Background
The use of medicines in child and adolescent psychiatry is increasing and, as a result, a higher number of adverse drug reactions (ADRs) can be assumed. Besides vaccines, methylphenidate and atomoxetine induce the highest number of ADR reports in children [1] and off-label use of antipsychotics and antidepressants in this age group may cause safety problems.

Aim
To identify potential safety signals for medicines used for psychiatric indications in children and adolescents.

Methods
Included were reports from the DCGMA database of individual case safety reports (Figure 1) involving antipsychotics, antidepressants or stimulants as suspected medicines and referring to children and adolescents. Besides a descriptive analysis we screened for signals by identifying reactions with ≥ 3 reports that are not labeled in the corresponding product information. These potential signals were matched with published reports in PubMed and VigiLyze® [2] (Figure 2).

Results
In approximately 13,400 (4.2 %) of 320,000 reports (1990 to August 2016) referring to small molecule drugs, the affected patients were between the ages of 3 to 17. The proportion of reports with suspected psychoactive medicines in this age group was about 20 % and has increased since the late 1990s. Most frequently suspected were stimulants (41 %), followed by antipsychotics (36 %), and antidepressants (23 %). Among the three most frequently suspected substances in each group citalopram and venlafaxine are not approved for this age group (n = 92) (Table 1).

Conclusion
By using a basic methodology we revealed potential safety signals for both substances with the highest number of records, methylphenidate and lisdexamfetamine. These signals should be further evaluated by other methods. The potential signal “obsessive-compulsive symptoms” found for lisdexamfetamine is already known for its active compound amphetamine. The revealed signal “priapism” for methylphenidate was recently verified by the Pharmacovigilance Risk Assessment Committee.

References

The authors have no conflict of interest directly relevant to the content of this poster presentation.

Figure 1: Composition of the database of individual case safety reports of the Drug Commission of the German Medical Association.

Figure 2: Selection of ICSRs and identification of potential safety signals.

Table 1: The table conveys identified potential signals, defined as ≥ 3 reports of adverse drug reactions associated with antipsychotics, antidepressants or stimulants.

Table 2: The table conveys identified potential signals, defined as ≥ 3 reports of adverse drug reactions not labeled in the corresponding product information, and the results of a search for equivalent reports in PubMed and VigiLyze® (WHO database of spontaneous reports).

Table 3: Number of case reports (all age groups) with suspected small molecule drugs 1990 to 2016 (approx. 320,000).