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Ethical approval
The results in this manuscript are informed by the analysis of anonymised secondary data provided by Cheshire & Merseyside Health & Care Partnership Combined Intelligence for Population Health Action (CIPHA). CHIPA's Data Access Committee approved access to the data and analysis contained in the study. No primary data or non-anonymised data were used in this study and as such, there is no requirement for research ethics committee review.

Data sharing
Data are accessible via CIPHA. Requests can be made to the Data Access Committee for extracts of the larger-scale data which cannot be released openly due to information governance requirements.

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Abstract

Objective
This study evaluates the impact of England's COVID-19 shielding programme on mortality in the City of Liverpool in North West England.

Study Design
Shielded and non-shielded people are compared using data from linked routine health records on all people registered with a general practitioner in Liverpool from April 2020 to June 2021.

Methods
A discrete time hazard model and interactions between the shielding status and the periods of higher risk of transmission are used to explore the effects of shielding across the major phases of the COVID-19 pandemic.

Results
Shielding was associated with a 34% reduction in the risk of dying (HR= 0.66, 95% CI 0.58 to 0.76) compared with a propensity-matched non-shielded group. Shielding appeared to reduce mortality during the first and third wave, but not the second wave, where shielding was not mandated by Government. The effects were similar for males and females, but more protective for those living in the least deprived areas of Liverpool.

Conclusions
It is likely that the shielding programme in Liverpool saved lives, although this seems to have been a little less effective in more deprived areas. A comprehensive programme of identifying vulnerable groups and providing them with advice and support is likely to be important for future respiratory virus pandemics. Additional support may be necessary for socioeconomically disadvantaged groups to avoid increased inequalities.

Keywords: COVID-19 pandemic | Shielding Programme| Mortality Risk | Lives saved

1. Introduction

At the beginning of the COVID-19 pandemic in the UK, Government sought to reduce the burden on healthcare facilities[1]. To prevent the NHS from being overwhelmed with COVID-19 patients and to reduce mortality, subgroups of the population were identified to be at high risk of severe COVID-19 if infected with the SARS-CoV-2 virus, and were provided with advice and support to reduce the risk of infection.[1]

On the 21st of March 2020, at the start of the pandemic,[2] The UK Government, via the Chief Medical Officer (CMO), published a list of criteria for which patients were deemed "extremely clinically vulnerable" to COVID-19.[3,4] Patients were identified nationally using secondary care records[5] and fell into several categories, including individuals with specific listed conditions such as cancer, chronic respiratory diseases (e.g., asthma), other chronic comorbidities (e.g., chronic heart disease), people who had undergone organ transplant or were pregnant.[3,4] The list of conditions and corresponding national guidance continued to evolve until May 2020 as evidence became available. These patients were sent a letter advising them to stay at home and shield (strictly self-isolate), even from others in their household. Early on many patients with eligible conditions for shielding did not receive advisory letters, partly because the national list only used secondary care records and would have missed people who only had a diagnosis in primary care and had not used secondary care. Some were then only included after contacting their GP. People advised to shield were eligible for furlough from work, statutory sick pay, and personal support such as home delivery of government-funded food and essential supplies.[6]

The advice to patients who were on the shielding list was relaxed in Summer 2020 as transmission subsided.[7] They were then re-introduced in December 2020 as the third wave of the COVID-19 pandemic commences, initially just in high transmission region, and then nationally in January 2021. In February 2021 a new evidenced based risk algorithm was introduced, called QCOVID, using linked primary and secondary care data from a sample of GP practices. This identified additional patients who were asked to shield nationally.[8] The shielding programme continued until April 2021, in England.[9]

In Liverpool a pre-existing system of linked primary, secondary and social care records for all patients registered with a GP in Liverpool, was used to identify a list of vulnerable people starting from the 14th of May 2020, that was more extensive than those identified using the national algorithm. This used primary and social care data, as well as secondary care data and was based on an extended set of conditions initially compiled by the British Medical Association. GP practices in Liverpool then checked these lists and added additional patients who based on their clinical judgement were high-risk. This led to a much larger proportion of the population being shielded in Liverpool compared to other similar areas.[9] The people on the Liverpool list offered the same advice as those on the national list as well as being offered a range of support from multiple agencies, including social welfare support and telehealth care (see supplementary Section S1 for details).

Previous studies have investigated the effects of shielding in the west of Scotland[10] and in England.[11] Jani et al.[10] found that shielded patients had higher rates of infection and mortality than the non-shielded. They concluded that despite the shielding programme, high risk individuals had an increased risk of death.[10] This study had a large sample size. However, the analysis was conducted on data from March to May 2020, which was early in the pandemic and only two months into the shielding programme. Inclusion criteria for the patients advised to shield was not finalised until May 2020, and therefore some patients may have been missed in the months before. The study was, however, unable to distinguish between the risk of mortality in the shielded group, that was due to their pre-existing co-morbidities and any reduction in that risk due to the shielding programme. Zarif et al.[11] used exact matching to create comparable groups between shielded and non-shielded and found that shielding reduced mortality only during the first wave of the pandemic. However, it is not clear whether the authors fully addressed survivorship bias, which could lead to such results. Other studies have compared the shielded population with the non-shielded population.[9,12] The common conclusion is that through their vulnerabilities, shielded individuals are more prone to the adverse consequences of COVID-19. The lack of strong counterfactuals does not allow the studies to infer causality, and the results are potentially undermined by selection bias, where the shielded die more because their vulnerabilities put them at greater risk of dying even after risk-reduction from shielding.

Our study aims at investigating potential causal effects. We hypothesise that if shielding reduced mortality risk, this effect would have been limited largely to periods of high-risk when shielding was specifically advised. We therefore aim to estimate the effect of shielding by comparing how mortality differences changed between the shielded and a matched group of non-shielded people during each pandemic wave.

2. Methods

2.1 Data and measures.

Our primary outcome was all-cause mortality from the Office of National Statistics (ONS). We used all-cause mortality because deaths caused by COVID-19 would not necessarily have COVID-19 recorded on death certificates particularly earlier in the pandemic when testing was less available. It is also possible that shielding reduced mortality risk from other conditions (e.g., through decreasing exposure to other respiratory diseases). As a secondary outcome we used mortality where COVID-19 was recorded as the underlying cause of death on deaths certificates defined based on ICD10 codes (U07.1 and U07.2). Data was available on the week of death.

Our exposure variable was shielding status. To be categorised as shielded, patients had either a national or local shielding flag in their NHS records. Data was available on the week that the person was first identified to be shielded.

We used anonymised primary and secondary linked healthcare data from people registered with a GP in Liverpool from April 2020 to June 2021. Variables from primary care records included age, sex, Body Mass Index (BMI) category, diagnosis with long term conditions (Diabetes,

Asthma, Cancer, Cardiovascular Disease, Dementia, Chronic kidney disease (CKD), Chronic Liver Disease (CLD), Heart failure, Neurological conditions, Chronic Obstructive Pulmonary Disease (COPD), Rheumatological conditions), the number of these conditions, number of drugs currently prescribed, presence of a learning disability, or a physical disability, the PRISM risk score, Frailty index and whether they were living in a care home. Based on the patient's residence their record was linked to an area-based measure of socioeconomic status the Indices of Multiple Deprivation (IMD 2019 score).[13] Variables from secondary care includes the number of emergency and elective hospital admission in the previous 12 months. Linked social care data was used to identify people in receipt of local authority social care. The inclusion of these variables in the analysis is justified by their potential to predict shielding status and the outcomes in analysis.[14]

2.2 Population and setting

Our study is based on 57,713 people over the age of 70 registered at a GP practice in Liverpool in April 2020, 25,024 who were shielded and 32,689 who were not shielded. We limited our analysis to people over the age of 70 because people shielded under the age of 70 were likely to be more heterogenous having conditions and risks that were less likely to be recorded in electronic health care records. Descriptive statistics are provided in Table S1, in Appendix. Section S1, in Appendix, provides more details about the shielding programme in Liverpool.

2.3 Statistical analysis

2.3.1 Survivorship bias

We randomly applied a placebo shielding start week to the non-shielded population such that the distribution of the placebo shielding start weeks is the same as for the shielded group (see Figure S1, in Appendix, for a comparison of the distributions). This is necessary to avoid survivorship bias (e.g., people in the shielded group must stay alive until they are shielded).[15] People dying before their placebo shielding date were removed from the study.

2.3.2 Matching

We derived propensity scores to match the shielded group on a 1:1 basis (nearest neighbour matching with a calliper of 0.2) with a group of non-shielded people based on the variables likely to predict shielding status and the outcomes in analysis, as described in the “Data and Measures” above. Given that there was still a marked disparity in observed characteristics even after matching, we further utilized inverse probability weights (IPW) derived from propensity scores.[16,17]

2.3.3 Discrete time hazard model

We modelled the time between shielding and death using a discrete time hazard model with a complementary log-log link function.[18,19] To model the baseline hazard we included a quadratic term for weeks since shielded . A quadratic term was selected based on a visual comparison of shape of the hazard distribution over time (see Figure S2, in appendix).

We additionally included an interaction term in the model between COVID-19 epidemic wave and shielding (Shielded in high-risk periods). To define the time periods for the COVID-19 waves we analysed the weekly COVID-19 mortality rate in Liverpool and identified those weeks that were

above the 20th percentile based on the distribution of mortality rates in all weeks of the study period. We hypothesised that shielding would have only been likely to have had an impact on mortality reduction during these periods of high-risk, with the mortality difference between groups in low transmission periods largely reflecting the differences in mortality risk due to residual confounding. We interpret the interaction term in the model as the potential causal effect, since it reflects the difference in the increase in mortality during pandemic waves between the shielded and the non-shielded groups. If shielding was protective, we would expect that during a pandemic wave the mortality risk in the shielded would increase to a lesser extent compared to the mortality the non-shielded. In sensitivity analysis we consider a broader definition for the pandemic wave – defining these as periods where the number of COVID-19 deaths in Liverpool was greater than 10 per week (see Model S1, in appendix, for the model formula).

2.3.4 Subgroups analysis

We estimated the effect of each separate pandemic wave in addition to the average effect across all waves, as the shielding policy and other government control measures differed between each wave, with shielding only explicitly recommended in waves 1 and 3.

We explored possible social heterogeneous effects, by interacting shielding in high-risk periods with indicators of gender and area deprivation. We divided the Index of Multiple Deprivation in 3: people living in areas with IMD decile lower than 3 were considered a “high deprivation” group; people living in areas with IMD decile higher than 3 but lower than 7 were considered a “medium deprivation” group; people living in areas with IMD decile higher than 7 were considered a “low deprivation” group.

2.3.5 Competing risks

To investigate the specificity of effects in relation to COVID-19 mortality we estimated a competing risks model estimating effect on COVID-19 mortality and mortality from other causes, using a multinomial model.

3. Results

Table 1: Comparison between shielded and non-shielded after matching and inverse probability weighting.

	Non-Shielded		Shielded		p-value
	Mean or %	SD	Mean or %	SD	
Age	78·81	6·45	78·8	6·59	0·907
Gender - Female	54%	50 p.p.	55%	5 p.p.	0·117
Diabetes	23%	42 p.p.	24%	43 p.p.	0·046
Body Mass Index Category	2·18	0·95	2·17	0·94	0·666
Cancer	30%	46 p.p.	31%	46 p.p.	0·046
Asthma	15%	36 p.p.	16%	36 p.p.	0·694
Cardiovascular disease	40%	49 p.p.	42%	49 p.p.	0·003
Dementia	4%	21 p.p.	6%	23 p.p.	<0·001

Local Authority Social care	21%	41 p.p.	23%	42 p.p.	0·008
Lived in care home	3%	17 p.p.	4%	19 p.p.	0·01
Chronic kidney disease	38%	49 p.p.	38%	49 p.p.	0·891
Heart failure	56%	5 p.p.	57%	5 p.p.	0·076
Neurological	1%	12 p.p.	2%	13 p.p.	0·17
COPD	16%	36 p.p.	19%	39 p.p.	<0·001
Rheumatology	71%	45 p.p.	72%	45 p.p.	0·079
IMD decile	2·95	2·44	2·98	2·46	0·364
Number of chronic conditions	0·74	0·83	0·82	0·91	<0·001
Number of prescribed drugs	7·96	4·05	8·27	4·38	<0·001
Learning disabilities	0·3%	6 p.p.	0·3%	6 p.p.	0·736
Physical disability score	0·91	0·29	0·91	0·29	0·569
PRISM Risk score	21·63	16·44	22·89	16·82	<0·001
Frailty Category	3·18	1·06	3·18	1·05	0·624
Emergency hospital admissions	0·35	1·02	0·39	0·97	0·013
Elective hospital admissions	0·52	4·14	0·64	5·09	0·11
Number of (weighted) observations	23013·18		24770·11		

Note: The table shows the averages for each variable used in the matching process, with standard deviations in parenthesis. When a variable average is described by a percentage, the standard deviation corresponds to percentage points (p.p.). Body Mass Index is a categorical variable: 1. Underweight; 2. Healthy; 3. Overweight; 4. Obese. Frailty is a categorical variable: 1. No frailty; 2. Mild frailty; 3. Moderate frailty; 4. Severe frailty. IMD decile is a categorical variable with 1 standing for the more deprived regions and 10 standing for the most affluent regions. This table describes 49,634 unique individuals.

Table 1 shows that the matching and inverse probability weighting are not enough to make the groups fully comparable in all the observed variables. While most of the matched variables are identical, the differences in diabetes, cancer, cardiovascular disease, dementia, social care, living in care home, COPD, number of conditions, number of prescriptions and risk score were statistically significant at 5%, higher in the shielded compared to the non-shielded.

Table 2 shows that the shielded were 1.55 times more likely to die (95% CI 1.43 to 1.67), and mortality increased by 2.3 times on average during pandemic waves for the non-shielded. However, the increase in mortality risk during pandemic waves for the shielded was markedly lower than for the non-shielded. Assuming the same relative increase in mortality during pandemic waves in the absence of the shielding programme, shielding would have reduced mortality risk during these periods by 34% (HR 0.66, 95% CI 0.58 to 0.76). Figure 1 illustrates this effect. The dashed blue line shows the predicted hazard ratio for the shielded population if the shielding policy had not been in effect. The hazard rate in the critical periods would be significantly higher without shielding.

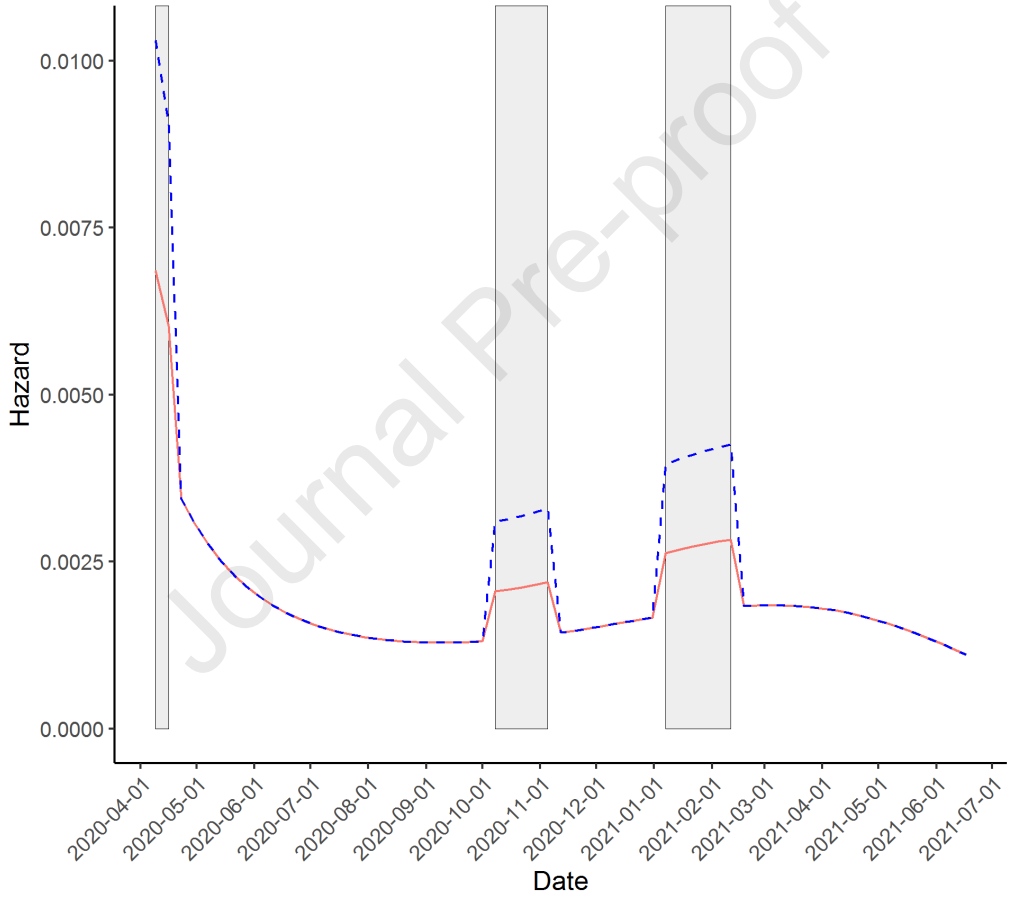
Table 2: Effects of shielding on mortality during pandemic waves.

Dependent variable: All deaths				
	Hazard Ratio	95%	CI	Pr(>|z|)
Shielded	1·55	1·43	1·67	p<0·001
High-risk periods	2·34	2·10	2·59	p<0·001
Shielded in high-risk periods	0·66	0·58	0·76	p<0·001

Note: This regression uses 2,727,495 observations with 49,634 unique individuals. Full regression table and results for the wider high-risk definitions are presented in table S2 and S3, respectively, in appendix.

Figure 1 shows the predicted mortality hazards from this model for the shielded during the pandemic and the estimated counterfactual of the predicted mortality hazard for this group in the absence of shielding. The dashed blue line shows the predicted hazard ratio for the shielded population if the shielding policy had not been in effect. The hazard rate in the critical periods would be significantly higher without shielding. For example, in the third wave, the hazard rate would increase from about 0·25% to roughly 0·40% amongst the shielded in the absence of shielding.

Figure 1: Predicted value of being shielded on the shielded



Dashed line – Shielded without shielding Solid line – Shielded with shielding

Note: The rectangles in the graph identify the waves of the COVID-19 pandemic. Figure S3, in appendix, illustrates the same results for the wider definition of high-risk periods.

Table 3: Separate effects of shielding in each COVID-19 by wave, gender and IMD.

Dependent variable: All deaths			
	Hazard Ratio	95% CI	Pr(>|z|)
Waves			

Shielded in Wave1	0·27	0·21	0·35	p<0·001
Shielded in Wave2	1·01	0·83	1·24	0·903
Shielded in Wave3	0·77	0·64	0·92	0·004
Gender				
Shielded in high-risk periods: Male	0·66	0·54	0·80	p<0·001
Shielded in high-risk periods: Female	0·67	0·56	0·80	p<0·001
IMD				
Shielded in high-risk periods: IMD high	0·75	0·64	0·87	p<0·001
Shielded in high-risk periods: IMD medium	0·62	0·47	0·82	p<0·001
Shielded in high-risk periods: IMD low	0·27	0·16	0·44	p<0·001

Note: These regressions use 2,727,495 observations with 49,634 unique individuals. Waves 1, 2 and 3 correspond to the weeks from April 9th to April 16th, October 10th to November 5th, and December 7th to February 11th, respectively. High deprivation is the baseline. High deprivation stands for people living in the most deprived areas (IMD ≤ 3); Medium deprivation stands for people living in the medium deprived areas (4 ≤ IMD ≤ 7); Low deprivation stands for people living in the least deprived areas (8 ≤ IMD). Tables S4, S5, S6, and S7, in appendix, display the full regressions tables.

Table 3 shows that the strongest effect of shielding was in the first wave (HR= 0.27, 95% CI 0.21 to 0.35). In the third wave, there was also a positive effect of shielding in reducing mortality (HR 0.77, 95% CI 0.64 to 0.92). However, there was no effect of shielding on mortality risk during the second wave (HR 1.01 95% CI 0.64 to 0.92).

Table 3 also shows the effects of shielding during high-risk periods discriminated by gender and IMD. We found no significant interaction with gender (HR of 0.67, 95%CI 0.56 to 0.80 for females against a HR 0.66, 95%CI 0.16 to 0.80 for males, during high-risk periods). However, we do observe a greater effect of shielding in more affluent areas (HR 0.27, 95%CI 0.16 to 0.44) compared to the most deprived areas (HR 0.75, 95% CI 0.64 to 0.87)

Table 4: Effects of shielding in high-risk periods on COVID-19 deaths (underlying cause) and other deaths.

Dependent variable: All deaths				
	Hazard Ratio	95%	CI	Pr(>|z|)
Effect of shielding on COVID-19 deaths	0·43	0·43	0·43	p<0·001
Effect of shielding on other deaths	0·77	0·77	0·77	p<0·001

Note: This regression uses 2,727,495 observations with 49,634 unique individuals. In this sample, 853 individuals died from COVID-19 and 3645 individuals died from other causes. Table S8, in appendix, displays the full regression table.

Table 4 displays a multinomial model dividing the effects of shielding by COVID-19 deaths and other deaths. During COVID-19 waves, both groups of deaths are reduced with shielding.

However, the effect is stronger in reducing COVID-19 deaths (HR 0.43, 95% CI 0.43 to 0.43), compared to other deaths (HR 0.77, 95% CI 0.77 to 0.77).

4. Discussion

During waves of the COVID-19 pandemic the mortality risk for the shielded group increased less than for the matched group with similar profiles of health conditions and demographics. This effect was, however, concentrated in waves 1 and 3 when shielding was explicitly recommended by Government, and we found no effect in wave 2 when shielding had not been recommended. We estimated that shielding overall reduced mortality risk during pandemic waves by 34%, preventing an estimated 496 deaths in Liverpool over the high-risk periods in the study. The effect was greatest where COVID-19 was recorded as the cause of death and was greater in the more affluent areas.

As shown previously,[10] we find that shielded individuals were more likely to die during the pandemic, even after accounting for observable differences in morbidity. However, this is likely to be the result of unobserved mortality risks, for example severity and stage of underlying conditions not reflected in our dataset. This leads us to believe that these results from previous studies are a consequence of lack of comparability between the shielded and non-shielded. That would be consistent with the selection criteria identifying the most vulnerable individuals to be shielded.[7] The use of propensity score matching, and inverse probability weighting are important steps in addressing the comparability issues, but they are limited by how much of the underlying propensity to die is reflected in the observable data.

The problem of lack of comparability can be partially circumvented by analysing the variations from low transmission periods to high-risk periods between shielded and non-shielded groups. In our analysis, we find that during high-risk periods the shielded population risk of death is lower when compared to the non-shielded. This is consistent with a 'switch-on, switch-off' logic, where people may be expected to follow the shielding recommendations more closely if the risk is higher. When the risk of infections and deaths was higher, the recommendations tended to become stricter, while becoming milder during the low-risk periods.[9] This potential explanation is strengthened by our wave heterogeneity analysis. When looking at the individual effect of each of the three waves identified in this analysis, only Wave 1 and Wave 3 show positive effects of shielding in preventing deaths. These correspond to the periods where shielding was fully or partially in effect, while Wave 2 corresponds to a period where shielding was not in effect (Figure S4, in Appendix).[9] Part of Wave 3 (as defined in our model) overlaps with a period where shielding was not implemented nationally, which may explain a smaller effect when compared to Wave 1.

Subgroup analysis showed no significant differences between females and males who are shielded in high-risk periods. Although the literature consistently shows that men and women had different levels of compliance to non-pharmaceutical interventions during the COVID-19 pandemic,[20,21] our results seem to indicate that the shielding recommendations during the higher risk periods may have been followed similarly across genders. When looking at the index of

multiple deprivation, the shielding effect during high-risk periods is providing more benefits to the least deprived. One possible explanation would be that people living in the least deprived areas have better conditions to self-isolate (e.g., bigger houses with spare rooms) when compared to people living in the most deprived areas.[22–24]

The competing risks' analysis showed that shielding during the high-risk periods had a stronger effect in reducing COVID-19 deaths than deaths from other causes. This result would be expected since the shielding policy was designed to reduce risk of infection from SARS-CoV-2. It is likely that there is some miss-classification of deaths as COVID-19 or other, based on underlying cause. For example, some of the other deaths may have had COVID-19 mentioned as a contributory but not underlying cause or due to lack of testing COVID-19 may have not been recorded even though it was the cause. This may have been more likely in the shielded population as they will have had multiple morbidities. This could have led to an underestimate of the effect on COVID-19 deaths relative to the effect on other deaths, in our analysis. Our analysis does suggest, however, that shielding also had an effect in reducing other causes of death during high-risk periods, which may be due to isolation protecting people from other potentially fatal respiratory infections.[25,26]

The main limitation of this paper is that we cannot evaluate the overall effect of shielding across all time periods due to endogeneity caused by selection bias. Still, we can evaluate the effects of shielding during the most critical periods, in which the shielding policy is expected to prevent more deaths. Another limitation is that vaccination was implemented towards the end of the study period (8 December 2020). Since vaccination was given first to the most vulnerable groups, part of the shielding effect may have been due to vaccination. In the first wave however, when no vaccine was yet developed, and isolation was the only COVID-19 infection preventing measure, our results show a stronger effect of shielding.

Furthermore, there were issues associated with the implementation of shielding that could influence our results. For instance, delays in granting shielding status to individuals may have resulted in infections occurring prior to their shielding period, or shielded patients in care homes not being adequately protected from infections introduced from hospital discharges.[27] These could mean that our results underestimate the potential effectiveness of a properly executed shielding program.

The findings of this paper are fundamental in documenting the ability of shielding policies in reducing the negative effects during a public health crisis. The programme in Liverpool targeted a relatively broad population, 10%, compared to an average of 7.8% on the 20% most deprived regions in England[9]. The approach applied in Liverpool using local linked data resources through the Combined Intelligence for Public Health action (CIPHA, www.cipha.nhs.uk) system was similar to the predictive risk model that was later recommended across the country (QCOVID[28]). As with many other control measures introduced during the pandemic[29,30] we find differential effects by socioeconomic status, meaning that such policies tended to increase inequalities. Whilst a number of measures were taken in Liverpool to support isolation for vulnerable groups (e.g., urgent need awards for food and fuel, council tax support, discretionary housing payments to help with rent[31,32]), it is likely that greater support would have been needed to prevent these inequalities. This paper is expected to provide information to policy makers to better understand

the impact of the shielding policy. This information should be incorporated in the design of other public health policies in potential future times of need.

Conclusion

Our results suggest that England's shielding policy substantially reduced deaths in the COVID-19 pandemic. The effect was strongest in reducing deaths from COVID-19 but was also substantial for other causes of death. The protective effect of shielding on mortality disappeared during the second wave of SARS-CoV-2, when shielding was not mandated. In other major phases of the pandemic, where shielding was mandated, the protective effects we observed applied equally to men and women but were weaker for those living in more deprived areas. These results provide important insights to policy makers since future public health crisis may arise where special actions may be needed to protect the most vulnerable, equitably.

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