



International Alliance for
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Workshop on Assessing Consequences of Maternal Immunization on Foetal Outcomes

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Title: Could Statistical methods matter?

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The typical analysis of preterm birth following vaccination of a pregnant mother in a randomised trial involves treating the timing of delivery as a simple binary outcome; before 37 weeks of gestational age is preterm. This is not generally statistically efficient. It is also dependent on accurate estimation of gestational age at birth, which is not necessarily easy, particularly in resource-poor settings.

Taking into account the continuous time from date of vaccination has several advantages. The outcome itself is measurable very precisely in all settings; it allows for the possibility of studying effects that could occur at very low gestational ages; regression methods can take estimated gestational age at vaccination into account. The latter is important because the proportion of preterm births varies with the timing of vaccination which is the start of follow-up in a trial.

Some suggestions for better methods of analysis taking these points into account will be presented. These include survival analysis methods like the proportional hazards (Cox) model. Methods chosen should reflect clinical relevance as well as being statistically efficient.

