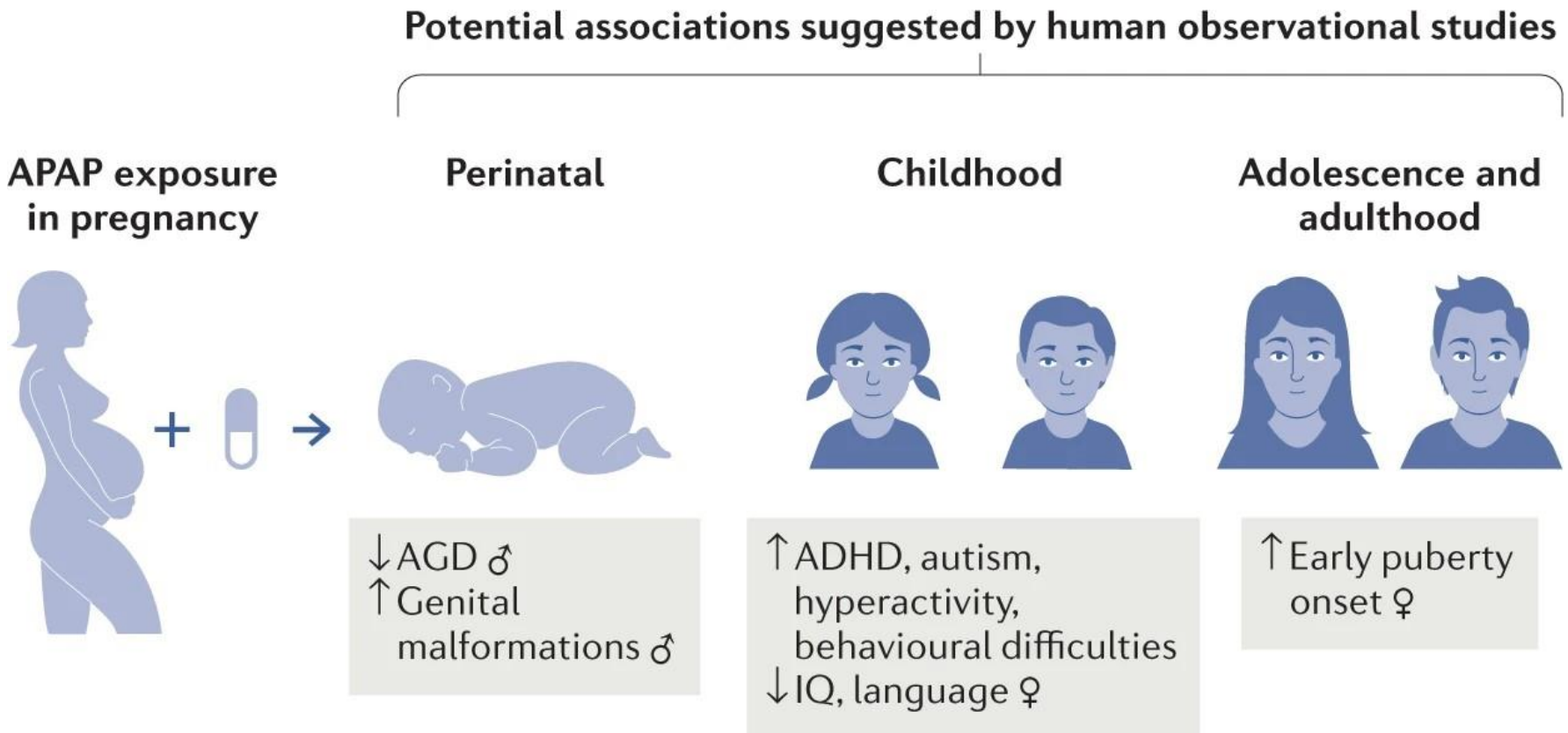


Consensus Statement | Open access | Published: 23 September 2021

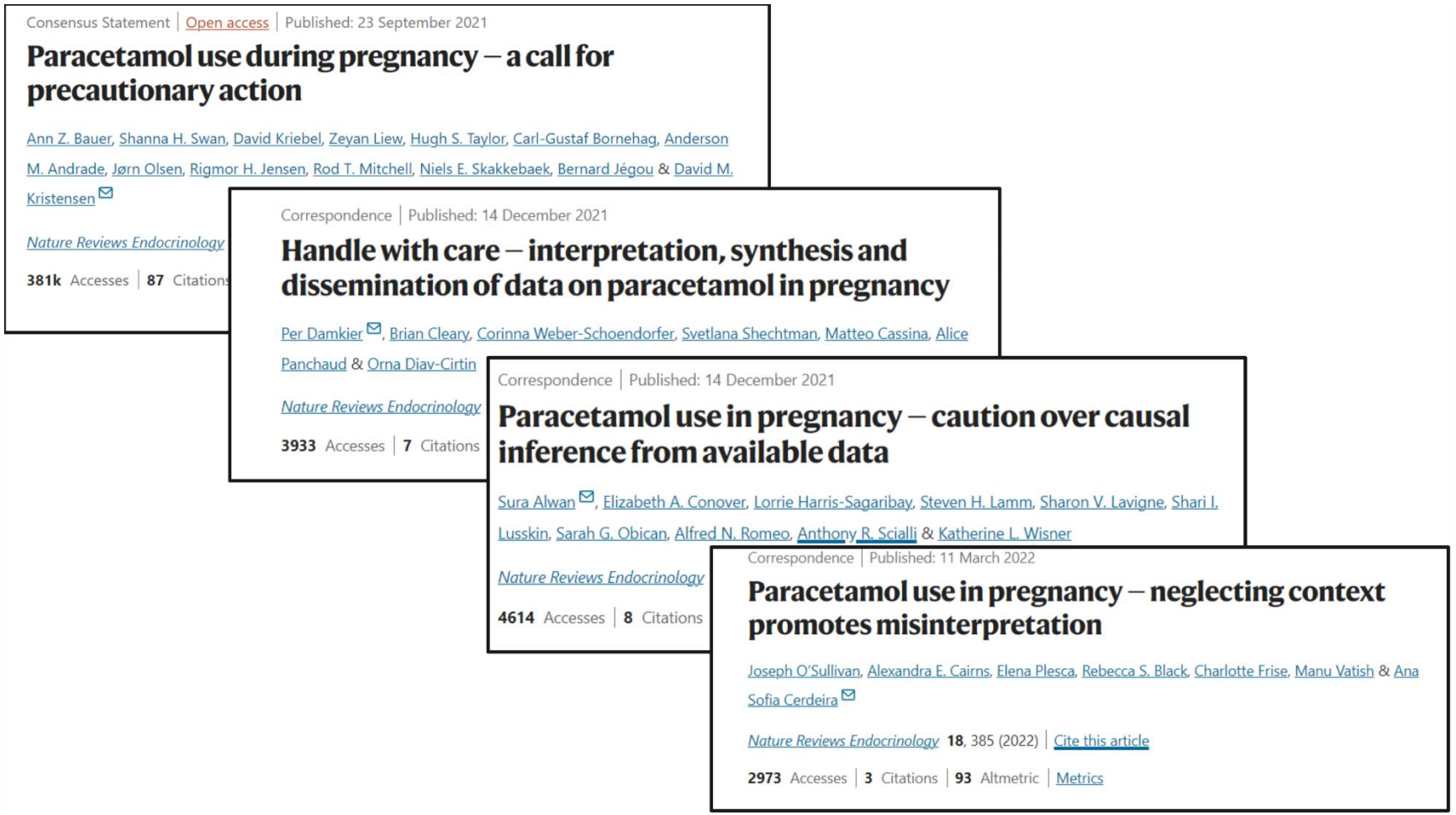
Paracetamol use during pregnancy – a call for precautionary action

Ann Z. Bauer, Shanna H. Swan, David Kriebel, Zeyan Liew, Hugh S. Taylor, Carl-Gustaf Bornehag, Anderson M. Andrade, Jørn Olsen, Rigmor H. Jensen, Rod T. Mitchell, Niels E. Skakkebaek, Bernard Jégou & David M. Kristensen

Nature Reviews Endocrinology **17**, 757–766 (2021) | Cite this article



SCIENTIFIC DEBATE



Consensus Statement | Open access | Published: 23 September 2021

Paracetamol use during pregnancy – a call for precautionary action

Ann Z. Bauer, Shanna H. Swan, David Kriebel, Zeyan Liew, Hugh S. Taylor, Carl-Gustaf Bornehag, Anderson M. Andrade, Jørn Olsen, Rigmor H. Jensen, Rod T. Mitchell, Niels E. Skakkebaek, Bernard Jégou & David M. Kristensen

Nature Reviews Endocrinology

381k Accesses | **87** Citations

Correspondence | Published: 14 December 2021

Handle with care – interpretation, synthesis and dissemination of data on paracetamol in pregnancy

Per Damkier, Brian Cleary, Corinna Weber-Schoendorfer, Svetlana Shechtman, Matteo Cassina, Alice Panchaud & Orna Diav-Cirtin

Nature Reviews Endocrinology

3933 Accesses | **7** Citations

Correspondence | Published: 14 December 2021

Paracetamol use in pregnancy – caution over causal inference from available data

Sura Alwan, Elizabeth A. Conover, Lorrie Harris-Sagaribay, Steven H. Lamm, Sharon V. Lavigne, Shari I. Lusskin, Sarah G. Obican, Alfred N. Romeo, Anthony R. Scialli & Katherine L. Wisner

Nature Reviews Endocrinology

4614 Accesses | **8** Citations

Correspondence | Published: 11 March 2022

Paracetamol use in pregnancy – neglecting context promotes misinterpretation

Joseph O'Sullivan, Alexandra E. Cairns, Elena Plesca, Rebecca S. Black, Charlotte Frise, Manu Vatish & Ana Sofia Cerdeira

Nature Reviews Endocrinology **18**, 385 (2022) | Cite this article

2973 Accesses | **3** Citations | **93** Altmetric | Metrics

THE WALL STREET JOURNAL.

U.S. | LAW

Lawsuits Seek to Link Tylenol Ingredient to Autism, ADHD

Judge to decide if plaintiffs in hundreds of cases can cite scientific claims that acetaminophen affects fetal development

By *Erin Mulvaney* Follow

Dec. 6, 2023 9:00 am ET

Top Class Actions

Lawsuits & Settlements | Legal News | Class Actions Explained | I Am a Lawyer | About Us

CVS, Rite Aid lawsuit alleges acetaminophen use during pregnancy caused child's autism

2022

FOLLOW ARTICLE

Top Class Actions

Lawsuits & Settlements | Legal News | Class Actions Explained | I Am a Lawyer

Target lawsuit claims acetaminophen use during pregnancy can cause neurodevelopmental disorders

Jessy Edwards | November 15, 2022

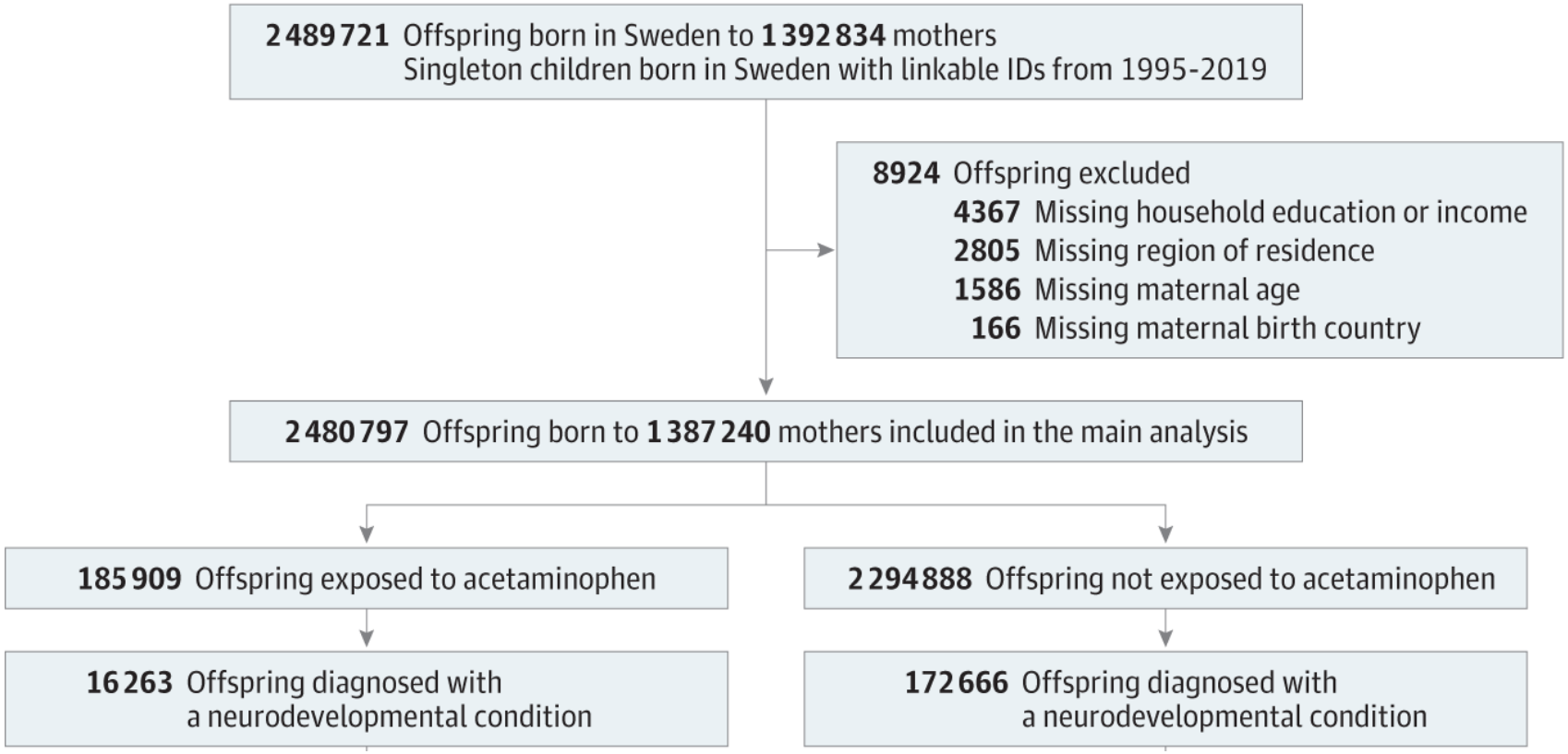
Category: Consumer News

FOLLOW ARTICLE

Exposure: Maternal self-reported consumption at antenatal visits (1995-) or dispensations of prescriptions (2005-).

Outcome: Autism, ADHD or intellectual disability in the National Patient Register.

Model: Time-to-event (Cox regression).



ANY ACETAMINOPHEN IN PREGNANCY

	Self-reported acetaminophen consumption or prescription dispensation ($N_{exposed}$=132,681)			
	Exposed cases	Hazard ratio[a]	95% CI	P-value
Autism	3,988 (3.0)	1.11	1.08-1.14	<0.001
ADHD	8,593 (6.5)	1.13	1.27-1.15	<0.001
Intellectual disability	1,382 (1.0)	1.18	1.12-1.23	<0.001
[a]Adjusted for birth year, sex and other analgesic use.				

DISPENSED DOSE (2005-)

	Hazard ratio[a]	95% CI	P-value
Autism			
Low dose (<166 mg/day)	**1.33**	**1.20-1.48**	**<0.001**
Medium Dose (166-429 mg/day)	**1.52**	**1.41-1.64**	**<0.001**
High Dose (≥430 mg/day)	**1.87**	**1.71-2.06**	**<0.001**
ADHD			
Low dose (<166 mg/day)	**1.46**	**1.36-1.57**	**<0.001**
Medium Dose (166-429 mg/day)	**1.75**	**1.65-1.85**	**<0.001**
High Dose (≥430 mg/day)	**1.97**	**1.83-2.11**	**<0.001**
Intellectual disability			
Low dose (<166 mg/day)	**1.34**	**1.14-1.58**	**<0.001**
Medium Dose (166-429 mg/day)	**1.47**	**1.30-1.66**	**<0.001**
High Dose (≥430 mg/day)	**1.92**	**1.65-2.22**	**<0.001**

[a]Adjusted for birth year and sex.

EVERYTHING CORRELATES IN OBSERVATIONAL STUDIES

One view of the value of epidemiology.
Davey Smith G, Ebrahim S. Epidemiology - is it time to call it a day? Int J Epidemiol. 2001;30(1):1-11

WHO USES ACETAMINOPHEN?

Acetaminophen exposure was more common among children born to birthing parents with:

- indications for acetaminophen (infections, fevers, etc.).
- co-prescription of related therapeutics.
- lower socioeconomic position.
- higher early pregnancy body mass index.
- who smoked during pregnancy.
- diagnoses of any psychiatric conditions & neurodevelopmental disorders.

ANY ACETAMINOPHEN IN PREGNANCY

	Minor adjustment[a]		
	Hazard ratio	95% CI	P-value
Autism	1.11	1.08-1.14	<0.001
ADHD	1.13	1.27-1.15	<0.001
Intellectual disability	1.18	1.12-1.23	<0.001

[a]Adjusted for birth cohort; child sex; other analgesics (aspirin, other NSAIDs, opioids, antimigraine)

ANY ACETAMINOPHEN IN PREGNANCY

	Minor adjustment[a]			Full adjustment[b]		
	Hazard ratio	95% CI	P-value	Hazard ratio	95% CI	P-value
Autism	1.11	1.08-1.14	<0.001	1.05	1.02-1.08	<0.001
ADHD	1.13	1.27-1.15	<0.001	1.07	1.05-1.10	<0.001
Intellectual disability	1.18	1.12-1.23	<0.001	1.05	1.00-1.10	0.05

[a]Adjusted for birth cohort; child sex; other analgesics (aspirin, other NSAIDs, opioids, antimigraine)

[b]Same as above, but also; birthing parent's diagnoses of migraine, chronic pain, infections, fevers, rheumatoid arthritis, and headaches; calendar period of delivery; parity; age at delivery (linear and cubic term); country of birth; residential region; cohabitation at delivery; early pregnancy body mass index; smoking status; diagnosis of autism, ADHD, and intellectual disability; history of psychiatric conditions and prescription use of psycholeptics, antidepressants, and antiseizure medication; health care visits in the year before pregnancy and an inadequate number of antenatal visits; and the highest household education and disposable income.

DISPENSED DOSE (2005-)

	Minor adjustment[a]		Full adjustment[b]	
	Hazard ratio[a]	95% CI	Hazard ratio[a]	95% CI
Autism				
Low dose (<166 mg/day)	**1.33**	**1.20-1.48**	1.01	0.91-1.12
Medium Dose (166-429 mg/day)	**1.52**	**1.41-1.64**	**1.11**	**1.03-1.20**
High Dose (≥430 mg/day)	**1.87**	**1.71-2.06**	**1.10**	**1.00-1.22**
ADHD				
Low dose (<166 mg/day)	**1.46**	**1.36-1.57**	**1.14**	**1.06-1.23**
Medium Dose (166-429 mg/day)	**1.75**	**1.65-1.85**	**1.25**	**1.18-1.33**
High Dose (≥430 mg/day)	**1.97**	**1.83-2.11**	**1.17**	**1.08-1.27**
Intellectual disability				
Low dose (<166 mg/day)	**1.34**	**1.14-1.58**	0.98	0.83-1.16
Medium Dose (166-429 mg/day)	**1.47**	**1.30-1.66**	1.06	0.93-1.20
High Dose (≥430 mg/day)	**1.92**	**1.65-2.22**	1.12	0.96-1.31

[a]Adjusted for birth cohort; child sex.

[b]Same as above, but also; other analgesics (aspirin, other NSAIDs, opioids, antimigraine), birthing parent's diagnoses of migraine, chronic pain, infections, fevers, rheumatoid arthritis, and headaches; calendar period of delivery; parity; age at delivery (linear and cubic term); country of birth; residential region; cohabitation at delivery; early pregnancy body mass index; smoking status; diagnosis of autism, ADHD, and intellectual disability; history of psychiatric conditions and prescription use of psycholeptics, antidepressants, and antiseizure medication; health care visits in the year before pregnancy and an inadequate number of antenatal visits; and the highest household education and disposable income.

CONFOUNDERS – OUR BEST ATTEMPT?

We typically only control for confounders that we observe and deem important – everything else we just "hope" is balanced enough.

- In epidemiology, we say that we suffer from confounding if we have not eliminated imbalances.

Common to match on:

- Sex, birth year, country of birth
  civil status, residential type,
  disposable income and social status.

Charles III
Male
Born in 1948
Raised in the UK
Married Twice
Lives in a castle
Wealthy and Famous
Former Prince
(of UK)

Ozzy Osbourne
Male
Born in 1948
Raised in the UK
Married Twice
Lives in a castle
Wealthy and Famous
Former Prince
(of darkness)

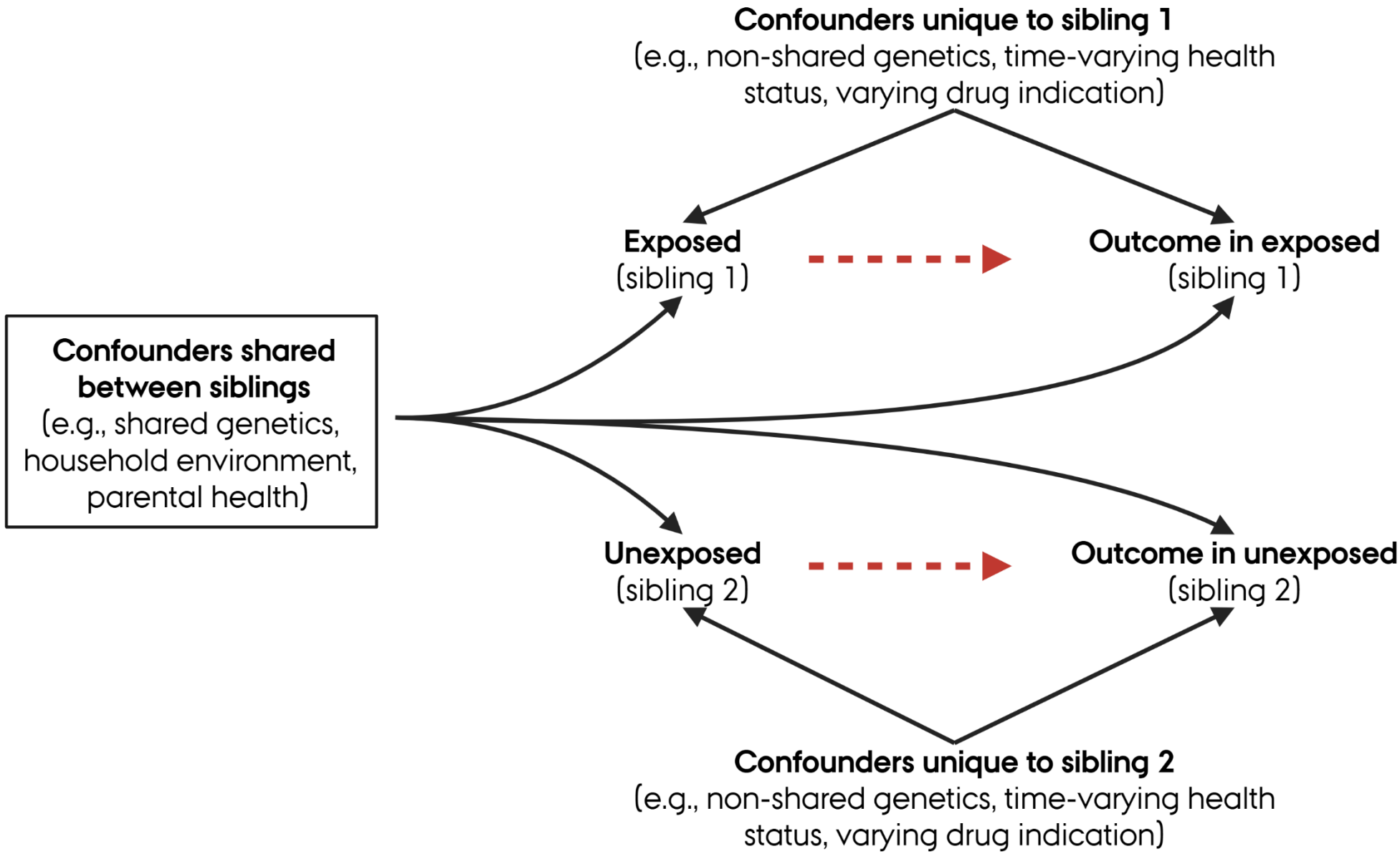
CONTROLLING FOR THE UNOBSERVABLE

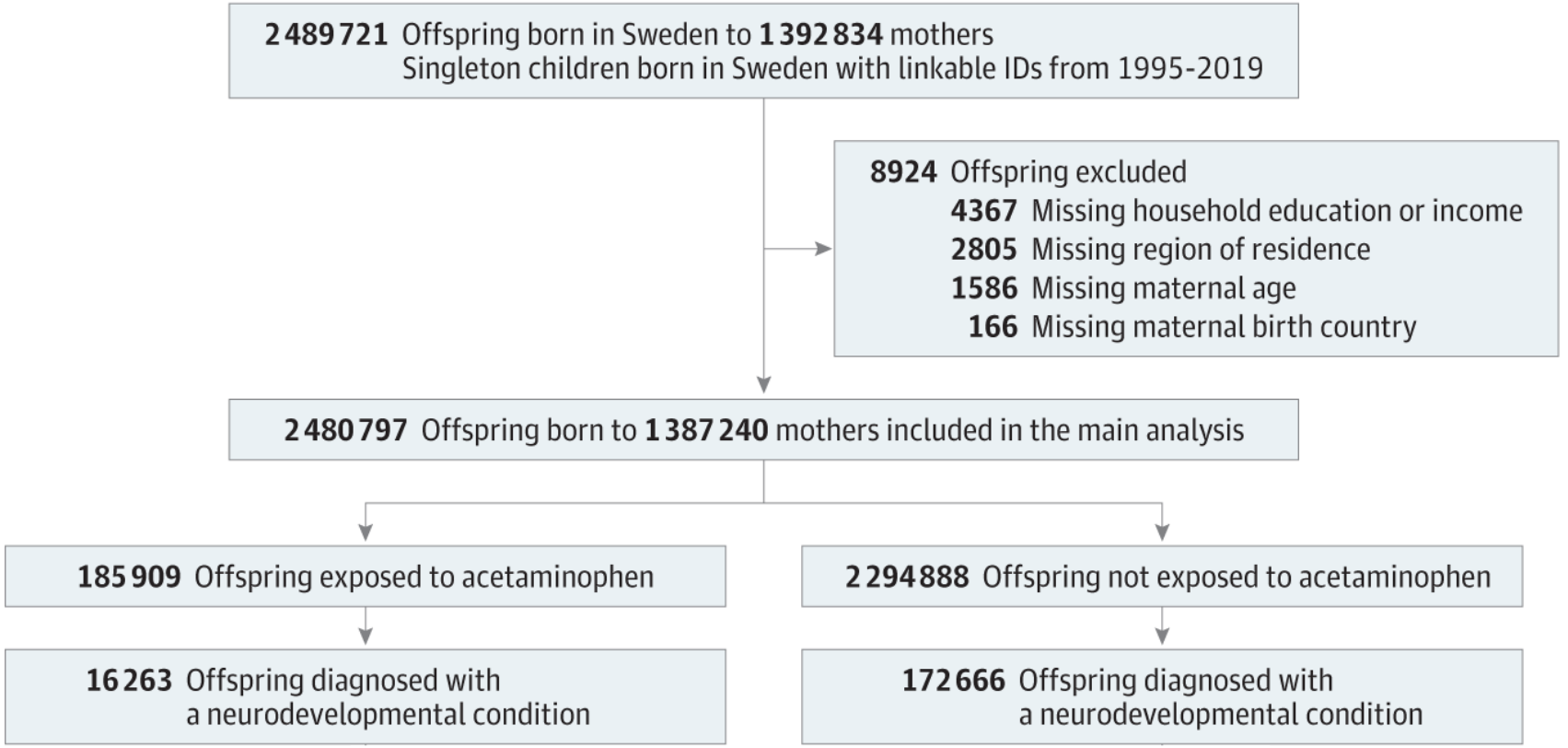
Families' structures offer a unique opportunity.

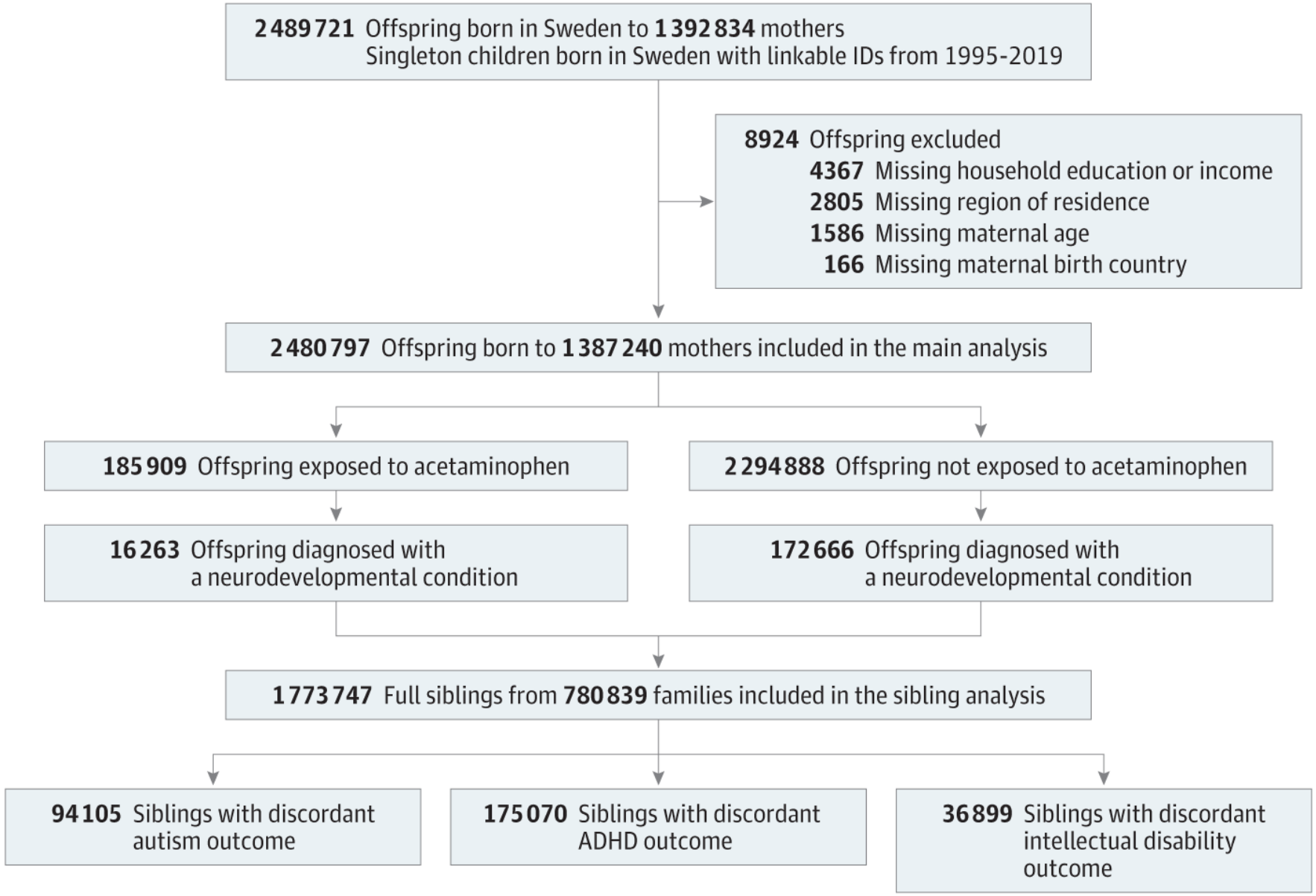
- Comparing them can account for all unobserved factors they share (genes & environment).
  - We can typically assume that they share a large (or some) part of the unobserved environmental confounders.

The principal idea: family members are more similar in unobserved (inc. unobservable and unknown) characteristics than two people in the general population. They, therefore, are more “exchangeable” than two people out of the general population.

- This idea is the strength of family-designs.


Confounders unique to sibling 1
(e.g., non-shared genetics, time-varying health status, varying drug indication)
Exposed
(sibling 1)
Outcome in exposed
(sibling 1)
Confounders shared between siblings
(e.g., shared genetics, household environment, parental health)
Unexposed
(sibling 2)
Outcome in unexposed
(sibling 2)
Confounders unique to sibling 2
(e.g., non-shared genetics, time-varying health status, varying drug indication)


2 489 721 Offspring born in Sweden to 1 392 834 mothers
Singleton children born in Sweden with linkable IDs from 1995-2019
8924 Offspring excluded
4367 Missing household education or income
2805 Missing region of residence
1586 Missing maternal age
166 Missing maternal birth country
2 480 797 Offspring born to 1 387 240 mothers included in the main analysis
185 909 Offspring exposed to acetaminophen
2 294 888 Offspring not exposed to acetaminophen
16 263 Offspring diagnosed with a neurodevelopmental condition
172 666 Offspring diagnosed with a neurodevelopmental condition


2 489 721 Offspring born in Sweden to 1 392 834 mothers
Singleton children born in Sweden with linkable IDs from 1995-2019
8924 Offspring excluded
4367 Missing household education or income
2805 Missing region of residence
1586 Missing maternal age
166 Missing maternal birth country
2 480 797 Offspring born to 1 387 240 mothers included in the main analysis
185 909 Offspring exposed to acetaminophen
2 294 888 Offspring not exposed to acetaminophen
16 263 Offspring diagnosed with a neurodevelopmental condition
172 666 Offspring diagnosed with a neurodevelopmental condition
1 773 747 Full siblings from 780 839 families included in the sibling analysis
94 105 Siblings with discordant autism outcome
175 070 Siblings with discordant ADHD outcome
36 899 Siblings with discordant intellectual disability outcome

ANY ACETAMINOPHEN IN PREGNANCY

	Full adjustment[a]		
	Hazard ratio[a]	95% CI	P-value
Autism	1.05	1.02-1.08	<0.001
ADHD	1.07	1.05-1.10	<0.001
Intellectual disability	1.05	1.00-1.10	0.05

[a]Adjusted for birth cohort; child sex; other analgesics (aspirin, other NSAIDs, opioids, antimigraine); birthing parent's diagnoses of migraine, chronic pain, infections, fevers, rheumatoid arthritis, and headaches; calendar period of delivery; parity; age at delivery (linear and cubic term); country of birth; residential region; cohabitation at delivery; early pregnancy body mass index; smoking status; diagnosis of autism, ADHD, and intellectual disability; history of psychiatric conditions and prescription use of psycholeptics, antidepressants, and antiseizure medication; health care visits in the year before pregnancy and an inadequate number of antenatal visits; and the highest household education and disposable income.

ANY ACETAMINOPHEN IN PREGNANCY

	Full adjustment[a]			Full sibling comparison[b]		
	Hazard ratio[a]	**95% CI**	**P-value**	**Hazard ratio[a]**	**95% CI**	**P-value**
Autism	**1.05**	**1.02-1.08**	**<0.001**	0.98	0.93-1.04	0.59
ADHD	**1.07**	**1.05-1.10**	**<0.001**	0.98	0.94-1.02	0.30
Intellectual disability	**1.05**	**1.00-1.10**	**0.05**	1.01	0.92-1.10	0.87

[a]Adjusted for birth cohort; child sex; other analgesics (aspirin, other NSAIDs, opioids, antimigraine); birthing parent's diagnoses of migraine, chronic pain, infections, fevers, rheumatoid arthritis, and headaches; calendar period of delivery; parity; age at delivery (linear and cubic term); country of birth; residential region; cohabitation at delivery; early pregnancy body mass index; smoking status; diagnosis of autism, ADHD, and intellectual disability; history of psychiatric conditions and prescription use of psycholeptics, antidepressants, and antiseizure medication; health care visits in the year before pregnancy and an inadequate number of antenatal visits; and the highest household education and disposable income.

[b]Same as above, but excluding birthing parent's birth country, psychiatric history, and diagnosis autism, ADHD, and intellectual disability.

DISPENSED DOSE (2005-)

	Minor adjustment[a]		
	Hazard ratio[a]	95% CI	P-value
Autism			
Low dose (<166 mg/day)	**1.33**	**1.20-1.48**	**<0.001**
Medium Dose (166-429 mg/day)	**1.52**	**1.41-1.64**	**<0.001**
High Dose (≥430 mg/day)	**1.87**	**1.71-2.06**	**<0.001**
ADHD			
Low dose (<166 mg/day)	**1.46**	**1.36-1.57**	**<0.001**
Medium Dose (166-429 mg/day)	**1.75**	**1.65-1.85**	**<0.001**
High Dose (≥430 mg/day)	**1.97**	**1.83-2.11**	**<0.001**
Intellectual disability			
Low dose (<166 mg/day)	**1.34**	**1.14-1.58**	**<0.001**
Medium Dose (166-429 mg/day)	**1.47**	**1.30-1.66**	**<0.001**
High Dose (≥430 mg/day)	**1.92**	**1.65-2.22**	**<0.001**

[a]Adjusted for birth year and sex.
[b]All covariates with discordance patterns.

DISPENSED DOSE (2005-)

	Minor adjustment[a]		
	Hazard ratio[a]	95% CI	P-value
Autism			
Low dose (<166 mg/day)	1.33	1.20-1.48	<0.001
Medium Dose (166-429 mg/day)	1.52	1.41-1.64	<0.001
High Dose (≥430 mg/day)	1.87	1.71-2.06	<0.001
ADHD			
Low dose (<166 mg/day)	1.46	1.36-1.57	<0.001
Medium Dose (166-429 mg/day)	1.75	1.65-1.85	<0.001
High Dose (≥430 mg/day)	1.97	1.83-2.11	<0.001
Intellectual disability			
Low dose (<166 mg/day)	1.34	1.14-1.58	<0.001
Medium Dose (166-429 mg/day)	1.47	1.30-1.66	<0.001
High Dose (≥430 mg/day)	1.92	1.65-2.22	<0.001

[a]Adjusted for birth year and sex.
[b]All covariates with discordance patterns.

DISPENSED DOSE (2005-)

	Minor adjustment[a]			Full sibling comparison[b]		
	Hazard ratio[a]	95% CI	P-value	Hazard ratio[a]	95% CI	P-value
Autism						
Low dose (<166 mg/day)	**1.33**	**1.20-1.48**	**<0.001**	0.85	0.67-1.07	0.17
Medium Dose (166-429 mg/day)	**1.52**	**1.41-1.64**	**<0.001**	0.96	0.79-1.16	0.64
High Dose (≥430 mg/day)	**1.87**	**1.71-2.06**	**<0.001**	0.88	0.68-1.14	0.33
ADHD						
Low dose (<166 mg/day)	**1.46**	**1.36-1.57**	**<0.001**	1.01	0.84-1.21	0.94
Medium Dose (166-429 mg/day)	**1.75**	**1.65-1.85**	**<0.001**	1.02	0.88-1.18	0.81
High Dose (≥430 mg/day)	**1.97**	**1.83-2.11**	**<0.001**	0.98	0.79-1.21	0.83
Intellectual disability						
Low dose (<166 mg/day)	**1.34**	**1.14-1.58**	**0.00**	0.87	0.60-1.24	0.43
Medium Dose (166-429 mg/day)	**1.47**	**1.30-1.66**	**<0.001**	0.97	0.74-1.27	0.82
High Dose (≥430 mg/day)	**1.92**	**1.65-2.22**	**<0.001**	0.93	0.63-1.38	0.73

[a]Adjusted for birth year and sex.
[b]All covariates with discordance patterns.

World Business Markets Sustainability Legal More

Litigation | Product Liability | Litigation | Corporate Structure | Healthcare Providers

Lawsuits claiming Tylenol causes autism lack scientific support, judge finds

By **Brendan Pierson**

December 19, 2023 10:02 PM GMT+1 · Updated 4 months ago

”THE HARVARD DEAN SAYS IT’S CAUSAL!”

Research | Open access | Published: 14 August 2025

Evaluation of the evidence on acetaminophen use and neurodevelopmental disorders using the Navigation Guide methodology

Diddier Prada, Beate Ritz, Ann Z. Bauer & Andrea A. Baccarelli

Environmental Health **24**, Article number: 56 (2025) | Cite this article

REUTERS®

World | Business | Markets | Sustainability | Legal | More

Litigation | Product Liability | Litigation | Corporate Structure | Healthcare Providers

Lawsuits claiming Tylenol causes autism lack scientific support, judge finds

By **Brendan Pierson**

December 19, 2023 10:02 PM GMT+1 · Updated 4 months ago

Research | Open access | Published: 14 August 2025

Evaluation of the evidence on acetaminophen use and neurodevelopmental disorders using the Navigation Guide methodology

Diddier Prada, Beate Ritz, Ann Z. Bauer & Andrea A. Baccarelli

Environmental Health **24**, Article number: 56 (2025) | Cite this article

WELL...

Harvard Dean Was Paid $150,000 as an Expert Witness in Tylenol Lawsuits

The Trump administration has cited Dr. Andrea Baccarelli's expertise to warn against using acetaminophen — the active ingredient in Tylenol — in pregnancy, based on an unproven autism link.

Dear Ms. Wolfe:

On September 22, 2025, HHS "initiate[d] a safety label change" about "chronic acetaminophen use in pregnant women." Ex. A, Health & Hum. Servs. Announcement on Autism; Ex. B, Health & Hum. Servs. Autism Announcement Fact Sheet. Simultaneously, HHS issued a Dear Doctor Letter stating that "the use of acetaminophen by pregnant women may be associated with an increased risk of … autism and ADHD in children." Ex. C, Letter from Martin Makary, Comm'r of Food and Drugs; *see PLIVA, Inc. v. Mensing*, 564 U.S. 604, 615 (2011) (holding that "Dear Doctor letters qualify as 'labeling'" under federal law).

The *reason* officials took this action matters more than the action itself. The FDA Commissioner, the Secretary of HHS, and indeed the President of the United States cited the analysis of Dr. Andrea Baccarelli, "the dean of the Harvard School of Public Health," and Appellants' expert here. Ex. D, Transcript of Health & Hum. Servs. Announcement on Autism. The FDA Commissioner directly quoted Dr. Baccarelli's opinion that "there is a causal relationship between prenatal acetaminophen use and neurodevelopmental disorders of ADHD and autism spectrum disorder." *Id.* This is the *title of* Dr. Baccarelli's expert report. A-1742, Expert Report of Dr. Andrea Baccarelli. Dr. Baccarelli then confirmed his discussions with these public-health figures, thanking them for taking the action recommended by his analysis. Ex. E, Statement by Dr. Andrea Baccarelli.

Expert opinion that is sound enough to persuade every Senate-confirmed federal scientist easily clears Rule 702(d)'s bar. Reasonable scientists can continue to debate Dr. Baccarelli's conclusions. But affirming a decision characterizing his approach as "junk science," *Amorgianos v. Nat'l R.R. Passenger Corp.*, 303 F.3d 256, 267 (2d Cir. 2002), would pose grave separation of powers concerns. The executive branch safeguards public health from dangerous pharmaceutical interventions. A decision holding that a jury may not hear the *same* expert evidence that the executive branch *credited* will badly damage the public trust required for the executive to take care that the public-health laws are faithfully executed.

RFK Jr. Admits He Can't Actually Tie Tylenol to Autism

Robert F. Kennedy Jr. said there isn't "sufficient" evidence to back up his claims.

CONCLUSIONS

Paracetamol use in pregnancy is not associated with autism once confounders are appropriately accounted for.

- Our findings have since been independently replicated in Japan, where the prevalence of paracetamol use is substantially higher (approximately 40%).

Paediatr Perinat Epidemiol. 2025 Sep 2. doi: 10.1111/ppe.70071. Online ahead of print.

Maternal Acetaminophen Use and Offspring's Neurodevelopmental Outcome: A Nationwide Birth Cohort Study

Yusuke Okubo [1], Itaru Hayakawa [2], Ryo Sugitate [3], Hiroki Nariai [4]

Affiliations + expand

PMID: 40898607 DOI: 10.1111/ppe.70071

CONCLUSIONS

Paracetamol use in pregnancy is not associated with autism once confounders are appropriately accounted for.

- Our findings have since been independently replicated in Japan, where the prevalence of paracetamol use is substantially higher (approximately 40%).

This ‘debacle’ underscores the need for more robust approaches and greater coordinated efforts in the pregnancy drug-safety field.

- Emerging methods in computation, omics, and causal inference hold substantial promise for advancing this area of research.

THANK YOU FOR LISTENING

Team effort:

Hugo Sjöqvist
Christina Dalman
Håkan Karlsson
Olof Stephansson
Stefan Johansson
Cecilia Magnusson
Renee M. Gardner
Brian K. Lee








This work was funded by NIH/NINDS 1R01NS107607

AARHUS
UNIVERSITY

Karolinska
Institutet