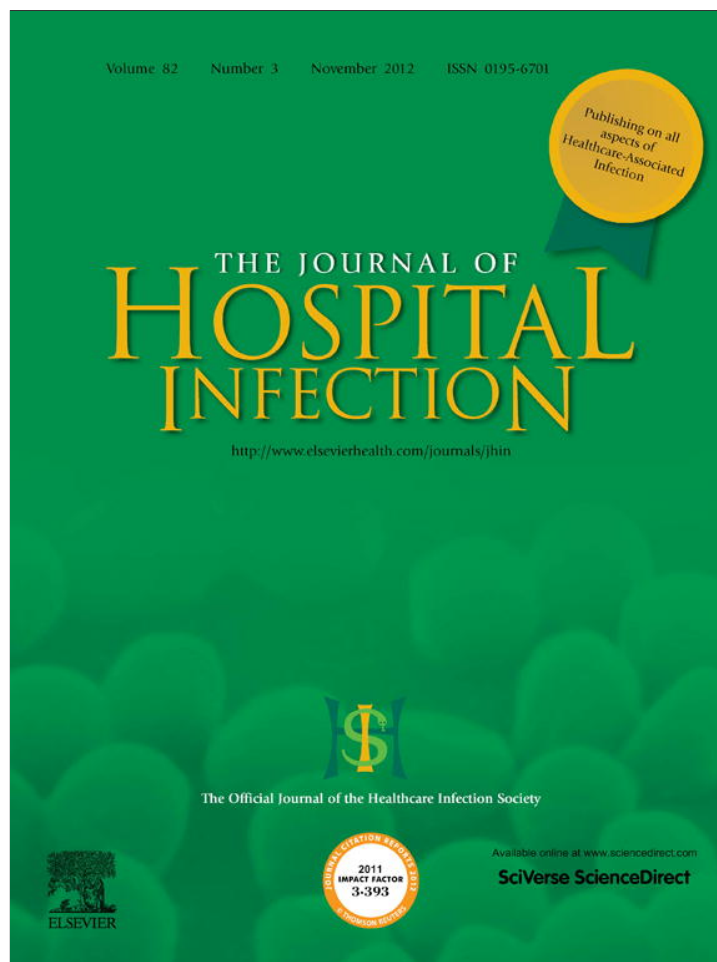


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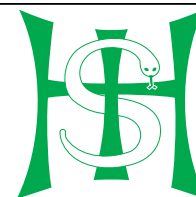
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Impact of the Ottawa Influenza Decision Aid on healthcare personnel's influenza immunization decision: a randomized trial

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SUMMARY

Background: Influenza immunization for healthcare personnel reduces frequency and severity of nosocomial influenza outbreaks and influenza-associated morbidity and mortality among patients. The Ottawa Influenza Decision Aid (OIDA) was developed to assist undecided healthcare workers in deciding whether or not to be immunized.

Aim: To assess the impact of the OIDA, and to ascertain whether its use would increase the level of confidence in healthcare workers' influenza immunization decision and positively affect their intent to be immunized.

Methods: Single-centre, single-blind, parallel-group, randomized controlled trial.

Findings: Eight per cent (151 of 1886) of the unimmunized healthcare personnel were randomized. Of 107 eligible respondents, 48 were in the Ottawa Influenza Decision Aid (OIDA) group and 59 in the control group. A statistically significant ($P = 0.020$) greater improvement in confidence in immunization decision was observed in the OIDA group compared with the control group. Whereas the odds of changing intent to be immunized from 'no/unsure' to 'yes' was 2.4 times greater in the OIDA group, this result did not reach statistical significance after adjusting for intent to be immunized at baseline. The post-OIDA intent to be immunized in the OIDA and control groups compared to the pre-OIDA intent to be immunized showed that the OIDA had a significant effect on reducing uncertainty ($P = 0.035$).

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Conclusions: Using an accessible, balanced, understandable format for all healthcare personnel about their influenza immunization decision appears to have an impact on both healthcare personnel's confidence in their immunization decision and in their intent to be immunized.

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Introduction

Annual influenza immunization mitigates the adverse health outcomes associated with influenza outbreaks. When provided to healthcare personnel, influenza vaccine reduces the frequency and severity of nosocomial influenza outbreaks, and reduces influenza-associated morbidity and mortality among patients by reducing the transmission of influenza from healthcare personnel to their vulnerable patients.¹ Despite national recommendations and proven effectiveness, influenza immunization coverage rates among healthcare personnel remain disappointingly low.^{1–3}

The decision to accept or refuse influenza vaccine each year may be a difficult one for many healthcare personnel. Healthcare personnel experience decisional conflict related to misperceptions about influenza, its risks, the role of healthcare personnel in its transmission to patients, and the importance and risks of vaccination.^{1,3–9} The use of decision aids has been shown to decrease decisional conflict and result in improved knowledge, more realistic expectations of benefit/risks and more active participation of individuals in decision-making.^{10–12} The Ottawa Influenza Decision Aid (OIDA) was developed based on these considerations.¹³

In 2007–2008, this bilingual tool was piloted in three facilities (two long-term care and one acute care) with the purpose of assessing the feasibility and ways in which organizations would use the OIDA. During the 2008–2009 influenza immunization campaign season, the OIDA was used by one children's hospital, three acute care hospitals and seven long-term care organizations. The OIDA was used in a variety of ways, at the discretion of participating healthcare organizations. Choices by organizations included attaching the OIDA to paystubs of all employees, targeting the OIDA for specific departments within the organization, general distribution at information fairs and targeted distribution by managers to staff who requested immunization information or for whom the manager felt would benefit from reviewing the OIDA.^{14,15}

Whereas pilot studies have demonstrated the feasibility of various strategies for implementing the OIDA in healthcare facilities, more information is required to determine whether the OIDA can have a positive influence on healthcare personnel who are undecided about receiving the influenza vaccine.

The objectives were to assess the impact of the OIDA. We hypothesized that the use of the OIDA among undecided healthcare personnel would (i) increase their level of confidence in their influenza immunization decision and (ii) that the use of the OIDA would positively affect their intent to be immunized.

Methods

Research ethics

This study was approved by the Providence Care Ethics Review Committee, the Bruyère Continuing Care Research

Ethics Board and the Ottawa Hospital Research Ethics Board. Participants were given an information and consent form. By completing the online study protocol, they were deemed to have given written informed consent.

Trial design

This was a single-centre, single-blind, parallel-group, randomized controlled trial, designed and executed in accordance with the 2010 Consort Guidelines (Table I).^{16–18} The 2010 CONSORT (CONsolidated Standards Of Reporting Trials) flow diagram is shown in Figure 1. The trial was registered at www.clinicaltrials.gov, NCT01207557. The full protocol can be found at http://www.chi.in.ca/OIDA_Pilot_RCT.html.

Trial design changes

The trial was conducted as outlined in the study protocol, with the exception of the trial start date. Because 2009–2010 was the year of pandemic H1N1 influenza, seasonal influenza immunization was delayed in Ontario, thus moving the trial start date to January 2010, rather than November 2009 as originally planned.

Participants

Eligible participants were employees of Providence Care in Kingston, Ontario in the St Mary's on the Lake and Mental Health Services sites (see Table II) who had not been immunized against influenza at six weeks from the start of the seasonal influenza immunization campaign. Employees who had been immunized during the first six weeks of the campaign were excluded from the trial.

Study settings

The trial was conducted during the 2009/10 influenza season in Providence Care in Kingston, Ontario. Providence Care is a multi-service, non-acute care healthcare organization operating programmes within the community, two hospital sites and one long-term care site. The healthcare personnel (as defined by the occupational health and safety department) working in the in-hospital rehabilitation, complex continuing care, geriatrics and mental health services programmes were asked to participate in the trial. This group of healthcare personnel had lower immunization rates than other programmes at Providence Care based on the occupational health and safety historical immunization records, which include the immunizations given on-site and off-site immunization records of individual personnel who provided this information to occupational health and safety.

Occupational health and safety records on all personnel made it possible to identify who had not yet been immunized after six weeks into the Providence Care seasonal influenza

Table 1
CONSORT 2010 checklist of information to include when reporting a randomized trial^a

Section/topic	Item no.	Checklist item	Reported on page no.
Title and abstract	1a	Identification as a randomized trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	2
Introduction Background and objectives	2a	Scientific background and explanation of rationale	3
	2b	Specific objectives or hypotheses	4
Methods Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	4
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	4
Participants	4a	Eligibility criteria for participants	4
	4b	Settings and locations where the data were collected	4–5
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	5
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	6
	6b	Any changes to trial outcomes after the trial commenced, with reasons	N/A
Sample size	7a	How sample size was determined	6
	7b	When applicable, explanation of any interim analyses and stopping guidelines	N/A
Randomization Sequence generation	8a	Method used to generate the random allocation sequence	6
	8b	Type of randomization; details of any restriction (such as blocking and block size)	6
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	6–7
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	6–7
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	7
	11b	If relevant, description of the similarity of interventions	N/A
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	7
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	N/A
Results			

Table I (continued)

Section/topic	Item no.	Checklist item	Reported on page no.
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, who received intended treatment, and who were analysed for the primary outcome	7
	13b	For each group, losses and exclusions after randomization, together with reasons	7
Recruitment	14a	Dates defining the periods of recruitment and follow-up	7
	14b	Why the trial ended or was stopped	4
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	7–8
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	7
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	8
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	8
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	N/A
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	N/A
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	9
Generalizability	21	Generalizability (external validity, applicability) of the trial findings	10
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	9–10
Other information			
Registration	23	Registration number and name of trial registry	10
Protocol	24	Where the full trial protocol can be accessed, if available	11
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	11

N/A, not applicable.

^a We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomized trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up-to-date references relevant to this checklist.

immunization campaign. For the purposes of this trial, these personnel were considered to be 'undecided'.

Interventions

The peer-reviewed OIDA is the first Canadian decision aid developed to address misconceptions and identified barriers of vaccine uptake in healthcare personnel; which include fear

of side-effects, mistrust in vaccine efficacy and lack of knowledge of current guidelines.¹³ The OIDA presents evidence-based information and guides the individual through a decision-making process, including deliberation of personal values and beliefs.¹³ It was developed and based on the Ottawa Personal Decision Framework (OPDS) and then adjusted to meet the International Patient Decision Aid Standards. The OIDA translates current research evidence into

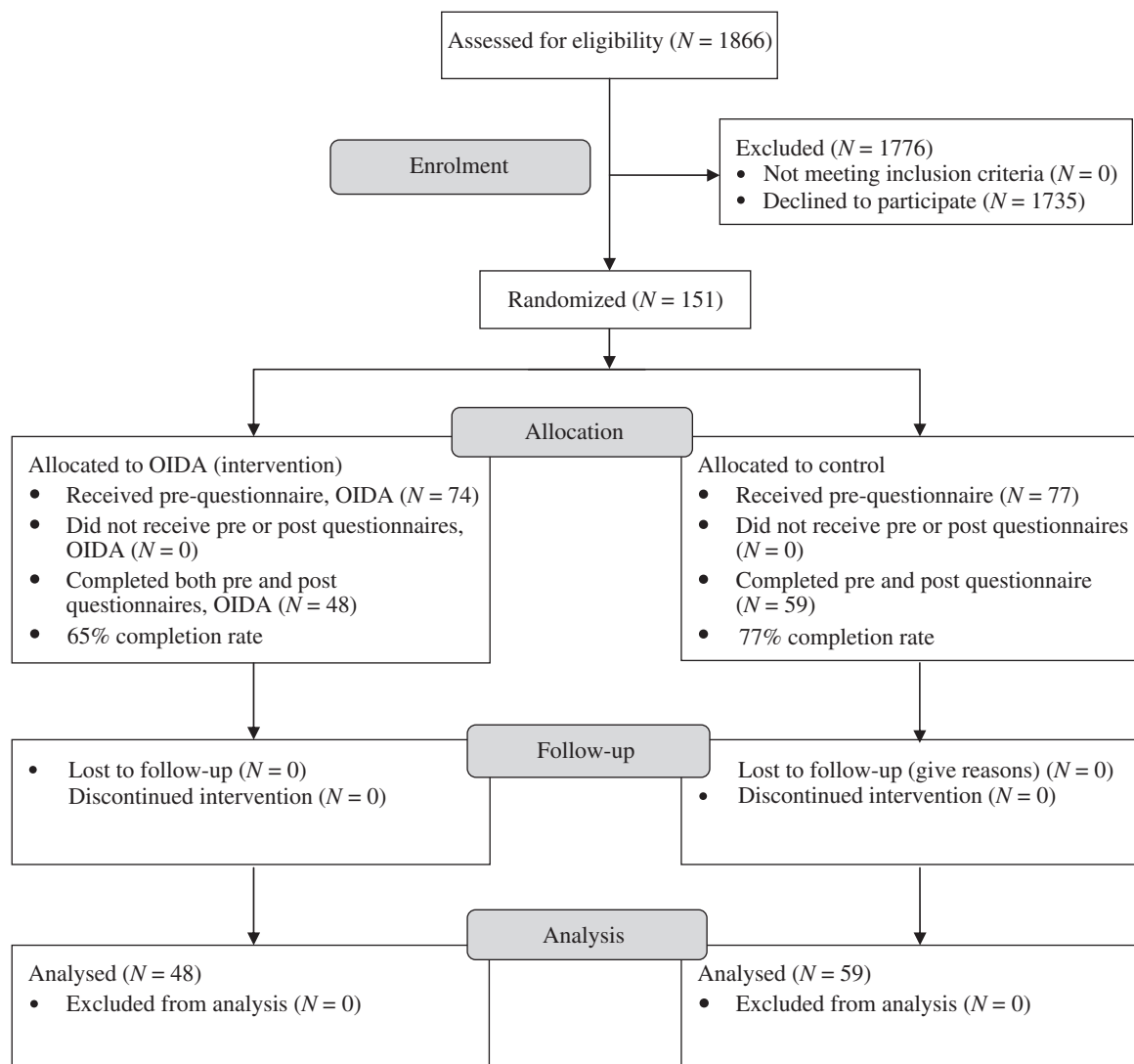


Figure 1. CONSORT 2010 flow diagram. OIDA, Ottawa Influenza Decision Aid.

an accessible, balanced, understandable format for all healthcare personnel.

In the present trial, all participants received the following: (i) pre-intervention questionnaire; (ii) usual Providence Care influenza immunization education pamphlet adapted for the web; (iii) post-intervention questionnaire. In addition to these materials, participants

Table II

Characteristics of trial participants

	OIDA group (%) (N = 48)	Control group (%) (N = 59)	P-value
Age (years)			
18–40	26% (N = 12)	22% (N = 2)	
41–55	57% (N = 26)	60% (N = 32)	
≥56	17% (N = 8)	17% (N = 9)	
	Refused: 2	Refused: 6	0.74
Female (%)	83% (N = 39)	80% (N = 44)	0.70
	Refused: 1	Refused: 4	

OIDA, Ottawa Influenza Decision Aid.

randomized to the OIDA intervention arm received the OIDA to complete online. The pre-intervention questionnaire assessed participant demographics (work site, main occupation) and current influenza immunization intent (yes, no or unsure). The post-intervention questionnaire assessed confidence in immunization decision, immunization intent and change in immunization as stated on the pre-intervention questionnaire.

Providence Care regularly uses email to communicate corporately with all personnel, so this was the method chosen for communication with the trial participants. Six weeks after the start of the influenza immunization campaign, unimmunized employees received an e-mail from the medical chief of staff, explaining the trial and providing a link to the online survey. Employees were encouraged to complete the survey during working hours.

Only the staff of the occupational health and safety department had access to the names of the employees. They were responsible for sending the e-mail on behalf of the medical chief of staff. These staff members were blinded to the allocation of staff to arms of the trial.

Table III

Decision to be immunized^{a,b} at the beginning and at the end of the trial among healthcare personnel in OIDA and control groups (N = 107)

	OIDA group (N = 48)	Control group (N = 59)	OR (95% CI)	P-value
Decision pre-intervention				
Yes	35% (N = 17)	22% (N = 13)		
No	38% (N = 18)	48% (N = 28)		
Unsure	27% (N = 13)	31% (N = 18)		
Decision post intervention				
Yes	46% (N = 22)	27% (N = 16)	2.4 (0.52, 12.5) ^c	0.326 ^c
No	42% (N = 20)	44% (N = 26)		
Unsure	13% (N = 6)	29% (N = 17)	0.20 (0.033, 0.91) ^d	0.035 ^d
Confidence score ^e	4.0	3.6	N/A	0.020 ^f

OIDA, Ottawa Influenza Decision Aid; OR, odds ratio; CI, confidence interval.

^a Exact logistic regression of post-intervention decision (unsure versus yes/no) versus intervention (OIDA versus control group), adjusted for pre-intervention decision.

^b Post-intervention question asked 'After reviewing the information provided, have you changed your decision about getting the flu shot?' (Yes, I will get the flu shot; No, I will not get the flu shot; or I am undecided about whether to get the flu shot.)

^c Exact logistic regression of post-intervention decision (yes vs unsure/no) versus intervention (OIDA vs control group), adjusted for pre-intervention decision.

^d Pre-intervention question asked 'Before reviewing the information that will follow, have you decided to get the flu shot this year?' (Yes, I will get the flu shot; No, I will not get the flu shot; or I am undecided about whether to get the flu shot.)

^e Post-intervention question asked 'After reviewing the information provided, are you more or less confident in your decision?' (Less confident ... More confident; Likert scale: 1, 2, 3, 4, 5).

^f P-value for Wilcoxon rank sum difference test.

Outcomes

Primary outcome measure

The primary outcome was confidence in the influenza immunization decision as reported on the post-intervention questionnaire.

Secondary outcome measure

The secondary outcome measure was impact on immunization intent assessed by comparison of self-reported intent to be immunized on the pre- and post-intervention questionnaires.

Sample size

After six weeks into the campaign, 1886 of the 3144 healthcare personnel had not yet reported being immunized and, thus, were eligible for the trial. Eight per cent (151 of 1886) responded to the invitation to participate in the trial and were subsequently randomized to either OIDA or control group.

Table IV

End of trial healthcare personnel level of confidence about influenza immunization decision^a by post-intervention decision (yes/no/unsure) in OIDA versus control group (N = 107)

Level of confidence (5 = high)	OIDA group			Control group		
	Yes	No	Unsure	Yes	No	Unsure
All subjects						
N	22	20	6	16	26	17
Mean	4.36	3.85	3.16	3.88	3.69	3.18

OIDA, Ottawa Influenza Decision Aid.

^a Post-intervention question asked 'After reviewing the information provided, are you more or less confident in your decision?' (Less confident ... More confident; Likert scale: 1, 2, 3, 4, 5).

Twenty-nine percent (44 of 151) were then excluded because they did not complete the pre and post questionnaire. Of the remaining 107 eligible respondents, 45% (48 of 107) were in the OIDA group and 55% (59 of 107) were in the control group.

Randomization

Sequence generation

The randomization list was generated using the randomization function in Excel 2002 (version 10.6856.6856 SP3).

Type

The list was processed to have a block size of four with individuals having a 50:50 chance of seeing the decision aid.

Allocation concealment mechanism

The list was imported from Excel into a Microsoft SQL Server database. The online application would sequentially assign a random identification number and their decision aid status (seeing the decision aid or not) from the randomization list when users logged into the survey.

Implementation

Ongoing online randomization started at the end of six weeks into the seasonal influenza immunization campaign and continued for the period when the trial actively was collecting data (about nine weeks).

Blinding

Only the programmer and statistician had access to the randomization process.

Statistical methods

In order to detect the effect of the intervention on the primary outcome measure, the group means for each arm of

the trial were calculated, and then the two arms were compared using a Wilcoxon rank-sum non-parametric test. For the secondary outcome measure, the proportion of participants reporting intent to be immunized (yes, no or unsure) was calculated before and after the intervention in each arm. The association between intent to be immunized (yes vs no/unsure), uncertainty (unsure vs yes/no) and intervention (OIDA or control) was estimated using exact logistic regression with the post-intervention decision as the dependent variable and intervention (OIDA or control) and pre-intervention decision as the independent variables. Exact odds ratios (OR) and 95% confidence intervals (CI) and associated *P*-value were used to determine association between intent to be immunized and trial arm. Analyses were conducted using SAS version 9.2.

Results

At the time the trial was conducted, 1866 staff were eligible for receiving the internet communication. Of this group, 8% (151 of 1866) chose to log on to the web and were randomized either to the OIDA group or to the control group. Of those allocated to the OIDA group, 65% (48 of 74) and 77% (59 of 77) allocated to the control group completed both pre and post questionnaires (Figure 1).

The OIDA and control groups were similar with regards to age and gender (Table II). Although the response rate was 8%, those who responded had comparable characteristics to healthcare personnel working who were approached to participate in the trial. Most of the participants in the trial were female; 83% in the OIDA group and 80% in the control group ($P = 0.70$). The age distribution was similar in both groups with 57% of the participants aged 41–55 years of age in the OIDA group and 61% in the control group ($P = 0.74$).

Baseline characteristics

The OIDA and control groups were similar with regards to age and gender (Table II). Most of the participants in the trial were female; 83% in the OIDA group and 80% in the control group ($P = 0.70$). The age distribution was similar in both groups with 57% of the participants aged 41–55 years of age in the OIDA group and 61% in the control group ($P = 0.74$).

Primary outcome: confidence in immunization decision

The primary outcome of this trial was post-intervention confidence in the immunization decision on a scale from 1 (low confidence) to 5 (high confidence). Post intervention, the mean confidence score was 4.00 in the OIDA group, and 3.60 in the control group ($P = 0.020$) (Table III).

Overall, confidence scores were lower among the participants who did not intend to be immunized or who were unsure, 3.85 and 3.16 respectively in OIDA group, versus 3.69 and 3.18 in the control group (Table IV).

Secondary outcome: decision to immunize

Reductions in uncertainty

At the beginning of the trial, 27% (13 of 48) in the OIDA group and 31% (18 of 59) in the control group were unsure about their

decision to be immunized in the 2009–2010 influenza season (Table III). At the end of the trial, this number was 13% (6 of 48) in the OIDA group and 29% (17 of 59) in the control group. A logistic regression model with the post-intervention decision as the dependent variable and intervention (OIDA or control) and pre-intervention decision as the independent variables yielded an exact OR of 0.20 (95% CI: 0.033–0.91; $P = 0.035$) for the association between intervention and post-intervention immunization decision (unsure vs yes/no) suggesting a significant effect of the OIDA on reducing uncertainty (Table III).

Movement towards immunization

Intention to be immunized increased 11% (from 35% to 46%) among participants in the OIDA arm compared with 5% (from 22% to 27%) in the control arm following the intervention (see Table III). There was no evidence of a statistically significant influence of trial arm on the intention to be immunized (yes versus no/unsure). Exact logistic regression analysis of post-test intention to be immunized versus intervention, adjusted for pre-intervention intention to be immunized yielded an exact odds ratio of 2.4 (95% CI: 0.52–12.5; $P = 0.326$).

Discussion

The primary intent of a decision aid is to improve the quality of decisions, including confidence in the decision. This randomized trial demonstrated that the OIDA was successful in this purpose as we observed a statistically significant ($P = 0.020$) greater improvement in confidence in immunization decision in the arm randomized to the OIDA compared to the arm randomized to control. We also observed a statistically significant decrease in individuals being unsure about their immunization decision in the arm that received the OIDA. Whereas the odds of changing intent to be immunized from 'no/unsure' to 'yes' was 2.4 times greater in the OIDA group compared with the control group, this result did not reach statistical significance after adjusting for intent to be immunized at baseline.

Results from this trial are consistent with previous studies that had evaluated the OIDA as a useful tool for healthcare workers considering influenza immunization.^{14,15} In two long-term care homes, 57 healthcare personnel completed the OIDA and an acceptability questionnaire. Ninety percent ($N = 51$) reported that the information in the decision aid was completely or mostly clear, 83% ($N = 47$) found that the OIDA helped them know that the decision is dependent on personal values, and about 75% ($N = 43$) reported that the OIDA was very or somewhat helpful when making a decision about influenza prevention choices.¹⁴ Similar results were seen in a sample of acute care hospital personnel, whereby 77% (47/61) reported that the OIDA helped them to recognize that a decision needs to be made with regards to influenza immunization.¹⁵

The 2009–2010 influenza season was disrupted by the H1N1 pandemic. The Province of Ontario (population 13.5 million), unlike some other jurisdictions, decided to delay the seasonal influenza vaccine distribution until December. This resulted in lower seasonal influenza immunization uptake among healthcare personnel than had been experienced in previous years.¹⁹ At Providence Care, the 2009–2010 rate was 26% compared with 45% in 2008–2009. Two explanations for this reduced rate could be as follows: healthcare personnel believed that the pH1N1 immunization was all that was needed and seasonal

influenza was not circulating in the typical autumn–winter influenza season.¹⁹

In this trial, the OIDA had been incorporated into a large-scale influenza immunization campaign and the OIDA showed a positive impact on decisional conflict about influenza immunization. Previous studies were not designed to delineate these kinds of results.¹³

This trial has some important strengths and weaknesses. Unlike most healthcare organizations, Providence Care was able to provide accurate and complete data on who had not been immunized after six weeks from the start of its immunization campaign. Also, its internal tracking software (Parklane) was used to track any changes between six weeks and the end of the campaign. These unique features of Providence Care ensured that follow-up e-mails at seven and nine weeks were only sent to personnel remaining unimmunized.

In the healthcare organization setting where this trial was conducted, tracking immunization status among participants in this trial was beyond the resources available. Because of issues of confidentiality, the occupational health and safety staff in this organization were the only people who could do this work. It was their determination that the task was beyond what their record system and staffing levels could accommodate for this request. This outcome is important for future studies of impact of the OIDA on immunization uptake.

The trial sought to examine both impact on confidence in their decision to be immunized as well as self-reported intent to be vaccinated. It is possible that the number completing the OIDA may have been greater if a paper as well as an online version of the OIDA had been available for trial subjects to complete. A multi-site randomized trial is being planned that will offer trial participants the opportunity to use the online or paper version of the OIDA. In addition, acute care organizations as well as long-term care organizations will be included to increase the external validity of our knowledge about the impact of the OIDA about healthcare personnel confidence in being immunized for influenza as well as their intent to be immunized.

Although the block randomization appeared to result in a balance between the groups, there was an imbalance in the response rate so that fewer participants completed the trial in the OIDA group than in the control group. This is a limitation of the study design given that participants could only be represented in the final sample if they completed the pre and post questionnaires. Response burden may have been slightly greater in the OIDA arm leading to these differential rates of inclusion.

The use of a randomized design reduced the likelihood of confounding variables being unequally distributed between the two arms. However, the low response rate, the impact of pH1N1, and the fact that the trial was conducted in only one healthcare organization limits the generalizability of its findings.

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Conflict of interest statement

None declared.

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