
Pre- and post-vaccination

EDITORIAL

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The incidence of gastroenteritis and otitis in children has decreased. Is this due to the rotavirus and pneumococcal vaccines?

The pneumococcal and rotavirus vaccines were introduced in Norway in 2006 and 2014 respectively. The Journal of the Norwegian Medical Association is now publishing two articles on presented cases of otitis and gastroenteritis in children since the vaccine was introduced ([1, 2](#)).

The figures clearly indicate that the number of cases has fallen, at least for gastroenteritis: after several years with stable figures, there was a sudden fall in 2016.

There are no statistics on otitis for earlier years, but the number of cases presenting at emergency primary health care units began to decline five years after the vaccine was introduced. The author's explanation is that this is when the vaccination coverage among 0–5-year-olds surpassed 90 %. Another possible explanation is the Child Immunisation Programme's shift from a 7-valent to a 13-valent pneumococcal vaccine in the spring of 2011.

It is natural to assume that the observed changes are due to the vaccines, but article author Sandvik duly notes that the Norwegian data does not document such a causal relationship. The norm is that randomised trials are needed to demonstrate the effect of a health intervention. Randomisation ensures that comparable groups are established – a prerequisite for being able to conclude that differences in incidence rates are due to the vaccine.

Why can't we just assume that children born before and after the introduction of the vaccines are comparable? One reason is that gradual changes over time can interfere with before-and-after comparisons. The decline in exposure to tobacco smoke, for example, may have resulted in fewer cases of otitis, something Sandvik himself points out (2). Quarterly breakdowns of the figures enable us to see whether the incidence was on the way down before the vaccines were introduced.

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Changes that occurred at approximately the same time as the introduction of the vaccine are more difficult to identify, such as whether there was a campaign against antibiotic use that reduced the number of parents seeking medical assistance for their child.

In addition, there is always a risk that analyses based on existing data will be 'data-driven', i.e. the researcher will allow findings in the data to influence the analytical approach adopted. Writing, and preferably publishing, the analysis plan before data is collected is therefore a good rule (3).

The analyses presented here may not be evidence of a causal link between the vaccination and the falling number of cases, but we already have such documentation in the form of randomised trials that have been collected and evaluated in systematic reviews from the Cochrane collaboration (4, 5). One such Cochrane review shows that the risk of severe gastroenteritis is halved among those who are vaccinated against rotavirus (4). Norwegian figures suggest a far more powerful effect – gastroenteritis among children was ten times as common before the vaccines were introduced (1). For the pneumococcal vaccine, the difference is even more striking: the Cochrane review shows little or no effect on the incidence of otitis (5), while the Norwegian figures show a significant decrease (2). This is reassuring, of course, but raises questions as to why the results differ.

A reasonable explanation is that the Norwegian results exaggerate the vaccine effect due to biases that can arise in non-randomised trials. However, it may partly be because randomised trials do not give the full picture in relation to vaccine effects. In most randomised trials, randomisation is done at the individual level. When half of the children in the community are vaccinated this also lowers the risk of infection for those who have not been vaccinated. However, a vaccine cannot create full herd immunity when only half of the children are vaccinated. Thus, the vaccine effect is underestimated.

Whether there are weaknesses in the randomised or non-randomised vaccine trials that explain the differing results is not easy to tell. However, although it is uncertain whether the pneumococcal vaccine prevents otitis, the effect of the vaccine is well documented for severe pneumococcal infections (6).

The Norwegian Institute of Public Health monitors the incidence of diseases before and after the introduction of vaccines (7, 8). Gastroenteritis and rotavirus vaccine results are imminent (personal message, Tone Bruun). It will be interesting to compare these with the studies in this journal and with the results from randomised trials.

LITERATURE

1. Sandvik H. Barn på legevakt med gastroenteritt før og etter innføring av rotavirusvaksinen. Tidsskr Nor Legeforen 2020; 140. doi: 10.4045/tidsskr.19.0761 [CrossRef]
2. Sandvik H. Barn på legevakt med ørebetennelse etter innføring av pneumokokkvaksinen. Tidsskr Nor Legeforen 2020; 140. doi: 10.4045/tidsskr.19.0727 [CrossRef]
3. Should protocols for observational research be registered? Lancet 2010; 375: 348. [PubMed][CrossRef]
4. Soares-Weiser K, Bergman H, Henschke N et al. Vaccines for preventing rotavirus diarrhoea: vaccines in use. Cochrane Database Syst Rev 2019; 3: CD008521. [PubMed]
5. Fortanier AC, Venekamp RP, Boonacker CWB et al. Pneumococcal conjugate vaccines for preventing acute otitis media in children. Cochrane Database Syst Rev 2019; 5: CD001480. [PubMed][CrossRef]
6. Lucero MG, Dulalia VE, Nillos LT et al. Pneumococcal conjugate vaccines for preventing vaccine-type invasive pneumococcal disease and X-ray defined pneumonia in children less than two years of age. Cochrane Database Syst Rev 2009; 4: CD004977. [PubMed][CrossRef]
7. Folkehelseinstituttet. Om rotavirus-studien. <https://www.fhi.no/studier/rotavirus-studie/om-rotavirus-studien/> Accessed 11.2.2020.
8. Magnus MC, Vestrheim DF, Nystad W et al. Decline in early childhood respiratory tract infections in the Norwegian mother and child cohort study after introduction of pneumococcal conjugate vaccination. Pediatr Infect Dis J 2012; 31: 951–5. [PubMed][CrossRef]

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