

Systematic review of the non-specific effects of BCG, DTP and measles containing vaccines

APPENDIX 4: SCREENING AND DATA EXTRACTION FORMS

Abstract Screening

Refid: 12, Skateboards: Are they really perilous? A retrospective study from a district hospital.
Rethnam U, Yesupalan RS, Sinha A.

BACKGROUND: Skateboarding has been a popular sport among teenagers even with its attendant associated risks. The literature is packed with articles regarding the perils of skateboards. Is the skateboard as dangerous as has been portrayed?

METHODS: This was a retrospective study conducted over a 5 year period. All skateboard related injuries seen in the Orthopaedic unit were identified and data collated on patient demographics, mechanism & location of injury, annual incidence, type of injury, treatment needed including hospitalisation.

RESULTS: We encountered 50 patients with skateboard related injuries. Most patients were males and under the age of 15. The annual incidence has remained low at about 10. The upper limb was predominantly involved with most injuries being fractures. Most injuries occurred during summer. The commonest treatment modality was plaster immobilisation. The distal radius was the commonest bone to be fractured. There were no head & neck injuries, open fractures or injuries requiring surgical intervention.

CONCLUSION: Despite its negative image among the medical fraternity, the skateboard does not appear to be a dangerous sport with a low incidence and injuries encountered being not severe. Skateboarding should be restricted to supervised skateboard parks and skateboarders should wear protective gear. These measures would reduce the number of skateboarders injured in motor vehicle collisions, reduce the personal injuries among skateboarders, and reduce the number of pedestrians injured in collisions with skateboarders.

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Abstract screening

Abstract level screening aims to "exclude" completely irrelevant references, but if it is unclear it should go to a next level

Is an abstract available?

- ☒ Yes
☐ No

Study type <i>Note: Do not exclude articles if the abstract suggest that they might be re-analyses</i>	<input type="radio"/> RCT <input type="radio"/> Retrospective/historical Cohort <input type="radio"/> Prospective Cohort <input type="radio"/> Cross-sectional <input type="radio"/> Case-Control <input type="radio"/> Ecological study <input type="radio"/> Case Report <input type="radio"/> Case Series <input type="radio"/> Case only study <input type="radio"/> Literature (narrative) review <input type="radio"/> Systematic Review or Meta-analysis <input type="radio"/> Commentary or Editorial <input type="radio"/> Other (please specify) <input type="text"/> <input type="radio"/> Cannot tell
Is the study in human subjects?	<input type="radio"/> Yes, in human subjects <input type="radio"/> No, in animal subjects <input type="radio"/> No, laboratory study <input type="radio"/> Other (please specify) <input type="text"/> <input type="radio"/> Cannot tell
Is all-cause mortality reported as part of the results? <i>Might be reported in different ways. For definitions click here.</i> <ul style="list-style-type: none">• All-cause mortality• Deaths from all causes• Child survival• Under 5 mortality• Child mortality	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Cannot tell <input type="radio"/> Other (please specify) <input type="text"/>
Which intervention(s) is/are included in the study? <i>[check all that apply]</i>	<input type="checkbox"/> Measles containing vaccine <input type="checkbox"/> DTP containing vaccine <input type="checkbox"/> BCG <input type="checkbox"/> Vitamin A <input type="checkbox"/> No childhood vaccine reported <input type="checkbox"/> Other (please specify) <input type="text"/> <input type="checkbox"/> Cannot tell

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Full-text Screening

Refid: 12, Skateboards: Are they really perilous? A retrospective study from a district hospital.
Rethnam U, Yesupalan RS, Sinha A.

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Full text screening

Did this study reported on BCG, DTP or Measles-containing vaccines?

- ☒ Yes
☐ No (please specify the vaccine)
☐ Cannot tell - Study in foreign language (please specify)

Study design

For information about different study designs, please click [here](#)

- ☐ Randomised controlled trial
☐ Quasi-randomised or Controlled clinical trial
☐ Case-control study
☐ Prospective and historical cohort studies
☐ Ecological studies
☐ Cross-sectional study
☐ Not primary research (e.g. review, commentary)
☐ Uncontrolled studies (e.g., case series or case report)
☐ Laboratory or animal studies
☐ Case only studies
☐ Other (please specify)

Were participants children at any age from 0 to 5 years?

- ☐ Yes
☐ No
☐ Unclear (please specify)
☐ Not applicable

Vaccines and/or interventions reported [check all that apply]

- ☐ BCG
☐ DTP-containing vaccines
☐ Measles-containing vaccines
☐ Vitamin A
☐ None of the above (please specify)
☐ Other (please specify)
☐ Not applicable

Is all-cause mortality reported as part of the results?

[All-cause mortality or deaths from all causes or child survival or under 5 mortality or child mortality]

For definitions click [here](#)

- ☐ Yes
☐ No
☐ Others (please specify)
☐ Not applicable

Comments

Form 1: Basic Information and Eligibility

P. Aaby, H. Ravn, A. Roth, A. Rodrigues, I. M. Lisse, B. R. Diness, K. R. Lausch, N. Lund, J. Rasmussen, S. Biering-Sorensen, H. Whittle and C. S. Benn. Early diphtheria-tetanus-pertussis vaccination associated with higher female mortality and no difference in male mortality in a cohort of low birthweight children: An observational study within a randomised trial. *Archives of Disease in Childhood*. 2012. 97:685-691

Attachments
25 Aaby 2012.pdf

[Submit Form](#) and go to [Next Form, New Instance - This reference](#) or [Skip to Next](#)

BASIC INFORMATION

Study name (First author last name-Country, year) <input type="text"/>	First author (last name) <input type="text"/> Year (4 digits) <input type="text"/>	Sponsor (Type of sponsor) <input type="checkbox"/> Government agency <input type="checkbox"/> Not for profit organization (including academic/WHO/etc) <input type="checkbox"/> Pharmaceutical industry <input type="checkbox"/> Other <input type="text"/> <input type="checkbox"/> Not reported
Sponsor (Name of sponsor) <input type="text"/>	Trial Registration Number <input type="text"/>	Companion papers (At this point companion papers should be already grouped, in this case there is no need to complete this question) <input type="text"/>

ELIGIBILITY CHECK

Study design <input type="radio"/> RCT <input type="radio"/> Quasi-RCT <input type="radio"/> Prospective cohort <input type="radio"/> Historical cohort <input type="radio"/> Ambi-directional cohort <input type="radio"/> Case-control <input type="radio"/> None of these/Unclear <input type="radio"/> Other (specify) <input type="text"/>	Includes children under 5 years? <input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unclear	Vaccines reported (Check all that apply) <input type="checkbox"/> BCG <input type="checkbox"/> DTP-containing vaccines <input type="checkbox"/> Measles-containing vaccines <input type="checkbox"/> None of the above (specify) <input type="text"/>
Outcomes reported (Check all that apply) <input type="checkbox"/> All-cause mortality only <input type="checkbox"/> Non-targeted mortality only <input type="checkbox"/> Both all-cause and non-targeted mortality <input type="checkbox"/> Neither (specify) <input type="text"/>	For what time points are mortality data available? (Please explain if any of the above are unclear) <input type="checkbox"/> One year <input type="text"/> <input type="checkbox"/> Five years <input type="text"/> <input type="checkbox"/> Neither <input type="text"/>	If eligibility is unclear, state reason <input type="text"/>

STUDY MOTIVATION

Purpose of study to examine effects of vaccine? <input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unclear	A priori analysis plan <input checked="" type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unclear Is there evidence of a protocol or pre-specified analysis plan? (Please provide details (e.g. url) if there is) <input type="text"/>
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[Submit Form](#) and go to [Next Form, New Instance - This reference](#) or [Skip to Next](#)

Form 2: Studied population

P. Aaby, H. Ravn, A. Roth, A. Rodrigues, I. M. Lisse, B. R. Dinessa, K. R. Lausch, N. Lund, J. Rasmussen, S. Biering-Sorensen, H. Whittle and C. S. Benn. Early diphtheria-tetanus-pertussis vaccination associated with higher female mortality and no difference in male mortality in a cohort of low birthweight children: An observational study within a randomised trial. *Archives of Disease in Childhood*. 2012. 97:685-691

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ABOUT THE STUDIED POPULATION

Area within country (name or description of area, province, district, village) <input type="text"/>	Country (name of country) <input type="text"/>
Urban or rural area, or both <input type="radio"/> Urban <input type="radio"/> Rural <input type="radio"/> Mixed <input type="radio"/> Not reported	Reported vaccine coverage in the studied population Percentage of children who received vaccination according to the country schedule in their first year of age (if reported). <input type="checkbox"/> Reported BCG vaccine coverage in the studied population (%) <input type="text"/> <input type="checkbox"/> Reported DTP-containing vaccine coverage in the studied population (%) <input type="text"/> <input type="checkbox"/> Reported measles-containing vaccine coverage in the studied population (%) <input type="text"/> <input type="checkbox"/> Not reported
Reported vaccine coverage refers to: <input type="radio"/> Study area <input type="radio"/> Country <input type="radio"/> Region <input type="radio"/> Not reported	Source of vaccine coverage data <input type="checkbox"/> Information in the article <input type="checkbox"/> Local report <input type="checkbox"/> National report <input type="checkbox"/> WHO estimates <input type="checkbox"/> Coverage survey <input type="checkbox"/> Other <input type="checkbox"/> Not reported
Background rate of measles in the community (cases per 1000 per year) <input type="text"/>	Age group to which measles rate applies <input type="text"/>
Background rates of pertussis in the community <input type="text"/>	Is the study limited to a specific group? If a specific group, what sort? <input checked="" type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Not clear <div style="display: flex; justify-content: space-between;"> <div> <input type="checkbox"/> Low birth weight <input type="checkbox"/> Chronically ill children <input type="checkbox"/> Twins <input type="checkbox"/> Other (specify) <input type="text"/> </div> <div> <input type="text"/> <input type="text"/> <input type="text"/> </div> </div>

[Submit Form](#) and go to [Next Form, New Instance - This reference](#) or [Skip to Next](#)

Form 3: Methods (RCT or Quasi-RCT)

<p>RefId: 12, Skateboards: Are they really perilous? A retrospective study from a district hospital.</p> <p>Retnam U, Yesuparan RS, Sinha A.</p> <p>Submit Form and go to <input type="button" value="1"/> or Skip to Next</p>	
<p>BACKGROUND: Skateboarding has been a popular sport among teenagers even with its attendant associated risks. The literature is packed with articles regarding the perils of skateboards, is the skateboard as dangerous as has been portrayed?</p> <p>METHODS: This was a retrospective study conducted over a 5 year period. All skateboard related injuries seen in the Orthopaedic unit were identified and data collated on patient demographics, mechanism & location of injury, annual incidence, type of injury, treatment needed including hospitalisation.</p> <p>RESULTS: We encountered 50 patients with skateboard related injuries. Most patients were males and under the age of 15. The annual incidence has remained low at about 10. The upper limb was predominantly involved with most injuries being fractures. Most injuries occurred during summer. The commonest treatment modality was plaster immobilisation. The distal radius was the commonest bone to be fractured. There were no head & neck injuries, open fractures or injuries requiring surgical intervention.</p> <p>CONCLUSION: Despite its negative image among the medical fraternity, the skateboard does not appear to be a dangerous sport with a low incidence and injuries encountered being not severe. Skateboarding should be restricted to supervised skateboard parks and skateboarders should wear protective gear. These measures would reduce the number of skateboarders injured in motor vehicle collisions, reduce the personal injuries among skateboarders, and reduce the number of pedestrians injured in collisions with skateboarders.</p>	
<p>METHODS</p> <p>The study design is:</p> <p><input checked="" type="radio"/> RCT or quasi-RCT</p> <p><input type="radio"/> Cohort</p> <p><input type="radio"/> Case-control</p> <p>Brief summary of eligibility criteria</p> <p>How was sample size determined? e.g. details of sample size calculation for the current study with data on NSE of vaccines (not for the original study, if this does not include data). This might often be not reported</p>	
<p>Start day of enrolment (e.g. 23 March 2001) Please state if not reported</p> <p>End day of enrolment (e.g. 23 March 2001) Please state if not reported</p> <p>Start day of follow-up (e.g. 23 March 2001) Please state if not reported</p> <p>End day of follow-up (e.g. 23 March 2001) Please state if not reported</p> <p>Age at first follow-up visit (months) Please state if not reported</p> <p>Period between follow-up visits (months) Please state if not reported</p> <p>Age at last follow-up visit (months) Please state if not reported</p>	<p>Details of non-regular follow-up visits Please state if not reported</p> <p>Were there interruptions to the provision of any vaccines during the period of study?</p> <p><input type="radio"/> Yes</p> <p><input type="radio"/> No</p> <p><input type="radio"/> Unclear</p> <p><input type="radio"/> Unknown</p>
<p>RCT or QUASI-RCT</p> <p>How many intervention groups were there?</p> <p><input type="radio"/> 1</p> <p><input type="radio"/> 2</p> <p><input type="radio"/> 3</p> <p><input type="radio"/> 4</p> <p><input type="radio"/> 5</p> <p><input type="radio"/> 6</p> <p>Type of comparison</p> <p><input type="radio"/> BCG vs no BCG</p> <p><input type="radio"/> DTP vs no DTP</p> <p><input type="radio"/> Measles vs no measles</p> <p><input type="radio"/> BCG vs other BCG</p> <p><input type="radio"/> DPT vs other DPT</p> <p><input type="radio"/> Measles vs other measles</p> <p><input type="radio"/> BCG vs DPT (or vice-versa)</p> <p><input type="radio"/> BCG vs Measles (or vice-versa)</p> <p><input type="radio"/> BCG vs DTP + Measles</p> <p><input type="radio"/> Not a comparison of vaccines</p> <p><input type="radio"/> Other comparison of vaccine schedules</p>	
<p>Brief summary of intervention group 1</p> <p>Brief summary of intervention group 2</p>	<p>Describe the randomization or allocation process (direct quotes from the text)</p>
<p>METHODS OF DATA COLLECTION</p> <p>How was mortality data collected?</p> <p><input type="checkbox"/> Not reported</p> <p><input type="checkbox"/> Verbal autopsy</p> <p><input type="checkbox"/> Facility health records</p> <p><input type="checkbox"/> Routine visits to homes</p> <p><input type="checkbox"/> Other (specify) <input type="text"/></p> <p>Summarize methods for collecting ALL-CAUSE mortality outcome data (how outcome was ascertained), including any attempts to blind assessors to treatment group</p> <p>Direct quotes from the text of the report should be included here</p> <p>Describe how missing mortality data were dealt with</p> <p>State any methods for seeking, imputing or otherwise dealing with missing mortality data. Direct quotes from the text of the report may be included here.</p> <p>Summarize methods for collecting NON-TARGETED mortality outcome data (how outcome was ascertained), including any attempts to blind assessors to treatment group</p> <p>Direct quotes from the text of the report should be included here</p> <p>Comments (if needed)</p> <p>Submit Form and go to <input type="button" value="2"/> or Skip to Next</p>	

Form 3: Methods (Cohort and Case-control studies)

Refid: 12, Skateboards: Are they really perilous? A retrospective study from a district hospital.
Rethnam U, Yesupalan RS, Sinha A.

[Submit Form](#) and go to [1](#) or [Skip to Next](#)

METHODS

The study design is:

- ☐ RCT or quasi-RCT
☒ Cohort
☐ Case-control

How was sample size determined?

e.g. details of sample size calculation for the current study with data on NSE of vaccines
(not for the original study, if this does not include data).
This might often be 'not reported'

Start day of enrolment (e.g. 23 March 2001) Please state if not reported	<input type="text"/>	Details of non-regular follow-up visits Please state if not reported	<input type="text"/>
End day of enrolment (e.g. 23 March 2001) Please state if not reported	<input type="text"/>		
Start day of follow-up (e.g. 23 March 2001) Please state if not reported	<input type="text"/>	Were there interruptions to the provision of any vaccines during the period of study?	
End day of follow-up (e.g. 23 March 2001) Please state if not reported	<input type="text"/>	<input type="radio"/> Yes	
Age at first follow-up visit (months) Please state if not reported	<input type="text"/>	<input type="radio"/> No	
Period between follow-up visits (months) Please state if not reported	<input type="text"/>	<input type="radio"/> Unclear	
Age at last follow-up visit (months) Please state if not reported	<input type="text"/>	<input type="radio"/> Unknown	

COHORT STUDY

Source of information on vaccination status <input type="checkbox"/> Recorded at point of vaccination <input type="checkbox"/> Review of vaccination centre records <input type="checkbox"/> Patient-held vaccination cards <input type="checkbox"/> Interview with parent or guardian <input type="checkbox"/> Physical exam of child <input type="checkbox"/> Other (specify) <input type="text"/> <input type="checkbox"/> Not reported	Describe how vaccination status was determined Full detail should be provided of how vaccination status was determined in order to define the various groups being compared <input type="text"/>	Strategy for pursuing missing data on vaccination status Describe what the researchers did to obtain information on vaccination status when it was not readily available from their primary data collection method. For example, vaccination status may have been sought retrospectively after a child had died. <input type="text"/>
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METHODS OF DATA COLLECTION

How was mortality data collected? <input type="checkbox"/> Not reported <input type="checkbox"/> Verbal autopsy <input type="checkbox"/> Facility health records <input type="checkbox"/> Routine visits to homes <input type="checkbox"/> Other (specify) <input type="text"/>	Summarize methods for collecting ALL-CAUSE mortality outcome data (how outcome was ascertained), including any attempts to blind assessors to treatment group Direct quotes from the text of the report should be included here <input type="text"/>
Describe how missing mortality data were dealt with State any methods for seeking, imputing or otherwise dealing with missing mortality data. Direct quotes from the text of the report may be included here. <input type="text"/>	Summarize methods for collecting NON-TARGETED mortality outcome data (how outcome was ascertained), including any attempts to blind assessors to treatment group Direct quotes from the text of the report should be included here <input type="text"/>
Comments (if needed) <input type="text"/>	

Form 4: Participants and Vaccines

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<div>Submit Form and go to or Skip to Next</div>	
PARTICIPANTS	
<p>Total number in the trial or cohort at the outset (number of people recruited into the whole original cohort)</p> <input type="text"/>	<p>Flow charts of groups and participants through the study Please report if study provides a flow chart, naming Ref ID, figure and page</p> <input type="text"/>
<p>Total number involved in analysis in this paper (number of children who form the basis of the current report)</p> <input type="text"/>	
<p>Which vaccines had (all or most of) the children received before the start of the study? Check all that apply</p> <p>This refers to vaccines received PRIOR TO CLASSIFICATION INTO EXPOSURE GROUPS. For randomized trials, these are vaccines received before randomization. For cohort studies, these are vaccines that all participants received.</p> <p><input type="checkbox"/> None <input type="checkbox"/> BCG <input type="checkbox"/> DTP 1 <input type="checkbox"/> DTP 1 and 2 <input type="checkbox"/> DTP 1, 2 and 3 <input type="checkbox"/> Varicella <input type="checkbox"/> Pertia <input type="checkbox"/> Rota <input type="checkbox"/> PCV <input type="checkbox"/> Hib <input type="checkbox"/> Other (specify) <input type="text"/> <input type="checkbox"/> Not reported</p>	<p>Age Age (in months) of children (at baseline) in the study as a whole. Please provide mean, median and range if available.</p> <input type="text"/> <p>Proportion of females</p> <input type="text"/> <p>Socioeconomic background Brief narrative summary for the study as a whole</p> <input type="text"/> <p>Ethnicity Brief narrative summary of ethnicities of children for the study as a whole</p> <input type="text"/> <p>Were any participants HIV infected?</p> <p><input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Not reported</p>
VACCINES	
<p>Which vaccines were given in the study?</p> <p><input checked="" type="checkbox"/> BCG <input checked="" type="checkbox"/> DTP <input checked="" type="checkbox"/> Measles</p> <p>BCG type/strain Check all that apply</p> <p><input type="checkbox"/> Connaught <input type="checkbox"/> Copenhagen <input type="checkbox"/> Danish (Statens) <input type="checkbox"/> Moreau (Brazilian) <input type="checkbox"/> Russian (Moscow) <input type="checkbox"/> Tice (BCG) <input type="checkbox"/> Tokyo (Japanese) <input type="checkbox"/> Volebacillus <input type="checkbox"/> Sophia (Bulgaria) <input type="checkbox"/> Madra <input type="checkbox"/> Coded by number only <input type="checkbox"/> Not reported <input type="checkbox"/> Other (specify) <input type="text"/></p> <p>Delivery strategy for BCG</p> <p><input type="radio"/> Routine <input type="radio"/> Campaign <input type="radio"/> By researchers (e.g. clinical trial) <input type="radio"/> Mixture (specify) <input type="text"/> <input type="radio"/> Not reported</p> <p>DTP type/strain Check all that apply</p> <p><input type="checkbox"/> DTP - Pertussis acellular <input type="checkbox"/> DTP - Pertussis whole (specify manufacturer) <input type="text"/> <input type="checkbox"/> Other (Specify) <input type="text"/> <input type="checkbox"/> Not reported</p> <p>Delivery strategy for DTP</p> <p><input type="radio"/> Routine <input type="radio"/> Campaign <input type="radio"/> By researchers (e.g. clinical trial) <input type="radio"/> Mixture (specify) <input type="text"/> <input type="radio"/> Not reported</p> <p>Measles type 1 or 2 doses plus campaigns</p> <p><input type="checkbox"/> Monovalent (M) <input type="checkbox"/> Measles-rubella (MR) <input type="checkbox"/> Measles-mumps-rubella (MMR) <input type="checkbox"/> Not reported</p> <p>Delivery strategy for measles</p> <p><input type="radio"/> Routine <input type="radio"/> Campaign <input type="radio"/> By researchers (e.g. clinical trial) <input type="radio"/> Mixture (specify) <input type="text"/></p> <p>Measles strain 1 or 2 doses plus campaigns</p> <p><input type="checkbox"/> Edmonston <input type="checkbox"/> Zagreb <input type="checkbox"/> Schwarz F88 <input type="checkbox"/> Moraten <input type="checkbox"/> AKC <input type="checkbox"/> CAM-70 <input type="checkbox"/> Leningrad-16 <input type="checkbox"/> Shanghai-191 <input type="checkbox"/> Cham-47 <input type="checkbox"/> Not reported <input type="checkbox"/> Other (specify) <input type="text"/></p> <p>Co-administration of vaccines If relevant</p> <input type="text"/>	
VITAMIN A	
<p>Is any vitamin A administration reported in the study?</p> <p><input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Not reported</p>	
<p>Comments (if needed)</p> <input type="text"/>	
<div>Submit Form and go to or Skip to Next</div>	

Form 5: Group Level Mortality Data

GROUP-LEVEL: A group of children up to 5 years with a distinct vaccine sequence/timing, for whom mortality data are reported

This is a multiple form and at least two of these should be completed per study

The table should be completed for all exposure groups that have been or could be compared in the study (where these exposure groups are distinct vaccine schedules). It must be completed for each randomized intervention from a randomized trial if the comparison is relevant to the review (e.g. not to be completed if the randomized comparison is (vitamin A) vs (no vitamin A)). Groups may overlap. For example, a randomized trial of (DPT) vs (no DPT) might present these two groups, but it might also present four groups according to whether or not children received BCG.

DEFINITION OF THE GROUP (VACCINES RECEIVED)

Brief descriptor of the group <input type="text"/>	Is this a randomized intervention group? RCTs of interventions other than vaccines presenting results for a relevant cohort of children should be treated as Cohort. <input type="radio"/> Yes <input type="radio"/> No
Number of vaccine events Number of vaccines or doses in the sequence/timing 2 <input type="text"/>	Each vaccine the children in the group received is a vaccine event. E.g. If they received BCG at birth, DTP 1 at 1 month, DTP 2 at 2 months and DTP 3 and measles simultaneously at 9 months, this would be 4 vaccination events.

VACCINE EVENT 1

Vaccine administered <input type="radio"/> BCG <input type="radio"/> BCG + DTP1 simultaneously <input type="radio"/> BCG + DTP2 or 3 simultaneously <input type="radio"/> DTP1 only <input type="radio"/> DTP2 only <input type="radio"/> DTP3 only <input type="radio"/> Measles only <input type="radio"/> Measles + DTP2 or 3 simultaneously <input type="radio"/> BCG + DTP + Measles simultaneously <input type="radio"/> Other (specify) <input type="text"/>	Age of children on this group when vaccine was administered (months) <input type="text"/> Age of children when data was collected (months) <input type="text"/> Any specific details about the vaccine that distinguishes it from other groups in the study <input type="text"/>
Was this vaccine (on this group) co-administered with vitamin A? Are there any contraindications or exclusion criteria for children receiving the vaccine? <input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Not reported	<input type="radio"/> Yes (specify) <input type="text"/> <input type="radio"/> No <input type="radio"/> No information

VACCINE EVENT 2

Vaccine administered <input type="radio"/> BCG <input type="radio"/> BCG + DTP1 simultaneously <input type="radio"/> BCG + DTP2 or 3 simultaneously <input type="radio"/> DTP1 only <input type="radio"/> DTP2 only <input type="radio"/> DTP3 only <input type="radio"/> Measles only <input type="radio"/> Measles + DTP2 or 3 simultaneously <input type="radio"/> BCG + DTP + Measles simultaneously <input type="radio"/> Other (specify) <input type="text"/>	Age of children on this group when vaccine was administered (months) <input type="text"/> Age of children when data was collected (months) <input type="text"/> Any specific details about the vaccine that distinguishes it from other groups in the study <input type="text"/>
Was this vaccine (on this group) co-administered with vitamin A? Are there any contraindications or exclusion criteria for children receiving the vaccine? <input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Not reported	<input type="radio"/> Yes (specify) <input type="text"/> <input type="radio"/> No <input type="radio"/> No information

Describe any other interventions in this group that may have been received differently from the other groups
Look particularly for malaria interventions, de-worming, micronutrient supplements, breast feeding, hygiene programs

DESCRIPTION OF CHILDREN IN THIS GROUP

Number in group <input type="text"/>	Age at baseline (months) <input type="text"/>	Proportion of females <input type="text"/>
Information on key confounding domains:		
Socioeconomic status	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unclear	
Distance from vaccination centre	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unclear	
Nutritional status	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unclear	
Child's health	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unclear	
Birth weight	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unclear	
Hygiene conditions	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unclear	
Is there any indication that some eligible children are missing from the group?	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unclear	

MORTALITY DATA FOR THIS GROUP

Type of data:

- ☒ All-cause mortality
☒ Non-targeted mortality

ALL-CAUSE MORTALITY DATA

Age of children for this outcome	<input type="text"/>
Number of children entering the study in this group	<input type="text"/>
Number of children analyzed on this group	<input type="text"/>
Number of deaths from all causes	<input type="text"/>
Child-months (days/years) of observation for deaths from all causes	<input type="text"/>
Source of data	<input type="text"/>
Report table number and row, or page and paragraph	<input type="text"/>

NON-TARGETED MORTALITY DATA

Age of children for this outcome	<input type="text"/>
Number of children entering the study in this group	<input type="text"/>
Number of children analyzed on this group	<input type="text"/>
Number of deaths from non-targeted causes	<input type="text"/>
Child-months (days/years) of observation for deaths from non-targeted causes	<input type="text"/>
Source of data	<input type="text"/>
Report table number and row, or page and paragraph	<input type="text"/>
State causes of mortality covered in non-targeted deaths	<input type="text"/>

MORTALITY DATA BY LEVELS OF AN EFFECT MODIFIER FOR THIS GROUP

Key effect modifiers are sex (female vs male) and vitamin A status
Please report "person-time" as described in the paper

Define modifier level 1 <input checked="" type="checkbox"/> Females <input type="checkbox"/> Vitamin A <input type="radio"/> Other (specify) <input type="text"/> <input type="radio"/> No modifier reported	Define modifier level 2 <input checked="" type="checkbox"/> Males <input type="checkbox"/> No vitamin A <input type="radio"/> Other (specify) <input type="text"/> <input type="radio"/> No modifier reported
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MODIFIER LEVEL 1 - FEMALES

Number in modifier level	<input type="text"/>
Number of deaths	<input type="text"/>
Child-months of observation	<input type="text"/>

MODIFIER LEVEL 2 - MALES

Number in modifier level	<input type="text"/>
Number of deaths	<input type="text"/>
Child-months of observation	<input type="text"/>

Source of data

Report table number and row, or page and paragraph

Comments for the statistician (if needed)

and go to or

Form 6: Comparison Level Data

COMPARISON-LEVEL DATA

Details and results for a comparison of two groups

Groups being compared <input type="radio"/> Vaccinated vs. unvaccinated children <input type="radio"/> Two vaccines <input type="radio"/> Sequence of vaccines <input type="radio"/> Same vaccine <input type="radio"/> Other (specify) <input type="text"/>	Nature of the comparison <input type="radio"/> BCG vs no BCG <input type="radio"/> Comparison of different BCG strategies <input type="radio"/> DPT vs no DPT <input type="radio"/> Comparison of different DPT strategies <input type="radio"/> Measles vs no measles <input type="radio"/> Comparison of different measles strategies <input type="radio"/> Other comparison of different vaccine schedules <input type="radio"/> Other (specify) <input type="text"/>
Brief description the intervention GROUP being compared <input type="text"/>	Brief description the controlled GROUP being compared <input type="text"/>

BASIC INFORMATION

Brief description of the comparison <input type="text"/>	This comparison is: <input type="radio"/> Randomized <input type="radio"/> Quasi-randomized <input type="radio"/> Observational
Outcome addressed in this form: <input type="radio"/> All-cause mortality (specify age) <input type="text"/> <input type="radio"/> Mortality due to causes other than vaccine preventable (specify age) <input type="text"/>	
Is the sample used in the comparison restricted to a subgroup of a larger cohort? <input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unclear	Please describe the subgroup or sample addressed in this comparison <input type="text"/>

POTENTIAL FOR CONFOUNDING: MAIN EFFECT

Summarize any other differences between children in two groups

RESULT: MAIN EFFECT

Reported effect measure is: check all that apply <input checked="" type="checkbox"/> Adjusted <input checked="" type="checkbox"/> Unadjusted <input type="checkbox"/> Not reported	The measure of effect is: <input type="radio"/> Risk Ratio/Risk Relative <input type="radio"/> Hazard Ratio/LogHR <input type="radio"/> Odds Ratio <input type="radio"/> Other (specify) <input type="text"/>	ADJUSTED Effect measure for death <input type="text"/> CI lower limit <input type="text"/> CI upper limit <input type="text"/> P value <input type="text"/>	UNADJUSTED Effect measure for death <input type="text"/> CI lower limit <input type="text"/> CI upper limit <input type="text"/> P value <input type="text"/>	List variables adjusted for <input type="text"/> Source of data <input type="text"/>	Notes on statistical methods used <input type="text"/>	Notes on missing data <input type="text"/>
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POTENTIAL FOR CONFOUNDING: EFFECT MODIFICATION

Differences in vaccines across effect modifiers

RESULT: EFFECT MODIFICATION

Define modifier levels NR for not reported <input checked="" type="checkbox"/> Females vs males (adjusted) <input type="checkbox"/> Females vs males (unadjusted) <input type="checkbox"/> Females vs males (NR) <input type="checkbox"/> Vitamin A vs no vitamin A (adjusted) <input type="checkbox"/> Vitamin A vs no vitamin A (unadjusted) <input type="checkbox"/> Vitamin A vs no vitamin A (NR) <input type="checkbox"/> Other (adjusted) <input type="text"/> <input type="checkbox"/> Other (unadjusted) <input type="text"/> <input type="checkbox"/> Other (NR) <input type="checkbox"/> No effect modifier reported	The measure of effect is: <input type="radio"/> Risk Ratio/Risk Relative <input type="radio"/> Hazard Ratio/LogHR <input type="radio"/> Odds Ratio <input type="radio"/> Other (specify) <input type="text"/> Clear Response	List variables adjusted for <input type="text"/>	Source of data <input type="text"/>
FEMALES - ADJUSTED Effect measure for death <input type="text"/> CI lower limit <input type="text"/> CI upper limit <input type="text"/> P value <input type="text"/>	MALES - ADJUSTED Effect measure for death <input type="text"/> CI lower limit <input type="text"/> CI upper limit <input type="text"/> P value <input type="text"/>	Interaction result is: <input type="radio"/> Ratio of risk ratios (relative risks) <input type="radio"/> Ratio of hazard ratios <input type="radio"/> Ratio of odds ratios <input type="radio"/> Other	
Interaction in RR/OR/HR for death E.g., RR in level 1 / RR in level 2 CI lower limit <input type="text"/> CI upper limit <input type="text"/> P value <input type="text"/>	Notes on statistical methods used to assess effect modification <input type="text"/>	Notes on missing data <input type="text"/>	

Form 7: Risk of Bias Assessment for RCTs

RISK OF BIAS: CONFOUNDING			
Was the allocation sequence random? <small>Select an Answer</small>	Report details Including quotes from the paper	Internal comment If needed	
Was the allocation sequence concealed? <small>Select an Answer</small>	Report details Including quotes from the paper	Internal comment If needed	
Were participants similar in important baseline characteristics? <small>Select an Answer</small>	Report details Including quotes from the paper Based particularly on pre-specified critical confounding domain	Internal comment If needed	
Risk of bias judgement for bias due to confounding <small>Select an Answer</small>	Rationale for the risk of bias judgement In which direction would a high risk of bias be anticipated to affect the effect estimate? <small>Select an Answer</small>	Internal comment If needed	
RISK OF BIAS: DEPARTURES FROM INTENDED INTERVENTIONS			
Were participants blinded? <small>Select an Answer</small>	Report details Including quotes from the paper	Internal comment If needed	
Were vaccine administrators blinded? <small>Select an Answer</small>	Report details Including quotes from the paper	Internal comment If needed	
Was the most important co-intervention balanced across groups? <small>Select an Answer</small>	Report details Including quotes from the paper	Internal comment If needed	
Was the rate of failure to administer the vaccine as intended low enough that it does not threaten the validity of the outcome estimate? <small>Select an Answer</small>	Report details Including quotes from the paper	Internal comment If needed	
Risk of bias judgement for bias due to departures from intended interventions <small>Select an Answer</small>	Rationale for the risk of bias judgement In which direction would a high risk of bias be anticipated to affect the effect estimate? <small>Select an Answer</small>	Internal comment (if needed)	
<input checked="" type="checkbox"/> All-cause mortality <input type="checkbox"/> Non-targeted mortality Additional comments for "all-cause mortality" if relevant Additional comments for "non-targeted mortality" if relevant			
RISK OF BIAS: MISSING DATA			
All-cause mortality			
Are outcome data reasonably complete? <small>Probably no</small>	Report details Including quotes from the paper	Internal comment If needed	
Are participants with missing data similar across groups? <small>Select an Answer</small>	Report details Including quotes from the paper	Internal comment If needed	
Were appropriate statistical methods used to account for missing data? <small>Select an Answer</small>	Report details Including quotes from the paper	Internal comment If needed	
Risk of bias judgement for bias due to missing data <small>Select an Answer</small>	Rationale for the risk of bias judgement In which direction would a high risk of bias be anticipated to affect the effect estimate? <small>Select an Answer</small>	Internal comment (if needed)	
RISK OF BIAS: TAKING MEASUREMENTS			
All-cause mortality			
Were outcome assessors adequately blinded to the intervention received by study participants? <small>Select an Answer</small>	Report details Including quotes from the paper	Internal comment If needed	
Was the outcome objective? <small>Select an Answer</small>	Report details Including quotes from the paper	Internal comment If needed	
Were the methods of outcome assessment comparable for experimental and control groups? <small>Select an Answer</small>	Report details Including quotes from the paper	Internal comment If needed	
Risk of bias judgement for bias in taking measurements <small>Select an Answer</small>	Rationale for the risk of bias judgement In which direction would a high risk of bias be anticipated to affect the effect estimate? <small>Select an Answer</small>	Internal comment If needed	
RISK OF BIAS: SELECTION OF THE REPORTED RESULT			
All-cause mortality			
Is an a priori analysis strategy available? <small>Select an Answer</small>	Report details Including quotes from the paper	Internal comment If needed	
Is there evidence that the reported results could not have been affected by selective reporting? E.g. from among multiple adjusted analyses, through exclusion of individuals <small>Select an Answer</small>	Report details Including quotes from the paper	Internal comment If needed	
Risk of bias judgement for bias in selection of the reported result <small>Select an Answer</small>	Rationale for the risk of bias judgement In which direction would a high risk of bias be anticipated to affect the effect estimate? <small>Select an Answer</small>	Internal comment If needed	
OVERALL SUMMARY RISK OF BIAS JUDGEMENT			
Risk of bias judgement for this outcome overall <small>Select an Answer</small>	Rationale for the risk of bias judgement In which direction would a high risk of bias be anticipated to affect the effect estimate? <small>Select an Answer</small>	Internal comment If needed	
General Comments			