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**Impact of a decision-aid tool on Influenza vaccine coverage among HCW in two French hospitals: a cluster-randomized trial.**

Florian Saunier<sup>1</sup>, Philippe Berthelot MD,Ph-D<sup>1,4,5</sup>, Benoît Mottet-Auselo MD <sup>2</sup>, Carole Pelissier MD, Ph-D<sup>3</sup>, Luc Fontana MD, Ph-D<sup>3</sup>, Elisabeth Botelho-Nevers MD, Ph-D <sup>1,4,5</sup>,  
Amandine Gagneux-Brunon MD, Ph-D<sup>1,4,5</sup>

<sup>1</sup> Department of Infectious Diseases, and Infection Control Unit, University Hospital of Saint-Etienne, France

<sup>2</sup> Infection Control Unit, Hospital of Roanne, France

<sup>3</sup> Department of occupational medicine, University Hospital of Saint-Etienne, France

<sup>4</sup> Groupe Immunité des Muqueuses et Agents Pathogènes, Centre International de Recherche en Infectiologie, Université Jean Monnet, Université de Lyon, Saint-Etienne, France

<sup>5</sup> Institut de Recherche PRESAGE, Chaire vaccination, Prévention et Contrôle de l'Infection, Université de Lyon Saint-Etienne, France

**Abbreviated title :** Impact of a decision aid on HCWs flu vaccination

**Word Count :** 2266

**Corresponding author :** Dr Amandine Gagneux-Brunon, 55 avenue Albert Raimond, 42055 Saint-Etienne, Cedex 2, phone number : + 33 4 77 12 08 13, fax number : +33 4 77 12 04 43, e-mail : [amandine.gagneux-brunon@chu-st-etienne.fr](mailto:amandine.gagneux-brunon@chu-st-etienne.fr)

**Keywords:** Decision aid; influenza; healthcare workers; vaccine; vaccine acceptance

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**Introduction**

During the 2018-2019 influenza season, more than 10 000 deaths were attributable to influenza in France [1]. Nosocomial outbreaks frequently occur [2]. Healthcare Workers (HCWs) vaccination against seasonal influenza has been shown to reduce the risk of nosocomial influenza [3]. The concept of herd immunity is particularly interesting in healthcare settings, as patients are often not good responders to vaccines [4]. Furthermore, seasonal influenza leads to HCWs absenteeism, and seasonal vaccination may reduce this absenteeism [5]. In Europe, HCWs vaccination against seasonal influenza is widely recommended, and mandatory in some countries [6,7].

In France, HCWs vaccination against seasonal influenza is recommended but not mandatory, and each year vaccine coverage in HCWs is estimated to be around 20 % [8,9] far from the objective of 75 % recommended by the World Health Organization and the Advisory Committee for Immunization Practice in the US [10].

Interventions to increase HCWs seasonal influenza vaccine coverage are critically needed. Lack of knowledge about seasonal influenza and misconceptions about the vaccine are well known barriers for HCWs immunization [4]. Decision aids (DAs) are evidence-based tools designed to help individuals making specific and deliberate choices among healthcare options [11]. A DA about seasonal influenza vaccination and dedicated to HCWs was developed in Ottawa in English and French languages [12] and was shown to be effective in reducing the decisional conflict and to increase the intention to get vaccinated [13]. The impact of this DA on the vaccine coverage was not evaluated.

Our aim was to evaluate the impact of this DA on the HCWs vaccine coverage against seasonal influenza in two French Hospitals.

26

## 27 **Material and methods**

### 28 *Study design*

29         The study was a cluster- randomized controlled intervention trial in which departments  
30 in two hospitals (a teaching one-center 1- and a non- teaching one -center 2-) were included in  
31 one of the study groups (intervention group or control group). In each center, the following  
32 information was collected: number of HCWs (physicians, nurses and auxiliary nurses) in each  
33 department, vaccine coverage in the previous season in each department (from the records of  
34 the department of occupational medicine), Each department represented a cluster. The cluster  
35 design was chosen because the intervention was proposed at the level of the department and  
36 not at the individual level. The block randomization was centralized and stratified on the  
37 number of HCWs in the departments, and on the vaccine coverage during the 2017-2018 Flu  
38 season. For the stratification on the vaccine coverage, the departments were classified in three  
39 groups according the observed vaccine coverage against seasonal influenza in 2017-2018:  
40 departments with a low vaccine coverage (<21 % in center 1, <15 % in center 2), departments  
41 with a medium vaccine coverage (21 to 35 % in center 1, and 15-35 % in center 2), and  
42 departments with a higher vaccine coverage (> 35 % in both centers). The 3 groups were  
43 defined according the tertiles of the vaccine coverage observed in 2017-2018 in each center.  
44 Data of vaccine coverage in the previous flu season were obtained from the occupational  
45 department of each hospital. Departments without reliable data about previous season vaccine  
46 coverage and number of HCWs were excluded.

47

### 48 *Intervention*

49         The creators of the DA gave us their agreement to use it and the DA was adapted from the  
50 French version of the Ottawa Influenza Decision aid (OIDA)[13].The DA was a leaflet. One  
51 thousand leaflets were distributed in all the departments included in the intervention group.

52 Two investigators (FS, BMA) ensured that the DA was available for caregivers in the  
53 departments in the intervention group by regular contact with the referent nurse in infection  
54 control or the head nurse. Questionnaires evaluating knowledge and decisional conflict were  
55 associated to the DA on the leaflet. In both groups, local initiatives for promotion of flu shots  
56 were continued (vaccination free of charge, vaccination in the departments by the nurses of  
57 occupational medicine unit, promotion of the vaccine by advertising).

58 The study was carried out during the 2018-2019 winter season with the campaign conducted  
59 for the intervention group between October 15, 2018 and January 30, 2019.

60

#### 61 *Data collection*

62 Number of flu vaccine doses for the professionals delivered during the 2018-2019 Flu season  
63 in each department was collected. Vaccine coverage was evaluated dividing the number of  
64 doses by the number of HCWs in each department.

65

#### 66 *Statistical analysis*

67 The primary outcome was the rate of influenza vaccination among HCWs during the 2018-  
68 2019 season in both groups. This rate was measured as follows: number of vaccinated  
69 professionals divided by the total of active professionals during 2018-2019 flu season. The  
70 number of HCWs that needed to be included to show a 10 % increase in global vaccine  
71 coverage with the intervention was determined by assuming a vaccine coverage of 30 % in  
72 the control group. An increase in vaccine coverage independently of the use of DA was  
73 anticipated due to the extension of vaccination mandates. With an alpha risk of 0.05 and a  
74 power of 0.90, the total number of HCWs to be included was calculated to be at least 954.  
75 The difference in the vaccination rate was expressed by the absolute difference between the  
76 two groups. All analyses were performed in intention to treat. A significance level of  $p < 0.05$

77 was chosen, and analyses were carried out with IBM SPSS statistics V 24 software (Chicago,  
78 Illinois, USA).

79 Secondary outcomes were the impact of the DA on the decisional conflict evaluated with the  
80 Sure test [14], and the impact of the DA on knowledge about the different options that exist to  
81 prevent influenza. These outcomes were measured in a subset of volunteer HCWs in both  
82 centers exposed to the DA. Qualitative variables were described by their frequency and  
83 percentages,  $\chi^2$  test and exact Fisher test were used to compare proportions.

84

### 85 *Ethics*

86 The study was approved by the regional ethics committee with the number  
87 IRBN542018/CHUSTE.

88

### 89 **Results**

90 Eighty-three departments among 85 were randomized (42 in the control group, and 41 in the  
91 intervention group), the medical specialties are depicted in Table 1. The median number of  
92 HCWs in each department was 40 (Interquartile Range 17-64). A total number of 3 547  
93 HCWs (1953 in center 1, and 1594 in center 2) were concerned by the study, 1968 worked in  
94 departments in the intervention groups and 1579 worked in departments in the control group.  
95 During the 2017-2018 season (before the intervention), global vaccine coverage was 23.6 %  
96 (95% CI 22.2-25%). It was in the previous season of 24.6 % (95 % CI 22.7-26.5 %) in the  
97 departments allocated to the intervention group, and 22.4 % (95 % CI 20.3-24.4%) in the  
98 departments allocated to the control group (p=0.119). During the study period, global vaccine  
99 coverage reached 35.2 % (95% CI 33.6-36.8 %), significantly higher than in the previous  
100 season, p<0.005). In the intervention group, 38.7 % (95 % CI 36.5-40.9 %) of the HCWs were  
101 vaccinated versus 31 % (95 % CI 28.7-33.3%) in the control group. The difference of vaccine

102 coverage between intervention and control groups was significant with a p value <0.005 and  
103 an increase rate of 25%. The mean absolute difference between 2017-2018 and 2018-2019  
104 seasons for vaccine coverage was 15.2 % in the intervention group ( $\pm 20.8$  %) and 9.6 % ( $\pm$   
105 13.6 %) in the control group (p= 0.02) (figure 1). Vaccine coverage increased between 2017-  
106 2018 and 2018-2019 seasons in 57 departments among 83 (28/39 in the control group and  
107 29/44 in the intervention group).

108 One hundred and fifty eight HCWs exposed to the DA (96 in center 1 (8.0%) and 62-in center  
109 2 (7.9%)) answered to the Sure test and to the questionnaire about the different options  
110 available to prevent influenza (Table 2). Eighty-one (51.3%) did not report any decisional  
111 conflict (Sure Test=4). Seventy-two (45.6%) had the intention to get vaccinated before the flu  
112 season. HCWs without a decisional conflict were more prone to get vaccinated (58 % vs 32.9  
113 %) than HCWs who have a decisional conflict (p<0.01). The mean score at the 4-point  
114 questionnaire about knowledge was  $3.0 \pm 1.2$ . There was a significant difference between  
115 scores of HCW with intention to get vaccinated compared to HCWs without intention to get  
116 vaccinated ( $3.5 \pm 0.77$  vs  $2.6 \pm 1.4$ , p<0.01).

117

## 118 **Discussion**

119 In this cluster-randomized trial, we observed a positive effect of a DA on the vaccine  
120 coverage against seasonal influenza in HCWs of two general hospitals (a university one and a  
121 non-university one) with a significant increase of 25%. To our knowledge, we carried out the  
122 first randomized clinical trial of a DA dedicated to HCWs, with vaccine coverage as primary  
123 outcome. In the group receiving the DA, vaccine coverage reached 38.7 %, whereas vaccine  
124 coverage was 31.0 % in the control group. The vaccine coverage observed after the  
125 intervention remained far from the objectives of 60-80 % to obtain a herd immunity [15,16].  
126 However, in a great multicomponent interventional study, 28.6 % vaccine coverage in the

127 intervention group compared with 17.8 % vaccine coverage in the control group was  
128 associated with a 2-fold decrease in the risk of contracting seasonal influenza during  
129 hospitalization for patients [17]. Interventions were multiple and complex with information  
130 stand, quiz on intranet, video testimonials with role models; a website, plenary meeting,  
131 involvement of board of directors, distribution of pins to vaccinated HCWs, personal  
132 invitation letter, extended vaccination hours [17].

133 Moreover, the vaccine coverage to obtain for herd immunity against influenza viruses  
134 varies according to vaccine effectiveness and the number of secondary cases per infected case  
135 [16]. We can hypothesize that the observed slight increase in vaccine coverage was associated  
136 with a decrease in the number of the cases of nosocomial influenza. Furthermore, vaccine  
137 effectiveness is much greater in HCWs than in hospitalized patients [18]. We did not collect  
138 information about incident nosocomial influenza in the current study.

139 Interestingly, we observed a general increase in vaccine coverage against seasonal  
140 influenza in both groups between 2017-2018 and 2018-2019 flu seasons. During these 2  
141 seasons there was no other change in the local vaccination campaign. First, we can  
142 hypothesize that HCWs in the control group got information from colleagues in the  
143 intervention group. Studies found that social influence, especially when peers receive or  
144 recommend influenza vaccination, is a factor associated to being vaccinated against influenza  
145 [19]. Secondly, since the extension of mandates vaccine in France for infants born after the  
146 first of January 2018, an increase in vaccine coverage was observed even in children not  
147 concerned by the extension of mandates vaccines suggesting that mandates vaccinations help  
148 decision making for individuals regarding vaccines [20]. Furthermore, vaccine confidence  
149 seems to increase in France, although France remained one of the leader countries of vaccine  
150 hesitancy [21,22]. However, no clear increase in seasonal influenza vaccine coverage was  
151 observed in the general population in France during the 2018-2019 season [23].

152 A DA provides information to individuals to help them making a decision. DAs are  
153 potential interesting tools to address vaccine hesitancy. Few DA were evaluated with vaccine  
154 coverage as primary outcome. Most of them were dedicated to parents for decision-making  
155 about Measles/Mumps/Rubella, and HPV immunization and showed promising results [24–  
156 26]. The OIDA, the DA we adapted here, was first evaluated in Canada. In the first  
157 evaluation, the OIDA improved vaccine confidence in HCWs [13]. Another DA (a web-based  
158 DA) dedicated to seasonal influenza vaccine was evaluated and was effective to reduce the  
159 decisional conflict in HCWs [27]. The reduction of the decisional conflict is probably crucial  
160 in HCWs. In the sample of HCWs who answered the questionnaire, 58 % of the HCWs  
161 without decisional conflict had the intention to get vaccinated before flu season. Different  
162 interventions have been evaluated to increase vaccine coverage against seasonal influenza in  
163 HCWs. A study carried-out in the Netherlands confirmed that multi-faceted interventions are  
164 effective to increase vaccine coverage, and to reduce the number of nosocomial cases of  
165 influenza [17]. All these results suggest that interventions aiming to improve knowledge  
166 about seasonal influenza and prevention tools might be efficient. In our study, HCWs with  
167 better knowledge about the different options (vaccine, antivirals) were more prone to get  
168 vaccinated before flu season. In a study ruled out in 33 nursing homes in Western France  
169 during the 2015-2016 season, better knowledge about seasonal influenza prevention tools, and  
170 perceived benefits of immunization were associated with a greater uptake of seasonal  
171 influenza vaccines among HCWs[9]. In this latter study, global vaccine coverage of HCWs  
172 was 20 % [9]. The positive impact of higher knowledge about influenza epidemiology and  
173 about the vaccine on vaccine uptake was also observed in a study conducted in Emergency  
174 rooms [28]. Furthermore, misconceptions about influenza and the vaccine are the main  
175 barriers to HCWs immunization against seasonal influenza. HCWs may have concerns about

176 the safety of the vaccine and about the effectiveness and are feared to get the flu with the  
177 vaccine. [28].

178 Our study had several limitations. First, randomization was performed based on data  
179 about number of HCWs and vaccine coverage during the previous flu season. The number of  
180 HCWs may have changed, since different departments were re-organized. Secondly, we did  
181 not perform any analysis of implementation (number of HCWs really exposed to the DA,  
182 acceptability of the DA, type of HCWs reached by the DA for example). Consequently, we  
183 are not able to know the number of HCWs really exposed to the DA, and the professional  
184 categories. It would be interesting to evaluate the impact of the DA in the different  
185 professional categories as large discrepancies are observed in vaccine coverage between  
186 physicians, nurses and auxiliary nurses [9,29]. Our study was not designed to collect the  
187 information of immunization in the different professional categories as we only collected the  
188 number of vaccine doses delivered to the HCWs in each department and no individuals data  
189 were collected in this cluster randomized trial. At last, vaccine coverage may be  
190 underestimated because some HCW were vaccinated outside the hospital.

## 191 **Conclusion**

192 This DA is an interesting tool to increase vaccine coverage in HCWs against seasonal  
193 influenza and additional studies may be carried out on a larger scale. However, in spite of the  
194 intervention, vaccine coverage against seasonal influenza remains low in HCW, suggesting  
195 that only multi-component interventions may provide better results.

196

197

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203

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207

208        *Conflict of interest:* All authors report no conflicts of interest relevant to this article.

209

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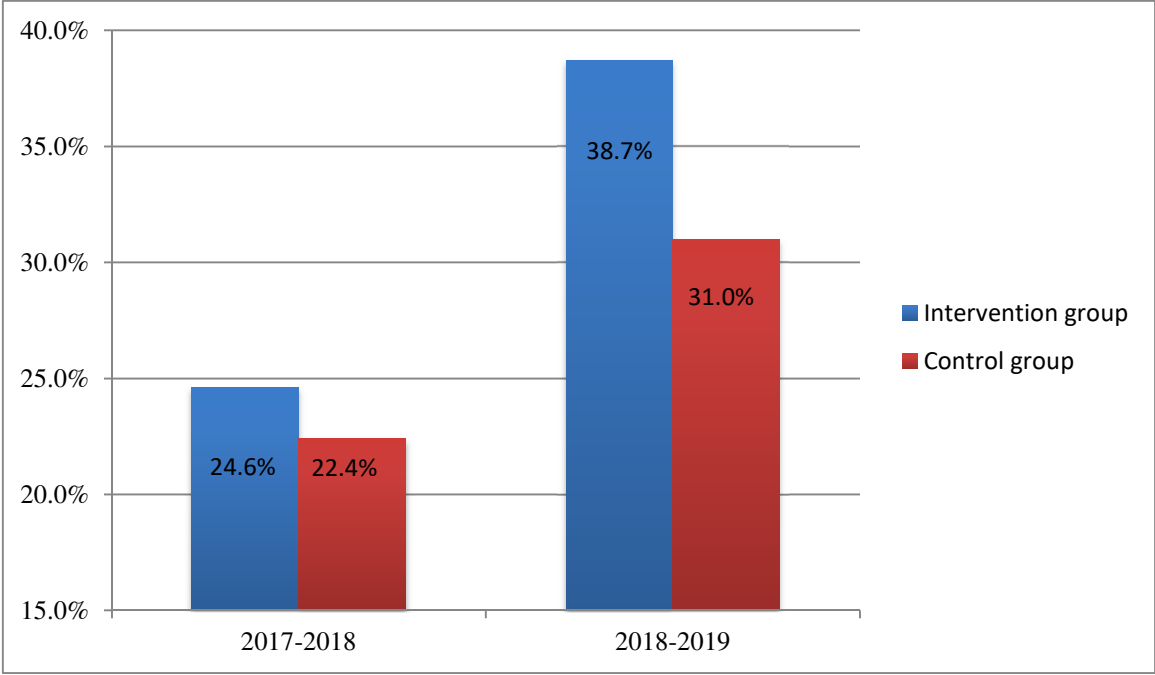
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305

306

307 **Figure (1): Vaccine rate in the intervention and control groups in 2017-2018 and 2018-2019 flu**  
308 **seasons**



**Figure 1: Vaccine rate in the intervention and control groups in 2017-2018 and 2018-2019 flu seasons**

Type of departments	Number of departments	Number of HCWs
Emergency rooms	5	284
Surgery	13	665
Medical departments	30	1341
Geriatric medicine	11	243
Psychiatry	9	310
Pediatric medicine	7	372
(including maternity ward, pediatric ICU)		
Adults ICU	2	235
Other (labs, radiology)	6	97
<b>Total</b>	<b>83</b>	<b>3547</b>

1 **Table 1: Characteristics of the departments involved in the study** (ICU : intensive care unit,  
2 HCW : healthcare workers, VC: vaccine coverage)

3

Variables	N=158 (%)
<b>Knowledge after DA use</b>	
Which option has the highest chance of you getting the flu? ( <i>No vaccine uptake, no antiviral pills</i> )	123 (77.8)
Which option has the lowest chance of patients dying from flu that was spread by their care providers? ( <i>Flu vaccine</i> )	123 (77.8)
Which option has the highest chance of a sore arm as a side effect? ( <i>Flu vaccine</i> )	132 (83.5)
Which option has the highest chance of nausea and vomiting as side effects? ( <i>antiviral pills</i> )	102 (64.5)
<b>Sure-test items</b>	
<b>Do you know enough about the benefits and side effects of each option?</b>	96 (60.8)
<b>Are you clear about which benefits and side effects matter most to you?</b>	118 (74.7)
<b>Do you have enough support and advice from others to make a choice?</b>	121 (76.6)
<b>Do you feel sure about the best choice for you?</b>	114 (72.1)
<b>Sure test =4</b>	<b>81 (51.3)</b>

5 **Table 2 : Evaluation of knowledge about the different options after DA use** (number and percentages of right answers,  
6 right answers are *in italics*), **Evaluation of the decisional conflict after DA use** (number and percentages of « yes », yes =1  
7 point, no= 0 point)

8

9