BMJ - Decision on Manuscript ID BMJ.2015.029119.R1

Body: 04-Nov-2015

Dear Dr. Turner:

Manuscript ID BMJ.2015.029119.R1 entitled "Safety of Live Attenuated Influenza Vaccine in Children with Egg Allergy: a multi-centre, non-randomised intervention study" which you submitted to BMJ,

Many thanks for sending us the revised version of your paper so quickly, and for your careful attention to the comments of editors and reviewers. Provided you are willing to address the following remaining concerns, we would like to publish the paper in the BMJ. In other words, we are provisionally offering acceptance but will make the final decision when we see the revised version.

Very truly yours,

Elizabeth Loder, MD, MPH
BMJ Editorial Team

In your response please provide, point by point, your replies to the following remaining editorial concerns, explaining how you have dealt with them in the paper.

* We still think that claims of safety should be toned down. For example, the abstract says "is unlikely to trigger a systemic allergic reaction in egg-allergic children and appears safe for use in most egg-allergic children." We recommend this be revised to something along the lines of "is unlikely to trigger a systemic allergic reaction in egg-allergic children" or "our results are compatible with a low risk of systemic allergic reactions in egg-allergic children."

* Results would be easier to follow if they were presented (in both the abstract and paper) in the order they were listed on clintrials, in other words if you led off with the primary outcome and first report the "incidence of allergic reaction within 2 hours," then report the "incidence of delayed symptoms" and finally report the results of the ACT test. Abstract should report the upper limit of the CI for both the main group and the subgroup of severely allergic children, i.e. should make plain the absolute risk estimates for the group as a whole and for the subgroup of children with previous severe reactions, which are .47% and 1.36%.

* on p 22 the statement "is safe..." should be changed to something less definite such as "compatible with a risk of systemic allergic reaction less than 1 in x."

* One small matter: could you clarify why in the methods section it says that children were observed for 30 minutes but the outcome reported is events within 2 hours?

* The title should describe this as a multicenter prospective cohort study.

Information for submitting a revision

Deadline: Your revised manuscript should be returned within one month.

How to submit your revised article: Log into http://mc.manuscriptcentral.com/bmj and enter your Author Center, where you will find your manuscript title listed under "Manuscripts with Decisions." Under "Actions," click on "Create a Revision." Your manuscript number has been appended to denote a revision.

You will be unable to make your revisions on the originally submitted version of the manuscript. Instead, revise your manuscript using a word processing program and save it on your computer. Once the revised manuscript is prepared, you can upload it and submit it through your Author Center. When submitting your revised manuscript, you will be able to respond to the comments made by the reviewer(s) and Committee in the space provided. You can use this space to document any changes you make to the original manuscript and to explain your responses. In order to expedite the processing of the revised manuscript, please be as specific as possible in your response to the reviewer(s). As well as submitting your revised manuscript, we also require a copy of the manuscript with changes highlighted. Please upload this as a supplemental file with file designation 'Revised Manuscript Marked copy'. Your original files are available to you when you upload your revised manuscript. Please delete any redundant files before completing the submission.

When you revise and return your manuscript, please take note of all the following points about revising your article. Even if an item, such as a competing interests statement, was present and correct in the original draft of your paper, please check that it has not slipped out during

revision. Please include these items in the revised manuscript to comply with BMJ style (see: http://www.bmj.com/about-bmj/resources-authors/article-submission/article-requirements and http://www.bmj.com/about-bmj/resources-authors/forms-policies-and-checklists).

Items to include with your revision (see http://www.bmj.com/about-bmj/resources-authors/article-types/research):

1. What this paper adds/what is already known box (as described at http://resources.bmj.com/bmj/authors/types-of-article/research)

2. Name of the ethics committee or IRB, ID# of the approval, and a statement that participants gave informed consent before taking part. If ethics committee approval was not required, please state so clearly and explain the reasons why (see http://resources.bmj.com/bmj/authors/editorial-policies/guidelines.)

3. Patient confidentiality forms when appropriate (see http://resources.bmj.com/bmj/authors/editorial-policies/copy_of_patient-confidentiality).

4. Competing interests statement (see http://resources.bmj.com/bmj/authors/editorial-policies/competing-interests)

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8. Data sharing statement (see http://www.bmj.com/about-bmj/resources-authors/article-types/research)

9. Funding statement and statement of the independence of researchers from funders (see http://resources.bmj.com/bmj/authors/article-submission/article-requirements).

10. Patient involvement statement (see http://www.bmj.com/about-bmj/resources-authors/article-types/research).

11. Please ensure the paper complies with The BMJ's style, as detailed below:

a. Title: this should include the study design eg "systematic review and meta-analysis."

b. Abstract: Please include a structured abstract with key summary statistics, as explained below (also see http://resources.bmj.com/bmj/authors/types-of-article/research). For every clinical trial - and for any other registered study- the last line of the abstract must list the study registration number and the name of the register.

c. Introduction: This should cover no more than three paragraphs, focusing on the research question and your reasons for asking it now.

d. Methods: For an intervention study the manuscript should include enough information about the intervention(s) and comparator(s) (even if this was usual care) for reviewers and readers to understand fully what happened in the study. To enable readers to replicate your work or implement the interventions in their own practice please also provide (uploaded as one or more supplemental files, including video and audio files where appropriate) any relevant detailed descriptions and materials. Alternatively, please provide in the manuscript urls to openly accessible websites where these materials can be found.

e. Results: Please report statistical aspects of the study in line with the Statistical Analyses and Methods in the Published Literature (SAMPL) guidelines http://www.equator-network.org/reporting-guidelines/sampl/. Please include in the results section of your structured abstract (and, of course, in the article's results section) the following terms, as appropriate:

For a cohort study: Absolute event rates over time (eg 10 years) among exposed and (where relevant) non-exposed groups; RRR (relative risk reduction.)

f. Discussion: To minimise the risk of careful explanation giving way to polemic, please write the discussion section of your paper in a structured way. Please follow this structure: i) statement of principal findings of the study; ii) strengths and weaknesses of the study; iii) strengths and weaknesses in relation to other studies, discussing important differences in results; iv) what your study adds (whenever possible please discuss your study in the light of relevant systematic reviews and meta-analyses); v) meaning of the study, including possible explanations and implications for clinicians and policymakers and other researchers; vi) how

your study could promote better decisions; vi) unanswered questions and future research

g. Footnotes and statements

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Date Sent: 04-Nov-2015