Reviewer's report

Title: Risk of serious complications and death from smallpox vaccination: A systematic review of the United States experience, 1963-1968

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Reviewer: Paolo Bonanni

Level of interest: not specified

Advice on publication: Other (see below)

The article represents an useful review of the risks of serious complications and deaths following smallpox vaccination. The methodology is well described, and strength and weakness of the analysis are correctly outlined. However, there are a few points that should be addressed by the Authors before acceptance of the article for publication.

Discretionary revisions

While changing the Conclusions section (see Compulsory revisions), the Authors could expand their considerations on the policy of voluntary vaccination of public officials in the light of the results of their review. It would be interesting to know their opinion on the balance between risks and benefits of smallpox immunization in selected groups of population.

Compulsory revisions

Page 8, Methods section, sub-heading 'Quantitative data synthesis': the Authors should explain more clearly how they solved the different classification of age groups in the study by Ratner.

Page 10, Results section, lines 3-10. There is a mistake in the counting of excluded studies. Their total number (to be subtracted from 18) is 11 and not 10, as erroneously reported.

Page 13, Results section, sub-headings Generalized vaccinia and Accidental infection (inadvertent autoinoculation). There is a mistake in the reporting of data of risk range of accidental infections (the same values of generalized vaccinia are erroneously reported). Table 5 probably supplies the right values (please check).

Page 15, Discussion section, first line. The sentence should be change as follows: 'To our knowledge, this is the first systematic review of the severe complications of smallpox vaccination in the USA'.

Page 18, Discussion section, paragraph starting with 'Fifth (limitation)'. While explaining why the CDC approach not to combine risk estimates from different studies is probably correct, the Authors should also give the reasons for maintaining the pooled summary measures in the article despite
some drawbacks they may present.

Page 20, Conclusions section. All the section should be re-written, since in its present form all Conclusions are an unnecessary duplication of information and considerations already reported in the Discussion section. It may be useful to use the section to express an opinion on the current policy of immunization in USA (see Discretionary revisions).

**Competing interests:**

None declared.