

# Bivirkninger hos barn, hva meldes og hvor vil vi?

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Farmasøyt og bivirkningsansvarlig  
RELIS Vest



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## REgionalt LegemiddelinformasjonsSenter

- Offentlig finansiert
- Produsentuavhengig
- Gratis
- For helsepersonell
  - Spørsmål og svar-tjeneste
  - Mottar bivirkningsmeldinger
  - Underviser, forsker og publiserer



RELIS Vest og Kildetek farmakologi  
Helsekost universitetssykehus



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## Prosjekt i 2011 med støtte fra Kompetansenettverket

- 10 år med bivirkningsmeldinger 2001-2010
- Inkludert meldinger der barnet er målet for behandlingen
  - dvs ikke via amming eller under graviditet
- Ekskludert bivirkninger av vaksiner
  - ofte forventede og lite alvorlige reaksjoner

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- Presentert på BK på Haukeland
- Poster på ISoP (International Society of Pharmacovigilance)
- Her på Solstrand
- Planlagt artikkel

**Gender differences in spontaneous adverse drug reaction (ADR) reporting in children in Norway 2001-2010**

Bjørnskov J, Skjerve J. *Journal of Clinical Pharmacy and Therapeutics* 2012; 37: 101-106. doi:10.1111/j.1365-2710.2011.01501.x

**Background:** A higher proportion of females than males in the adult population has been documented in children. Spontaneous ADR reporting has particularly been documented in higher girls in Norway in contrast to higher boys reporting the birth administration.

**Objective:** To describe gender differences in spontaneous reports of ADRs in Norwegian children.

**Method:** The Norwegian ADR database 2001-10 (29 434 reports)

**Inclusion:** Reports affecting children <15 years

**Exclusion:** Reports of ADRs from drug exposure in breast feeding, breastfeeding, skin or vaccine and reports with no causal relation

**Results:** 767 reports (2.6%) from 150 unique girls and 363 (1.2%) from 363 unique boys

**Conclusion and conclusions:** Gender differences in spontaneous reports of ADRs in children <15 years in Norway during the last decade are such that differences can be found in specific drugs and age groups. Spontaneous reports do not reflect true differences, but our study documents a reporting pattern that seems to reflect the prescribing pattern in Norway, in that an higher rate of new ADR(s) (prescription, over-the-counter, drug use, cosmetics) in boys and the prescribing of oral contraceptives in girls. A clinical course of gender prescribing pattern is being followed by a higher rate of ADR(s) reactions, have particularly been associated with females.

**Keywords:** children, gender, reporting, spontaneous, adverse drug reaction

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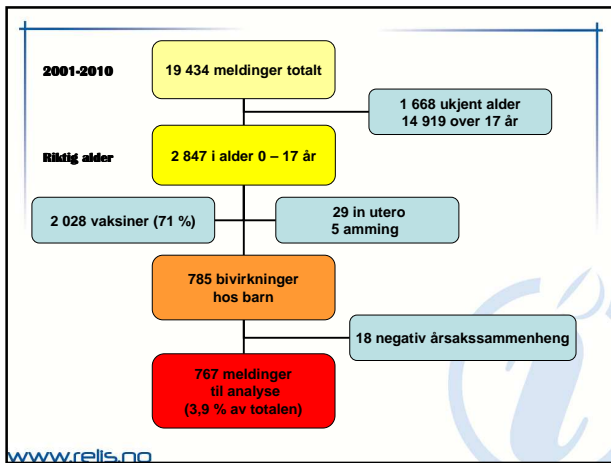
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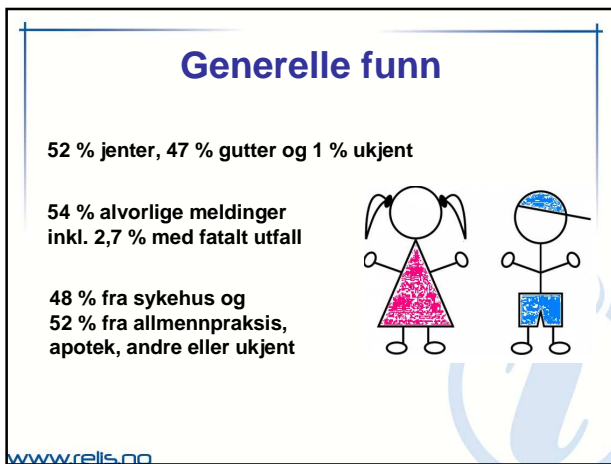
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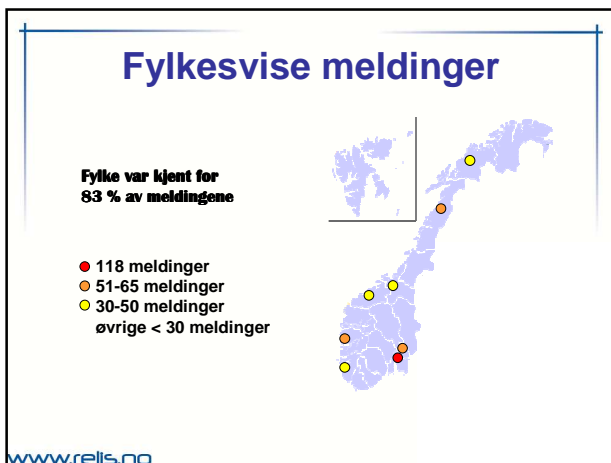
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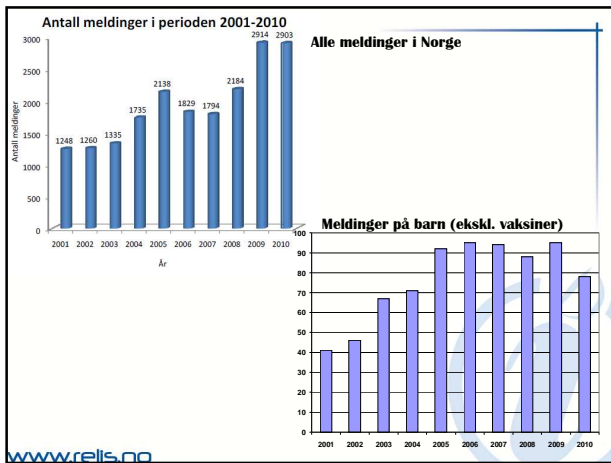
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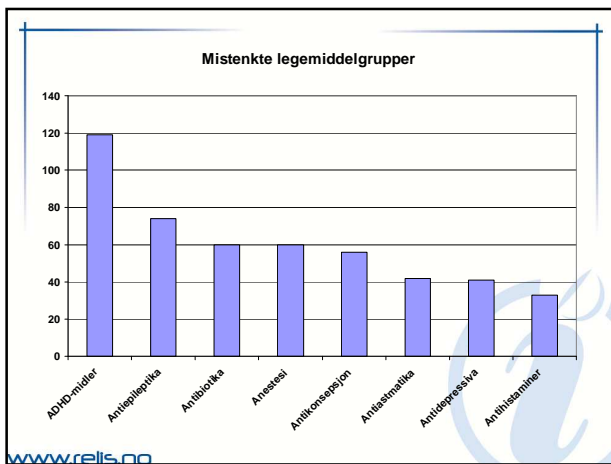
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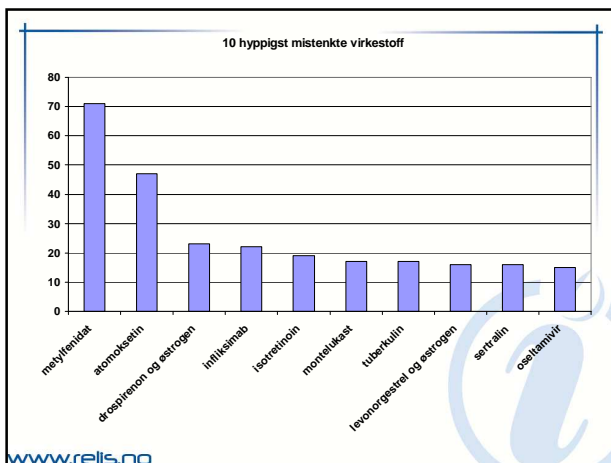
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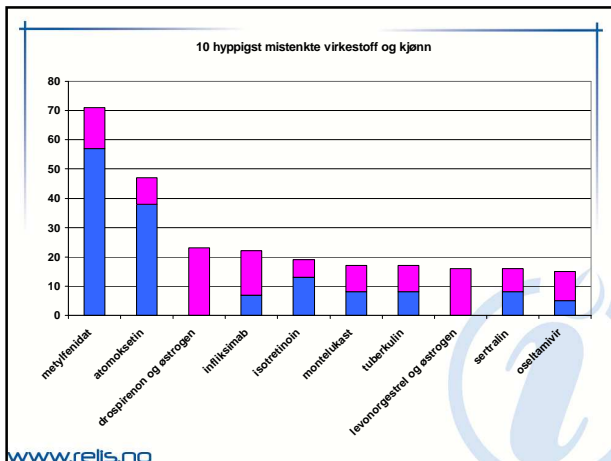
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## Hvor står vi ...

- Jeg mener at:
  - det meldes for få bivirkninger hos barn
  - meldingene er for lite tilgjengelige (datateknisk) for effektiv vurdering av risiko
  - det mangler et bivirkningsforum som gjelder barn
    - mellom barneavdelinger, forskningsmiljøer, RELIS, Legemiddelverket, primærhelsetjenesten, akuttmedisin, brukere

**Dette gir begrensede muligheter for å identifisere og redusere risiko ved legemiddelbehandling av barn**

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## Hvor vil vi?

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## Forslag til tiltak

### Flere meldinger

- Hvilke bivirkninger?
  - ALLE?
  - alvorlige, uventede, interaksjoner, overdoseringer, naturmidler ...
- Av hvem?
  - ALLE?
  - ev. bivirkningsansvarlig "superbruker", RELIS kan gi opplæring og formidle informasjon

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## Forslag til tiltak

### Bedre tilgang til data

- Midler til IT-tjenester for utvikling av bedre søkemuligheter i bivirkningsdatabasen

### Bivirkningsforum

- Samarbeid med Kompetansenettverket
- "Superbruker" på alle barneavdelinger

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**Meld en bivirkning  
før pepperkakene må bakes!**



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