PEDIATRIC SAFETY EVALUATION OF AN AS-ADJUVANTED H5N1 PREPANDEMIC CANDIDATE VACCINE IN CHILDREN AGED 6-9 YEARS. A PHASE II STUDY

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BACKGROUND AND AIMS:
Children suffer severe effects of influenza and play a major role in disease transmission, therefore prepandemic influenza vaccination of children may be a highly effective measure to contain the spread of pandemic influenza and to reduce its morbidity and mortality.

METHODS:
This phase II paediatric study (107066/NCT00502593) evaluated the safety of two immunizations administered 21 days apart of an H5N1 split virus influenza vaccine containing 1.9µg HA adjuvanted with an oil-in-water emulsion-based Adjuvant System (H5N1/AS group) as compared to immunizations with the non-adjuvanted seasonal influenza vaccine Fluarix™ marketed by GlaxoSmithKline. For this partial preliminary analysis, 69 children aged 6-9 years completed the safety evaluation (H5N1/AS:N=51, Control:N=18). Solicited local (SLS) and general (SGS) symptoms, adverse events (AE) and serious AE (SAEs) were recorded.

RESULTS:
Considering the entire follow-up, injection site pain was the most frequent SLS in both H5N1/AS and control groups (44/51 vs. 12/18), with grade-3 pain in 5 children from the H5N1/AS group vs. 0 in the Control group. SGS were more frequent in the H5N1/AS group. Grade-3 SGS were reported in 4/51 children in the H5N1/AS (2 headaches, 1 gastrointestinal disorder, 1 myalgia) and in 1/18 in the control group (1 fever). Most symptoms lasted 1-2 days with no increase of ESPID 2008 – Med Affairs selection Abstracts and Symposia – Influenza franchise – Anar Andani – Sami Limam duration or severity with the second dose. No distinct pattern of symptomatology was noted. No SAEs were reported.

CONCLUSIONS:
In children aged 6-9 years, the candidate H5N1 AS-adjuvanted vaccine did not raise any safety concerns and the reactogenicity profile was clinically acceptable.