EFFICIENCY IN INFLUENZA VACCINE PACKAGING
A Comparison of Fluzone® Intradermal, Influenza Virus Vaccine to Fluzone Vaccine Prefilled Syringe Presentation

SUMMARY

Health care professionals administering adult influenza vaccines have multiple products from which to choose. Influenza vaccines are packaged in multi-dose and single-dose vials, in prefilled syringes that require a needle for intramuscular injection, and in prefilled syringes with a microneedle for intradermal injection. There are several criteria that are evaluated when determining product selection; efficiency, the ease and speed at which a dose of vaccine can be delivered, should be considered a key factor in that determination.

During the 2013-2014 flu season, The Verden Group conducted a study to measure the efficiency of using Fluzone Intradermal vaccine in order to compare it with using the Fluzone vaccine prefilled syringe. We compared the Fluzone Intradermal vaccine efficiency findings to a 2012 study that measured efficiency using Fluzone vaccine prefilled syringe vaccine doses. The results showed that when compared to prefilled syringe (PFS) doses administered intramuscularly, between 31 and 46 seconds can be saved per dose by using Fluzone Intradermal vaccine. This article demonstrates the potential implications of this 46-second savings on influenza immunization in various clinical settings.

Use of Fluzone Intradermal Vaccine in a Flu Clinic Setting

Many organizations choose to administer influenza vaccines in a flu clinic setting. Employers offer workplace flu clinics on set days and times, medical practices may choose to hold specific flu clinics outside of routine visits, and retail-based clinics and pharmacies routinely administer influenza vaccinations as stand-alone events.

We therefore included a ‘flu clinic’ setting in the study to assess what efficiency may be gained by using Fluzone Intradermal vaccine in this type of environment and how through-put (or workflow) time can be impacted.

Table 1: Time Taken to Administer Fluzone Intradermal Vaccine in a Flu Clinic Setting Versus Fluzone Vaccine Prefilled Syringe

<table>
<thead>
<tr>
<th>2012 Study: Fluzone Vaccine Prefilled Syringe</th>
<th>2013 Study: Fluzone Intradermal Vaccine</th>
<th>Time Saved</th>
</tr>
</thead>
<tbody>
<tr>
<td>87 seconds</td>
<td>56 seconds</td>
<td>31 seconds</td>
</tr>
</tbody>
</table>
Implications of Time Saved in the Flu Clinic Setting

In a flu clinic setting (workplace, medical practice, or pharmacy), the time to administer Fluzone Intradermal vaccine averaged 56 seconds versus 87 seconds for Fluzone vaccine prefilled syringe. That time savings of 31 seconds per dose could result in the ability to dispense up to 23 additional doses per hour. By simply dividing the seconds available in an hour by the time taken to administer a dose, we can calculate the opportunity for additional administrations within a given flu clinic ‘session.’

Example: Additional Doses Possible Within a 4-hour Flu Clinic by Using Fluzone Intradermal Vaccine:

PFS: 14,400 seconds / 87 seconds per dose = 165 doses

Fluzone Intradermal Vaccine: 14,400 seconds / 56 seconds per dose = 257 doses

Additional Doses Possible to Administer = 92 doses

Use of Fluzone Intradermal Vaccine in an Office Visit Setting

A substantial proportion of immunizers are clinicians working in traditional medical practice settings, where influenza vaccines may be administered during routine encounters rather than as stand-alone events. We therefore included a medical practice setting in the study to assess what efficiency may be gained by using Fluzone Intradermal vaccine in this type of environment and how it impacted through-put (or workflow) time.

Please Note: The data collected in the 2012 study assessing through-put time for Fluzone vaccine prefilled syringe was performed in a retail-based clinic setting. Those vaccinations were typically performed as stand-alone events rather than as part of a visit.

While the components of the data collected were the same in both studies, some components were performed in different ways. For example, within the practice setting, documentation was extensive and counseling occurred as a separate event. In the retail-based setting, counseling occurred concurrent to the administration and documentation was performed on paper and scanned into the record. Therefore, the time observed in the 2012 study (Fluzone vaccine prefilled syringe) included preparation, administration and clean up times with documentation, and counseling occurring concurrently rather than as a separate processes. Since the way in which immunizers counsel and document vaccinations vary, regardless of vaccine presentation, we have excluded counseling time in the practice setting from the efficiency calculation when comparing one study to another. The documentation and counseling time for the practice setting is listed separately below.
Table 2: Time Taken to Administer Fluzone Intradermal Vaccine in a Practice Setting Versus Fluzone Vaccine Prefilled Syringe

<table>
<thead>
<tr>
<th>2012 Study: Fluzone Vaccine Prefilled Syringe</th>
<th>2013 Study: Fluzone Intradermal Vaccine</th>
<th>Average Time Saved</th>
<th>Average Documentation and Counseling Time in the Practice Setting</th>
</tr>
</thead>
<tbody>
<tr>
<td>87 seconds</td>
<td>41 seconds</td>
<td>46 seconds</td>
<td>59 seconds</td>
</tr>
</tbody>
</table>

* Note: Counseling time was highest for patients and clinicians unfamiliar with Fluzone Intradermal vaccine (maximum time observed was 179 seconds). Those patients and clinicians familiar with Fluzone Intradermal vaccine had substantially lower times (minimum 13 seconds).

Implications of Time Saved in the Practice Setting

When compared to Fluzone vaccine prefilled syringe administered in a clinic setting where counseling and documentation is integrated and a concurrent component of the administration process, the administration time saved is an average of 46 seconds per dose. Unlike flu clinics, rather than time saved directly converting to additional doses being administered, the time saved may help to translate into less compressed patient visit time and reduced wait times for patients.

The average primary care physician spends approximately 18 minutes with the patient during a routine encounter. Saving nearly a minute (46 seconds), or close to 5% of the time on an encounter, frees the clinician to attend to other matters such as reducing wait time for the next patient or using the time to address patient education needs beyond influenza.

Conclusion

There is significant opportunity to improve the efficiency of administration of influenza vaccine through the use of Fluzone Intradermal vaccine.

Specifically, when used for flu clinics in the workplace or when offered in medical offices during flu clinic sessions, the time savings can allow up to an additional 23 doses administered every hour. And for medical practices dispensing influenza vaccine during the course of routine visits, the opportunity to reduce patient wait times, decompress visit time, and thereby improve clinical efficiency, is compelling.

While there are concerns that counseling time is greater when administering Fluzone Intradermal vaccine, observations indicate that is primarily true only for patients receiving the product for the first time. While counseling time was essentially the same for patients who had received Fluzone vaccine prefilled syringe for the first time or multiple times, patients receiving a Fluzone Intradermal vaccine for the second time were observed requiring substantially less counseling.

Based on this study, employers and health care professionals that offer influenza vaccines in a flu clinic setting have an opportunity to materially increase the value of their influenza vaccine programs in terms of being able to dispense more vaccine doses without having to add additional time to do so. For clinicians offering influenza vaccines in medical practice settings as part of routine visits, the opportunity to improve the speed at which vaccines are administered can translate to improved efficiency.

**About the Study**

**Purpose and Design**

The purpose of the study was to determine what, if any, time differences existed between administering Fluzone Intradermal vaccine and Fluzone vaccine prefilled syringe.

The study was designed to capture, through the use of time-motion observations, the time involved from the initial ‘hand-on-the-fridge’ to obtain the dose through documenting the administration in the patient’s record.

Two key organizational types were included in the 2013-2014 study, in order to assess the impact on different types of influenza vaccine administration workflow: a medical practice and an employer health clinic. The medical practice selected was Warner Family Practice, a busy office serving a large patient population in Arizona, and the employer selected was the Boston Police Department through its Medical Unit’s Employee Flu Clinic program.

At both organizations, data was collected on the administration of Fluzone Intradermal vaccine through the use of time-motion studies. The data points collected during the time-motion observations included:

1. **Preparation**: Time taken to locate refrigerated dose, open packaging, prepare for injection
2. **Administration**: Time taken to locate the injection site, clean the area, administer the injection and dress the site (if necessary)
3. **Clean up**: Time taken to dispose of empty packaging (if any)
4. **Documentation**: Time taken to appropriately record vaccine administration
5. **Counseling**: Time taken to counsel patient about vaccine and side effects

The data collected from this field study was compared to a similar time-motion study, conducted on Fluzone vaccine prefilled syringe in a retail-based clinic setting during the 2012-2013 flu season. The 2012 study included all 5 components listed above, but note that counseling occurred concurrent with administration. That is, unlike an office visit setting, counseling was not performed as a separate component of the encounter. In comparing the 2012-2013 Fluzone vaccine prefilled syringe retail-based clinic study to the 2013-2014 Fluzone Intradermal vaccine study, the ‘total time’ was used to compare doses administered in the flu clinic, and the practice time without the separate counseling time was used to calculate the time efficiency difference.
Primary Data
Data was collected at Warner Family Practice over the course of 5 days by an observer at its Phoenix, Arizona, location in October 2013. Fifty-one (51) observations were made during that period of approximately 10 health care providers administering influenza vaccines. The average time across all complete observations (including separate documentation and counseling) for Fluzone Intradermal vaccine was 100 seconds or 1 minute, 40 seconds.

Data was collected at the Boston Police Department’s Health Clinic over 3 flu clinic sessions held on different dates during October and November 2013. One hundred ninety-five (195) Fluzone Intradermal vaccine observations were made during that period of 1 provider administering influenza vaccines. The average time across all complete observations for Fluzone Intradermal vaccine was 56 seconds.

Comparative Analysis
The primary data collected on Fluzone Intradermal vaccine administration times was compared to a similar time-motion study conducted by the Verden Group, and performed on Fluzone vaccine prefilled syringe administration in a retail-based clinic (RBC) setting during the 2012-2013 flu season.

That data was collected at 10 RBC locations observing 12 health care providers administering Fluzone vaccine prefilled syringe. During the course of observations, some patients received a flu shot only and some flu vaccines were administered during office visits. The total time for administration of Fluzone vaccine prefilled syringe was 87 seconds or 1 minute, 27 seconds.

Data on the same components of the influenza administration process was collected in both studies. Each clinician administers vaccinations in slightly different ways; therefore some components were performed concurrently - such as counseling and documentation - as doses were administered. However, by normalizing variables across observations and focusing on efficiency metrics, we were able to effectively compare variables affecting efficiency from one study to another.
IMPORTANT SAFETY INFORMATION

Indication
Fluzone Intradermal vaccine is an inactivated influenza virus vaccine indicated for active immunization of persons 18 through 64 years of age against influenza disease caused by influenza virus subtypes A and type B contained in the vaccine.

Safety Information
Erythema, induration, swelling, and pruritus at the injection site occur more frequently with Fluzone Intradermal vaccine than with Fluzone vaccine. Other adverse reactions to Fluzone Intradermal vaccine include pain at the injection site; headache, myalgia, and malaise. Adverse reactions other than those listed above may occur. Fluzone Intradermal vaccine should not be administered to anyone with a known hypersensitivity (eg, anaphylaxis) to any vaccine component, including egg protein, or to a previous dose of any influenza vaccine. If Guillain-Barré syndrome has occurred within 6 weeks of previous influenza vaccination, the decision to give Fluzone Intradermal vaccine should be based on careful consideration of the potential benefits and risks. Vaccination with Fluzone Intradermal vaccine may not protect all individuals.

Before administering Fluzone Intradermal vaccine, please click here for full Prescribing Information.