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## Adjusting working conditions and evaluating the risk of infection during the COVID-19 pandemic in different workplace settings – a study protocol for an explorative modular mixed methods approach

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38 ABSTRACT

Introduction: Currently, many countries affected by the COVID-19 pandemic discuss ways how the "lockdown-restrictions" could be lifted to restart the economy and public life after the first wave of the COVID-19 disease has subsided. This study protocol describes an approach designed to provide an in-depth understanding of how companies and their employees deal with their working conditions during the COVID-19 pandemic. We are also interested in how and why the risk of infection with SARS-CoV-2 could vary across different professional activities, company sites and regions with different epidemiological activity or infection control measures. We expect the results of this study to contribute to the development of working conditions protecting the health of employees during and beyond the COVID-19 pandemic. 

Methods and Analysis: An explorative multimodal mixed methods approach will be applied. Module 1 comprises a document analysis of prevailing federal and regional laws and regulations at the respective location of the participating company. Module 2 includes qualitative interviews with key actors at different company. Module 3 is a repeated standardized employee survey designed to capture potential changes in the participants' experiences and attitudes towards working conditions, occupational safetv regulations/measures, and infection control measures during the COVID-19 pandemic. Module 4 comprises SARS-CoV-2 seroprevalence testing. This is carried out by the medical service of the participating company sites as a voluntary offer for employees. Qualitative data will be analyzed through document and content analysis. The complexity of the quantitative analysis depends on the response rates of modules 3 and 4.

**Ethics and Dissemination:** The approval of the study design was received in June 2020 60 from the responsible local ethical committee of the Medical Faculty, University of Tuebingen 61 and University Hospital Tuebingen (No.: 423/2020BO). The results will be presented at 62 national and international conferences and published in peer-reviewed journals.

1 2		
2 3 4	72	STRENGTH AND LIMITATIONS OF THIS STUDY
5	73	One of the first studies to provide a comprehensive understanding of how companies
6 7	74	implement and employees perceive and accept the "new normal" regarding working
8 9	75	conditions during the COVID-19 pandemic.
10	76	• The linkage of complementary methods (document analysis, interviews with company
11 12	77	stakeholders, employee-surveys, testing of antibodies against SARS-CoV-2) will
13	78	allow an in-depth exploration of work practices and experiences in relation to
14 15	79	occupational safety regulations/measures, infection control regulations/measures,
16 17	80	and the actual and perceived risk of infection.
18	81	• Depending on the areas of interest and resources of the participating companies, the
19 20	82	modular approach enables the implementation of up to four substudies, also allowing
21	83	for a cross-sectional or a longitudinal study design.
22 23	84	• The implementation of multiple modules requires comprehensive resources in terms
24 25	85	of time, qualified scientific staff and the organization of the cooperation with different
26	86	company sites as well as different companies.
27 28	87	company sites as well as different companies.
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### INTRODUCTION

#### Background

At the beginning of 2020, the disease COVID-19 (Corona Virus Disease 2019), triggered by the coronavirus SARS-CoV-2 (severe acute respiratory syndrome coronavirus 2), has developed into a pandemic.<sup>1</sup> Without specific therapeutics or an effective vaccine available in the first quarter of 2020, many health care systems and governments responded to the rapid spread of the virus and the significant lethality of COVID-19 with the traditional means of containment: identification of cases and if necessary treatment under guarantine conditions. contact tracing and isolation of suspect cases, closure of schools and other educational institutions, non-system-relevant public institutions and businesses. In addition, most of the governments imposed contact restrictions and curfews considerably affecting everyday life of the population. For such a package of measures the term "lockdown" has become established. A lockdown lasting several weeks does not only result into a temporary restriction of civil rights such as freedom of assembly, but also into a considerable impairment of the economy.<sup>2-5</sup> Currently, debates revolve around which conditions and in which way the "lockdown-restrictions" could be lifted to restart the economy and public life after the first wave of the COVID-19 disease has subsided. This poses new challenges for local and global society: How can restrictions be relaxed without triggering another, even stronger and possibly uncontrollable wave of infection? Under these conditions, enterprises cannot simply "go back to business as usual"<sup>2</sup>, and national and international recommendations regarding occupational health and safety standards tailored to the risks of SARS-CoV-2 infection have been developed.6-8 

New studies on coronaviruses and COVID-19 have explored a variety of safety-related dimensions including social public safety, psychological health and domestic safety, medicine treatment and vaccine safety or the occupational safety of employees.<sup>9</sup> The latter focuses particularly on working conditions and safety of healthcare professionals in clinical or ambulant settings.<sup>10-12</sup> Furthermore, research has looked at COVID-19 stressors on migrant workers<sup>13</sup> and commercial drivers<sup>14</sup> <sup>15</sup>, and at measures to control the spreading of the corona virus in workplaces including engineering and administrative controls (e.g. proper ventilation, restricting staff gatherings) as well as the provision of personal protective equipment (e.g. protective masks or clothing).<sup>16</sup> As of yet, we are not aware of any studies linking different data sources, perspectives and methods to provide an in-depth understanding in which ways companies and their employees deal with their working conditions during the COVID-19 pandemic and how different experiences and attitudes may impact variations in the occurrence of infections with SARS-CoV-2. The results of our study are expected to facilitate the effort of companies and executive managers to protect the 

health of their employees over the course of the COVID-19 pandemic, also preparing themfor future challenges such as the next wave of influenza.

# 128 Study aim and research questions

The Institute of Occupational and Social Medicine and Health Services Research (IASV),
University Hospital Tuebingen, aims to explore how companies adjust to new occupational
health and safety standards designed to prevent the spreading of the COVID-19 disease. We
will focus on the following research questions:

- Under which prevailing regulations and recommendations are working conditions
   adjusted in different work-place settings?
- 135 2. How do employers and their employees assess and accept their "new normal"?
  - 3. How and why could the risk of infection vary across different company sites and professional activities?

# 139 METHODS AND ANALYSIS 30

Previous contact of the IASV to representatives of the initially participating company's chief medical services resulted in the development of a cooperative project exploring occupational health and safety issues related to the COVID-19 pandemic. The transdisciplinary project group has academic and practical expertise in occupational medicine, health sciences, health services research, and sociology and jointly discussed and developed the realization of the study design in the participating company.

## 147 Study design

The IASV conceptualized an explorative multi-modular mixed methods approach<sup>17</sup> <sup>18</sup> following the GRAMMS-guidelines (supplementary file 1) developed by O'Cathain et al. (2008)<sup>19</sup>. Mixed method designs have become an integral part of health-related and health services research, providing a variety of quantitative and qualitative tools complementing each other in order to gain a comprehensive understanding of complex research questions.<sup>19</sup> <sup>20</sup> The approach comprises three modules (modules 1 - 3 in figure 1) which can be applied either as an entire set or companies can choose particular modules depending on their research interest and resources. The approach also allows the extension of additional modules. To begin with, modules 1 - 3 will be implemented in a large multinational engineering and technology company with headquarters and various sites in Germany where several thousands of employees pursue a variety of professional activities differing in their work-related risk of infection with SARS-CoV-2. An additional fourth module (figure 1) will be 

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- 160 conducted by the participating companies' medical service. As the approach is transferable
  161 to other settings, the team of the IASV plans to extend this research design to other
  162 companies, institutions and public authorities.

**Figure 1** Illustration of the applied explorative modular mixed methods design

In module 1, prevailing national and local laws as well as occupational health and safety regulations of the respective site will be analyzed. In module 2, gualitative interviews with company stakeholders will be conducted at the beginning and the end of the survey period. In module 3 we will focus on the perspective of employees conducting several waves of a standardized survey. Module 4 will comprise SARS-CoV-2 antibody testing for employees offered as a voluntary occupational health service by the participating company and carried out by the company's medical service. Using these methods in combination, we expect to be able to provide different perspectives, explanations and a deeper understanding of how companies and their employees adjust to working conditions during the COVID-19 pandemic in particular ways and how different attitudes and behaviors may impact their perceived and measured risk of infection. 

Each module can stand by itself; however, selecting the entire set (modules 1 - 3) or even extending it (module 4) will provide the most comprehensive understanding of the study objective. The initial company agreed to participate in modules 1 - 3 and to conduct module 4. Further companies can combine particular modules depending on their specific interests and resources. For example, if a company was particularly interested in why certain measures of infection protection during the COVID-19 pandemic may be accepted, ignored or rejected it would be advisable to take part at least in modules 1 and 3. For a deeper understanding it would also be advisable to include module 2. In order to evaluate how and why the results of the antibody testing (module 4, carried out by the participating company) and the perceived risk of infection may vary across company sites or areas of professional activities, a combination of all modules or at least modules 1, 3 and 4 would be recommended. As all data collection methods complement each other, data integration (e.g. converting coded qualitative data into variables for statistical analysis<sup>21</sup>, triangulation of qualitative and quantitative data) depends on the number of modules a company chooses to participate in.22

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# 56 192 Patient and public involvement 57

Neither patients nor the public were and are involved in the planning of the design, the
 recruitment, instrument development, data analysis, and reporting or dissemination plans of
 this study.

# 196 Study duration

As the participating company will take part in the complete set of modules including multiple
survey and blood sampling waves, we anticipate a study duration of 18 months (Table 2).
The actual survey period for the company is 13 months.

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# **Table 1** Study plan including a full set of modules (modules 1-4)

Project month	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18
Study preparation*	x	x	x															
			Мо	dule 1	– doc	umen	t analy	/sis (p	revaili	ng lav	vs and	regul	ations	)				
Document analysis				x	x	x	x	x	x	x	x	x	x	x	x			
			N	lodule	2 – qı	ualitati	ve inte	erview	s with	comp	any st	akeho	lders					
Qualitative interviews**				то	4					T1								
Qualitative analysis					x	x	x	x	x	x	x	x	x	x	x	x	x	
Feedback to company										x							x	
						Мо	dule 3	– emp	loyee	surve	у							
Pretest			x															
Quantitative survey				то		T1		~		T2					Т3			
Quantitative analysis					x	x	x	x	x	x	x	x	x	x	x	x	x	
Feedback to company								x		•			x				x	
			Мос	dule 4	-SAR	S-CoV	-2 anti	body t	esting	and a	aggreg	ated a	analys	is				
Blood sample collection***			то						T1	2				T2				
Analysis			x	x	x	x	x	x	х	х	х	х	х	х	x	x	x	
Feedback to company																	x	
Publication														х	x	x	x	)

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 \*Literature research, development and adjustment of the survey instruments to specifics of the participating company (employee survey, interview guide), consultation of the responsible data protection officer.

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\*\*In the event of relevant changes in the incidence of infection (e.g. local outbreak) or operational procedures (e.g. new infection control measures or procedures), further interviews with company stakeholders can be arranged. If the T2-survey in module 3 is conducted earlier, the T1-phase in Module 2 will also be shifted forward.

\*\*\*Seroprevalence testing is a voluntary occupational health offer which will be undertaken by the company's medical officer. The frequency of blood sampling depends on the company's resources and operational capacity. As the participants of module 3 could provide information on their SARS-CoV-2 antibody status, the survey waves of module 4 preceed the survey waves of module 3. Presuming individual consent of each participant, the aggregated results of servoprevalence testing (by job activity) can be linked to the results of the other modules. 

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- 60 216

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### Study procedures: setting, sampling, data collection and analysis

As companies are responsible for occupational health and safety to protect their employees, company owners and executive managers play a crucial part in preparing and responding to disease outbreaks, such as the COVID-19 pandemic.<sup>23</sup> This includes, for example, the adaption of workplace settings to protect workers, the development of action plans for resuming production after a period of closure or managing an increasing number of teleworkers.<sup>7</sup> Companies and their occupational health service have also been advised to prepare for the potential physical, mental and psychosocial effects of the "new normal" on employees.23 

For all groups of employees, the working conditions are changing as a result of new infection control measures (e.g. distance and hygiene rules, modification of work schedules). On the one hand, groups of employees are exposed to an increased work-related risk of infection due to the necessity of working on-site closely together with other personnel (e.g. company medical service, plant security, personnel working on the assembly line). On the other hand, there are groups of employees (e.g. administrative staff) who can also work from home. Although this reduces the work-related risk of infection, new physical and psychological burdens and challenges arise with regard to working conditions and work design (e.g. ergonomically adequate workstations at home, organization of childcare, dissolving boundaries between work and private life, loss of immediate team support). 

To capture potential regional and activity-related differences in the occupational risk and perception of infection, purposive sampling<sup>24</sup> will be used to include about six different company sites of the initially participating company. Inclusion criteria comprise a combination of sites providing the greatest possible contrast between different fields of activities (e.g. personnel working in open-plan offices/telework versus personnel on the assembly line). Furthermore, the company sites' responsible executive managers, employee organization and medical service will need to agree to the participations of the respective sites. 

*Module 1* is a continuous literature search and document analysis<sup>25</sup> of prevailing federal and regional laws, and occupational health and safety and infection control regulations at the respective sites of the participating companies carried out by the IASV. This will provide a broader legal, infectiological, and organizational cultural context for the interpretation of the results of the other modules. An information letter accompanied by a consent form will be sent to the responsible contact person (e.g. executive manager). With the consent of the management and the employee organization, the company will be invited to provide documents and a short questionnaire with general company information (e.g. size of the company sites, number of employees in different departments and branches, job descriptions), and information on current health and safety measures (e.g. contact 

restrictions, telework regulations, working in fixed teams, implementation of hygiene rules). This information will also allow the calculation of response rates for modules 3 and 4.

*Module 2* will comprise gualitative interviews with key actors at different company sites (e.g. executive managers, members of the employee organization). The IASV will address them as experts of their respective departments who can provide an overview of daily working procedures and who are involved in problem solution processes.<sup>26</sup> The interdisciplinary project team will develop a semi-structured interview guide according to the SPSS method developed by Hellferich (2004)<sup>27</sup> covering these topics: 

- Workplace design and organization of working procedures in the context of the COVID-19 pandemic;
- Assessment of work-related stress and strain; -
- Expectations and attitudes towards infection control and occupational health and safety measures;
- Expectations and attitudes towards SARS-CoV-2 antibody tests.

Purposive sampling<sup>24</sup> will be used to invite interview partners from different company sites and different fields of activities (e.g. administrative responsibilities, organization of work at the assembly line, provision of occupational health services) if they have worked at their current job for at least 6 months and have a knowledge of German at least at B1-level.<sup>28</sup> The participants will receive information on interview procedures, data protection and data management accompanied by an individual consent form. We plan to conduct interviews with the same participants at the beginning and the end of the study period to capture potential changes in their experiences and attitudes. In the event of relevant changes in the incidence of infection (e.g. local outbreak) or adjustment of company procedures (e.g. new measures of infection protection), further interviews could be arranged. All interviews will be conducted by the team of the IASV. Based on experience from previous projects, the duration of the interviews will take about 30-45 minutes.<sup>29</sup> Interviews will be audio taped and transcribed by a professional company according to a simplified system whereby transcription is word by word, but not phonetically<sup>30</sup>. Quality checks, de-personalization and pseudonymization of the data will be undertaken by the team of the IASV conducting the fieldwork. The data will be imported into MAXQDA<sup>31</sup>, and analysis will be carried out by the team of the IASV following the steps of qualitative content analysis, including the development of a coding frame, the segmentation of the material, the testing of the coding frame, the evaluation of the trial coding and the completion of the main coding.<sup>32</sup> Several mutual data analysis sessions with the partners from the company are planned. All data will remain at the IASV. 

288 Sample size:

One interview per addressed field of activity at the time of the initial (T0) and the next-to-last (T2) online survey. The total number of interviews cannot be determined at this stage because it depends on the number of company sites included in the entire study. Due to a rather specific research aim, high sample specificity and quality of dialogue<sup>33</sup>, we assume eight participants from our partner company will provide sufficient information for the aspired analysis. Thus, we expect a minimum number of 16 interviews to reach data saturation<sup>29</sup> (four interviewees at two company sites interviewed at the beginning and the end of the survey period).

Module 3 comprises several waves of a repeated standardized (anonymous) employee survey carried out by the IASV. Closed and open questions are being designed to capture potential changes in the participants' experiences and attitudes towards working conditions during the COVID-19 pandemic as well as their perceived risk of infection at the workplace and outside the working environment.<sup>34</sup> Depending on the participating companies' preferences, a paper-based or online questionnaire is being developed. The questions are based on national and international recommendations regarding occupational health and safety standards and infection control measures, tailored to the risks of SARS-CoV-2 infection<sup>6-8</sup>, established recommendations of evaluating work-related stress and strain<sup>35</sup>, as well as existing questionnaires<sup>e.g.36</sup>. According to the explorative design, we did not predefine one specific outcome, but addressed these aspects: the risk of infection perceived by employees, their experiences and attitudes towards infection protection at the workplace. and the associated psychological stress and strain. This will provide context to interpret the occurrence of infections (self-reported antibody status, aggregated results of antibody testing) as well as for recommendations concerning infection protection at the workplace. Main subject areas of the questionnaire are summarized in Table 1.

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5		Subject areas	Themes
6		Evaluation of implemented SARS-	e.g. distance regulations, hygiene rules, organization
7		CoV-2-related occupational health and	of telework and teams working on-site, provision of
, 8		safety standards	protective equipment, workplace design
9		Evaluation of work-related stress and	e.g. work-related stress and strain before and during
10		strain related to the COVID-19	the COVID-19 pandemic concerning work content/task,
11		pandemic	organization of work, working environment, social
12			relations, new patterns of work
13		Assessment of perceived and potential	e.g. concern of being infected at the workplace number
14		risk of infection at the workplace	of contacts with others, working in fixed teams, working on-site or at home, acceptance and practicability of
15			hygiene rules at work (keeping distance, wearing
16			masks)
17		Assessment of perceived and potential	e.g. concern of being infected outside the working
18		risk of infection outside the working	environment, number of social contacts, contact to risk
19		environment	groups, travel behavior, practiced leisure activities
20			(low-contact vs. contact sports)
21		Sociodemographic and	e.g. age, sex, marital status, educational background,
22		medical information potentially related	work experience, current occupation, number of
23		to the prevalence of SARS-CoV-2	children and their attendance in day-care centers or
24		infections	schools, relevant underlying medical conditions, if
25			available: SARS-CoV-2 antibody status
26		Other relevant measures	e.g. control measures for personality factors, resilience
27			and social desirability

Table 2 Subject areas and themes of the questionnaire

The questionnaire will be pretested by a group of academic volunteers as well as by representatives of the target audience. Participation in each survey wave is voluntary. Survey invitations will be organized by the participating company (e.g. via company e-mail accounts, company newsletter, posters, postcards). Taking part requires employees to be of legal age with a knowledge of German at least at B1-level<sup>28</sup>, and - in case of an online-survey -internet access via PC, tablet, or smartphone. Individual consent to participate is given by the study participants after sufficient information on data protection and data management at the beginning of the survey. At the end of the first survey wave, participants will be asked to generate an 8-digit code which can be used to merge the data of each person anonymously over subsequent survey waves.<sup>37</sup> The completion of the survey is expected to take approximately 25 minutes. In case of an online-survey, the individual survey responses will be managed via the established online tool Unipark.<sup>38</sup> In case of a paper-pencil questionnaire, each survey sheet will be scanned at the University Hospital Tuebingen using an OCR system.<sup>39</sup> All data will remain at the IASV and will be analyzed applying appropriate descriptive and inferential statistics in SPSS.<sup>40</sup> Depending on the sample size, a biometrician will be involved in discussing the development of hypothesis testing models which can be applied if a sufficient number of respondents take part in the survey. 

334 Sample size:

According to the exploratory design, we aim to invite the entire staff of the participating company sites (n  $\sim$  22.000). Stratification can only be carried out if a sufficient number of cases per subgroup is reached (>=10).

Module 4: SARS-CoV-2 seroprevalence testing will be carried out as a voluntary company offer for employees by the occupational service of the participating company sites; hence, all individual data are subject to doctor-patient confidentiality and will remain with the participating company's medical service. In terms of quality assurance, the IASV research team will advise on database design, selection of antibody tests (type, pharmaceutical supplier) the content of a short participant questionnaire completed when blood sampling takes place (age, sex, work location, field of activity), and analysis procedures. Testing and aggregated epidemiological evaluations at the company level will be carried out according to applicable medical regulations.<sup>41</sup> <sup>42</sup> Presuming individual consent of each participant, the results of the antibody tests (aggregated to company specific operational activities, e.g. infections in open plan office versus assembly line) can be anlyzed in combination with the results of the other modules by the IASV. As module 4 is of exploratory nature, data will be analyzed applying appropriate descriptive and inferential statistics in SPSS.<sup>40</sup>

32 352 Sample size:

Due to the currently low prevalence of SARS-CoV-2 in Germany (<2%)<sup>43</sup>, serological diagnostic and hypothesis testing are only suitable for larger epidemiological studies including a sufficient number of cases allowing for stratification. For example, assuming a small effect size  $(n^2 = 0.01)$  for the detection of potential differences in the seroprevalence across employees from four different areas of activity at a power of 80%, statistical analysis would require a sample size of 271 persons per area of activity (n = 1084 employees) to obtain a statistically significant result performing a single factor ANOVA ( $\alpha = .05$ ).<sup>44</sup> 

### 361 Data protection

Relevant data protection regulations will be observed for all data collected and coordinated with the responsible ethics committee, academic and company data protection officers, as well as the respective company physicians and representatives of the employee organization. Concerning module 1, the company sites will decide whether and how they provide company-related information. All other data (e.g. federal and regional COVID-19-related regulations) are available publicly. Depending on the extent of the information provided by the companies and the official information available, the respective legal and organizational context of different work-place settings is compiled by the IASV. 

Participants taking part in module 2 will provide individual consent to be interviewed by project members of the IASV. The digital audio recordings and original (non-pseudonymized) transcripts will be stored in the secure network of the University Hospital Tuebingen and destroyed after the completion of the analyses. For the analysis, all names, places and references that would allow drawing conclusions about a person or the participating company or company site will be pseudonymized by project members of the IASV. The pseudonymized transcripts will only be accessible to project members of the IASV, stored in the secure network of the University Hospital Tuebingen. All other persons will have access only to the interview excerpts cited in reports or publications. In terms of module 3, the participants provide individual consent to take part in the anonymous employee survey. In case of an online survey, the questionnaire data will be collected via the established survey tool Unipark complying with security requirements according to the information security standard ISO/IEC 27001.45 In case of a paper-pencil guestionnaire, all data will be scanned at the University Hospital Tuebingen.<sup>39</sup> All data will be transferred to SPSS<sup>40</sup> and stored in the secure network or a lockable archive of the University Hospital Tuebingen. Individual data will only be accessible for project members of the IASV. 

The collection and pseudonymization of the individual serum samples during module 4 will be organized by the company's medical service and is subject to medical confidentiality. Presuming individual consent of each participant, project members at the University Hospital Tuebingen will receive data on the seroprevalence of employees aggregated to areas of activity, also including aggregated demographic information (age, sex). If the response rate is low (<=10/area of activity), these data will be aggregated with the data from other company sites and if necessary with other areas of activity. 

In line with the German guidelines for storing research data<sup>46</sup>, all data compiled by the IASV (modules 1 - 3) as well as the aggregated data received by the participating company (module 4) will be stored for 10 years after the final publication in the secure network of the University Hospital Tuebingen and destroyed thereafter. These data will be accessible only to IASV-personnel involved in the research project. 

49 398 50 200

# 399 Ethics and dissemination

# 400 Research ethical approval 53

401 The study and all study-related documents were designed following the principles formulated
 402 in the current version of the Declaration of Helsinki<sup>47</sup>. The approval of the study design was
 403 received in June 2020 from the responsible local ethical committee of the Medical Faculty,
 404 University of Tuebingen and University Hospital Tuebingen (No.: 423/2020BO).

## **Progression of the study**

407 The development of the research instruments are in progress. The recruitment of the first
408 wave of participants has commenced 21<sup>th</sup> July 2020 and is anticipated to continue until
409 October 2020.

10 411 Dissemination

Study results will be published in peer-reviewed journals and presented at international andnational conferences.

**41**4

# **Discussion**

There are some pros and cons associated with our study approach. Although the triangulation (and integration) of evidence is an integral part of mixed methods research<sup>17</sup>. the design of our study is unique in terms of the modular approach we specifically developed for assessing how companies and their employees experience and adjust to working conditions during the COVID-19 pandemic. Furthermore, the design is transferable to other companies, institutions and public authorities. Depending on their areas of interest and resources, the modular approach enables the implementation of up to three substudies conducted by the IASV, also allowing for a cross-sectional or a longitudinal study design with multiple survey and interview waves. Additional substudies such as SARS-CoV-2 seroprevalence testing can be implemented and conducted by the participating companies. Each of the quantitative (employee survey, SARS-CoV-2 antibody testing) and qualitative method (document analysis, interviews with company stakeholders) applied can stand by itself; however, in linking different data sets and methods (document analysis, descriptive and interferential statistics, content analysis) as well as a variety of perspectives (researchers, company stakeholders, workers) the integration<sup>21</sup> of the individual results will provide a detailed analysis of the overall research objective. In terms of resources (e.g. time, required gualification of the personnel, organizational effort), we expect that the combination of the methods applied will mitigate some of the limitations inherent for quantitative (numeric description of phenomena, complexity of statistical analysis dependent on survey response rate, superficial understanding of participants' experiences, attitudes and causal relationships) and qualitative research (e.g. small sample, results not statistically representative of a population, time consuming data collection and analysis).<sup>48</sup> 

Finally, we want to highlight potential concerns of the participants that may occur over the course of the study. Since the company's medical service is involved in data collection (module 4), the participants may be concerned that their test results or their responses from the interviews and questionnaires (modules 2 and 3) have a negative impact on their working conditions or employment. We aim to avoid this issue by communicating our comprehensive

data protection concept, by providing extensive information on the study, and by emphasizing the participants' right to withdraw from the study without any negative consequences. The project leader and responsible researchers will also be available to answer questions occurring over the course of the study period. Furthermore, the pseudonymized (module 2) and non-aggregated anonymized (module 3) data remains exclusively at the Institute of Occupational Medicine, Social Medicine and Health Services Research, University Hospital Tuebingen and will be evaluated there. The company (i.e. company owners, executive managers, works council, company medical service) will only receive aggregated evaluations. With respect to the antibody testing (module 4), this offer will be a completely voluntary occupational health service for company employees and the physician of the responsible medical service will provide information about the usual risks and side effects of blood sampling. 

With this study, we aim to provide an in-depth analysis of occupational health and safety challenges related to the process of resuming and continuing work-related activities during the COVID-19 pandemic. This includes, for example the consideration of work activities requiring on-site presence - possibly in close contact with colleagues, suppliers or the public - as well as issues associated with an increased use of telework. We expect that our study will contribute to the development of working conditions ensuring that job-related activities can be designed as safe as possible to the requirements of occupational health and safety regulations and to the particular needs of companies and their employees. 

36 463

# 37 38 464 **DECLARATIONS** 39

### **Contributors**

All authors contributed to the development of the study design. ER and MR were involved in
obtaining approval from the Ethics Committee of the Medical Faculty, University Hospital of
Tuebingen. ER is the primary investigator and drafted this study protocol with contributions
from all authors. All authors provided critical feedback on the manuscript, read and approved
the final version.

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10 11	483	
12	484	Disclaimer
13 14	485	The funding sources had no role in the design of the study and will not be involved in the
15 16	486	conduct, collection, management, analysis, interpretation or dissemination of any data or
16 17	487	results of the research.
18 19	488	
20 21	489	Competing interests
22 23	490	None declared.
24 25	491	
25 26	492	Ethics approval and consent to participate
27 28	493	Ethical approval for this study was obtained from the Ethics Committee of the Medical
29	494	Faculty, University Hospital of Tuebingen (reference number: 423/2020BO). Informed written
30 31	495	consent to participate will be obtained from all participants.
32 33	400	
33 34	496	
35 36	497	Provenance and peer review
37	498	Not commissioned; externally peer reviewed.
38 39	499	
40 41	500	Data sharing statement
42	501	Our manuscript describes a study protocol. As such, we cannot elaborate on unpublished
43 44	502	data.
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2 3	503	Supplementary material
4 5	504	Supplementary file S1: Good Reporting of A Mixed Methods Study (GRAMMS) checklist <sup>19</sup>
6	505	
7 8	506	References
9	507	1. World Health Organization. Coronavirus. Available: https://www.who.int/health-
10 11	508	topics/coronavirus#tab=tab_1 [Accessed 19 May 2020].
12 13	509	2. Dorn F, Khailaie S, Stöckli M, et al. [The common interest of health and economy: A
13 14	510	scenario calculation for the containment of the corona pandemic. A joint study of the
15 16	511	ifo Institute (ifo) and the Helmholtz Centre for Infection Research (HZI). ifo
17	512	Schnelldienst digital 6/2020 13 May 2020]. München: ifo Institut 2020.
18 19	513	3. Tagesschau. [VW shutting down again - news from 13.05.2020]. Available:
20	514	https://www.tagesschau.de/wirtschaft/vw-produktion-105.html [Accessed 19 May
21 22	515	2020].
23 24	516	4. Veitinger T. [Bosch - environmental protection despite pandemic. Heidenheim News from
25	517	30.04.2020]. Available: https://www.hz.de/wirtschaft/wirtschaft-
26 27	518	ueberregional/umweltschutz-trotz-pandemie-45870919.html [Accessed 19 May 2020].
28 29 30 31 32 33 34 35	519	5. Verma S, Gustafsson A. Investigating the emerging COVID-19 research trends in the field
	520	of business and management: A bibliometric analysis approach. J Bus Res
	521	2020; <b>118</b> :253-61. doi: 10.1016/j.jbusres.2020.06.057. [published Online First:
	522	2020/07/02.].
	523	6. Cirrincione L, Plescia F, Ledda C, et al. COVID-19 Pandemic: Prevention and Protection
36	524	Measures to Be Adopted at the Workplace. Sustainability 2020;12(9) doi:
37 38	525	10.3390/su12093603.
39	526	7. EU-OSHA. EU GUIDANCE. Covid-19: Back to the workplace. Adapting workplaces and
40 41	527	protecting workers. European Agency for Safety and Health at Work: EU-OSHA 2020.
42 43	528	8. Federal Ministry of Labour and Social Affairs. [SARS-CoV-2- Occupational Safety
43 44	529	Standard from 16.04.2020]. Available:
45 46	530	https://www.bmas.de/SharedDocs/Downloads/DE/PDF-Schwerpunkte/sars-cov-2-
47	531	arbeitsschutzstandard.pdf? blob=publicationFile&v=4 [Accessed 19 May 2020].
48 49	532	9. Haghani M, Bliemer MCJ, Goerlandt F, et al. The scientific literature on Coronaviruses,
50	533	COVID-19 and its associated safety-related research dimensions: A scientometric
51 52	534	analysis and scoping review. <i>Saf Sci</i> 2020:104806. doi: 10.1016/j.ssci.2020.104806.
53 54	535	[published Online First: 2020/05/10.].
55	536	10. Ambigapathy S, Rajahram GS, Shamsudin UK, et al. How should front-line general
56 57	537	practitioners use personal protective equipment (PPE)? Malays Fam Physician
58	538	2020; <b>15</b> (1):2-5.
59 60		

1		
2 3	539	11. Chen Y, Pradhan S, Xue S. What are we doing in the dermatology outpatient department
4 5	540	amidst the raging of the 2019 novel coronavirus? J Am Acad Dermatol
6	541	2020; <b>82</b> (4):1034. doi: 10.1016/j.jaad.2020.02.030. [published Online First:
7 8	542	2020/02/23.].
9	543	- 12. Cheung JC-H, Ho LT, Cheng JV, et al. Staff safety during emergency airway
10 11	544	management for COVID-19 in Hong Kong. The Lancet Respiratory Medicine
12 13	545	2020; <b>8</b> (4) doi: 10.1016/s2213-2600(20)30084-9.
14	546	13. Alahmad B, Kurdi H, Colonna K, et al. COVID-19 stressors on migrant workers in Kuwait:
15 16	547	cumulative risk considerations. <i>BMJ Glob Health</i> 2020; <b>5</b> (7):e002995. doi:
17	548	10.1136/bmjgh-2020-002995.
18 19	549	14. Lemke MK, Apostolopoulos Y, Sonmez S. A novel COVID-19 based truck driver
20 21	550	syndemic? Implications for public health, safety, and vital supply chains. Am J Ind
22	551	<i>Med</i> 2020; <b>63</b> (8):659-62. doi: 10.1002/ajim.23138. [published Online First:
23 24	552	2020/05/27.].
25	553	15. Lemke MK, Apostolopoulos Y, Sonmez S. Syndemic frameworks to understand the
26 27	554	effects of COVID-19 on commercial driver stress, health, and safety. J Transp Health
28 29 30	555	2020; <b>18</b> :100877. doi: 10.1016/j.jth.2020.100877. [published Online First:
	556	2020/06/06.].
31 32	557	16. Rafeemanesh E, Ahmadi F, Memarzadeh M. A Review of the Strategies and Studies on
33	558	the Prevention and Control of the New Coronavirus in Workplaces. Arch Bone Jt Surg
34 35	559	2020; <b>8</b> (Suppl1):242-46. doi: 10.22038/abjs.2020.47410.2323.
36 37	560	17. Mayring P. [Triangulation of evidence and mixed methods in health research]. In: Haring
38	561	R, ed. [Health Sciences]. Berlin, Heidelberg: Springer Berlin Heidelberg 2019:133-41.
39 40	562	18. Niederberger M, Peter L. [Mixed methods studies in the health sciences. A critical map].
41	563	Z Evid Fortbild Qual Gesundhwes 2018; <b>133</b> :9-23. doi: 10.1016/j.zefq.2018.02.008.
42 43	564	[published Online First: 2018/04/02.].
44 45	565	19. O'Cathain A, Murphy E, Nicholl J. The quality of mixed methods studies in health
46	566	services research. J Health Serv Res Policy 2008;13(2):92-8. doi:
47 48	567	10.1258/jhsrp.2007.007074. [published Online First: 2008/04/18.].
49	568	20. Tariq S, Woodman J. Using mixed methods in health research. JRSM Short Rep
50 51	569	2013; <b>4</b> (6):2042533313479197. doi: 10.1177/2042533313479197. [published Online
52	570	First: 2013/07/26.].
53 54	571	21. Bryman A. Integrating quantitative and qualitative research: how is it done? Qualitative
55 56	572	<i>Research</i> 2016; <b>6</b> (1):97-113. doi: 10.1177/1468794106058877.
57	573	22. Fielding NG. Triangulation and Mixed Methods Designs. Journal of Mixed Methods
58 59	574	Research 2012; <b>6</b> (2):124-36. doi: 10.1177/1558689812437101.
60		

1		
2 3	675	22 Eadel M. Selemen, I. Deserthe A. Corenevirus outbreak: the role of companies in
4	575 576	23. Fadel M, Salomon J, Descatha A. Coronavirus outbreak: the role of companies in
5 6	576 577	preparedness and responses. <i>The Lancet Public Health</i> 2020; <b>5</b> (4) doi:
7	577	10.1016/s2468-2667(20)30051-7.
8 9	578	24. Guetterman TC. Descriptions of Sampling Practices Within Five Approaches to
10 11 12	579	Qualitative Research in Education and the Health Sciences. Forum: Qualitative Social
	580	Research 2015; <b>16</b> (2): <u>http://nbn-resolving.de/urn:nbn:de:0114-fqs1502256</u> .
13	581	25. Wolff S. [Analysis of documents and field analyis]. In: Flick U, von Kardorff E, Steinke I,
14 15	582	eds. [Qualitative research A manual (5th edition)]. Reinbek bei Hamburg: Rowohlt
16 17	583	Taschenbuch Verlag 2007:502 – 13.
17 18	584	26. Britten N. Qualitative interviews in medical research. BMJ (Clinical research ed)
19 20	585	1995; <b>311</b> (6999):251-3. [published Online First: 1995/07/22.].
21	586	27. Hellferich C. [The quality of qualitative data. Manual for conducting qualitative interviews].
22 23	587	Wiesbaden: VS Verlag für Sozialwissenschaften. 2004.
24 25 26 27 28 29 30	588	28. Council of Europe. Common European Framework of Reference for Languages (CEFR).
	589	Available: https://www.coe.int/en/web/common-european-framework-reference-
	590	languages [Accessed 21 July 2020].
	591	29. Aldiabat KM, Le Navenec C. Data saturation: The mysterious step in grounded theory
	592	methodology. The Qualitative Report 2018;23(1):245-61.
31 32	593	30. Dresing T, Pehl T. [Research in practice: interviews, transcription & analysis. Instructions
33	594	and control systems for qualitative researchers; 8th edition]. Marburg: dr dresing &
34 35	595	pehl GmbH 2018.
36 27	596	31. MAXQDA. The Art of Data Analyis. Available: https://www.maxqda.com/how-to-analyse-
37 38	597	qualitative-data [Accessed 25 Jan 2020].
39 40	598	32. Schreier M. Qualitative content analysis in practice. London: Sage 2012.
41	599	33. Malterud KS, , D; Guassora, AD Sample Size in Qualitative Interview Studies: Guided by
42 43	600	Information Power. Qualitative Health Research 2016;26(13):1753–60.
44	601	34. Taddicken M. [Online-Survey]. In: Möhring W, Schlütz D, eds. [Handbook of standardised
45 46	602	survey procedures in communication science]. Wiesbaden: Springer Fachmedien
47	603	Wiesbaden 2013:201-17.
48 49	604	35. Gemeinsame Deutsche Arbeitsschutzstrategie (GDA), editor. Occupational Safety and
50 51	605	Health in Practice. Recommendations for implementing psychosocial risk
52	606	assessment. Berlin: Management of the GDA Mental Health Working Programme, c/o
53 54	607	Federal Ministry of Labour and Social Affairs, 2014.
55	608	36. COSMO open. COVID-19 Snapshot Monitoring (COSMO) - [Questionnaires 2020].
56 57	609	Available: https://dfncloud.uni-erfurt.de/s/Cmzfw8fPRAgzEpA [Accessed 25 May
58	610	2020].
59 60	- • •	

1		
2 3	611	37. Justus-Liebig-Universität Giessen. [Code for panel studies]. Available: https://www.uni-
4 5	612	giessen.de/org/admin/stab/stl/servicestelle/panelcode [Accessed 21 May 2020].
6	613	38. UNIPARK & questback. [Developing Online-Surveys easily]. Available:
7 8	614	https://www.unipark.com/?gclid=EAlalQobChMliL3u9o7P6QIViK3tCh2cpgD-
9	615	EAAYASAAEgKa9 D BwE [Accessed 25 May 2020].
10 11 12 13 14	616	39. OCR System GmbH. OCR System. Available: <u>https://www.ocr-systeme.de/en/</u> [Accessed
	617	14 Aug 2020].
	618	40. IBM. SPSS software. Available: https://www.ibm.com/analytics/spss-statistics-software
15 16	619	[Accessed 21 July 2020].
17 18 19	620	41. Federal Ministry of Justice and Consumer Protection & Federal Office of Justice.
	621	Ordinance on Occupational Health Care (ArbMedVV) - Available:
20 21	622	https://www.gesetze-im-internet.de/englisch_arbmedvv/index.html [Accessed 19 May
22	623	2020].
23 24	624	42. Federal Ministry of Justice and Consumer Protection & Federal Office of Justice. Act on
25 26	625	Occupational Physicians, Safety Engineers and Other Occupational Safety
27	626	Specialists. Available: https://www.gesetze-im-internet.de/asig/ [Accessed 19 May
28 29 30	627	2020].
	628	43. Blankenfeld H, Grill E, Kaduszkiewicz H, et al. [Antibody Assays Against SARS-CoV-2:
31 32	629	Why a Good Test Does not Always Produce Proper Results]. ZFA 2020;96(5):230-33.
33 34	630	doi: 10.3238/zfa.2020.0230-0233.
35	631	44. Hemmerich WA. [StatistikGuru: Calculating sample size for single factor ANOVA].
36 37	632	Available: https://statistikguru.de/rechner/stichprobengroesse-einfaktorielle-
38	633	anova.html [Accessed 26 May 2020].
39 40	634	45. UNIPARK & questback. [Data protection]. Available:
41 42	635	https://www.unipark.com/datenschutz/ [Accessed 20 May 2020].
42 43	636	46. Deutsche Forschungsgemeinschaft (DFG). [Guideline for storing research data].
44 45	637	Available:
46	638	https://www.dfg.de/download/pdf/foerderung/antragstellung/forschungsdaten/richtlinie
47 48	639	n_forschungsdaten.pdf [Accessed 21 July 2020].
49	640	47. World Medical Association. Declaration of Helsinki: Ethical principles for medical
50 51	641	research involving human subjects. 2013; <b>310</b> (20):2191-94, doi:
52 53	642	10.1001/jama.2013.281053.
54	643	48. Vanderstoep SW, Johnston DD. Research Methods for Everyday Life: Blending
55 56	644	Qualitative and Quantitative Approaches. San Francisco: Jossey-Bass 2009.
57	645	
58 59		
60		

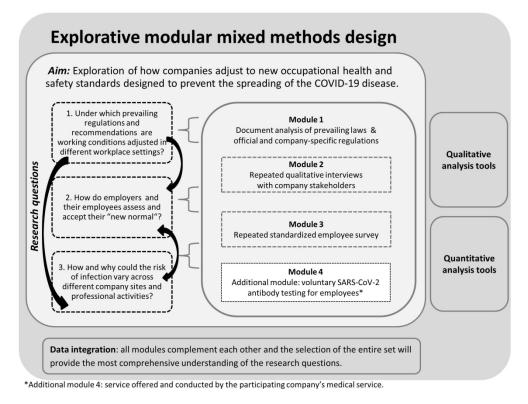


Figure 1 Illustration of the applied explorative modular mixed methods design

201x153mm (300 x 300 DPI)

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# Supplementary file S1 - Good Reporting of A Mixed Methods Study (GRAMMS) checklist\*

Guideline

Describe the justification for using a mixed methods approach to the research question Describe the design in terms of the purpose, priority and sequence of methods Describe each method in terms of sampling, data collection and analysis Describe where integration has occurred, how it has occurred and who has participated in it

Describe any limitation of one method associated with the present of the other method

Describe any insights gained from mixing or integrating methods

Section: page

METHODS AND ANALYSIS - study design: pg. 5 – 6 and figure 1 METHODS AND ANALYSIS - study duration: pg. 7, figure 1, table 1 METHODS AND ANALYSIS – study procedures: pg. 8 - 13 METHODS AND ANALYSIS - study design: figure 1 and pg. 6 and discussion, pg. 14; we describe and discuss how we expect data integration to proceed. Describing specific insights is not yet applicable as data collection, analysis and integration has not commenced. Discussion - pg. 14 - 15

METHODS AND ANALYSIS - study design: pg. 5 - 6 and figure 1 where we describe what we expect from applying a mixed method design. Describing specific insights is not yet applicable as data analysis, data collection, analysis and integration has not commenced.

\* O'Cathain A, Murphy E, Nicholl J. The quality of mixed methods studies in health services research. J Health Serv Res Policy. 2008;13: 92-98.

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# **BMJ Open**

## Adjusting working conditions and evaluating the risk of infection during the COVID-19 pandemic in different workplace settings in Germany – a study protocol for an explorative modular mixed methods approach

Journal:	BMJ Open
Manuscript ID	bmjopen-2020-043908.R1
Article Type:	Protocol
Date Submitted by the Author:	19-Oct-2020
Complete List of Authors:	Rind, Esther; University of Tubingen Institute of Occupational and Social Medicine, Kimpel, Klaus; Medical Services, Robert Bosch GmbH, PO Box 10 60 50, 70049 Stuttgart Preiser, Christine; University of Tubingen Institute of Occupational and Social Medicine; University of Tuebingen Faculty of Medicine, Coordination Centre, Core Facility for Health Services Research Papenfuss, Falko; Medical Services, Robert Bosch GmbH, PO Box 10 60 50, 70049 Stuttgart Wagner, Anke; University Hospital of Tübingen, Institute of Occupational and Social Medicine and Health Services Research Alsyte, Karina; Medical Services, Robert Bosch GmbH, PO Box 10 60 50, 70049 Stuttgart Siegel, Achim; University Hospital Tübingen, Institute of Occupational and Social Medicine and Health Services Research Klink, Antje; Medical Services, Robert Bosch GmbH, PO Box 10 60 50, 70049 Stuttgart Steinhilber, Benjamin; University Hospital Tübingen, Germany, Institute of Occupational and Social Medicine and Health Services Research Kauderer, Johanna; Medical Services, Robert Bosch GmbH, PO Box 10 60 50, 70049 Stuttgart Rieger, Monika A.; Institute for Occupational Medicine, Social Medicine and Health Services Research , University Hospital Tuebingen
<b>Primary Subject Heading</b> :	Occupational and environmental medicine
Secondary Subject Heading:	Occupational and environmental medicine, Public health
Keywords:	COVID-19, OCCUPATIONAL & INDUSTRIAL MEDICINE, Infection control < INFECTIOUS DISEASES

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4	1	<b>Title:</b> Adjusting working conditions and evaluating the risk of infection during the COVID-19
5 6	2	pandemic in different work-place settings in Germany – a study protocol for an explorative
7	3	modular mixed methods approach
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### ABSTRACT

 Introduction: Currently, many countries, affected by the COVID-19 pandemic, discuss ways how the "lockdown-restrictions" could be lifted to restart the economy and public life after the first wave of the COVID-19 disease has subsided. This study protocol describes an approach designed to provide an in-depth understanding of how companies and their employees in Germany deal with their working conditions during the COVID-19 pandemic. We are also interested in how and why the risk of infection with SARS-CoV-2 could vary across different professional activities, company sites and regions with different epidemiological activity or infection control measures in Germany. We expect the results of this study to contribute to the development of working conditions protecting the health of employees during and beyond the COVID-19 pandemic. 

Methods and Analysis: An explorative multimodal mixed methods approach will be applied. Module 1 comprises a document analysis of prevailing federal and regional laws and regulations at the respective location of the participating company. Module 2 includes qualitative interviews with key actors at different companies. Module 3 is a repeated standardized employee survey designed to capture potential changes in the participants' experiences and attitudes towards working conditions, occupational safetv regulations/measures, and infection control measures during the COVID-19 pandemic. Module 4 comprises SARS-CoV-2 seroprevalence testing. This is carried out by the medical service of the participating company sites as a voluntary offer for employees. Qualitative data will be analyzed through document and content analysis. The complexity of the quantitative analysis depends on the response rates of modules 3 and 4. 

Ethics and Dissemination: The approval of the study design was received in June 2020 from the responsible local ethical committee of the Medical Faculty, University of Tuebingen and University Hospital Tuebingen (No.: 423/2020BO). The results will be presented at national and international conferences and published in peer-reviewed journals.

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3 4	72	
5 6	73	STRENGTH AND LIMITATIONS OF THIS STUDY
7	74	One of the first studies to provide a comprehensive understanding of how companies
8 9	75	implement and employees perceive and accept the "new normal" regarding working
10 11	76	conditions in Germany during the COVID-19 pandemic.
12	77	• The linkage of complementary methods (document analysis, interviews with company
13 14	78	stakeholders, employee-surveys, testing of antibodies against SARS-CoV-2) will
15 16	79	allow an in-depth exploration of work practices and experiences in relation to
17	80	occupational safety regulations/measures, infection control regulations/measures,
18 19	81	and the actual and perceived risk of infection.
20 21	82	• Depending on the areas of interest and resources of the participating companies, the
22	83	modular approach enables the implementation of up to four substudies, also allowing
23 24	84	for a cross-sectional or a longitudinal study design.
25 26	85	• The implementation of multiple modules requires comprehensive resources in terms
27	86	of time, qualified scientific staff and the organization of the cooperation with different
28 29	87	company sites as well as different companies.
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### INTRODUCTION

#### Background

At the beginning of 2020, the disease COVID-19 (Corona Virus Disease 2019), triggered by the coronavirus SARS-CoV-2 (severe acute respiratory syndrome coronavirus 2), has developed into a pandemic.<sup>1</sup> Without specific therapeutics or an effective vaccine available in the first quarter of 2020, many health care systems and governments responded to the rapid spread of the virus and the significant lethality of COVID-19 with the traditional means of containment: identification of cases and if necessary treatment under guarantine conditions. contact tracing and isolation of suspect cases, closure of schools and other educational institutions, non-system-relevant public institutions and businesses. In addition, most of the governments imposed contact restrictions and curfews considerably affecting everyday life of the population. For such a package of measures the term "lockdown" has become established. A lockdown lasting several weeks does not only result into a temporary restriction of civil rights such as freedom of assembly, but also into a considerable impairment of the economy.<sup>2-5</sup> Currently, debates revolve around which conditions and in which way the "lockdown-restrictions" could be lifted to restart the economy and public life after the first wave of the COVID-19 disease has subsided. This poses new challenges for local and global society: How can restrictions be relaxed without triggering another, even stronger and possibly uncontrollable wave of infection? Under these conditions, enterprises cannot simply "go back to business as usual"<sup>2</sup>, and national and international recommendations regarding occupational health and safety standards tailored to the risks of SARS-CoV-2 infection have been developed.<sup>6-8</sup> The term "new normal" arose, meaning that as long as there will be no vaccination for SARS-CoV-2 and no effective treatment, the state of exception will last, including implementation of and adherence to strict hygiene measures, as well as social and physical distancing in private life and workplaces for individual and collective protection. 

New studies on coronaviruses and COVID-19 have explored a variety of safety-related dimensions including social public safety, psychological health and domestic safety, medicine treatment and vaccine safety or the occupational safety of employees.<sup>9</sup> The latter focuses particularly on working conditions and safety of healthcare professionals in clinical or ambulant settings.<sup>10-12</sup> Furthermore, research has looked at COVID-19 stressors on migrant workers<sup>13</sup> and commercial drivers<sup>14</sup> <sup>15</sup>, and at measures to control the spreading of the corona virus in workplaces including engineering and administrative controls (e.g. proper ventilation, restricting staff gatherings) as well as the provision of personal protective equipment (e.g. protective masks or clothing).<sup>16</sup> As of yet, we are not aware of any studies linking different data sources, perspectives and methods to provide an in-depth understanding in which ways companies and their employees deal with their working Page 7 of 23

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conditions during the COVID-19 pandemic and how different experiences and attitudes may

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4 5 6	128	impact variations in the occurrence of infections with SARS-CoV-2. The results of our study											
	129	are expected to facilitate the effort of companies and executive managers to protect the											
7 8	130	health of their employees over the course of the COVID-19 pandemic, also preparing them											
9	131	for future challenges such as the next wave of influenza.											
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12	132												
13 14 15 16 17 18 19 20	133												
	134	The Institute of Occupational and Social Medicine and Health Services Research (IASV)											
	135	University Hospital Tuebingen, aims to explore how companies in Germany adjust to new											
	136	occupational health and safety standards designed to prevent the spreading of the COVID-											
	137	19 disease. We will focus on the following research questions:											
21 22	138	1. Under which prevailing regulations and recommendations are working conditions											
23 24	139	adjusted in different work-place settings in Germany?											
25	140	2. How do employers and their employees in Germany assess and accept their "new											
26 27	141	normal"?											
28 29	142	3. How and why could the risk of infection vary across different German company sites											
30 31 32 33 34 35 36 37	143	and professional activities?											
	144												
	145	METHODS AND ANALYSIS											
		4											
38	146	Previous contact of the IASV to representatives of the initially participating company's chief											
39 40	147	medical services resulted in the development of a cooperative project exploring occupational											
41	148	health and safety issues related to the COVID-19 pandemic. The transdisciplinary project											
42 43 44 45 46	149	group has academic and practical expertise in occupational medicine, health sciences,											
	150	health services research, and sociology and jointly discussed and developed the realization											
	151	of the study design in the participating company.											
47	152												
48 49 50 51 52 53 54 55 56 57 58 59 60	153	Study design											
	154	The IASV conceptualized an explorative multi-modular mixed methods approach <sup>17</sup> <sup>18</sup>											
	155	following the GRAMMS-guidelines (supplementary file 1) developed by O'Cathain et al.											
	156	(2008) <sup>19</sup> . Mixed method designs have become an integral part of health-related and health											
	157	services research, providing a variety of quantitative and qualitative tools complementing											
	158	each other in order to gain a comprehensive understanding of complex research questions. <sup>19</sup>											
	159	$^{20}$ The approach comprises three modules (modules 1 – 3 in figure 1) which can be applied											
	160	either as an entire set or companies can choose particular modules depending on their											
	161	research interest and resources. The approach also allows the extension of additional 5											

modules. The complete explorative multi-modular approach is initially tested and evaluated in one company. Modules 1 – 3 will be carried out in a large German leading global supplier of technology and services. The company employs roughly 400,000 associates in approximately 60 countries worldwide, thereof 132,000 in Germany in more than 100 locations where employees pursue a variety of professional activities differing in their work-related risk of infection with SARS-CoV-2...An additional fourth module (figure 1) will be conducted by the participating company's medical service. As the approach is transferable to other settings, the team of the IASV plans to extend this research design to other companies, institutions and public authorities. 

#### Figure 1 Illustration of the applied explorative modular mixed methods design

In module 1, prevailing national and local laws as well as occupational health and safety regulations of the respective site will be analyzed. In module 2, gualitative interviews with company stakeholders will be conducted at the beginning and in the middle of the survey period. In module 3 we will focus on the perspective of employees conducting three waves of a standardized survey. Module 4 will comprise SARS-CoV-2 antibody testing for employees offered as a voluntary occupational health service by the participating company and carried out by the company's medical service. Using these methods in combination, we expect to be able to provide different perspectives, explanations and a deeper understanding of how companies and their employees adjust to working conditions in Germany during the COVID-19 pandemic in particular ways and how different attitudes and behaviours may impact their perceived and measured risk of infection. 

Each module can stand by itself; however, selecting the entire set (modules 1 - 3) or even extending it (module 4) will provide the most comprehensive understanding of the study objective. The initial company agreed to participate in modules 1 - 3 and to conduct module 4. Further companies can combine particular modules depending on their specific interests and resources. For example, if a company was particularly interested in why certain measures of infection protection during the COVID-19 pandemic may be accepted, ignored or rejected it would be advisable to take part at least in modules 1 and 3. For a deeper understanding it would also be advisable to include module 2. In order to evaluate how and why the results of the antibody testing (module 4, carried out by the participating company) and the perceived risk of infection may vary across company sites or areas of professional activities, a combination of all modules or at least modules 1, 3 and 4 would be recommended. As all data collection methods complement each other, data integration (e.g. converting coded qualitative data into variables for statistical analysis<sup>21</sup>, triangulation of 

3 4	197 198	qualitative and quantitative data) depends on the number of modules a company chooses to participate in. <sup>22</sup>																		
5 6 7 8 9 10 11 12 13	199	participate	,																	
	200	Patient and public involvement																		
	201	Neither pa	atien	ts no	or th	e pu	blic v	were	and	l are	invo	olved	in t	he p	lanni	ng c	of the	e des	sign,	the
	202					•								•		•			•	
	203	recruitment, instrument development, data analysis, and reporting or dissemination plans of this study.																		
14 15		-																		
16 17 18 19 20	204	Study duration																		
	205	As the participating company will take part in the complete set of modules including multiple																		
	206	survey and blood sampling waves, we anticipate a study duration of 18 months (Table 1).																		
	207	The actua	l sur	vey p	perio	d for	the c	omp	any i	is 13	mon	ths.								
21 22	208																			
22	209	Table 1 Stu	udy p	lan ir	icludi	ng a	full se	t of n	nodul	les (n	nodul	es 1-	4)							
24 25 26 27 28 29 30 31 32		Project month	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18
		Study preparation*	x	x	x				D.											
					Mo	dule 1	– doc	umen	t analy	ysis (p	orevail	ing lav	vs and	l regul	ations	;)				
		Document analysis				x	x	x	x	x	x	x	x	x	x	x	x			
					N	lodule	2 – qı	alitati	ve int	erview	s with	comp	any s	takeho	ders					
33 34		Qualitative interviews**						то				•		T1						
35		Qualitative analysis						x	x	x	x	x	x	x	x	x	x	x	x	
36 37		Feedback to company									x	Z	7						x	
38 39 40 41 42				1			1	Мо	dule 3	– emj	ployee	surve	y	1			1	1		L
		Pretest			x															
		Quantitative survey				т0	то	то			T1	T1	T1			Т2	T2	T2		
43 44		Quantitative analysis					x	x	x	x	x	x	x	x	x	x	x	x	x	
45 46		Feedback to company								x					х				x	
47			1	1	Mo	dule 4	-SAR	S-CoV	-2 anti	ibody	testing	g and a	aggreg	gated a	analys	is	1	1		
48 49 50		Blood sample collection***			то	то	то				T1	T1	T1			Т2	T2	T2		
51		Analysis			x	x	x	х	х	x	x	x	x	x	х	х	x	x	x	
52 53 54 55 56 57 58 59 60		Feedback to company																	x	
		Publication														x	x	x	x	x
	210 211 212 213 214	participating protection of **In the ev	*Literature research, development and adjustment of the survey instruments to specifics of the participating company (employee survey, interview guide), consultation of the responsible data protection officer. **In the event of relevant changes in the incidence of infection (e.g. local outbreak) or operational procedures (e.g. new infection control measures or procedures), further interviews with company																	
	215	stakeholde	rs ca	n be a	arran	ged.					-									-

\*\*\*Seroprevalence testing is a voluntary occupational health offer which will be undertaken by the

company's medical officer. The frequency of blood sampling depends on the company's resources

and operational capacity. Presuming individual consent of each participant, the aggregated results of

servoprevalence testing (by job activity) can be linked to the results of the other modules.

### 222 Study procedures: setting, sampling, data collection and analysis

As companies are responsible for occupational health and safety to protect their employees, company owners and executive managers play a crucial part in preparing and responding to disease outbreaks, such as the COVID-19 pandemic.<sup>23</sup> This includes, for example, the adaption of workplace settings to protect workers, the development of action plans for resuming production after a period of closure or managing an increasing number of teleworkers.<sup>7</sup> Companies and their occupational health service have also been advised to prepare for the potential physical, mental and psychosocial effects of the "new normal" on employees.23

For all groups of employees, the working conditions are changing as a result of new infection control measures (e.g. distance and hygiene rules, modification of work schedules). On the one hand, groups of employees are exposed to an increased work-related risk of infection due to the necessity of working on-site closely together with other personnel (e.g. company medical service, plant security, personnel working on the assembly line). On the other hand, there are groups of employees (e.g. administrative staff) who can also work from home. Although this reduces the work-related risk of infection, new physical and psychological burdens and challenges arise with regard to working conditions and work design (e.g. ergonomically adequate workstations at home, organization of childcare, dissolving boundaries between work and private life, loss of immediate team support). 

To capture potential regional and activity-related differences in the occupational risk and perception of infection risk, purposive sampling<sup>24</sup> will be used to include about six different company sites of the initially participating company. Inclusion criteria comprise a combination of sites providing the greatest possible contrast between different fields of activities (e.g. personnel working in open-plan offices/telework versus personnel on the assembly line). Furthermore, the company sites' responsible executive managers, employee organization and medical service will need to agree to the participations of the respective sites. 

*Module 1* is a continuous literature search and document analysis<sup>25</sup>. The objective is to present workplace-related, legal, infectiological and social conditions facing companies in the context of the COVID-19 pandemic following the first lockdown in Germany. Three researchers from the IASV analyse and discuss prevailing federal and regional laws (e.g., from the Federal Ministry of Health and from the Federal Ministry of Labour and Social 

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Affairs), the development of infection rates in Germany (e.g., from the Robert Koch Institute), and occupational health and safety and infection control regulations at the respective sites of the participating companies. This will provide a broader legal, infectiological, and organizational cultural context for the interpretation of the results of the other modules. An information letter accompanied by a consent form will be sent to the responsible contact person (e.g. executive manager). With the consent of the management and the employee organization, the company will be invited to provide documents and a short questionnaire with general company information (e.g. size of the company sites, number of employees in different departments and branches, job descriptions), and information on current implemented health and safety measures (e.g. contact restrictions, telework regulations, working in fixed teams, implementation of hygiene rules). This information will also allow the calculation of response rates for modules 3 and 4. 

*Module 2* will comprise qualitative interviews with key actors at different company sites (e.g. executive managers, members of the employee organization). The IASV will address them as experts of their respective departments who can provide an overview of daily working procedures and who are involved in problem solution processes.<sup>26</sup> The interdisciplinary project team will develop a semi-structured interview guide according to the SPSS method developed by Hellferich (2004)<sup>27</sup> covering these topics: 

- <sup>33</sup> 271 Workplace design and organization of working procedures in the context of the
   <sup>34</sup> 272 COVID-19 pandemic;
- <sup>36</sup> 273 Assessment of work-related stress and strain;
   <sup>37</sup>
- 274 Expectations and attitudes towards infection control and occupational health and
   275 safety measures;
- 41 276 Expectations and attitudes towards SARS-CoV-2 antibody tests.

Purposive sampling<sup>24</sup> will be used to invite interview partners from different company sites and different fields of activities (e.g. administrative responsibilities, organization of work at the assembly line, provision of occupational health services) if they have worked at their current job for at least 6 months and have a knowledge of German at least at B1-level.<sup>28</sup> The participants will receive information on interview procedures, data protection and data management accompanied by an individual consent form. We plan to conduct interviews with the same participants at the beginning and in the middle of the study period to capture potential changes in their experiences and attitudes. In the event of relevant changes in the incidence of infection (e.g. local outbreak) or adjustment of company procedures (e.g. new measures of infection protection), further interviews could be arranged. All interviews will be conducted by the team of the IASV. Based on experience from previous projects, the duration of the interviews will take about 30-45 minutes.<sup>29</sup> Interviews will be audio taped and

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transcribed by a professional company according to a simplified system whereby transcription is word by word, but not phonetically<sup>30</sup>. Quality checks, de-personalization and pseudonymization of the data will be undertaken by the team of the IASV conducting the interviews. Interviewees will have the opportunity to re-read their interviews and give feedback on passages they consider as risky. The data will be imported into MAXQDA<sup>31</sup>, and analysis will be carried out by two researchers of the IASV following the steps of qualitative content analysis, including the development of a coding frame, the segmentation of the material, the testing of the coding frame, the evaluation of the trial coding and the completion of the main coding.<sup>32</sup> Preliminary results will be presented to further members of the study team to discuss remaining open questions and ensure quality control. All data will remain at the IASV.

### 22 300 Sample size:

If applicable, we plan to include two company sites and several fields of activity in each site (e.g. production halls, open space offices, workplaces with high frequency of customer contacts) to the sample. We plan to conduct one interview per addressed field of activity at the time of the initial online survey (T0) and a follow-up interview with the same person after the second online survey (T1). The total number of interviews cannot be determined at this stage because it depends on the number of company sites included in the entire study. Due to a rather specific research aim, high sample specificity and quality of dialogue<sup>33</sup>, we assume eight participants per company will provide sufficient information for the aspired analysis. Thus, we expect a minimum number of 16 interviews to reach data saturation<sup>29</sup> (four interviewees at two company sites interviewed at the beginning and the end of the survey period). 

*Module 3* comprises three waves of a repeated standardized (anonymous) employee survey carried out by the IASV. T0 allows to capture the initial status in summer/autumn 2020 in Germany. T1 will cover the winter months, while T2 will again be carried out in summer 2021. This approach makes it possible to identify different phases and probably also peaks during the ongoing COVID-19 pandemic. Closed and open questions on our questionnaire are being designed to capture potential changes in the participants' experiences and attitudes towards working conditions during the COVID-19 pandemic as well as their perceived risk of infection at the workplace and outside the working environment.<sup>34</sup> Depending on the participating companies' preferences, a paper-based or online questionnaire is being developed. The questions are based on national and international recommendations regarding occupational health and safety standards and infection control measures, tailored to the risks of SARS-CoV-2 infection<sup>6-8</sup>, established recommendations of evaluating work-related stress and strain<sup>35</sup>, as well as existing guestionnaires<sup>e.g.36</sup>. According to the

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explorative design, we did not predefine one specific outcome, but addressed these aspects: the risk of infection perceived by employees, their experiences and attitudes towards <text> infection protection at the workplace, and the associated psychological stress and strain. This will provide context to interpret the occurrence of infections (self-reported antibody status, aggregated results of antibody testing) as well as for recommendations concerning infection protection at the workplace. Main subject areas of the questionnaire are summarized in Table 2. 

> For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml

Subject areas	Themes
Evaluation of implemented SARS-	e.g. distance regulations, hygiene rules, organization
CoV-2-related occupational health and	of telework and teams working on-site, provision of
safety standards	protective equipment, workplace design
Evaluation of work-related stress and	e.g. work-related stress and strain before and during
strain related to the COVID-19	the COVID-19 pandemic concerning work content/task
pandemic	organization of work, working environment, social
	relations, new patterns of work
Assessment of perceived and potential	e.g. concern of being infected at the workplace number
risk of infection at the workplace	of contacts with others, working in fixed teams, workin
	on-site or at home, acceptance and practicability of
	hygiene rules at work (keeping distance, wearing masks)
Assessment of perceived and potential	e.g. concern of being infected outside the working
risk of infection outside the working	environment, number of social contacts, contact to risl
environment	groups, travel behaviour, practiced leisure activities
	(low-contact vs. contact sports)
Sociodemographic and	e.g. age, sex, marital status, educational background,
medical information potentially related	work experience, current occupation, number of
to the prevalence of SARS-CoV-2	children and their attendance in day-care centers or
infections	schools, relevant underlying medical conditions, if
	available: SARS-CoV-2 antibody status
Other relevant measures	e.g. control measures for personality factors, resilience
	and social desirability

The questionnaire will be pretested by a group of academic volunteers as well as by representatives of the target audience. Participation in each survey wave is voluntary. Survey invitations will be organized by the participating company (e.g. via company e-mail accounts, company newsletter, posters, postcards). Taking part requires employees to be of legal age with a knowledge of German at least at B1-level<sup>28</sup>, and - in case of an online-survey -internet access via PC, tablet, or smartphone. Individual consent to participate is given by the study participants after sufficient information on data protection and data management at the beginning of the survey. At the end of the first survey wave, participants will be asked to generate an 8-digit code which will be the same for all survey waves and can be used to merge the data of each person anonymously over subsequent survey waves.<sup>37</sup> Participants can (but do not have to) provide the result of the seroprevalence testing to the questionnaire. The completion of the survey is expected to take approximately 25 minutes. In case of an online-survey, the individual survey responses will be managed via the established online tool Unipark.<sup>38</sup> In case of a paper-pencil questionnaire, each survey sheet will be scanned at the University Hospital Tuebingen using an Optical Character Recognition (OCR) system.<sup>39</sup> All data will remain at the IASV and will be analyzed applying appropriate descriptive and inferential statistics in SPSS.<sup>40</sup> Depending on the sample size, a biometrician will be involved in discussing the development of hypothesis testing models which can be applied if a sufficient number of respondents take part in the survey. 

**353** 

Sample size:

cases per subgroup is reached (>=10).

According to the exploratory design, we aim to invite the entire staff of the participating

company sites (n ~ 22.000). Stratification can only be carried out if a sufficient number of

Module 4: SARS-CoV-2 seroprevalence testing will be carried out as a voluntary company

offer for employees by the occupational service of the participating company sites; hence, all

individual data are subject to doctor-patient confidentiality and will remain with the

participating company's medical service. In terms of quality assurance, the IASV research

team will advise on database design, selection of antibody tests (type, pharmaceutical

supplier) the content of a short participant questionnaire completed when blood sampling

takes place (age, sex, work location, field of activity), and analysis procedures. Testing and

aggregated epidemiological evaluations at the company level will be carried out according to

applicable medical regulations.<sup>41 42</sup> Presuming individual consent of each participant, the

results of the antibody tests (aggregated to company specific operational activities, e.g.

infections in open plan office versus assembly line) can be anlyzed in combination with the

results of the other modules by the IASV. As module 4 is of exploratory nature, data will be

Due to the currently low prevalence of SARS-CoV-2 in Germany (<2%)<sup>43</sup>, serological diagnostic and hypothesis testing are only suitable for larger epidemiological studies including a sufficient number of cases allowing for stratification. For example, assuming a small effect size ( $n^2 = 0.01$ ) for the detection of potential differences in the seroprevalence across employees from four different areas of activity at a power of 80%, statistical analysis would require a sample size of 271 persons per area of activity (n = 1084 employees) to obtain a statistically significant result performing a single factor ANOVA ( $\alpha = .05$ ).<sup>44</sup> 

analyzed applying appropriate descriptive and inferential statistics in SPSS.<sup>40</sup>

#### 49 382 Data protection

Sample size:

Relevant data protection regulations will be observed for all data collected and coordinated with the responsible ethics committee, academic and company data protection officers, as well as the respective company physicians and representatives of the employee organization. Concerning module 1, the company sites will decide whether and how they provide company-related information. All other data (e.g. federal and regional COVID-19-related regulations) are available publicly. Depending on the extent of the information 

3 389 provided by the companies and the official information available, the respective legal and
 3 390 organizational context of different work-place settings is compiled by the IASV.

Participants taking part in module 2 will provide individual consent to be interviewed by project members of the IASV. The digital audio recordings and original (non-pseudonymized) transcripts will be stored in the secure network of the University Hospital Tuebingen and destroyed after the completion of the analyses. For the analysis, all names, places and references that would allow drawing conclusions about a person or the participating company or company site will be pseudonymized by project members of the IASV. The pseudonymized transcripts will only be accessible to project members of the IASV, stored in the secure network of the University Hospital Tuebingen. All other persons will have access only to the interview excerpts cited in reports or publications. In terms of module 3, the participants provide individual consent to take part in the anonymous employee survey. In case of an online survey, the questionnaire data will be collected via the established survey tool Unipark complying with security requirements according to the information security standard ISO/IEC 27001.45 In case of a paper-pencil questionnaire, all data will be scanned at the University Hospital Tuebingen.<sup>39</sup> All data will be transferred to SPSS<sup>40</sup> and stored in the secure network or a lockable archive of the University Hospital Tuebingen. Individual data will only be accessible for project members of the IASV. 

The collection and pseudonymization of the individual serum samples during module 4 will be organized by the company's medical service and is subject to medical confidentiality. Presuming individual consent of each participant, project members at the University Hospital Tuebingen will receive data on the seroprevalence of employees aggregated to areas of activity, also including aggregated demographic information (age, sex). If the response rate is low (<=10/area of activity), these data will be aggregated with the data from other company sites and if necessary with other areas of activity.

In line with the German guidelines for storing research data<sup>46</sup>, all data compiled by the IASV (modules 1 - 3) as well as the aggregated data received by the participating company (module 4) will be stored for 10 years after the final publication in the secure network of the University Hospital Tuebingen and destroyed thereafter. These data will be accessible only to IASV-personnel involved in the research project. 

<sup>52</sup> 53 419

### 54 420 Ethics and dissemination

#### 56 421 **Research ethical approval**

The study and all study-related documents were designed following the principles formulated
 in the current version of the Declaration of Helsinki<sup>47</sup>. The approval of the study design was

received in June 2020 from the responsible local ethical committee of the Medical Faculty,
University of Tuebingen and University Hospital Tuebingen (No.: 423/2020BO).

#### 6 426

### **Progression of the study**

The development of the research instruments are in progress. The recruitment of the first
wave of participants has commenced 21<sup>th</sup> July 2020 and is anticipated to continue until
October 2020.

# <sup>14</sup> 431

### 16 432 **Dissemination**

433 Study results will be published in peer-reviewed journals and presented at international and434 national conferences.

# <sup>22</sup> 436 **Discussion**

There are some pros and cons associated with our study approach. Although the triangulation (and integration) of evidence is an integral part of mixed methods research<sup>17</sup>, the design of our study is unique in terms of the modular approach we specifically developed for assessing how companies and their employees experience and adjust to working conditions in Germany during the COVID-19 pandemic. Furthermore, the design is transferable to other companies, institutions and public authorities in Germany. However, this is not an international study. Therefore, the gained results from Germany may not be translatable to other countries. Depending on their areas of interest and resources, the modular approach enables the implementation of up to three substudies conducted by the IASV, also allowing for a cross-sectional or a longitudinal study design with multiple survey and interview waves. Additional substudies such as SARS-CoV-2 seroprevalence testing can be implemented and conducted by the participating companies. Each of the quantitative (employee survey, SARS-CoV-2 antibody testing) and gualitative method (document analysis, interviews with company stakeholders) applied can stand by itself; however, in linking different data sets and methods (document analysis, descriptive and interferential statistics, content analysis) as well as a variety of perspectives (researchers, company stakeholders, workers) the integration<sup>21</sup> of the individual results will provide a detailed analysis of the overall research objective. In terms of resources (e.g. time, required qualification of the personnel, organizational effort), we expect that the combination of the methods applied will mitigate some of the limitations inherent for quantitative (numeric description of phenomena, complexity of statistical analysis dependent on survey response rate, superficial understanding of participants' experiences, attitudes and causal relationships) and qualitative research (e.g. small sample, results not statistically representative of a population, time consuming data collection and analysis).48

Finally, we want to highlight potential concerns of the participants that may occur over the course of the study. Since the company's medical service is involved in data collection (module 4), the participants may be concerned that their test results or their responses from the interviews and questionnaires (modules 2 and 3) have a negative impact on their working conditions or employment. We aim to avoid this issue by communicating our comprehensive data protection concept, by providing extensive information on the study, and by emphasizing the participants' right to withdraw from the study without any negative consequences. The project leader and responsible researchers will also be available to answer questions occurring over the course of the study period. Furthermore, the pseudonymized (module 2) and non-aggregated anonymized (module 3) data remains exclusively at the Institute of Occupational Medicine, Social Medicine and Health Services Research, University Hospital Tuebingen and will be evaluated there. The company (i.e. company owners, executive managers, works council, company medical service) will only receive aggregated evaluations. With respect to the antibody testing (module 4), this offer will be a completely voluntary occupational health service for company employees and the physician of the responsible medical service will provide information about the usual risks and side effects of blood sampling. 

With this study, we aim to provide an in-depth analysis of occupational health and safety challenges related to the process of resuming and continuing work-related activities during the COVID-19 pandemic. This includes, for example the consideration of work activities requiring on-site presence - possibly in close contact with colleagues, suppliers or the public - as well as issues associated with an increased use of telework. We expect that our study will contribute to the development of working conditions ensuring that job-related activities can be designed as safe as possible to the requirements of occupational health and safety regulations and to the particular needs of companies and their employees. 

#### DECLARATIONS

Contributors 

All authors contributed to the development of the study design. ER, CP, AW, AS, BS and MAR conceptualised modules 1 - 3 and KK, FP, KA, AK and JK had the initial idea for module 4. ER and MAR were involved in obtaining approval from the Ethics Committee of the Medical Faculty, University Hospital of Tuebingen. ER is the primary investigator and drafted the manuscript. All authors provided critical feedback on the manuscript, read and approved the final version. 

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#### Disclaimer

The funding sources had no role in the design of the study and will not be involved in the conduct, collection, management, analysis, interpretation or dissemination of any data or results of the research.

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- Competing interests
  - None declared.
- Ethics approval and consent to participate
- Ethical approval for this study was obtained from the Ethics Committee of the Medical Faculty, University Hospital of Tuebingen (reference number: 423/2020BO). Informed written consent to participate will be obtained from all participants.
- Provenance and peer review
  - Not commissioned; externally peer reviewed.

#### Data sharing statement

Our manuscript describes a study protocol. As such, we cannot elaborate on unpublished data.

1		
2 3	527	Supplementary material
4 5	528	Supplementary file S1: Good Reporting of A Mixed Methods Study (GRAMMS) checklist
6	529	
7 8	530	References
9	531	1. World Health Organization. Coronavirus. Available: https://www.who.int/health-
10 11	532	topics/coronavirus#tab=tab_1 [Accessed 19 May 2020].
12 13	533	2. Dorn F, Khailaie S, Stöckli M, et al. [The common interest of health and economy: A
13 14	534	scenario calculation for the containment of the corona pandemic. A joint study of the
15 16	535	ifo Institute (ifo) and the Helmholtz Centre for Infection Research (HZI). ifo
17	536	Schnelldienst digital 6/2020 13 May 2020]. München: ifo Institut 2020.
18 19	537	3. Tagesschau. [VW shutting down again - news from 13.05.2020]. Available:
20	538	https://www.tagesschau.de/wirtschaft/vw-produktion-105.html [Accessed 19 May
21 22	539	2020].
23 24	540	4. Veitinger T. [Bosch - environmental protection despite pandemic. Heidenheim News from
25	541	30.04.2020]. Available: https://www.hz.de/wirtschaft/wirtschaft-
26 27	542	ueberregional/umweltschutz-trotz-pandemie-45870919.html [Accessed 19 May 2020].
28	543	5. Verma S, Gustafsson A. Investigating the emerging COVID-19 research trends in the field
29 30	544	of business and management: A bibliometric analysis approach. J Bus Res
31 32	545	2020; <b>118</b> :253-61. doi: 10.1016/j.jbusres.2020.06.057. [published Online First:
33	546	2020/07/02.].
34 35	547	6. Cirrincione L, Plescia F, Ledda C, et al. COVID-19 Pandemic: Prevention and Protection
36	548	Measures to Be Adopted at the Workplace. Sustainability 2020;12(9) doi:
37 38	549	10.3390/su12093603.
39 40	550	7. EU-OSHA. EU GUIDANCE. Covid-19: Back to the workplace. Adapting workplaces and
40	551	protecting workers. European Agency for Safety and Health at Work: EU-OSHA 2020.
42 43	552	8. Federal Ministry of Labour and Social Affairs. [SARS-CoV-2- Occupational Safety
44	553	Standard from 16.04.2020]. Available:
45 46	554	https://www.bmas.de/SharedDocs/Downloads/DE/PDF-Schwerpunkte/sars-cov-2-
47 49	555	arbeitsschutzstandard.pdf? blob=publicationFile&v=4 [Accessed 19 May 2020].
48 49	556	9. Haghani M, Bliemer MCJ, Goerlandt F, et al. The scientific literature on Coronaviruses,
50 51	557	COVID-19 and its associated safety-related research dimensions: A scientometric
52	558	analysis and scoping review. <i>Saf Sci</i> 2020:104806. doi: 10.1016/j.ssci.2020.104806.
53 54	559	[published Online First: 2020/05/10.].
55	560	10. Ambigapathy S, Rajahram GS, Shamsudin UK, et al. How should front-line general
56 57	561	practitioners use personal protective equipment (PPE)? Malays Fam Physician
58 59	562	2020; <b>15</b> (1):2-5.
59 60		

1 2		
2 3	563	11. Chen Y, Pradhan S, Xue S. What are we doing in the dermatology outpatient department
4 5	564	amidst the raging of the 2019 novel coronavirus? J Am Acad Dermatol
6	565	2020; <b>82</b> (4):1034. doi: 10.1016/j.jaad.2020.02.030. [published Online First:
7 8	566	2020/02/23.].
9 10	567	12. Cheung JC-H, Ho LT, Cheng JV, et al. Staff safety during emergency airway
11	568	management for COVID-19 in Hong Kong. The Lancet Respiratory Medicine
12 13	569	2020; <b>8</b> (4) doi: 10.1016/s2213-2600(20)30084-9.
14	570	13. Alahmad B, Kurdi H, Colonna K, et al. COVID-19 stressors on migrant workers in Kuwait:
15 16	571	cumulative risk considerations. <i>BMJ Glob Health</i> 2020; <b>5</b> (7):e002995. doi:
17	572	10.1136/bmjgh-2020-002995.
18 19	573	14. Lemke MK, Apostolopoulos Y, Sonmez S. A novel COVID-19 based truck driver
20 21	574	syndemic? Implications for public health, safety, and vital supply chains. Am J Ind
22	575	<i>Med</i> 2020; <b>63</b> (8):659-62. doi: 10.1002/ajim.23138. [published Online First:
23 24 25	576	2020/05/27.].
	577	15. Lemke MK, Apostolopoulos Y, Sonmez S. Syndemic frameworks to understand the
26 27	578	effects of COVID-19 on commercial driver stress, health, and safety. J Transp Health
28 29 30 31 32 33	579	2020; <b>18</b> :100877. doi: 10.1016/j.jth.2020.100877. [published Online First:
	580	2020/06/06.].
	581	16. Rafeemanesh E, Ahmadi F, Memarzadeh M. A Review of the Strategies and Studies on
	582	the Prevention and Control of the New Coronavirus in Workplaces. Arch Bone Jt Surg
34 35	583	2020; <b>8</b> (Suppl1):242-46. doi: 10.22038/abjs.2020.47410.2323.
36 37	584	17. Mayring P. [Triangulation of evidence and mixed methods in health research]. In: Haring
38	585	R, ed. [Health Sciences]. Berlin, Heidelberg: Springer Berlin Heidelberg 2019:133-41.
39 40	586	18. Niederberger M, Peter L. [Mixed methods studies in the health sciences. A critical map].
41	587	Z Evid Fortbild Qual Gesundhwes 2018; <b>133</b> :9-23. doi: 10.1016/j.zefq.2018.02.008.
42 43	588	[published Online First: 2018/04/02.].
44	589	19. O'Cathain A, Murphy E, Nicholl J. The quality of mixed methods studies in health
45 46	590	services research. J Health Serv Res Policy 2008;13(2):92-8. doi:
47 48	591	10.1258/jhsrp.2007.007074. [published Online First: 2008/04/18.].
49	592	20. Tariq S, Woodman J. Using mixed methods in health research. JRSM Short Rep
50 51	593	2013; <b>4</b> (6):2042533313479197. doi: 10.1177/2042533313479197. [published Online
52	594	First: 2013/07/26.].
53 54	595	21. Bryman A. Integrating quantitative and qualitative research: how is it done? Qualitative
55 56	596	Research 2016; <b>6</b> (1):97-113. doi: 10.1177/1468794106058877.
56 57	597	22. Fielding NG. Triangulation and Mixed Methods Designs. Journal of Mixed Methods
58 59	598	Research 2012; <b>6</b> (2):124-36. doi: 10.1177/1558689812437101.
60		

1		
2 3 4 5		
	599	23. Fadel M, Salomon J, Descatha A. Coronavirus outbreak: the role of companies in
	600	preparedness and responses. <i>The Lancet Public Health</i> 2020; <b>5</b> (4) doi:
6 7	601	10.1016/s2468-2667(20)30051-7.
8 9 10 11 12 13 14 15 16 17 18	602	24. Guetterman TC. Descriptions of Sampling Practices Within Five Approaches to
	603	Qualitative Research in Education and the Health Sciences. Forum: Qualitative Social
	604	Research 2015;16(2):http://nbn-resolving.de/urn:nbn:de:0114-fqs1502256.
	605	25. Wolff S. [Analysis of documents and field analyis]. In: Flick U, von Kardorff E, Steinke I,
	606	eds. [Qualitative research A manual (5th edition)]. Reinbek bei Hamburg: Rowohlt
	607	Taschenbuch Verlag 2007:502 – 13.
	608	26. Britten N. Qualitative interviews in medical research. BMJ (Clinical research ed)
19	609	1995; <b>311</b> (6999):251-3. [published Online First: 1995/07/22.].
20 21	610	27. Hellferich C. [The quality of qualitative data. Manual for conducting qualitative interviews].
22	611	Wiesbaden: VS Verlag für Sozialwissenschaften. 2004.
23 24	612	28. Council of Europe. Common European Framework of Reference for Languages (CEFR).
25	613	Available: https://www.coe.int/en/web/common-european-framework-reference-
26 27	614	languages [Accessed 21 July 2020].
28 29	615	29. Aldiabat KM, Le Navenec C. Data saturation: The mysterious step in grounded theory
29 30	616	methodology. The Qualitative Report 2018;23(1):245-61.
31 32 33	617	30. Dresing T, Pehl T. [Research in practice: interviews, transcription & analysis. Instructions
	618	and control systems for qualitative researchers; 8th edition]. Marburg: dr dresing &
34 35	619	pehl GmbH 2018.
36	620	31. MAXQDA. The Art of Data Analyis. Available: https://www.maxqda.com/how-to-analyse-
37 38	621	gualitative-data [Accessed 25 Jan 2020].
39	622	32. Schreier M. Qualitative content analysis in practice. London: Sage 2012.
40 41	623	33. Malterud KS, , D; Guassora, AD Sample Size in Qualitative Interview Studies: Guided by
42 43	624	Information Power. <i>Qualitative Health Research</i> 2016; <b>26</b> (13):1753–60.
43 44	625	34. Taddicken M. [Online-Survey]. In: Möhring W, Schlütz D, eds. [Handbook of standardised
45 46 47	626	survey procedures in communication science]. Wiesbaden: Springer Fachmedien
	627	Wiesbaden 2013:201-17.
48 49	628	35. Gemeinsame Deutsche Arbeitsschutzstrategie (GDA), editor. Occupational Safety and
50	629	Health in Practice. Recommendations for implementing psychosocial risk
51 52	630	assessment. Berlin: Management of the GDA Mental Health Working Programme, c/o
53	631	Federal Ministry of Labour and Social Affairs, 2014.
54 55 56 57 58		
	632	36. COSMO open. COVID-19 Snapshot Monitoring (COSMO) - [Questionnaires 2020].
	633	Available: <a href="https://dfncloud.uni-erfurt.de/s/Cmzfw8fPRAgzEpA">https://dfncloud.uni-erfurt.de/s/Cmzfw8fPRAgzEpA</a> [Accessed 25 May
59	634	2020].
60		

2		
3 4	635	37. Justus-Liebig-Universität Giessen. [Code for panel studies]. Available: https://www.uni-
5	636	giessen.de/org/admin/stab/stl/servicestelle/panelcode [Accessed 21 May 2020].
6 7	637	38. UNIPARK & questback. [Developing Online-Surveys easily]. Available:
8	638	https://www.unipark.com/?gclid=EAIaIQobChMIiL3u9o7P6QIViK3tCh2cpgD-
9 10	639	EAAYASAAEgKa9_D_BwE [Accessed 25 May 2020].
11 12 13 14 15	640	39. OCR System GmbH. OCR System. Available: <u>https://www.ocr-systeme.de/en/</u> [Accessed
	641	14 Aug 2020].
	642	40. IBM. SPSS software. Available: https://www.ibm.com/analytics/spss-statistics-software
16	643	[Accessed 21 July 2020].
17 18	644	41. Federal Ministry of Justice and Consumer Protection & Federal Office of Justice.
18 19	645	Ordinance on Occupational Health Care (ArbMedVV) - Available:
20 21	646	https://www.gesetze-im-internet.de/englisch_arbmedvv/index.html [Accessed 19 May
22	647	2020].
23 24	648	42. Federal Ministry of Justice and Consumer Protection & Federal Office of Justice. Act on
25 26	649	Occupational Physicians, Safety Engineers and Other Occupational Safety
20 27	650	Specialists. Available: <u>https://www.gesetze-im-internet.de/asig/</u> [Accessed 19 May
28 29	651	2020].
30	652	43. Blankenfeld H, Grill E, Kaduszkiewicz H, et al. [Antibody Assays Against SARS-CoV-2:
31 32	653	Why a Good Test Does not Always Produce Proper Results]. <i>ZFA</i> 2020; <b>96</b> (5):230-33.
33	654	doi: 10.3238/zfa.2020.0230-0233.
34 35	655	44. Hemmerich WA. [StatistikGuru: Calculating sample size for single factor ANOVA].
36 37	656	Available: https://statistikguru.de/rechner/stichprobengroesse-einfaktorielle-
38	657	anova.html [Accessed 26 May 2020].
39 40	658	45. UNIPARK & questback. [Data protection]. Available:
41	659	https://www.unipark.com/datenschutz/ [Accessed 20 May 2020].
42 43	660	46. Deutsche Forschungsgemeinschaft (DFG). [Guideline for storing research data].
44	661	Available:
45 46 47	662	https://www.dfg.de/download/pdf/foerderung/antragstellung/forschungsdaten/richtlinie
	663	n_forschungsdaten.pdf [Accessed 21 July 2020].
48 49	664	47. World Medical Association. Declaration of Helsinki: Ethical principles for medical
50 51 52 53 54 55	665	research involving human subjects. 2013; <b>310</b> (20):2191-94, doi:
	666	10.1001/jama.2013.281053.
	667	48. Vanderstoep SW, Johnston DD. Research Methods for Everyday Life: Blending
	668	Qualitative and Quantitative Approaches. San Francisco: Jossey-Bass 2009.
56 57	669	
58 59		
60		

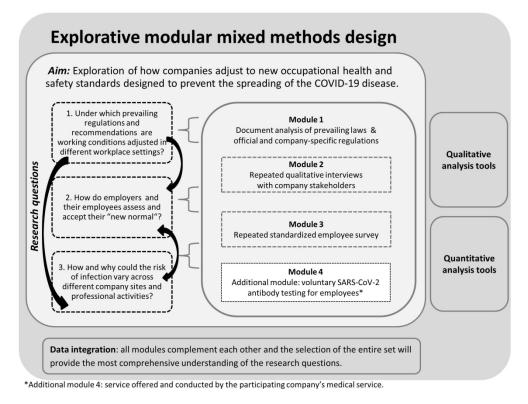


Figure 1 Illustration of the applied explorative modular mixed methods design

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# Supplementary file S1 - Good Reporting of A Mixed Methods Study (GRAMMS) checklist

Guideline

Describe the justification for using a mixed methods approach to the research question Describe the design in terms of the purpose, priority and sequence of methods Describe each method in terms of sampling, data collection and analysis Describe where integration has occurred, how it has occurred and who has participated in it

Describe any limitation of one method associated with the present of the other method

Describe any insights gained from mixing or integrating methods

Section: page

METHODS AND ANALYSIS - study design: pg. 5 – 6 and figure 1 METHODS AND ANALYSIS - study duration: pg. 7, figure 1, table 1 METHODS AND ANALYSIS – study procedures: pg. 8 - 13 METHODS AND ANALYSIS - study design: figure 1 and pg. 6 and discussion, pg. 15; we describe and discuss how we expect data integration to proceed. Describing specific insights is not yet applicable as data collection, analysis and integration has not commenced. Discussion - pg. 15 - 16

METHODS AND ANALYSIS - study design: pg. 5 - 6 and figure 1 where we describe what we expect from applying a mixed method design. Describing specific insights is not yet applicable as data analysis, data collection, analysis and integration has not commenced.