# Effect of Aspiration and Non-Aspiration of Syringe prior to Intramuscular Administration of Influenza Vaccine in Pain Perception of Children 9 to 15 Years of Age Consulting at the Out-patient department of a Tertiary Government Hospital

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## ABSTRACT

**Objective:** To determine the effect of aspiration and non-aspiration of syringe prior to intramuscular administration of influenza vaccine in pain perception of children 9 to 15 years of age consulting at the Out Patient Department of a Tertiary Government Hospital

**Design:** Randomized controlled clinical Trial

**Setting:** Out Patient Department of a Tertiary Government Hospital

**Participants:** One-hundred twenty children 9 to 15 years old consulting at the Out Patient Department

**Methodology:** Subjects were randomized into two groups and were given influenza vaccine with and without aspiration prior to intramuscular injection.

**Outcome Measures**: Primary outcome measure is the degree of pain experienced by the subject using the Numeric Rating Scale.

**Results:** A total of one hundred twenty children were randomized to either Group A or Group B. IBMSPSS version 21 was used as statistical software. Differences in mean heart rate at baseline and after the intervention within group is significantly different (p value < 0.01). Mean heart rate in between group at baseline and after administration of influenza vaccine is not significantly different ( p value >0.05). The difference in mean oxygen saturation at baseline and after immunization within group is significantly different. Mean oxygen saturation between group pre and post immunization is not statistically different (p value 0.309). Analysis showed there is a significant difference in mean pain scores between Group A and Group B ( p value 0.046)

**Conclusion**: This study showed a statistically significant lower pain score for Group A (without aspiration) than Group B (with aspiration). The physiological pain responses, used as outcome measures in this study did not have significant differences between two groups. The result of this study will unleash in health care professionals the burden on whether or not to aspirate before intramuscular administration of vaccine.

**Keywords:** *aspiration, non-aspiration, influenza vaccine, pain assessment, intramuscular injection*

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## INTRODUCTION

Acute pain is one of the most common adverse stimuli experienced by children, as a result of injury, illness, and medical procedures like drug administration and immunizations.[1] In any country, immunization in the pediatric population is essential as it decreases the morbidity and mortality of vaccine-preventable diseases.[2] However, pain associated with immunization can lead to pre-procedural anxiety, needle fears, healthcare avoidance behaviors, and noncompliance with vaccination schedules.[3]

Accurate assessment of acute pediatric pain can help dispel myths that children's pain is less severe than that of adults, aid medical staff and clinicians in accurately diagnosing and treating children's pain, and allow researchers to investigate pain and its correlates.[4]

Pediatricians are responsible in alleviating the pain and suffering of children. In order to achieve these goals, pediatricians need to expand their knowledge, use appropriate assessment tools and techniques, anticipate painful experiences and intervene accordingly.[1] A number of strategies are available to diminish pain associated with immunization like procedural interventions (injection techniques), physical interventions (body position and activity), pharmacologic interventions (pain medicine), or even process intervention.[3]

The guidelines to aspirate prior to an intramuscular injection were originally recommended for reasons of safety, to avoid the inadvertent injection of vaccine material intravenously instead of intramuscularly. The lack of reported publication might suggest that aspiration is effective.[5] However, the US Advisory Committee on Immunization Practices (ACIP) does not make any recommendations on aspiration during vaccination.[6]

Despite the many recommendations, not all clinicians adopt to such strategies hence more studies were contemplated to support these guidelines. This paper seeks to answer the question: What is the effect of aspiration and non-aspiration of syringe before intramuscular administration of influenza vaccine in pain perception of children nine to fifteen years of age consulting at the Outpatient Department of a Tertiary Government Hospital.

### REVIEW OF RELATED LITERATURE

In order for a clinician to manage childhood pain, he/she should be able to assess pain accurately. A child's pain may depend on the child's capability to express their pain. It is also based on a child's age, experience and their changes throughout their developmental changes. Studies have shown that self -report visual analogue and numerical scales are effective pain assessment tools in children and adolescents.[7]

Several studies to reduce pain associated with immunization have been cited. Se Na, Joohyun, et al, showed significantly lower pain scores in children when EMLA was applied prior to venipuncture procedures. The study concluded that the pain scale were significantly lower in the experimental group (EMLA) compared to those in the control group (Placebo) as determined by three rating scale which include the Faces Pain Rating Scale ($p=0.008$), the Procedure Behavior Checklist ($p=0.001$), and the Visual Analogue Scale (VAS) ($p=0.006$). However, the changes in the children's pulse rate and oxygen saturation were not significantly different between the two groups. Nevertheless, the pulse rate and oxygen saturation of the experimental group were more stable during the time of the injections.[8]

A randomized placebo-controlled clinical trial done among pre-school children in Cabiao, Nueva Ecija compared the effectiveness of ice gel compress for five and ten minutes with topical Lidocaine – Prilocaine cream in reducing pain associated with Diphtheria-Pertussis-Tetanus (DPT) vaccination. The study showed that lidocaine-prilocaine was not significantly different between ice gel compress at 5 minutes and ice gel compress at 10 minutes (p values $> 0.300$). Ice gel at 10 minutes has statistically significant lower pain scores compared with the ice gel at 5 minutes ($p$ value$=0.015$).

The placebo group has significantly higher pain score compared to the three other treatment groups (p values $<0.001$). Lidocaine-prilocaine and ice gel compress at 10 minutes are not significantly different. Ice gel compress at 5 minutes and placebo are not statistically different. Lidocaine-prilocaine and icegel compress at 10 minutes are significantly different with the placebo and ice gel compress at 5 minutes (p values $< 0.001$). There was statistically significant difference in the increase in heart rates ($p$ value $= 0.0134$) and reduction of O2 saturation ($p$ value $= 0.0109$) among treatment groups.[9]

In 2014, Girish, Ravi, et al conducted a randomized controlled trial among 200 infants 6 weeks to one and half years of age receiving routine intramuscular vaccination. They were randomly assigned by computer-generated random numbers into 'Standard group' receiving immunization using standard slow technique with aspiration and 'Pragmatic group' receiving immunization using "pragmatic" technique without aspiration. The entire vaccination procedure was videotaped. Videos were scored for pain using Modified Behavioral Pain Scale (MBPS) by 2 clinical psychologists. Pain was scored within 15 seconds of the immunization. Cry time was measured by a different person from the start of cry till it ends. The author concluded that the "standard" slow technique was significantly more painful and took longer to administer (5-10 second) when compared to pragmatic technique (1-2 second). Cry duration is lesser in the pragmatic group than standard group, but it is statistically not significant.[10]

**SIGNIFICANCE OF THE STUDY**

Childhood immunizations are strategies which widely control the spread of vaccine-preventable diseases. Pain associated with immunizations is a hindrance to the success of this program. Management of pain associated with immunizations can benefit the health care providers, the children and the parents. The key goal is, less pain experienced during immunizations, a more compliant parents and patient to future immunizations.

The result of this study can benefit the health care provider facilitate a faster and convenient way to administer vaccines. This strategy will shorten patient waiting time and improved the quality of health care.

Children with reduced pain during vaccination will have less fear in subsequent clinic visit. An improved compliance to immunizations would mean completion of all the recommended vaccines. Moreover, children will have maximum protection from vaccine-preventable diseases.

A decrease pain during immunization will encourage parents to complete their child's immunization. Parents of a fully immunized child will have less work day of absences from illness and hospitalization and when translated in peso would mean savings. A disease-free child will relieve the parents from stress and worries of the possible complications of the disease.

The results of this study can guide health policy makers formulate guidelines/recommendation on strategies to decrease pain associated with immunization that will enhance parents and patients compliance to childhood vaccination.

**GENERAL OBJECTIVE:**

To determine the effect of aspiration and non aspiration of syringe prior to intramuscular administration of influenza vaccine in pain perception of children 9 to 15 years of age consulting at the Out Patient Department of a Tertiary Government Hospital.

**SPECIFIC OBJECTIVES:**

1. To compare the pain level using the Numerical Rating Scale (NRS) among children given influenza vaccine with and without aspiration prior to intramuscular administration.
2. To determine the effect of aspiration and non aspiration of syringe on oxygen saturation and heart rate in children before and after intramuscular injection of influenza vaccine.
3. To determine the adverse effect of aspiration and non aspiration of syringe prior to influenza vaccine.

**OPERATIONAL DEFINITION:**

1. Primary outcome measure

The primary outcome measure will be the degree of pain experienced by the subject using the Numeric Rating Scale.

**Numerical Rating Scale** –The primary outcome measure is the degree of pain as reported by the patient using the Numerical Rating Scale (NRS).[11] The subjects will give a self-report of pain after the influenza vaccination. The scale will be from zero to ten with zero being 'no pain' and ten being 'severe pain'. A lower average pain score will indicate that intramuscular injection without aspiration is effective in reducing pain associated with vaccination.

2. Secondary outcome measure

2.1 Heart Rate Difference **–** The difference between pre- and post- injection heart rate as measured by a portable finger-type pulse oximeter. A lower increase in heart rate from the baseline will be interpreted as a lower degree of pain from the injection.[9]

2.2 $O_2$ Saturation Difference - The difference between pre- and post- injection oxygen saturation as measured by a portable finger-type pulse oximeter. A lower decrease in oxygen saturation from the baseline will be interpreted as a lower degree of pain from injection.[9]

3. Adverse Reactions

Adverse reactions are change in color, itchiness or indurations which may appear during the course of the study on the area of vaccination.

Change in Color – Redness or blanching (change from pinkish to pale) on the area where the vaccine was administered

Itchiness – A tingling or uneasy irritation of the skin that causes a desire to scratch the affected area

Induration – Localized hardening of the soft tissue or the skin.

**METHODOLOGY:**

1. RESEARCH DESIGN

This is a randomized controlled clinical trial which determined the degree of pain as perceived by children and adolescents after influenza immunization.

2. SETTING AND DURATION

The study took place in the Out Patient Department of a Tertiary Government Hospital.

3. SAMPLE SIZE ESTIMATE

The sample size was computed using the Formula of Cochrane. The minimum sample size requirement is 34 subjects with 17 patients for each group. This is based on mean pain response of 5.6 in the aspiration technique and 3.3 in the non aspiration technique, with a standard deviation of 2, 95% confidence level and 90% power. A 30% allowance for the drop-outs was determined with the minimum sample size increased to 120 subjects. Sixty subjects were allocated for each group.

4. ELIGIBILITY CRITERIA

Included in the study were children 9 to 15 years old consulting at the Out Patient Department; children eligible for influenza immunization; and children with written informed consent from their parents or guardians and assent signed by the participants in the study.

Excluded in the study were children with acute febrile illness; children with history of convulsions or severe allergic reactions to influenza vaccine; children with history of allergies to egg protein; children with skin lesion over the injection site; and children who could not communicate verbally.

5. STUDY PROCEDURE

A letter was submitted to the Medical Center Chief of the Tertiary Government Hospital requesting permission to conduct a study at the Out-Patient Department.The research was reviewed and approved by the Institutional Review Board.

A research orientation was conducted among the members of the research team. Their duties and responsibilities were discussed with each member of the team. Letters and instructions were distributed to parents/guardians of possible study participants discussing the research objectives and procedures. The principal investigator conducted an interview along with the parents/guardians and performed a thorough physical examination. The subjects were screened based on the inclusion and exclusion criteria. An assistant investigator secured informed consent from the parents/guardians and assent forms from the subjects prior to the study.

A statistician prepared a computer-generated randomization list. The list was unknown to the other members of the research team including the primary investigator. A patient data form was used to collect all relevant clinical information and outcome measures. Data were gathered and analyzed accordingly (Appendix A).

<u>Randomization and Group Allocation</u>

Subjects were assigned into groups by randomization. Results of randomization of treatment allocation were placed in opaque envelopes, arranged chronologically. Each envelope indicated which group the subject would belong. Subjects assigned for the injection without aspiration were included in Group A while those assigned for injection with aspiration were in group B. The paper also denoted a three-digit code which coincided with the designated computer-generated randomization list.

In Group A, the needle was inserted at 90 degrees with steady pressure. No aspiration was performed. The vaccine was rapidly injected and the needle withdrawn. In Group B, the needle was inserted at 90 degrees with steady pressure. Aspiration was performed. The vaccine was rapidly injected and then the needle was withdrawn.

The randomized list of the subjects was kept classified and was revealed only after the completion of the study.

Vaccine Description

The vaccine used in this study was Influvac® 2016 an inactivated influenza vaccine. The vaccine is produced by Abbot Products Operations AG. It is a trivalent subunit influenza vaccine. A 0.5 ml dose contains neuraminidase and 15 mcg of hemagglutinin antigen for each virus strain present in the vaccine. The virus strains used in the vaccine for 2016/2017 are: an A/California/7/2009 (H1N1) pdm09-like virus; an A/Hong Kong/4801/2014 (H3N2)-like virus; and a B/Brisbane/60/2008-like virus. The vaccine is a colorless, clear liquid. It is thimerosal-free, mercury-free, and contains no preservative. Its route of administration is through intramuscular injection or deep subcutaneous injection. In this study, it was administered to children intramuscularly.

Vaccine Administration

Each subject was called to the treatment room of the Out-Patient Department one at a time. A nurse investigator 1 took the heart rate and oxygen saturation with a pulse oximeter prior to the administration of the vaccine. The nurse investigator 1 performed proper hand hygiene by cleansing with a waterless alcohol-based hand rub as recommended by the Centers for Disease Control and Prevention (CDC).[12] The deltoid region was pre-sterilized with a cotton ball damped in 70% isopropyl alcohol.[13] The nurse investigator number 1 administered the influenza vaccine intramuscularly, with or without aspiration depending on the subject's treatment allocation. The used syringe and needle devices were placed in biohazard containers that were closable, puncture-resistant and leak-proof. Cold chain was maintained until vaccines were administered. Emergency medications like Epinephrine, Diphenhydramine and Hydrocortisone were on hand at the site of the study. The Emergency Department was notified in the event that an adverse reaction would be experienced by any of the subjects.

Outcome Measurement

The assistant investigator number 2 determined and recorded the heart rate and oxygen saturation after the administration of vaccine. The assistant investigator number 2 helped out the subjects in reporting their pain level using the numerical rating scale, wherein 0 is equivalent to no pain, numbers 1, 2, and 3 is mild pain; numbers 4, 5 and 6 is moderate pain and numbers 7 to 10 mean severe pain (Appendix B).

The Primary investigator collated the data, checked them for completeness and accuracy, encoded them in MS Excel. Then they were statistically analyzed.

## ETHICAL CONSIDERATION

This study protocol was evaluated by the Institutional Review Board - Ethics Committee of Quirino Memorial Medical Center.

The study was done according to the Principles in the Declaration of Helsinki. Parents and subjects were informed of the purpose, procedures, risk and benefits related to the study. A voluntary informed consent and assent were obtained prior to inclusion to the study. Confidentiality was practiced with utmost care.

Contact numbers of the investigator was provided to the parents/guardians of the subjects.

## DATA MANAGEMENT AND ANALYSIS

Continuous data were described using means and standard deviations while categorical data were expressed in frequency and percentages. Differences between two groups with continuous variables were tested using t-test for independent samples while changes of averages from baseline to posttest within group were tested using Paired t-test. Fischer exact test was used in establishing association between gender and groups. Any associated p-values lesser than 0.05alpha were considered significant. IBMSPSS version 21 was used as statistical software.

## RESULTS

One hundred twenty children met the inclusion criteria and were randomized to either Group A or Group B. The ages of the children ranges from 9 – 15 years. The mean age for Group A (Without Aspiration) is 11.35 years (2.01 SD). The mean age group for

Group B (With Aspiration) is 12.12 years (2.05 SD). Shown in Figure 1 is the mean age of participants in the two treatment group. The mean age in both groups were statistically significant (p value 0.041). Majority of the participants in both groups were male (61% in Group A and 53 % in Group B). The sex distribution of participants in both study groups showed no statistically significant difference (p value 0.356).

***Table 1 Mean Age in Years and Sex Distribution of Participants in Group A and Group B***

| | Group A | | Group B | | |
|---|---|---|---|---|---|
| | **Mean** | **Std. Deviation** | **Mean** | **Std. Deviation** | **p – value** |
| **Age (years)** | 11.35 | ±2.01 | 12.12 | ±2.05 | 0.041 |
| **Gender:** | | | | | |
| **Male** | 37 (61.7) | | 32 (53.3) | | 0.356 |
| **Female** | 23 (38.3) | | 28 (46.7) | | |

Shown in Table 2 is the mean heart rate of participants at baseline and after intramuscular injection of influenza vaccine. The mean heart rate of participants in Group A (without aspiration) decreased from 93.25 bpm at baseline to 91.25 bpm post injection (p value <0.01). In comparison the mean heart rate in Group B (with aspiration) increased from 92.28 bpm at baseline to 94.43 bpm post injection (p value <0.01). The differences in mean heart rate at baseline and after the intervention within group is significantly different (p value < 0.01). Analysis of the mean heart rate in between group at baseline and after administration of influenza vaccine is not significantly different ( p value >0.05).

***Table 2 Comparative Mean Heart Rate of Group A and Group B at Baseline and Post Intramuscular Administration of Influenza Vaccine***

| | Group A | | Group B | | |
|---|---|---|---|---|---|
| **Phase** | **Mean** | **Std. Deviation** | **Mean** | **Std. Deviation** | **p value** |
| Baseline | 93.25 | ±20.11 | 92.28 | ±17.23 | 0.778 |
| Post | 91.25 | ±19.54 | 94.43 | ±21.21 | 0.629 |

Table 3 outlines the mean oxygen saturation of Group A and Group B at baseline and after immunization. The mean oxygen saturation in Group A ( without aspiration) decreased from 97.68% at baseline to 96.93% post immunization (p value < 0.01). In comparison the mean oxygen saturation in Group B (with aspiration) decreased from 97.57% at baseline to 96.32% at post immunization (p value < 0.01). The difference in mean oxygen saturation at baseline and after immunization within group is significantly different. Analysis of the mean oxygen saturation between group pre and post immunization is not statistically different (p value 0.309).

***Table 3 Comparative Mean Oxygen Saturation of Group A and Group B at Baseline and Post Intramuscular Injection of Influenzae Vaccine***

| | Group A | | Group B | | |
|---|---|---|---|---|---|
| **Phase** | **Mean** | **Std. Deviation** | **Mean** | **Std. Deviation** | **p value** |
| Baseline | 97.68 | ±1.14 | 97.57 | ±1.48 | 0.629 |
| Post | 96.93 | ±3.43 | 96.32 | ±3.18 | 0.309 |

Table 4 shows the comparative mean pain scores of Group A (without aspiration) and Group B (with aspiration) post-intramuscular injection. The mean pain score of participants in Group A is 1.72. In comparison, the mean pain score of participants in Group B is 2.47. The analysis showed there is a significant difference in mean pain scores between Group A and Group B ( p value 0.046).

***Table 4 Comparative Mean Pain Scores of Group A and Group B Post Intramuscular Injection of Influenza Vaccine***

| | Group A | | Group B | |
|---|---|---|---|---|
| **Phase** | **Mean** | **Std. Deviation** | **Mean** | **Std. Deviation** |
| Pain score | 1.72 | ±1.66 | 2.47 | ±2.36 |

**DISCUSSION:**

Development and administration of immunization is one of the greatest achievements in public health of this generation. Studies have shown that this strategy have markedly decrease vaccine-preventable disease. However, pain associated with procedures like Injection in immunizations hinders its purpose. Pain is

an inherently subjective multifactorial experience and should be dealt accordingly. Clinicians should find efficient and convenient strategies to administer vaccines and achieve health for all in 2020. Aspiration prior to injection is a part of the process of performing vaccinations that has been a wide-spread clinical practice yet has never been substantiated by scientific data.

This study showed that intramuscular administration of influenza vaccine without aspiration in adolescent children 9 to 15 years old is less painful as compared to intramuscular injection with aspiration. Pain scores were significantly lower in the group with no aspiration prior to intramuscular injection (p value 0.046). Physiologic pain responses like heart rate and oxygen saturation were included in the assessment of pain in the study. In children given with influenza vaccine without aspiration, they demonstrated a significant decrease in heart rate from baseline to post-injection (p value <0.01) as compared to a significant increase in heart rate from baseline to post -injection (p value <0.01) in the group given with vaccine with aspiration. This study also showed a quantifiable decrease in oxygen saturation between groups however not statistically significant. No adverse reactions like blanching, itchiness and rashes were observed during the study.

In congruence with this research, the studies made by Ipp, and Girish also determined acute pain response in routine immunizations in infants using different methodology but revealing similar outcomes. In the country, same study was done in school-aged children comparing their response in intramuscular injection of influenza vaccine with and without aspiration. Rayco noted a significant less painful experience in children given influenza vaccine without aspiration. It provided a possible explanation that rapid injection is less painful in children.[15]

This study can be relevant in applying interventions in alleviating acute pain in children. This can help improve techniques in vaccination procedures which are performed frequently in clinics. With this, we can expect more compliant parents and patients in immunization that may result to a lesser occurrence of vaccine-preventable diseases.

## CONCLUSION

This study showed a statistically significant lower pain score for Group A (without aspiration) than Group B (with aspiration), p value 0.046. The physiological pain responses, used as outcome measures in this study did not have significant differences between two groups (p value >0.05). The result of this study will unleash in health care professionals the burden on whether or not to aspirate before intramuscular administration of vaccine.

## LIMITATIONS AND RECOMMENDATIONS

This study is limited to intramuscular immunization only. This is not generalized to all aspiration techniques prior to intramuscular injection procedures like drug administration.

It is recommended that future studies use bigger samples for more accurate determination of statistical significance.

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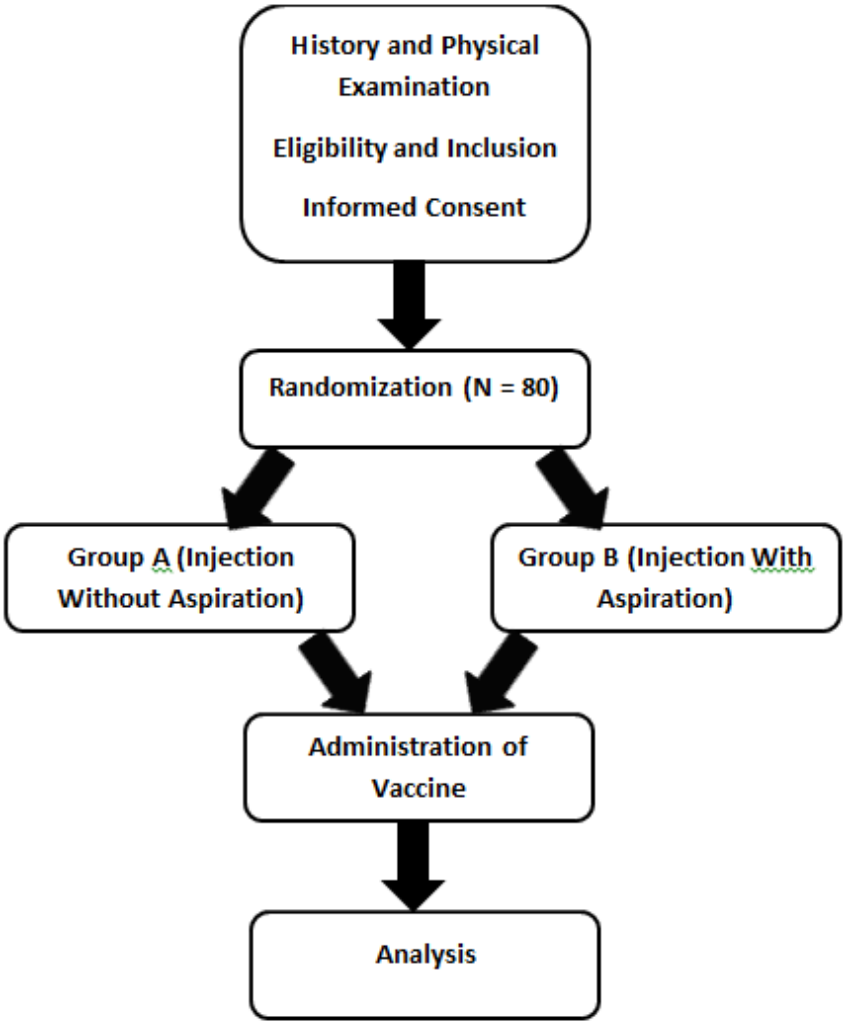
**APPENDIX A**

**Flow of Procedure**

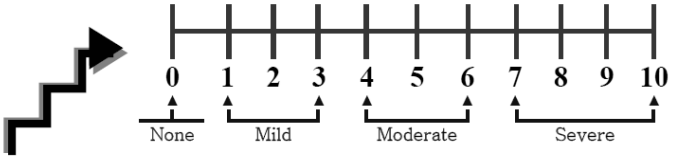



**APPENDIX B**
**Patient Assessment Sheet**

**Patient number:**

| | Before Vaccination | After Vaccination |
|---|---|---|
| Heart Rate | | |
| Oxygen Saturation | | |

Numeric Rating Scale




Adverse Reactions:
_____ Redness
_____ Blanching
_____ Itchiness

Others: _____

Assessor: _____
Date: _____