Electronic Supplementary Material 1

Article Title
Safety of Intranasal Quadrivalent Live Attenuated Influenza Vaccine (QLAIV) in Children and Adolescents: A Post Marketing Prospective Cohort Study in England in the 2014-15 season

Journal
Drug Safety

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PARENT/LEGAL GUARDIAN INFORMED CONSENT FORM

Please send this form back to the DSRU together with any assent forms your child may have signed, if appropriate.

FLU VACCINE *feedback study*

A Postmarketing Noninterventional Cohort Study of the Safety of Live Attenuated Influenza Vaccine (LAIV) in Subjects 2 Through 17 Years of Age.

Patient Study Identification Code

PSIC: P

Vaccination Site Identification Code

VSIC: V

MAIN CONSENT FORM

PATIENT DETAILS ▶

Personal details of person vaccinated (vaccinee)

Forename:

Surname:

Date of birth: Gender:

NHS number (if known):

Personal details of representative (e.g. parent/guardian/next of kin) of person vaccinated

Forename:

Surname:

Address:

Relationship to person vaccinated:

Email Address:

Contact telephone number:

State the preferred method for completion of study questionnaires:

Paper (Surface mail): ☐	Email: ☐

I wish to receive a pre-paid voucher for my participation in the study	☐
I do not wish to receive a pre-paid voucher and would like the DSRU to donate to a children's charity of their choice on my behalf	☐

INFORMED CONSENT FORM ▶

Please initial boxes below ▼

1.	I confirm that I have read and understand the information sheet for the above study. I have had the opportunity to consider the information and ask questions, and have had these answered satisfactorily.	☐
2.	I understand that my child's participation is voluntary and that my child is free to withdraw at any time, without giving any reason, without their medical care or legal rights being affected.	☐
3.	I give permission for relevant parts of my child's GP medical charts to be accessed by their GP or other care team staff in connection with this study.	☐

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Tel: (023) 8040 8600
www.dsru.org

MAIN CONSENT FORM

Please initial box below ▼

4.	I agree to my child's GP being contacted to find out more information about any side effects experienced following vaccination.	☐

GP CONTACT DETAILS

Name:

Address:

Postcode:

Telephone No:

Please initial boxes below ▼

5.	I agree to information, from which my child can be identified, being held by the research team at the Drug Safety Research Unit together with data collected during the study.	☐
6.	I agree for my child to take part in the study.	☐
7.	I agree for the research team to contact me in the future about further Drug Safety Research studies.	☐

Name of child

.....

Name of child's legal representative (PRINT) Signature Date

....

Patient Study Identification Code

PSIC: P

Vaccination Site Identification Code

VSIC: V

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INFORMED CONSENT FORM FOR PARTICIPANTS AGED 16-17 YEARS

Please send this form back to the DSRU

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Patient Study Identification Code	Vaccination Site Identification Code
PSIC: P	VSIC: V

MAIN CONSENT FORM PATIENT DETAILS ▶

Personal details of person vaccinated (vaccinee)

Forename:

Surname:

Date of birth: Gender:

NHS number (if known):

Address:

Email address:

Contact telephone number:

State the preferred method for completion of study questionnaires:

Paper (Surface mail): ☐	Email: ☐

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3.	I give permission for relevant parts of my GP medical charts to be accessed by my GP or other care team staff in connection with this study.	☐
4.	I agree to my GP being contacted to find out more information about any side effects experienced following vaccination	☐

GP CONTACT DETAILS

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Address:

Postcode:

Telephone No:

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7.	I agree for the research team to contact me in the future about further Drug Safety Research studies.	☐

Name (PRINT) Signature Date

....

Patient Study Identification Code (PSIC)

PSIC: P

Vaccination Site Identification Code (VSIC)

VSIC: V

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ENROLMENT QUESTIONNAIRE

PSIC: P

VACCINATION DETAILS

Has the vaccinee had the nasal 'flu vaccination?

Yes ▼ ☐	No ☐
If **YES**, specify date of vaccination:	

Location (address) of vaccination site:

Did the vaccinee have another vaccination on the same day as the nasal 'flu vaccine?

Yes ▼ ☐	No ☐
If **YES**, specify vaccine name:	

Has the vaccinee had any other vaccines in the last month?

Yes ▼ ☐	No ☐
If **YES**, provide further information on the type of vaccination and date?	
Vaccine name:	
Date:	

MEDICAL CONDITIONS

Does the vaccinee have any of the following chronic underlying medical conditions (as diagnosed by a medical professional)?

Asthma	Yes ☐	No ☐
Diabetes	Yes ☐	No ☐
Heart disease	Yes ☐	No ☐
Chronic kidney disease	Yes ☐	No ☐
Immunosuppression	Yes ☐	No ☐
Moderate/severe liver disease	Yes ☐	No ☐
Blood disorder	Yes ☐	No ☐

PREGNANCY

Is the vaccinee currently pregnant?

Yes ▼ ☐	No ☐
If **YES**, provide expected date of delivery Date:	

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MEDICATION

Does the vaccinee take any medicines prescribed by the doctor or over-the-counter medicines?

Yes ▼ ☐	No ☐

If **YES**, give details of medicines in the table below:

	Name of Medicine	Dose	How often taken
Medicine 1			
Medicine 2			
Medicine 3			
Medicine 4			
Medicine 5			

FURTHER CONTACT

a. Are you happy for us to contact you again to find out more information about any reported problems following the vaccination?

Yes ☐	No ☐

b. Are you happy for us to contact the vaccinee's GP or health professionals to find out more information about prescriptions and any possible side effects relating to the vaccine?

Yes ☐	No ☐

c. Are you happy for us to contact you again in future about further drug safety research studies?

Yes ☐	No ☐

Thank you for completing this questionnaire

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DAY 14 QUESTIONNAIRE

PSIC: P

SYMPTOMS SINCE VACCINATION

Did the vaccinee experience any of the following, either on the day of vaccination (after being vaccinated) or during the subsequent 14 days?

	No	Yes	Date* symptom started	Date symptom stopped
High temperature (i.e. greater than 38.0°C)	☐	☐ ▼		
If **YES**, then give temperature recorded, if available:	temp:			
Nausea and vomiting	☐	☐		
Generally feeling unwell (malaise)	☐	☐		
Headache	☐	☐		
Decreased appetite	☐	☐		
Rash	☐	☐		
Muscle pain or joint pain	☐	☐		
Itchy or red eyes	☐	☐		
Any of the following: Swelling of the face, lips or tongue, difficulty breathing, feeling of dizziness/ light-headedness, general itchiness with a rash	☐	☐		
Wheezing	☐	☐		
Nasal congestion / runny nose	☐	☐		
Mouth or throat pain	☐	☐		
Cough	☐	☐		
Nosebleed	☐	☐		
Increased irritability (if the child is between two and four years)	☐	☐		
Increased crying (if the child is between two and four years)	☐	☐		

**If you're unsure of the date, provide the approximate number of days after vaccination when the symptom started and how long (how many days) symptoms lasted.*

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DAY 14 QUESTIONNAIRE

MEDICATION

Are there any other symptoms that the vaccinee has experienced since vaccination?

Yes ▼ ☐	No ☐
If **YES**, give details of symptoms and date symptoms started:	

Has the vaccinee visited the GP about any of the symptoms listed above?

Yes ☐	No ☐

Has the vaccinee been admitted to hospital with any of the symptoms listed above?

Yes ☐	No ☐

Have there been any changes to the vaccinee's medication since receiving the vaccination ?

Yes ▼ ☐	No ☐
If **YES**, give details of medicines and date of change	

Thank you for completing this questionnaire

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GP FOLLOW-UP QUESTIONNAIRE

PSIC: P

Did the patient visit you about the symptoms/event described in the covering letter?

Yes ▼ ☐	No ☐

If **YES**, provide any further details you have of the event, including:

Date of onset of event:	d	d	/	m	m	/	y	y	y	y
Date of end of event:	d	d	/	m	m	/	y	y	y	y

Detailed clinical description (for multiple events please describe separately):

Diagnosis:

Management and final outcome:

Did the patient report symptoms stated above before vaccination with live attenuated influenza vaccine Fluenz Tetra ®?

Yes ☐	No ☐

At the time of the event, was the patient taking any other prescribed medication?

Yes ▼ ☐	No ☐

If **YES**, list drugs including form and dose:

Drug	Form	Dose

At the time of the event, was the patient known to be taking food supplements, Over-The-Counter (OTC) or herbal therapies?

Yes ▼ ☐	No ☐	DK ☐

If **YES**, list products:

List any relevant past medical history including recent immunisations and medical conditions:

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GP FOLLOW-UP QUESTIONNAIRE

Do you think the event was related to the vaccination?

Yes ☐	No ▼ ☐	DK ☐
If **NO**, was another cause established?:		
Yes ▼ ☐	No ☐	DK ☐
If **YES**, specify cause of event:		

Provide the batch number of the Fluenz Tetra® vaccine administered to the patient, if known:

Lot:

Please return this questionnaire and copies of any relevant hospital correspondence in the FREEPOST envelope provided.

Thank you for your assistance.

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