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Reading Paper

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JAGIELLONIAN UNIVERSITY MEDICAL COLLEGE

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Points: /13

Read the article below, then according to what you have read complete Task Sheet 1.

Efficacy of a Tetravalent Dengue Vaccine in Healthy Children and Adolescents

Methods

(1) In this phase 3, double-blind, randomized, placebo-controlled trial, we enrolled healthy children and adolescents at 26 sites in which dengue is endemic in Brazil (4 sites), Colombia (4), the Dominican Republic (2), Nicaragua (1), Panama (4), the Philippines (4), Sri Lanka (4), and Thailand (3); participants received their first injections between September 2016 and March 2017. The trial is being conducted in accordance with the Declaration of Helsinki and the International Council for Harmonisation Tripartite Guidelines for Good Clinical Practice, as well as in accordance with applicable local regulations. Informed assent or consent forms and the trial protocol and its amendments (available with the full text of this article at NEJM.org) were reviewed and approved by institutional review boards, independent ethics committees, and health authorities. Written informed assent or consent was obtained from all participants or their parents or legal guardians before enrolment. During the trial, consent was obtained again from participants when they legally became adults. At the time of this analysis, the process of obtaining repeat consent for some participants was ongoing. Should any of these participants decline to provide repeat consent, data that were collected after they had reached legal adult age will be removed from future analyses.

(2) The trial sponsor, Takeda Vaccines, is responsible for the overall trial design (taking into consideration the investigators' input), trial site selection, and data analysis. The trial investigators are responsible for data collection and day-to-day trial site management. To maintain blinding in this ongoing trial, certain authors employed by the sponsor, including a statistician, and the medical writers had access to group- and individual-level trial data and vouch for the accuracy and completeness of the data. Other authors had access only to the data presented in this article. All the authors vouch for the fidelity of the trial to the protocol. Medical writers at OLC Bioscience who were paid by the sponsor prepared the first draft of the manuscript on the basis of an outline previously agreed on by all the authors. All the authors provided critical input during manuscript preparation and approved the submitted version. An independent data and safety monitoring committee has access to unblinded safety data on request.

(3) Children and adolescents 4 to 16 years of age who met the trial entry criteria were randomly assigned in a 2:1 ratio to receive two doses of vaccine or placebo, 3 months apart. Randomization was stratified according to region (Asia-Pacific region or Latin America) and age (4 to 5 years, 6 to 11 years, or 12 to 16 years). A subpopulation of 4000 of the 20,099 participants who underwent randomization was randomly selected for additional safety and immunogenicity assessments. During

the trial, investigators, participants and their parents or guardians, and representatives of the sponsor who advise on trial conduct remain unaware of the trial-group assignments. One or more designated pharmacists or vaccine administrators at each site are aware of the trial-group assignments but have no role in the collection or assessment of participant safety data.

(4) This ongoing trial consists of three parts for each participant, with active surveillance during parts 1 and 2 and modified active surveillance during part 3 (Fig. S1 in the Supplementary Appendix available at NEJM.org). Participants or their parents or guardians are contacted at least weekly for the entire trial duration to remind them to present for evaluation of febrile illness (defined as body temperature ≥38°C in any 2 of 3 consecutive days) to ensure identification of dengue cases. Part 1 was complete after 120 cases of virologically confirmed dengue had been confirmed for the analysis of the primary end point and participants had had 12 months of follow-up after the second vaccination. Data from part 1 are reported here. Part 2 lasts for another 6 months for the assessment of secondary efficacy end points, to be followed by an additional 3 years in part 3 for the evaluation of long-term efficacy and safety.

(657 words)
source: https://www.nejm.org/doi/full/10.1056/NEJMoa1903869

TASK SHEET 2

1) Match the phrases expressing the message of a given paragraph (A-F) with the appropriate number indicating the paragraph (1 - 4). There are two options that do not match any of the paragraphs.

A	critical part of the trial	-
B	trial procedures	
C	participants, randomisation, blinding	
D	sponsors of the trial	
E	authors' responsibilities	
F	trial oversight	

/4 points

2) Choose the best answer (A, B, C, or D) in each question according to what you have read.

Q01

	A	Healthy children and adolescents with dengue were enrolled in the study.
	B	Four children from Panama and three children from Thailand were enrolled in the study.
	C	Healthy children and healthy adolescents were enrolled in the study .
	D	Twenty six healthy children and adolescents from Brazil were enrolled in the study.

Q02

	A	The trial is conducted in Helsinki.
	B	The trial is conducted in accordance with the local and international regulations.
	C	The trial is conducted with the Declaration of Helsinki in mind, regardless of the local regulation.
	D	The trial is conducted in accordance with the local regulations, regardless of the Declaration of Helsinki.

Q03

	A	Informed consent was obtained from all participants' parents and legal guardians.
	B	Either participants or their parents or legal guardians gave informed consent .
	C	Participants' legal guardians and parents were responsible for the informed consent.
	D	Participants' legal guardians were responsible for the informed consent.

Q04

	A	Medical writers had access to individual and group- level trial data only.
	B	Medical writers had access only to the data presented in the article.
	C	Authors other than medical writers and a statistician had no access to the individual and group-level data .
	D	Authors other than medical writers and a statistician were part of the monitoring committee, so they had access to individual and group-level data.

Q05

	A	All authors were critical about the manuscript preparation .
	B	All authors submitted critical versions of the manuscript .
	C	All authors in the safety monitoring committee unblinded the data on request
	D	All authors' made important contribution to the manuscript.

Q06

	A	All children and adolescents 4 to 16 years of age met the trial entry criteria.
	B	All children and adolescents 4 to 16 years of age received two doses of vaccine.
	C	All children and adolescents 4 to 16 years of age received two doses of placebo.
	D	All children and adolescents 4 to 16 years of age received vaccine or placebo.

Q07

	A	All pharmacists at each site were aware of the trial group assignments.
	B	All pharmacists at each site were aware of the assessment of participant safety data.
	C	Some pharmacists or vaccine administrators at each site had access to participants' data.
	D	Some pharmacists or vaccine administrators at each site knew about group assignments.

Q08

	A	Participants contacted their parents at least once a week for the entire trial duration.
	B	Participants' parents contacted their guardians at least weekly for the entire trial.
	C	Participants were contacted weekly by the researchers during the entire trial duration.
	D	Participants contacted the researchers once a week during the entire trial duration.

Q09

	A	Participants met to remind their parents to present for evaluation of febrile illness.
	B	Parents met to remind the participants to present for evaluation of febrile status.
	C	Researchers contacted participants to remind them to present for evaluation of febrile status.
	D	Researchers were contacted by participants to be reminded to present for evaluation of febrile status.

/9 points

1) Match the phrases expressing the message of a given paragraph (A-F) with the appropriate number indicating the paragraph (1 - 4). There are two options that do not match any of the paragraphs.

A	critical part of the trial	-
B	trial procedures	4
C	participants, randomisation, blinding	3
D	sponsors of the trial	-
E	authors' responsibilities	2
F	trial oversight	1

/4 points

2) Choose the best answer (A, B, C, or D) in each question according to what you have read.

Q01

	A	Healthy children and adolescents with dengue were enrolled in the study.
	B	Four children from Panama and three children from Thailand were enrolled in the study.
x	C	Healthy children and healthy adolescents were enrolled in the study.
	D	Twenty six healthy children and adolescents from Brazil were enrolled in the study.

Q02

	A	The trial is conducted in Helsinki.
x	B	The trial is conducted in accordance with the local and international regulations.
	C	The trial is conducted with the Declaration of Helsinki in mind, regardless of the local regulation.
	D	The trial is conducted in accordance with the local regulations, regardless of the Declaration of Helsinki.

Q03

	A	Informed consent was obtained from all participants' parents and legal guardians.
x	B	Either participants or their parents or legal guardians gave informed consent.
	C	Participants' legal guardians and parents were responsible for the informed consent.
	D	Participants' legal guardians were responsible for the informed consent.

Q04

	A	Medical writers had access to individual and group- level trial data only.
	B	Medical writers had access only to the data presented in the article.
x	C	Authors other than medical writers and a statistician had no access to the individual and group-level data.
	D	Authors other than medical writers and a statistician were part of the monitoring committee, so they had access to individual and group-level data.

Q05

	A	All authors were critical about the manuscript preparation.
	B	All authors submitted critical versions of the manuscript.
	C	All authors in the safety monitoring committee unblinded the data on request.
x	D	All authors' made important contribution to the manuscript.

Q06

	A	All children and adolescents 4 to 16 years of age met the trial entry criteria.
	B	All children and adolescents 4 to 16 years of age received two doses of vaccine.
	C	All children and adolescents 4 to 16 years of age received two doses of placebo.
x	D	All children and adolescents 4 to 16 years of age received vaccine or placebo.

Q07

	A	All pharmacists at each site were aware of the trial group assignments.
	B	All pharmacists at each site were aware of the assessment of participant safety data.
	C	Some pharmacists or vaccine administrators at each site had access to participants' data.
x	D	Some pharmacists or vaccine administrators at each site knew about group assignments.

Q08

	A	Participants contacted their parents at least once a week for the entire trial duration.
	B	Participants' parents contacted their guardians at least weekly for the entire trial.
x	C	Participants were contacted weekly by the researchers during the entire trial duration.
	D	Participants contacted the researchers once a week during the entire trial duration.

Q09

	A	Participants met to remind their parents to present for evaluation of febrile illness.
	B	Parents met to remind the participants to present for evaluation of febrile status.
x	C	Researchers contacted participants to remind them to present for evaluation of febrile status.
	D	Researchers were contacted by participants to be reminded to present for evaluation of febrile status.

/9 points