

The APAC-VALUE study: A global characterisation study of VALproate Utilisation and Exposure among women and men of childbearing age

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Background

Valproate remains an important and highly effective therapy for epilepsy and several neuropsychiatric conditions however, evidence established over several decades linking in utero exposure to major congenital malformations and later neurodevelopmental harms has prompted extensive but heterogeneous international regulatory restrictions on its use in women of childbearing age. More recently, several international regulatory agencies have extended safety communications to men of reproductive age, citing potential concerns regarding adverse neurodevelopmental outcomes in offspring conceived during paternal valproate exposure, although recommendations and restrictions differ substantially across jurisdictions. Despite these evolving warnings, little is known about how regulatory actions influence real-world valproate utilisation patterns internationally. The APAC-VALUE (VALproate Utilisation and Exposure) study aims to characterise global patterns of valproate use among women and men of childbearing age and evaluate how utilisation trends vary across countries with differing regulatory responses.

Methods

APAC-VALUE is a multinational, observational drug utilisation study using routinely collected administrative and dispensing data from participating countries and regions. The study will examine valproate dispensing and prescribing patterns among individuals of childbearing age over time, with stratification by sex, age group, indication where available, and regulatory jurisdiction. Interrupted time-series and descriptive analyses may be used to evaluate temporal changes in valproate utilisation before and after major regulatory safety warnings and risk minimisation measures. Population characteristics including treatment duration and pathways, concomitant antiseizure medication use, healthcare utilisation, and switching patterns may also be explored to better understand prescribing behaviour and potential differences in clinical practice internationally.

Results

The study is being conducted over several weeks within the OHDSI APAC community. Results are pending but will describe international trends in valproate utilisation among women and men of childbearing age, including changes associated with major regulatory interventions. The study will also identify differences in prescribing patterns and patient characteristics across participating jurisdictions.

Conclusion

The APAC-VALUE study will provide one of the first global characterisations of valproate utilisation in populations of reproductive age across diverse regulatory environments. Findings will offer important insight into the real-world impact of evolving safety communications and may inform future regulatory policy, clinical guidance, and risk minimisation strategies aimed at balancing treatment effectiveness with reproductive safety considerations.