Swine Flu (Novel Influenza A H1N1) Vaccine Study

CHILDREN OVER 5 YEARS OF AGE DIARY

DIARY 1 / DIARY 2

7 DAY HEALTH DIARY

Study No:

First name: ____

Date of Vaccination: ____/______/______ Time of vaccination: ______

RIGHT **/ LEFT** ARM

INSTRUCTIONS

Please note that Day 0 is the day of vaccination, Day 1 is the next day and so on. At about the same time each evening, please fill in the chart overleaf

HOW AND WHEN TO MEASURE YOUR CHILDS TEMPERATURE

Take the temperature under the arm (axillary)

Day 0 -6 hours after the injection / later that evening (6 - 8 pm)
Day 1 - 7 -Evening (6 - 8 pm)

Look at the vaccination site and measure the maximum width of any redness or swelling using the ruler and fill in the chart accordingly

GENERAL SYMPTOMS

*Please **circle** the appropriate number. If you child has symptoms then please evaluate the severity (mild, moderate or severe) of the symptom(s). Please complete each day.*

	Day 0 (Day of vaccine)		***Day 1***		***Day 2***		***Day 3***		***Day 4***		***Day 5***		***Day 6***		***Day 7***		***Please send in diary card now***
Has your child been generally unwell? 0 None 1 Mild – transient with no limitation on normal activity 2 Moderate – some limitation in daily activity 3 Severe – unable to perform normal daily activity	0	1	0	1	0	1	0	1	0	1	0	1	0	1	0	1	***If symptom was ongoing at day 7, document on memory aid card***
	2	3	2	3	2	3	2	3	2	3	2	3	2	3	2	3	
Has your child had a headache? 0 None 1 Mild – transient with no limitation on normal activity 2 Moderate – some limitation in daily activity 3 Severe – unable to perform normal daily activity	0	1	0	1	0	1	0	1	0	1	0	1	0	1	0	1	
	2	3	2	3	2	3	2	3	2	3	2	3	2	3	2	3	
Has your child felt nauseous or vomited? 0 None 1 Mild - 1-2 episodes without interfering with routine 2 Moderate Several episodes and cannot keep any food down 3 Severe: Frequent episodes and taking nothing by mouth	0	1	0	1	0	1	0	1	0	1	0	1	0	1	0	1	
	2	3	2	3	2	3	2	3	2	3	2	3	2	3	2	3	
Has your child had diarrhoea? **0 None** **1 Mild –** More loose stools than usual **2 Moderate** – Frequent runny stools without much solid material **3 Severe** – Multiple liquid stools without much solid material	0	1	0	1	0	1	0	1	0	1	0	1	0	1	0	1	
	2	3	2	3	2	3	2	3	2	3	2	3	2	3	2	3	
Has your child been eating less than usual/had a loss of appetite? **0 None** **1 Mild –** Eating less than normal for 1-2 meals **2 Moderate** Missed 1-2 meals completely **3 Severe** Refused most or all meals	0	1	0	1	0	1	0	1	0	1	0	1	0	1	0	1	
	2	3	2	3	2	3	2	3	2	3	2	3	2	3	2	3	
Has your child had muscle pain? 0 None 1 Mild – transient with no limitation on normal activity 2 Moderate – some limitation in daily activity 3 Severe – unable to perform normal daily activity	0	1	0	1	0	1	0	1	0	1	0	1	0	1	0	1	
	2	3	2	3	2	3	2	3	2	3	2	3	2	3	2	3	
Has your child had joint pain? 0 None 1 Mild – transient with no limitation on normal activity 2 Moderate – some limitation in daily activity 3 Severe – unable to perform normal daily activity	0	1	0	1	0	1	0	1	0	1	0	1	0	1	0	1	
	2	3	2	3	2	3	2	3	2	3	2	3	2	3	2	3	

VACCINE SITE SYMPTOMS: Please score any pain or tenderness at the injection site and measure any swelling or redness at the injection site.

	Day 0 (***Day of vaccine)***		***Day 1***		***Day 2***		***Day 3***		***Day 4***		***Day 5***		***Day 6***		***Day 7***		
Has there been pain at the injection site? 0 None 1 Mild – transient with no limitation on normal activity 2 Moderate – some limitation in daily activity 3 Severe – unable to perform normal daily activity	0	1	0	1	0	1	0	1	0	1	0	1	0	1	0	1	If symptom was ongoing at day 7, document on memory aid card
	2	3	2	3	2	3	2	3	2	3	2	3	2	3	2	3	
RIGHT / LEFT arm maximum swelling (mm)																	
RIGHT / LEFT arm maximum redness (mm)																	

TEMPERATURE

Day	Day 0 Evening	Day 1 Evening	Day 2 Evening	Day 3 Evening	Day 4 Evening	Day 5 Evening	Day 6 Evening	Day 7 Evening
Axillary (under arm) temperature**	°C	°C	°C	°C	°C	°C	°C	°C
Any medication for pain or temperature used?	**YES / NO**	**YES / NO**	**YES / NO**	**YES / NO**	**YES / NO**	**YES / NO**	**YES / NO**	**YES / NO**
If medication used please specify name								

*****TEMPERATURE (UNDER ARM):*** For an accurate temperature place the tip of the thermometer against the skin under the armpit and hold your child with his or her arm by their side closed for approximately 1 minute until the rapid beeps confirming that the temperature measurement is complete (see instruction leaflet enclosed with the thermometer for further information). On days 1 to 7, please measure your child's temperature at approximately the same time on each day.

If your child feels warm at any other time of day please record the date and time below:

_______°C ____/____/____ _____:_____ _______°C ____/____/____ _____:_____

_______°C ____/____/____ _____:_____ _______°C ____/____/____ _____:_____

_______°C ____/____/____ _____:_____ _______°C ____/____/____ _____:_____

If you need to see a doctor during the 7 day period following immunisation, please take this diary with you and tell the doctor about the study.

If your child is unwell at all, if you need to call a doctor or your child is seen by a doctor or is given any medicine then please write the details below:

Date	***Problem***	***Action taken*** (please circle answer)			***Medicine given***		
						(1st medicine)	(2nd medicine)
Start date: ____/____/____		Did you telephone a GP?	**Yes**	**No**	Name:	____________	____________
		Was your child seen by a GP?	**Yes**	**No**	Start date:	____________	____________
Stop date: ____/____/____		Seen by GP at	**Home/Surgery**		End date:	____________	____________
		Taken to hospital?	**Yes**	**No**	Dosage:	____________	____________
		Admitted to hospital	**Yes**	**No**			
						(1st medicine)	(2nd medicine)
Start date: ____/____/____		Did you telephone a GP?	**Yes**	**No**	Name:	____________	____________
		Was your child seen by a GP?	**Yes**	**No**	Start date:	____________	____________
Stop date: ____/____/____		Seen by GP at	**Home/Surgery**		End date:	____________	____________
		Taken to hospital?	**Yes**	**No**	Dosage:	____________	____________
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Start date: ____/____/____		Did you telephone a GP?	**Yes**	**No**	Name:	____________	____________
		Was your child seen by a GP?	**Yes**	**No**	Start date:	____________	____________
Stop date: ____/____/____		Seen by GP at	**Home/Surgery**		End date:	____________	____________
		Taken to hospital?	**Yes**	**No**	Dosage:	____________	____________
		Admitted to hospital	**Yes**	**No**			
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Start date: ____/____/____		Did you telephone a GP?	**Yes**	**No**	Name:	____________	____________
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Stop date: ____/____/____		Seen by GP at	**Home/Surgery**		End date:	____________	____________
		Taken to hospital?	**Yes**	**No**	Dosage:	____________	____________
		Admitted to hospital	**Yes**	**No**			
						(1st medicine)	(2nd medicine)
Start date: ____/____/____		Did you telephone a GP?	**Yes**	**No**	Name:	____________	____________
		Was your child seen by a GP?	**Yes**	**No**	Start date:	____________	____________
Stop date: ____/____/____		Seen by GP at	**Home/Surgery**		End date:	____________	____________
		Taken to hospital?	**Yes**	**No**	Dosage:	____________	____________
		Admitted to hospital	**Yes**	**No**			

If you, your doctor or anyone else needs advice regarding the study, he/she should contact:

H1N1 Study Team
Oxford Vaccine Group
Centre for Clinical Vaccinology and Tropical Medicine
Churchill Hospital
Old Road, Headington
Oxford
OX3 7LJ

Tel: 01865 857080
Email: ovg@paediatrics.ox.ac.uk

24 hour emergency telephone number: 07699 785400

Thank you for taking the time to fill in this diary. We would be grateful if you would return it to us using the prepaid envelope provided.

If you have lost the envelope, we would be obliged if you would post it to:

The Clinical Trials Admin Team
Immunisation Department
Health Protection Agency
61 Colindale Avenue
London
NW9 5EQ

Swine Flu (Novel Influenza A H1N1) Vaccine Study

INFANTS AND CHILDREN UNDER 5 YEARS OF AGE DIARY

DIARY 1 / DIARY 2

7 DAY HEALTH DIARY

Study No:

First name: ____

Date of Vaccination: ____/______/______ Time of vaccination: ______

RIGHT / **LEFT** **ARM / LEG**

INSTRUCTIONS

Please note that Day 0 is the day of vaccination, Day 1 is the next day and so on. At about the same time each evening, please fill in the chart overleaf

HOW AND WHEN TO TAKE YOUR CHILDS TEMPERATURE

Take the temperature under the arm (axillary)

Day 0 -6 hours after the injection / later that evening (6 - 8 pm)
Day 1 - 7 -Evening (6 - 8 pm)

Look at the vaccination site and measure the maximum width of any redness or swelling using the ruler and fill in the chart accordingly

GENERAL SYMPTOMS

*Please **circle** the appropriate number. If you child has symptoms then please evaluate the severity (mild, moderate or severe) of the symptom(s).*

	Day 0 (Day of vaccine)		***Day 1***		***Day 2***		***Day 3***		***Day 4***		***Day 5***		***Day 6***		***Day 7***		***Please send in diary card now***
Has your child been feeding less than usual? 0 None 1 Mild – Eating less than normal for 1-2 feeds/meals 2 Moderate – Missed 1-2 feeds/meals completely 3 Severe – Refused most or all feeds/meals	0	1	0	1	0	1	0	1	0	1	0	1	0	1	0	1	***If symptom was ongoing at day 7, document on memory aid card***
	2	3	2	3	2	3	2	3	2	3	2	3	2	3	2	3	
Has your child been less active than usual? 0 None 1 Mild – transient with no limitation on normal activity 2 Moderate – some limitation in daily activity 3 Severe – unable to perform normal daily activity	0	1	0	1	0	1	0	1	0	1	0	1	0	1	0	1	
	2	3	2	3	2	3	2	3	2	3	2	3	2	3	2	3	
Has your child been more irritable than usual? 0 None 1 Mild – Continuously irritable for less than 1 hour 2 Moderate – Continuously irritable for 1 to less than 3 hours 3 Severe – Continuously irritable for 3 or more hours	0	1	0	1	0	1	0	1	0	1	0	1	0	1	0	1	
	2	3	2	3	2	3	2	3	2	3	2	3	2	3	2	3	
Has your child cried persistently? 0 None 1 Mild – Cried continuously for less than 1 hour 2 Moderate – Cried continuously for 1 to less than 3 hours 3 Severe – Cried continuously for 3 or more hours	0	1	0	1	0	1	0	1	0	1	0	1	0	1	0	1	
	2	3	2	3	2	3	2	3	2	3	2	3	2	3	2	3	
Has your child vomited? 0 None 1 Mild – 1-2 episodes without interfering with routine 2 Moderate – Several episodes & cannot keep any food down 3 Severe – Frequent episodes & taking nothing by mouth	0	1	0	1	0	1	0	1	0	1	0	1	0	1	0	1	
	2	3	2	3	2	3	2	3	2	3	2	3	2	3	2	3	
Has your child had diarrhoea? 0 None 1 Mild – More loose stools than usual 2 Moderate – Frequent runny stools without much solid material 3 Severe Multiple liquid stools without much solid material	0	1	0	1	0	1	0	1	0	1	0	1	0	1	0	1	
	2	3	2	3	2	3	2	3	2	3	2	3	2	3	2	3	

VACCINE SITE SYMPTOMS: Please score any pain or tenderness at the injection site and measure any swelling or redness at the injection site.

	Day 0 (Day of vaccine)	***Day 1***	***Day 2***	***Day 3***	***Day 4***	***Day 5***	***Day 6***	***Day 7***	
Has there been pain at the injection site? 0 None 1 Mild – transient with no limitation on normal activity 2 Moderate – some limitation in daily activity 3 Severe – unable to perform normal daily activity	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	If symptom was ongoing at day 7, document on memory aid card
RIGHT / LEFT arm maximum swelling (mm)									
RIGHT / LEFT arm maximum redness (mm)									

TEMPERATURE

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Any medication for pain or temperature used?	**YES / NO**	**YES / NO**	**YES / NO**	**YES / NO**	**YES / NO**	**YES / NO**	**YES / NO**	**YES / NO**
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_______°C ____ / ____ / ____ _____ : _____ _______°C ____ / ____ / ____ _____ : _____

_______°C ____ / ____ / ____ _____ : _____ _______°C ____ / ____ / ____ _____ : _____

_______°C ____ / ____ / ____ _____ : _____ _______°C ____ / ____ / ____ _____ : _____

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Date	***Problem***	***Action taken*** (please circle answer)			***Medicine given***		
Start date:		Did you telephone a GP?	**Yes**	**No**		(1st medicine)	(2nd medicine)
____/____/____		Was your child seen by a GP?	**Yes**	**No**	Name:	____________	____________
Stop date:		Seen by GP at	**Home/Surgery**		Start date:	____________	____________
____/____/____		Taken to hospital?	**Yes**	**No**	End date:	____________	____________
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Stop date:		Seen by GP at	**Home/Surgery**		Start date:	____________	____________
____/____/____		Taken to hospital?	**Yes**	**No**	End date:	____________	____________
		Admitted to hospital	**Yes**	**No**	Dosage:	____________	____________
Start date:		Did you telephone a GP?	**Yes**	**No**		(1st medicine)	(2nd medicine)
____/____/____		Was your child seen by a GP?	**Yes**	**No**	Name:	____________	____________
Stop date:		Seen by GP at	**Home/Surgery**		Start date:	____________	____________
____/____/____		Taken to hospital?	**Yes**	**No**	End date:	____________	____________
		Admitted to hospital	**Yes**	**No**	Dosage:	____________	____________
Start date:		Did you telephone a GP?	**Yes**	**No**		(1st medicine)	(2nd medicine)
____/____/____		Was your child seen by a GP?	**Yes**	**No**	Name:	____________	____________
Stop date:		Seen by GP at	**Home/Surgery**		Start date:	____________	____________
____/____/____		Taken to hospital?	**Yes**	**No**	End date:	____________	____________
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