FORM A2: CASE-CONTROL STUDY

(https://www.moncsr.gov.om/)

Use this section if the research is a retrospective analytical study involving clinical cases (e.g. patients) and controls. Case-control studies are usually employed to estimate the strength of association between a clinical condition or an outcome of interest with the prior exposure to a potential causal / risk factor.

If any of the items are not applicable to your study, please mention “NA” to indicate Not Applicable in the corresponding response box. You should also add any additional information that is pertinent or specific to your study in the section provided for it.

9. STUDY GROUP / CASES

9.1 Specify the criteria used to define a CASE as a case in the study (e.g. clinical diagnosis, disease specific characteristic, outcome of interest, etc.)

The case definition for dengue infection as well as the definitions of warning signs, severe dengue, and dengue shock syndrome (DSS), will be referenced from the WHO 2009 guidelines (WHO, 2009). All cases of dengue will be defined as a patient admitted with a diagnosis of probable dengue confirmed by either being seropositive for dengue non-structural glycoprotein 1 (NS1), and/or Immunoglobin lin M (IgM) antibodies, and/or by polymerase chain reaction (PCR). Dengue-associated death will be defined

Reviewers Comments :

No comments

10.1 What is the Source / Reference / Target population of CASES for the purpose of the study?

The target population, cases, are patients who have been diagnosed with dengue and admitted in 2023 in Muscat.

10.2 Who are the accessible participants (to be drawn from the source /reference population) who are under consideration for the study?

dengue patient who was not admitted, not having confirmed testing of dengue, not on the same period 2023

10.3 How will the potential study participants (CASES) be accessed / invited to participate in the study from

the accessible population?

Electronic e-notification system for cases examined by health care professionals at primary, secondary, and tertiary health institutions.
2.2. Contact investigation for early diagnosis of cases.

Reviewers Comments :

10.1: The answer does not fit the question. Please read the question carefully and answer it accordingly.
10.2: The answer does not fit the question. Please read the question carefully and answer it accordingly.==========2nd review: please make sure to answer the question as stated in 10.2.

11.

11.1 Specify the inclusion criteria.

1-dengue confirmed cases: either being seropositive for dengue non-structural glycoprotein 1 (NS1), and/or Immunoglobin lin M (IgM) antibodies, and/or by polymerase chain reaction (PCR).
2- admitted cases
3- death confirmed due to dengue: a death resulting from or as a direct consequence of acute dengue infection.
4- period 2023

11.2 Specify the exclusion criteria.

1- not confirmed cases
2- not admitted
3- not on the same period year 2023

11.3 : After applying the inclusion / exclusion criteria, does the selected study population of CASES closely represent the source / reference /target population such that the study findings and conclusions will apply to the reference population? (External validity). Briefly explain.

population of infected people because they were matched with cases of death regarding age and sex and 4 or 5 will be selected for every case of death.

12.1 : How will the required sample be selected from eligible CASES?

according to the case definition: patients who have been diagnosed and admitted as having dengue cases and died of dengue on the same period 2023.

12.2 : Describe briefly the sampling technique including any sub-categories.

All death cases of dengue in Muscat governate in the year 2023 have been reported by the hospitals during admission time and the final diagnosis was death due to dengue. This includes all hospitals in Muscat that admitted dengue cases in the same period.

Reviewers Comments :

11.3: The answer does not fit the question. Please read the question carefully and answer it accordingly.
12.1: The answer does not fit the question. Please read the question carefully and answer it accordingly.
12.2: Please specify the hospitals? and will you collect data from the hospital records?

13. SAMPLE SIZE ESTIMATION OF THE CASES

13.1 : What is the proposed sample size?

All the fatal cases of dengue reported in 2023 (19) and 3 controls for each fatal case matched socio demographically with cases

13.2 What is the basis for sample size calculation and how was it calculated? Indicate the anticipated variability, margin of error, confidence level, effect size or other measures to justify sample size.

The study sample will be 95 patients and deaths. The sample size is calculated as follows: All cases (deaths) will be selected (19), and four controls from the same pool of patients will be matched for each case of death (76). Therefore, the total sample size will be 95.

Reviewers Comments :

13.1: what is the reason of selecting the patients only in 2023 as it leads to low number of cases in your study? It will be better to include other years in order to increase the number of cases.
13.2: Here you mentioned 4 controls for each case and in the summary your mention 5 control for each case?

13.3 What are the baseline study factors (characteristics / parameters / variables) relevant to the study that will be measured at the beginning of the study?

The data variables will include socio-demographic characteristics, such as age and sex, as well as clinical details, including the presence of fever and associated symptoms important clinical signs such as altered sensorium, abnormal reflexes, ascites, bleeding manifestations, pallor, icterus, edema, hypotension, and circulatory failure will also be collected, along with the presence of complications. Biochemical parameters, including hemoglobin, total cell count, ESR, platelet count, electrolyte imbalance, liver function, and renal function, will be considered. Thrombocytopenia will be defined as a platelet count of less than 100,000 at any point during illness. Risk factors for dengue mortality and mortality rate in different seasons and month of year will also be assessed.

Reviewers Comments :

No comments

14. CONTROL GROUP

14.1 Specify the selection technique of the control group. Indicate the source population, accessible population and selection process.

Controls will be randomly selected from DF patients admitted during the same study period, matched with cases for age and sex, with five controls chosen for every dengue-associated death.

14.2 Is the study group and control group similar except for the outcome factor (e.g.: disease)? What are the relevant measures of similarity that are to be matched between Cases and Controls (e.g.: age group, gender, severity of disease, ethnicity, socio-economic status, BMI etc.)? Measure only those that can have a confounding effect on the association between the study factors.

matched with cases for age and sex, with five controls chosen for every dengue-associated death.

14.3 How many controls will be selected for each case (e.g.: 1 Case to 4 Controls, 1: 1 etc.). Indicate the justification and feasibility.

3 controls were chosen for every dengue-associated death.

14.4. How will the eligible participants be enrolled / allocated to the study?

- ○ Random allocation
- ○ Systematic allocation
- ◉ Convenient sample
- ○ All eligible

14.5. Describe briefly the sampling technique including any sub-categories.

matched with cases for age and sex,Admitted on the same period 2023

Reviewers Comments :

14.1: Please refer to the comments in the summary regarding the appropriate case: control ratio.
14.2: Please refer to earlier comments regarding matching the cases and control by age and gender.
14.3: Please refer to earlier comments regarding the case: control ratio.
14.4: You mentioned convenient sampling while in the summary you mentioned random sampling. Please specify the sampling technique of the control group.
14.5: The answer does not fit the question. Please read the question carefully and answer it accordingly.

15. INFORMED CONSENT

15.1 Explain briefly how, when and by whom informed consent will be taken? How will it be ensured that the consenter / participant has fully understood all the rights, duties and privileges of consenting including the right to withdraw at any time and other inalienable rights that have to be granted due to the nature of the study?

The study will be getting approval by the Ethics Committee of the Directorate General of Health Services in Muscat Governorate, MOH. Data will be gathered from existing health information systems and within the disease surveillance and control reports.

Attach a copy of the consent form.
Upload :
Choose File No file chosen

15.2 Is there likely to be any perceived coercion/undue pressure (direct or indirect) or incentive (material or otherwise) that may influence the participation in the study? Briefly explain how this issue is addressed.

there is no coercion that can influence the participation in this study

Reviewers Comments :

15.2: The answer does not fit the question. Please read the question carefully and answer it accordingly.

16. Measuring instrument (Instrument used for determining OUTCOME [e.g.: disease] measurement): Describe how the outcome of interest in the study will be gathered. Specify how the instrument will be evaluated for Validity and Reliability.

Comparisons across different age groups for initial presentation with warning signs, pre-morbid illnesses, criteria for severe dengue, and causes of death were performed using Pearson Chi-Square tests. The two-sided statistical significance level, p-value, was set at 0.05 for all inferential analyses in this study.

Reviewers Comments :

16. The answer does not fit the question. Please read the question carefully and answer it accordingly.

17. What are the EXPOSURE factors that are to be studied (as specified in the hypothesis / research question)?

The data variables will include socio-demographic characteristics, such as age and sex, as well as clinical details, including the presence of fever and associated symptoms important clinical signs such as altered sensorium, abnormal reflexes, ascites, bleeding manifestations, pallor, icterus, edema, hypotension, and circulatory failure will also be collected, along with the presence of complications. Biochemical parameters, including hemoglobin, total cell count, ESR, platelet count, electrolyte imbalance, liver function, and renal function, will be considered. Thrombocytopenia will be defined as a platelet count of less than 100,000 at any

Reviewers Comments :

No comments

18. Confounders:

18.1 Are there other known risk factors that could affect the outcome factors either directly or indirectly? If yes, how will they be accounted for?

age group, gender should be accounted for both case and control group

18.2 What is the time period between exposure and outcome? Is it biologically reasonable?

in our study, there is no clear period between the exposure, dengue infection, and outcome, death or recovery.

18.3 Who and how will Exposure factors be estimated?

Electronic-based data will be extracted having the required information for estimation of risk and predictive factors

18.4 What are the potential bias in the estimation of the Exposure. How will bias such as Recall Bias be reduced.

The study will use secondary data and records.

19 Measuring instrument (Instrument used for Exposure [Risk factor] measurement): Describe how the outcome of interest in the study will be gathered. Specify how the instrument will be evaluated for VALIDITY and RELIABILITY

.

Risk factors will be estimated through Lab results. the outcome of interest will be dichotomous, (dead and alive)

Reviewers Comments :

18.3: Kindly, mention the source of data? Are your going to retrieve the data from the hospital records and if yes, which hospital?

20. Blinding: Will the person evaluating the Exposure be aware of the outcome status of the subject. How will blinding of the Exposure evaluator to the outcome be achieved?

The study will use secondary data and the design is a case-control

Reviewers Comments :

No comments

21. Data Synthesis and Management : Note: Please include a copy of the Data collection pro forma along with this application in 'Attachments' section)

1-age and sex, as well as clinical details,
2-including the presence of fever and associated symptoms important clinical signs such as altered sensorium, abnormal reflexes, ascites, bleeding manifestations, pallor, icterus, edema, hypotension, and circulatory failure will also be collected, along with the presence of complications. Biochemical parameters, including hemoglobin, total cell count, ESR, platelet count, electrolyte imbalance, liver function, and renal function, will be considered. Thrombocytopenia will be defined as a platelet count of less than 100,000 at any point during illness. Risk factors for dengue mortality and mortality rate in different seasons and month of year

Attach a copy of the Data collection pro form.

Upload :

Choose File No file chosen

21.1 What are the important variables that will be collected & what are the nature/characteristics of the variables (ordinal, nominal, continuous, categorical etc.)?

Sociodemographic variables. the outcome factor is dichotomous and predictive factors are both categorical and continuous.

21.2 Indicate the computer program that will be used for data entry and data analysis.

R Sofware

21.3 Indicate the likely statistical tests that will be performed in analysing the data (Odds Ratio, multivariate analysis, confidence levels, level of significance etc. to be used in analysing the data).

Descriptive statistics for categorical data and inferential statistics will be in the form of logistic regression modeling for evaluation of fatality predictive factors

21.4 Quality Control of Data: What steps will be taken to ensure quality control of the data (data is properly collected, data entry is accurate, transcribed and decoded correctly, managed appropriately etc.)

Data will be extracted from the electronic platform and will be cleaned and validated by two data scientists. Data will be exported to R software for statistical analysis

Reviewers Comments :

21.3: Suggest to consult a statistician or epidemiologist before stating the data collection.

22.1 Please describe your work plan / timetable / Gantt chart. (Alternatively, it can be attached in 'Attachments' section)

the data collection will be for the year 2023

22.2 What is the anticipated conclusion that may result from the study and how can it be used to improve / enhance scientific knowledge, patient management, professional or administrative practice or influence policy making?

This study's findings will contribute to the existing knowledge of dengue epidemiology in Oman, specifically focusing on fatalities.

22.3 Beneficiaries of the research: Who will be the potential beneficiaries of the study and its application?

This study's findings will contribute to the existing knowledge of dengue epidemiology in Oman, specifically focusing on fatalities. The identification of demographic risk factors and potential contributors to mortality will assist in designing targeted interventions and public health policies to reduce dengue-related deaths in Oman.

22.4 How will the conclusions of the study be disseminated for use by the scientific / professional / administrative community?

The identification of demographic risk factors and potential contributors to mortality will assist in designing targeted interventions and public health policies to reduce dengue-related

Reviewers Comments :

22.3: This question is intended to describe the beneficiaries of the research, such as: patients, medical, policy makers.....etc. Please re-check your answer.

23. What are the potential short comings of the study?

This study's findings will contribute to the existing knowledge of dengue epidemiology in Oman, specifically focusing on fatalities.

24.1 Priority and Importance of the study / research topic.

The identification of demographic risk factors and potential contributors to mortality will assist in designing targeted interventions and public health policies to reduce dengue-related deaths in Oman.

24.2 Is your chosen research topic part of the ‘Health Research Priorities’ as listed in the booklet by the Ministry of Health?

- ○ Yes
- ◉ No

If yes, kindly mention to which priority topic your research is related to.

Reviewers Comments :

23: The answer does not fit the question, please read the question carefully and answer it accordingly.

25. Highlight the ethical issues in the study and how they have been addressed.(Refer the 'Ethical Checklist' for relevant particulars)

The study will be getting approval by the Ethics Committee of the Directorate General of Health Services in Muscat Governorate, MOH. Data will be gathered from existing health information systems and within the disease surveillance and control reports.

26. Will the research take up any additional resources of the department / hospital / health facility, including but not limited to human resource, time, equipment, consumables, reagents, investigations, bed occupancy, finances etc. If yes, list them. Will the research adversely affect any of the normal services of the health facility? Has due permission been obtained from the appropriate authority to use the resources of the health facility? (Please include letter of approval(s) in 'Attachments' section)

NA

27. Pilot Study / Pre-test: Will there be a Pilot Study or a Pre-test of the questionnaire (data gathering instrument) that will be used in this study. If yes, how, when, where and by whom it will be done and how it may help the study. If no, justify why it is not required/necessary.

no pilot study

28. Any other additional information (if applicable)?

NA

Reviewers Comments :

25: What about the anonymity of the patients?

24. Are you planning to apply for a research grant through the Centre of Studies & Research of the Ministry of Health?

- ○ Yes
- ◉ No

If Yes, please submit / attach the Budget Form. (For more details about research grants, refer to the Health Research Funding Guideline)

Attachments:

Kindly attach all additional documents in this section:

1. List of Abbreviations (if applicable)

Choose File No file chosen

Download Doc (https://www.mohcsr.gov.om/wp-content/uploads/research_form_uploads/Abbreviations36.docx)

2. Curriculum Vitae of the P.I.

Choose File No file chosen

Download Doc (https://www.mohcsr.gov.om/wp-content/uploads/research_form_uploads/CV55.docx)

3. Curriculum Vitae of the Co-P.I./s

Choose File No file chosen

4. Participation Information Sheet

Choose File No file chosen

5. Informed Consent for Research Participants

Choose File No file chosen

6. Letter of Endorsement for the Study / Institutional Approval

Choose File No file chosen

7. Letter from Supervisor (for supervised studies)

Choose File No file chosen

8. Letter from Sponsor (for sponsored studies)

Choose File No file chosen

9. Data Collection Tools / Instrument

Choose File No file chosen

Download Doc (https://www.mohcsr.gov.om/wp-content/uploads/research_form_uploads/dengue morta data draft -1.xlsx)

10. Sample spreadsheet for the Data entry

Choose File No file chosen

11. Work plan / Timetable / Gantt chart

Choose File No file chosen

12. Other Information relating to the study

Choose File No file chosen

“ Declaration – To be signed by the Principal Investigator (P.I.) ”

If the application is accepted, I (we) declare that I (we) shall be actively engaged in, control the project and agree to provide progress reports and final report to the committee for revision before final dissemination of it.

I (we) confirm that the details of this proposal are a true representation of the research to be undertaken. I (we) will ensure that the research does not deviate from the protocol described. If significant protocol amendments are required as the research progresses, I (we) shall submit these to the Research and Ethical Review Committee for approval.

I (we) shall ensure that only the analysis specified in the protocol will be done on the samples. If I (we) send patients’ blood, body fluids or tissues outside the country for analysis, due permissions to do so will be obtained. Any unused or remaining samples will be disposed as per laboratory guidelines for specimen disposal.

Signature :

maryam

Date :

11/11/2023

Ethical Review Scoring Form (Only Used By Reviewer)

Clarity of the proposal

0

Are all aspects of the proposal consistent with international best practices?

0

How comprehensive and up to date is the review of literature?

0

New Idea: Is the proposal just a repetition of an earlier work or is it a new idea? (Novelty of proposal)

0

Scientific importance of the objectives of the proposals

0

Yield of the proposed research: Will it generate useful information / outcome at both the national and scientific level to improve the efficiency of the health system

0

Quality and feasibility of the research methodology and work plan

0

Research plan and management

0

Qualification and experience of the research team for the project implementation

0

Adequate manpower

0

Appropriate time schedule to carry out the research

0

Select Review Status :

Approval after Major changes

2nd Review

Select Review Status :

Approval after Major changes

General Reviews :

Please reply to each comment.

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Recent News

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January 15,2024
(https://www.mohcsr.gov.om/latest-news/clinical-trial-workshop/)

'Publication Support Program' from MoHERI
(https://www.mohcsr.gov.om/latest-news/publication-support-program-from-moheri/)
September 12,2023
(https://www.mohcsr.gov.om/latest-news/publication-support-program-from-moheri/)

MoHERI announces Call for National Research Award
(https://www.mohcsr.gov.om/latest-news/moheri-announces-call-for-national-research-award-2023-submission/)
July 03,2023
(https://www.mohcsr.gov.om/latest-news/moheri-announces-call-for-national-research-award-2023-submission/)

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