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Original Research

Did the UK's public health shielding policy protect the clinically extremely vulnerable during the COVID-19 pandemic in Wales? Results of EVITE Immunity, a linked data retrospective study



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ABSTRACT

Introduction: The UK shielding policy intended to protect people at the highest risk of harm from COVID-19 infection. We aimed to describe intervention effects in Wales at 1 year.

Methods: Retrospective comparison of linked demographic and clinical data for cohorts comprising people identified for shielding from 23 March to 21 May 2020; and the rest of the population. Health records were extracted with event dates between 23 March 2020 and 22 March 2021 for the comparator cohort and from the date of inclusion until 1 year later for the shielded cohort.

Results: The shielded cohort included 117,415 people, with 3,086,385 in the comparator cohort. The largest clinical categories in the shielded cohort were severe respiratory condition (35.5%), immunosuppressive therapy (25.9%) and cancer (18.6%). People in the shielded cohort were more likely to be female, aged ≥ 50 years, living in relatively deprived areas, care home residents and frail. The proportion of people tested for COVID-19 was higher in the shielded cohort (odds ratio [OR] 1.616; 95% confidence interval [CI] 1.597–1.637), with lower positivity rate incident rate ratios 0.716 (95% CI 0.697–0.736). The known infection rate was higher in the shielded cohort (5.9% vs 5.7%). People in the shielded cohort were more likely to die (OR 3.683; 95% CI: 3.583–3.786), have a critical care admission (OR 3.339; 95% CI: 3.111–3.583), hospital emergency admission (OR 2.883; 95% CI: 2.837–2.930), emergency department attendance (OR 1.893; 95% CI: 1.867–1.919) and common mental disorder (OR 1.762; 95% CI: 1.735–1.789).

Conclusion: Deaths and healthcare utilisation were higher amongst shielded people than the general population, as would be expected in the sicker population. Differences in testing rates, deprivation and pre-existing health are potential confounders; however, lack of clear impact on infection rates raises questions about the success of shielding and indicates that further research is required to fully evaluate this national policy intervention.

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Summary

What is already known on this topic

Some people, particularly those with pre-existing conditions, are more vulnerable to serious harms resulting from COVID-19 infection than others.

What this study adds.

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The three largest clinical categories in the shielded cohort were people with a severe respiratory condition (35.5%), people on immunosuppressive therapy (25.9%), and people with cancer (18.6%).

People in the shielded cohort were more likely to be female, aged >50 years, living in more deprived areas, resident in care homes and frail.

Deaths and healthcare resource utilisation were higher in the shielded population than in those not included in this policy initiative but impact on infection rates was not clear.

How this study might affect research, practice or policy.

These findings indicate that caution should be exercised before applying this policy in a future pandemic until further evidence is available about costs, benefits and harms of shielding.

Background

During the COVID-19 pandemic, it became apparent at an early stage that the virus was seriously affecting some parts of the general population. However, there was a lack of definitive evidence about who was at greatest risk. Evidence emerged during the early months of 2020 that older age was strongly associated with risk of death,¹ whereas analyses from China² and the United Kingdom³ identified a higher risk of death among patients with pre-existing conditions, such as cardiovascular disease, respiratory disease, immunodeficiency and cancer. A cohort study of over 17 million primary care records in England⁴ confirmed the association between diagnoses, such as diabetes and asthma, and the risk of death from COVID-19 and also highlighted the risks associated with deprivation, old age and being male and Black or South Asian.

International responses to the COVID-19 pandemic included national lockdowns that restricted population movement to slow disease transmission.⁵ Non-pharmaceutical interventions included physical distancing, handwashing and stay at home advice.⁶ The World Health Organisation recognised that some people are at higher risk than others from COVID-19 and advocated care plans be inclusive of monitoring and support if some groups, such as older people, were urged to stay at home for an extended period of self-isolation.⁷

In response to increasing transmission and deaths from COVID-19, uniquely, the UK government introduced a new intervention called 'shielding'. Although there were minor variations in implementation, this policy intervention in Wales was similar to the rest of the United Kingdom. Individuals identified as being at the highest risk of serious illness or death following COVID-19 infection were sent personal communications by letter, text or email strongly advising them to stay at home and to self-isolate, including from anyone – even family members – sharing the same premises for at least 12 weeks. Governments across the United Kingdom developed methods, including predictive algorithms⁸ and clinical screening, to identify people thought to be most vulnerable to COVID-19-related hospital and intensive care unit (ICU) admissions or death for shielding. People with diagnoses, including cancer, transplants, immunodeficiency, serious heart conditions, respiratory problems, and under certain treatments, such as immunosuppressant medications, were identified for shielding from routine national and local NHS data sources.^{9–12} People resident in care homes were excluded from shielding.^{11,13} In England, this shielded population was estimated at 1.5 million, and in Wales 130,000.¹⁴

The shielding policy intended to protect those at the highest risk of serious harm, including death from COVID-19,¹⁵ with the mechanism for protection being avoidance of infection. The shielding policy was a new public health intervention, introduced

in the 2020 pandemic without prior evidence of effects on health outcomes, costs or behaviour.

Aim

This study aimed to describe the shielded cohort and compare routine health outcomes between this high-risk population and the rest of the unshielded general population in Wales at 1 year after the introduction of the shielding intervention.

Objectives

The objectives were to describe the shielded population in terms of demographic and clinical characteristics and to compare with the non-shielded population.

- Demographic characteristics
- COVID-19 test, infection and mortality
- All-cause mortality, ICU and hospital admissions and emergency department (ED) attendances.
- Mental health outcomes

Methods

In this article, we follow the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement guidelines.¹⁶

Study design

We undertook a retrospective comparative analysis of demographic and clinical characteristics, COVID-19 tests and results, deaths and healthcare resource utilisation between people identified for inclusion in the shielding policy and everyone else in Wales.

Data were accessed and analysed via the Secure Anonymised Information Linkage (SAIL) Databank (www.saildatabank.com), a remotely accessible, privacy-protecting Trusted Research Environment, accredited under the Digital Economy Act.^{17,18}

Data sources

The C20 Cohort was created in response to the outbreak of COVID-19 to provide a population-level electronic data resource to facilitate research assessing the impact of the COVID-19 pandemic in Wales.¹⁹ The C20 Cohort comprises more than 3.2 million people who were alive and living in Wales on 1 January 2020 or who moved into or were born in Wales after that date.

People identified for shielding are tagged within the C20 Cohort with a date of inclusion. Health outcomes were derived from routinely collected electronic health record data sources held within SAIL, including the Annual District Death Daily; Annual District Death Extract; the Consolidated Death Data Source; the COVID-19 Pathology Data; the Patient Episode Database for Wales; the Critical Care Data Set; and the Welsh Longitudinal General Practice data sources.

Participants

C20 Cohort members alive and living in Wales on 23 March 2020 were included, with those identified for shielding between 23 March 2020 and 21 May 2020 allocated to the shielded cohort and others allocated to the non-shielded comparator cohort (Fig. 1). Age (in years) was calculated as at 23 March 2020 and grouped in 5-year age bands up to 85 years, with all older ages grouped together. Anonymised address fields where individuals were registered as living at

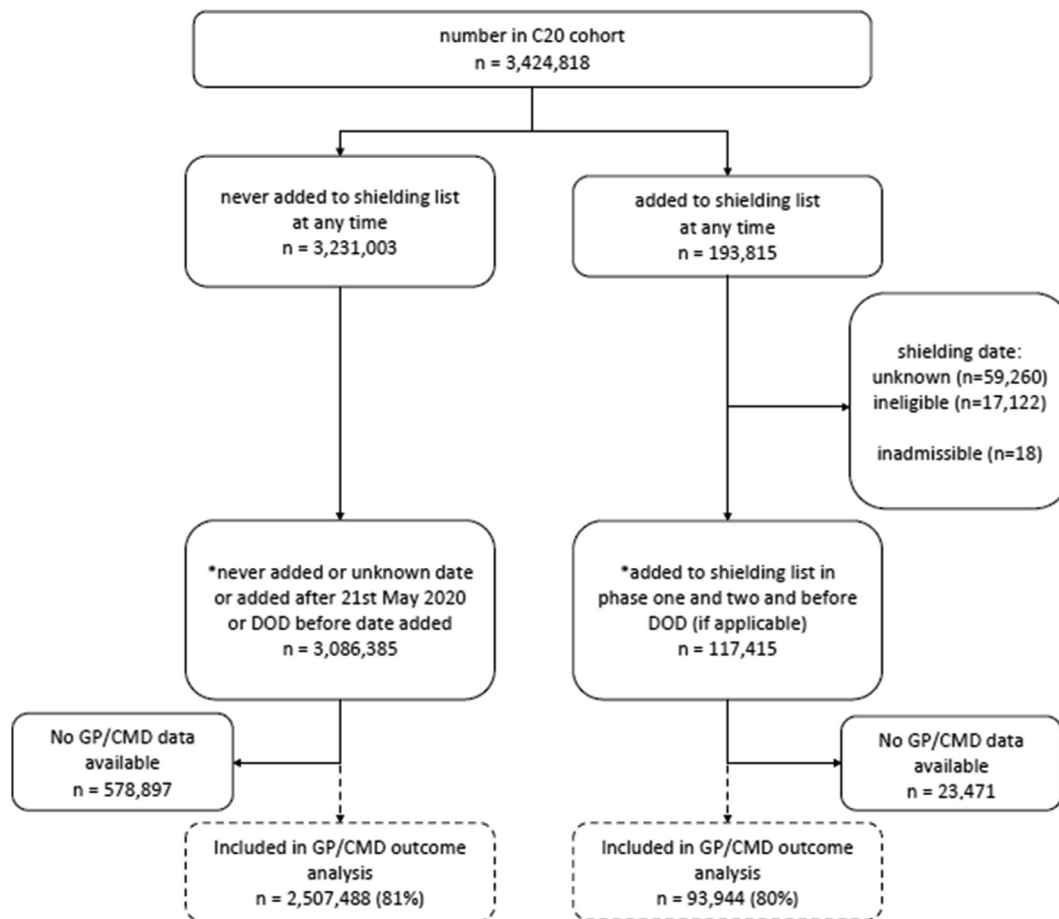


Fig. 1. Cohort recruitment flowchart.

the time of cohort entry were used to identify those living in Care Homes by linking to a list of residential care homes within Wales, as well as the corresponding statistical geography codes, which were used to categorise deprivation based on the 2019 Welsh Index of Multiple Deprivation. Frailty Categories were based on an Electronic Frailty Index score,^{20,21} calculated as at 23 March 2020.

Outcomes

We used routine health data to assess the following outcomes.

1. COVID-19 infection tests
2. Positive COVID-19 infection tests
3. Deaths from COVID-19 and all-cause

4. ED attendances
5. Emergency hospital admissions and days in hospital
6. ICU admissions and days in ICU
7. Indicators of common mental disorder (CMD)

Table 1
Shielded cohort clinical categories.

CEV category	n = 117,415	%
Severe respiratory conditions	41,711	35.5
Immunosuppression therapy	30,464	25.9
Cancer	21,895	18.6
Rare diseases	13,207	11.2
Severe organ disease	6529	5.6
Organ transplant recipients	2014	1.7
Other	822	0.7
Renal dialysis	635	0.5
Pregnancy with congenital heart disease	138	0.1

CEV, clinically extremely vulnerable.

Health records were extracted with event dates between 23 March 2020 and 22 March 2021 for the non-shielded (comparator) cohort and from the date of inclusion until 1 year later for the shielding cohort, except for data relating to mental health outcomes. CMD General practitioner (GP) events (diagnoses, symptoms and treatments for CMD) were assessed monthly during the study period, using an established method,²² based on a search of primary care records in 13-month windows centred on each month. Given the almost complete coverage of the population of Wales, we have identified no significant source of bias in participants included in the analysis or in the completeness of information available on these participants.

Analysis

Profiles for both the shielded and non-shielded cohorts describe the number and percentage of people by age, sex, deprivation category, care home residential status and frailty score. Counts and percentages of clinical vulnerability categories were produced for the shielded cohort.

Frequencies for each health outcome were generated for the shielded and non-shielded cohorts, as well as clinical subgroups within the shielded cohort. Event, count and measurement

Table 2
Shielded and non-shielded cohort demographic characteristics.

Cohort	Shielded (n = 117,415)	Non-shielded (n = 3,086,385)
Sex, n (%)		
Male	54,473 (46.4)	1,545,471 (50.1)
Female	62,942 (53.6)	1,540,914 (49.9)
Age (years), median (LQ, UQ)	66 (53, 75)	41 (22, 59)
Age group (years), n (%)		
0–19	4768 (4.1)	689,915 (22.4)
20–39	9865 (8.4)	811,478 (26.3)
40–59	28,723 (24.5)	813,797 (26.4)
60–79	58,099 (49.5)	617,367 (20.0)
80+	15,960 (13.6)	153,828 (5.0)
WIMD²: n (%)		
Missing	5797 (4.9)	208,852 (6.8)
Recorded	111,618 (95.1)	2,877,533 (93.2)
WIMD quintile: n (% recorded)		
1. Most deprived	24,832 (22.2)	591,184 (20.5)
2	23,553 (21.1)	575,100 (20.0)
3	22,019 (19.7)	571,523 (19.9)
4	20,956 (18.8)	566,235 (19.7)
5. Least deprived	20,258 (18.1)	573,491 (19.9)
Care home status: n (%)		
Care home resident	1113 (0.9)	14,072 (0.5)
Other	116,302 (99.1)	3,072,313 (99.5)
Frailty category: n (%)		
Missing GP data	19,904 (17.0)	540,662 (17.5)
Recorded	97,511 (83.0)	2,545,723 (82.5)
Frailty category: n (% recorded)		
Fit	40,654 (41.7)	2,178,021 (85.6)
Mild	37,711 (38.7)	287,362 (11.3)
Moderate	15,111 (15.5)	66,045 (2.6)
Severe	4035 (4.1)	14,295 (0.6)

WIMD, Welsh Index of Multiple Deprivation.

outcomes were analysed using generalised linear models, with an appropriate link function (negative binomial for counts) and logarithmically transformed dependent variables for heavily skewed measurement outcomes; sex (factor) and age (covariate; linear and quadratic) were included as independent variables, with interaction between age and sex.

Generalised linear models were fitted using SPSS (version 26); models retained all independent variables; no adjustment was made for multiple testing.

Comparisons between shielded and non-shielded cohorts were based on estimated odds ratios (ORs) for binary outcomes, estimated incident rate ratios (IRRs) for count outcomes and estimated differences (Δ) for measurement outcomes, with 95% confidence intervals (CIs) for these estimates.

Research management and public involvement

The EVITE Immunity research team includes clinical, policy, academic, methodological and public contributors who have equal responsibility in all decisions to develop, manage and deliver this study. Two public contributors (L.B. and L.D.) are co-applicants and members of the Research Management Group and work with six more public contributors via a Patient Advisory Panel. An independent Study Steering Committee includes two further public contributors. Our public contributors were directly or indirectly affected by the implementation of the shielding policy.^{23,24}

Results

Cohort profiles

Through the use of algorithms and screening of routine NHS data, a total of 193,815 individuals were identified as eligible for the

shielding intervention. With inclusion restricted to those identified between 23 March and 21 May (the first and second phases of the shielding policy implementation) and linked to the C20 Cohort, we included 117,415 people in the shielded cohort for analysis (Fig. 1), with the remaining 3,086,385 allocated to the non-shielded comparator cohort.

The three largest categories within those identified for shielding comprised people with a severe respiratory condition (35.5%), with immunosuppressive therapy (25.9%), and cancer (18.6%; Table 1).

Women made up a slightly higher proportion of the shielded cohort (53.6% vs 49.9%); people aged ≥ 50 years made up a much higher proportion of the shielded cohort (79.6% vs 39%); people living in areas of relatively high deprivation made up a slightly higher proportion of the shielded cohort (highest two quintiles: 43.3 vs 40.5%); people resident in care homes made up a higher proportion of the shielded cohort (0.9 vs 0.5%); and people categorised as mildly, moderately or severely frail made up a much higher proportion of the shielded cohort (58.3% vs 14.5%; Table 2).

Health outcomes

Testing

A total of 130,039 COVID-19 tests were recorded during 1-year follow-up for 44,523 individuals in the shielded cohort, an average of 1.11 tests per person, with 37.9% of the cohort tested at least once. This compares with an average of 0.83 tests per person and 30.8% tested at least once in the non-shielded cohort (Table 3). After adjusting for age and sex, the OR for persons tested was 1.616 (95% CI: 1.597–1.637) for the shielded cohort relative to the non-shielded cohort. All clinical sub-cohorts had an OR >1 relative to the non-shielded cohort, with the highest OR for the cancer sub-cohort (Table 4).

Within persons tested, 15.6% (6939/44,523) of the shielded cohort recorded a positive test; compared with 18.5% (176,120/950,818) in the non-shielded cohort. After adjusting for age and sex, the OR for persons with a positive test was 0.716 (95% CI: 0.697–0.736) for persons tested in the shielded cohort relative to those tested in the non-shielded cohort. For clinical sub-cohorts, the corresponding ORs were all <1, with the lowest OR for the cancer sub-cohort.

The known infection rate in the shielded cohort was 5.9% and in the non-shielded cohort was 5.7%. We extrapolated from tested sub-cohorts to entire cohorts based on demographic characteristics alone and assumed similar infection rates between tested and untested. Using these assumptions, 15.5%–15.9% (95% confidence) of the entire shielded cohort would have tested positive, compared with 18.6%–18.7% of the entire non-shielded cohort.

Mortality

After adjusting for age and sex, the OR for mortality in the shielded cohort was 3.683 (95% CI: 3.583–3.786) relative to the non-shielded cohort. COVID-19 was less likely to have been recorded as a cause (15.3% vs 21.4%). There was variation among the shielded clinical sub-cohorts, with cancer patients showing the highest mortality (1.3%).

Healthcare utilisation

Critical care admissions, emergency admissions, and ED attendances were all more likely amongst people in the shielded cohort: ORs 3.339 (95% CI: 3.111–3.583), 2.883 (95% CI: 2.837–2.930) and 1.893 (95% CI: 1.867–1.919), each with some variation across the four clinical sub-cohorts in the shielded cohort. The IRRs for the number of attendances and admissions in the shielded cohort were all significantly >1 relative to the non-shielded cohort, both for entire cohorts and within those attending or admitted.

Mental health outcomes

After adjusting for age and sex, the OR for an indicated CMD in the shielded cohort was 1.762 (95% CI: 1.735–1.789) relative to the non-shielded cohort, with ORs >1 in all clinical sub-cohorts.

Discussion

Key findings

People were more likely to have been identified for inclusion in the shielding intervention with increasing age, frailty and residence in deprived areas. Although people living in care homes were intended to be excluded from shielding, we found more than 1000 people included in the shielded cohort who were care home residents, almost double the proportion of care home residents in the general population.

Reported infection rate was higher in the shielded cohort than the non-shielded general population; however, testing rates were higher, and infection rates amongst those not tested in each cohort are unknown.

Limitations

Our analyses were adjusted for differences in distributions by age and sex to facilitate general descriptive comparisons in observed rates of events. However, comparisons made in this article do not take into account of deprivation status or clinical vulnerability. In phase 2 of the EVITE Immunity study, we will carry out more complex analyses, with a matched control cohort of non-shielded people within the general population, as well as inclusion

of self-reported outcomes in samples. We will also adjust for other differences, for example, deprivation, ethnicity and frailty.

We found a higher rate of testing for COVID-19 in the shielded population, potentially causing an overstated infection rate in this cohort compared with the general population. It is possible that a higher number of people within the shielded cohort were tested without symptoms of COVID-19, for example, as a requirement before attending hospital for routine treatment or due to anxiety, or that people in the shielded population were more likely to experience symptoms, for example, those with chronic obstructive pulmonary disease (COPD), which triggered higher testing rates. Testing availability varied considerably across the period of study and also geographically. Systematic differences in the way testing processes were implemented give rise to challenges in interpreting differences in recorded infection rates. It is neither credible nor to assume that all those untested would have tested negative nor that the rate of positive tests would have been similar in the untested to those tested. But we have no data on which to estimate where the true rate of infection should lie – we therefore present a range of 5.9–15.9% in the shielded cohort and 5.7–18.7% in the non-shielded cohort, as the likely outer limits. We will explore this further in phase 2 of this study, using a matched cohort design.

Implications

We took an ‘intention to treat’ analysis approach,²⁵ with no attempt to account for variation in adherence to the shielding guidance because this is not possible to determine from administrative data. This generates a real-life evaluation of policy. Subsequent research will include analysis of linked data from questionnaires, which include self-reported adherence to shielding advice, and qualitative interviews, which will seek to understand people’s experiences of the shielding policy. It is likely the autonomy and agency for some people on the shielding list to control their level of adherence would have been dependent on a number of factors, such as mobility, household composition, access to services (supermarkets, for example), geographical location or hospitalisation. These factors have not been considered in this analysis.

Shielding was an untested public health policy that was introduced in the United Kingdom early in the pandemic, in contrast to other countries where there was more focus on closing borders, lockdown, test and trace systems. The shielding policy was based on assumptions rather than evidence of effectiveness. There were uncertainties about (1) risk factors, (2) the performance of predictive risk stratification models in this context, (3) the ability and willingness of clinically vulnerable people to carry out the strict self-isolation advised and (4) primary transmission routes.

The United Kingdom, in common with other countries, experienced high levels of nosocomial infection and infection in care homes and healthcare settings, with transmission presumed to be through contact with other patients, health professionals and care givers.^{26,27} We found a very high rate of contact with health services throughout this period for people in the shielded cohort. It is likely that despite efforts to support shielding for those at highest risk, clinically vulnerable people were exposed to other people with COVID-19 at home, in care homes, or in hospital or other healthcare settings, for example, people requiring dialysis, and then been vulnerable to infection and serious harm despite all intentions to avoid these outcomes.

We found a higher rate of all-cause mortality in the shielded population, as well as higher rates of health service utilisation. This is likely to be due to a higher level of sickness in the shielded population, and we do not attribute these differences to the introduction of shielding.

Table 3
Frequency counts of Health outcomes in the Shielded cohort and sub-cohorts: comparison with non-shielded general population.

Health outcomes	Shielded cohort and sub-cohorts					Non-shielded cohort (<i>n</i> = 3,086,385)
	All (<i>n</i> = 117,415)	Severe respiratory condition (<i>n</i> = 41,711)	Immunosuppression therapy (<i>n</i> = 30,464)	Cancer (<i>n</i> = 21,895)	All others (<i>n</i> = 23,345)	
Testing						
Persons tested: <i>n</i> (proportion of cohort or sub-cohort)	44,523 (0.379)	15,890 (0.381)	10,367 (0.340)	8933 (0.408)	9333 (0.400)	950,818 (0.308)
Persons tested positive: <i>n</i> (proportion of persons tested)	6939 (0.156)	2517 (0.158)	1721 (0.166)	1232 (0.138)	1469 (0.157)	176,120 (0.185)
Tests recorded: <i>n</i> (average per person)	130,039 (1.11)	46,292 (1.11)	27,286 (0.90)	26,699 (1.22)	29,762 (1.27)	2,551,739 (0.83)
Positive tests recorded: <i>n</i> (average per person tested)	9132 (0.205)	3408 (0.214)	2126 (0.205)	1626 (0.182)	1972 (0.211)	192,353 (0.202)
Mortality						
All causes: <i>n</i> (proportion of cohort or sub-cohort)	7950 (0.068)	3101 (0.074)	774 (0.025)	2776 (0.127)	1299 (0.056)	27,934 (0.009)
COVID-19 related: <i>n</i> (proportion of all deaths)	1220 (0.153)	608 (0.196)	172 (0.222)	238 (0.086)	202 (0.156)	5987 (0.214)
Healthcare utilisation						
Persons with an ED attendance: <i>n</i> (proportion of cohort or sub-cohort)	29,142 (0.248)	11,781 (0.282)	5893 (0.193)	5495 (0.251)	5973 (0.256)	424,032 (0.137)
Total ED attendances (average per person in cohort/sub-cohort)	51,461 (0.438)	21,995 (0.527)	9552 (0.314)	9097 (0.415)	10,817 (0.463)	630,767 (0.204)
Persons with a critical care admission: <i>n</i> (proportion of cohort or sub-cohort)	989 (0.008)	334 (0.008)	199 (0.007)	211 (0.010)	245 (0.010)	4701 (0.002)
Total critical care admissions (average per person in cohort/sub-cohort)	1120 (0.010)	383 (0.009)	225 (0.007)	235 (0.011)	277 (0.012)	5140 (0.002)
Total bed days – ICU (average bed days per admission)	6162.0 (5.50)	1989.0 (5.19)	1332.5 (5.92)	1210.5 (5.15)	1630.0 (5.88)	37,275.5 (7.25)
(average bed days per person with an ICU admission)	(6.23)	(5.96)	(6.70)	(5.74)	(6.65)	(7.93)
Persons with an emergency admission: <i>n</i> (proportion of cohort or sub-cohort)	22,212 (0.189)	8829 (0.212)	3926 (0.129)	5010 (0.229)	4447 (0.190)	161,307 (0.052)
Total emergency admissions (average per person in cohort/sub-cohort)	39,267 (0.334)	15,392 (0.369)	6507 (0.214)	9156 (0.418)	8212 (0.352)	229,084 (0.074)
Total bed days – emergency admissions (average bed days per admission)	385,384.0 (9.81)	155,026.5 (10.07)	65,825.0 (10.12)	78,881.5 (8.62)	85,651.0 (10.43)	1,998,733.5 (8.72)
(average bed days per person with an emergency admission)	(17.35)	(17.56)	(16.77)	(15.74)	(19.26)	(12.39)
Common mental disorder						
Persons with CMD flag data (proportion of cohort or sub-cohort)	93,944 (0.800)	33,982 (0.815)	24,424 (0.802)	16,818 (0.768)	18,720 (0.802)	2,507,448 (0.812)
Persons flagged with CMD (proportion of persons with CMD flag data)	26,400 (0.281)	11,655 (0.343)	6230 (0.255)	3857 (0.229)	4658 (0.249)	422,750 (0.169)

CMD, common mental disorder; ED, emergency department; ICU, intensive care unit.

Table 4
Comparisons, adjusted for age and gender, of health outcomes in the shielded cohort and sub-cohorts, relative to the non-shielded general population.

Health outcomes		Shielded cohort	Shielded sub-cohorts			
		All (n = 117,415)	Severe respiratory condition (n = 41,711)	Immunosuppression therapy (n = 30,464)	Cancer (n = 21,895)	All others (n = 23,345)
Testing						
Persons tested: OR (95% CI)	Within cohort/sub-cohort	1.616 (1.597, 1.637)	1.759 (1.724, 1.795)	1.253 (1.223, 1.283)	1.916 (1.864, 1.969)	1.687 (1.643, 1.732)
Persons tested positive: OR (95% CI)	Within persons tested	0.716 (0.697, 0.736)	0.725 (0.694, 0.757)	0.769 (0.730, 0.810)	0.608 (0.572, 0.646)	0.760 (0.718, 0.804)
Tests recorded, per person: IRR (95% CI)	Within cohort/sub-cohort	1.298 (1.287, 1.309)	1.324 (1.306, 1.343)	0.983 (0.967, 0.999)	1.448 (1.422, 1.475)	1.565 (1.538, 1.593)
Positive tests recorded: IRR (95% CI)	Within persons tested	0.852 (0.832, 0.872)	0.862 (0.830, 0.895)	0.877 (0.837, 0.920)	0.735 (0.697, 0.776)	0.930 (0.885, 0.977)
Mortality						
All causes: OR (95% CI)	Within cohort/sub-cohort	3.683 (3.583, 3.786)	3.059 (2.936, 3.187)	1.903 (1.765, 2.053)	7.265 (6.944, 7.601)	3.671 (3.450, 3.907)
COVID-19–related deaths: OR (95% CI)	Within all deaths	0.667 (0.623, 0.715)	0.852 (0.775, 0.936)	1.059 (0.890, 1.259)	0.351 (0.306, 0.403)	0.701 (0.600, 0.818)
Healthcare utilisation						
Persons with an ED attendance: OR (95% CI)	Within cohort/sub-cohort	1.893 (1.867, 1.919)	2.147 (2.100, 2.195)	1.471 (1.429, 1.514)	1.882 (1.825, 1.942)	2.025 (1.966, 2.087)
ED attendances, per person: IRR (95% CI)	Within cohort/sub-cohort	1.960 (1.939, 1.982)	2.263 (2.225, 2.302)	1.483 (1.449, 1.518)	1.820 (1.776, 1.866)	2.133 (2.085, 2.183)
ED attendances, per person: IRR (95% CI) [a]	Within persons with ≥ 1 ED attendances	1.494 (1.466, 1.522)	1.678 (1.632, 1.724)	1.220 (1.170, 1.272)	1.258 (1.206, 1.313)	1.603 (1.542, 1.665)
Persons with an ICU admission: OR (95% CI)	Within cohort/sub-cohort	3.339 (3.111, 3.583)	2.801 (2.501, 3.137)	2.835 (2.458, 3.271)	3.333 (2.898, 3.833)	4.752 (4.173, 5.411)
ICU admissions, per person: IRR (95% CI)	Within cohort/sub-cohort	3.485 (3.261, 3.726)	2.974 (2.674, 3.307)	2.930 (2.561, 3.351)	3.404 (2.980, 3.887)	4.915 (4.349, 5.554)
ICU admissions, per person: IRR (95% CI) [b]	Within persons with ≥ 1 CC admission	1.453 (1.179, 1.789)	1.612 (1.172, 2.217)	1.372 (0.899, 2.092)	1.290 (0.833, 1.997)	1.376 (0.938, 2.017)
ICU bed days, per person: Δ (95% CI) [c]	Within cohort/sub-cohort	0.009 (0.008, 0.009)	0.008 (0.007, 0.008)	0.007 (0.006, 0.007)	0.010 (0.009, 0.011)	0.013 (0.012, 0.014)
ICU bed days, per person: Δ (95% CI) [d]	Within persons with ≥ 1 CC admission	-0.149 (-0.210, -0.088)	-0.177 (-0.277, -0.078)	-0.130 (-0.256, -0.004)	-0.149 (-0.272, -0.026)	-0.131 (-0.246, -0.016)
Persons with an emergency admission: OR (95% CI)	Within cohort/sub-cohort	2.883 (2.837, 2.930)	2.833 (2.763, 2.905)	2.173 (2.099, 2.250)	3.401 (3.290, 3.515)	3.304 (3.193, 3.420)
Emergency admissions, per person: IRR (95% CI)	Within cohort/sub-cohort	3.107 (3.068, 3.147)	2.913 (2.856, 2.972)	2.330 (2.266, 2.396)	3.681 (3.588, 3.777)	3.741 (3.643, 3.842)
Emergency admissions, per person: IRR (95% CI) [b]	Within persons with ≥ 1 emergency admission	1.717 (1.679, 1.756)	1.583 (1.530, 1.637)	1.516 (1.441, 1.595)	1.835 (1.759, 1.915)	1.978 (1.892, 2.068)
Emergency admission bed days, per person: Δ (95% CI) [c]	Within cohort/sub-cohort	0.221 (0.218, 0.224)	0.248 (0.243, 0.252)	0.119 (0.114, 0.124)	0.288 (0.282, 0.294)	0.251 (0.245, 0.256)
Emergency admission bed days, per person: Δ (95% CI) [d]	Within persons with ≥ 1 emergency admission	0.247 (0.231, 0.262)	0.102 (0.169, 0.215)	0.231 (0.197, 0.264)	0.234 (0.204, 0.265)	0.365 (0.333, 0.397)
Common mental disorder						
Persons with CMD flag data: OR (95% CI)	Within cohort/sub-cohort	0.982 (0.967, 0.996)	1.100 (1.073, 1.128)	0.967 (0.940, 0.995)	0.822 (0.796, 0.848)	0.972 (0.942, 1.004)
Persons flagged with CMD: OR (95% CI)	Within person with CMD flag data	1.762 (1.735, 1.789)	2.597 (2.535, 2.660)	1.313 (1.274, 1.353)	1.336 (1.287, 1.387)	1.594 (1.539, 1.650)

ED, emergency department; ICU, intensive care unit.

[a] modelling uses further attendances as the dependent variable, to improve model fit.

[b] modelling uses further admissions as the dependent variable, to improve model fit.

[c] modelling uses a log-transformed dependent variable to improve model fit, but this transformation does not remove the spike at 0.

[d] modelling uses a log-transformed dependent variable, to improve model fit.

We do not believe that there is any reason that results from the entire population of Wales would be any different from other areas of the United Kingdom – although of course there may be differences in sub-populations, for example, those with high levels of deprivation, older residents or people from ethnic minorities.

A study comparing COVID-19 outcomes between shielded and non-shielded populations in the West of Scotland describes a similar trend in infection rates, with the shielded population having an infection rate eight times higher than those considered 'low risk' as well as having higher rates of mortality.²⁸ Our findings are similar to those reported in a Scottish study, which found that the shielding population had a higher risk of mortality from COVID-19.²⁹ Interestingly, a study of the English population during the first 12 weeks of the shielding policy found that during the first 21 days of the policy, mortality in the shielded cohort was half that of the non-shielded matched cohort. However, during the following 9 weeks, mortality in the shielded group rose significantly to 1.5 times higher than in the matched cohort, which although shows a similar trend; it is a much smaller difference than reported in our study.³⁰

Evidence is now emerging regarding the effects of shielding on infections, deaths and general health and well-being, but this is still very limited.^{28,31} Shielded people and their families made great efforts to isolate and protect themselves from COVID-19 infection and subsequent harms, including death. This isolation and restrictions on going out may have affected the mental and physical health of people included in this public health policy intervention, without evidence so far of substantive protective effects.^{32,33}

Conclusions

Further research using a matched comparator group, self-reported outcomes and costs are needed to fully evaluate the effects of this policy intervention. Initial findings from the EVITE Immunity study show that there is some uncertainty about the success of the policy in terms of reducing COVID-19 infections in the shielded cohort. Higher rates of mortality and health service utilisation were to be expected in a clinically vulnerable population – but a clinically effective shielding policy may have been expected to reduce COVID-19 infection rates to a higher degree than we found in this study.

Author statements

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Ethical approval

This study was undertaken with the approval of the SAIL IGRP (project number 0911). No NHS research ethics application was required.

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Competing interests

The authors declare that they have no competing interests.

Data availability statement

The data used in this study are available in the SAIL Databank at Swansea University, Swansea, UK. All proposals to use SAIL data are subject to review by an independent Information Governance Review Panel (IGRP).

Author contributions

The study was conceived and led by H.S. The study was designed by H.S. in collaboration with R.A.L., A.W., J.L., A.A., R.B., L.B., A.C.S., A.E., H.E., B.A.E., S.J., A.J., M.K., A.P., B.S. and V.W. J.L. and A.A. undertook the data preparation, with analysis led by H.S. and A.W. H.S. and A.W. drafted the initial article with contributions from all authors. All authors read the first draft of the article and approved the final document for submission.

Transparency statement

The lead author (the manuscript's guarantor) affirms that this article is an honest, accurate and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned have been explained.

References

- Romero Starke K, Petereit-Haack G, Schubert M, Kämpf D, Schliebner A, Hegewald J, et al. The Age-Related Risk of Severe Outcomes Due to COVID-19 Infection: A Rapid Review, Meta-Analysis, and Meta-Regression. *Int. J. Environ. Res. Public Health* 2020;17:5974. <https://doi.org/10.3390/ijerph17165974>.
- Guan WJ, Liang WH, Zhao Y, Liang HR, Chen ZS, Li YM, et al. Comorbidity and its impact on 1590 patients with COVID-19 in China: a nationwide analysis. *Eur Respir J* 2020 May 14;55(5):2000547. <https://doi.org/10.1183/13993003.00547-2020>.
- Atkins JL, Masoli JA, Delgado J, Pilling LC, Kuo CL, Kuchel GA, et al. Preexisting comorbidities predicting COVID-19 and mortality in the UK biobank community cohort. *J Gerontol A Biol Sci Med Sci* 2020 Oct 15;75(11):2224–30. <https://doi.org/10.1093/geron/glaa183>.
- Williamson E, Walker AJ, Bhaskaran K, Bacon S, Bates C, Morton CE, et al. OpenSAFELY: factors associated with COVID-19-related hospital death in the linked electronic health records of 17 million adult NHS patients. *MedRxiv* 2020. <https://doi.org/10.1101/2020.0506.20092999>.
- Xuefei Ren Pandemic and lockdown: a territorial approach to COVID-19 in China. Italy and the United States. *Eurasian Geogr Econ* 2020;61(4–5):423–34. <https://doi.org/10.1080/15387216.2020.1762103>.
- World Health Organization. *WHO COVID-19 preparedness and response progress report-1 February to 30 June 2020*. 2020 August 3.

7. World Health Organization. 2020 WHO COVID-19 strategy update – 14 April 2020. 2020 April 14.
8. Steyerberg EW. Evaluation of clinical usefulness. *Clinical prediction models*. Cham: Springer; 2019. p. 309–28.
9. Clift AK, Coupland CA, Keogh RH, Diaz-Ordaz K, Williamson E, Harrison EM, 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>.
10. UK Government. Guidance on shielding and protecting people who are clinically extremely vulnerable from COVID-19 [webpage]. Gov.UK; 2020. www.gov.uk/government/publications/guidance-on-shielding-and-protecting-extremely-vulnerable-persons-from-covid-19/guidance-on-shielding-and-protecting-extremely-vulnerable-persons-from-covid-19. [Accessed April 2022].
11. NHS Digital. COVID-19–high risk shielded patient list identification methodology. <https://nwis.nhs.wales/coronavirus/coronavirus-content/coronavirus-documents/covid-19-high-risk-shielded-patient-list-identification-methodology-v3-2-17th-august/>, 2020. [Accessed May 2022].
12. Davies AR, Song J, Bentley L, Akbari A, Smith T, Carter B, et al. COVID-19 in Wales: The impact on levels of health care use and mental health of the clinically extremely vulnerable. *Public Health Wales Research and Evaluation*. Public Health Wales; 2021. <https://phw.nhs.wales/services-and-teams/knowledge-directorate/research-and-evaluation/publications/covid-19-in-wales-the-impact-on-levels-of-health-care-use-and-mental-health-of-the-clinically-extremely-vulnerable/>.
13. Anand JC, Donnelly S, Milne A, Nelson-Becker H, Vingare EL, Deusdad B, et al. The covid-19 pandemic and care homes for older people in Europe–deaths, damage and violations of human rights. *Eur J Soc Work* 2021 Aug 11:1–2.
14. Hodgson K, Butler JE, Davies A, Houston S. Briefing: Assessing the impact of COVID-19 on the clinically extremely vulnerable population. The Health Foundation; 2021. <https://health.org.uk/sites/default/files/upload/publications/2021/NDL%20Briefing%20Assessing%20the%20impact%20of%20COVID%20on%20the%20clinically%20extremely%20vulnerable%20population%201021.pdf>.
15. Whitty C, Powis S. Department of health and social care. Shielding update, 8th July 2020. www.england.nhs.uk/coronavirus/wp-content/uploads/sites/52/2020/07/C0661-letter-to-nhs-shielding-guidance-changes-july-2020.pdf; 2020.
16. von Elm EB, Altman DG, Egger M, Pocock SJ, Gøtzsche PC, Vandenbroucke JP, STROBE Initiative. The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement: guidelines for reporting observational studies. *J Clin Epidemiol* 2008;**61**(4):344–9. PMID: 18313558.
17. Ford DV, Jones KH, Verplancke JP, Lyons RA, John G, Brown G, et al. The SAIL Databank: building a national architecture for e- health research and evaluation. *BMC Health Serv Res* 2009;**9**(1):157. <https://doi.org/10.1186/1472-6963-9-157>.
18. Lyons RA, Jones KH, John G, Brooks CJ, Verplancke JP, Ford DV, et al. The SAIL databank: linking multiple health and social care datasets. *BMC Med Inform Decis Mak* 2009;**9**(1):3.
19. Lyons J, Akbari A, Torabi F, Davies GI, North L, Griffiths R, et al. Understanding and responding to COVID-19 in Wales: protocol for a privacy-protecting data platform for enhanced epidemiology and evaluation of interventions. *BMJ Open* 2020 Oct 21;**10**(10):e043010. <https://doi.org/10.1136/bmjopen-2020-043010>.
20. Clegg A, Bates C, Young J, Ryan R, Nichols L, Ann TE, et al. Development and validation of an electronic frailty index using routine primary care electronic health record data. *Age and Ageing* 2016 May;**45**(3):353–60. <https://doi.org/10.1093/ageing/afw039>.
21. Hollinghurst J, Fry R, Akbari A, Clegg A, Lyons RA, Watkins A, et al. External validation of the electronic Frailty Index using the population of Wales within the Secure Anonymised Information Linkage Databank. *Age and ageing* 2019 Nov 1;**48**(6):922–6. <https://doi.org/10.1093/ageing/afz110>.
22. 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 Mar 15;**16**:35. <https://doi.org/10.1186/s12911-016-0274-7>.
23. Evans BA, Gallanders J, Griffiths L, Harris-Mayes R, James M, Jones S, et al. Public involvement and engagement in primary and emergency care research: the story from PRIME Centre Wales. *Int J Popul Data Sci* 2020;**5**(3):1363. Research NIFH. UK Standards for Public Involvement 2019 [Available from: <https://sites.google.com/nih.ac.uk/pi-standards/home>].
24. Staniszewska S, Brett J, Mockford C, Barber R. The GRIPP checklist: strengthening the quality of patient and public involvement reporting in research. *Int J Technol Assess Health Care* 2011 Oct;**27**(4):391–9.
25. Gupta SK. Intention-to-treat concept: a review. *Perspect Clin Res* 2011 Jul;**2**(3):109–12. <https://doi.org/10.4103/2229-3485.83221>.
26. Ponsford MJ, Jefferies R, Davies C, Farewell D, Humphreys IR, Jolles S, et al. Burden of nosocomial COVID-19 in Wales: results from a multicentre retrospective observational study of 2508 hospitalised adults. *Thorax* 2021 Dec 1;**76**(12):1246–9.
27. Ponsford MJ, Ward TJ, Stoneham SM, Dallimore CM, Sham D, Osman K, et al. A Systematic Review and Meta-Analysis of Inpatient Mortality Associated With Nosocomial and Community COVID-19 Exposes the Vulnerability of Immunosuppressed Adults. *Front Immunol* 2021 Oct 6;**12**:744696.
28. Jani BD, Ho FK, Lowe DJ, Traynor JP, MacBride-Stewart SP, Mark PB, et al. Comparison of COVID-19 outcomes among shielded and non-shielded populations. *Sci Rep* 2021;**11**:15278.
29. Agrawal U, Azcoaga-Lorenzo A, Fagbamigbe AF, Vasileiou E, Henery P, Simpson CR, et al. Association between multimorbidity and mortality in a cohort of patients admitted to hospital with COVID-19 in Scotland. *J R Soc Med* 2022;**115**:22–30.
30. Zarif A, Joy M, Sherlock J, Sheppard JP, Byford R, Akinyemi O, et al. The impact of primary care supported shielding on the risk of mortality in people vulnerable to COVID-19: English sentinel network matched cohort study. *J Infect* 2021;**83**:228–36.
31. McKeigue PM, McAllister DA, Caldwell D, Gribben C, Bishop J, McGurnaghan S, et al. Relation of severe COVID-19 in Scotland to transmission-related factors and risk conditions eligible for shielding support: REACT-SCOT case-control study. *BMC Med* 2021;**19**:149. <https://doi.org/10.1186/s12916-021-02021-5>.
32. Fisher A, Roberts A, McKinlay AR, Fancourt D, Burton A. The impact of the COVID-19 pandemic on mental health and well-being of people living with a long-term physical health condition: a qualitative study. *BMC public health* 2021;**21**(1):1–12.
33. Santomauro DF, Herrera AM, Shadid J, Zheng P, Ashbaugh C, Pigott DM, et al. Global prevalence and burden of depressive and anxiety disorders in 204 countries and territories in 2020 due to the COVID-19 pandemic. *The Lancet* 2021;**398**(10312):1700–12.