Title: REPEAT IMMUNISATION OF 17-48-MONTH-OLD CHILDREN WITH A REFORMULATED

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Background and aims: Immunological memory enables superior protection from annual influenza vaccination and faster recovery with less morbidity if naturally infected. This study (NCT01702454) assessed safety and immunological memory, manifested as an anamnestic
response to a QIV booster (with antigenically divergent H3N2 and B/Yamagata strains), 1
year after 2-dose primary vaccination with QIV (QIV-primed) or non-influenza vaccines
(QIV-unprimed) in 6-35-month-olds (NCT01439360).

Methods: In this phase-III, open-label, multi-centre study, 17-48-month-old children received
a QIV booster (n=241; QIV-primed; Day 0) or 2 QIV primary doses (n=229; QIV-unprimed;
Days 0+28). Antibody responses were assessed by haemagglutination inhibition (HI) at Days
0+7. Safety endpoints were solicited and unsolicited adverse events (AEs) during 7 and 28
days post-dose 1, respectively, and serious AEs (SAEs) during 6 months of follow-up.

Results: Day 7 post-vaccination HI antibody responses were higher in QIV-primed than in
QIV-unprimed children despite the 2-strain update (Table). The most frequently reported
solicited AEs were injection site pain (40.2%[95%CI:33.9-46.7] [QIV-primed];
26.8%[95%CI:21.1-33.0] [QIV-unprimed]) and irritability (32.4%[95%CI:26.5-38.7] [QIV-
primed]; 26.3%[95%CI:20.7-32.6] [QIV-unprimed]). Fever (axillary) >38.0°C was reported
in 2.5%[95%CI:0.9-5.4] of QIV-primed and 4.9%[95%CI:2.5-8.6] of QIV-unprimed subjects;
fever >39.0°C in 0.8%[95%CI:0.1-3.0] and 0.4%[95%CI:0.0-2.5] of subjects, respectively.
No vaccine-related SAEs were reported.

Conclusions: QIV induced robust anamnestic HI responses in QIV-primed children despite
the 2-strain update. These data support QIV’s effective induction of immune memory after
primary vaccination of toddlers and its capacity to enhance immunity, with an acceptable
safety profile, after an annual booster.

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