CORRESPONDENCE

The Safety of Drug Therapy in Children

by Stefan Wimmer, PD Dr. rer. nat. Antje Neubert, and
Prof. Dr. med. Dr. h.c. Wolfgang Rascher in issue 46/2015

Weakening Objections

There is a lack of awareness that, after licensing, further reporting is essential to sufficiently detect risks. This is especially drastic following vaccinations, for which a mandatory reporting of suspected cases of reactions surpassing those expected (with a non-compliance penalty of up to 25 000 Euro) is in place since 2001 as part of the German Infection Protection Act (*Infektionsschutzgesetzes*). However, the leaflet is usually not even handed out („Please read this information carefully before your child receives this vaccine“). The lack of reporting procedures within the medical community—which unfortunately also applies to the „alternative“ providers (including naturopaths) who like to discuss vaccination effects—was highlighted by the Paul-Ehrlich-Institute (PEI) in 2002 (1): a maximum of 5% of severe adverse drug reactions are reported. Ways to improve this were also indicated, for instance through training, which Scott et al. (2) reported in 1990 to increase reporting rates by up to a factor of 17. Deutsches Ärzteblatt also published articles about this in 1991 and 1999. Thus, 95% of such adverse drug reactions cannot be analysed, leaving large gaps in our knowledge (Dittmann, in *Vaccines*, 1999 and [3]). How is it even possible to carry out benefit–risk evaluations for licensing, vaccine recommendation, and usage when the risk can not be calculated and the effectiveness of vaccination programs can not be evaluated, as was published 2004, 2009, and 2013 in the same journal? Why is nothing concrete being done by PEI or RKI (which hosts the German Standing Committee on Vaccination [STIKO]), drug commissions, professional unions, or others to change this condition and thereby weaken the important objections raised by critical people?

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REFERENCES

1. Keller-Stanislawski B, Hartmann K: Auswertung der Meldungen von Verdachtsfällen auf Impfkomplicationen nach dem Infektionsschutzgesetz. Bundesgesundheitsbl 2002; 344–54.
2. Scott HD, Thacher-Renshaw A, Rosenbaum SE, et al.: Physician reporting of adverse drug reactions. Results of the Rhode Island Adverse Drug Reaction Reporting Project. JAMA 1990; 263: 1785–8.
3. Dittmann S: Risiko des Impfens und das noch größere Risiko, nicht geimpft zu sein. Bundesgesundheitsbl Gesundheitsfo Gesundheitsch 2002; 45: 316–22.
4. Wimmer S, Neubert A, Rascher W: The safety of drug therapy in children. Dtsch Arztebl Int 2015; 112: 781–7.

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Mr. Fridrich has received reimbursement from Libertas & Sanitas e. V. for publication fees, conference registration fees, travel and accommodation expenses, and scientific meeting preparation fees. He is the author of several books about vaccinations.

In Reply:

The general statement, about the importance of developing awareness for reporting possible adverse drug reactions is valid. However, the cited sources documenting the low reporting rate of vaccine adverse events (which are not from Germany) are more than 25 years old (1), a time before the introduction of statutory reporting about any adverse effects potentially resulting from vaccinations. The most recent reports and reporting rates for suspected vaccine adverse effects were unfortunately not cited (2, 3). These works show that the reporting rate has risen gradually since 2001, when legally mandatory reporting of suspected adverse effects or vaccination complications was introduced (2). In 2013, the Paul-Ehrlich-Institute reported 3299 suspected cases, with 12 278 adverse reactions (3). No other drug class has such a high rate of physicians reporting as do vaccines, allowing us to conclude that the legal reporting requirement contributes to vaccine safety. Unfortunately, physicians rarely report adverse events for other drugs. These spontaneous reports however are essential for allowing early detection of new signs of risk.

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REFERENCES

1. Scott HD, Thacher-Renshaw A, Rosenbaum SE, et al.: Physician reporting of adverse drug reactions. Results of the Rhode Island Adverse Drug Reaction Reporting Project. JAMA 1990; 263: 1785–8.
2. Weißer K, Meyer C, Petzold D, Mentzer D, Keller-Stanislawski B: Verdachtsfälle von Komplikationen nach dem Infektionsschutzgesetz und Verdachtsfälle von Nebenwirkungen (von Impfstoffen) nach dem Arzneimittelgesetz vom 1.1.2004 bis zum 31.12.2005. Bundesgesundheitsbl Gesundheitsforsch Gesundheitsschutz 2007; 50: 1404–17.
3. Mentzer D, Stanislawski B: Daten zur Pharmakovigilanz von Impfstoffen aus dem Jahr 2013. Bulletin zur Arzneimittelsicherheit 2015; 1: 12–20.
4. Wimmer S, Neubert A, Rascher W: The safety of drug therapy in children. Dtsch Arztebl Int 2015; 112: 781–7.

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