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A Systematic, Thematic Review of Social and Occupational Factors Associated With Psychological Outcomes in Healthcare Employees During an Infectious Disease Outbreak. — Source link

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ABSTRACT

Objective To conduct a systematic literature review to identify social and occupational factors affecting the psychological wellbeing of healthcare workers involved in the SARS crisis.

Methods Four literature databases were searched and data extracted from relevant papers. **Results** 18,005 papers were found and 22 included in the review. The psychological impact of SARS on employees appeared to be associated with occupational role; training/preparedness; high-risk work environments; quarantine; role-related stressors; perceived risk; social support; social rejection/isolation; and impact of SARS on personal or professional life.

Conclusions To minimise the psychological impact of future outbreaks of infectious diseases, healthcare workers should be prepared for the potential psychological impact; employers should encourage a supportive environment in the workplace and ensure that support is in place for those most at risk, for example those with the most patient contact.

INTRODUCTION

Outbreaks of emerging infectious diseases occur regularly. When they do, they can trigger an intense, international healthcare response, with thousands of healthcare workers finding themselves at the frontline of attempts to quell the outbreak. One of the best documented major outbreaks of recent times was the outbreak of severe acute respiratory syndrome (SARS), first observed in China in late 2002 and spreading to 29 countries, affecting mostly China, Singapore, Taiwan and Toronto, Canada. SARS was an example of an 'emerging infectious disease' i.e. one that appears for the first time in a population or increases rapidly in incidence or geographic range¹. The SARS crisis was unprecedented in terms of infectiousness and how quickly the illness spread to different countries² and was also notable for the high number of healthcare workers who contracted the illness³.

Healthcare workers in locations affected by SARS reported symptoms of anxiety and depression in the immediate aftermath⁴. However, at the time there was little evidence available regarding which factors may put such workers at risk of poor mental health or how to mitigate the psychological effects of the outbreak². Although there has now been much research published identifying the psychological effects of working in healthcare during such an outbreak⁵, there has to date not been a systematic literature review of the various risk factors which may make certain workers more susceptible to mental health problems.

Previous reviews of the psychological impact of disasters and extreme events on various employees (including deployed humanitarian relief workers, disaster responders and non-routinely trauma-exposed employees who experience a disaster) have identified several common social and occupational factors predicting psychological outcomes^{6,7,8}. These include training and preparedness; extent of traumatic exposure; social support; job demands; perceptions of safety or risk; and impact on personal life.

In this review we examine factors associated with psychological outcomes among healthcare workers involved in the SARS crisis. We use the results of the review to identify recommendations for interventions to reduce the risk of adverse mental health outcomes and foster post-incident resilience within healthcare organisations who may be affected by epidemics, pandemics or emerging infectious diseases in the future.

METHOD

Inclusion criteria

We developed the following set of inclusion criteria which papers had to meet in order to be included in the review:

- Must report on primary, quantitative research;
- Must be published in a peer-reviewed journal;
- Must be written in English;
- Must report on social or occupational factors affecting the psychological wellbeing of healthcare workers involved in the SARS crisis.

Searching and screening

The initial review was carried out through composing three lists of search terms as part of a wider set of reviews on the psychological impact of disasters on employees generally. Search 1 covered terms related to psychological wellbeing, such as 'anxiety' and 'post-traumatic stress'. Search 2 covered terms relating to all extreme events, and was informed by the Emergency Events Database⁹; terms relevant to this particular review included 'pandemic', 'SARS' and 'severe acute respiratory syndrome'. Search 3 covered terms relating to occupational groups; terms relevant to this particular review included 'doctor', 'nurse' and 'healthcare worker'. The full search strategy can be seen in Appendix I.

The three searches were combined and one author (SKB) ran the searches on MEDLINE®, Embase, PsycINFO® and Web of Science databases. Resulting citations were downloaded to EndNote© software version X7 (Thomson Reuters, New York, USA) where duplicates were removed and SKB evaluated titles for relevance. Following the title screening, two authors (SKB, RD) screened the abstracts of all remaining papers against the inclusion criteria and removed any clearly not relevant. The same two authors then screened the full texts of all remaining citations, again removing any not meeting the inclusion criteria. The reference lists of remaining papers were then hand-searched for any additional potentially relevant studies which had not been found in our initial searches.

Data extraction, quality appraisal and data synthesis

We designed spreadsheets to allow data to be systematically extracted from papers. The information we extracted included publication year; country of study; design; time period of study; participant information ('n', age, gender, occupation); wellbeing outcomes and how they were measured; predictive factors and how they were measured; main results; conclusions; and limitations.

We appraised the quality of the studies in three different areas: study design; data collection/methodology; and analysis/interpretation of results. We used a quality assessment tool designed for a previous review⁶ and informed by existing quality appraisal tools^{10,11,12}. The quality appraisal tool can be seen in Appendix II.

To synthesise the data, we performed thematic analysis on the results of the studies in order to group common factors associated with the psychological wellbeing of healthcare workers into a typology. Relevant data was coded and used to develop descriptive themes – for example, any data regarding support from colleagues or families was coded as 'social support'. We therefore developed a list of all social and occupational factors which were examined as potential predictors of wellbeing in the papers, and any predictive factor identified by at least two studies was accepted as a theme. Factors only described in one paper were excluded as it was unclear whether there was any support for these factors; any factors described in two or more papers were included as we felt that given the small number of papers, this was sufficient – or at least worth exploring. Previous reviews have used a similar method of accepting any predictive factor mentioned by at least two studies 6,7,8. If disagreements between studies were found then both viewpoints were discussed.

RESULTS

The initial search yielded 18,005 studies, of which 170 were relevant to the broader set of reviews and 22 were relevant for inclusion in the current paper. Details of the number of papers excluded at each screening stage can be seen in Appendix III. A summary of papers included in this review is presented in Table I.

Overall quality of each paper was assessed as the total percentage of quality appraisal items endorsed. The quality was generally high, with a mean quality rating of 81.9% (range 60%-100%). The main reasons for poor quality appraisal were lack of standardised measures, poor

response rates, and statistical tests not being rigorous enough or clearly described. These limitations are considered further in the discussion. Despite small differences in quality, all papers were given equal weighting in that all are discussed in equal amounts of detail in this paper; however where there were discrepancies in findings, the limitations of the papers are considered.

The themes we found in the data have been divided into occupational factors and social factors. Key findings are discussed here, with the evidence described in more detail in Supplementary Table I.

Occupational Factors

Occupational role

Many of the studies included participants from a range of different occupational roles, including but not limited to doctors, nurses, healthcare assistants, technicians, and administrative employees. Papers comparing psychological wellbeing across different roles showed that those more heavily involved with direct patient care, in particular those working as nurses, had poorer outcomes. For example, nurses were more likely to show symptoms of post-traumatic stress than any other hospital employees¹³, more likely to report high stress levels and common mental disorders than healthcare assistants¹⁴ and were the group most likely to report high levels of distress, followed by allied health care professionals, doctors, and finally staff not working in patient care¹⁵. One study¹⁶ also found greater levels of stress in nurses than in doctors, which may have been related to the fact that nurses were also more likely to report having an increased workload. Another study¹⁷ found that overall distress level was highest in nurses, followed by doctors and healthcare workers.

Only one paper found higher levels of anxiety in support staff than doctors or nurses¹⁸. In this study, anxiety was higher among frontline staff than administrative controls, as expected, but was highest in the group of support staff referred to as 'workmen', followed by healthcare assistants and nurses; these groups reported significantly higher anxiety than doctors, allied health workers, technicians, administrative staff and transport workers.

Specialised training and preparedness

Three studies highlighted the importance of preparedness, in terms of either specialised training or previous experience working during a crisis. In one study¹⁹, healthcare workers who were confident in their infection control knowledge and skills had lower stress levels according to the Perceived Stress Scale²⁰ than those who felt less prepared. Those who perceived their training as inadequate were more likely to experience burnout, post-traumatic stress symptoms and longer continuing perceived risk even after the crisis was over⁵. A third study showed that the only protective factor against anxiety was having had previous training in handling infectious disease outbreaks²¹.

Working in high-risk environments

Related to occupational role was the theme of 'working in high-risk environments'; working in units deemed to be 'high risk' was associated with poor mental health outcomes in many studies. Several studies compared frontline workers in units at high risk for contagion with workers in lower-risk environments, with the majority showing poorer outcomes for those in high-risk environments.

Employees who worked in high-risk units (typically defined as those with high levels of exposure to SARS patients) were found to report greater stress and avoidance²², a higher level of post-traumatic stress symptoms²³ and higher alcohol consumption and greater post-traumatic stress symptoms²⁴ than those not working in high-risk units. One study²⁵ reported a variety of differences between workers in high-risk and low-risk environments, with those in high-risk environments more likely to report fatigue, poor sleep, health worries, and fear of social contact during the SARS crisis, along with greater depression and anxiety post-SARS. Although high-risk and low-risk workers had equally high perceived stress overall in this study, high-risk workers selected a significantly higher percentage of negative responses. Staff providing direct SARS patient care had higher levels of distress²⁶, post-traumatic stress symptoms¹³, emotional exhaustion²⁷, stress¹⁴ and distress, intrusive symptoms, avoidance, hyperarousal and concerns about stigma²⁸ than those who did not work directly with patients.

Another study²⁹ also reported greater post-traumatic stress symptoms in staff working in high-risk units, although interestingly a univariate logistic regression showed that taking care of only one SARS patient was associated with higher post-traumatic stress symptoms and intrusive symptoms than taking care of none or of two or more SARS patients. The authors

suggested this may be due to those working with two or more patients having their sense of self-efficacy and confidence in managing risk bolstered by repeated exposure to SARS patients without being infected.

Similarly, while one study³⁰ found that nurses classified as 'high risk' (in this study, defined as working in wards caring solely for SARS patients) and 'moderate risk' (not working in SARS units but having some contact with patients suspected of having SARS or who might be redeployed to care for SARS patients at some point) reported greater stress than those with no SARS contact at all, it was those classified 'moderate risk' who experienced greater stress and reported feeling less able to cope. This could, again, be due to confidence being bolstered having successfully avoided infection following high exposure to SARS patients in the high-risk group, or it may be due to the 'moderate risk' group having greater role uncertainties, less availability of personal protective equipment, or being less psychologically prepared than those who knew they would be working in high-risk environments.

One paper noted that, though high-risk workers tended to score more poorly on mental health measures, there were also positive outcomes associated with working in high-risk environments. One study¹⁸ found that frontline healthcare workers were more likely to be anxious, experience burnout, report prejudice from others, and report greater perceived risk than administrative staff; however, they also felt more encouraged, and felt greater solidarity with colleagues.

Only one paper³¹ reported no significant relationship between wellbeing outcomes and working in high-risk environments. The authors explain this by describing the complexity of psychosocial responses to trauma and suggesting that perhaps factors other than exposure (e.g. personality, associated losses) may be more influential. However it must be noted that this paper had several limitations which may have affected their results, such as lack of baseline data pre-SARS, a cross-sectional design and only one sample of participants (from a public, primary healthcare setting) which may not be generalisable to healthcare workers as a whole.

There were mixed results on how working in high-risk environments affected wellbeing over time: one study²⁵ found that healthcare workers in high-risk (SARS isolation) units had greater perceived risk over time whereas perceived risk decreased for the control group of

workers in psychiatric inpatient units. Meanwhile, another study³² found that though nurses working in SARS units had greater depression and anxiety at baseline than those in non-SARS units, by the end of the study there were no differences between the groups and there had been a significant improvement in functioning over time for the nurses in the high-risk group.

Quarantine

Being quarantined as a staff member during health-related crises appeared to have a negative impact on mental wellbeing. Being quarantined was the factor most strongly associated with acute stress disorder in a stepwise multiple logistic regression³³, and was also found in the same study to be associated with feeling stigmatised, reluctance to work or considering resigning, and deterioration of work performance. Being quarantined was also associated with greater post-traumatic stress symptoms and higher alcohol intake^{23,24}. Length of time in quarantine was found to predict anger and avoidance behaviours²⁷, with those quarantined for longer showing more adverse effects.

Job stress

Job-related stressors during the SARS crisis included compromised ability to do one's job and lack of control over work, including involuntary conscription. Two studies^{13,19} reported that general 'work/job-related stress' was associated with poorer mental health outcomes, but this term was not clearly defined and likely differed between the two papers.

Other papers explained what was meant by the term 'job stress' or looked at more specific work-related factors. For example, one study¹⁵ reported that ability to do one's job being affected by the precautionary SARS measures was significantly associated with emotional distress. Another study¹⁷ found that feeling vulnerability and a loss of control, as well as changes in work, were associated with overall distress level, and vulnerability/loss of control was also associated with distress in a multiple regression.

One paper¹⁴ reported that job-related stress was a significant predictor of poor mental health: in this paper, job-related stress encompassed 'work' (heavy workload, hazardous environment, deployment, unclear job instructions, ambiguous infection control policies, lack of feedback, being blamed for mistakes, and lack of appreciation), 'personal' (including interference of work with home life, disrupting plans, isolation, and fear of getting infected or

infecting others) and 'role' (including uncertain job prospects, handling colleagues' negative emotions, being discriminated against as high-risk, and dealing with the high expectations of the public).

Control over work, in terms of whether the specific role was voluntary or not, had an impact on wellbeing. For example, one study¹⁴ found that those who were willing to work in SARS units reported poorer mental health than those who did not want to. Similarly, another paper³⁴ found that 'conscripts' (those who did not volunteer but were made to care for SARS patients) reported higher levels of anxiety and depression than volunteers. Interestingly, one paper²² found that although nurses involuntarily deployed to high-risk SARS units were more likely to report stress reaction syndrome than controls, voluntary nurses working in high-risk units were in fact more likely to show symptoms of stress. However, involuntarily deployed nurses were more likely to report post-traumatic stress symptoms, intrusive symptoms, avoidance and depression than controls and more likely to report intrusive symptoms, depression and psychoticism than nurses voluntarily working in high-risk units.

Perceptions of safety, threat and risk

Several papers showed a relationship between psychological wellbeing and perceived safety (or lack of) and risk.

Greater trust in equipment and infection control procedures predicted lower emotional exhaustion and lower state anger in nurses²⁷. Perception of greater personal disease-related risk was significantly associated with increased concern for personal or family health in hospital workers¹⁵ while belief that precautionary workplace measures were sufficient was associated with decreased levels of concern; perception of personal risk also predicted post-traumatic stress symptoms^{23,29}. Duration of perceived risk was correlated with overall number of adverse outcomes in healthcare workers⁵. One paper¹⁴ found that 'job stress' was associated with poor mental health (as noted in the previous section): one aspect of their 'job stress' factor included perceived risk to one's own health and risk of infecting friends, colleagues or family.

One paper¹³ found that 'health fear', along with social isolation and job stress, accounted for 29% of the variance in total IES scores; however, concerns about protection and dissatisfaction with hospital safety procedures did not contribute to total IES scores.

Social Factors

Organisational support

Poor organisational support was associated with avoidance behaviour and state anger in nurses²⁷. Inadequate psychological support from employers as well as inadequate insurance/compensation, frontline staff feedback not reaching administrators, and poor sense of 'team spirit' were identified as risk factors for poor mental health¹⁴.

Friends/family support

Greater family support was associated with lower risk of mental health problems in healthcare workers¹⁴ and lower anxiety in nurses³⁴. The latter paper also found that poor family support before SARS was associated with depression and poor sleep, while poor family support after SARS was associated with anxiety and sleep problems.

Social rejection or isolation

One paper¹⁶ found that healthcare workers who believed people avoided them or their families in relation to their work with SARS patients were twice as likely to score above the cut-off for caseness on the Impact of Event Scale³⁵.

Being 'isolated' was associated with distress in doctors, nurses and healthcare assistants working in emergency departments¹⁷, though the authors do not make clear whether this refers to physical or social isolation. Social isolation was found to mediate the association of contact with SARS patients and being a nurse with psychological stress in healthcare workers¹³

Being discriminated against was associated with poor mental health in healthcare workers¹⁴. Being treated differently by people because of working in a hospital was associated with greater concern for health in hospital workers¹⁵.

Impact on life

Personal or family life affected by SARS was associated with increased concern for personal/family health and emotional distress in hospital workers¹⁵ and avoidance and hyperarousal in healthcare workers²⁹.

DISCUSSION

We found evidence of a number of social and occupational factors affecting mental health outcomes in healthcare workers involved in the SARS crisis.

Firstly, it appeared that training, and consequential feelings of preparedness, were protective of mental health. This is unsurprising as perceived adequacy of training and feelings of preparedness have been associated with more positive psychological wellbeing in humanitarian relief workers, disaster responders and trauma-exposed employees in general^{6,7,8}. In particular, the increased confidence in ability to do one's job as a result of specialised training appeared to be protective. Previous research with healthcare workers preparing for an influenza epidemic has suggested that pre-disaster training and education programmes are helpful in terms of increasing confidence^{36,37}.

Occupational role often had an effect on psychological outcomes, with those directly involved in patient care and in particular nurses more likely to experience adverse mental health effects. This has been supported by research on other disease outbreaks; for example, in a study of hospital workers during the H1N1 pandemic in Japan³⁸, nurses were more likely to report feeling exhausted, and report stronger anxiety about infection, than doctors. It may thus be that SARS nurses are more likely to suffer poor mental health because they are likely to have the most direct patient contact.

Indeed, working in high-risk environments such as SARS intensive care units and greater exposure to SARS patients were generally associated with poorer mental health. Similar findings have been reported in a study on the H1N1 pandemic³⁸, showing that workers in infected wards and fever consultation centres had stronger anxiety, more exhaustion, and higher post-traumatic stress symptoms than those in low-risk work environments. However, two studies in this review suggested it was healthcare workers at 'moderate' risk, i.e. those who worked with only one SARS patient or who had some contact with suspected cases of SARS but outside of SARS-specific units, who were most at risk of adverse psychological outcomes. This may be due to greater training or learned coping in those deemed 'high risk', and the uncertainties involved in the 'moderate risk' settings, or the possibility that they had no time to get used to, or desensitise to, the risky environment they found themselves working in.

Other occupational stressors significantly associated with poor mental health included being quarantined, compromised ability to do one's job, and a lack of control over work. In particular, those who were involuntarily deployed to work with SARS patients tended to experience more adverse psychological outcomes. It is therefore important to ensure that quarantined employees and involuntary conscripts in particular are given adequate support in the aftermath of the crisis.

Feeling unsafe and vulnerable to infection were also predictors of poor mental health. Perceived threat or lack of safety have also been shown to be predictors of poor wellbeing in disaster responders and emergency personnel^{39,40} and more recently were noted as important concerns in a qualitative study of staff deployed to Africa during the 2014/15 Ebola outbreak⁴¹. Again, specialised training may help to minimise the amount of risk felt by employees and thus lead to more positive outcomes. It should be noted here that it poor mental health may bias estimates of risk, and so the correlation between perceived risk and mental health symptoms may be bidirectional. Therefore treatment of the distress symptoms themselves, or cognitive behavioural approaches designed to alter the negative thinking patterns of those with potentially biased estimates of risk, may also be helpful in improving mental health symptoms and potentially lessening risk estimates.

Support, from both employers and friends and family, appeared to be important: good social support could be a protective factor against poor mental health, while those with poor perceived support were more likely to suffer adverse outcomes. In particular, negative social experiences such as rejection, isolation, and discrimination were associated with poor psychological outcomes. Similar findings have been reported in military personnel⁴² and police⁴³.

The impact of the crisis on personal lives also appeared to have an effect on psychological wellbeing, though this was discussed in few studies. Previous research has suggested that disaster responders may experience greater psychological problems post-incident if their own lives have been negatively affected, e.g. through loss of housing/income or reduced contact with family^{40,44}. However, there has also been much research suggesting that humanitarian work can have a positive impact on life: qualitative research involving relief workers and healthcare workers who have responded to disasters and disease outbreaks has suggested that

they experience positive effects such as personal growth, a greater appreciation for life and a sense of achievement^{41,45}. It may be useful for preparatory training packages and interventions to encourage healthcare workers to focus on the potential positive impact of their work or to consider coping strategies which may help them to see the positive effects of working in a crisis. The impact of such training should be tested in future studies.

Suggestions and recommendations

Recent literature has made suggestions for how trauma-exposed organisations can support their staff^{46,47,48}: for example, encouraging team cohesion, peer support training, and precrisis training emphasising the potential psychological impact of the role. It is notable that there is no evidence for the use of formal psychological screening procedures either before deployment or afterwards^{49,50}.

Based on the results of this review we have developed the following list of considerations for protecting the mental health of healthcare workers who assist with the management of future outbreaks of emerging infections:

- Provide appropriate specialised training to equip healthcare workers with the skills, knowledge and confidence to operate under challenging conditions – for example, infection control training
- As camaraderie between colleagues is important, managers should ensure they are approachable and supportive and they should encourage supportive relationships between their employees including encouraging them to attend courses or workshops aimed at developing team cohesion
- Managers should ensure there is regular adequate communication of up-to-date facts about the epidemic and how to best protect oneself
- Managers should prepare employees for the potential impact of negative experiences such as isolation and discrimination and ensure support measures are in place for those who may face these experiences
- Occupational health policies or support systems promoting psychological wellbeing should be developed

- Educational interventions aimed at addressing psychological distress and developing coping mechanisms to manage the fear of infection or infecting others should be developed and tested
- Training or interventions to emphasise the potential positive effects of working in a crisis, such as personal growth should be developed and tested
- Web-based support or discussion groups may be useful to provide support during the crisis with no fear of transmission, thus potentially reducing feelings of social isolation.

Limitations

The overall quality of the literature was high, but there are several important limitations to the data reviewed here which must be noted. Firstly, the majority of studies reviewed were cross-sectional and thus can only suggest associations rather than causality. Prospective, longitudinal studies and randomised controlled trials are needed to adequately explore risk factors. The fact that much of the research was conducted at the height of the crisis means that potentially either a) the full impact of SARS and its long-term effects may be underestimated as the data was collected so soon or b) the psychological impact could be overestimated as mental health symptoms may have improved naturally with time. Also, pre-SARS rates of psychological distress were not recorded for comparison and so it is difficult to ascertain the moderating effects of social and occupational factors on distress without knowing levels of, for example, stress prior to the crisis.

Nearly all studies were conducted while the SARS crisis was ongoing, or immediately after, and as SARS was still a newly-emerging disease when the research was carried out, there was a lack of standardised instruments specifically exploring SARS-related issues and so many studies used their own, study-specific questionnaires which had not been validated.

Many of the studies reviewed had very low response rates – of the 18 studies which reported response rates, 9 of them had a response rate below 50%. Many of the studies were advertised to, for example, all hospital staff, and the voluntary nature of participant selection may have caused selection bias. For example, the studies may have had more salience for those who felt particularly psychologically affected by the SARS crisis and so they may be over-represented in the samples.

Conclusion

Though we found several risk factors which could lead to poor wellbeing in healthcare workers following an outbreak, there was some evidence to suggest that the impact of these factors may be mitigated by appropriate training and provision of support. Further research in future outbreaks is required to ascertain whether any training and support initiatives are indeed able to bolster psychological resilience.

APPENDIX 1 – Search strategy Appendix I: Search strategy

Search: EMBASE 1980 – 2015; EMBASE 1974 – 1979; EMBASE Classic 1947 – 1973;

Ovid Medline 1946 – 2015; PsycINFO 1806 – 2015; Web of Science.

Search 1 (psychological wellbeing);

Well?being; anxiety; panic; post?traumatic stress; PTSD; stress; "mental health"; depress*; neurosis; adjustment disorder*; distress; psychological; resilience; coping; "mental

disorder*"; "positive psychology"; "satisfactory life"; mindfulness; flourish; pleasure; flow;

growth

=COMBINE WITH OR

Search 2 (disasters);

Anthrax; avalanche; avian influenza; bioterrorism; bird flu; blizzard; bomb*; chemical spill;

Chernobyl; cyclone; drought; disaster*; earthquake; Ebola; emergenc*; explosion; fire;

Fukushima; H1N1; H5N1; hurricane; industrial accident; landslide; massacre; mass killing;

MERs; Middle East respiratory syndrome; pandemic; nuclear radiation; radiological; SARs;

severe acute respiratory syndrome; September 11th; shooting*; storm; swine flu; terroris*;

Three Mile Island; tidal wave; tornado; tsunami; typhoon; volcanic eruption; volcano; World

Trade Center.

=COMBINE WITH OR

Search 3 (occupational search terms);

Organisation*; organization*; occupation*; employee*; employer*; workforce*; worker*;

business; team; emergency response; healthcare provider*; healthcare worker*; construction

work*; fire?fighter*; fire officer*; paramedic*; doctor*; nurse*; police; first aid responder*;

personnel; hospital administrator; military.

=COMBINE WITH OR

Combine Search 1 AND Search 2 AND Search 3

APPENDIX 2 – Quality appraisal form

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All questions are answered with 'yes' or 'no'.

Section 1: Study design

- 1. Was the research question/objective clearly stated?
- 2. Were all subjects selected or recruited from the same or similar populations (including the same time period)?
- 3. Were the inclusion and exclusion criteria for being in the study pre-specified and applied uniformly to all participants?
- 4. Was the study population and size clearly specified and defined?

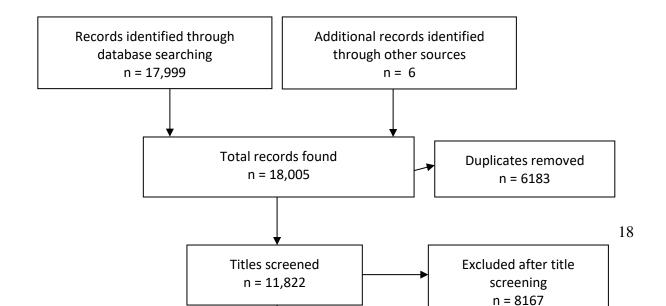
Section 2: Data collection and methodology

- 5. Were standardised measures used, or where measures are designed for the study, attempts to ensure reliability and validity were made?
- 6. Were the data collected in a way that addressed the research issue?
- 7. Was the participation rate stated and at least 50%?
- 8. Was the number of participants described at each stage of the study?
- 9. If the study followed participants up, were reasons for loss to follow-up explained?

Section 3: Analysis and interpretation of results

- 10. Were details of statistical tests sufficiently rigorous and described?
- 11. Were details of confidence intervals given?
- 12. Were potential confounding variables measured and adjusted statistically for their impact on the relationship between exposure(s) and outcome(s)?
- 13. Was the answer to the study question provided?
- 14. Are the findings related back to previous research?
- 15. Do conclusions follow from the data reported?
- 16. Are conclusions accompanied by the appropriate caveats?

APPENDIX 3 – Flow chart of screening and inclusion/exclusion



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