

Oral presentation

Open Access

## AMSP (Arzneimittelsicherheit in der Psychiatrie) as a model for a pharmacovigilance system for psychiatric inpatient populations

Hans-Jürgen Møller

Address: Psychiatric University Department Munich, Germany  
from International Society on Brain and Behaviour: 3rd International Congress on Brain and Behaviour  
Thessaloniki, Greece. 28 November – 2 December 2007

Published: 17 April 2008

*Annals of General Psychiatry* 2008, **7**(Suppl 1):S46 doi:10.1186/1744-859X-7-S1-S46

This abstract is available from: <http://www.annals-general-psychiatry.com/content/7/S1/S46>

© 2008 Møller; licensee BioMed Central Ltd.

The AMSP-Project (Arzneimittelsicherheit in der Psychiatrie) is a prospective multicenter program for continuous assessment of ADRs of marketed psychotropic drugs in psychiatric inpatients under naturalistic conditions of routine clinical treatment. It corresponds to a dynamic cohort study meaning the cohort - the patient population of the participating clinics - is changing over time. Currently 60 hospitals in Germany, Switzerland, Austria, Belgium and Hungary are participating in the AMSP project, monitoring about 30,000 inpatients per year. Severe ADRs are detected by active and regular screening of all participating wards by local drug-monitors. They are documented and analysed in a standardised manner, to allow easy data collection and retrieval for more in depth analyses. Causality assessments include time correlations, alternative causes, underlying diseases, spontaneous events and knowledge about the same type of ADR. Each severe ADR case, and the association between ADR and pharmacological treatment, is discussed during pharmacovigilance conferences, held several times per year.

To estimate the incidence of all assessed ADRs all prescriptions of the wards are assessed on two references per year. Use of psychotropic drugs has been changing drastically over the years emphasizing the need for continuous ADR assessment to detect resulting changing ADR patterns. Incidences for severe ADRs of 1.5% about have been found. The mean hospitalisation length of the surveyed psychiatric patient population is compared to that of the serious ADR cases. The length of hospitalisation for serious ADR cases showed to be more than doubled.

The database exists now for 15 years and several studies have been undertaken using pharmacoepidemiological tools to assess cause and effect.

Besides being an efficient pharmacovigilance instrument, the AMSP-Project has turned out to be a valuable quality assurance instrument in as much as it seems to increase the awareness of participating physicians and other health providers of drug safety issues.