Refid: 1, There and Back Again: A Review of Residency and Return Migrations in Sharks, with Implications for Population Structure and Management.
Chapman DD, Feldheim KA, Papastamatiou Y, Hueter RE

1. Which outcome are you completing this form for? If they have BOTH clinical cure AND bacterial cure data, you should complete this form once for each outcome

- bacteriologic cure
- clinical cure

Bias arising from the randomization process

1.1. Was the allocation sequence random?

Yes - If the authors reported random allocation and provided details about the method used to generate a random sequence that show that the allocation sequence included a formal random process (e.g., random number generator / table, coin toss, randomized within blocks or stratum using a random process).

Probably Yes - If the authors reported that study was conducted under FDA or Good clinical practices management but did not explicitly state that allocation to treatment group was random and provide details on sequence generation

No - If the authors reported that allocation to treatment group was based on owner preference or another clearly non-random process

Probably no – If the authors described the use of systematic allocation (either every other animal, "gate cutting", "chute order", or every other day, etc) OR said they used "blocking" (e.g. allocation by age, weight, sex, parity or lactation number) but didn't include description of a random component (such as "first in block was determined by a coin toss).

No Information Random – If the authors used the word "random" but did not provide any details on how the sequence was generated.

No information at all - if the authors did not provide any information on how they allocated to treatment group.

(1.1)

- Yes
- Probably yes
- No
- Probably no
- No information random
- No information at all

Clear Response ()

Text from the manuscript to support the above response

1.2. Was the allocation sequence concealed until participants were recruited and assigned to interventions?

Allocation concealment is related to the way that subjects are enrolled into the study. Was the intervention to be received concealed from the person enrolling animals into the trial until the animal was assessed for eligibity and enrolled?

Yes - for studies where there are inclusion criteria (for example, if animal must have disease X to be included in the trial), if the person deciding whether or not the animal is eligible for the trial does so before they have any information on which intervention group will be assigned.

Probably yes - For trials where all are eligible (e.g. for vaccine trials where all animals or pens will be included in the trial), this is a moot concept so include these trials here.

Probably no - the authors state that allocation was concealed, but don't provide details of the concealment

No - there were eligibility criteria, and the authors explcitly stated that allocation was not concealed

No information - the authors do not provide any information on whether allocation was or was not concealed.

(1.2)

- Yes
- Probably yes
- No
- Probably no
- No information

Clear Response (i)

Text from the manuscript to support the above response

1.3. Were there baseline imbalances that suggest a problem with the randomization process?

Yes - If the authors reported the baseline data for each intervention group and there were meaningful imbalance between groups (the differences between groups are large, these may be statistically significant / not significantly significant / or not assessed statistically).

Probably yes - If the authors stated that the study was conducted under FDA or Good clinical practices management, but the group size per randomization site (e.g. per farm) was < 100 each, and baseline data were NOT reported for each group.

No - If the authors reported the baseline data for each of the intervention groups and there was no imbalance between groups.

Probably No - If the study was conducted under FDA or Good clinical practices management, and group size is > 100 for each site of randomization (not overall), even if there was no baseline data reported for each group. In this circumstance, it is very unlikely that such imbalances would occur.

No Information - No baseline data for each group was reported, nor did the authors report the use of FDA or Good clinial management practices - then say "no information" regardless of the study size of Q1.1 response.

(1.3)

- Yes
- Probably yes
- No

- Probably no
- No information

Clear Response ()

Text from the manuscript to support the above response

Risk of bias judgement (randomization process)

Low High Some concerns Clear Response ()

Bias due to deviations from intended interventions

2.1. Were participants aware of their assigned intervention during the trial?

This should automatically be answered as "no", because the participants are animals and therefore cannot be blinded, per se

(2.1)

- Yes
- Probably yes
- No
- Probably no
- No information

Clear Response ()

Text from the manuscript to suport the above response

2.2. Were care givers aware of participants' assigned intervention during the trial?

Yes - the authors explicitly stated that blinding was NOT used (either explicitly for care givers or "for all study personnel)

No - the authors state explicitly state that blinding of care givers (or all study personnel) WAS used

No information - authors did not state whether or not blinding of care givers was used

(2.2)

- Yes
- Probably yes
- No
- Probably no
- No information

Clear Response ()

Text from the manuscript to suport the above response

Was "Yes" or "Probably yes" or "no information" selected for 2.1 or for 2.2?

- (•) Yes
- ( ) No

Clear Response (i)

2.3. Were there deviations from the intended intervention beyond what would be expected in usual practice?

"intended intervention" refers to both the protocol for the allocated invention and also the equivalent management of study subjects across the entire follow-up period regardless of intervention group

Yes - the authors explicitly stated that there were deviations from the intended intervention (for instance, during the trial, animals received additional treatments because of an outbreak or based on disease severity)

No - the authors explicitly state that there were no deviations in the intended interventions between groups

No information - there is no discussion related to deviations from the intended intervention

(2.3)

- (•) Yes
- ( ) Probably yes
- ( ) No
- ( ) Probably no
- ( ) No information

Clear Response (i)

Text from the manuscript to suport the above response

2.4. Were these deviations from intended intervention unbalanced between groups and likely to have affected the outcome?

Yes - the authors explicitly stated that the deviations from the intended intervention differed by intervention group (e.g. different rations, different co-treatment, different farms) and that imbalance may have impacted the outcome (i.e. the deviation was related to an outcome - such as ration differences with ADG as an outcome)

Probably yes - interventions were allocated at the individual level, and it is possible that animals could have been differentially managed (e.g., individually allocated animals being managed differently, such as different level of milking scrutiny based on assumed intervention group) and this differential management could have affected the outcome

Probably no - the animals were housed / managed within a group and differential care between groups would be implausible

No - the deviations from intended interventions were not imbalanced or any imbalances would not be likely to affect the outcome

(2.4) - only need to answer if question to 2.3 was Y or PY or no information

- Yes - answer if you think that differential care could have meaningfully impacted the outcome
- Probably yes
- No
- Probably no
- No information

Clear Response (i)

Text from the manuscript to suport the above response

2.5. Were any participants analyzed in a group different from the one to which they were assigned?

NOTE: there are 2 reasons why the number in each intervention group may change over the course of a trial:

- lost to follow-up - the total sample size will be smaller
- deviation from intended intervention and per-protocol analysis - the number per group will change, but the overal sample size will not.

THIS QUESTION refers to the second of these choices

If it is a short term intervention, like a vaccine then this question should always be answered as "no".

Yes - The intervention is something that needs to be maintained over time (e.g. a teat sealant may fall off before the time that it is supposed to be used). If this is the type of intervention being evaluated, if the authors stated that some individuals did not complete the entire course of intervention (e.g., the teat sealant fell off), and the authors stated that it was a per protocol analysis, or the numbers suggest that it was a per protocol analysis (the number in each intervention group changes between allocation and analysis beyond those animals lost to follow up)

Probably yes - The intervention is something that needs to be maintained over time (e.g. a teat sealant may fall off before the time that it is supposed to be used). If this is the type of intervention being evaluated, if the authors stated that some individuals did not complete the entire course of intervention (e.g., the teat sealant fell off), and there is no information on sample size per group included in the analysis.

Probably no - The intervention is something that needs to be maintained over time (e.g. a teat sealant may fall off before the time that it is supposed to be used). If this is the type of intervention being evaluated, if the authors stated that there were no protocol deviations or the number analyzed per group suggest an intention to treat (ITT) analysis, but it is not explicitly stated that an ITT approach to analysis was used.

No - For interventions that need to be maintained over time, the authors explicitly state that all participants were analyzed in the group to which they were allocated (ITT analysis). Also if the intervention was a short term one (e.g. vaccine or most antibiotic treatment regimens), the anwer should be no.

No information - Interventions that need to be maintained over time, where there is no information on whether or not their were intervention deviations and it is not possible to determine whether the numbers analyzed per treatment group represent a per-protocol or ITT approach.

(2.5)

- Yes
- Probably yes
- No
- Probably no
- No information

Clear Response ()

Text from the manuscript to suport the above response

Risk of bias judgement (deviations from intended interventions)

Low High Some concerns Clear Response ()

Bias due to missing outcome data

3.1. Were outcome data available for all, or nearly all, participants randomized?

NOTE: there are 2 reasons why the number in each intervention group may change over the course of a trial:

- lost to follow-up - the total sample size will be smaller
- deviation from intended intervention and per-protocol analysis - the number per group will change, but the overal sample size will not.

THIS QUESTION refers to the first one of these options.

Yes - there were no animals lost to follow-up. To determine this, the authors need to have reported the number of animals enrolled (or allocated to treatment group) and also the number analyzed per group. Also "yes" if the authors explicitly state that no (or few) animals were lost to follow up.

Probably yes - the authors reported the numbers included in the analysis and the number was < 5% of the total number of animals enrolled in the trial (e.g., received a treatment)

No - Losses to follow up were >5%.

Probably no - not an option for this question.

No information - It was not possible to determine if there were any animals lost to follow up. This may be because they never report the number per group enrolled, OR don't report the number per group analyzed.

(3.1)

Yes
Probably yes
No
Probably no
No information

Clear Response ()

Text from the manuscript to suport the above response

3.2. If N/PN/NI to 3.1: Are the proportions of missing outcome data and reasons for missing outcome data similar across intervention groups?

Yes - the missing data appear equal or nearly equal between groups

No - the missing data are not equal between groups

No information - the authors did not report the numbers missing per group

(3.2)

- Yes
- Probably yes
- No
- Probably no
- No information

Clear Response (0)

Text from the manuscript to support the above response

3.3.If N/PN/NI to 3.1: Is there evidence that results were robust to the presence of missing outcome data?

The previous question mentioned "reasons for missing", but we have incorporated this concept under this question.

Yes - the authors conducted a worst-case scenario analysis (or other sensitivity analysis) to account for missing data OR the data were missing at random (e.g., lost ear tags, samples lost in transit to the lab)

No - the missing data do NOT appear to be missing at random (e.g., the reason they are missing may be related to the outcome - such as more severe disease, because of side effects, or euthanized for humane reasons)

No information - not information was provided on the reasons for losses to follow up

(3.3)

- Yes
- Probably yes
- No
- Probably no
- No information

Clear Response (0)

Text from the manuscript to support the above response

Risk of bias judgement (missing outcome data)

Low (•) High ( ) Some concerns Clear Response (0)

Bias in measurement of the outcome

4.1. Were outcome assessors aware of the intervention received by study participants?

Yes - the authors state that blinding was NOT used (either explicitly for outcome assessors or "for all study personnel)

No - the authors state explicitly state that blinding of outcome assessors (or all study personnel) WAS used

No information - the authors did not state whether or not blinding of outcomes assessors (or all study personnel) was used

(4.1)

- (•) Yes
- ( ) Probably yes
- ( ) No
- ( ) Probably no
- ( ) No information

Clear Response (i)

Text from the manuscript to suport the above response

4.2. If Y/PY/NI to 4.1: Was the assessment of the outcome likely to be influenced by knowledge of intervention received?

Yes - the outcome was subjectively measured (e.g., pain scores, morbidity based on clinical disease)

No - the outcome was objectively measured (e.g. rectal temperature, laboratory diagnosis, average daily gain)

Probably no - the outcome was subjectively measured, but the trial occured over a longer time, such that outcome assessors may have known treatment group at allocation but are unlikely to remember at the time of outcome assessment

No information - the authors did not describe outcome assessment in sufficient detail to determine if it was subjectively or objectively measured

(4.2)

- ( ) Yes
- ( ) Probably yes
- ( ) No
- ( ) Probably no
- ( ) No information

Clear Response (i)

Text from the manuscript to suport the above response

Risk of bias judgement (outcome measurement)

( ) Low (•) High ( ) Some concerns Clear Response (i)

Bias in selection of the reported result

5.1. Are the reported outcome data likely to have been selected, on the basis of the results, from multiple outcome measurements (e.g. scales, definitions, time points) within the outcome domain?

Yes / probably yes - if the trial protocol or the methods section of the trial report includes a different approach to the measurement of the outcome than measurement approach presented for that outcome results section of the trial report OR if the protocol / methods section describes multiple approaches to measurement of the outcome, but only a subset of these outcome measurement approaches are presented in the results (NOTE: this means that you will need to find the trial report, but given how few of these that we will see, please try to find them an check). As an example, if the protocol / methods state that disease status was determined by veterinarians and by owners, but on the data for the veterinarian-accessed outcomes are mentioned in the results.

No / probabaly no - there is clear evidence (usually through examination of a trial protocol or the description of the outcome measurement in the methods section) that all reported results for the outcome domain correspond to all intended outcome measurements, OR
There is only one possible way in which the outcome domain can be measured (hence there is no opportunity to select from multiple measures), OR
Outcome measurements are inconsistent across different reports on the same trial, but the trialists have provided the reason for the inconsistency and it is not related to the nature of the results.

No information - The a priori measurement approach is not available, or the intentions for measuring the outcome are not reported in sufficient detail to enable an assessment, and there is more than one way in which the outcome domain could have been measured.

(5.1)

- ○ Yes
- ○ Probably yes
- ○ No
- ○ Probably no
- ○ No information

Clear Response ⓘ

Text from the manuscript to suport the above response

5.2. Are the reported outcome data likely to have been selected, on the basis of the results, from multiple analyses of the data?

A particular outcome domain may be analysed in multiple ways. Examples include: unadjusted and adjusted models; final value vs change from baseline vs analysis of covariance; transformations of variables; conversion of continuously scaled outcome to categorical data with different cut-points; different sets of covariates for adjustment; different strategies for dealing with missing data. Application of multiple methods generates multiple effect estimates for a specific outcome domain. If multiple estimates are generated but only one or a subset is reported on the basis of the results (e.g. statistical significance), there is a high risk of bias in the fully reported result.

"Yes/Probably yes" - There is clear evidence (usually through examination of a trial protocol or statistical analysis plan) that a domain was analysed in multiple ways, but data for only one or a subset of analyses is fully reported (without justification), and the fully reported result is likely to have been selected on the basis of the results. Selection on the basis of the results arises from a desire for findings to be newsworthy, sufficiently noteworthy to merit publication, or to confirm a prior hypothesis. For example, trialists who have a preconception or vested interest in showing that an experimental intervention is beneficial may be inclined to

selectively report analyses that are favourable to the experimental intervention.

"No/Probably no" - There is clear evidence (usually through examination of a trial protocol or statistical analysis plan) that all reported results for the outcome domain correspond to all intended analyses. or There is only one possible way in which the outcome domain can be analysed (hence there is no opportunity to select from multiple analyses). or Analyses are inconsistent across different reports on the same trial, but the trialists have provided the reason for the inconsistency and it is not related to the nature of the results.

"No information" - Analysis intentions are not available, or the analysis intentions are not reported in sufficient detail to enable an assessment, and there is more than one way in which the outcome domain could have been analysed.

(5.2)

- ○ Yes
- ○ Probably yes
- ○ No
- ○ Probably no
- ○ No information

Clear Response (1)

Text from the manuscript to suport the above response

Risk of bias judgement (reported result selection)

○ Low ○ High ◉ Some concerns Clear Response (1)

Overall risk of bias judgement

Low risk of bias

- The study is judged to be at low risk of bias for all domains for this result.

Some concerns

- The study is judged to be at some concerns in at least one domain for this result.

High risk of bias

- The study is judged to be at high risk of bias in at least one domain for this result.
- The study is judged to have some concerns for multiple domains in a way that substantially lowers confidence in the result.

NOTE: The below question will automatically determine the overall risk of bias based on all above bias judgements. If any of the above bias domains were considered high risk, overall bias will be high risk. If at least one bias domain resulted in some concerns, overall bias will be some concerns. Importantly, the Revised RoB 2.0 tool suggested guidelines indicate that if there are some concerns for multiple domains ("in a way that substantialy lowers confidence in the result"), the study could be considered at high risk. The automated feature cannot make judgements and thus any concerns (i.e. computed overall risk is "some conerns" but the reviewer believes it should be considered "high risk") should be in included in the comments box.

Risk of bias judgement (overall bias)

○ Low ◉ High ○ Some concerns Clear Response (1)

Additional comments