

## **Study protocol: Risks and harm linked to medication errors in the pediatric population**

Alma Mulac<sup>1</sup> and Anne Gerd Granås<sup>1,2</sup>

<sup>1</sup>Department of Pharmacy, The Faculty of Mathematics and Natural Sciences, University of Oslo, Norway

<sup>2</sup>Norwegian Centre for eHealth Research, University Hospital of North Norway, Tromsø, Norway

**Introduction:** Medication errors are associated with considerable patient harm and are a financial burden for our health systems. Pediatric patients are specifically vulnerable for medication errors as many medications used in children are off-label and must be adapted to patient weight.

**Aim:** To investigate medication errors in children and identify risks in medication management linked to patient harm. The study will specifically focus on identifying medications and practices associated with patient harm.

**Method:** This protocol describes an incident report analysis from a two-year period 2016-2017 reported to the Norwegian Incident Reporting System. The reports will be analyzed using a mixed-methods approach. The quantitative part involves classification of incident reports to the stage in the medication management they occurred, error type, patient age, medications involved in the error and patient harm. The qualitative part involves a content analysis of incident reports with the aim of identifying risk areas in medication management for the pediatric population. The content analysis will also involve addressing error causes and will be performed by two authors. Upon identifying risk areas and error causes these will be discussed in relation to changes in the digitalization of medication management that has evolved since the errors were reported and ways to mitigate harm from medication errors by using technology and other systemic measures.

**Ethics:** Ethical approval is not required as the incident reports contain anonymized data.

**Dissemination of results:** The results of the study will be published in a peer-review journal and disseminated in relevant conferences, scientific meetings and webinars.