Author's response to reviews

Title: Assessing Nonresponse Bias at Follow-up in a Large Prospective Cohort of Relatively Young and Mobile Military Service Members

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Author's response to reviews: see over
We appreciate the reviewers’ thoughtful critique of our manuscript. Below, we respond to each point raised by the reviewers. We hope that they find that we have adequately addressed their concerns and that the manuscript is now suitable for publication.

Sincerely,

Alyson Littman, Edward Boyko, Isabel Jacobson, Jaime Horton, Gary Gackstetter, Besa Smith, Tomoko Hooper, Paul Amoroso, and Tyler Smith, for the Millennium Cohort Team.

Reviewer #1

This is a topic of great interest to me and part of the work described in this paper is similar to a study reported by myself and colleagues in this journal on a UK-based military cohort (Tate07). The authors do not seem to be aware of this work, but I think they should find it very relevant to this study.

We appreciate this comment and are indeed familiar with the work of reviewer #1 and colleagues. The focus of our study, however, was on potential nonresponse bias at follow-up rather than at initial enrollment of the cohort.

Major compulsory revisions

1. The results are interesting in that they confirm other findings including those of our UK-based military study (Tate07) that less well-educated young men of lower rank etc. are less likely to respond to questionnaires, in this case the second time round. However, the authors have failed to examine what would seem to be a much greater possible cause of non-response bias – i.e. that only 30% of the original sample agreed to complete the initial questionnaire. Without accounting for the characteristics of these original “non-responders” who represent a much greater proportion of the sample than non-responders to the follow-up, the claims of the conclusions cannot be upheld.

The reviewer makes an important point about factors related to nonresponse to an initial invitation to enrollment, and it is interesting that we identified factors similar to the UK-based military study. These factors were reported in a previous publication [1]. We agree that nonresponse to the original survey is important and have conducted multiple investigations to understand potential biases in the enrolled cohort based on an initial 36% participation rate among those eligible and able to be contacted. Previously published Millennium Cohort studies [1-10] have included 1) an investigation of differences in early vs. late responders, 2) a comparison of the cohort to the overall military population, 3) analyses to adjust health
outcomes based on the inverse of the sampling and response patterns, 4) evaluation of the early mortality experience among Millennium Cohort participants and invited non-participants, and 5) investigations of health characteristics prior to enrollment. These thorough evaluations of possible biases have demonstrated that Cohort members are generally representative of the US military, that health prior to enrollment did not influence participation, and that Cohort questionnaire data are reliable and internally consistent [1-10].

Our current study evaluates factors associated with nonresponse at follow-up, rather than at the time of initial enrollment of cohort members. Our objective was to assess the extent of potential response bias that might affect measures of association between exposures and outcomes in longitudinal assessments. We have revised the title of the manuscript to reflect this focus. We have also revised our manuscript to better describe the context of this study within both the larger research setting, and specific to the Millennium Study Cohort.

2. In order to justify the conclusions, the authors need to consider non-response to both questionnaires, not just the follow-up. This should be possible as many of the factors related to non-response (i.e. the demographic and military data) were presumably known for the whole sample, and, as far as one can determine from the conclusions, it seems that these were the characteristics that had most influence on the weights.

Please see our response to item #1 above.

3. Once this has been done, it might then be possible to make further inferences on non-response related to measures based on answers to the follow up questionnaire using the propensity scores based on the whole sample.

We agree that understanding factors influencing nonresponse at baseline is important to correctly estimating the baseline prevalence of health conditions and states of the larger target population. As noted above in #1, we have conducted numerous analyses to assess and understand the degree to which the Millennium Cohort is representative of the military as a whole. The aim of the current study was to understand how nonresponse to the follow up questionnaire may have led to bias in prospective analyses.

Minor Essential Revisions

4. “The major threat to the validity of results from such studies is nonresponse to follow-up surveys” … Change “the major threat” to “a (possible) major threat”. I would argue that misclassification is a greater threat, see Tate07, and in any case the conclusions of this study (which says that non-response is not a major problem in this study) contradicts this statement.

The reviewer makes a good point. We have revised the text accordingly.
5. “Nevertheless, few studies have investigated factors predicting nonresponse in cohorts of younger adult participants.” Tate 07 analysed non-response for a very similar population (UK military). Please cite.

We acknowledge the importance of differentiating nonresponse at enrollment into a study and at follow-up in a longitudinal study and have cited Dr. Tate’s study, as well as reworded the phrase referred to above to read as follows: “Nevertheless, few studies have investigated factors predicting follow-up nonresponse in longitudinal cohorts of younger adult participants.”

6. Page 6. The numbers quoted for the responders do not seem to add up. 76,018 individuals completed the baseline questionnaire and 76,861 (of these?) were alive at the time of the follow up – please amend or explain the increase.

There was an inadvertent typographical error that we thank the reviewer for noticing. The error has been corrected. 77,047 individuals completed the questionnaire, of which 29 were determined to be ineligible and 86 had missing demographic data and thus were not included in analyses. One hundred and fifty seven initial responders died prior to when the invitation for the follow-up survey was made, leaving 76,775 for primary analyses. In the methods of the revised manuscript, we now state, “A total of 77,047 eligible individuals completed the baseline questionnaire; over half of the respondents did so online. Beginning in June 2004, cohort members were recontacted via e-mail and postal service to complete a follow-up survey. Twenty-nine of the responders to the baseline survey were later determined to be ineligible and 157 individuals died before June 2004. Methods for determining vital status are described in detail elsewhere [3]. Of the 76,861 individuals presumed alive at the time of the administration of the follow-up survey (June 2004–February 2006), 55,046 individuals completed it. After excluding 86 individuals with missing responses for covariates (see Statistical analyses section), 76,775 individuals were included in the analyses of baseline factors and 54,960 individuals were included in analyses as responders to the follow-up survey.”

7. The results section is confusing – particular wrt to the section describing the distribution of the propensity scores, depicted in Figure 1. I suggest that this section is removed and that the authors focus on how these scores relate to the measured characteristics.

We have revised the results section for clarity.

Discretionary Revisions

8. The methods section is overly long. Some methods are fairly standard for this type of analysis (e.g. propensity scores) and could be referenced instead of described in such detail. The results section could also benefit from being more succinct.

We have revised the methods and results to be more succinct.
9. This study could benefit from an analysis, or at least a discussion, of the potential threat of misclassification bias, as this could pose a far greater threat to the results than non-response. Were any questions built into the second questionnaire to check for this e.g. asking the same question again in a slightly different way? If so an analysis of such responses could be very informative. It is a shame that so many studies neglect to look at misclassification, and only check for non-response bias.

We agree that misclassification bias could potentially have a greater impact on the results than non-response bias. The issue of misclassification has been and continues to be a topic that is important to investigators involved in the Millennium Cohort Study. Assessing misclassification bias was outside the scope of this study, but we agree that such analyses, as described by the reviewer, would be very informative. Millennium Cohort Team members have published several manuscripts to date on this subject [5, 11-13] but will also likely produce several more in the future.

10. It would also be interesting to investigate whether the mode of answering the questionnaire had an effect on the responses

Yes, we agree and have previously investigated whether the mode of answering the questionnaire (web vs. paper) affected response at baseline [7]. In addition, in our current study, we evaluated whether mode of answering the questionnaire was associated with response to the follow-up survey. Because there was no association, we did not include this variable in Table 1. We do, however, report this result in the manuscript.
Reviewer #2

Major Compulsory Revisions
There are certain issues with this manuscript reflecting methodological concerns that require attention and clarification:

1. This manuscript may inadvertently introduce confusion into the use of the term “combat”. Using the definition in LeardMann et al, BMJ 2009;338:b1273), a “combat” experience was defined based on self-report of combat-related exposures, such as observing refugees, dead bodies, etc. As used in this manuscript, “military combat exposures” appears to imply objective assessment of deployment to a combat zone (as in Table 1) from DMDC-provided data, which is not equivalent, as certain deployments are not associated with such traumatic exposures.

If this error is confirmed, I would consider it essential that the manuscript make it clear that “deployment” and not “combat” is associated with increased response propensity, so as to avoid confusion across other published MCS manuscripts.

We appreciate the reviewer noting this possible source of confusion. Reviewer #2 is correct in stating that there is an important difference between being (1) deployed in support of conflicts or contingency operations and (2) exposure to combat or combat-related experiences (as described above). In the article by LeardMann et al, and in other Millennium Cohort Study manuscripts, combat exposure was defined based on self-report of combat-related exposures such as observing refugees, dead bodies, etc. In contrast, information about deployment is based on data from the Defense Manpower Data Center. This information is more clearly conveyed in the revised manuscript. In addition to clarification in the methods section of our manuscript, we have also revised Table 1 to be more explicit about the data sources for each variable.

2. It is rather difficult for me to accept the hypothesis that self-reported exposures and outcomes that would otherwise be reported on the follow-up survey are not to some significant degree influencing response propensity, and hence invalidating the critical Missing At Random (MAR) assumption and the conclusions of this analysis, particularly in relation to certain critical subgroups.

Assuming the correction noted in (1) above, although the data reassuringly suggest that “deployments” since 2001 are associated with a slight increase in response propensity, it is certainly not clear to me that all deployment experiences result in equal response propensity, particularly in relation to interactions based on frequency of deployment experience, deployment to a “combat” experience (using the definition in LeardMann et al, 2009), and interaction of age, military pay grade, baseline mental health status, and military status at follow-up. It seems reasonable that such differences in propensity must also be assumed to be influenced to some degree by significant differences in exposures and health outcomes.
For example, it is known that young, enlisted personnel, particularly in the Army and Marines, are facing unprecedented deployment pressures, often being deployed on “combat” tours of 12 to 15 months with barely 12 months of recuperation time between tours. It seems reasonable that these pressures are resulting in significant negative effects on response propensity among this group that may not be experienced by other study participants. Of concern, and contrary to the tone of the conclusion, the findings of this analysis do not inspire confidence that the MCS study design is adequately capturing without bias the unique experiences and outcomes of these members.

An explicit reassurance of this fact supported by data would prove beneficial, but not sufficient, in defending the MAR assumption against this reasonable threat, and would help to alleviate criticism that major findings from the MCS may not, in fact, be heavily influenced by some form of “healthy-responder” bias which would tend to skew many findings towards the null.

Specifically, it would be very helpful to see a table, preferably in the manuscript, revealing response status stratified by both deployment and “combat” experience between 2001 and 2006 among some of the groups seemingly at particularly high-risk for non-response: 17-24 year olds, those with baseline major depressive disorder, and among those no longer in military service.

We agree that nonresponse is likely associated with self-reported exposures and outcomes (and data from this study support this contention). The fact that self-reported exposures and data are associated with nonresponse, in fact, provides support for the missing at random assumption, which assumes that “missingness” depends on observed/measured data. The fact that so much data were collected at baseline also reduces the likelihood that some unmeasured factors that are associated with nonresponse were not captured [14]. Nevertheless, we acknowledge that it is important to consider interactions between variables, such as the ones noted by the reviewer. To address the point raised by the reviewer regarding whether we may have not fully accounted for variability in response based on the joint factors of age and deployment as well as age and self-reported military exposures (which is a proxy for exposure to combat), we have rerun our models including an interaction term between self-reported military exposures and age (p for interaction = 0.09) and between deployment and age (p for interaction = 0.41). Thus, it does not appear that after considering all of the other covariates and interaction terms already included in the model, that propensity scores (and consequently results adjusted for nonresponse) would differ importantly from those previously presented. These additional analyses and results are reported in the revised manuscript.

3. Current popular concerns related to the cumulative health effects of military service are increasingly focused towards these service members, particularly towards those among the group with a history of mental health disorders prior to deployment. Such concerns, of course, underscore that there is no substitute for adequate follow-up among these service members to support proper
epidemiological inference in this population. A statement to this effect should be prominent in the manuscript, particularly in reference to the results of the requested analysis.

We appreciate this suggestion and agree. There is no substitute for adequate follow-up among these service members to support proper epidemiological inference in this population. In the revised manuscript, we have added the following statement at the end of the discussion, “Nevertheless, there is no substitute for adequate follow-up to support proper epidemiologic inference; efforts to achieve and maintain high response rates are a worthwhile investment in this, and all prospective cohort studies.”

4. Among non-responders, it would be helpful if the authors could confirm the data sources and methods utilized to ascertain contact information among the 3000-large non-responder ancillary study referenced in the Conclusions section.

The reviewer’s inquiries regarding this ancillary study have prompted us to examine the methods of this study more closely in relation to the current manuscript. Interviewers in the ancillary study of nonresponders attempted to contact nonresponders via telephone to ask them a few questions about their reason for nonresponse and their current health status. As a first step, publicly available data sources were used to trace nonresponders, specifically, the National Change of Address database from the US Postal Service, Telematch (a computerized telephone number service that uses a name, street address and zip code to match against residential white pages to determine a telephone number), and COMSERV, Inc (a computerized system containing a comprehensive database of information on deceased individuals). For those not traced using publicly available data sources, more intensive tracing was accomplished via searching a series of proprietary databases that included information obtained from public and other sources of information, including the Internal Revenue Service, Directory Assistance, reverse directories, residential sources, specialized directories, and other consumer databases.

Only postal mail and email are used to contact Millennium Cohort Study participants at baseline and in follow-up surveys. As the interviews for the ancillary study were conducted via telephone, the contact information sought was for valid telephone numbers, not postal or email addresses. Thus, upon closer inspection, we feel that results from this ancillary study are relatively uninformative in relation to understanding the primary reasons for nonresponse. We also feel that explaining the study methods and possible limitations would be a distraction to the reader and therefore have removed it from the discussion.

5. It appears from Reference 10 (Ryan et al, 2007) that taxpayer records, likely referenced by Social Security Number, are utilized to obtain current address. If this is correct, how do the authors explain such a high rate of non-contact?

With such a high rate of operational tempo over the past decade, the location of military personnel who deploy frequently and for sometimes lengthy periods of time or who are called up to move and backfill positions around the country is a large problem for contacting this
young and mobile group. We now state in the discussion in the revised manuscript, “Second, we were unable to determine whether people did not respond due to refusal (i.e., they received the questionnaire, but chose not to complete it) or inability to be contacted (e.g., the questionnaire was never received due to a change in address, deployment or occupational situation preventing contact via postal or electronic mail, or blocked e-mails). With such a high rate of operational tempo over the past decade, the location of military personnel who deploy frequently and for sometimes lengthy periods of time or who are required to move and backfill positions around the country is a large problem for contacting this young and mobile group. As our study population consists of primarily young adults who are also highly mobile, it is plausible that frequent residential moves (typical of the current military lifestyle) may be unrelated to health outcomes. Nevertheless, we were unable to determine whether nonresponse was associated with outcomes under study and potentially incompatible with the MAR assumption.”

6. Additionally, it would be helpful to know whether records available through the Veterans Administration (VA) are utilized at all during contact tracing, and whether varying categories of separation from military service appear to be correlated with certain patterns of response propensity. Are accessing Veterans Administration health benefits or the awarding of a disability rating correlated with response propensity?

The original hope and plan for the study was to link Millennium Cohort Study members with VA databases. However, such linkage for outcome data or contact information has not been accomplished because of data security concerns.

7. Related to (3), the results alluded to in the Conclusions section that approximately half of all non-responders could not be located are, contrary to the tone of this section, also not reassuring, and suggest another significant potential source of bias not addressed in this analysis which seriously threatens the MAR assumption.

The nonresponse study conducted among a sample of 3,000 nonresponders at baseline was a telephone non-response study, so tracing efforts were to locate valid telephone numbers only. Findings from this ancillary study are only of limited utility because the majority of contact for Millennium Cohort participants is currently through email, not telephone. Thus, although approximately 50% of the sample from this ancillary study could not be located via a valid telephone number, we are hesitant to extrapolate this finding to all nonresponders in general since the main method of contact with our participants in 2004 (and subsequently as well) was through email. As noted in #4, we feel that including information on the nonresponse study will be a distraction; results are simply too difficult to interpret given the difference in mode of contact.

Given the findings presented, and pending the results of the authors’ response to (6), it would seem reasonable to entertain the hypothesis that access to health care through the VA system could affect both response propensity and health
outcomes to some significant degree, and that exposures and health outcomes as ascertained on the survey may also be significantly contributory to later access to VA care and likelihood of later contact. The implications of these possibilities should be discussed in greater detail in the Conclusions section as they relate to the MAR assumption.

Please see our response to #6 above. The Millennium Cohort does not currently have access to VA databases to obtain information on its cohort members, with the exception of ascertaining deaths. However, since 2008, the Millennium Cohort Study has been unable to access VA data on deaths as well.

8. Given the previous concerns, the presentation of data in Tables 2 through 4 distracts from a presentation of data more vital in judging the validity of the MAR assumption. Tables 2 through 4, and the corresponding sections devoted to their discussion in the Methods and Results sections, should be reserved for a stronger defense of this assumption, and a more open discussion of the threats to the validity of recent MCS findings, particularly as they relate to outcomes among the “combat” deployed cohort.

We are unaware of a way to empirically test the MAR assumption, as that would require data that were not in fact observed. However, there is support from the literature [15] that MAR is a reasonable assumption, especially in a study such as the Millennium Cohort where such a vast amount of data were collected on participants such that it is possible to consider a large number of factors (as well as interactions between those factors) and their association with response.

Minor Essential Revisions

9. More specifically, I remain somewhat confused as to how so few of the 77,047 enrolled and consenting cohort members prospectively enrolled in Panel 1 seem to be available at follow-up and reporting “combat” experiences (e.g. only 5,410 as reported in LeardMann et al, 2009), given that “combat” experiences would at least by anecdotal reports tend to comprise a significant proportion of recent deployments. As a number of published MCS manuscripts focus primarily or secondarily on the experiences of this “combat” deployed cohort, it is worthwhile to focus additional commentary on this area as it may relate to the potential for bias. Is information available to compare these cohort proportions against the entire force, so as to confirm representativeness? At face value, Panel 1 of the MCS appears increasingly non-representative of the current military force, particularly the portion of the military force at greatest concern in regards to health outcomes. Is so, this should be explicitly commented on.

It is our understanding that the Reviewer #2 is making the observation that the proportion of Panel 1 Millennium Cohort members who reported combat exposures appears to be low. Because this study was launched prior to the US’s involvement in the conflicts in Iraq and Afghanistan, these numbers would be expected to be lower for the first enrollment panel
compared with a random sample of military service members in 2010. The number to which
the reviewer refers from the LeardMann et al. study includes only those deployed between
baseline and follow-up, defined as between 2001 and 2004, from Panel 1 cohort members
(note that Panel 1 cohort members included those who were sampled from active duty and
Reserve and National Guard members in 2000).

The Millennium Cohort Study currently has three enrollment panels; Panel 2 and Panel 3 were
recruited in 2004 and 2007, respectively, thereby representing newer military accessions and
the current military force. Approximately 50% of cohort members have deployed in support of
the wars in Iraq and Afghanistan, and half of those are reporting combat exposures across all
panels. This is reasonable for a population-based study—not all deployers see combat, as the
reviewer notes.

10. It is not clear to me where the figure of N=76,775 comes from. I am attempting to
reconcile this figure with the N=77,047 reported as comprising the Panel 1
population in Reference 10 (Ryan et al, 2007). The discrepancy appears to be
due to ascertainment of death among some study members, but is not clear to
me how the authors determined whether a cohort member remained alive at the
time of the analysis. Could detailed clarification please be provided? Also, is it
correct to say that some deaths may not be ascertained?? If so, it may be more
correct to state “76,861 individuals thought to be alive” on page 6.

We have rewritten the methods so that the reader is better able to understand how the
numbers in this study correspond to other published Millennium Cohort Study reports. We also
now give a reference for a recently published paper which provides detailed methods on
ascertainment of deaths [3]. Finally, although errors in identifying deaths are relatively
uncommon, to be more precise, we now refer to the 76,775 as “individuals presumed alive” in
the revised manuscript.

Discretionary Revisions

11. This is a minor point, but Figure 1 could be significantly improved in appearance
through the use of an alternative software package; as it appears currently it
resembles the raw output of Stata. A properly formatted histogram consisting of
solid bars (not asterisks), with a clear white background, variable-width font for
labels, and a formatted box-plot would be well worth the effort for publication.

The reviewer’s point is well taken. We have created a new figure.

Reviewer #3

Major Compulsory Revisions

Methodological problems
1. In this kind of analysis, it is usual to group subjects into propensity classes, in order to avoid giving too much weight to few subjects with extreme values (see for instance: Jenkins et al., Am J Epid, 2008;167:369-374): when looking at figure 1 and the small number of subjects with a very low probability of responding, this should obviously have been done here.

In conducting our analyses, we considered creating quintiles of propensity scores (as recommended by the reviewer and employed for example in [16]), as well as treating propensity scores as a continuous variable [14] (as we presented in the submitted manuscript). The primary reason to group subjects into propensity classes is to avoid giving too much weight to a small number of subjects with extreme values. Such methods are a compromise between reducing bias and variance inflation. However, the down side of grouping is a loss of information and control for the construct the propensity score was intended to measure (non-response in our case). Our smallest propensity score (0.0696) led to a weight of 14.4; only 0.4% (n=229) of scores were less than or equal to 0.25 (equal to a weight of 4), suggesting that extreme values would give moderately high weights to only a few subjects. Thus, we felt that more was to be gained in terms of bias reduction from using the more precise continuous variable. The 95% confidence intervals widened only a relatively small amount, suggesting that variance inflation due to large weights was not a problem.

2. I do not understand what are “p-values methods” (page 8, last line of para 1).

In the revised manuscript, we have made it more clear what was intended by the phrase “p-value methods”. We now state, “The same factors were retained in our model whether we determined inclusion based on a $P$ value <0.05 or a lower AIC.”

3. There no mention at all of deaths occurring between the inception of the cohort and the FU survey: does it means that deaths were not traced?

In the revised manuscript, we clarify that deaths occurring between the inception of the cohort and the follow up survey were ascertained via linkage to several databases as describe in detail above to comment #4 to the second reviewer and described in detail elsewhere [3]. Please see the response to point #6 from Reviewer #1 for the text included in the revised manuscript.

4. There are some discrepancies in the numbers of subjects at baseline: page 6 line 2, 76,018 subject completed the baseline questionnaire, elsewhere they are 76,681, and sometimes 76,775… You should have read more carefully your manuscript before submission!

We appreciate the reviewer’s attention to detail and have now corrected the errors so that the numbers reported are consistent and correct.

5. The Methods section is not clearly written and a little bit confusing: a clear description of each step of the analyses would help.
We have revised the methods to be more clearly written.

6. Page 12, 3 lines before the end, it is stated that the OR for drinking problems and PTSD in Marine was 1.73 in the unweighted analysis and 1.60 in the weighted one, but I cannot see these figures in Table 4.

The estimates in question are now presented in Table 4.

7. Why some FU data (military status at FU) were introduced as “Baseline characteristics” (table 1)? This is very confusing.

We included follow-up data that were obtained on all participants from the Defense Manpower Data Center because we hypothesized that separation from military service was an important characteristic that might influence response. As this information was available on all participants, regardless of response, we were able evaluate whether or not this was in fact true. We have revised the methods and tables to better document the sources of the data and at what point in time they were obtained.

Minor Essential Revisions
There are some mistakes in the references:
   8. Ref 5: “of the findings…” (not “of the finigs…”)

We have corrected this spelling error.

9. Ref 8 is not complete

We have added the necessary information to make this reference complete.

   10. Ref 15: “of the wars…” (not “of the warns…”)

We have corrected this spelling error.

11. The figure 1 is a raw output from the computer: it could have been nicer!

We have revised the figure.

12. Finally, this manuscript needs some rewriting and editing.

The manuscript has been revised for clarity as suggested.

Discretionary Revisions
   13. The models which were constructed cannot be verified in this kind of exercise, and it could be worth to perform analyses for the same associations than in this manuscript at baseline, with and without the subjects who did not answer at the FU survey, comparing the results of the 2 sets of association measures: this would be a quite strong way of validating the models.
We are not completely sure of what the reviewer is asking. Our best interpretation is that he is asking for a comparison of results using a complete cases analysis versus methods that account for nonresponse (e.g., weighting) to assess whether substantial differences exist between these two methods. These analyses are presented in Tables 2-4, and in general the results of the weighted analysis confirm initially reported findings of the previously reported complete case analyses, thereby providing support for the validity of our models.

References


