Vaccine 33 (2015) 6635–6640

Contents lists available at ScienceDirect

Vaccine

journal homepage: www.elsevier.com/locate/vaccine

Differences in efficiency, satisfaction and adverse events between self-administered intradermal and nurse-administered intramuscular influenza vaccines in hospital workers

Brenda L. Coleman[a,b,*], Shelly A. McNeil[c,d], Joanne M. Langley[c,e], Scott A. Halperin[c,d], Allison J. McGeer[a,b]

[a] Mount Sinai Hospital, 600 University Avenue, Toronto, ON, Canada
[b] University of Toronto, 155 College Street, Toronto, ON, Canada
[c] Canadian Center for Vaccinology, Dalhousie University, 6299 South Street, Halifax, NS, Canada
[d] QE II Health Sciences Centre, Nova Scotia Health Authority, 1276 South Park Street, Halifax, NS, Canada
[e] IWK Health Centre, Nova Scotia Health Authority, 5980 University Avenue, Halifax, NS, Canada

ARTICLE INFO

Article history:
Received 11 June 2015
Received in revised form 17 October 2015
Accepted 23 October 2015
Available online 31 October 2015

Keywords:
Influenza vaccines
Intradermal
Intramuscular
Vaccination
Campaign

ABSTRACT

Vaccinating healthcare workers against influenza takes tens of thousands of hours of work annually. This study was undertaken to determine the acceptability, success rate, and time to vaccinate healthcare workers in nurse-led groups that self-vaccinated with intradermal influenza vaccine compared with nurse-administered intramuscular vaccine.

Methods: Volunteer hospital workers were randomly assigned to groups that either self-administered intradermal influenza vaccine (Intanza®) in a nurse-led group or received nurse-administered intramuscular vaccine (Vaxigrip®). Research assistants timed vaccination procedures; pre- and post-injection questionnaires assessed acceptability and reactogenicity.

Results: 810 adults, 21–69 years of age, from two study sites were vaccinated: 401 self-administered the intradermal vaccine while 409 received their intramuscular vaccine from a nurse. Of those who self-administered for the first time, 98.5% were successful on their first attempt with an additional 1.5% on their second attempt. Acceptability was high: 96% were very or somewhat certain that they administered the vaccine correctly, 83% would choose intradermal influenza vaccine again and of those, 75% would choose self-administration again, if given the choice. It took 51.3–72.6 s per person for the nurses to guide the groups through the self-administration process, which was significantly less time than it took to individually administer the intramuscular vaccines (93.6 s).

Conclusion: Self-administration of intradermal influenza vaccine by people working in healthcare settings is a possible alternative to nurse administered vaccinations, with nurse-led group sessions a good way of teaching the technique while being available to respond to unanticipated problems (NCT01665807).

1. Introduction

Influenza is a highly contagious viral respiratory tract infection caused primarily by influenza virus types A or B. Each year, 5–10% of adults and 20–30% of children are infected and three to five million cases of influenza result in severe sickness, resulting in 250,000 to 500,000 deaths worldwide [1].

Vaccination programs greatly reduce influenza burden. Among healthy adults, trivalent inactivated influenza vaccine prevents about 60% of symptomatic influenza [2]. Vaccination of healthcare workers reduces mortality and morbidity in patients [3–6], reduces illness in the workers themselves [7,8], and is cost-effective for hospitals because of the reduced absenteeism [9–11]. Although programs based on nurse-administered intramuscular vaccination are effective, easy access to vaccination for hospital staff remains a challenge, in part because of large numbers of staff working evening, night, and weekend shifts. If regular recipients of seasonal vaccine can self-administer vaccine, the potential exists

* Corresponding author at: Corresponding author at: Mount Sinai Hospital, Microbiology, 600 University Avenue, Room 218, Toronto, ON, Canada M5G 1X5. Tel.: +1 416 586 4538; fax: +1 416 586 8358.
E-mail addresses: bcoleman@mtsinai.on.ca (B.L. Coleman), shelly.mcneil@cdha.nshealth.ca (S.A. McNeil), jmlangle@dal.ca (J.M. Langley), scott.halperin@dal.ca (S.A. Halperin), amcgeer@mtsinai.on.ca (A.J. McGeer).

http://dx.doi.org/10.1016/j.vaccine.2015.10.095
0264-410X/

to improve the efficiency of mass vaccination campaigns during pandemics.

The most common delivery route for inactivated influenza vaccines is intramuscular injection. However, intradermal vaccines induce equal or superior immune responses in healthy adults [12–14]. In some age groups, intradermal vaccination also has the advantage of requiring a lower dose per person which would permit more people to be vaccinated in situations of limited vaccine supply. Another advantage is the potential for self-administration. Intanza® (Sanofi Pasteur, Toronto, Canada), for example, uses the BD Soluvia™ microinjection system (Franklin Lakes, NJ). Our previous study determined that 92% of healthcare workers successfully self-administered intradermal influenza vaccine on their first attempt with no difference in immunogenicity compared with those vaccinated by a research nurse [15].

There is wide variation in the estimated time to vaccinate individuals, even in large clinic settings. During mass influenza vaccination clinics, times ranged from 1.6 min (for pre-filled syringes) to 9 min for injections using multi-dose vials [16,17]. In office settings, children have been vaccinated in about 2 min for either intramuscular or intranasal influenza vaccines [18] while emergency room nurses took an average of 4 min to vaccinate adults with influenza or pneumococcal vaccine [19]. Coleman et al. report that the median time for healthcare workers to self-administer Intanza® using written instructions was 4 min, including 2 min to read instructions and 2 min to inject the vaccine [15].

We hypothesized that, on average, self-administration of intradermal vaccine would require less time than nurse-administration of intramuscular vaccine. The objectives of this study were to compare the time to self-vaccinate with intradermal vaccine compared to nurse-administered intramuscular vaccine in group settings; to estimate the time required for self-administration of intradermal influenza vaccine using written instructions; to determine acceptability and success of self-vaccination with intradermal influenza vaccine in adults, and to compare local and systemic reactogenicity of self-vaccination with Intanza® and nurse-administration with Vaxigrip® (Sanofi Pasteur).

2. Methods

2.1. Study design

Both parts of this study were conducted at Mount Sinai Hospital, Toronto and the IWK Health Centre and Queen Elizabeth II Health Sciences Centre, Halifax, Canada. Part A was an open cluster-randomized controlled trial while Part B was a time trial of people who had self-injected intradermal influenza vaccine once before, two seasons earlier. Adults eligible to receive the 2012–2013 influenza vaccine were recruited from the participating hospitals using a variety of advertising techniques, study registration lists, and word of mouth. Participants were required to be 18–69 years old, able to complete study questionnaires, no history of a severe reaction to influenza vaccine, and willing to self-inject intradermal influenza vaccine. A sample size of 800 (400 per group) would provide 80% power to detect a difference of 30 s with a Type I error of 5% based on an estimated standard deviation of 1.5 s. Means, standard errors, and 95% confidence intervals were calculated for normally distributed data, including pain scores from 11-point visual analogue scales, with between group comparisons using Student's *t*-test and analysis of variance. Group comparisons of non-normally distributed data used Wilcoxon rank sum and Kruskal–Wallis *U* tests. Logistic regression was used to determine associations between binary outcomes, adjusting for demographic and study design variables. Regression diagnostics were performed on all models.

The study was approved by the Research Ethics Boards at participating hospitals and registered with clinicaltrials.gov (NCT01665807).

2.2. Part A (cluster-randomized)

In Part A, participants signed up for group sessions held at various times of day and days of the week. Groups (minimum size 6) were randomly assigned to either self-administer intradermal or receive nurse-administered intramuscular influenza vaccine. Research assistants performed randomization, using blocks of 4–6 as identified by an online clinical trials randomization program [20] while the research nurse explained the study and participants completed informed consent forms, eligibility forms, and a pre-vaccination questionnaire. Following this, the study nurse informed the group of their random assignment. No one was allowed to enter the session after it began.

Participants in groups randomized to the nurse-administration study arm were given influenza vaccine for the 2012–2013 season by an experienced nurse following hospital procedures: i.e., ascertaining eligibility for vaccination, answering questions about the vaccine, drawing up the vaccine, preparing the site, injecting the vaccine, deploying the needle shield, disposing of the syringe, applying a bandage, and registering the vaccination. Using a stopwatch, a research assistant timed each vaccination, starting when the participant sat in the chair and stopping once the nurse had completed the registration. Vaxigrip® was provided in multi-dose vials with 0.5 mL doses drawn into 1 mL syringes and injected into the deltoid using 25 ga, 1″ or 1.5″ needles.

Participants in the self-administration arm were asked to self-vaccinate as a group. The research nurse distributed the individual packages containing the vaccine syringes, alcohol wipes, and bandages, reviewed eligibility, and answered questions (as above). Following a piloted and practiced script and using a dummy syringe, the nurse demonstrated how to clean hands using alcohol hand rub, open the package, prepare the injection site, remove the needle shield, inject the vaccine, activate the needle shield, and dispose of the syringe. S/he assisted participants that had questions or concerns and registered the vaccination. If the nurse or participant identified an error that was unsafe (e.g., finger touched needle prior to injection) or an obvious failure (i.e., vaccine was released from the syringe before injection), the participant was offered a second attempt. If the second attempt ended in failure or the participant did not wish to make a second attempt, he/she was offered nurse-administered vaccine and deemed a failure for study purposes. Research assistant(s) timed the group's time, starting with the nurse's distribution of supplies and stopping once all participants had been vaccinated and the nurse had completed all registrations. Intanza® (9 or 15 μg, as appropriate) was provided in single-dose syringes with 30 g, 1.5 mm needles for intradermal injection into the deltoid area.

Completion of study-specific tasks (study consent, pre- and post-vaccination questionnaires, and providing and explaining Day 8 questionnaires) was not included in study times. The 10-item pre-vaccination questionnaire collected information on previous influenza vaccination, attitudes toward influenza vaccinations, occupation, and experience giving injections. The 5-item post-vaccination questionnaire asked about the pain of injection with self-vaccinators also asked how certain they were that they properly vaccinated themselves and what would make self-vaccination easier in future (e.g., change instructions). The 8-item Day 8 questionnaire, based on the questionnaire used by Scheifele et al. [21], elicited the greatest severity of adverse effects and whether they caused absenteeism or healthcare consultation. It also asked acceptability questions: whether participants