Imperial College London

Staff and Safety eFfects of Epidemics (SSAFE)

Study Management Group

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Sponsor

Imperial College London is the main research Sponsor for this study. For further information regarding the sponsorship conditions, please contact the Head of Research Governance and Integrity at r.nicholson@imperial.ac.uk .

Funder

No funding has been received in relation to this study.

This protocol describes the SSAFE study and provides information about procedures for entering participants. Every care was taken in its drafting, but corrections or amendments may be necessary. These will be circulated to investigators in the study. Problems relating to this study should be referred, in the first instance, to the Principal Investigator.

This study will adhere to the principles outlined in the UK Policy Frame Work for Health and Social Care Research It will be conducted in compliance with the protocol, Data Protection Act 2018 and General Data Protection Regulations (Europe) and other regulatory requirements as appropriate.

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1. INTRODUCTION

1.1 Background

The global outbreak of the novel coronavirus, designated SARS-CoV-2, has led to an increase in patients with suspected or confirmed respiratory illnesses, termed Covid-19. The pandemic has led to unprecedented strains on the healthcare services globally, including China, Singapore, South Korea, Japan and Italy, which had experienced the initial surge of affected patients. Previously, in 2002, the first outbreak of SARS had far-reaching impact on healthcare systems of countries globally on how patient care was delivered. A key component of this entailed the safety of healthcare workers, who are at the frontline in managing critically unwell patients. Previous studies have reported a significantly negative impact on both physical and psychological well-being of medical staff, who are exposed to infectious agents but also experience increasing cognitive workload. This has led to high rates of burnout in the short-term and increased prevalence of psychological illness, including depression, anxiety and post-traumatic stress disorder in the long-term.

The current situation in the United Kingdom (UK) is significantly different to the previous SARS outbreak. Firstly, the scale of the disease burden is much higher, as evident from the number of reported cases; distribution of affected countries; mortality rates; absence of accurate and dynamic diagnostic methodology; and lack of effective treatment. Compared to 2002, the population has increased in size and consists of a larger proportion of elderly who have been shown to have worse outcomes with SARS-Cov2. This directly increases the workload on NHS staff and leads to poor morale. In a healthcare system that is already facing pressures to meet high demand, the sudden and steep increase in admissions as well as the associated morbidity of specific patient cohorts only further enhances the challenges of resource allocation. The impact on healthcare workers (HCWs), patients and services is therefore anticipated to be significant.

1.2 Study Rationale

To date, there is no study evaluating the impact of the SARS-Cov2 on the safety and mental well-being of healthcare workers. Thus, the present study aims to understand the effect of the COVID-19 pandemic on safety culture, burnout, anxiety, and depression amongst healthcare workers. The outcomes from this observational, cohort study will be useful in understanding the behaviours of medical staff under pressure, and will directly have relevance in similar high-stakes situations in the future.

The study also includes the most junior and potentially vulnerable members of the healthcare team, redeployed to help during the COVID-19 pandemic: recent medical graduates, referred to as "interim Foundation year doctors" (FiY1s), who have been asked to start working prior to their normal commencement of placements in August.

Anecdotal evidence suggests that the interim FY1s have been very satisfied with the current arrangement and support in place as well as the opportunity to shadow for a prolonged period in advance of starting their real placement in August. This study aims to investigate these suggestions and determine what measures put in place by the medical schools and trusts have been particularly helpful in achieving the high satisfaction suggested amongst the cohort

A modified version of the SSAFE questionnaire has been especially created for this subgroup and is called 'Staff and Safety eFfects of Epidemics on Foundation Trainees in Year 1' (SSAFEFTY1) study. Outcomes from this study will help to understand the effectiveness of strategies used to deploy new medical graduates during a national health emergency situation and could inform decisions about training and preparation of medical students for emergency deployment in the future.

2. STUDY OBJECTIVES

This study aims to understand the effect of the COVID-19 pandemic on safety culture, burnout, anxiety, and depression amongst healthcare workers.

The primary outcome measure will be the measure of safety attitudes throughout the pandemic, as measured by the Safety Attitudes Questionnaire (SAQ). The secondary outcome measures will evaluate three aspects: burnout; as well as anxiety and depression; as measured by the Oldenberg Burnout Inventory (OBI), and Hospital Anxiety and Depression Scale (HADS), respectively.

Secondary outcomes for SSAFEFTY1 will evaluate satisfaction with training and preparation leading up to their deployment and support received during the FiY1 post in the midst of the COVID- 19 pandemic.

3. STUDY DESIGN

The SSAFE study is a longitudinal survey-based study involving healthcare workers involved in managing patients during the COVID-19 pandemic. Participants will receive an invite to complete a survey about their experiences during the COVID-19 pandemic. Invites will be issued through direct email communication, social media (twitter). The survey will remain open for 12 weeks, and invites will be sent out every week. Responses will be grouped and analysed on a weekly basis.

The study will recruit doctors, nurses and other healthcare workers in the UK and Italian healthcare systems. There is a broad inclusion criteria to improve the generalisability of the results. HCWs in an institution that has not treated any COVID patients in the proceeding 7 days will be excluded. Invitations shall be distributed using best-practice measures on social media, distribution lists, targeted email communications and aim to generate a representative sample of healthcare workers. Each participant will provide informed consent to give personal identifiable information which will be held according to GDPR regulations. There is no target recruitment size. As direct comparisons are not being drawn, a power calculation has not been performed.

Invitations to complete the survey will be distributed periodically, until the conclusion of the study. Invitations will be distributed via the Pansurg platform (pansurg.org, targeted email communications, and social media (twitter).

The survey will collect information related to the participant; the context they are working in and different clinically validated psychological questionnaires. Information about the participant will include demographic details such as age and gender; site of work; role in healthcare; specialty before and after deployment and average number of hours worked. Information about context of the participant will include the number of COVID-19 cases in the hospital and specialty; their contact with such patients; and their attitudes towards managing these patients and working in that environment. The survey will contain specific psychological assessments, including the Oldenberg Burnout Inventory (OBI), Hospital Anxiety and Depression Scale (HADS), and Safety Attitudes Questionnaire (SAQ), to measure HCW wellbeing and safety culture.

The Staff and Safety eFfects of Epidemics on Foundation Trainees in Y1 (SSAFEFTY1) survey will be adapted for the interim FY1 doctors and will not include the OBI or HADS assessments, but replaces these with specific questions adapted from the GMC National Training Questionnaire. The survey will include two questions to identify the medical school attended by the participant and which trust they are working in as an FiY1. Specific questions pertaining to the nature of their FiY1 posts will include; length of induction, specialty to which they have been deployed, and details of support arrangements received.

Information about psychological support services will be provided on the final page of the survey in case respondents are affected by any of the issues raised. Due to the anonymous nature of the survey, we will be unable to offer individualised assistance. No personal identifiable information will be collected in the survey. Separately, healthcare workers can register interest to participate by submitting their email to the pansurg platform. There will be no means by which the investigators can identify individual participants.

The primary outcome measure will be the measure of safety attitudes throughout the pandemic. The secondary outcome measures will evaluate three aspects: burnout as measured by OBI; anxiety and depression as measured by the HADS; and workplace safety as measured by SAQ.

Secondary outcomes for the SSAFEFTY1 subgroup will evaluate satisfaction with training and preparation leading up to the recent medical graduates deployment and support received during their FiY1 post in the midst of the COVID-19 pandemic

Explanatory variables will be collected including age, gender, speciality, staff grade, hours worked over the last 7 days, number of COVID-19 cases in the hospital, normal specialty, whether redeployed, and current speciality. It is anticipated the time to complete the survey is 10 to 15 minutes. The survey is not intended to be modified over the course of the research, however should feedback be received that it is too long, or if there is a significant proportion of incomplete surveys, one or two of the validated instruments may be removed and analysis limited to the primary outcome measure.

The survey will be administered using the Google Forms platform, all data will be collected in a password protected google drive, with access limited to the study group.

Registration of interest will be available throughout the study period. The study will last for 12 weeks or until the end of the pandemic as declared by the WHO, whichever is later. Participation information sheets and the protocol will be available as a hyperlink embedded in the survey as well as on pansurg.org. Questions relating to consent will be included in the survey rubric with implied consent by participants completing the survey. If the rate of responses drops below 20 per week, the survey will be terminated early.

Data will be analysed on a cross-sectional basis following each 7-day survey period. Descriptive statics will outline baseline characteristics. Analysing the cohorted responses over time will allow identification of general trends based.

Data will be made freely available in an anonymised format and displayed as a dashboard at [www.pansurg.org/research]. Significant events will be plotted over time to guide analysis of special cause variation and common cause variation.

Further data analysis shall be performed to compare outcomes both between distinct groups of individuals at specific time points, but also longitudinally within the same groups. A Shapiro-Wilk test shall be performed to evaluate whether the data is parametric. Data shall be analysed using either a t-test or Mann-Whitney U test if it is parametric or non-parametric, respectively. Demographic details shall be analysed according to Fischer's exact test, with statistical significance at $p<0.05$. Subgroup analyses will be conducted to identify differences in the primary and secondary outcome measures between groups in terms of geography, redeployment, number of cases in hospital, to identify those at high risk of poor psychological wellbeing or safety culture. A direct comparison between UK and Italian cohorts will be performed, however the results are likely to be subject to confounding from country specific factors which may limit a more detailed comparison.

4. PARTICIPANT RECRUITMENT

4.1 Pre-recruitment evaluations

There are no pre-recruitment evaluations

4.2 Inclusion Criteria

The study will recruit doctors, nurses and other healthcare workers in the UK and Italian healthcare systems. There is a broad inclusion criteria to improve the generalisability of the results

The SSAFEFTY1 study will recruit doctors who graduated from medical school in 2020 and are working in interim FY1 posts in the UK .

Participants will be recruited through a variety of means; (1) the PanSurg platform (www.pansurg.org), here healthcare workers have been invited to register interest in assisting in COVID-19 research and have registered their email giving consent to be contacted about future research. (2) social media (Twitter and LinkedIn) and (3) targeted e-mail communication with participants who are known to the study group.

4.3 Exclusion Criteria

HCWs in an institution that has not treated any COVID patients in the proceeding 7 days will be excluded. This is intended to ensure that respondents are representative of the intended study population.

4.4 Withdrawal Criteria

Participants are able to withdraw at any time and are under no obligation to complete the survey. All data is anonymised from the point of entry, any incomplete data will be evaluated and may be used in the study results. It will not be possible to delete individual data as it is anonymised and investigators will not be able to identify which responses are linked to a given respondent.

Participants should contact Max Denning at max.denning@nhs.uk with any further questions.

5. ADVERSE EVENTS

5.1 Definitions

Adverse Event (AE): any untoward occurrence in a participant.

Serious Adverse Event (SAE): any untoward and unexpected occurrence or effect that:

- **Results in death**
- **Is life-threatening** – *refers to an event in which the subject was at risk of death at the time of the event; it does not refer to an event which hypothetically might have caused death if it were more severe*

- **Requires hospitalisation**
- **Results in persistent or significant disability or incapacity**

5.2. Reporting Procedures

All adverse events should be reported. Any questions concerning adverse event reporting should be directed to the Principal Investigator in the first instance.

5.2.1 Non serious AEs

All such events, whether expected or not, should be recorded.

5.2.2 Serious AEs

An SAE form should be completed and emailed to the Principal Investigator within 24 hours.

All SAEs should be reported to the Ethics and Research Governance Coordinator where in the opinion of the Principal Investigator, the event was:

- 'related', i.e. resulted from the administration of any of the research procedures; and
- 'unexpected', i.e. an event that is not listed in the protocol as an expected occurrence

Local investigators should report any SAEs as required by their Local Research Ethics Committee, Sponsor and/or Research & Development Office.

6. ASSESSMENT AND FOLLOW UP

There will be no follow up following the study period.

7. REGULATORY ISSUES

7.1 Ethics approval

The Principal Investigator has obtained approval from the Head of Department and Joint Research Compliance Office (JRCO). The study will be conducted in accordance with the recommendations for physicians involved in research on human subjects adopted by the 18th World Medical Assembly, Helsinki 1964 and later revisions.

7.2 Consent

Consent to enter the study is implied by completion of the survey. The participant information sheet and protocol are linked to the survey and can also be accessed on the study website (http://pansurg.org) . The right of the participant to refuse to participate without giving reasons will be respected. All participants are free to withdraw at any time.

7.3 Confidentiality

The Principal Investigator will preserve the confidentiality of participants taking part in the study and fulfil transparency requirements under the General Data Protection Regulation for health and care research. Data and all appropriate documentation will be stored for a minimum of 10 years after the completion of the study, including the follow-up period. The survey will be administered using the Google Forms platform, all data will be collected in a password protected google drive, with access limited to the study group.

7.4 Indemnity

Imperial College London holds negligent harm insurance policies which apply to this study.

7.5 Sponsor

Imperial College London will act as the main Sponsor for this study

7.6 Funding

This study is not funded.

7.7 Audits

The study may be subject to inspection and audit by Imperial College London under their remit as sponsor and other regulatory bodies to ensure adherence to GCP and the UK Policy Framework for Health and Social Care Research.

8. STUDY MANAGEMENT

The day-to-day management of the study will be co-ordinated through Max Denning.

9. PUBLICATION POLICY

The initial results of this study will be published in a peer-reviewed medical journal. Following the study period, the results will be collated and again submitted for publication. Anonymised data will be made freely available in an open access format on the group website (pansurg.org).

10. REFERENCES

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