Reviewer's report

Title: Information and informed consent in infant vaccinations

Version: 2 Date: 3 December 2013

Reviewer: Emma Quinn

Reviewer's report:

Discretionary Revisions

Abstract

(1) Suggest shorter sentence construction needs to be used here in the results section. Less semi colons could be used and more short sentences should be written.

Introduction

(2) Given the authors are wanting to publish in an international journal I would suggest a little more detail on what ‘mandatory vaccination’ exactly means in Italy.

(3) It is suggested that a definition of “informed consent” needs to either be mentioned here or in the methods section. For example; are the authors evaluating the doctor’s duty to inform the parent about the vaccine, the benefits, risks and possible complications?

Results

(4) Suggest restructuring results section here with three key points after describing the demographics of respondents: (1) n#s receiving the form, (2) n#s reading the form and (3) n#s signing the form.

Discussion

(5) Paragraph 2 – For example it might be helpful to expand on what exactly has been debated about regarding the role of informed consent in infant vaccination and discuss this in relation to the study results.

(6) Paragraph 2 – please could the authors clarify what they mean in the sentence ”sometimes we allow parents to refuse”…by “we”..who is “we”?

(7) Paragraph 3 – The study results demonstrate that parents may not be receiving the consent forms and that only half sign the consent forms etc. I suggest the authors quote their data here and have sentence summarising the implications of your results.

Minor Essential Revisions

(8) The writing requires some revision in terms of English language and grammar. The reviewer appreciates that writing a journal article in a language other than your first language spoken at home, may be difficult. However to
publish this article in an English language journal, further work is required.

Introduction

(9) Paragraph 2 - please clarify the aim and outputs of the study, clearly stating whether you are evaluating health care providers role in the process of informed consent, or whether you are evaluating parent’s knowledge of vaccines or both.

(10) Paragraph 2/last sentence – Please rewrite and correct the English in this sentence.

Methods

(11) Last sentence - please could the authors clarify whether they refer to written informed consent in regards to consent to participate in the study or something else?

Results

(12) When referring to data in either Table 1 or 2 please reference it at the end of the sentence.

(13) Please consistently use percentages when quoting data and/or total numbers i.e. (numerator/denominator) in this section.

Discussion

(14) Paragraph 1 - I think it is misleading to start the overall summary of the results of this study by mentioning “other potential sources” of information i.e. media. These were not evaluated in the study and no conclusions can be drawn about the impact of these sources of information.

(15) Paragraph 2 – Vaccination has both individual (i.e. protection against infection and severe disease) and collective benefits (i.e. herd immunity may provide additional benefit through reduced transmission in the population). Have the authors taken these into consideration in your discussion of the difference in biomedical ethics in this paragraph?

(16) The last sentence in the conclusion section does not make sense. Are the authors saying that the informed consent process is not adequate enough to help provide parents the information they need to make an informed decision? “informed consent” does not “inform parents” itself.

Major Compulsory Revisions

Aim/abstract

(17) The aim of the study needs to be reworded so that it is clear exactly what the study is evaluating e.g. is it the process of obtaining informed consent from parents for vaccination of their children in vaccination centres in Italy? Clarification of the outcome measures for this study is needed.

Methods

(18) Methods are appropriate, but require some further clarity. Sample size – further explanation of the authors derived at the sample size would be helpful
here. For example; what level of power and significance was assumed?

(19) Informed consent – The authors have provided no detail here on how they evaluated the “clarity and completeness” of the informed consent forms. Completeness can potentially be evaluated by checking against government recommendations as you list in the results section, but “clarity” is something that would require evaluation from the parent’s point of view on whether they understood the information in the consent form. Could the authors please update this section and the results section accordingly to demonstrate clearly the outcomes they were evaluating?

Results

(20) Last sentence – “only 35% (364/1039) of parents” this data is not in Table 2. Please add this data to Table 2 or better explain how you arrived at recording this result.

(21) Table 3 – please update the response set headings for the question “Do you know which vaccines are mandatory?” – the response sets “Not correct” “Hexavalent” etc either need to be changed completely or require further explanation in the methods section.

(22) Last paragraph – “with the exception of the difference between centres’ distribution of informed consent” – the authors did not mention this measurement in the methods section. Either add the method for this evaluation or omit these results altogether. Also the authors should mention the methods you used to examine any significant differences in the data according to demographics.

Discussion

(23) Further rewriting is needed before the discussion section demonstrates an adequate balance between reporting data and discussing the results in light of other relevant studies or work. For example do parents need to be better educated about the consent process, what it means and how they can become informed about vaccines? Or do health care workers need to be trained in how to provide informed consent procedures and information to parents? Or both?

Level of interest: An article whose findings are important to those with closely related research interests

Quality of written English: Needs some language corrections before being published

Statistical review: No, the manuscript does not need to be seen by a statistician.

Declaration of competing interests:

I declare that I have no competing interests.