PROTOCOL APPROVAL

Title: Critical Care and Deployed nurses: the impact of COVID-19 on work-related stress

Signatures

By signing this document, I am confirming that I have read, understood and approve the protocol for the above study.

Prof Diane Dixon		06/10/2020
Chief Investigator	Signature	Date

Work-related stress: The Impact of COVID-19 on Critical Care and Redeployed Nurses

1 RATIONALE FOR STUDY

The contribution made by critical care nurses (CCNs) and those deployed to critical care areas during this pandemic has been vital, and their expertise in caring for the increased number of critically ill patients, essential; thus their well-being to allow them to continue in these roles is crucial. During the peak of covid-19, CCNs worked in a highly charged environment with additional challenges such as the high acuity and associated mortality rate of COVID-19 patients, delivering care using personal protective equipment, communicating and supporting relatives at a distance, and the well-publicised potential risks to personal and family health. This may lead to an increase in work-related stress and its consequences at individual, unit, and organisational levels. Staff redeployed to intensive care units will face these issues also but have the added challenges of an unfamiliar environment and may feel they do not have the required skill set to care for these severely ill patients. In general, work-related stress in CCNs can lead to a range of physical[1] and psychological[2] sequalae that may present as 'burnout' [3,4,5](around 16-33%), resulting in negative outcomes such as reduced quality of care, increase in staff sickness and increased staff turnover. Factors associated with CCN work-related stress are based on a poor-quality literature and tend to be inconsistent with poor conceptualisation of work-related stress and a lack of underpinning theoretical framework, but will include individual, and job characteristics.

It is not unreasonable to assume that the covid-19 pandemic and its intensified challenges will result in increased CCN work-related stress, however we do not yet have robust evidence of the impact of this pandemic, and its consequences. Importantly, to appreciate fully the impact of this pandemic, we need to understand how work-related stress changed pre- to post-covid. Further, boards and professional organisations have provided a range of resources to support staff (e.g. self-help guides, intensive care society well-being resources) but with little or no evaluation. If we are to support CCNs appropriately, we need urgently to understand the impact of covid-19, evidence the specific stressors and their importance, how these interact and subsequently impact on CCNs and their organisations. Without knowing this, we cannot identify confidently an appropriate range of measures to protect this vital workforce, or indeed when to implement them.

Prior to COVID-19, we recruited 557 staff across Scotland from 20 intensive care units, to a theory-based cross-sectional survey of work-related stress, a response rate of 47%. This high response rate ensures the validity of our approach and perceived importance for this professional group. This work gives us a unique and excellent baseline for levels of CCN work-related stress, and associated predictors, to allow pre v post-COVID comparisons. Importantly this work is theoretically informed by a contemporary model of work-related stress; the Job Demand-Resource Model (JD-R)[6]. The JD-R allowed us to measure, understand and test a range of CCN individual factors (personal resources e.g. resilience), work environment and job characteristics (job demands (e.g. workload) and job resource

(e.g. autonomy) variables that may lead to either negative (health impairment, reduced job satisfaction, burnout) or positive (work engagement, commitment) outcomes for staff, and importantly organisational outcomes (intention to remain and quality of care). Replicating this study and comparing results pre- and post-COVID-19 gives us a unique opportunity to identify the specific consequences of COVID-19 on: a) CCNs in Scotland and England, b) redeployed nurses, and c) quality of care and intention to remain in critical care/nursing.

In addition, we will evaluate the support services offered to staff over the course of the pandemic to establish whether they met staff needs and addressed the sources of stress identified by the Job-Demand Resource model. We propose also a series of interviews with staff to better understand their experience of COVID-19 and to seek their views of the supportive measures provided during the pandemic. Together, this work will identify, i) support services that do and those that do not address sources of staff stress identified by the J-DR model, ii) support services received positively and negatively by staff, and iii) needs staff experienced that were not addressed by the available support.

This is a two-phase mixed methods study to assess the impact of COVID-19 on CCNs' and redeployed staff work-related stress. Phase 1 will replicate a pre-COVID cross-sectional study and Phase 2 will use a qualitative approach to further understand the challenges and consequences of delivering critical care services within this pandemic.

1.1 OUR RESEARCH QUESTIONS ARE:

In relation to the COVID-19 pandemic:

1. What is the prevalence of work-related stress in CCNs (burnout, mental health, posttraumatic stress symptoms, job satisfaction) and how does this compare with before the pandemic?
2. What is the prevalence of work-related stress in nurses redeployed to critical care units and how does this compare to that of CNNs before and after COVID-19?
3. For CCNs which personal characteristics, and job demands, predict, or are associated with:
    a. work-related stress outcomes?
    b. work engagement and commitment?
4. How do personal and job resources moderate/mediate the relationship between job demands and work-related stress outcomes?
5. What has been the impact of COVID-19 on:
    a. CCNs' intention to remain working in critical care?
    b. Redeployed nurses' intention to remain working in nursing?
6. What were the experiences of CCNs and redeployed nurses working during the pandemic?
7. To what extent did the supportive measures implemented across NHS Boards, address the staff needs, and can we identify future appropriate measures?

Aims: The aim of this study is to establish the: a) impact of COVID-19 on CCNs, and those deployed to critical care units, and b) prevalence of work-related stress and the subsequent impact on intention to remain and quality of care. A secondary aim is an in-depth exploration of the experiences of CCNs' and those deployed to critical care units, during the COVID-19 pandemic and to understand which service initiatives were accessed and their usefulness.

1.2 OBJECTIVES:

1. To establish and compare current levels of work-related stress in a cohort of CCNs with levels before the COVID-19 pandemic.
2. To establish current levels of work-related stress in nurses redeployed to critical care units during the COVID-19 pandemic.
3. To identify personal characteristics, job demands, job resources and personal resources that predict work-related stress, intention to remain and quality of care in CCNs during COVID-19.
4. To understand the relationship between personal resources, job demands and work-related stress in CCNs and nurses deployed to critical care units.
5. To understand the consequences to: a) the individual and b) wider organisation of working in critical care during the COVID-19 pandemic.
6. To identify which service measures were implemented across NHS Boards and to examine:
    a. Whether they address the sources of stress identified in the J-DR model
    b. How these were perceived by staff in terms of accessibility and usefulness
7. To gain an in-depth understanding of the experiences of CCNs and nurses deployed to critical care units during the COVID-19 pandemic.
8. To triangulate the findings to identify the support needs of CNNs and redeployed staff during a pandemic and how those might be best addressed both during and after a pandemic.

2 METHODS

This two-phase mixed methods study (QUANT – qual) will replicate our recently completed cross-sectional pre-COVID survey. Analyses of that survey are ongoing and the final measures to be used in the planned study will be informed those analyses (which include detailed psychometric analyses). The range of symptoms emerging from the pandemic is a particular area of concern (BBC News 14/06/20) and we will include a measure of posttraumatic stress.

Participants Both Phases

CCNs: CCNs employed within ICUs caring for patients with level 3 care requirements in all 20 adult critical care units in NHS Scotland and 3 units in England (Birmingham, and London (King's and Guy's and St Thomas')). Inclusion criteria are NMC registered nurses with substantive part-time or full-time contracts. Exclusion criteria are unregistered staff with caring roles (auxiliary/support workers), RNs on permanent agency/bank contracts.

Nurses redeployed to critical care areas: Those registered nurses who were redeployed to critical care areas on at least 2 occasions; we will only know the numbers involved once the study is initiated. Inclusion criteria are NMC registered nurses with substantive part-time and full-time contracts. Exclusion criteria are unregistered staff with caring roles (auxiliary/support workers), RNs on permanent agency/bank contracts.

The five Units with the highest proportion of staff completing the survey will be awarded £100 in book tokens.

Sample Size: Power calculations have been made for the two mental health outcomes. In summary, for both mental health outcomes a sample size of ~500 (achieved at baseline with

fewer units involved) will provide adequate power (80%) to detect a small effect in the GHQ-12 and the estimated prevalence of PTSD (24%) with a precision of 0.035 and confidence of 95%. Scotland has a lower proportion of BAME citizens compared to other parts of the UK. Therefore, the three additional units selected to take part in the project were identified for inclusion based, not only on their high admission rates, but because of their ability to address the need to better represent the experiences of staff from black and minority ethnic groups. The total sample eligible to participate in the baseline study was ~1224. Preliminary discussions with the units in England suggest that an estimate of an eligible sample of ~2500 will be available for the current study (CNNs and deployed nurses). The baseline study achieved a recruitment rate of 48%, which if achieved here would provide a sample of n=1200.

2.1 PHASE 1: THEORY BASED SURVEY OF OCCUPATIONAL STRESS

2.1.1 Recruitment and Consent

- ICU managers in each of the critical care units will be contacted to a) identify a unit champion and b) determine the number of eligible CCNs within each unit and the number of deployed nurses.
- Unit champions (local PIs) will be recruited via the unit manager (a strategy that worked well in the previous study). The research team will contact and meet with each unit champion (either virtually or in person) to introduce the study and clarify their role/responsibilities.
- The survey questionnaire will take approximately 30mins to complete.

Paper based responses

- Blank, sealed questionnaire packs including a return envelope, a participant information sheet will be either given in person by a research team member or sent to unit champions to distribute to eligible participants.
- Unit champions will identify and arrange for the questionnaire packs to be distributed to CCNs and deployed nurses and identify a return area for completed packs.
- Posters describing the study will be provided to each champion around 2 weeks prior to data collection.
- Completed questionnaires will be placed within a sealed container on each ICU and a suitable place for redeployed staff.
- Sealed containers will be collected by a member of the research team three weeks after recruitment commences in the unit/hospital or depending upon restrictions, sent to the team in Aberdeen as required.

Online responses

- For those wishing to complete an online version of the survey, a link will be provided on the PIS and on the front of the paper questionnaire.

Consent (Phase 1)
Consent will be evident by return of completed anonymised questionnaires. Unit identifiers only will be included to allow unit level analysis. A written consent form will not be required for participants of phase 1. Participants will be provided with contact details for

agencies/organisations to self-refer in the event of any emotional distress at any point during participation in this study. We will also give access to a self-help psychological wellbeing toolkit (developed in one NHS Board in Scotland).

2.1.2 Measures

Demographic Details
Demographic variables will include age, relationship status, number of children, RN band/grade, tenure on the unit, number of years nursing experience and critical care nursing experience, gender, highest level of qualification, full/part time work and shift length.

Measures of the JD-R Model
We propose to use replicate range of generic measures capturing all aspects of the JD-R model that were used successfully in our recently completed study. The one exception will be the addition of a measure of Posttraumatic Stress symptoms as this has emerged as a concern in the media. We will 'sense check' the proposed measures with 6 CCNs to ensure that we have not missed important variables.

Job Characteristics
Job and personal characteristics will be measured using subscales from the Questionnaire on the Experience & Evaluation of Work (QEEW 2.0)[16], a specific relative's questionnaire, and a resilience scale.

- **Job Demands** include 7 subscales (pace & amount of work: emotional load: mental load: physical effort: complexity: work organisation: role conflict) (32 items). Two profession specific sub-scales (13 items) emerged from the literature review were adapted from the Customer-Related Social Stressors questionnaire (CSS)[17].
- **Job Resources** include 12 subscales (learning opportunities: job autonomy: task clarity: feedback: relationship with supervisor: relationship with colleagues: effectiveness in achieving goals: quality: well-being focus: staffing (52 items).
- **Personal Resources** include resilience with Connor Davidson Resilience Scale (CD-RISC)[18] (10-item).

Outcome Measures

Personal Outcomes

- **Burnout Syndrome** measured using the 'Maslach Burnout Inventory for Health Services Survey' (MBI-HSS)[19] (22-items), a 3 factor construct, capturing emotional exhaustion, depersonalisation and personal accomplishment.
- **Posttraumatic stress symptoms** using the PCL-5 11[20] this captures the DSM-V symptoms, consistent with the diagnosis of Post-traumatic stress disorder (PTSD).
- **Mental health** using the GHQ-12 (12 items) [21] a measure of mental health well-being.
- **Work engagement**, using the Utrecht Work Engagement Scale (UWES)[22] (9 items) and 3 factor structure: vigour, dedication, and absorption.
- **Job Satisfaction (1-item)** from the QEEW2.0[16]
- Other individual outcomes including '**Turnover'** (3-items), '**Recovery after Work'** (6-items), '**Detachment after Work'** (3-items), (using the QEEW 2.0)[16].

Organisational Outcome

Intention to remain in critical care using 2 subscales from the QEEW 2.0[16]: '**Certainty about future**' (3 items) & **'Changing jobs'** (3 items) and **Quality of care** using a 15-item patient safety questionnaire.

Support Services
Participants will also be asked to identify supportive measures provided by their Health Board during the pandemic. They will be asked also, how often they used these services, their accessibility, how useful they found them, and to identify any gaps in this provision.

Unit level data
We will collect unit level data to explore cross unit differences. This will include number of ICU beds, staffing levels, number and pattern of COVID-19 admissions, mortality rates, APACHEII scores, and details of service reconfiguration.

2.1.3 Analyses

Demographics of the population will be described using appropriate descriptive statistics (mean (SD), median (IQR) and number (%)). Work related stress will be compared between the two cohorts using the chi squared test, t-test and ANOVA (or non-parametric equivalents). Linear and logistic regression analysis will examine the relationship between job demands, job resources, personal resources and demographics on health impairment (BOS, sleep quality, depression and anxiety), motivation (WE and vitality), mental health etc. Structural equation modelling will be used to examine mediating, moderating and latent factors in these relationships.

Two researchers independently will map the support measures identified by staff to the constructs in the JD-R model to identify the theoretical constructs addressed by the support services offered to staff. Kappa will be used to assess agreement. By this means the support services that target the sources of stress shown to be significant contributors to personal and occupational outcomes will be identified in addition, this process will also identify areas of unmet need.

PHASE 2.2: QUALITATIVE INTERVIEWS WITH CCNS AND REDEPLOYED STAFF

2.2.1 Recruitment

Consenting survey participants will be selected for interview as required to ensure representation across clinical bandings. Informed consent will be obtained and a suitable time for the interview arranged. Recruitment will be via the unit champions.

Consent (Phase 2)

- A consent to contact form will be included in the questionnaire pack for those who wish to participate in the individual interviews.
- To ensure anonymity of their questionnaire responses, this will be returned in a separate envelope, in the return box, and will include the participant's name and contact details.
- A member of the research team will contact the participant to arrange a suitable time for the interview, provide the participant information and verbal informed consent will be obtained prior to the start of the interview.

- The interviewer will either read each statement on the consent form to the participant or share their screen. Verbal consent will be obtained to each statement and will be recorded. Copies of the completed form with be stored on UoA servers.

Withdrawal Procedure: interview participants who wish to withdraw from the study can do so at any time up to the point at which the data are anonymised. Participants who withdraw during the interview will be asked for permission to retain the data already collected anonymously for analysis. Participants who wish to withdraw after the interview is complete can contact the study RA (or PI).

PHASE 2: THEORY BASED QUALITATIVE INTERVIEWS

2.2.2 Interviews

To listen to and understand further CCNs experiences of working in critical care units during the pandemic, we will conduct individual interviews with staff. This will allow more in-depth exploration of the specific issues faced by CCNs in the pandemic including their strategies for dealing with the challenging environment. We plan to recruit around 25 CCNs and around 10 redeployed nurses who will represent the range of clinical bandings to capture potentially different stressors. The 10 redeployed staff are likely to be staff nurses as more senior nurses tend not to be moved to other areas, but if this is not the case we will recruit across the bandings. We will interview until data saturation is reached using an established stopping criterion[23]. We have anticipated and resourced up to 25 CCN interviews, and 10 redeployed staff interviews. We will recruit participants from units that reflect the different sizes and patient demographics. If social distancing measures are still in place, we will interview either via an on-line video platform or by phone, according to interviewee preference. Interviews will be recorded and transcribed by an external company.

An initial theory-based interview guide will be developed. The Job Demand Resource model specifies three theoretical domains that influence outcomes, namely, job demands, job resources, and personal resources; the topic guide will be structured to explore these domains. We will use information from our recent survey, recent 'sense check interviews with CCNs, and evidence in the literature and media reports to populate the topic areas in the interview guide; where possible (this will be dependent upon timing), we will also use findings from Phase 1. We will ask participants to describe local supportive initiatives and their views on accessibility, usefulness, and effectiveness. This will allow us to understand their experiences and how such staff may be supported in a future pandemic. Interviews will take approximately 60mins.

2.2.3 Analyses

Transcribed data will be analysed using a modification of the framework method[24]. The J-DR model will provide the initial coding framework to which the interview data will be charted. In this way the content of the interviews captured by the J-DR model is extracted to the coding framework. The remaining interview content is then analysed using the standard framework method to identify and chart content that is not captured by the J-DR model. In this way the adequacy of the J-DR model is examined and its expression in this situation detailed. Further, the additional content can be evaluated relative to the components of the J-DR model and independently of them. By this method the application of theory is preserved and our qualitative understanding builds in a cumulative theory-based manner. This method will be applied to the content of the interviews that covers the personal

experience of working during the pandemic and content that discusses the experience of the support services offered.

2.3 Integration of data

The application of the J-DR model to both the quantitative and qualitative data facilitates integration of the data. In this way we will be able to present a unique account of the impact of COVID-19 on this workforce. Comparisons with our baseline data provide an opportunity that will likely not exist elsewhere. In these unparalleled times, we do not yet know whether COVID-19 has had a sustained detrimental effect on this workforce; this is vital information to obtain.

3. Data Management and Data Protection:

The PI and study staff involved with this project will comply with the requirements of the General Data Protection Regulations (GDPR) and the Data Protection Act 2018. The HRA recommended wording to fulfil transparency requirements under the GDPR for health and care research has been included in the PIS.

The PI and study staff will also adhere, if appropriate, to the current version of the NHS Scotland Code of Practice on Protecting Patient Confidentiality. Access to collated participant data will be restricted to the PI and appropriate study staff.

Computers used to collate the data will have limited access measures via user names and passwords.

Published results will not contain any personal data that could allow identification of individual participants.

Data Handing and Processing:

Phase 1 Quantitative Data

Completed questionnaires will be returned to the research team at the University of Aberdeen. Questionnaire responses will be entered into and SPSS file, which will be stored on a secure network project folder provided for this study by central IT services at the University of Aberdeen. Professor Diane Dixon is the owner of the project folder and will control who has access and at what level. Only named staff from research team will have access to the project folder. Completed questionnaires will be stored in a locked cabinet in a safe facility at the University of Aberdeen.

Statistical data will be analysed in situ by named researchers at the University of Aberdeen. All subsequent analyses will be from this anonymised dataset.

Paper questionnaires will be stored for 10 years after the end of the study. The final anonymised dataset will be archived and retained in line with the Sponsor's archiving SOP. At the end of the study in accordance with Research Council Guidance we will make the anonymised dataset accessible for other researchers. Consent will be sought from participants for their anonymised data to be used in this way.

Phase 2 Qualitative Data

Interview data will be recorded on a secure online platform, and transcribed by an approved transcription service into nVivo. Only research team members involved in data analysis will have access to raw data and this will be controlled by PI Professor Diane Dixon. We will anonymise respondents' identity.

Transfer of Data: anonymised interview data will be transferred to the transcription service using UoAs secure transfer system ZendTo. All planned analyses will take place at the University of Aberdeen and transfer of data are envisaged. However, should transfer of data be required all data will be anonymised and the transfer will use the secure ZendTo system. Data will only be transferred between members of the research team and will be t and from their employing institution's secure servers.

At the end of the study and after the research team have completed their published work from the study anonymized data may be released for secondary analysis in response to appropriate requests from researchers

Indemnity:

The University of Aberdeen is Sponsoring the study.

Insurance: The University of Aberdeen will obtain and hold a policy of Public Liability Insurance for legal liabilities arising from the study.

Indemnity: The Sponsor does not provide study participants with indemnity in relation to participation in the Study but has insurance for legal liability as described above.

4. Study Management and Oversight

Study Management Group: The study will be co-ordinated by a Study Management Group, consisting of the two grant holders: Dixon and Rattray and the co-I Louise McCallum.

Study Management: The research fellow employed by the study will oversee the study and will be accountable to the CIs (Dixon and Rattray). The Research Fellow will be responsible for checking the recruitment rate at each site. However, this remains the overall responsibility of the CI. Any queries will be resolved by the PI or delegated member of the study team.

Study Steering Group: A study steering group will check on progress against stated milestones. The steering group will be composed of a PI (Dixon); Liz Whittaker, a critical care nurse (retired), and Dr Vivien Swanson, Reader in Health Psychology at the University of Stirling and Health Psychology lead at NES. The steering group will be Chaired by Professor Natalie Pattison, who is the Florence Nightingale Foundation Clinical Professor of Nursing at the University of Hertfordshire.

5. **Inspection of Records**

The PI and all institutions involved in the study shall permit study related monitoring, audits, and REC review. The PI agrees to allow the Sponsor or, representatives of the Sponsor, direct access to all study records and source documentation.

Study Conduct Responsibilities

The PI will seek approval for any amendments to the Protocol or other study documents from the Sponsor (in the first instance), REC and NHS R&D Office(s). Amendments to the protocol or other study documents will not be implemented without these approvals.

In the event that the PI needs to deviate from the protocol, the nature of and reasons for the deviation will be recorded in the CRF, documented and submitted to the Sponsor. If this necessitates a subsequent protocol amendment, this will be submitted to the Sponsor for approval and then to the appropriate REC and lead NHS R&D Office for review and approval.

In the event that a serious breach of GCP is suspected, this will be reported to the Sponsor immediately using the form "Breach Report Form".

End of Study

The end of study is defined as the last phase 2 interview. The Sponsor, PI and/or the Study Steering Group have the right at any time to terminate the study for clinical or administrative reasons.

The end of the study will be reported to the Sponsor and REC within 90 days, or 15 days if the study is terminated prematurely. The PI will ensure that any appropriate follow up is arranged for all participants.

A summary report of the study will be provided to the Sponsor and REC within 1 year of the end of the study.

Reporting, Publication and Notification of Results

Authorship Policy: Ownership of the data arising from this study resides with the study team and their respective employers. On completion of the study, the study data will be analyzed and tabulated, and a study report will be prepared

Publication: The study report will be used for publication and presentation at scientific meetings. Investigators have the right to publish orally or in writing the results of the study.

Summaries of results will also be made available to Investigators for dissemination within their areas (where appropriate and according to their discretion).

Peer review will take 2 forms. Manuscripts will be submitted for peer review by the target journal. The research team will hold a stakeholder event during which they will present the study findings and receive feedback and input from the attendees.

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