Establishing the impact of COVID-19 on the health outcomes of domiciliary care workers in Wales using routine data: a protocol for the OSCAR study

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Abstract

Introduction

Domiciliary care workers (DCWs) continued providing social care to adults in their own homes throughout the COVID-19 pandemic. Evidence of the impact of COVID-19 on health outcomes of DCWs is currently mixed, probably reflecting methodological limitations of existing studies. The risk of COVID-19 to workers providing care in people's homes remains unknown.

Objectives

To quantify the impact of COVID-19 upon health outcomes of DCWs in Wales, to explore causes of variation, and to extrapolate to the rest of the UK DCW population.

Methods

Mixed methods design comprising cohort study of DCWs and exploratory qualitative interviews. Data for all registered DCWs in Wales is available via the SAIL Databank using a secured, privacy-protecting encrypted anonymisation process. Occupational registration data for DCWs working during the pandemic will be combined with EHR outcome data within the SAIL Databank including clinical codes that identify suspected and confirmed COVID-19 cases. We will report rates of suspected and confirmed COVID-19 infections and key health outcomes including mortality and explore variation (by factors such as age, sex, ethnicity, deprivation quintile, rurality, employer, comorbidities) using regression modelling, adjusting for clustering of outcome within Health Board, region and employer. A maximum variation sample of Welsh DCWs will be approached for qualitative interview using a strategy to include participants that vary across factors such as sex, age, ethnicity and employer. The interviews will inform the quantitative analysis modelling. We will generalise the quantitative findings to other UK nations.

Discussion

Using anonymised lin occupational and EHR data and qualitative interviews, the OSCAR study will quantify the risk of COVID-19 on DCWs' health and explore sources of variation. This will provide a secure base for informing public health policy and occupational guidance.

Keywords

domiciliary care worker; COVID-19; mortality; natural experiment; administrative data

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Introduction

Domiciliary Care Workers (DCWs) form a substantial part of the UK social care workforce and are employed in both the public and private sector to support adults at home [?]. In 2014/15 873,500 people in the UK received home care from 629,400 carers employed through 10,176 organisations [?]. Support provided by domiciliary carers varies but often includes personal care, which demands close contact between a DCW and the person being supported. Whereas support workers may provide assistance for activities such as attending appointments, trips to shops or managing financial affairs, registered DCWs assist with bodily functions, manage continence, assist with oral and dental care, help with getting dressed, and provide other personal care involving intimate personal touching.

In Wales, registration routes for DCWs are open for those: (i) with qualifications in health and social care (mostly Diploma Qualifications and Credit Framework or National Vocational Qualification) who account for 64.1% of those registered in 2020; and (ii) without qualifications but who have sufficient experience as assessed by their manager against required competencies [?]. By June 2020, there were 19,637 registered DCWs in Wales, of whom 84% were female, 48% worked in the private sector and 44% had started in their current role within the last three years [?]. Similarly, in England, most DCWs are female (84%), and most work part-time (54%), about half work on zero hours contracts (48%), are aged on average 44 years old, and staff turnover is high (35%) [?].

The most common causes of injury and ill health within domiciliary care provision identified by the UK Health and Safety Executive are those due to moving and handling, and dealing with challenging behaviour [?]. This is borne out in empirical work which also highlights some of the benefits experienced by carers of this working environment such as ability to work independently and caring for others [?]. Skills for Care reported that the percentage of days lost to sickness in domiciliary care services in England doubled between March and August 2020 compared to the pre-COVID era (6.9% versus 3.4%) but provide no further detail about cause [?].

Since the emergence of COVID-19 as a global health concern, [?] the Office for National Statistics (ONS) data show general population mortality rates in England and Wales involving COVID-19 (between 9th March and 25th May 2020) of 19.1 (males) and 9.7 (females) per 100,000 [?]. However, for 'care workers and home carers' (SOC2010 code 6145) the comparable rates for the same time period are 71.1 (males) and 25.9 (females) per 100,000. These data rely on occupational classification being available but are absent for many individuals reported as dying with some COVID-19 involvement (17.5% and 37.5% missing for males and females respectively) [?]. Furthermore, the published ONS data provide no additional insight into broader health outcomes for DCWs consequent to the COVID-19 pandemic.

In contrast to the ONS data, a prospective survey of COVID-19 infection (i.e. positive polymerase chain reaction (PCR) test result for SARS-CoV-2) among DCWs currently working in England conducted by Public Health England in June 2020 found prevalence rates in line with the general population (0.1%, 95% confidence interval of 0.02%–0.40%) [?]. However, the Public Health England survey was conducted after the peak of the first wave of COVID-19 infection in England using a convenience sample, opportunistic recruitment and included fewer staff self-isolating than might have been expected. Self-selection by provider and by carer (the overall response rate was 52.8% and varied by region) as well as an indication that the sample overrepresented large-scale provider organisations limits the generalisability of the survey's findings. Furthermore, the point prevalence estimate obtained provides no evidence about longer-term COVID-19 exposure.

An on-going COVID-related workforce study led by Ulster University is exploring the wellbeing of health and social care workers across the UK using self-reported standardised measures supplemented with free-text responses [?]. The survey is not specific to DCWs, uses a convenience sampling framework, and does not aim to capture objectively recorded health outcomes. Nevertheless, current early recommendations from the work such as improving support arrangements for staff otherwise reliant on statutory sick pay and the sustainability of adequate access to personal protective equipment (PPE) are factors which are likely to be highly relevant to safer working practice amongst the DCW workforce. Outside of the UK other work assessing the impact of COVID-19 for workers providing care in the home includes a qualitative study from New York City. The study identified the pressures on staff balancing work and personal lives, variations in support and information provided by agencies including personal protective equipment, and feelings of being both at increased risk but also invisible to others [?].

In Wales, governmental concerns about the lack of occupational sick pay in the independent adult social care workforce (over 90%) and an income reduction to statutory sick pay (to £95.85 per week) led to additional financial support for staff with suspected or actual symptoms of COVID-19 or who would otherwise be required to self-isolate [?]. The scheme was introduced specifically to remove disincentives for eligible staff to remain off work because of COVID-19. Guidance to support both care workers and their clients in this sector on a range of topics such as use of personal protective equipment, contact between colleagues, and COVID-19 vaccination has also been provided and updated by the UK government [?].

The potential vulnerability of both domiciliary care recipients and care providers to COVID-19 is illuminated by the ONS data but as noted by other authors has received scant attention, for example, by comparison to the care home (facility-based long-term care services) sector [?]. The currently available evidence means we do not fully understand the impact of COVID-19 on domiciliary care worker mortality, how COVID-19 has affected carer health outcomes more broadly, and the risk factors which contribute to these. This study aims to delineate the impact of COVID-19 on domiciliary care workers through individual level linkage of occupational registration data to secure anonymised electronic health record (EHR) and administrative data for the Welsh population.

Methods

Study aim

To quantify rates of suspected and confirmed COVID-19 infection and key health outcomes as a consequence of COVID-19 for domiciliary care workers in Wales and thereby to inform service planning and public health policy to protect this key workforce.

Specific objectives

- *1:* To undertake qualitative interviews with DCWs to inform the analytic models assessing determinants of COVID-19 infection and key health outcomes.

- *2a:* To quantify rates of suspected and confirmed COVID-19 infection.

- *2b:* To quantify rates of direct and / or indirect effects of the pandemic looking at key health outcomes such as mental health contacts, diagnoses, psychotropic medication and admissions, fit notes, respiratory infections not necessarily recorded as COVID-19, deaths involving COVID-19 / all-causes of death.

- *2c:* To explore outcome variation within the population of DCWs by demographics, work-related factors, lifestyle and comorbidities.

- *2d:* To explore changes over time (pre- and during COVID-19) to identify the potential excess in respiratory infections not necessarily recorded as COVID-19.

- *3:* To examine how generalisable the quantitative findings are to other UK nations.

Study design

The OSCAR study (Outcomes for Social Carers: an Analysis using Routine data) is a population-level mixed methods retrospective routine data linkage study with analysis guided by exploratory qualitative interviews. Initial exploratory interviews will be used to identify potential sources of variation in COVID-19 risk (e.g. working practices, non-occupational exposures) and will be used to inform the quantitative analysis modelling. A purposive sample of Welsh DCWs will be identified and approached for interview. For the interviews we will use a maximum variation sampling strategy to include diverse participants across sex, age, ethnicity, region, and employer classification. Data for all DCWs in Wales registered by 1st April 2020 are held by Social Care Wales (SCW) and available via the Secure Anonymised Information Linkage (SAIL) Databank (Swansea University) using a secured, encrypted and anonymisation process. This data source will be combined with EHR outcome data within the SAIL Databank including clinical codes that identify suspected and confirmed COVID-19 cases and mortality.

Qualitative study (Objective 1)

Eligibility

Participants in the qualitative study will include registered DCWs at the time of COVID-19 in Wales. DCWs who self-report at screening not working for a substantial time (no less than four months) during the pandemic (e.g. due to shielding) or who are either unable or unwilling to provide informed consent will be excluded.

Identification and approach

DCWs will be informed of and invited to participate in the study through formal and informal networks such as care providing organisations. A participant interview invitation letter will give information on the study. DCWs will have as much time as they need to consider the study and decide whether they would like to participate. DCWs who are interested will contact the study team via phone or email. The researcher will ask some basic information to ensure a maximum variation sampling strategy. These screening items will include number of years working as DCW, sex, ethnicity, role, region of work, employer classification and whether they work for a number of social care employers.

The screening questions will confirm, in real time, (i) eligibility and (ii) sample composition. The researcher will maintain an ongoing list of recruited DCWs meeting these sample parameters. This will be reviewed by the researcher prior to each new individual DCW contact to determine how the sample needs to be further developed (e.g. whether more females are required). A balanced matrix in the sample is not required (e.g. an equal number of males / females in each age band for each type of employer). Instead, we are looking to ensure, for example, that we have some variation by sample parameters within the group of DCWs interviewed (i.e. a mixture of males and females, of younger and older participants).

Consent

DCWs will be notified immediately if the interview will proceed and a suitable time agreed. If we have reached the quota for a sampling stratum (e.g. sufficient number of care workers employed privately already accrued) then the care worker can be notified immediately if an interview is not required. A researcher trained in Good Clinical Practice (GCP) will take informed consent remotely (via telephone or online/video recording software) and record this consent discussion before the interview. The researcher will follow a consent script developed in consultation with the regulator, SCW and approved by the ethics committee.

Sample size

The sample for the qualitative study will be approximately $n = 30$. Given the specificity of the research question, the approach to constructing a suitable sample, the depth of the planned interview schedule, and the use to which we aim to apply the results, we consider that the sample size provides sufficient information power [?]. However, through reviewing emerging themes and following any adjustment to

the interview schedule we will monitor sample size adequacy and add further interviews as required.

Interview schedule

A semi-structured interview topic guide will explore:

- description and views of the interviewee's role as a DCW over time (before COVID-19 and changes during COVID-19), e.g. explore challenges, fears, positive aspects;

- DCW's own health experiences and impact on wider life (e.g. family);

- experience of PPE provision and utilisation;

- how social distancing etc. has been reflected in own work practices (e.g. knowledge of policy, practice experience); and

- perceived value of existing formal public health guidance regarding working practices.

Due to the semi-structured nature of the interview, other topics may arise and the wording and order of questions will be flexible to reflect the individual interview.

Qualitative analysis

Interviews will be recorded, transcribed, anonymised and thematically analysed. Qualitative coding software, NVivo, will be used to manage the transcripts. A coding framework will be developed and refined with a second researcher and double coding carried out on a sample (around 10%) of the data and discrepancies discussed. Analysis will explore narratives suggesting factors that may serve to increase or decrease COVID-19 exposure, appraisal of potential COVID-19 symptoms, and presentation for and response to testing. These may include factors that correspond to data available in the quantitative dataset (e.g. ethnicity, co-morbidities) as well as those that are not. Early outputs from the qualitative analysis will inform the quantitative analytic (directed acyclic graph or DAG) model assessing determinants of COVID-19 infection and key health outcomes, for example, by illustrating potential casual relationships, mediators and confounders [?]. It is likely that the qualitative findings will include potential risk factors for which administrative data are not available in our dataset. However, their role as potential sources of unobserved confounding can still be highlighted by depicting them in the DAG model [?].

Quantitative study (Objectives 2 & 3)

Study population

The study population will be all DCWs registered in Wales who did not subsequently opt-out to their data being linked for research when SCW data were added to the SAIL Databank.

Study participants: eligibility criteria

- *Inclusion:* The quantitative study will include all registered DCWs at the time of COVID-19 in Wales who

did not opt-out to the data being linked for research ($n = 17,366$).

- *Exclusion:* Any people or records not containing high quality linkage results or key linkage fields will be removed, and DCWs not resident in Wales by 1st March 2020 will be excluded.

Primary and secondary outcomes and their derivation

The primary outcome is the rate of confirmed COVID-19 in registered DCWs.

Secondary outcomes are:

- Rate of suspected COVID-19, contacts for mental health and diagnoses, psychotropic medication and admissions, fit notes, respiratory infections including influenza-like illness (ILI), pneumonia, exacerbations of severe asthma

- Non-COVID-19 hospital admissions for respiratory conditions including pneumonia and exacerbations of severe asthma

- Deaths involving COVID-19 and all-cause mortality.

Coding for the primary outcome: Clinical coding that identifies confirmed (and also for secondary outcomes, suspected) COVID-19 cases [?] will be derived from all-Wales data sources currently received by SAIL:

- *COVID-19 test results (PATD)*: daily individual results from PCR tests (negative (suspected) / positive (confirmed)) for COVID-19 and serology tests / antigen tests (i.e. as becomes available);

- *Welsh Longitudinal GP (WLGP)*: COVID-19 specific Read codes (1JX-suspected, 65PW–Coronavirus contact, A795-Coronavirus infection);

- *Patient Episode Database for Wales (PEDW)*: diagnoses for confirmed and suspected COVID-19 cases (ICD10 codes U07.1, U07.2, B972, U049, Z038, Z115);

- *NHS 111 call (NHSO)*: NHS 111 call data on self-reported symptoms related to COVID-19.

Coding for chronic conditions: Diagnostic and medication codes for chronic conditions (including respiratory conditions) will primarily be identified through previous work in this area [?]. These codes will come from the Welsh Longitudinal GP and PEDW data.

Coding for mental health conditions: Diagnostic and medication codes for mental health conditions will primarily be identified through previous work in this area [?]. These codes will come from the Welsh Longitudinal GP data.

Data sources

Social care wales workforce data

Under the Care Standards Act 2000, SCW maintains a register of DCWs in Wales [?]. Coverage as of March

2020 (pre-pandemic) included more than 17,000 DCWs and will be the study population when describing outcomes. The data contains information on DCWs such as qualification, qualification route, employer, length of employment, county of work, date of registration, ethnicity. Data for all registered DCWs in Wales is available from the SAIL Databank and made accessible as a core-restricted data source [? ? ?]. Equivalent aggregate data are available in Scotland, [?] Northern Ireland [?] and England [?] at a national level (i.e. not available for linkage at person level).

SAIL databank

The SAIL Databank is a privacy protecting Trusted Research Environment and the national data safe haven for Wales holding de-identified data sources made available to researchers in an anonymised format. Data are principally for individuals living in Wales and using Welsh services (e.g. health and other public services). Data sources include health, education, housing, and employment. The data sources requested for the OSCAR study (Figure ??) are:

- *Annual District Death Extract:* All deaths registered relating to Welsh residents. These data are collected from death registrations [?];

- *COVID-19 shielded people list:* A list of people at "high risk" of complications from COVID-19, who should be shielded for at least 12 weeks at the start of the pandemic in March 2020 [?];

- *COVID-19 test results (PATD):* daily individual results from PCR tests (negative (suspected) / positive (confirmed)) for COVID-19 and serology tests / antigen vaccines (i.e. as becomes available) [?];

- *COVID-19 Test Trace and Protect:* A list of people who have been identified to Public Health Wales as having COVID-19, and any people they may have interacted with during a time frame where infection transfer may have occurred, known as test, trace and protect system;

- *Emergency Department Dataset:* Data captured for all NHS Wales Accident and Emergency department attendances. Data are collected and coded at each hospital [?];

- *NHS 111 call (NHSO):* Any calls made to NHS 111 services, which brings together NHS Direct Wales and GP out-of-hours services calls;

- *Outpatient Database for Wales (OPDW):* Attendance for all NHS Wales hospital outpatient appointments, including those who did not attend. Data are collected and coded at each hospital [?];

- *Patient Episode Database for Wales (PEDW):* NHS Wales hospital admissions data includes attendance and clinical information (diagnosis, operations performed). Data are collected and coded at each hospital via the central Patient Administrative System (PAS) using medical coding terminology (ICD10 and OPCS) [?];

- *Welsh Demographic Service Dataset (WDSD):* Information about individuals registered with a general practice in Wales or who use NHS services. This dataset provides linkage on the individual level via the anonymised linking field (ALF) and at the residential level via the Residential-ALF [?];

- *Welsh Longitudinal GP (WLGP):* Data captured by each GP practice for their patients in their electronic health record includes signs, symptoms, test results, diagnoses, prescribed treatments and referrals. Data are recorded using Read Code terminology [?].

Office for National Statistics

Data collected as part of the 2011 census made available as a linked data source. Data sought will be country of birth and ethnicity as these are invariant over time, unlike other variables also available via ONS such as household size or highest level of qualification. Data are made available via the SAIL Databank following ONS Research Accreditation Panel approval.

Exposure and follow-up period

The COVID-19 exposure period will start at 1st March 2020. Short-term outcomes will be examined to 28th February 2021 allowing us to look at the first waves of the COVID-19 pandemic. Wave 1 is taken from 1st March 2020 to 31st August 2020 (reflecting a period before relaxing of lockdown in Wales) and Wave 2 from 1st September 2020 to 28th February 2021. A subsequent time point reflecting longer-term outcomes, from 1st March 2021, will also be examined, for example, a date at which a further policy threshold / phase is reached.
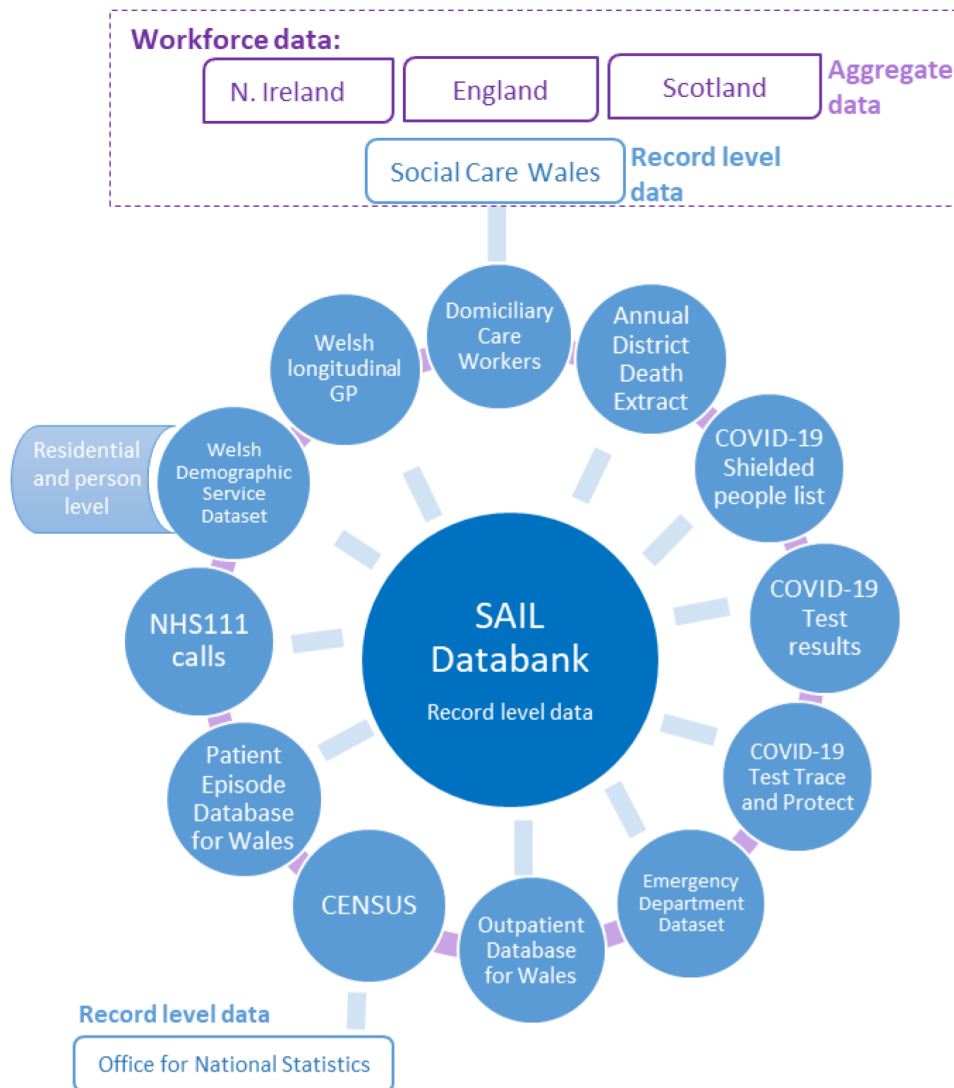
Analysis

Power calculation

There are 17,366 registered DCWs in the dataset available for linkage. The estimated incidence of confirmed COVID-19 in the general population as of 16th May 2020 was 382 per 100,000 population per week [?] and we expect the incidence to be greater in DCWs. With this large study population we are able to reliably estimate the rate of COVID-19 within a confidence interval of $\pm$ 92.7 (i.e. based on 382 cases per 100,000 population per week, 95% CI = 289.3 to 474.7).

Data management

Data sources within SAIL will be provided by the SAIL Databank team following the approval of our request made to the independent Information Governance Review Panel. SAIL data are housed in a privacy protecting Trusted Research Environment, protected by a suite of physical, technical and procedural control measures, which taken together comprise a privacy-by-design, proportionate governance model. SAIL is ISO 27001 accredited (IS632731), holds NHS Digital Data Security and Protection Toolkit (Organisation code 8WG95) and is accredited by the UK Statistics Authority. Requested data can be viewed using the SAIL Gateway, a privacy-protecting safe haven and remote access system [?]. A detailed analysis plan will be published before analysis commences.

Figure 1: Datasets for the OSCAR study

Quantitative analysis

Objective 2a-c

We will describe the study population of DCWs in Wales by age, sex, ethnicity, role, deprivation quintile, health board, rurality, employer classification, comorbidities [?] and lifestyle factors (e.g. smoking, as available in primary care datasets). We will identify DCWs not working at time of COVID due to shielding for the purpose of sensitivity analyses. We will report the rate of suspected and confirmed COVID-19 infections and key health outcomes and explore variation by the above factors using regression modelling, adjusting for clustering of outcome within Health Board, region and employer classification. A directed acyclic graph (DAG) will be constructed to identify the relationships between and among the variables in causal pathways.

Objective 2d

Changes over time in the DCW population will be examined for potential excess respiratory infections (ILI, pneumonia, exacerbations of severe asthma, all cause hospital admissions)

not necessarily recorded as COVID-19. We will describe and compare the trend in outcomes pre- to post-COVID-19 onset using interrupted time series. Increased morbidity may provide a proxy indication of COVID-19 infection, for example, where it was not formally tested for or recorded.

Objective 3

Using up-to-date aggregate DCW workforce data from Scotland, Northern Ireland and England we will compare these populations to the Welsh DCW workforce and assess generalisability of quantitative findings to each other nation using propensity score methods [? ? ?]. If key workforce characteristic are not represented in comparison, the Welsh DCW workforce data will be weighted to the different nation's aggregated populations using weighting and the prevalence of COVID-19 estimated.

Withdrawal

Prior to data being transferred to SAIL from Social Care Wales, all DCWs will have had the opportunity to opt-out of

their data going into the SAIL Databank for use in research. This generic process was not particular to the OSCAR study.

Triangulation

Following the initial contribution of the qualitative analysis to the DAG model, a subsequent point of triangulation will involve a qualitative and quantitative researcher independently confirming key findings from their respective finalised analyses [?]. They will then meet to explore the impact of COVID-19 on health outcomes and reasons for variation. This is likely to involve both visual and narrative summaries of data (e.g. map of statistical associations, narrative thematic map). This may provide greater understanding for observed statistical associations and indicate caution based on known unobserved quantitative variables.

Study timelines

The study commenced on 28th October 2020 and will run for 18-months.

Oversight

A study advisory group will provide scientific and policy oversight, progress monitoring and help interpret emergent findings. The group will comprise academics, representatives from regulatory bodies and skills sector councils, a provider body in Wales, and a care worker. Meetings are expected to be held at four points in the study. Cardiff University will act as Sponsor for the study [SPON1836-20].

Public involvement

The study advisory group will include one DCW. In addition to support provided to all study advisory group members by the research team, the advisory group's DCW representative will be offered the opportunity to sign up to the Involving People Community (Wales), through which additional training and support is available.

Governance and compliance

The study received approval from the School of Medicine Research Ethics Committee, Cardiff University [SMREC 20/106, 20/114]. Approval was obtained from the SAIL Information Governance Review Panel, Swansea University (Project ID: 1126) and data access will be granted to named staff. Approval from the ONS Research Accreditation Panel has been provided (16/12/2020). Approval from Social Care Wales has been provided (26/01/2021).

Reporting

Study findings will be reported in accordance with applicable reporting guidelines for observational studies using administrative data (STROBE [?] and RECORD [?]) and qualitative studies (i.e. COREQ [?]).

Discussion

Early in the pandemic, the emergence of COVID-19 was identified as a new occupational disease, particularly for health care workers, as was the need to address the consequent mental health needs of front-line staff [? ?]. Subsequent analyses focusing upon workers in social care present a mixed picture of the impact upon domiciliary care workers in the UK, probably due to differences in methodological approach. Prior to the COVID-19 pandemic, employment conditions such as zero-hours working and delivery context have received some attention in terms of domiciliary carer mental well-being [? ?]. Despite empirical occupational health research linking generic working demands (e.g. workload, temporary working) to adverse outcomes such as burnout, relatively little is known about the objective health of the UK's domiciliary care workforce, either pre- or during the COVID-19 pandemic. Our study aims to address this deficit. As DCWs work with vulnerable clients, better protection for care workers is also likely to reduce risks to this sizeable community-based population.

In Wales and other devolved nations, all DCWs working with adults have to register with a regulatory body. The potential to link such registration data to EHR outcome data held in the SAIL Databank provides a unique opportunity to explore a range of health outcomes (including COVID-19 infection and mortality) for DCWs working in Wales during the COVID-19 pandemic. Whilst the existing ONS analysis provided insights into differential impact of COVID-19 by occupational group, Wales is the only UK nation where contemporary DCW registration data are available for data linkage [?]. The limitations of the lack of contemporary and specific data are illustrated by a recent study using UK Biobank data to assess occupation and risk of severe COVID-19 [?]. Occupation data at study enrolment (2006–2010) and at a subsequent point of data collection (2014–2019) were compared and for 'social care workers' (a broad categorisation which included several occupational groups including care assistants and home carers as well as others such as social workers and clergy) the rate of agreement was found to be 57.24% (this compared to 88.4% for healthcare professional). The study found a relative risk for severe COVID-19 of 2.13 (95% CI: 1.25, 3.63) for social care workers when controlling for all available covariates. Therefore, our study will include all DCWs in Wales working during the pandemic, something not possible via the ONS analysis. It will more fully establish the range of adverse health outcomes affecting DCWs and how socio-demographics, employment, and co-morbidities may vary risk. No DCWs were recorded as dissenting for their registration data to be made available for linkage. However, the number of records available for analysis is slightly lower than initially reported to the research team (by approximately 300 records). The reasons for these and any other records not being included in final analyses will be explored and reported in study outputs.

Despite the comprehensive study population likely to be available in the OSCAR study, the recording of some data could introduce bias. One example is coding for COVID-19 biased towards individuals presenting in primary or secondary healthcare and the potential changing of coding due to service changes and consultation reductions in primary healthcare. We

can address this by examining historical data and incorporating self-reported data from NHS 111 calls to obtain a clearer picture of the symptomatic population. Another potential bias may be caused by missing information, especially relevant for ethnicity. This will be imputed using a method developed by SAIL for the Technical Advisory Group to create a universal ethnicity code. This will be especially important considering the evidence regarding COVID-19 risk differences by ethnicity [?]. Multiple imputation will be performed to assess the impact of missing outcome data and further detail will be provided in the finalised statistical analysis plan. The potential to acquire further data from other sources currently housed by SAIL (e.g. Welsh Dispensing Data Set: data captured at each pharmacy around Wales for all dispensed drug prescriptions, including dosage and quantity; ZOE app: self–reported symptoms, including demographics, health screening questions, COVID-19 testing, symptoms and treatment received [? ?] as well as COVID-19 vaccinations) will add value to the OSCAR study cohort.

To date, the policy response to COVID-19 has included specific occupational guidance to domiciliary care workers in each devolved nation for the use of PPE. The value of the OSCAR study will only be realised if its findings are effectively and promptly used to inform public health and occupational recommendations. Therefore, to support nation-specific approaches to communicating and learning from the research we will create an Implementation Reference Group with bi-directional links to UK practice and policy. The group's membership will comprise people with lived experience of care and support at home, care workers, personal assistants, representation from regulators/sector skills councils, home care providers and home care provider groups. The group will meet in preparation of disseminating results at 12-month and 18-month milestones. It is expected that the group will provide rapid recommendations to drive public health initiatives for DCW safety, including modified working practices and longer-term service planning to support DCW health needs.

Conclusion

The study will inform the development of policy and practice guidance to deal with subsequent waves of COVID-19. Our links with Social Care Wales and, through them, to the regulators and skills sector councils across all four nations of the UK, will allow our findings to be rapidly transferred into policy and practice.

Acknowledgements

Ethics approval and consent to participate

The study protocol has approval from a Research Ethics Committee (REC) that is legally recognised by the United Kingdom Ethics Committee Authority for review and approval [SMREC 20/106 and SMREC 20/114].

Competing interests

The authors declare that they have no competing interests.

Funding statement

Authors' contributions

MR and RCJ are co-chief investigators of the study. FLW is responsible for study management. RCJ, AA and HJ are responsible for statistical planning, data management and data analysis. LBH and HP are responsible for qualitative planning, data collection and analysis. All authors have contributed to and are responsible for the final design of the study.

References

1. Ravalier JM, Fidalgo AR, Morton R, Russell L. The influence of zero-hours contracts on care worker well-being. Occupational Medicine. 2017;67(5):344-9. https://doi.org/10.1093/occmed/kqx043

2. Holmes J. United Kingdom Home Care Association summary. An overview of the domiciliary care market in the United Kingdom. 2016. Accessed 2020 Dec 22. https://www.ukhca.co.uk/pdfs/DomiciliaryCareMarketOverview2015.pdf

3. Social Care Wales. Domiciliary Care Workers on the Register. 2020. Accessed 2020 Dec 22. https://socialcare.wales/cms_assets/file-uploads/Domiciliary-Care-Workers-on-the-Register.pdf

4. Health and Safety Executive. Domiciliary care provided in people's own homes. Accessed 2020 Dec 22. https://www.hse.gov.uk/healthservices/domiciliary-care.htm

5. Quinn MM, Markkanen PK, Galligan CJ, Sama SR, Kriebel D, Gore RJ, et al. Occupational health of home care aides: Results of the safe home care survey. Occup Environ Med. 2016;73(4):237–45. https://doi.org/10.1136/oemed-2015-103031

6. Skills for Care. The state of the adult social care sector and workforce in England. Accessed 2020 Dec 22. https://www.skillsforcare.org.uk/adult-social-care-workforce-data/Workforce-intelligence/publications/national-information/The-state-of-the-adult-social-care-sector-and-workforce-in-England.aspx

7. Wang C, Horby PW, Hayden FG, Gao GF. A novel coronavirus outbreak of global health

concern. The Lancet. 2020; 395(10223):470–3. https://doi.org/10.1016/S0140-6736

8. Office for National Statistics. Coronavirus (COVID-19) related deaths by occupation, England and Wales. Release date: 26th June 2020. 2020. Accessed 2020 Dec 22. https://www.ons.gov.uk/peoplepopulationandcommunity/healthandsocialcare/causesofdeath/datasets/coronaviruscovid19relateddeathsbyoccupationenglandandwales

9. Public Health England. Pilot point prevalence survey of COVID-19 among domiciliary care staff in England. London; 2020. Accessed 2020 Dec 22. https://www.gov.uk/government/publications/covid-19-prevalence-survey-domiciliary-care-staff-in-england

10. McFadden P, Gillen P, Moriarty J, Mallett J, Schroder H, Ravalier J, et al. COVID-19 Health and Social Care Workforce Study May-July 2020. 2020. Accessed 2020 Dec 22. https://niscc.info/app/uploads/2020/11/Workforce-Survey-Exec-Sum-May_with-cover-7.pdf

11. Sterling MR, Tseng E, Poon A, Cho J, Avgar AC, Kern LM et al. Experiences of home health care workers in New York City during the coronavirus disease 2019 pandemic: a qualitative analysis. JAMA Internal Medicine. 2020:180(11):1453-1459. https://doi.org/10.1001/jamainternmed.2020.3930

12. Welsh Government. Statutory sick pay enhancement scheme: integrated impact assessment. Accessed 2021 May 21. https://gov.wales/statutory-sick-pay-enhancement-scheme-integrated-impact-assessment-html

13. Department of Health and Social Care. Guidance: Coronavirus (COVID-19): provision of home care. Updated 11th May 2021. Accessed 2021 May 13. https://www.gov.uk/government/publications/coronavirus-covid-19-providing-home-care/coronavirus-covid-19-provision-of-home-care

14. Glynn JR, Fielding K, Shakespeare T, Campbell O. Covid-19: excess all cause mortality in domiciliary care. BMJ. 2020. 370:m2751. https://doi.org/10.1136/bmj.m275

15. Malterud K, Siersma V, Guassora A. Sample Size in Qualitative Interview Studies: Guided by Information Power. Qual Health Res. 2016;26(13):1753–60.

16. Williams TC, Bach CC, Matthiesen NB, Henriksen TB, Gagliardi L. Directed acyclic graphs: a tool for causal studies in paediatrics. Vol. 84, Pediatric Research. Nature Publishing Group; 2018. p. 487–93. https://doi.org/10.1038/s41390-018-0071-3

17. Tennant PW, Harrison WJ, Murray EJ, Arnold KF, Berrie L, Fox MP et al. Use of directed acyclic graphs (DAGs) to identify confounders in applied health research: review and recommendations. International Journal of Epidemiology, 2020, 1–13. https://doi.org/10.1093/ije/dyaa213

18. De Lusignan S, Williams J. To monitor the COVID-19 pandemic we need better quality primary care data. 2020; https://doi.org/10.3399/bjgpopen20X101070

19. Clift A K, Coupland C A C, Keogh R H, Diaz-Ordaz K, Williamson E, Harrison E M et al. Living risk prediction algorithm (QCOVID) for risk of hospital admission and mortality from coronavirus 19 in adults: national derivation and validation cohort study BMJ 2020; 371 :m3731. https://doi.org/10.1136/bmj.m3731

20. John A, McGregor J, Fone D, Dunstan F, Cornish R, Lyons RA, et al. Case-finding for common mental disorders of anxiety and depression in primary care: An external validation of routinely collected data. BMC Med Inform Decis Mak. 2016;16(1):1–10. https://doi.org/10.1186/s12911-016-0274-7

21. Social Care Wales. The Domiciliary Care Worker: Practice guidance for domiciliary care workers registered with Social Care Wales. 2018. Accessed 2021 Feb 1. https://socialcare.wales/cms_assets/file-uploads/Practice-Guidance-Version-1.pdf

22. Lyons RA, Jones KH, John G, Brooks CJ, Verplancke J-P, Ford D V, et al. The SAIL databank: linking multiple health and social care datasets. BMC Med Inform Decis Mak. 2009;9(1):1-8. https://doi.org/10.1186/1472-6947-9-3

23. Jones KH, Ford D V., Jones C, Dsilva R, Thompson S, Brooks CJ, et al. A case study of the Secure Anonymous Information Linkage (SAIL) Gateway: A privacy-protecting remote access system for health-related research and evaluation. J Biomed Inform. 2014;50:196–204. https://doi.org/10.1016/j.jbi.2014.01.003

24. Ford D V, Jones KH, Verplancke J-P, Lyons RA, John G, Brown G, et al. The SAIL Databank: building a national architecture for e-health research and evaluation. BMC Health Services Research. 2009;9:157. https://doi.org/10.1186/1472-6963-9-157

25. Scottish Social Services Council. Scottish Social Service Sector: Report on 2018 Workforce Data. An Official Statistics Publication for Scotland. 2019. Accessed 2020 Dec 2. https://data.sssc.uk.com/images/WDR/WDR2018.pdf

26. Northern Ireland Social Care Council. About us. Accessed 2020 Dec 2. https://niscc.info/about

27. SAIL Databank. Annual District Death Extract. Accessed 2020 Dec 2. https://data.ukserp.ac.uk/Asset/View/3

28. SAIL Databank. COVID-19 shielded people list. Accessed 2020 Dec 2. https://data.ukserp.ac.uk/Asset/View/41

29. SAIL Databank. COVID-19 Pathology Test Results. Accessed 2020 Dec 2. https://data.ukserp.ac.uk/Asset/View/53

30. SAIL Databank. Emergency Department Dataset. Accessed 2020 Dec 2. https://data.ukserp.ac.uk/Asset/View/13

31. SAIL Databank. Outpatient Database for Wales. Accessed 2020 Dec 2. https://data.ukserp.ac.uk/Asset/View/14

32. SAIL Databank. Patient Episode Database for Wales. Accessed 2020 Dec 2. https://data.ukserp.ac.uk/Asset/View/15

33. SAIL Databank. Welsh Demographic Service Dataset. Accessed 2020 Dec 2. https://data.ukserp.ac.uk/Asset/View/20

34. SAIL Databank. Primary Care GP Dataset. Accessed 2020 Dec 2. https://data.ukserp.ac.uk/Asset/View/17

35. Public Health Wales. PHW dashboard. Accessed 2021 Feb 1. https://public.tableau.com/profile/public.health.wales.health.protection#!/vizhome/RapidCOVI%0AD-19virology-Public/Headlinesummary

36. Jones KH, Ford DV, Thompson S, Lyons R. A Profile of the SAIL Databank on the UK Secure Research Platform. Int J Popul Data Sci. 2019;4(2). https://doi.org/10.23889/ijpds.v4i2.1134

37. Northern Ireland Social Care Council. Northern Ireland Social Care Council. Accessed 2020 Jun 30. https://niscc.info/about

38. Noble H, Heale R. Triangulation in research, with examples. Evid Based Nurs. 2019;22(3):67–8.

39. von Elm E, Altman DG, Egger M, Pocock SJ, Gøtzsche PC, Vandenbroucke JP, et al. Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement: guidelines for reporting observational studies. BMJ. 2007 Oct;335(7624):806–8.

40. Benchimol EI, Smeeth L, Guttmann A, Harron K, Moher D, Petersen I, et al. The REporting of studies Conducted using Observational Routinely-collected health Data (RECORD) Statement. PLoS Med. 2015;12(10):e1001885. http://journals.plos.org/plosmedicine/article/file?id=10.1371/journal.pmed.1001885&type=printable

41. Tong A et al. Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups. International Journal for Quality in Health Care, Volume 19, Issue 6, December 2007, Pages 349–357, https://doi.org/10.1093/intqhc/mzm042

42. Koh D. Occupational risks for COVID-19 infection. Occup Med. 2020;70(1):3–5. https://academic.oup.com/occmed/article/70/1/3/5763894

43. Xiang YT, Yang Y, Li W, Zhang L, Zhang Q, Cheung T, et al. Timely mental health care for the 2019 novel coronavirus outbreak is urgently needed. Vol. 7, The Lancet Psychiatry. 2020;7(3):228–9. https://doi.org/10.1016/S2215-0366(20)30046-8

44. Ravalier J, Morton R, Russell L, Rei Fidalgo A. Zero-hour contracts and stress in UK domiciliary care workers. Health Soc Care Community. 2019;27(2):348–55. https://doi.org/10.1111/hsc.12652

45. Mutambudzi M, Niedwiedz C, MacDonald EB, Leyland A, Mair F, Anderson J, et al. Occupation and risk of severe COVID-19: Prospective cohort study of 120 075 UK Biobank participants. Occup Environ Med. 2020; https://doi.org/10.1136/oemed-2020-106731

46. Niedzwiedz CL, O CA, Dinesh Jani B, Demou E, Ho FK, Celis-Morales C, et al. Ethnic and socioeconomic differences in SARS-CoV-2 infection: prospective cohort study using UK Biobank. BMC Med. 2020;18(160). https://doi.org/10.1186/s12916-020-01640-8

47. ZOE App. COVID Symptom Tracker. Accessed 2020 Dec 2 https://covid.joinzoe.com/data

48. Health Data Research Innovation Gateway. COVID-19 Symptom Tracker Dataset. Accessed 2020 Dec 2 https://web.www.healthdatagateway.org/dataset/cb29d860-da77-45a0-80e4-913d445f5a50

Abbreviations

ALF:	Anonymised linking field
DAG:	Directed acyclic graph
DCW:	Domiciliary Care Workers
EHR:	electronic health record
Fit note:	Notes issued by doctors to provide evidence of the advice given about a person's fitness for work. They help patients and their employer consider ways to return to work.
GCP:	Good Clinical Practice
ILI:	influenza-like illness
NHSO:	NHS 111 call
ONS:	the Office for National Statistics
OPDW:	Outpatient Database for Wales
OSCAR study:	Outcomes for Social Carers: an Analysis using Routine data
PATD:	COVID-19 test results
PCR:	polymerase chain reaction
PEDW:	Patient Episode Database for Wales
PPE:	personal protective equipment
SAIL:	Secure Anonymised Information Linkage
SCW:	Social Care Wales
WDSD:	Welsh Demographic Service Dataset
WLGP:	Welsh Longitudinal GP