PEER REVIEW HISTORY

BMJ Open publishes all reviews undertaken for accepted manuscripts. Reviewers are asked to complete a checklist review form (**http://bmjopen.bmj.com/site/about/resources/checklist.pdf**) and are provided with free text boxes to elaborate on their assessment. These free text comments are reproduced below.

ARTICLE DETAILS

TITLE (PROVISIONAL)	A surveillance study to determine the accuracy of mild traumatic brain injury diagnosis in an emergency department: protocol for a retrospective cohort study.
AUTHORS	Pozzato, Ilaria; Cameron, Ian; Meares, Susanne; Kifley, Annette; Vu, Kim Van; Liang, Anthony; Gillett, Mark; Craig, Ashley; Gopinath, Bamini

VERSION 1 - REVIEW

REVIEWER	Marcel Dijkers Icahn School of Medicine at Mount Sinai, New York NY, USA
REVIEW RETURNED	12-Apr-2017

| GENERAL COMMENTS | This is a protocol for a retrospective emergency department (ED) records-based study of mild traumatic brain injury (mTBI). One can wonder whether publishing this protocol is mustard after the meal, and circumvents the emerging consensus that studies should not begin until a protocol has been published: chart auditors WERE trained.

There are two mTBI rates that can be determined for a particular ED:
1. The real number of scientifically determined number of mTBI cases among all patients treated.
2. The number of TBI cases identified and diagnosed by the ED staff.
It is never clear in this protocol whether the authors are after #1 or #2, or the discrepancy between #1 and #2, and the reasons for discrepant cases. They use such terms as providing 'incidence rates of hospital presentations [sic] involving mTBI' which seems to indicate they are after #1, but in the same sentence state that they are out to 'identify factors that are independently associated with documenting a positive mTBI diagnosis in ED', which suggests their interest is in determining when/in what type of patient the ED staff over- and underdiagnoses mTBI. That is even more explicit in their "strength and limitations" #2, where it is stated that the study will identify 'limitations in the current diagnosis and/or documentation of mTBI in ED'. Certainly, if one starts with #2, one can consult the records and throw out the false positives the ED staff has in its tally, but in this way one never will get at the false negatives. To truly get at #1, one needs a prospective study with a complete, lengthy and expensive work-up that is completely independent of what the ED staff has done or will do.

It is unclear in this write-up to what length the authors will go to identify the false negatives. If they state that they will review skull X-rays, is that for the #2 cases they have found in the electronic record |

(which list just a single diagnosis, or maybe just a symptom), or are they going to review EVERY skull X-ray and determine (based on the X-ray and possibly additional info) that the patient had a mTBI, whether such was the diagnosis of the ED staff or not? The same for all other possible indicators of mTBI mentioned: mechanism of injury consistent with possible mTBI; head (non-brain) injury; symptoms such as pain, neurological and behavioral symptoms. I bet 80% of all ED attenders have pain; the record of all of them will be scrutinized to see that that pain was associated with mTBI?

Some other issues:
How is 'diagnostic terminology' complicating accurate clinical [sic] identification of mTBI in the ED?
How are traffic injury mTBIs complicated by insurance issues?
Incidence rates depend on accurate estimates of the population at risk. How will those estimates be achieved, and will mTBI diagnosed in people from outside the local area be disregarded in calculating incidence rates, and/or included in identifying factors contributing to ED staff misdiagnosis?
Are there other EDs in the catchment area, whose records need to be included in the study in order to get reliable incidence rates?
The word power is never mentioned. The authors expect about 500 mTBI cases (before culling false positives? After?), but they never state that that number is sufficient to establish an incidence estimate for 50-55 year old females, with 'acceptable accuracy', whatever that means. Plus or minus 200%? 2000%?
Why are cases with 'pre-existing cognitive impairment' going to be excluded? Their mTBI is not a TBI? And: HOW will they be excluded – the ED staff does a complete and detailed medical history, detailing every TIAA since birth?
What is an optimal score on the A-WPTAS? Is the A-WPTAS routinely administered to everyone coming to the ED? Everyone diagnosed by the ED staff with mTBI?
Are inpatients with TBI ever admitted through channels other than the ED? Why do we not hear about them, and about SNOMED, until the statistical section? Ditto for the 95% Cis – are those the 'acceptable accuracy estimates'?
What criterion was used to determine that IP and KVV, the auditors, had adequate, let alone maximal consistency in identifying mTBI cases? And how come inter-rater reliability still will be assessed?
How are specific [sic] mTBI incidence rates among people who have had a motor vehicle crash going to be determined? The investigators are going to ride with the local police, get the name of everyone involved in a crash, and cross-check their names with ED mTBI diagnosis lists?

And all of this is wrapped in language that makes it hard to understand what the authors plan to do and how and why. This is a sampling, from just one page – the crucial abstract:
Page 3, approximate line:
5: but what does unpublished literature say? Is it even 'literature'?
7: result in vulnerable subgroups?
12: recommended: by whom?
14: hospital-based data: until they move and go live with grandma?
16: quantifying presence?
21: rates of hospital presentations: does that include presentations by the nursing staff at ANMF meetings?
30: 'clinical' records are not electronic? How are they 'subsequent'?
34: presented with any diagnosis indicative of mTBI: who made that diagnosis? The patient? The bartender at Joe's pub? Do all ED

	patients in NSW arrive neatly pre-labeled? 39: =<15: that means anywhere from 3 to 15. And because the operational criteria are connected with OR, that means that what traditionally has been called severe and moderate TBI will be included. Oy Veh! 47: accuracy around: really – that's how you scientists express that? 50: is that 'accuracy around correlates'?

REVIEWER	Cameron Jeter The University of Texas Health Science Center at Houston United States of America
REVIEW RETURNED	20-Apr-2017

GENERAL COMMENTS	This protocol is for retrospectively determining the accuracy of mild traumatic brain injury (mTBI) in an emergency department. The research proposed meets a need of the field to determine the incidence of mTBI, as this number is largely unknown. Once known, more effective, timely interventions can be developed and implemented. The specific goals of this study were to establish the rate of mTBI in an emergency room, determine the incidence of mTBI by mode of injury, and identify the factors associated with positive mTBI diagnosis. Comments are below. Major 1. If this is a protocol for a future study, why is the chosen one-year audit period (June 2015-June 2016) so far in the past? Why in discussion of sample size are time periods from 2010 and 2011 chosen, rather than more recent? By the time the study is completed and published, the determined incidence rate of mTBI may be inaccurate. Minor 1. For the study limitation listed, it is recommended to begin with a statement that this study will determine the incidence of mTBI from an ED, not the general community. As written, one wonders why the limitation is listed at all, as the authors never state they will determine mTBI incidence in all of Sydney. 2. "Mild TBI" is used in the Introduction after the term has been defined as the abbreviation "mTBI." 3. Also in the Introduction, discussion of citation 24 is confusing. Please clarify. The study is described initially as a prospective cohort study, but then says it used retrospective ICD-9 assignment. Only after looking the paper up was it clear the study prospectively evaluated patients for mTBI and compared this incidence to that of ICD-9 codes assigned on discharge. 4. In the figure, define CT and mTBI.

VERSION 1 – AUTHOR RESPONSE

Reviewer 1:

One can wonder whether publishing this protocol is mustard after the meal, and circumvents the emerging consensus that studies should not begin until a protocol has been published: chart auditors WERE trained.

Author response: BMJ Open accepts the following: 'Protocol manuscripts should report planned or ongoing research studies. If data collection is complete, we will not consider the manuscript.' We would like to reiterate that our study is ongoing and will not be completed until the end of this year.

The preliminary phase of the current study involved chart auditors being trained in the case identification process, and this was required before commencing the actual study. Furthermore, publishing this protocol enables a more detailed explanation of the methodology and rationale for it than may be possible within the length constraints of the final study report.

There are two mTBI rates that can be determined for a particular ED:
1. The real number of scientifically determined number of mTBI cases among all patients treated.
2. The number of TBI cases identified and diagnosed by the ED staff.
It is never clear in this protocol whether the authors are after #1 or #2, or the discrepancy between #1 and #2, and the reasons for discrepant cases. They use such terms as providing 'incidence rates of hospital presentations [sic] involving mTBI' which seems to indicate they are after #1, but in the same sentence state that they are out to 'identify factors that are independently associated with documenting a positive mTBI diagnosis in ED', which suggests their interest is in determining when/in what type of patient the ED staff over- and underdiagnoses mTBI. That is even more explicit in their "strength and limitations" #2, where it is stated that the study will identify 'limitations in the current diagnosis and/or documentation of mTBI in ED'. Certainly, if one starts with #2, one can consult the records and throw out the false positives the ED staff has in its tally, but in this way one never will get at the false negatives. To truly get at #1, one needs a prospective study with a complete, lengthy and expensive work-up that is completely independent of what the ED staff has done or will do.
Author response: Thank you for the opportunity to clarify this important point.
This study's main objective is to ascertain #1, i.e. 'the real number of scientifically determined number of mTBI cases among all patients treated' in an ED in New South Wales (NSW), Australia. Aim #1 will be achieved by conducting a retrospective chart review, with a comprehensive and systematic approach to data extraction. Medical records of all patients aged 18-65 years who presented to ED during the study period (June 2015-June 2016) will be examined for the presence of any relevant mTBI criteria, as per the WHO definition. This is not a prospective study, hence, mTBI estimates, though not restricted to diagnosis assigned by ED staff, may be affected by the availability and accuracy of information in ED records. This is now acknowledged as a study limitation, and is stated on p. 4, last bullet point.

We would like to clarify that the discrepancy between #1 and #2, is a secondary objective of this study. To determine #2, i.e. 'the number of TBI cases identified and diagnosed by the ED staff', diagnoses listed in clinical records by ED physicians and the assigned diagnostic codes (SNOWMED and ICD-10 codes) will be examined. For the purposes of the study, a medically designated mTBI is defined by a diagnosis of mild TBI (i.e., mild TBI, TBI) or concussion (i.e. post-concussive syndrome or symptoms). Nevertheless, according to pilot testing, #2 is likely to be difficult to determine. The reason for this may be twofold: the term 'head injury' is used irrespectively of an actual brain injury; other coding indicators are assigned as ED diagnosis (other trauma, mechanism of injury or symptom). If this finding is confirmed by actual investigation, the false-positives and false-negatives cannot be correctly identified. We have now clarified the above aims in the Introduction (see p. 7, first para).

It is unclear in this write-up to what length the authors will go to identify the false negatives. If they state that they will review skull X-rays, is that for the #2 cases they have found in the electronic record (which list just a single diagnosis, or maybe just a symptom), or are they going to review EVERY skull X-ray and determine (based on the X-ray and possibly additional info) that the patient had a mTBI, whether such was the diagnosis of the ED staff or not? The same for all other possible indicators of mTBI mentioned: mechanism of injury consistent with possible mTBI; head (non-brain) injury; symptoms such as pain, neurological and behavioral symptoms. I bet 80% of all ED attenders have pain; the record of all of them will be scrutinized to see that that pain was associated with mTBI?
Author response: With regards to the study's primary objective #1, a two-step process was designed to review every ED record meeting study age and interval period. Step 1: A screening process will

identify all cases with possible indicators of mTBI (pain, neurological and behavioural symptoms, injury, trauma, etc.) as ED discharge diagnosis. Among those, definite non-TBIs (e.g. no traumatic mechanism, mechanism of injury inconsistent with mTBI) will be excluded based on triage presenting information. Step 2: A thorough medical records review (including imaging data, ambulance notes, nursing diary, medication chart, ED assessment, discharge summary, etc) will validate occurrence of mTBI based on relevant WHO criteria and verify exclusion criteria for the screened possible mTBI cases. This is now made clearer under the 'Patient screening and data collection' section of the Methods (see paras 1 and 2 on p. 9 and para 1 on p. 10).

Some other issues:
How is 'diagnostic terminology' complicating accurate clinical [sic] identification of mTBI in the ED?
Author response: As mentioned above, the documented ED diagnoses may not be pertinent to the identification of mTBI. This sentence has now been re-phrased for clarity (see p. 5 lines 21-24).

How are traffic injury mTBIs complicated by insurance issues?
Author response: We have now removed this statement from the Introduction, as we can see that it will confuse the readers.

Incidence rates depend on accurate estimates of the population at risk. How will those estimates be achieved, and will mTBI diagnosed in people from outside the local area be disregarded in calculating incidence rates, and/or included in identifying factors contributing to ED staff misdiagnosis?
Author response: This is not a population-based study. The study's aim is to estimate occurrence of mTBI in the ED of Royal North Shore Hospital (RNSH) in Sydney (NSW, Australia). Thus, the population at risk in this context includes all people aged 18-65 years who were admitted to ED RNSH during the study period.

Are there other EDs in the catchment area, whose records need to be included in the study in order to get reliable incidence rates?
Author response: This is beyond the scope of this study (see above).

The word power is never mentioned. The authors expect about 500 mTBI cases (before culling false positives? After?), but they never state that that number is sufficient to establish an incidence estimate for 50-55 year old females, with 'acceptable accuracy', whatever that means. Plus or minus 200%? 2000%?
Author response: We estimate that approximately 30,000 ED attendances will be screened and that 500 mTBI cases will be identified from RNSH medical records over a 1-year period. This sample size provides high precision of estimation of mTBI incidence in the ED setting (95% confidence intervals of ± 0.2% for the overall point estimate, and ± 1.6% for a study stratum that includes only 1% of the total sample). We have now detailed this in the Methods (pg 13, para 1, last lines).

Why are cases with 'pre-existing cognitive impairment' going to be excluded? Their mTBI is not a TBI? And: HOW will they be excluded – the ED staff does a complete and detailed medical history, detailing every TIAA since birth?
Author response: Pre-existing cognitive impairment is a confounding factor, complicating interpretation of poor performance in the PTA scale and neurological evaluation. Pilot testing informed us that adequate documentation of premorbid conditions is available from ED clinical records. To consider pre-morbid intellectual/ cognitive impairments is also recommended according to A-WPTAS administration instructions.

What is an optimal score on the A-WPTAS? Is the A-WPTAS routinely administered to everyone coming to the ED? Everyone diagnosed by the ED staff with mTBI?

Author response: An 'optimal score' is defined as the maximum score (i.e.18/18) that can be obtained in PTA testing. According to A-WPTAS instructions, administration is recommended following mild head injury to those with a GCS of 13-15 (<24hrs post injury) with impact to the head resulting in confusion, disorientation, anterograde or retrograde amnesia, or a brief LOC less than 30 minutes in duration. When the scale is administered in the absence of the above evidence and the maximum score is obtained, this suggests indeterminate evidence of mild TBI. There is inconsistent implementation of PTA testing across EDs in NSW, which is likely due to mTBI guidelines not being explicit. For instance, Health Guidelines for initial management of closed head injury in adults (2011), states that 'assessment for PTA should be performed on all mild head injury patients in the emergency department'.

Are inpatients with TBI ever admitted through channels other than the ED? Why do we not hear about them, and about SNOMED, until the statistical section? Ditto for the 95% Cis – are those the 'acceptable accuracy estimates'?
Author response: We have added this as a limitation and discussed in the limitation section (see p. 4 lines 17-18).

What criterion was used to determine that IP and KVV, the auditors, had adequate, let alone maximal consistency in identifying mTBI cases? And how come inter-rater reliability still will be assessed?
Author response: Inter-rater reliability was assessed as measure of consistency in case identification between the two chart auditors, IP and KVV, after a training period. Training included a careful review of study inclusion/exclusion criteria and case identification processes, and was followed by pilot tests of several patient records from which study feasibility and chart retrieval procedures were established. Percent agreement in case identification at initial screening among the two auditors was 91%, demonstrating high agreement (≥90% for 4 or fewer categories in the two-rater model). Discrepancies in case identification were analyzed and discussed to clarify issues. After training, inter-rater reliability will be no longer assessed and now moving forward the two auditors will be involved in the two separate phases of records review.

The following paragraph has now been re-phrased for clarity: 'Two chart auditors (IP and KVV) were trained in study inclusion and exclusion criteria and case identification, and pilot testing was conducted to work through disagreements or differences of opinion until the two auditors arrived at a common understanding and were extracting the same cases at initial screening (percent agreement of 91%). The first stage of the screening procedure was then assigned to KVV and the second stage to IP, so each step will be consistently undertaken by the same chart auditor.' (see p. 11, last para).

How are specific [sic] mTBI incidence rates among people who have had a motor vehicle crash going to be determined? The investigators are going to ride with the local police, get the name of everyone involved in a crash, and cross-check their names with ED mTBI diagnosis lists?
Author response: As mentioned above, this is not a population-based study. Achievable outcome for the current study is the estimate of which proportion of positive mTBI cases admitted to RNSH ED was due to a motor vehicle crash. We agree with the reviewer that wording in the outcomes section may be confusing. It has now been re-phrased for clarity (see p. 11, para 2).

And all of this is wrapped in language that makes it hard to understand what the authors plan to do and how and why. This is a sampling, from just one page – the crucial abstract:
Page 3, approximate line:
5: but what does unpublished literature say? Is it even 'literature'?
Author response: The term 'unpublished' has been removed and replaced with 'existing' (see p. 3 line 1).

7: result in vulnerable subgroups?

Author response: Vulnerable subgroups are described in Karr et al., 2014 (reference 6). These include prior brain injury, past adverse neurological events, psychiatric problems, litigation cases. We have now added the initial comma to make the meaning clear that mTBI may result in cognitive deficits among vulnerable subgroups (see p. 3 line 2-3).

12: recommended: by whom?
Author response: This expression has been removed.

14: hospital-based data: until they move and go live with grandma?
Author response: The authors are unclear about this query from the Reviewer.

16: quantifying presence?
Author response: The sentence has been re-phrased for clarity. 'This project will advance existing research by estimating the occurrence of mTBI and quantifying the accuracy of mTBI diagnoses by ED staff through a comprehensive audit of ED records' (see p. 3 lines 7-8).

21: rates of hospital presentations: does that include presentations by the nursing staff at ANMF meetings?
Author response: This expression has been removed.

30: 'clinical' records are not electronic? How are they 'subsequent'?
Author response: The sentence has been rephrased (see p. 3 line 13).

34: presented with any diagnosis indicative of mTBI: who made that diagnosis? The patient? The bartender at Joe's pub? Do all ED patients in NSW arrive neatly pre-labeled?
Author response: The term 'diagnosis' has been replaced with 'clinical features' for clarity (see p. 3 line 15).

39: =<15: that means anywhere from 3 to 15. And because the operational criteria are connected with OR, that means that what traditionally has been called severe and moderate TBI will be included. Oy Veh!
Author response: Although moderate/severe TBIs are mentioned as study exclusion criteria, we agree that such wording may lead to misinterpretation. Operational criteria for clinical identification of mTBI have been re-phrased as follows: 'the presence of: (i) a GCS of 13-15 after 30 minutes post-injury or on presentation to hospital; (ii) one or more of the following: duration of post-traumatic amnesia (PTA) for less than 24 hours, confusion or disorientation, a witnessed loss of consciousness for ≤30 minutes, and/or positive CT brain scan.' Pages 3, 8, 9 and 10 and Figure 1 have been updated accordingly.

47: accuracy around: really – that's how you scientists express that?
50: is that 'accuracy around correlates'?
Author response: This sentence has been re-phrased as 'accuracy of the estimates of incidence of a positive mTBI diagnosis' (see p. 3 lines 22-23).

Reviewer 2:

Major
1. If this is a protocol for a future study, why is the chosen one-year audit period (June 2015-June 2016) so far in the past? Why in discussion of sample size are time periods from 2010 and 2011 chosen, rather than more recent? By the time the study is completed and published, the determined incidence rate of mTBI may be inaccurate.
Author response: This study employs a retrospective design. A retrospective chart review uses pre-

recorded data to answer the study's research questions, hence, missing or incorrect information is likely to influence study findings. Given that updates on clinical records often occur after the ED visit date, these including additional or revised medical documentation (e.g. ambulance records, discharge summary) or retrospective allocation of diagnostic codes, the one-year time audit period was chosen to allow completeness of medical records at the time of commencement of study data collection. On the other hand, 2010-2011 was the time period when the previous investigation by Meares was conducted; this pilot study informed the design of the current study.

Minor

1. For the study limitation listed, it is recommended to begin with a statement that this study will determine the incidence of mTBI from an ED, not the general community. As written, one wonders why the limitation is listed at all, as the authors never state they will determine mTBI incidence in all of Sydney.
Author response: Thank you for this comment. The statement suggested by the Reviewer has now been added at the beginning of the limitation section to make it clearer for the readers.

2. "Mild TBI" is used in the Introduction after the term has been defined as the abbreviation "mTBI."
Author response: Recommended change has been made.

3. Also in the Introduction, discussion of citation 24 is confusing. Please clarify. The study is described initially as a prospective cohort study, but then says it used retrospective ICD-9 assignment. Only after looking the paper up was it clear the study prospectively evaluated patients for mTBI and compared this incidence to that of ICD-9 codes assigned on discharge.
Author response: Recommended changes have been incorporated.

4. In the figure, define CT and mTBI.
Author response: Figure 1 has been updated and recommended abbreviations have been incorporated.

VERSION 2 – REVIEW

REVIEWER	Marcel Dijkers Icahn School of Medicine at Mount Sinai, USA
REVIEW RETURNED	31-May-2017

| GENERAL COMMENTS | The authors have made modifications that specify what they plan to do under this protocol – clarifying that they are not collecting the data that are crucial to incidence rates – the size of the underlying population. Nothing (Nothing!) is said of the population of RNSH's catchment area. Or do the authors really want to determine incidence of mTBI among the (18-65 year old) 'population' of people entering the RNSH's ED? Or even the incidence of mTBI incurred in the ED – e.g. by means of falls off gurneys? There is plenty of clumsy language suggesting the latter – e.g. 3/50: "mTBI incidence in the ED setting"; 7/5: "incidence rates in an ED setting".

However, the title suggests that this is not intended to be an incidence study, but one of the correctness of ED-made mTBI diagnoses: "A surveillance study to determine the accuracy of mild traumatic brain injury diagnosis in an emergency department". If such is the case, we can forget about an underlying population – but the authors need to revise their 'power analysis', to focus it on false positives and false negatives of ED-made diagnoses. They also should be aware of the fact that false positives may easily be found, but it is a different case for false negatives. For instance, many |

people with SCI (explicitly EXcluded in this study, for whatever reason) have mTBI as determined in the rehab setting – but the ED record says nothing about it, because the ED staff is so focused on treating the SCI that they never even look into mTBI. I assume that the same happens in other major injury cases due to violence, traffic, or falls.

There is plenty of other clumsy language that suggests little understanding of what is the goal and what are the means. For instance, in order to find possible TBI cases all ED charts will be reviewed completely for
1) a diagnosis of head trauma, head injury or brain injury;
2) a mechanism of injury consistent with a possible mTBI (e.g. transport-related accident, assault, or fall);
3) an injury description that includes head lacerations, bruising, swelling, facial fractures, or other musculoskeletal injuries; and
4) mTBI-related symptoms, such as pain, neurological or behavioral symptoms.
The 'and' suggests that all four criteria need to be met, but even if we grant an 'or', the following statement: "Triage presenting information will then be reviewed and the individual excluded if the mechanism of injury is not consistent with mTBI" would suggest that a plausible mechanism of injury (2) is all that is needed – so why even go looking for a diagnosis, or facial damage, or symptoms – especially such non-specific symptoms as pain. Doesn't 90% of people attending an ED have pain?

Reading of the paper by an English-major third party with a big red pencil should go far to drive out most of the remaining poor phrasing, poor word choice, clumsy constructions, and violations of scientific english, such as
• All abbreviation in the abstract (and the text) should be expanded the first time used
• Non-existing literature cannot confirm anything (3/5 and elsewhere)
• ED records are not medical records? (4/30)
• How is 'identification' different from diagnosis? (4/32)
• mTBI symptoms disappear yet they persist? (5/23-9)
• social morbidity? Marx again with the illnesses of society?
• Research is under-diagnosed? (5/38-41)
• Inclusion criteria are persons? (8/5)
• Etc, etc.

GENERAL COMMENTS	Authors' edits have clarified many ambiguous points in the manuscript.

VERSION 2 – AUTHOR RESPONSE

Reviewer 1:

The authors have made modifications that specify what they plan to do under this protocol – clarifying

that they are not collecting the data that are crucial to incidence rates – the size of the underlying population. Nothing (Nothing!) is said of the population of RNSH's catchment area. Or do the authors really want to determine incidence of mTBI among the (18-65 year old) 'population' of people entering the RNSH's ED? Or even the incidence of mTBI incurred in the ED – e.g. by means of falls off gurneys? There is plenty of clumsy language suggesting the latter – e.g. 3/50: "mTBI incidence in the ED setting"; 7/5: "incidence rates in an ED setting".

Author response: Thank you for the opportunity to clarify this important point. Royal North Shore Hospital (RNSH) is a large hospital in the Sydney metro region (NSW, Australia) serving a population of 213,000 inhabitants in 2016, across four local government areas. The overall number of RNSH ED attendances in the prior year was approximately 80,000, of these, 30,000 were people aged 18-65 years old who had presented to RNSH ED.

We would like to emphasize again that this is not a community-based incidence or prevalence study. The population being studied does consist of persons aged 18-65 years who attended the ED of RSNH during the study period. However, the study's primary aim is to determine the correctness of mTBI diagnosis in this group.

While the study will produce mTBI estimates, though not a true incidence or prevalence of mTBI in the NSW population or RNSH catchment, findings will advance research knowledge by quantifying the presence of mTBI diagnosis documented in an ED setting. No prior studies have provided published findings on this in Australia. Hence, our study will provide previously unavailable data on the number of patients who received an mTBI diagnosis in NSW ED.

We have now added information about the RNSH catchment area in the Method section (see p. 8, first para 1).

However, the title suggests that this is not intended to be an incidence study, but one of the correctness of ED-made mTBI diagnoses: "A surveillance study to determine the accuracy of mild traumatic brain injury diagnosis in an emergency department". If such is the case, we can forget about an underlying population – but the authors need to revise their 'power analysis', to focus it on false positives and false negatives of ED-made diagnoses. They also should be aware of the fact that false positives may easily be found, but it is a different case for false negatives. For instance, many people with SCI (explicitly EXcluded in this study, for whatever reason) have mTBI as determined in the rehab setting – but the ED record says nothing about it, because the ED staff is so focused on treating the SCI that they never even look into mTBI. I assume that the same happens in other major injury cases due to violence, traffic, or falls.

Author response: Further to the previous point, the power analysis was performed for estimating rates of mTBI diagnosis among ED attendances (aged 18-65 years) over a 1-year study period. We consider the analyses are appropriate as they are currently described, and would not be improved by adding power calculations for false positives and false negatives of ED-made diagnoses. Indeed, we do not consider this as the key objective of the study.

Furthermore, given the exploratory nature of this investigation and that no previous data are available about mTBI estimates in NSW ED, we believe that the reviewer's request is outside the scope of the present study.

Furthermore, we consider that the study title closely reflects the overall study aim, which is to determine the rates of documented mTBI diagnosis in a NSW ED. According to the World Health Organization (WHO) definition - epidemiological surveillance is 'the continuous, systematic collection, analysis and interpretation of health-related data needed for the planning, implementation, and evaluation of public health practice'.

There is plenty of other clumsy language that suggests little understanding of what is the goal and what are the means. For instance, in order to find possible TBI cases all ED charts will be reviewed completely for
1) a diagnosis of head trauma, head injury or brain injury;
2) a mechanism of injury consistent with a possible mTBI (e.g. transport-related accident, assault, or fall);
3) an injury description that includes head lacerations, bruising, swelling, facial fractures, or other musculoskeletal injuries;
and
4) mTBI-related symptoms, such as pain, neurological or behavioral symptoms.
The 'and' suggests that all four criteria need to be met, but even if we grant an 'or', the following statement: "Triage presenting information will then be reviewed and the individual excluded if the mechanism of injury is not consistent with mTBI" would suggest that a plausible mechanism of injury (2) is all that is needed – so why even go looking for a diagnosis, or facial damage, or symptoms – especially such non-specific symptoms as pain. Doesn't 90% of people attending an ED have pain?

Author response: We would like to reiterate that a two-step process was established to comprehensively review the ED records. The preliminary screening process (Step 1) occurs for the sole purpose of narrowing down the number of ED records that will be reviewed in full (which is Step 2), i.e. to exclude definitive non-TBI cases, not to identify possible mTBIs. The selection criteria detailed by the Reviewer in the above refers to Step 1 only and these comprise all key search terms used to select possible cases of mTBI from the ED discharge diagnosis field. Triage information of these selected cases are then reviewed to exclude all definitive non-TBI cases, based on whether there was a traumatic mechanism involved, or whether the mechanism of injury was consistent with mTBI. Unfortunately, this information is not always available from the discharge diagnosis fields.

The wide list of key terms selected for Step 1 reflect the variety of possible discharge diagnoses used by ED clinicians, which can be either the injury mechanism, type of injury or simply the presentation symptoms. Indeed, this two-step approach is a significant strength of our study design as it will allow us to comprehensively document mTBI cases in ED, which the Reviewer himself agrees as being important, as it is not uncommon for mTBI to be missed or undiagnosed, or given the uncertainty over the diagnosis that mTBI frequency is under- or over-estimated.

We agree with the reviewer that use of 'or' is more appropriate and this has now been changed for clarity (see p.9, para 1).

Reading of the paper by an English-major third party with a big red pencil should go far to drive out most of the remaining poor phrasing, poor word choice, clumsy constructions, and violations of scientific english, such as
• All abbreviation in the abstract (and the text) should be expanded the first time used
• Non-existing literature cannot confirm anything (3/5 and elsewhere)
• ED records are not medical records? (4/30)
• How is 'identification' different from diagnosis? (4/32)
• mTBI symptoms disappear yet they persist? (5/23-9)
• social morbidity? Marx again with the illnesses of society?
• Research is under-diagnosed? (5/38-41)
• Inclusion criteria are persons? (8/5)
• Etc, etc.

Author response: We have improved language throughout the whole manuscript and we now believe it reads significantly better.

Reviewer 2:

Authors' edits have clarified many ambiguous points in the manuscript.
We thank Reviewer 2.