

# Contraindicated and off-label drug use in pediatric outpatients in the Nordic countries

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## RATIONALE

Real-life data on off-label use of drugs - contraindicated drug use in particular - are scarce. Only a few pharmacoepidemiological register studies have included nationwide data from several countries. Earlier we identified that the Nordic citizens form an outstandingly large and homogenous population for outpatient studies also in children (1).

## OBJECTIVES

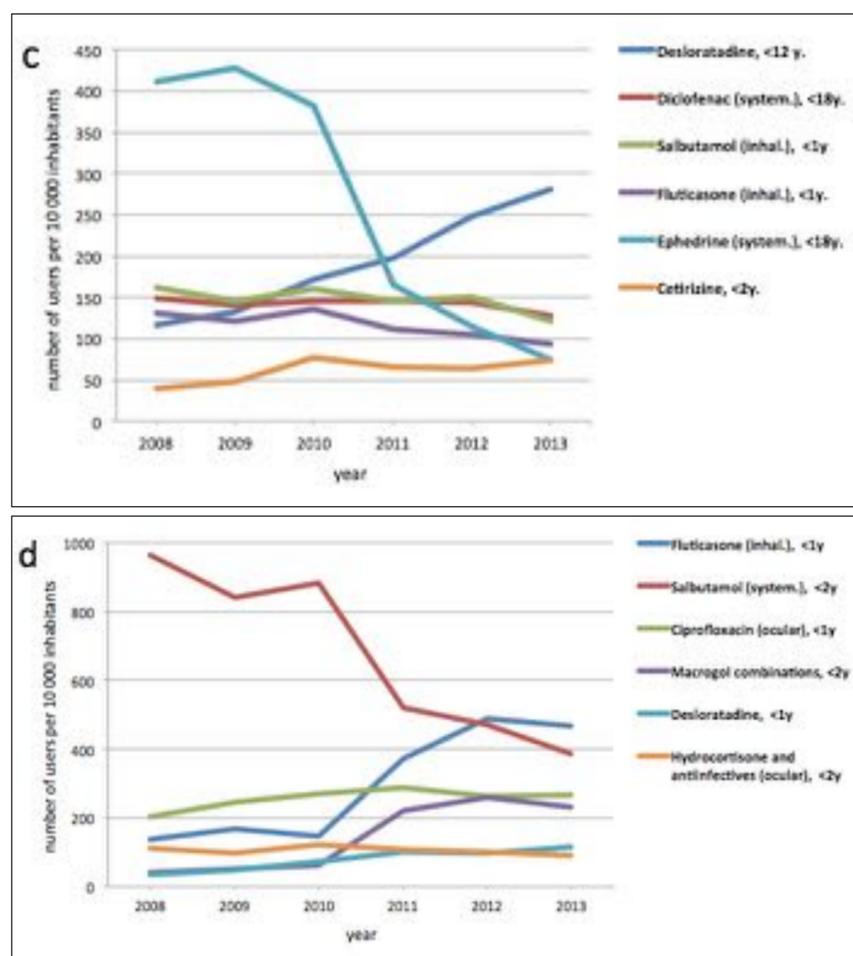
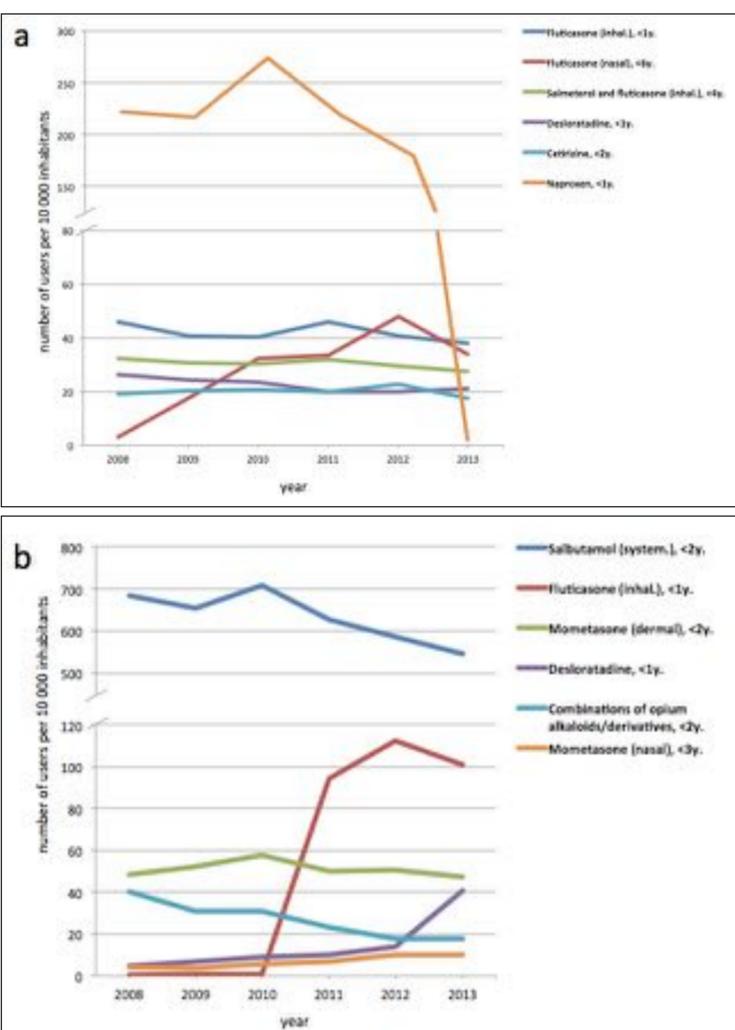
The aim of the study was to evaluate the occurrence of off-label drug use, and utilization of medicines contraindicated for children, despite the restriction in the summary of product characteristics (SPCs) in Finland, Sweden, Norway and Denmark.

## METHODS

Drugs with contraindications and potential off-label use, in terms of age and dose, for pediatric patients were searched in electronic SPCs. Finnish SPCs that mention any type of pediatric patients in the contraindications chapter were searched first, and the results were then reviewed in Swedish, Norwegian and Danish SPCs. The survey on off-label use focused on the 30 most commonly used drugs in children in Nordic countries (1).

Users of all contraindicated drugs and of the most commonly used off-label drugs were identified in national administrative prescription databases in the four Nordic countries run by The Social Insurance Institution of Finland, The National Board of Health and Welfare in Sweden, The Norwegian Institute of Public Health, and The National Institute for Health Data and Disease Control in Denmark. The searches were based on anatomical therapeutic chemical classification codes (ATCs).

No personal level data was requested for this study, thus no ethical approval was applied. EPID Research is a member of the European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (ENCePP) and all the work there is done following the ENCePP Code of Conduct.



**Figure 1**

Six most commonly used off-label drugs in children and adolescents in a) Finland, b) Sweden, c) Norway, and d) Denmark

## ACKNOWLEDGEMENTS

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- Rosa Juuti, MSc from EPID Research is acknowledged for presenting the poster in ICPE 2016.

## REFERENCES

- Prami T, Långström D, Iso-Mustajärvi I, Sandler N. Pediatric outpatient drug use in the Nordic countries – Survey on national administrative register data. *Eur J Pediatr* 2016; submitted.

## RESULTS AND CONCLUSIONS

Of 49 contraindicated drugs found, the greatest proportional use was found for etoricoxib in Finland (N=1388; 2.5/10,000 <16-y./year), diclofenac in Sweden (N=1212; 1.4/10,000 <14-y./year), oxymetazoline in Norway (N=2160; 29/10,000 <2-y./year), and for zopiclone in Denmark (N=1586; 2.2/10,000 <18-y./year). The common utilization of these drugs stood up in these particular countries only. For oxymetazoline this may be due to strict age limit especially in Norway; for zopiclone there was an age limit only in Denmark. The same does not explain the wider contraindicated use of etoricoxib in Finland or diclofenac in Sweden. There were no remarkable changes between the study years in relation to contraindicated drug use, which was the case in off-label used drugs. The most commonly used off-label drugs in each country by years are shown in Figure 1.