Low 2016/17 season vaccine effectiveness against hospitalised influenza A(H3N2) among elderly: awareness warranted for 2017/18 season

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Rapid communications

In 2016/17, the influenza season in Europe was characterised by an early start (week 46, 2016) and a predominance of A(H3N2) viruses. Overall, 89% of strains reported to the European Centre for Disease Prevention and Control (ECDC) were A(H3N2) viruses [1]. High hospitalisation rates and case fatality ratios were reported among persons aged 65 years and above [2]. These factors, along with the high vaccine effectiveness (VE) observed against A(H3N2) in the 2016/17 season, suggest that the A(H3N2) vaccine component has not changed for 2017/18 season, and physicians and public health experts should be aware that VE can be low where A(H3N2) viruses predominate.

In a multicentre European hospital study we measured influenza vaccine effectiveness (IVE) against A(H3N2) in 2016/17. Adjusted IVE was 17% (95% confidence interval (CI): 1 to 31) overall; 25% (95% CI: 2 to 43) among 65–79-year-olds and 13% (95% CI: −15 to 30) among those ≥ 80 years. As the A(H3N2) vaccine component has not changed for 2017/18, VEs against A(H3N2) should be similar to those observed in 2016/17, which are lower than expected against A(H1N1) and A(H3N1) strains.

Since the A(H3N2) vaccine component has not changed in 2017/18, we present the final 2016/17 season IVE against hospitalisation with influenza A(H3N2) among persons aged 65 years and above in Europe, to inform on the level of IVE that can be expected against A(H3N2) in the upcoming 2017/18 season.

Study design

We conducted a multicentre hospital-based test-negative design (TND) case-control study in 27 hospitals from 10 countries (Croatia, Finland, France, Hungary, Italy, Lithuania, the Netherlands, Portugal, Romania and Spain) according to a generic protocol adapted to each local setting [4]. The detailed methods are described elsewhere [5]. In brief, hospital teams identified and swabbed patients aged 65 years and above,
**Table 1**
Characteristics of influenza A(H3N2) hospitalised cases (n = 1,073) and test-negative controls (n = 1,541), I-MOVE + study, Europe, influenza season 2016/17

| Characteristic                                                                 | Influenza A(H3N2) cases (n = 1,073) | Controls (n = 1,541) |
|--------------------------------------------------------------------------------|-------------------------------------|----------------------|
| Median age in years (range)                                                    | 81 (65–102)                         | 80 (65–102)          |
| **Aged 65–69 years**                                                           | 457/1,073 42.6                      | 770/1,541 50.0       |
| Sex = male                                                                      | 516/1,072 48.1                      | 815/1,535 53.1       |
| 2016/17 seasonal influenza vaccination                                         | 556/1,073 51.8                      | 894/1,541 58.0       |
| 2015/16 seasonal influenza vaccination                                         | 578/1,054 54.8                      | 896/1,525 58.8       |
| **Current and previous vaccination status**                                    |                                     |                      |
| 2016/17 seasonal vaccine only                                                  | 46/1,054 4.4                        | 99/1,525 6.5         |
| 2015/16 seasonal vaccine only                                                  | 73/1,054 6.9                        | 112/1,525 7.3        |
| 2015/16 and 2016/17 seasonal vaccines                                          | 505/1,054 47.9                      | 784/1,525 51.4       |
| **Type of 2016/17 vaccine**                                                    |                                     |                      |
| Not vaccinated                                                                  | 517/1,007 48.2                      | 647/1,421 42.0       |
| Inactivated subunit egg                                                         | 243/1,007 22.6                      | 431/1,421 28.0       |
| Inactivated split virion egg                                                    | 229/1,007 21.3                      | 321/1,421 20.8       |
| Adjuvanted                                                                      | 18/1,007 1.7                        | 22/1,421 1.4         |
| **Underlying conditions**                                                       |                                     |                      |
| Diabetes mellitus                                                              | 325/1,072 30.3                      | 473/1,540 30.7       |
| Heart disease                                                                   | 710/1,070 66.4                      | 1,032/1,541 67.0     |
| Lung disease                                                                    | 392/1,069 36.7                      | 672/1,534 43.8       |
| Cancer                                                                         | 201/1,069 18.8                      | 369/1,533 24.1       |
| Renal disease                                                                   | 223/1,071 20.8                      | 319/1,539 20.7       |
| Stroke                                                                         | 125/879 14.2                        | 176/1,287 13.7       |
| Rheumatologic disease                                                           | 157/1,070 14.7                      | 341/1,539 22.2       |
| Obesity[b]                                                                     | 124/1,062 11.7                      | 154/1,527 10.1       |
| Any underlying condition                                                        | 996/1,063 93.7                      | 1,456/1,531 95.1     |
| At least two underlying conditions                                              | 776/1,025 75.7                      | 1,206/1,491 80.9     |
| Functional impairment                                                           | 399/1,066 37.4                      | 588/1,529 38.5       |
| Hospitalisations in past 12 months                                              | 353/1,063 33.2                      | 668/1,526 43.8       |
| Current smoker                                                                  | 182/901 20.2                        | 318/1,220 26.1       |
| **Potential for misclassification**                                             |                                     |                      |
| Antivirals received before swabbing                                             | 177/1,069 16.0                      | 90/1,535 5.8         |
| Swabbing within 3 days of symptom onset                                         | 653/1,073 58.7                      | 876/1,541 56.2       |
| **Study sites**                                                                 |                                     |                      |
| Croatia                                                                        | 31/1,073 2.9                        | 13/1,541 0.8         |
| Finland                                                                        | 20/1,073 1.9                        | 50/1,541 3.2         |
| France                                                                         | 119/1,073 11.1                      | 209/1,541 13.6       |
| Hungary                                                                        | 8/1,073 0.7                         | 19/1,541 1.2         |
| Italy                                                                          | 73/1,073 6.8                        | 136/1,541 8.8        |
| Lithuania                                                                      | 67/1,073 6.2                        | 58/1,541 3.8         |
| Navarre, Spain                                                                  | 242/1,073 22.6                      | 290/1,541 18.8       |
| The Netherlands                                                                 | 40/1,073 3.7                        | 63/1,541 4.1         |
| Portugal                                                                       | 49/1,073 4.6                        | 29/1,541 1.9         |
| Romania                                                                        | 90/1,073 8.4                        | 103/1,541 6.7        |
| Spain[^]                                                                      | 334/1,073 31.1                      | 571/1,541 37.1       |

[^] MOVE+: Integrated Monitoring of Vaccines in Europe plus.

[a] N represents the total number of cases or controls with available information.

[b] Defined as body mass index ≥ 30 kg/m^2.

[^] Excluding Navarre.
hospitalised with signs compatible with a severe acute respiratory infection (SARI) defined as at least one systemic and one respiratory sign or symptom. Swabs were tested with reverse-transcriptase polymerase chain reaction (RT-PCR) for influenza A(H3N2), A(H1N1)pdm09 and B. We compared the odds of vaccination between patients positive for influenza A(H3N2) virus and those negative for any influenza virus. We calculated IVE as (1-odds ratio (OR)).

We measured IVE stratified by age group (65–79 year-olds and ≥ 80 year-olds), presence of underlying conditions (diabetes mellitus, cancer, heart or lung disease, and presence of at least two underlying chronic diseases) and 2015/16 seasonal influenza vaccination status. In a one-stage approach, using logistic regression with the study site as a fixed effect, we adjusted IVE estimates for date of symptoms onset, age (as cubic splines) and individual underlying conditions. We excluded these 22 records from all analyses.

The median age of A(H3N2) cases was 81 years (range: 65–102 years) while that of controls was 80 (range: 65–102 years). Ninety-four percent of cases and 95% of controls had at least one underlying condition (p = 0.14). Controls were more likely than cases to have underlying lung disease (44 vs 37%, p < 0.05), rheumatologic disease (22 vs 15%, p < 0.05) and cancer (24 vs 19%, p < 0.05), to have been hospitalised in the past 12 months (44 vs 33%, p < 0.05) and to be current smokers (26 vs 20%, p < 0.05) (Table 1).

Due to the small number of cases, we were not able to measure IVE against influenza A(H1N1)pdm09 and B. We excluded these 22 records from all analyses.

The one-stage pooled adjusted IVE was 17% (95% confidence interval (CI): 1 to 31) overall; 25% (95% CI: 2 to 43) among patients aged 65–79 years and 10% (95% CI: −15 to 30) among those aged 80 years and above. Among patients with specific underlying conditions, IVE ranged between 19% (95% CI: −1 to 35) among patients with heart disease and 35% (95% CI: 14 to 51) among patients with lung disease (Table 2).

The 2016/17 seasonal IVE was −2% (95% CI: −44 to 28) among patients who had received 2015/16 seasonal influenza vaccine and 39% (95% CI: −3 to 59) among patients not vaccinated in 2015/16 (Table 2). Taking as a reference patients unvaccinated in 2015/16 and

### Table 2

| Population and patient characteristics | Vaccinated /cases | % | Vaccinated /controls | % | Adjusted IVE | 95% CI |
|---------------------------------------|------------------|---|---------------------|---|--------------|--------|
| **Aged 65 years and above - age/time** | 556/1,073        | 52 | 894/1,541           | 58 | 17           | 1 to 31 |
| **Aged 65 years and above - full model** | 544/1,041        | 52 | 868/1,494           | 58 | 14           | −3 to 29 |
| **Aged 65–79 years - age/time**      | 175/457          | 38 | 382/770             | 50 | 25           | 2 to 43 |
| **Aged 80 years and above - age/time** | 381/616          | 62 | 512/771             | 66 | 13           | −12 to 32 |
| **According to underlying diseases**  |                  |   |                     |   |              |        |
| Diabetes mellitus                     | 183/320          | 57 | 295/468             | 63 | 22           | −8 to 44 |
| Heart disease                         | 378/703          | 54 | 622/1,024           | 61 | 19           | −1 to 35 |
| Lung disease                          | 209/386          | 54 | 440/668             | 66 | 35           | 14 to 51 |
| Cancer                                | 105/198          | 53 | 227/362             | 63 | 21           | −19 to 47 |
| At least two underlying chronic diseases | 414/767          | 54 | 732/1,196           | 61 | 17           | −2 to 33 |
| **According to previous vaccination** |                  |   |                     |   |              |        |
| Not vaccinated in 2015/16              | 46/473           | 10 | 99/623              | 16 | 39           | −3 to 59 |
| Vaccinated in 2015/16                 | 502/572          | 88 | 776/887             | 87 | −2           | −44 to 28 |
| **Sensitivity analyses**              |                  |   |                     |   |              |        |
| Swabbed within 3 days                 | 502/872          | 58 | 333/629             | 53 | 8            | −16 to 28 |
| No antivirals before swabbing         | 867/1,446        | 60 | 509/904             | 56 | 14           | −3 to 29 |

I MOVE+: Integrated Monitoring of Vaccines in Europe plus.

* Variables used for adjustment:
  - age/time: adjusted for study site, age and onset date (modelled as a restricted cubic spline with 3 and 4 knots respectively);
  - full model: adjusted for study site, onset date, age (modelled as a restricted cubic spline with 3 and 4 knots respectively), lung diseases, heart diseases, diabetes, obesity, renal diseases, cancer and hospitalisation in the past 12 months;
  - other estimates were adjusted for study site, onset date, age (modelled as a restricted cubic spline with 3 and 4 knots respectively) and hospitalisation in the past 12 months.

Vaccine effectiveness against influenza A(H3N2) in 2016/17

We included 1,073 influenza A(H3N2) cases, nine A(H1N1)pdm09 cases, 13 cases of influenza B and 1,541 controls between week 47, 2016 and week 14, 2017.
same vaccine component A/Hong Kong/4801/2014 supported the WHO recommendation to maintain the vaccine component [10]. Consequently, European data were considered as antigenically similar to the 2016/17 that most circulating viruses that could be analysed week 5/2017, available antigenic data from the World Based on specimens received from week 40/2016 to influenza A(H1N1)pdm09 and 38% (95% CI: 25 to 53) against influenza B [9]. It was 43% (95% CI: 33 to 53) in seasons when circulating and vaccine A(H3N2) strains were antigenically different was 14% (95% CI: −3 to 30) among persons aged 65 years and above. They also suggest a modifying effect of 2015/16 vaccination modified the 2016/17 IVE. Although too imprecise to be conclusive, our results could suggest that patients vaccinated in both seasons benefited from a residual protection from the 2015/16 vaccine, with no additional effect of the 2016/17 vaccine uptake.

**Discussion**

In the 2016/17 influenza season, A(H3N2) viruses largely predominated. IVE against hospitalisation with influenza A(H3N2) virus infection among persons aged 65 years and above was low at 17%. The IVE point estimate was even lower (10%) among patients aged 80 years and above. IVE was similar among patients with heart disease, diabetes mellitus and cancer. The IVE point estimate was higher among patients with lung disease. While 95% CIs were largely overlapping, the 2016/17 IVE point estimate was lower (IVE: −2%) among patients vaccinated also in 2015/16 than among those unvaccinated in 2015/16 (IVE: 39%).

Low IVE against influenza A(H3N2) among persons aged 65 years and above has been previously observed in hospital settings [6-8]. A recent meta-analysis measured that the pooled IVE against hospitalisation with influenza A(H3N2) in seasons when circulating and vaccine strains were antigenically different was 14% (95% CI: −3 to 30) among persons aged 65 years and above [9]. It was 43% (95% CI: 33 to 53) in seasons when circulating and vaccine A(H3N2) strains were antigenically similar; 48% (95% CI: 37 to 59) against influenza A(H1N1)pdm09 and 38% (95% CI: 25 to 53) against influenza B [9].

Based on specimens received from week 40/2016 to week 5/2017, available antigenic data from the World Health Organization (WHO) European Region indicated that most circulating viruses that could be analysed were considered as antigenically similar to the 2016/17 vaccine component [10]. Consequently, European data supported the WHO recommendation to maintain the same vaccine component A/Hong Kong/4801/2014 (clade 3C.2a) for influenza A(H3N2) in the 2017/18 season vaccine for the northern hemisphere [11]. However, one third of viruses isolated during the above-mentioned period could not be assigned to an antigenic reporting category, reflecting technical challenges or antigenic changes in circulating viruses. Genetic data from Europe centralised at the ECDC suggested that circulating A(H3N2) viruses had undergone considerable genetic diversification during the above-mentioned period, with the emergence of subclusters within clade 3C.2a and subclade 3C.2a1 [10].

In September 2017, WHO updated the A(H3N2) component to A/Singapore/INFIMH-16-0019/2016 (subclade 3C.2a1) in the 2018 seasonal vaccine for the southern hemisphere [12]. The latest WHO update on 2 October 2017, reported that influenza A(H3N2) viruses were still predominating worldwide in September 2017. Further genetic information was not provided at this stage [13].

**Conclusion**

Our results suggest a low IVE against hospitalised influenza A(H3N2) among persons aged 65 years and above, particularly among patients aged 80 years and above. They also suggest a modifying effect of 2015/16 influenza vaccination on 2016/17 IVE. The A(H3N2) virus component included in the 2017/18 vaccine will remain the same as in the 2016/17 season. The latest WHO influenza surveillance report suggests that influenza A(H3N2) viruses were predominating worldwide in August 2017. Low IVE may be expected during the 2017/18 season in case of predominant circulation of A(H3N2) viruses. However, IVE against influenza A(H1N1)pdm09 and B are usually reported to be higher. Close monitoring of virological surveillance data will be required to prompt early promotion of complementary measures such as the use of antivirals or non-pharmaceutical interventions.

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Acknowledgements

Funding: The I-MOVE+ project has received funding from the European Union’s Horizon 2020 research and innovation programme under grant agreement No 634446. The Lithuanian I-MOVE+ study sites were supported by a grant from the Research Council of Lithuania (SEN-03/2015). We are grateful to all patients, medical staff, study nurses and epidemiologists from the 12 study sites who actively participated in the study.

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Finland: Jukka Jokinen, Outi Lyytikäinen and Arto Palmu (study design, protocol writing), Päivi Sirén (clinical data collection), Esa Ruokokoski (data management), The laboratory staff in Viral Infections Unit of THL, Tampere University Hospital, Hatanpää Hospital (collaboration with the clinical work and data collection).

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Conflict of interest

None declared.

Authors’ contributions

Marc Rondy was involved in the original methodological design of the study (generic protocol). He coordinated the European hospital IVE network, undertook the statistical analysis on which the research article is based and led the writing of the research article.

Alain Moren initiated the original methodological design of the study. He coordinated the European hospital IVE network and contributed to the writing of the research article.

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