

Rotavirus vaccine and T1D: Is an 11% rise cause for alarm?

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Rotavirus vaccination was expected to lower the risk of type 1 diabetes by preventing infections that may trigger it. A Norwegian nationwide study published in *Diabetologia* and presented at EASD 2026 found the opposite pattern, an 11% rise in incidence, and then showed why that rise probably is not the vaccine's doing.^{1,2}

KEY TAKEAWAYS

- **The Pivot:** Type 1 diabetes incidence in children aged 0.5 to 5 years rose 11% after Norway introduced rotavirus vaccination, but negative controls suggest the vaccine is probably not the cause.
- **The Data:** Among 740,744 children, 846 developed type 1 diabetes, and the adjusted hazard ratio for 2 vaccine doses was 1.17, not statistically significant, while hepatitis B and pneumococcal vaccine changes showed similar rises.
- **The Action:** Continue routine rotavirus vaccination, and read the 11% figure as an unexplained population trend, not as evidence of vaccine harm.

Environmental factors, including infections, have long been suspected of influencing the risk of type 1 diabetes, and earlier studies of rotavirus vaccine and type 1 diabetes have been conflicting. Rotavirus spreads by the faecal-oral route and is a common cause of gastroenteritis, with the greatest risk of severe illness in children under 5. Rotavirus vaccines have substantially reduced severe infection, hospitalisation and death, so any hint of a downside is worth testing carefully.²

Norway offered the authors a natural experiment. The monovalent live-attenuated vaccine Rotarix entered the national childhood immunisation programme in September 2014, and uptake was fast and high, at 92.8% among infants. The team, led by PhD student Maria Östman of the University of Oslo, followed all children born in Norway from 2007 to 2019, comparing those born before and after introduction, with follow-up for type 1 diabetes from 0.5 to 5 years of age and data collected until 31 December 2024.^{1,2}

The Numbers

Among 740,744 children, 846 were diagnosed with type 1 diabetes before the age of 5. An interrupted time series compared the incidence predicted from the pre-vaccine trend with what was actually observed afterwards, and found a relative increase in incidence of 11% after the vaccine was introduced in September 2014. In an adjusted analysis of individual children, the hazard ratio for those fully vaccinated with 2 doses versus those unvaccinated was 1.17, which was not statistically significant.^{1,2}

The authors say their result gives no evidence of reduced risk, and instead shows higher incidence, which contradicts their own hypothesis that protection from rotavirus infection would lower type 1 diabetes. On its face, that is the kind of result that could have produced a misleading headline linking a childhood vaccine to diabetes. The authors themselves chose to test it further before drawing that conclusion.²

The test was the use of negative controls. If the rise reflected the rotavirus vaccine, similar rises should not follow changes to the immunisation programme that have no plausible link to type 1 diabetes. Yet incidence in children born after the introduction of the hepatitis B vaccine in 2016 rose by a similar amount, and it also rose after the switch from the 7-valent to the 13-valent pneumococcal vaccine in 2011. Three unrelated changes produced the same pattern.²

The authors conclude that the 11% rise may be related to other, unknown changes in the environment, not to the rotavirus vaccine. They add that they do not believe any of the changes to the vaccination programme, alone or together, explain the increase, and that they cannot rule out other unidentified factors, given that the same pattern appears after every change even though they hypothesised the rotavirus vaccine would lower the risk and the other 2 would not affect it.²

Other Explanations and What Remains Open

The authors also considered other explanations. The COVID-19 pandemic was followed by rising type 1 diabetes incidence in many countries, including a temporary increase in Norway in 2022 followed by a decrease, but a recent study of Swedish and Norwegian adolescents found no increase in incidence after COVID-19 infection. A change to prenatal guidelines in June 2018, which introduced ferritin testing in the first trimester, was also considered, because high iron levels are suspected to be associated with type 1 diabetes.²

They judged the guideline change unlikely to matter, because iron levels are usually low in pregnancy and because only children born in 2019 were both affected by the change and included in the study. Incidence of type 1 diabetes has also risen generally over past decades, with year-to-year fluctuation, which means a before-and-after comparison across a 12-year birth window will always carry some background drift.²

The wording of the authors' own conclusion is deliberate. They say they do not believe rotavirus vaccination increases the risk of type 1 diabetes, and that more studies in different settings with different vaccines are needed before concluding anything. That matters because Norway used only Rotarix, whereas Germany and Italy use both Rotarix and RotaTeq, and Finland and Iceland use RotaTeq alone, so results from one vaccine and one country cannot be assumed to apply everywhere.²

The study was published in *Diabetologia*, the journal of EASD, and presented as short oral presentation 368. The authors declare no conflict of interest. They also stress the importance of studying other environmental factors that could be associated with type 1 diabetes, since the unexplained rise seen after several unrelated programme changes is itself a finding worth pursuing. For clinicians, the message for parents is that this result should not change vaccination advice.^{1,2}

CLINICAL IMPLICATIONS

This is a case where the study's own design protects against a wrong conclusion. A single before-and-after comparison would have shown an 11% rise and invited a causal story. By applying the same test to vaccine changes with no plausible link to type 1 diabetes, and finding the same rise, the authors showed that the signal is probably a feature of the period rather than of one vaccine.

For clinicians asked by parents about the result, the accurate answer has 3 parts. The hazard ratio for vaccinated children, 1.17, was not statistically significant. The rise in incidence followed unrelated programme changes just as it followed rotavirus vaccination. And the authors themselves say they do not believe the vaccine raises risk. Rotavirus vaccines have reduced severe infection and hospitalisation, which remains the established benefit.

What remains unanswered is why incidence in young Norwegian children rose across several birth cohorts. That question is open, and the authors call for studies of other environmental factors. Until further studies with different vaccines and settings are available, the finding should not alter immunisation schedules.

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REFERENCES

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