



Needle-Free Injection™



## PharmaJet Overview & Value

- *History of Needle-Free Jet Injection*
- **Stratis® Needle-free Injector**
- **Why Stratis for Flu Shots?**
- **Regulatory Clearances**
- **Clinical Study Results**
- **User Experience Data – Patients**
- **User Experience Data – Healthcare Providers**
- **Cost/Benefit Comparison**
- **Education & Training Tools**
- **Value of Needle-free for**
  - Pharmacies
  - Public Health Providers
  - Healthcare Institutions

*Colorado Children's Immunization Coalition  
Meeting – January 15, 2015*

**PharmaJet®**

# PharmaJet®

*Needle-Free Injection™*



Needle-Free Jet Injection  
History for Immunization

# Needle-Free Jet Injection - Clinical Efficacy & Safety

## 60 Years of Published Evidence across ~250 studies

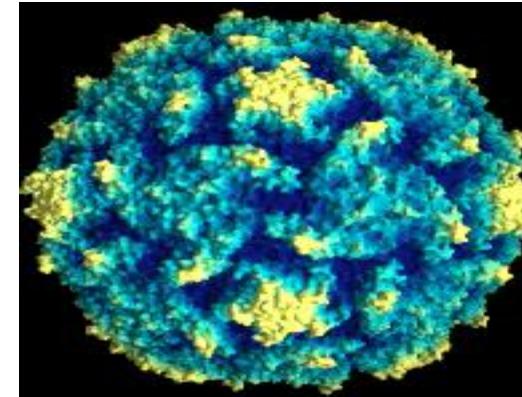
- Delivery by jet injection is equal to or better than needle & syringe as evaluated by immune response
- Increased local site reactions with jet injection; well tolerated

### Inactivated Vaccines:

- Botulism
- Cholera
- DTP
- Hepatitis A
- Hepatitis B
- **Influenza**
- Japanese encephalitis
- Meningococcal A, C
- Polio
- Tetanus
- Typhoid
- Novel: DNA, Peptide

### Live Vaccines:

- BCG
- Measles
- Mumps
- MMR
- Measles-Smallpox
- Rubella
- Smallpox
- Yellow Fever



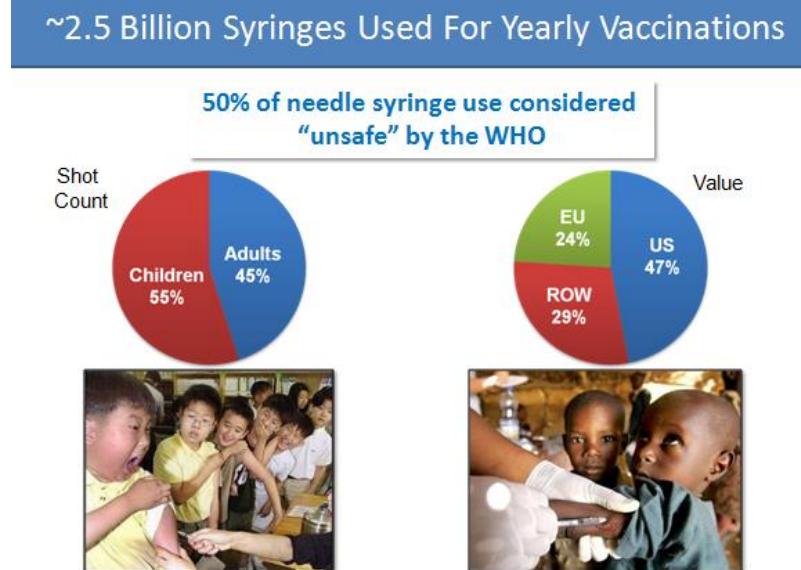
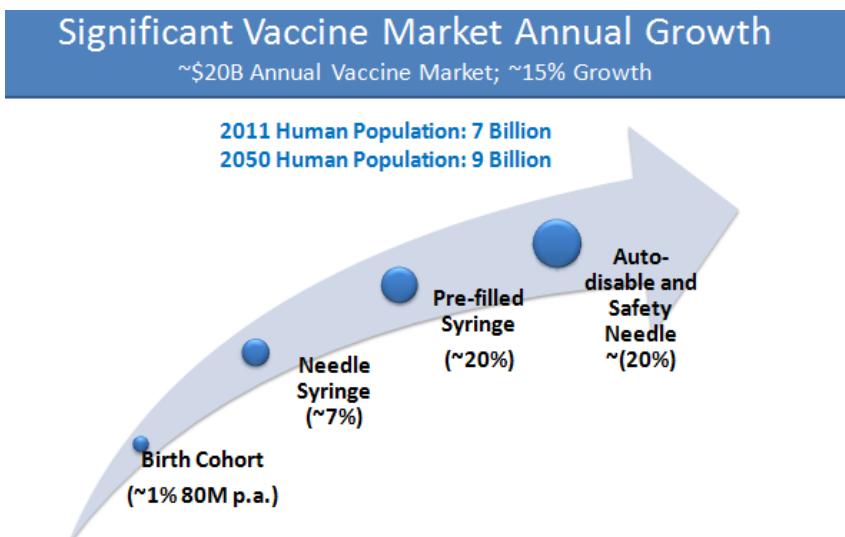
Vaccines, 5th ed. Philadelphia, PA: Saunders (Elsevier); 2008;1357-1392 [ISBN 978 1 4160 3611 1].  
Weniger BG, Papania MJ. Alternative Vaccine Delivery Methods [Chapter 61]. In: Plotkin SA, Orenstein WA, Offit PA, eds.

### ❖ Centers for Disease Control and Prevention – [CDC 2011 General Recommendations on Immunizations](#)

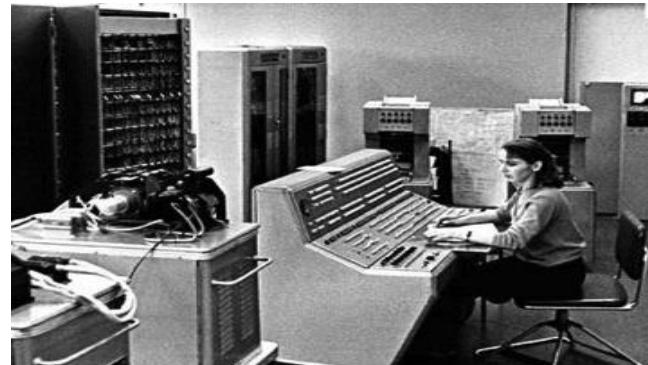
*"Jet injectors prevent needle-stick injuries to health-care providers and can overcome improper, unsterile reuse and other drawbacks of needles and syringes. Immune responses generated by jet injectors against both attenuated and inactivated viral and bacterial antigens are usually equivalent to, and occasionally greater than, immune responses induced by needle injection."*

# Focus: Vaccines

- Large growing global market
- Immunization:
  - Core requirement for healthy populations
  - Least expensive form of preventative healthcare
- Many vaccines under development providing large future opportunity
- Needle stick, re-use, and pass along disease create need for “safe injection”
- 50% of needle syringe use considered “unsafe” by the WHO<sup>3</sup>
- Simple training, safe, consistent delivery



# Needle-Free is not new, but PharmaJet is the “new” Needle-Free



Safe. Easy. No Needle.



PharmaJet's needle-free, single use, auto-disable, spring powered injector passes WHO PQS testing and evaluation, becoming the first needle-free jet injection device cleared for UNICEF procurement for 101 countries (January 2013)

**PharmaJet**

# Global Demonstrated Benefit & Acceptance



## Cambodia Mass Immunization Program:

<http://www.youtube.com/watch?v=8lZ4pbNzUP0>

## Cambodia Healthcare Worker Interview:

<http://www.youtube.com/watch?v=ExwEdTX-udI>

## Kuwait National Immunization Week

[http://www.youtube.com/watch?v=p\\_LUGjrqUpk&feature=youtu.be](http://www.youtube.com/watch?v=p_LUGjrqUpk&feature=youtu.be)

<http://www.youtube.com/watch?v=oKwnAZSw6N0>

Global experiences in clinics, pharmacies, and mass immunization venues have confirmed care-giver and patient utility and preference vs. needle-syringe delivery (usually ~90% prefer PharmaJet)

**PharmaJet®**

# PharmaJet®

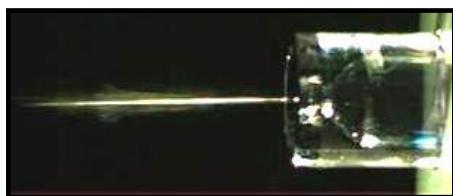
*Needle-Free Injection™*



PharmaJet's Immunization Device

# Stratis® Needle-free Jet Injector

- Safe, easy, cost effective and a better experience for patient and caregiver.



## 0.5mL Intramuscular (IM) Injections



**PharmaJet®**

# Stratis Workflow – Fast & Intuitive

1. Prepare Injector



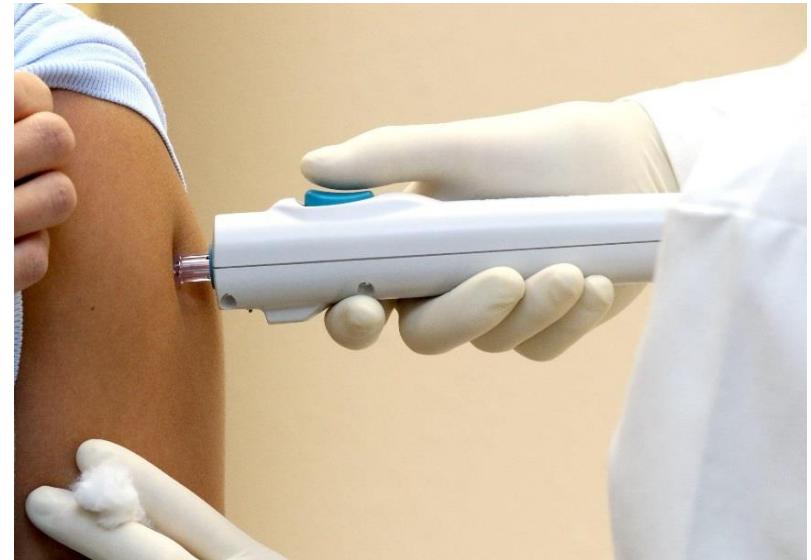
2. Fill Syringe



3. Load Injector



4. Give Injection



- Time competitive with needle-syringe  
<http://pharmajet.com/product/>

Majority of users are self-trained within 20 minutes

# Regulatory Clearances



PharmaJet's Class II medical devices allow for delivery of "various medications and vaccines" under their 510k marketing clearances.



## PharmaJet Quality

## Rigorous Testing Standards

- FDA-registered and listed
- Good Manufacturing Practices
- WHO/PQS Certified
- ISO 13485 QMS compliant
- ISO 21649 Needle Free WW Standard compliant
- ISO 10993, ISO 11737 Single Use, Sterility compliant
- ISO 11607, ISO 11135, and ISO 11137

## *FDA News – August 19<sup>th</sup>, 2014*

Articles

## Pharmajet's Needle-Free Injector Approved by FDA for Delivery of Flu Vaccine

Jet Injector delivers single dose of influenza flu vaccine without a needle!

!

**GOLDEN, Colo. – August 19, 2014 –** Pharmajet<sup>®</sup>, the developer of the needle-free injection technology to administer liquid medications and vaccines to patients, today announced the U.S. Food and Drug Administration (FDA) has approved the **Stratis<sup>®</sup> 10 mL Small Volume Free<sup>®</sup> Injection System** for delivery of flu vaccine.<sup>1</sup> In individuals aged 18 to 64 years.<sup>2</sup>

"Healthcare providers now have the option to deliver flu vaccine without a needle," said Ron Lowy, Pharmajet's CEO and President. "The Pharmajet injection technology is an especially important innovation for the millions of individuals due to needle fear and anxiety. Our products are big improvements to public health through broader immunization and improved access for caregivers and patients."<sup>3</sup>

!

The Occupational Safety & Health Administration (OASH) has more than 800,000 needlestick injuries to healthcare workers estimated to cost more than \$15 billion annually (Fact Review).<sup>4</sup> Pharmajet's needle-free injection technology needlessly avoids the potential cross-contamination, risk and disposal costs.<sup>1</sup>

!

The Pharmajet injector delivers the vaccine by needle-free injection that penetrates the skin in about one tenth of a second. The AFLUFLU<sup>®</sup> flu vaccine from bioCSL throughout the season!!!

## Needle-free jet injection for administration of influenza vaccine: a randomised non-inferiority trial

Line McRae<sup>1</sup>, Jennifer Anderson<sup>1</sup>, Kristen Meltz<sup>1</sup>, Brianne Choi<sup>1</sup>, Karen Capobianco<sup>1</sup>, Nancy Lu<sup>2</sup>, Carolyn Deeney<sup>1</sup>, Daniel P. Patti<sup>3</sup>, Michael J. Bannister<sup>3</sup>

**Summary**

Background Administration of vaccines by needle-free techniques such as jet injection is often preferred to needle and syringe, which results in the need to touch the vaccine, needles and the risk of needlestick injury. We aimed to assess immunogenicity and safety of inactivated influenza vaccine given by needle-free jet injector compared with needle and syringe.

Methods In this randomised, comparative, open-label trial, we randomised 112 healthy adults aged 18 to 64 years to receive a standard dose of inactivated influenza vaccine (0.25 mL) by needle and syringe or by needle-free jet injection (Stratis, Pharmajet, Golden, CO, USA) with needle and syringe. Randomisation was done in a computer-generated randomisation schedule with a block size of 100. Because of the nature of the intervention, the study was not double-blind. The primary outcome was the geometric mean titres (GMTs) of haemagglutination-inhibition (HAI) antibody titres three weeks after the first injection included in the vaccine. We included an explanatory analysis of the primary outcome to assess the safety of the needle-free jet injector. We also performed a post-hoc analysis of the primary outcome to assess the seroprotection rate difference between the two groups.

Results For this unadjusted, comparative trial, we randomised 112 healthy adults aged 18 to 64 years to receive a standard dose of inactivated influenza vaccine in the University of Colorado health system, with stratification by age (18–39 years, 40–64 years, and 65–69 years) and sex. The mean age was 41 years (SD 11) and the mean HAI antibody titre three weeks for the two groups included in the vaccine. We included an explanatory analysis of the primary outcome to assess the safety of the needle-free jet injector. We also performed a post-hoc analysis of the primary outcome to assess the seroprotection rate difference between the two groups.

The mean HAI antibody titre three weeks after the first injection included in the vaccine was 5.3 (95% CI 4.8–5.8) for the needle-free jet injector group and 5.2 (95% CI 4.7–5.7) for the needle and syringe group (mean difference 0.1, 95% CI −0.5 to 0.7, P=0.8). The mean HAI antibody titre three weeks after the first injection included in the vaccine was 1:32 for A/H1N1, 1:32 for A/H3N2, and 1:64 for B/strains. The jet injector group and the needle and syringe group had the same seroprotection rates (95% CIs) for all three strains. The seroprotection rate for A/H1N1 was 95.5% (95% CI 88.0–100.0) for the needle-free jet injector group and 95.0% (95% CI 87.5–100.0) for the needle and syringe group. The seroprotection rate for A/H3N2 was 5.3% (95% CI 0.0–10.6) for the needle-free jet injector group and 5.7% (95% CI 0.0–11.2) for the needle and syringe group. The seroprotection rate for B/strains was 6.6% (95% CI 0.0–13.2) for the needle-free jet injector group and 5.7% (95% CI 0.0–11.4) for the needle and syringe group. We recorded one adverse event in three participants, none of which were related to the vaccine.

The seroprotection rates for all three strains were similar for the needle-free jet injector and the needle and syringe groups. In this trial, needle-free jet injection was as safe as needle and syringe administration of inactivated influenza vaccine given by needle and syringe. The needle-free jet injector may be a safe alternative method of administration of inactivated influenza vaccine.

**Introduction** During the 2012–13 influenza season, the northern hemisphere<sup>1</sup> experienced 150 participants to receive inactivated influenza vaccine (IIV) by needle and syringe. In this trial, we aimed to compare the immunogenicity, with participants with two serous samples were included (75 in the jet injector group and 75 in the needle and syringe group). We also performed a post-hoc analysis of the primary outcome to assess the safety of the jet injector. We also performed a post-hoc analysis of the primary outcome to assess the seroprotection rate difference between the two groups.

The jet injector group and the needle and syringe group had the same seroprotection rates (95% CIs) for all three strains. The seroprotection rate for A/H1N1 was 95.5% (95% CI 88.0–100.0) for the needle-free jet injector group and 95.0% (95% CI 87.5–100.0) for the needle and syringe group. The seroprotection rate for A/H3N2 was 5.3% (95% CI 0.0–10.6) for the needle-free jet injector group and 5.7% (95% CI 0.0–11.2) for the needle and syringe group. The seroprotection rate for B/strains was 6.6% (95% CI 0.0–13.2) for the needle-free jet injector group and 5.7% (95% CI 0.0–11.4) for the needle and syringe group. We recorded one adverse event in three participants, none of which were related to the vaccine.

The seroprotection rates for all three strains were similar for the needle-free jet injector and the needle and syringe groups. In this trial, needle-free jet injection was as safe as needle and syringe administration of inactivated influenza vaccine given by needle and syringe. The needle-free jet injector may be a safe alternative method of administration of inactivated influenza vaccine.

## U.S. Food and Drug Administration Protecting and Promoting Your Health

## FDA Updated Communication on Use of Jet Injectors with Inactivated Influenza Vaccines

Date Issued: August 15, 2014

Audience: Healthcare professionals who administer inactivated influenza vaccines

**Purpose:** The Food and Drug Administration (FDA) is providing updated information to healthcare professionals on the use of the inactivated influenza vaccine, Afluria (manufactured by biotCSL Pty Ltd). On August 15, 2014, FDA approved the use of the Afluria<sup>®</sup> Influenza Vaccine, Intramuscular Inactivated, the Pharmajet Stratis needle-free injection system (manufactured by Pharmajet Inc) for intramuscular injection in adults 18 through 64 years of age. For adults 18 through 64 years of age, Afluria may be administered by intramuscular injection using a needle-free injection system.

FDA continues to recommend that healthcare professionals use a sterile needle and syringe to administer Afluria to persons 18 through 17 years of age and to persons 65 years of age and older.

FDA continues to recommend that healthcare professionals use a sterile needle and syringe to administer other inactivated influenza vaccines.

- **Summary of the Issue**
- **Background Information**
- **Safety and Effectiveness of Afluria Administered with Pharmajet Stratis Needle-Free Injection System**
- **Administration of Afluria to Other Age Groups and Administration of Other Inactivated Influenza Vaccines**
- **Recommendations/Actions**
- **Questions and Answers**
- **Contact Information**

### Summary of the Issue

FDA has approved the administration of the inactivated influenza vaccine, Afluria (manufactured by biotCSL Pty Ltd) for use with the Pharmajet Stratis needle-free injection system (manufactured by Pharmajet Inc) for intramuscular injection in adults 18 through 64 years of age. Afluria continues to be approved for intramuscular injection using a sterile needle and syringe for persons 5 years of age and older.

In the past several years FDA has received questions regarding the use of jet injector devices to administer inactivated influenza vaccines. Inactivated influenza vaccines that are approved by the FDA have information in their labels that healthcare professionals should refer to for information on how to administer the vaccine. For example, with the exception of Afluria, which may also be administered IM with the Pharmajet Stratis Needle-Free Injection System to adults ages 18 through 64, all other inactivated influenza vaccines licensed for IM injection are approved for administration using a sterile needle and syringe only.

bioCSL Pty Ltd

Pharmajet Inc

Stratis

U.S. Food and Drug Administration

U.S. National Institutes of Health

World Health Organization

</div

## PharmaJet

# PharmaJet®

*Needle-Free Injection™*



Needle-Free Market Drivers

# The Economic Burden (and Incentive) Around Influenza

## An Easy Money Saver: the Flu Shot

Pharmacies Offer Them; Health Law Makes Them Affordable

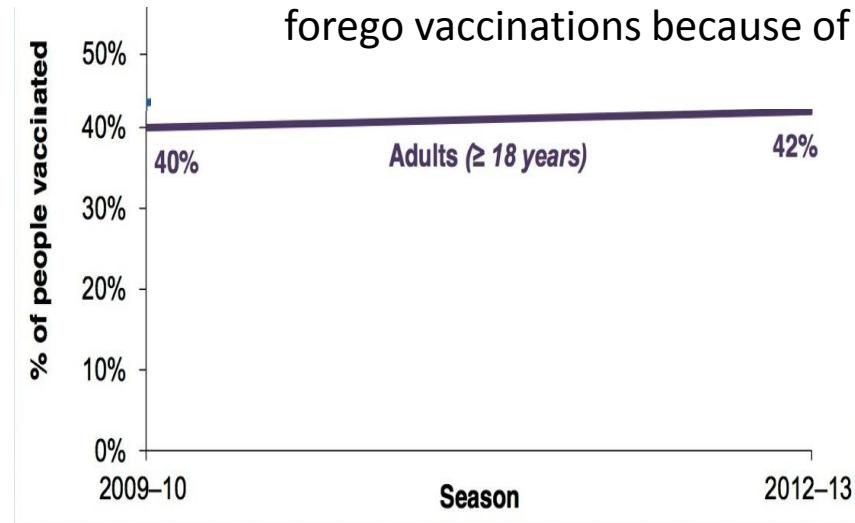


The CDC estimates that the flu costs the U.S. more than \$87 billion a year and results in 17 million lost workdays.

CONFIDENTIAL

# Why Needle-free Jet Injectors for Flu Shots?

- ✧ **CDC:** Recommends all US citizens over 6 months old receive an annual influenza vaccination.
- ✧ **HHS:** *Healthy People 2020* campaign that includes the goal of 70% flu immunization compliance by the year 2020. (90% for HCP)
- ✧ **However, flu immunization rates hover at ~40% for the past 5 years.<sup>1</sup>**
  - The US adult population needs improved delivery options, better access and better convenience for receiving a flu shot.
  - **Needles are a barrier to immunization;** Up to 24% of people forego vaccinations because of an aversion to needle injections.<sup>2</sup>



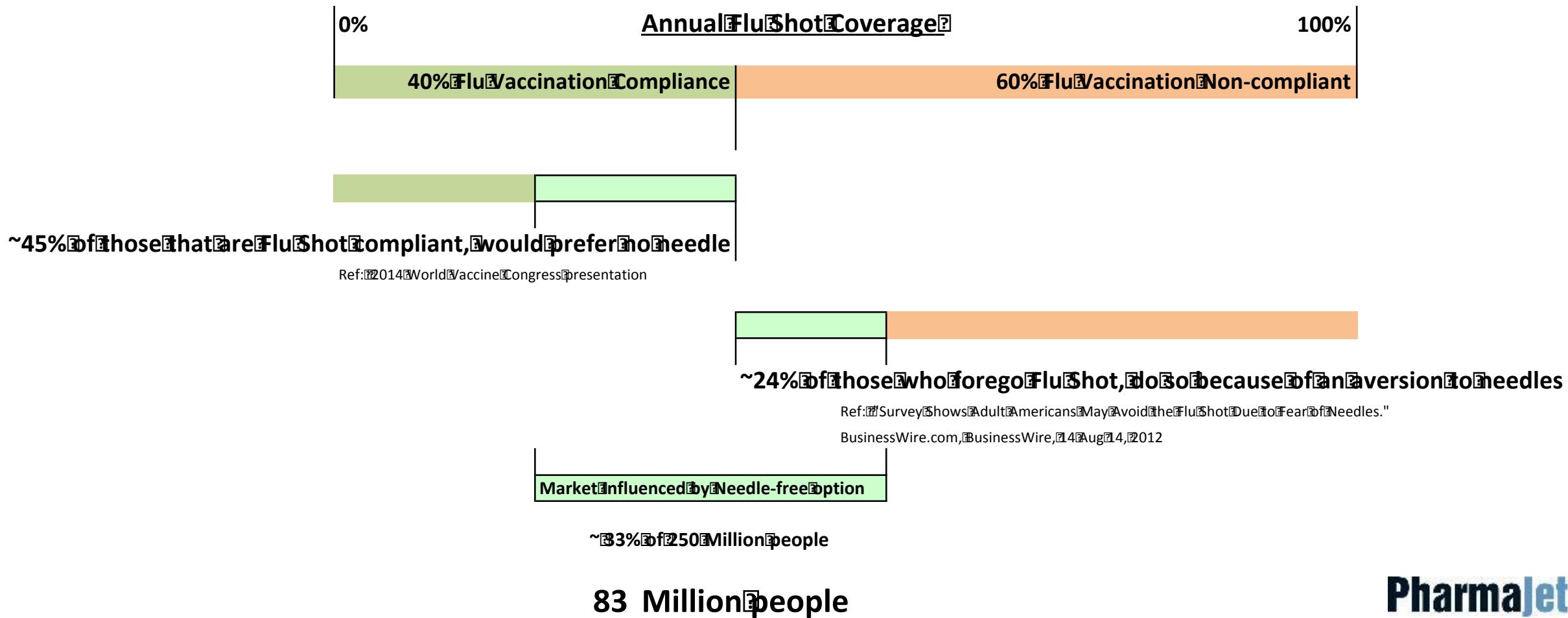
<u>Compliance</u> <u>'13-'14 Flu Season (est.)</u>	
18-49:	24.7%
50-64:	39.2%
>65:	60.4%

- ✧ **PharmaJet can help facilitate increased immunization coverage.**

**PharmaJet**<sup>®</sup>

# Market Opportunity

PharmaJet provides a safe, effective, needle-free option for retail pharmacies focused on attracting new customers



# Value Proposition – Saves Lives and Money



- No needle!
- Single use
- Auto-disabling
- Inherent dose accuracy
- Simple waste disposal (syringe has no needle)
- Minimal dead space

# Value Proposition – Saves Lives and Money



## COST OF NEEDLE INJECTIONS



For healthcare providers, **the cost of administering vaccines goes beyond the price of the needle and syringe.** To provide immunizations, facilities often need to pay for specialty training, sharps management and disposal, and costly testing and treatment for needlestick injuries.



### VACCINATION TRAINING

**\$245–\$345**

per person

The cost per person of the Pharmacy-Based Immunization Delivery class offered by the American Pharmacists Association.<sup>1</sup>



### COST OF NEEDLESTICK INJURIES

**\$3,000+**

per needlestick injury

The cost per needlestick injury, which entails lab and labor fees for testing, counseling and the cost of post-exposure follow-ups.<sup>2</sup>

**\$1.8 Billion**

annually

Annual treatment costs of diseases contracted from needlestick injuries in the United States.<sup>3</sup>

**\$3 Billion**

The total amount of money spent annually on needlestick injuries in the United States.<sup>3</sup>



### SHARPS MANAGEMENT AND DISPOSAL

**\$30**

each container

The disposal cost of one sharps container containing 100 used needles.<sup>4</sup>

**That equals 30 cents per needle disposal cost.<sup>4</sup>**

Large healthcare facilities can spend as much as

**\$89k per year** on

disposable sharps containers alone.<sup>5</sup>

Disposing of said containers can cost up to **\$30k per year.**<sup>5</sup>

**\$10 Billion**

annually

Amount spent by American healthcare facilities on waste disposal each year.<sup>6</sup>



### LABOR COST FOR SHARPS MANAGEMENT

**Up to \$15k**

Labor cost associated with managing an in-house sharps program, which entails:<sup>6</sup>

- Purchasing
- Warehouse
- Environmental Services
- Nursing
- Hazardous Waste Staff
- Handling
- Receiving
- Inventory
- Collection
- Transport
- Packing
- Monitoring
- Distribution

### THE ECONOMIC BENEFIT OF NEEDLE-FREE

Needle-free options like the **PharmaJet Needle-Free Injector** eliminate the possibility of needlestick injuries and reduce sharps management and disposal costs.

# Value Proposition – Saves Lives and Money

Needlestick injuries can expose healthcare workers to over **20 different bloodborne pathogens** including **HIV, hepatitis B virus, and/or hepatitis C virus**.



## CDC estimates rates of seroconversion are:

(development of detectable specific antibodies to microorganisms in the blood serum as a result of injection)

**HepB- 6%-30%** after needlestick injuries

**HepC- 1.8%**

**HIV- 0.3%**



## When do needlestick injuries occur?

**40%** of injuries occur after use and before disposal of sharp devices

**41%** of injuries occur during the use of sharp devices on patients

**15%** of injuries occur during or after disposal



## Who are exposed to needlestick injuries?



15% are Technicians

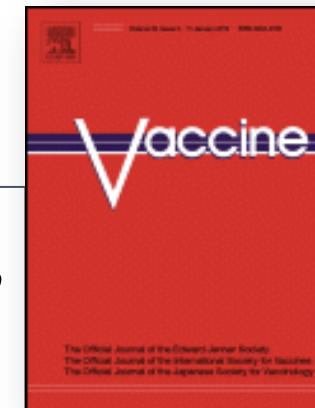
4% are Students, 3% Housekeeping/Maintenance, 1% Dental and 1% Clerical/Admin



- Safe for you and me
- Intuitive
- Cost effective

16,17,18,19,20,21,22

# Needles Contribute to Immunization Non-Compliance



*Survey of the prevalence of immunization non-compliance due to needle fears in children and adults.*

Taddio, A *et al*  
Vaccine, Vol. 30:32, July 2012; 4807-4812

- “Needle fears are a barrier to immunization in children and adults.”
- Surveyed: 1907 children and parents
  - 24% of adults and 63% of children report a fear of needles.
  - Close to 10% of all candidates are non-compliant due to needles.

# PharmaJet®

*Needle-Free Injection™*



Influenza Example:  
Patient Experience & Clinical Confirmation

# Clinical Study Results

## Immunogenicity - *Seroprotection Rate*

28 days post-vaccination

Articles

Needle-free jet injection for administration of influenza vaccine: a randomised non-inferiority trial

John McNamee, Jonathan Anderson, Walter Wertheimer, Roger Tsui, Karen Capell, and Nancy J. Corriveau, David P. Hall, Paul M. Wiedermann, David A. L. Cooper, and Michael J. D. Houghtaling

Summary

Background Administration of vaccines by needle-free technology such as jet injection might offer an alternative to needle and syringe for the administration of vaccines. We conducted a randomised trial in healthy adults aged 18–65 years who attended one of four employee health clinics in the University of Colorado health system, with stratification to site, to receive a single dose of the trivalent inactivated influenza vaccine. Adults given either needle-free jet injection or needle and syringe were injected with a standardised dose of 0.5 mL of the vaccine. The randomisation was done with a computer-generated randomisation schedule with a block size of 100. Because of the nature of the study, informed consent was waived. The primary outcome was seroprotection, defined as a four-fold increase in the antibody titer. Seroprotection was defined three times in series for the three viral strains included in the vaccine. We included six coparticipant sites in the study, and the study was powered to detect a difference in seroprotection rates of 10% between the two groups. The seroprotection rate of the jet injectee group was regarded as noninferior to that of the needle and syringe group if the upper bound of the 95% confidence interval (CI) for the jet injectee seroprotection rate was less than 1.5 times the lower bound of the 95% CI for the needle and syringe seroprotection rate (a difference of 15% in seroprotection rates). We used a two-tail group comparison. This study is registered with ClinicalTrials.gov, number NCT00800201.

Findings During the 2012–13 influenza season of the northern hemisphere, we allocated 1520 participants to receive vaccination by needle-free jet injection (n=762) or needle and syringe (n=758). In the needle-free jet injection group, 98.1% of participants were seroprotected, compared with 97.5% in the needle and syringe group. The immune response to A/H1N1 when given by needle-free jet injection met the criteria for noninferiority. The immune response to A/H3N2 and B strains did not meet the criteria for noninferiority. The seroprotection rate for the A/H1N1, A/H3N2, and B strains upper bound of the 95% CI for the needle and syringe group was 100%, 98.1%, and 97.5% for A/H1N1, A/H3N2, and B strains, respectively. The seroprotection rate criteria for noninferiority for the A/H1N1, A/H3N2, and B strains upper bound of the 95% CI of the seroprotection rate for the needle-free jet injectee group was 98.6%, 97.6%, and 97.0% for A/H1N1, A/H3N2, and B strains. We recorded serious adverse events in three participants, none of which were study related.

Interpretation The immune response to influenza vaccine given with the jet injection device was noninferior to the immune response to the same vaccine given with a needle and syringe, and the jet injection device had a similar safety profile, but was associated with a higher frequency of local injection site reactions than was the use of needle and syringe. The needle-free jet injectee device could be used as an alternative method of administration of adult trivalent influenza vaccine.

Funding Biomedical Advanced Research and Development Authority (BARDA), PATH, Inotech, and Pharmajet.

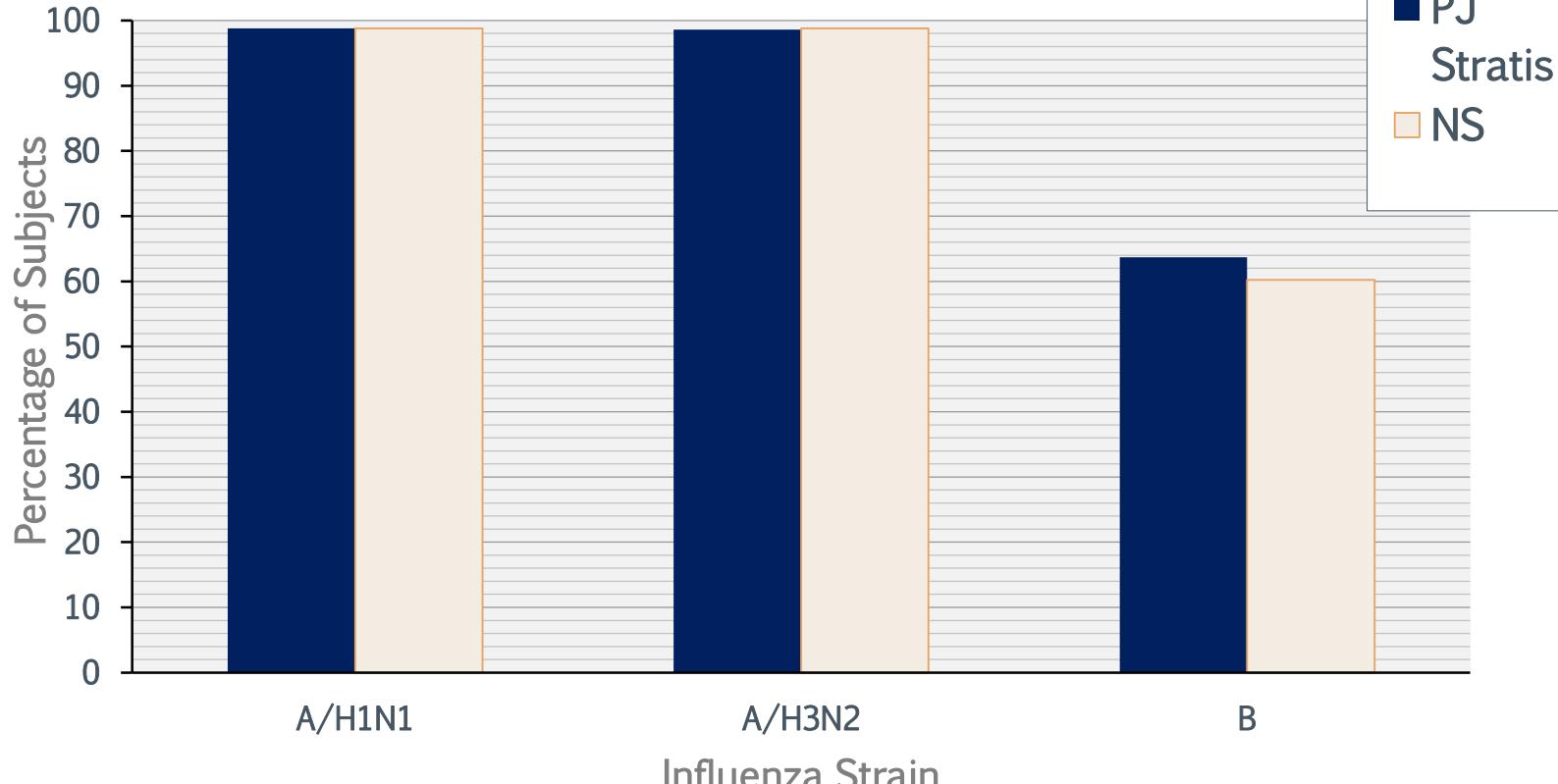
Introduction

Since 2009, the US Centers for Disease Control and Prevention (CDC) Advisory Committee on Immunization Practices (ACIP) has recommended that all healthy adults aged 18 years and older receive an annual influenza vaccine. The ACIP also recommends vaccination for all people in the United States aged 6 months or older who do not have contraindications. Present estimates indicate that approximately 40% of the United States population does not receive an annual influenza vaccine. The reasons for this low vaccination rate are not fully understood, but standard administration carries a risk of needlestick injuries for both patients and healthcare workers.<sup>1</sup>

Needle-free vaccine delivery has the potential to improve safety and stimulate influenza immunogenicity by providing an alternative to needle and syringe for improving safety. Needle-free vaccine delivery has been recommended by the World Health Organization and the Alliance for Vaccines and Immunization.<sup>2,3</sup> The CDC, the American Academy of Pediatrics, and the American Academy of Family Physicians have recommended needle-free vaccine delivery for the prevention of influenza in children.<sup>4</sup> The Pharmajet<sup>®</sup> needle-free jet injection device uses a high pressure source of liquid drug to penetrate tissue and deliver the drug to the desired depth. First developed in

www.bmjjournals.org Published online May 20, 2013. http://dx.doi.org/10.1136/bmjjournals.2012.090484

**PJ Stratis non-inferior to Needle/Syringe;  
Seroprotection Rate Comparable in Both Groups**



**PharmaJet<sup>®</sup>**

# Clinical Study Results

**Articles**

Needle-free jet injection for administration of influenza vaccine: a randomised non-inferiority trial

John McNamee, Jonathan Anderson, Walter Werth, Rongy Chia, Karen Capell, and Noreen J. Conroy, David P. Holt, Paul M. Wadhera, David J. L. Smith, and Michael J. O'Farrell

**Summary**

Background Administration of vaccines by needle-free technology such as jet injection might offer an alternative to standard needle and syringe injection. We conducted a randomised non-inferiority trial to compare the immunogenicity and safety of inhaled influenza vaccine given by needle-free jet injection compared with standard needle and syringe.

Methods We conducted a randomised, non-inferiority trial, in which we randomised 112 healthy adults aged 18-65 years who attended one of four employee health clinics in the University of Colorado health system, with stratification by site, to receive one dose of the trivalent inactivated influenza vaccine. Adults given either needle-free jet injection or standard needle and syringe injection (Plumtree, Golden, CO, USA) received a 0.25-mL dose of inactivated influenza vaccine with a compensated adjuvant cocktail with a stock dose of 100. Because of the nature of the study, immunogenicity was assessed by a central laboratory using a standardised enzyme-linked immunosorbent assay. Adverse events were self-reported three times in series for the three viral strains included in the vaccine. We included six coparticipant assessments of each adverse event, with a minimum of three assessments per participant. The primary outcome was seroconversion rate. The immune response of the jet injector group was regarded as noninferior to that of the needle and syringe group if the seroconversion rate in the jet injector group was at least 90% of the seroconversion rate in the needle and syringe group. The upper bound of the 95% CI for the trivalent seroconversion rate difference was 1.5 times, and the upper bound of the three 95% CIs for the trivalent seroconversion rate difference was 3 times the upper bound of the three 95% CIs for the needle and syringe seroconversion rate difference. We used a 1% two-sided significance level. This study is registered with ClinicalTrials.gov, number NCT00860201.

**Findings** During the 2012-13 influenza season of the northern hemisphere, we allocated 1120 participants to receive vaccination by needle-free jet injection (n=562) or needle and syringe (n=562). In the needle-free jet injection group, 26.2% of participants experienced pain, 16.7% experienced tenderness, 10.1% experienced itching, and 18.1% experienced redness. In the needle and syringe group, 11.1% experienced pain, 5.8% experienced tenderness, 2.7% experienced itching, and 1.8% experienced redness. The difference in the percentage of subjects experiencing pain was statistically significant ( $P < 0.001$ ), as was the difference in the percentage of subjects experiencing tenderness ( $P < 0.001$ ), itching ( $P < 0.001$ ), and redness ( $P < 0.001$ ).

**Interpretation** The immune response to influenza vaccine given with the jet injector device was noninferior to the immune response to influenza vaccine given with standard needle and syringe, but the jet injector device had a different safety profile, but was associated with a higher frequency of local injection site reactions than was the use of needle and syringe. The needle-free jet injector device could be used as an alternative method of administration of adult trivalent influenza vaccine.

**Funding** Biomedical Advanced Research and Development Authority (BARDA), PATH, NACCHO, and Pharmajet.

**Introduction**

Since 2009, the US Centers for Disease Control and Prevention (CDC) Advisory Committee on Immunization Practices (ACIP) has recommended that all healthy adults aged 18 years and older receive an annual influenza vaccine, even for those who do not have contraindications. Present estimates indicate that approximately 40% of the US population aged 18 years and older do not receive an annual influenza vaccine. The main reason for this is that many individuals are afraid of needles and/or are afraid of needles. The needle-free jet injector device may be a high-pressure source of liquid drug to penetrate tissue and deliver the drug to the desired depth. First developed in

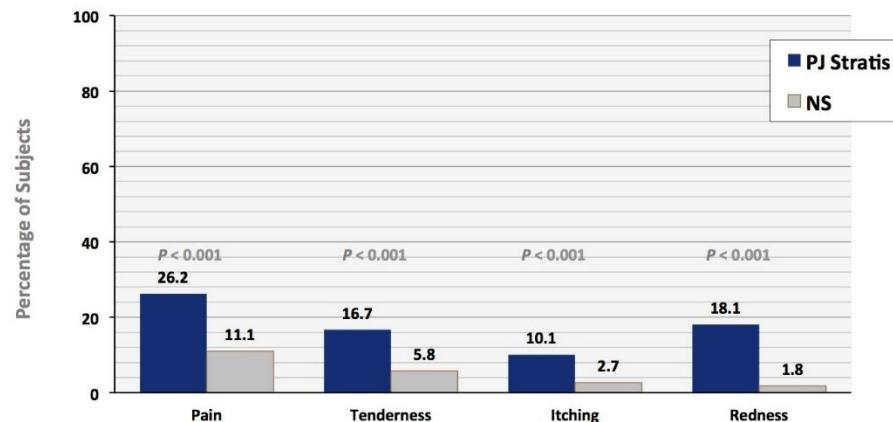
© 2013 The Authors. *Journal of Clinical Pharmacy and Therapeutics* © 2013 Blackwell Publishing Ltd

## Safety

### Immediate Local Reactions ( $\leq 30$ min)

Higher frequency with PJ Stratis, but mild in intensity and well-tolerated

- No bruising noted in either group
- No difference in swelling between groups (both  $< 1.0\%$ )
- All local reactions were only Grade 1 or 2

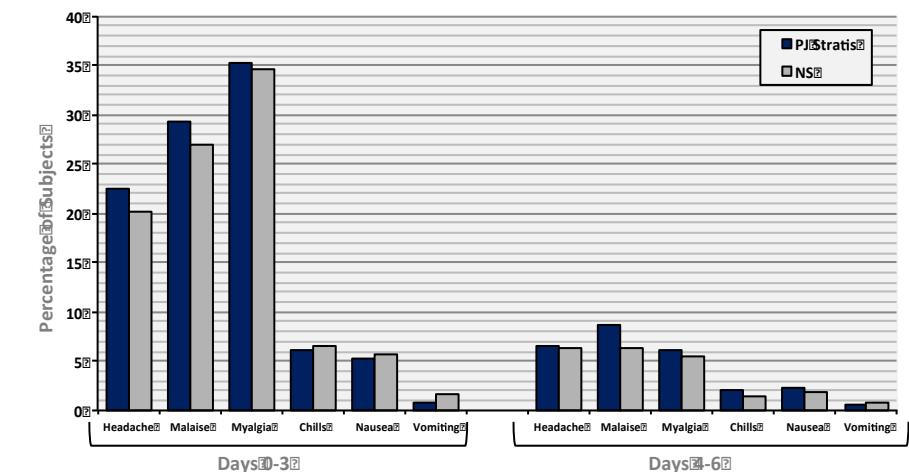


## Safety

### Solicited Systemic Adverse Events

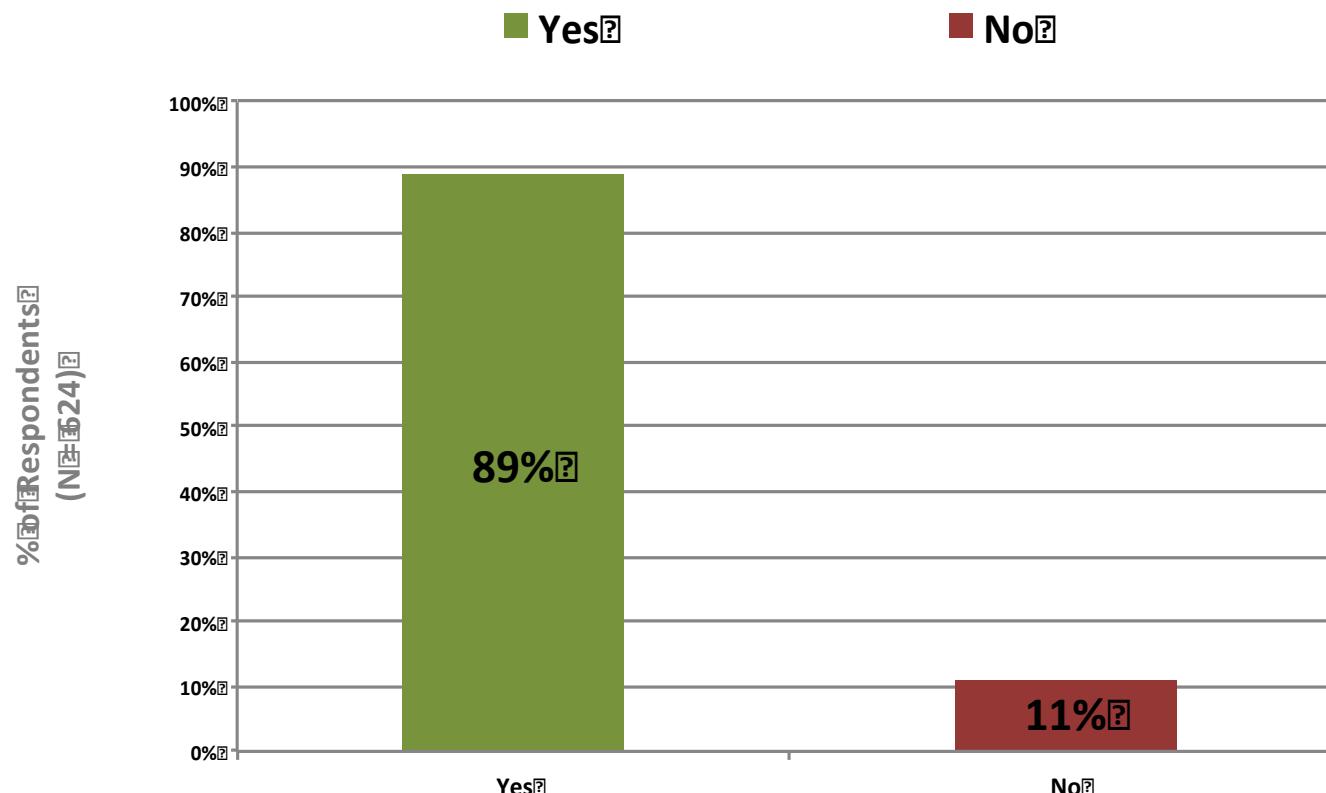
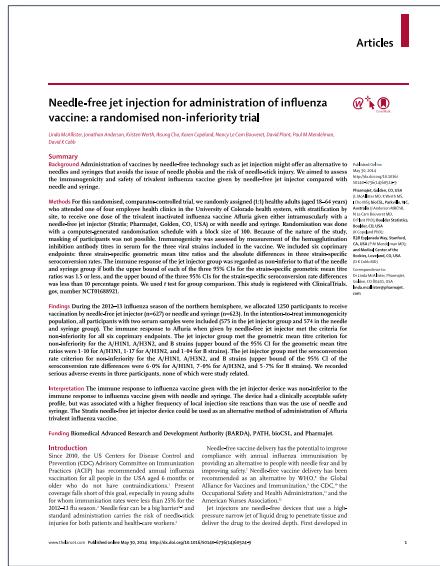
Days 0-3 and Days 4-6

Systemic adverse events were comparable between groups



# Clinical Study Results

Subjects that received a Stratis jet injection were asked  
“Would you choose Stratis for your next injection?”  
(at day 10 post-injection)



# Clinical Study Results

**ACIP** Advisory Committee on  
Immunization Practices



- Podium Presentation at October ACIP meeting - October 29, 2014
- 30 minute update on PharmaJet Injector use with bioCSL *Afluria*
- JIFI study results; regulatory status; user preference data
- Very positive visibility and credibility for PharmaJet non-inferiority and safety

*“PharmaJet can help facilitate broader immunization compliance”*

**PharmaJet**<sup>®</sup>

# User Experience Data – Patient Feedback



**FLU SHOT DAY**  
OCT. 9, 2014 | 9:00 AM - 3:00 PM  
Madison Plaza Lobby

# FLUZILLA

WILL YOU BE READY?

For all UTHSC students, employees, post-docs, residents, & retirees.  
Produced by: University Health Services, College of Pharmacy, the Office  
of Student Life, APhA-ASP, & the SGAEC.

Featuring traditional Fluviron trivalent & needleless, jet injector Afluria vaccine.

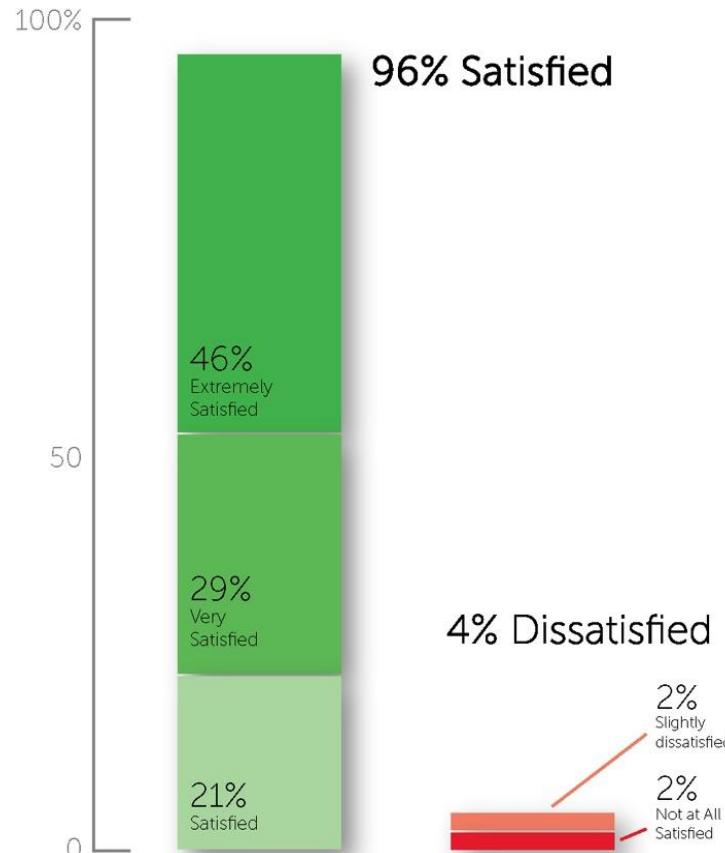




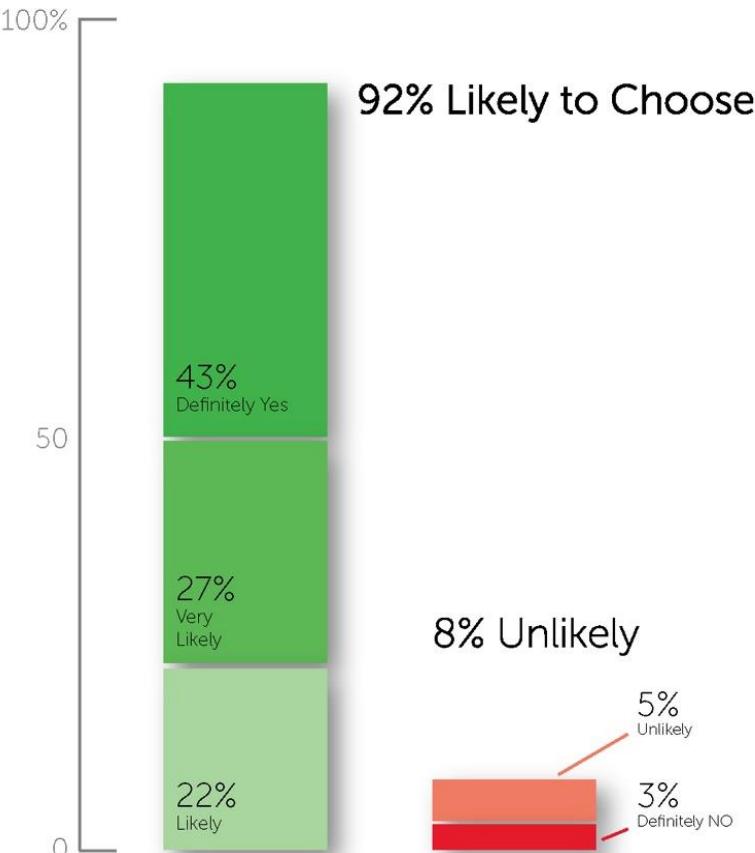
## 500 Needle-free injections – Oct. 2014



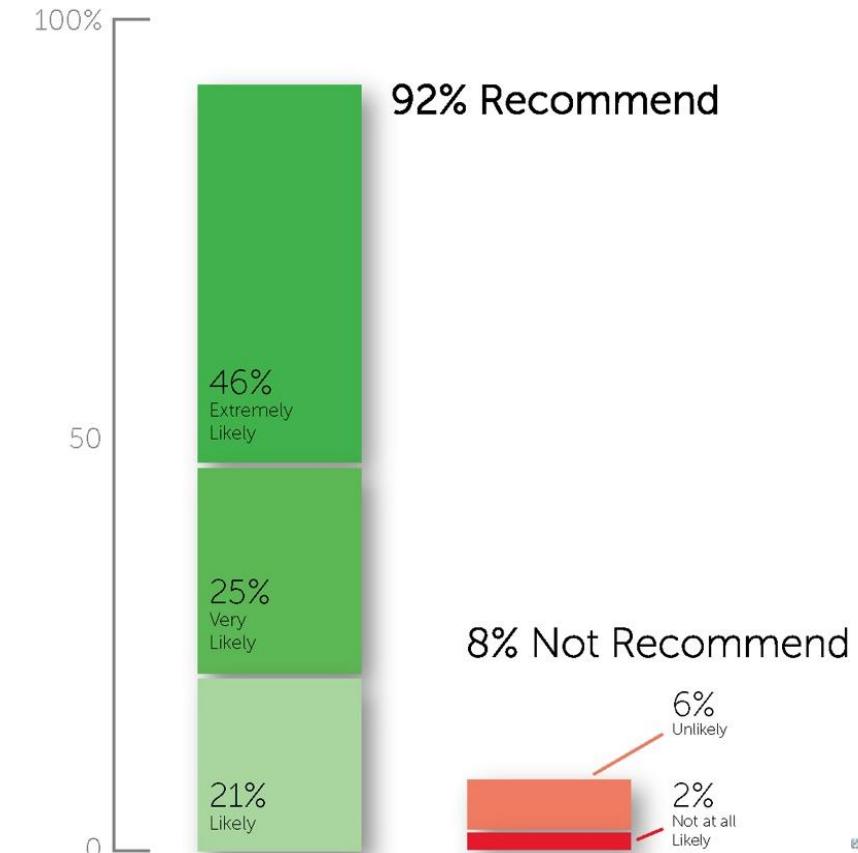
How satisfied were you with today's Needle-Free Flu Shot?



For next year's flu vaccination, will you choose to receive your flu shot with a Needle-Free Injection?



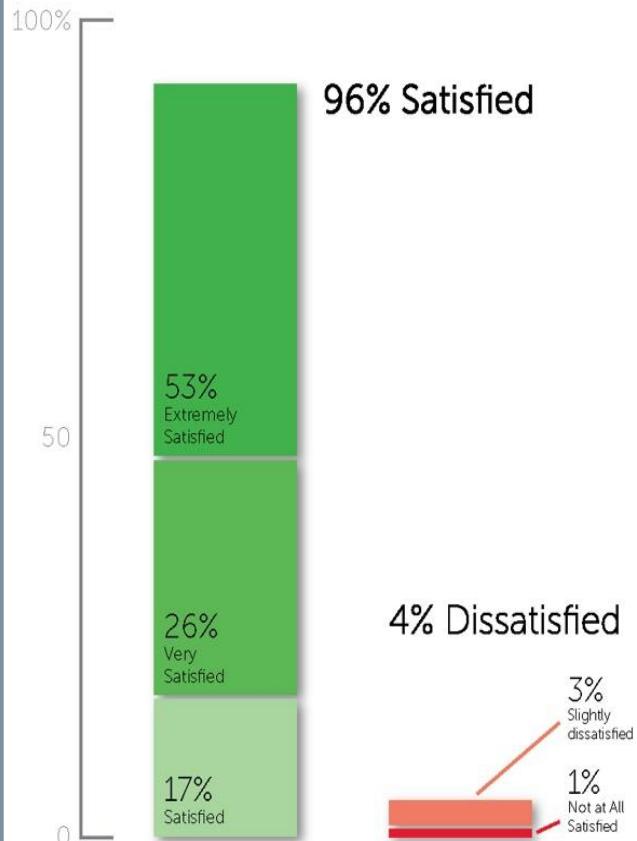
How likely are you to recommend a Needle-Free Flu Shot to family and friends?



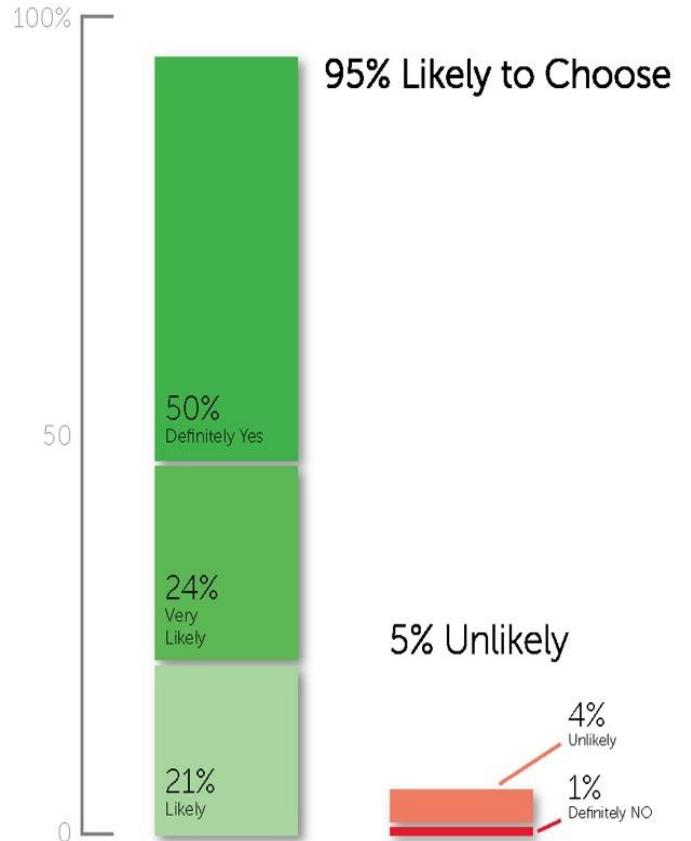
## 699 Needle-free injections – Nov. 2014



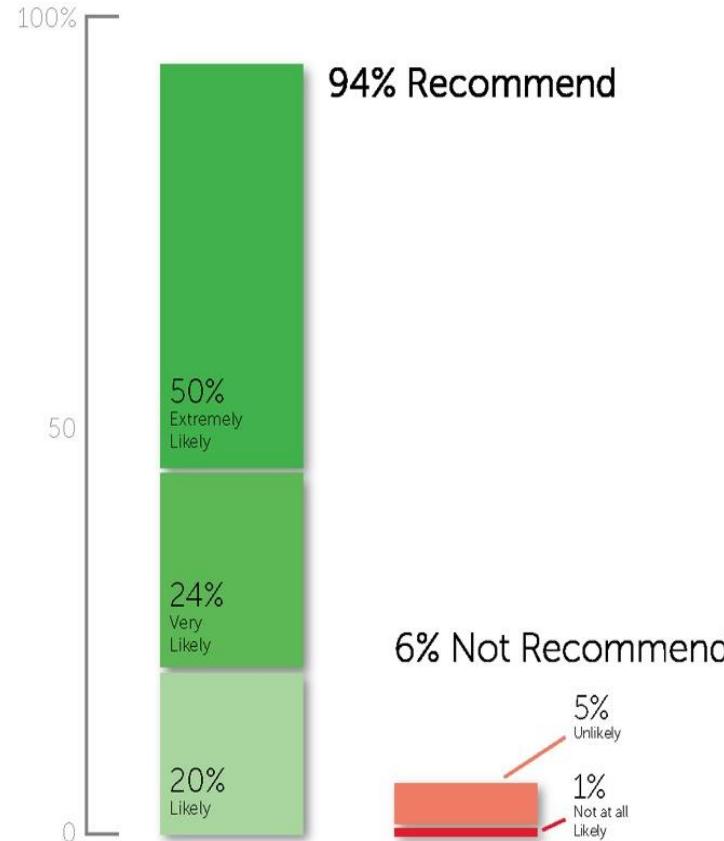
How satisfied were you with today's Needle-Free Flu Shot?



For next year's flu vaccination, will you choose to receive your flu shot with a Needle-Free Injection?



How likely are you to recommend a Needle-Free Flu Shot to family and friends?

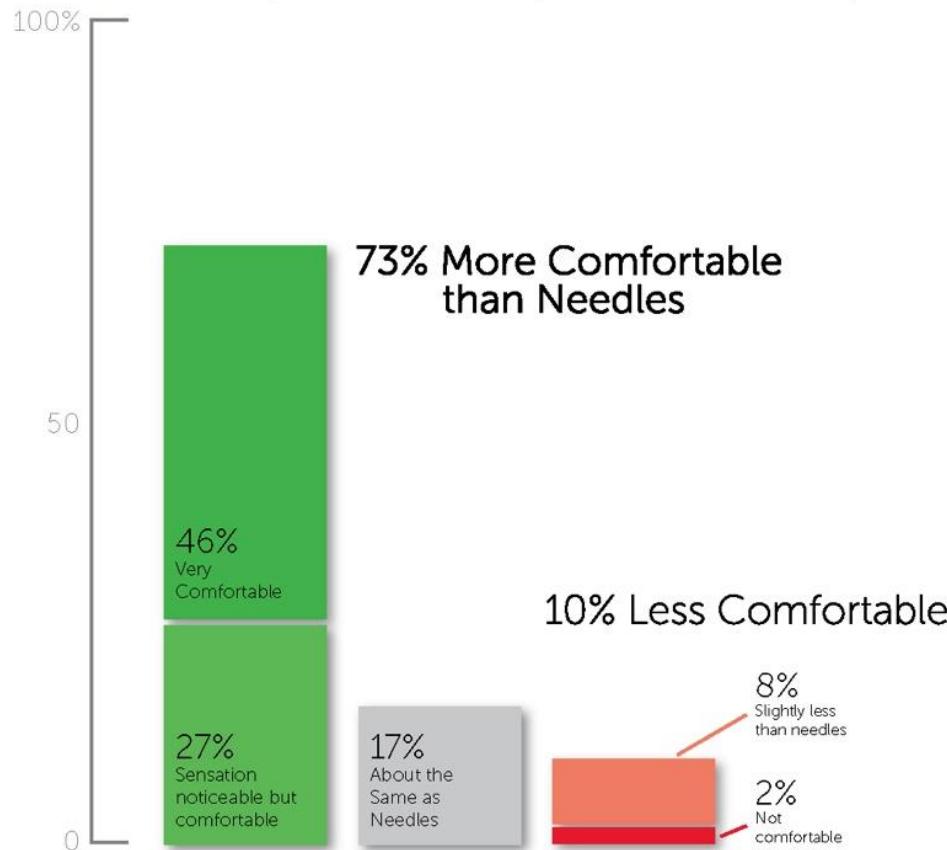


New Jersey Public Health, November, 2014

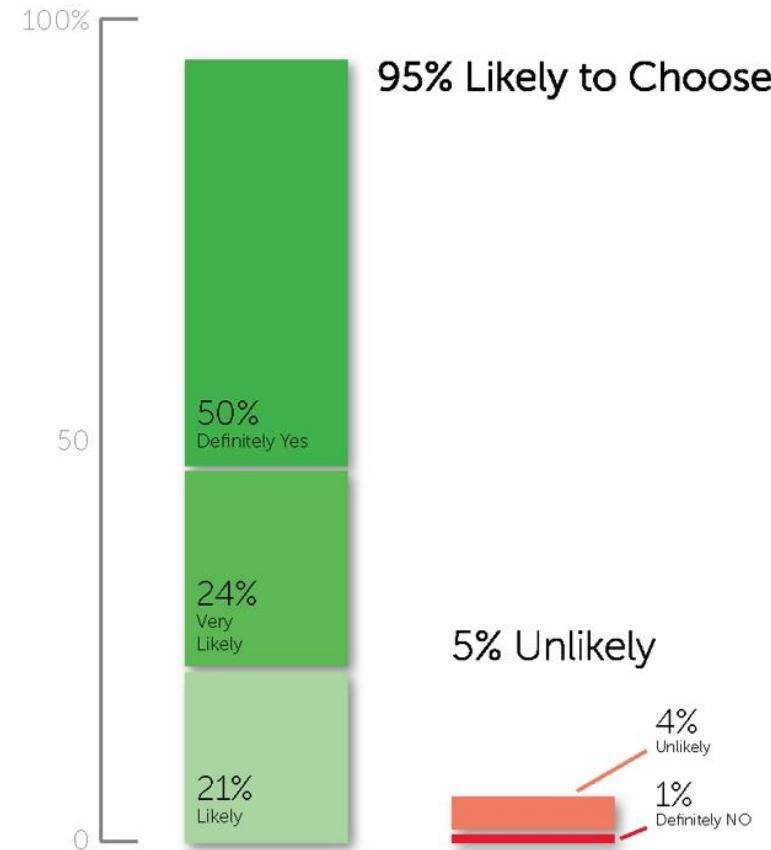
## 699 Needle-free injections – Nov. 2014



Considering all factors, compare how comfortable today's Needle-Free Injection was versus your previous needle injections.



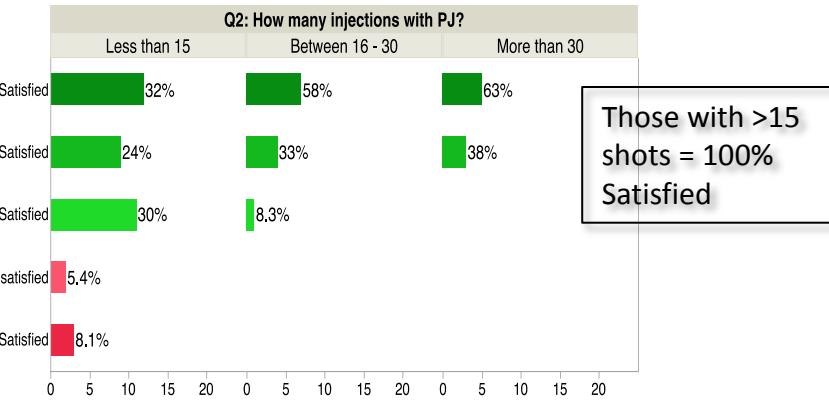
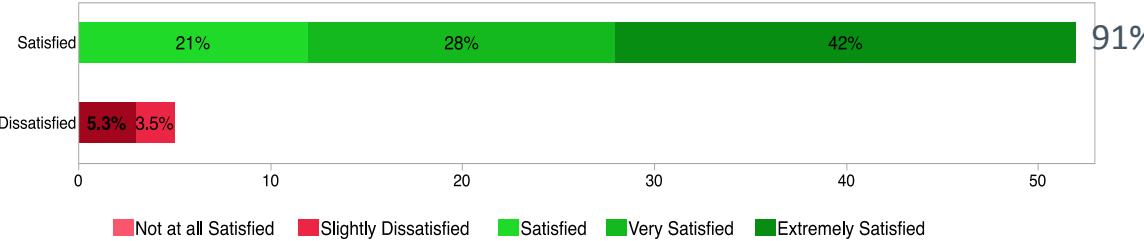
For next year's flu vaccination, will you choose to receive your flu shot with a Needle-Free Injection?



# User Experience Data - Healthcare Providers

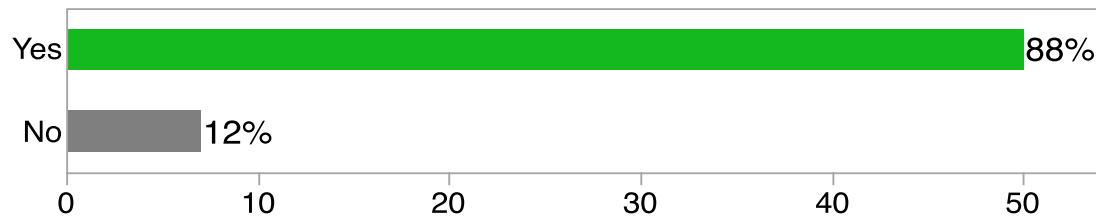
91%  
Satisfied

## How satisfied were you with the Ease of Use?



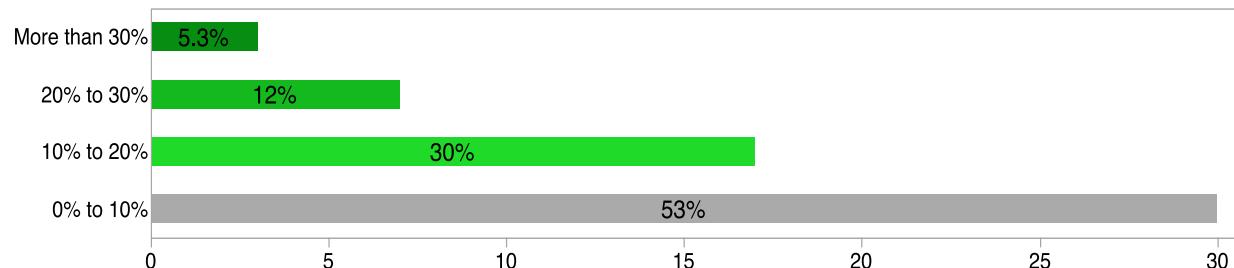
## For next year's flu vaccinations, would you like the option of Needle-Free Shots at your facility?

88% Want  
Needle-Free



## How much could your flu vaccinations increase next year by offering the option of a Needle-Free Flu Shot?

~50% believe  
immunization  
rates could  
increase >10%



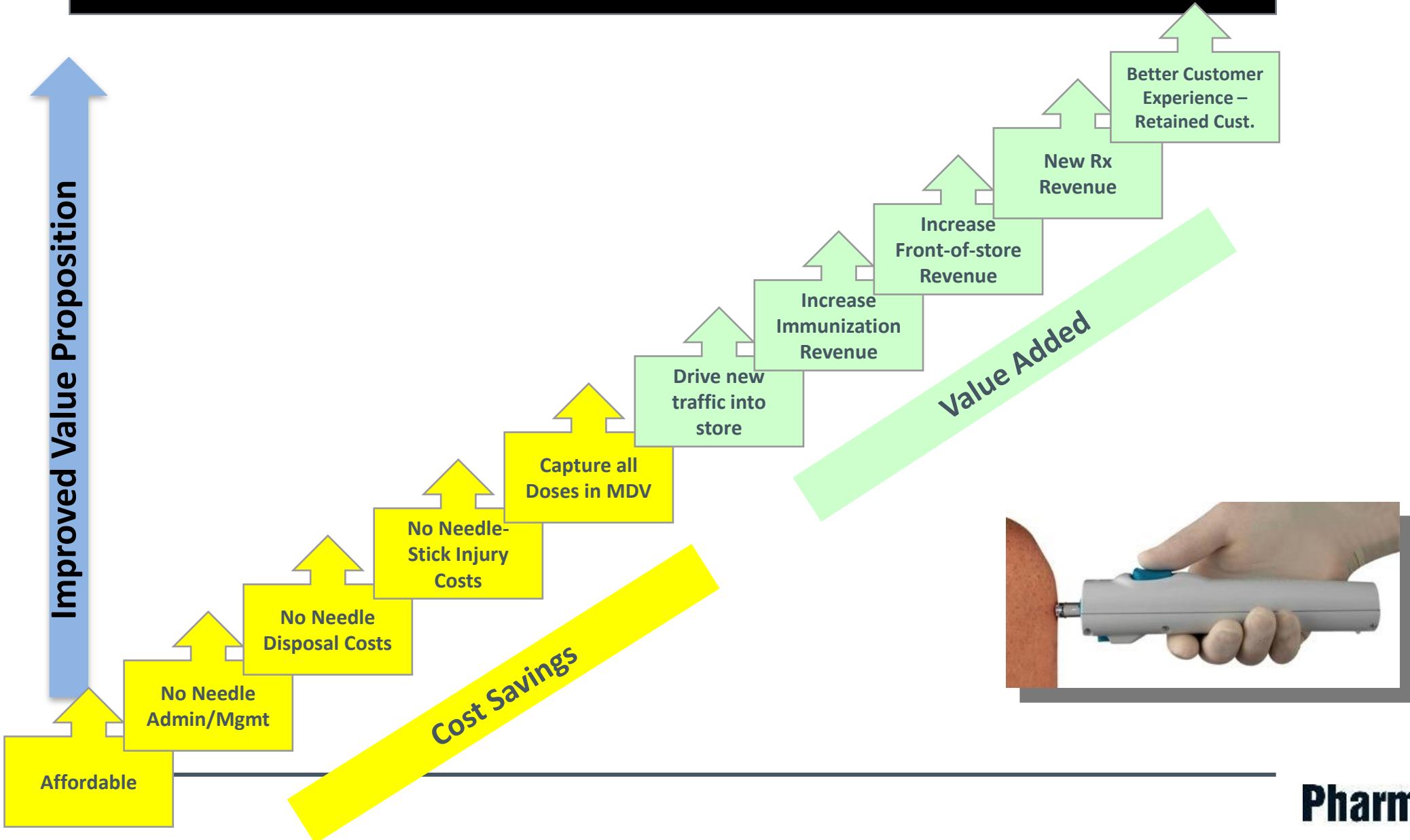
# PharmaJet®

*Needle-Free Injection™*



Demonstrated Benefits

# Cost/Benefit Analysis



# Summary

## PharmaJet Needle-free Flu Shots

### 1. Product addresses market need

- › Problem = needles; Solution = Needle-free

### 2. Optimized Features and Benefits

- › *Stratis* design launched and field validated

### 3. Regulatory Clarity

- › FDA 510k clearance; And, specific labeling on *bioCSL Afluria* flu vaccine

### 4. Positive Clinical Results – safety and immunogenicity data

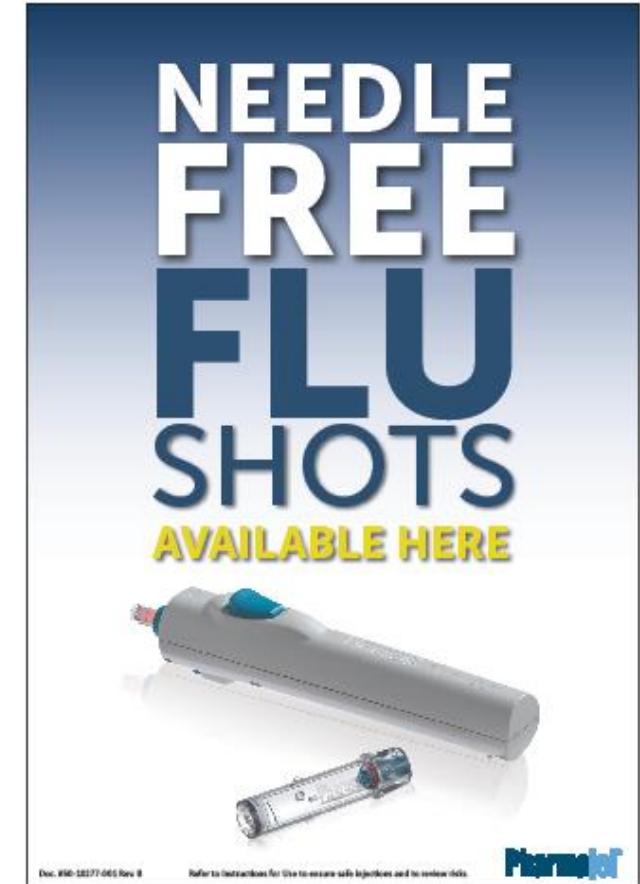
- › Published in August 2014 issue of The LANCET

### 5. Overwhelmingly positive user experience data – 2014 flu season

- › Patients and Healthcare Providers desire the *Stratis* Injector

### 6. Value added for User

- › Optimized product offering for best customer experience
- › Financial benefits flow through (no sharps, compliance, dose savings, cost savings)



**PharmaJet**

# Overall Value of Needle-Free Injections

**PharmaJet provides a safe, effective, needle-free option for retail pharmacies, public health, and large hospital system users**

## **1. Expands customer choices** - providing patients with the most accessible care

- Expands offering of vaccine and delivery options

## **2. Inspires patients to seek out immunization** - with differentiation of offering vs. needles

- Creates excitement with a distinctive and innovative offering – word of mouth may contribute to more people being vaccinated
- Addresses those that avoid immunization due to needles, but understand the importance or need for influenza immunization (first responders/public task employees, healthcare workers, hospital administrative and technical staff, and their family members)

## **3. New customers equate to measurable incremental sales**

- Fosters conversations between pharmacy staff interaction and customers – new customers and increased purchase of other products

## **4. Safer Work Environment for Pharmacy Employees and Community**

- Herd immunity (greater immunization range) has proven positive economic impact
- Reduces needle-stick and pass along disease, testing, and disposal costs related to mass or high-volume immunization settings

## **5. Unique Positioning/Marketing/Advertising Opportunities**

- Potential to offer unique solutions to today's healthcare challenges
- Positions provider as an innovator offering new and safe alternative to needles



# Economic Value-Added for Pharmacies

- **Drive New Traffic into Stores**
  - Innovative Offering Attracts New Customers from Competition
- **Increased Immunization Revenue \$**
  - Vaccination Services Increased; Matches Pharmacy Corporate Focus
- **Increased Front-of-Store Revenue \$**
  - Larger Spend per Customer Store Visit
- **New Rx Script Customers**
  - New Customers that become long-term customers for prescriptions
- **Better Customer Experience**
  - Retained Customer
  - Pharmacy Staff-to-Customer Interaction yields 59% rate of purchasing a non-Rx products



# Educational Support



## ➤ **Informational** ([www.pharmajet.com](http://www.pharmajet.com))

- Videos
  - Pharmacist demonstration
  - Workflow comparison vs. needle & syringe



## ➤ **Self-Training**

- User Guide - Laminated workflow demonstration guide
- Educational Video - System components & workflow
- Webinar - Pre-recorded video with assessment tollgates
- Frequently Asked Questions
- Starter Kit (shipped with each hardware set)
  - Self-guided review of IFU and User Guide
  - Login registration as new user on website
  - Self-guided tour through Educational Roadmap

## ➤ **PharmaJet conducted training** (On demand)

- WebEx – individual and/or group hands on with Q&A
- On-Site Training
  - Train the Trainer
  - Initial implementation at stores/sites

**PharmaJet**®

# References

1. PharmaJet Inc., McAllister (2013) "PJ-501-12 Jet Injection For Influenza - Clinical Study Report", internal company report, December 2013.
2. Hiller A. Vaccines continue to bolster pharma market. PharmPro. December 2, 2010. Need WHO Reference, <http://www.pharmpro.com/articles/2010/12/business-Vaccines-Continue-to-Bolster-Pharma-Market/>
3. "Unsafe Injections in the Developing World and Transmission of Bloodborne Pathogens: a review"; L. Simonsen, A. Kane, J. Lloyd, M. Zaffran, and M. Kane. Bulletin of the World Health Organization : the International Journal of Public Health 1999 ; 77(10) : 789-80; <http://apps.who.int/iris/handle/10665/56699> [http://www.who.int/features/2013/vaccine\\_prelqualification/en/](http://www.who.int/features/2013/vaccine_prelqualification/en/)
4. PharmaJet, Inc. (2014) "61-10191 Post Market Surveillance – New Jersey Public Health Flu Campaign", internal company report, November 2014.
5. PharmaJet, Inc. (2014) "61-10190 Post Market Surveillance – University of Tennessee Flu Campaign", internal company report, November 2014.
6. "Pharmacist Immunizers Fill an Essential Public health Role." Lamb, Edward. About.com. Web. <<http://pharmacy.about.com/od/Certification/a/Pharmacists-Immunizers-Fill-An-Essential-Public-Health-Role.htm>>.
7. "Pharmacy-Based Immunization Delivery (APhA2014)." Pharmacist.com. N.p., n.d. Web. <<http://elearning.pharmacist.com/products/1393/pharmacy-based-immunization-delivery-apha2014>>.
8. "Needlestick Injuries Are Preventable Events." *Needlestick Injuries Are Preventable Events*. Healthcare Risk Management Review, 09 May 2013. Web. < <http://www.hrmronline.com/news/needlestick-injuries-are-preventable-events>>.
9. "Competition Comparison." *StingerSHIELD*. N.p., n.d. Web. <<http://stingershield.com/CompetitionComparison.pdf>>.
10. "BD Sharps Disposal by Mail Worry Free Needle Disposal." [amazon.com](http://www.amazon.com). Web. <<http://www.amazon.com/Sharps-Disposal-Mail-Worry-Needle/dp/B001IKKHF4/ref=sr>>.
11. "Minimizing Regulated Medical Waste." Yeshnowski, Marcy. Tetra Tech EM Inc. Web. <[http://wsppn.org/pdf/hospital/04\\_2%20Minimizing%20RMW\\_AZ.pdf](http://wsppn.org/pdf/hospital/04_2%20Minimizing%20RMW_AZ.pdf)>.
12. "Saving Sharps, Saving Money: Recycling Medical Waste." McInerney, Mike. Earth 911. October, 26, 2011. Web. < <http://earth911.com/news/2011/10/26/saving-sharps-saving-money-recycling-medical-waste/>>.
13. "Lancet", <http://www.ncbi.nlm.nih.gov/pubmed/24881803> [http://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(14\)60524-9/abstract](http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(14)60524-9/abstract)
14. Gallup's annual Honesty and Integrity Survey – <http://campaignforaction.org/community-post/2013-gallup-poll-nursing-most-trustworthy-profession>
15. JD Power: Source: J.D. Power 2014 U.S. Pharmacy StudySM
16. "Safer Needle Devices: Protecting Health Care Workers." *OSHA.gov*. OSHA, n.d. Web. <<https://www.osha.gov/dte/library/bloodborne/saferneedledevices/index.html>>.
17. "Sharps Safety Workbook." *CDC.gov*. The Center for Disease Control and Prevention, n.d. Web. <<http://www.cdc.gov/sharpssafety/pdf/WorkbookComplete.pdf>>.
18. "Cost of Needle Stick Injuries." *LeEject.com*. LeEject Syringe & Needle, n.d. Web.
19. <[http://www.leeject.com/Download/LeEject\\_Appendix3.pdf](http://www.leeject.com/Download/LeEject_Appendix3.pdf)>.
20. "Needlestick Injuries Are Preventable Events." *Needlestick Injuries Are Preventable Events*. Healthcare Risk Management Review, 09 May 2013. Web. <<http://www.hrmronline.com/news/needlestick-injuries-are-preventable-events>>.
21. "Frequently Asked Questions - Needlesticks." *OSHA.gov*. OSHA, n.d. Web.
22. <<https://www.osha.gov/needlesticks/needlefaq.html>>.
23. Vaccines, 5th ed. Philadelphia, PA: Saunders (Elsevier); 2008;1357-1392 [ISBN 978 1 4160 3611 1]. Weniger BG, Papania MJ. Alternative Vaccine Delivery Methods [Chapter 61]. In: Plotkin SA, Orenstein WA, Offit PA, eds.
24. Economic value of vaccination programs. <http://www.ncbi.nlm.nih.gov/pubmed/12583457>