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Review Paper

Community-oriented actions by food retailers to support community well-being: a systematic scoping review

C. Lee [a, b, *], E.R.W. Bassam [a], I. Kuhn [c]

[a] Cambridge Institute for Sustainability Leadership and Cambridge Public Health. 1 Trumpington Street, Cambridge, CB2 1QA, UK
[b] Cambridge Public Health, Interdisciplinary Research Centre, University of Cambridge, Forvie Site, Robinson Way, Cambridge, CB2 0SR, UK
[c] University of Cambridge Medical Library, University of Cambridge School of Clinical Medicine, Box 111 Cambridge Biomedical Campus, Cambridge, CB2 0SP, UK

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ABSTRACT

Objectives: Growing inequalities, austerity public funding, and the COVID-19 pandemic have contributed to heightened interest in mobilising the assets and resources within communities to support health and well-being. We aimed to identify the type of actions or initiatives by food retail stores intended to support local communities and contribute to well-being.
Study design: A Scoping Review.
Method: A scoping review was conducted in Scopus, Web of Science, and of grey literature to identify the extent of study of food retail stores in supporting community well-being, types and outcomes recorded from community-oriented actions. Data extraction included: population targeted, the content of initiative/action, outcomes recorded and key insights. Studies were grouped into broad categories relating to their actions and objectives.
Results: Actions were associated with either strengthening communities or public health prevention or promotion. Few studies reported clearly on impact, and most accounts of impact on well-being and broader community outcomes were narrative accounts rather than objectively measured. Although rigorous capture of outcomes was absent, there were consistent themes around partnership and community insights that are relevant to the development and implementation of future actions in communities.
Conclusions: This is an under-researched area that may nevertheless hold potential to support the broader public health effort in communities. To provide clear recommendations for specific investments, there is merit in identifying a subset of health and well-being outcomes most likely to be associated with food retailer community actions in order to assess and capture impact in future. We propose that the theoretical underpinning associated with asset-based approaches, which take account of context and community conditions, would be a useful framework for future study.

Introduction

Inequalities, well-being, and community assets

The UK is widely acknowledged to be one of the most unequal societies[1] exacerbated by a decade of austerity in public services disproportionately impacting the poorest regions.[2] The enduring global pandemic and corresponding policies to control it, such as reduced access to public space and constraints on community support groups' ability to operate, have further affected the most vulnerable groups, disadvantaged areas, and worsened structural inequalities through associated turmoil in employment and job security.[3,4]

As economic performance and Gross Domestic Product (GDP) – value added through the production of goods and services – are increasingly criticised as masking such inequalities, community well-being is gaining traction as a useful lens through which to assess a country. Community well-being is conceptualised as '*the combination of social, economic, environmental, cultural, and political conditions identified by individuals and their communities as essential*

* Corresponding author. Cambridge Institute for Sustainability Leadership and Cambridge Public Health. 1 Trumpington Street, Cambridge, CB2 1QA, UK.
E-mail address: Caroline.Lee@cisl.cam.ac.uk (C. Lee).

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for them to flourish and fulfil their potential.[5, p.358] Hence, as well as structural drivers such as education and employment, *community conditions* are also emphasised as highly influential on wider determinants of health and well-being.[6–9] Correspondingly, there has been increasing emphasis in recent policy on place-based strategies and community-centred approaches that understand and identify the role of local resources or 'assets', and their 'mobilisation' in favour of improving well-being outcomes for the population.[9–12]

These assets can be: direct actions; formal services; infrastructure around organisations, such as partnerships and networks of support between people in a community; the built environment and community spaces; community knowledge and insights, and human resources like staff and volunteers.[7,9] The impact of these aspects, specifically on health, well-being and inequalities, has hence become a focus both of study and theory development on asset-based approaches.[13,14]

Social responsibility

Research and evaluation of the role of community-centred and asset-based approaches have, however, almost entirely focused on the statutory, voluntary and community sectors. Corporations, whether in retail, finance or insurance, nevertheless have well-established Corporate Social Responsibility (CSR) strategies aspects of which may contribute to community conditions and social infrastructure.[15] We suggest that many business operations, goods and services have the potential to affect dimensions of human well-being, for example: indirectly through support to community groups and buildings, grant funding and donations; or directly by designating staff with responsibilities for making community links and get involved with local groups and 'good causes'.

A 'unique' position?

As well as supporting livelihoods and local economies as providers of employment, corporate organisations can influence education and training, community connections, and physical and mental health (and behaviours) through the supply of goods and services. Supermarkets, large self-service food stores which are a recognisable face of food retail, also have what is described as an 'anchor positioning', being present in thousands of localities and interacting daily face-to-face with the public both as customers and workforce. Indeed, the 'lynchpin' status of food stores within communities has been highlighted in the well-managed supply of essentials during the COVID-19 pandemic, a factor boosting trust in the sector.[16]

We argue that a community-centred and asset-based lens offers a strong rationale through which to consider food retailers more strategically as contributors to the well-being of their catchment communities. Supermarkets in particular need to find a way to bring together economic and social value for customers and their communities at the time of considerable change and high competition.[17] In order to gain a solid understanding – and a strong foothold – with their customer base, hyper-local insights which could include key drivers for well-being could be key.

Aims

Given the context of enduring inequalities across the UK and austerity budgets for public services, exacerbated by the global COVID-19 pandemic, there is a need for action to improve community well-being. Accepting that community-centred and contextualised action is important to addressing inequalities, the evidence base is nevertheless still developing, even in respect of the statutory and voluntary sector.[14,18,19] We are still further behind in understanding what role and impact the private sector has in this space, so there is an urgent need to discover the current state of play. By performing a global scoping review of community-oriented initiatives by food stores and supermarkets – as an example of food retail embedded in communities – we aimed to identify the type of actions engaged in which could support well-being outcomes in local communities.

Methods

To determine the scope of the published literature and the extent to which impact is reported, we asked: what kind of studies have been conducted on food retailer actions to support communities; what are the types of activities described; and what evidence of outcomes or impact on community well-being is presented? In line with the stated purposes for a scoping review,[20] we followed the PRISMA guideline[21] and updated guidance[22] to examine the types of evidence published, identify key concepts and gaps in the research.

Search strategy

Pilot searches were run through Scopus in July 2020 using a combination of search blocks for (1) Community engagement intervention; (2) Food retail organisations and food shops; (3) deprived communities; (4) outcomes associated with well-being. Search strategies were then refined with the keywords being identified through seed papers and iterative searches and run in February 2021 for Scopus and Web of Science Core Collection. Further references were found via forward and backward citation tracking of included papers and tracking of included papers using www.connectedpapers.com. A search of the grey literature was carried out using a sequence of Google strategies, with five pages of results being screened per search string. English language websites of key food retailers were also searched for published and unpublished literature. See Appendix A for full strategies.

Inclusion criteria and study selection

Two researchers independently screened results against the inclusion criteria in EndnoteX9, and papers were included if they were based on: *Primary research* (studies or evaluations of community interventions involving food retail stores); *Descriptive reports* of community interventions involving food retail stores; *Secondary research* (reviews of community interventions involving food retail stores). Papers were excluded if they had no direct mention of either food retail stores or actions related to community well-being. We also excluded papers describing well-being-related interventions if the food retail stores were not actively engaged (e.g. childhood obesity actions not initiated by the store or involving actions within the store). The decisions, where either reviewer was uncertain, were discussed and reconciled with any disagreements referred to a third reviewer.

Charting the results

Data were extracted on the actions described in the full papers according to a template based on the TiDier checklist,[23] including population/issue; the aim of initiative; inputs/delivery; type of outcome reported; and any qualitative observations or insights pertinent to the review questions. In keeping with the ambitions of a scoping review to largely 'map' the evidence, no formal assessment of quality was performed.[22] Basic analysis was carried out to map the distribution of studies by type and population of interest, and tables were produced to summarise the range of actions

covered by the literature, content, inputs and any reported outcome. To provide a synthesis of the literature, we considered alignment between the different types of action/intervention identified and a UK framework of community-centred approaches to supporting well-being (10, 18). We then created a final categorisation, according to which we present our results, below.

Results

The searches of electronic databases found 5003 titles and abstracts once duplicates were removed; 5083 records were identified, including 80 from hand searches, grey literature searches, connectedpaper.com and reference mining (see Fig. 1), and the titles and abstracts of these were screened to decide whether they were in scope. Then 69 papers were retrieved and assessed. This resulted in 24 papers extracted and coded to produce a 'map' of literature in this area. Table 1 presents the included studies and data charting summary (see Table 2).

Type of paper

There was a range of documents captured (24), reflecting the breadth of sources searched, with research papers being the most frequent (11). Of the research papers, methods included four case studies, two evaluations, two papers on the same natural experiment, one combination of a literature review and multistage qualitative research, one matched case-control, and one (adapted) Asset-Based Community Development collaboration. Six reports published by either retailers or policy actors were included (6), four discussion papers (4), two web-based articles (2), and one conference paper (1).

Population of interest

The majority of studies were carried out in the UK, with a further nine of relevance both to the UK and global food retail practice. In terms of the population targeted by the initiative, most focused on a neighbourhood or city with high deprivation (13) or a targeted 'vulnerable' population, such as people with specific health conditions (6), and one paper covered both (1). The remaining actions reported were either non-targeted or not well described (4).

The food retailer approach to supporting the community

Two broad categories of intervention were identified out of the process of charting and synthesis: strengthening communities; and public health promotion and prevention. Further sub-categories emerged based on the detail of actions, e.g. 'strengthening communities' included: community regeneration; community cohesion; and community infrastructure. 'Public health promotion and prevention' comprised: promotion of healthy lifestyles; and prevention or control of specific health conditions or diseases. Some papers straddled sub-categories, either because single interventions incorporated multiple approaches; or multiple interventions were covered by the same paper (e.g. in the case of a retailer report).

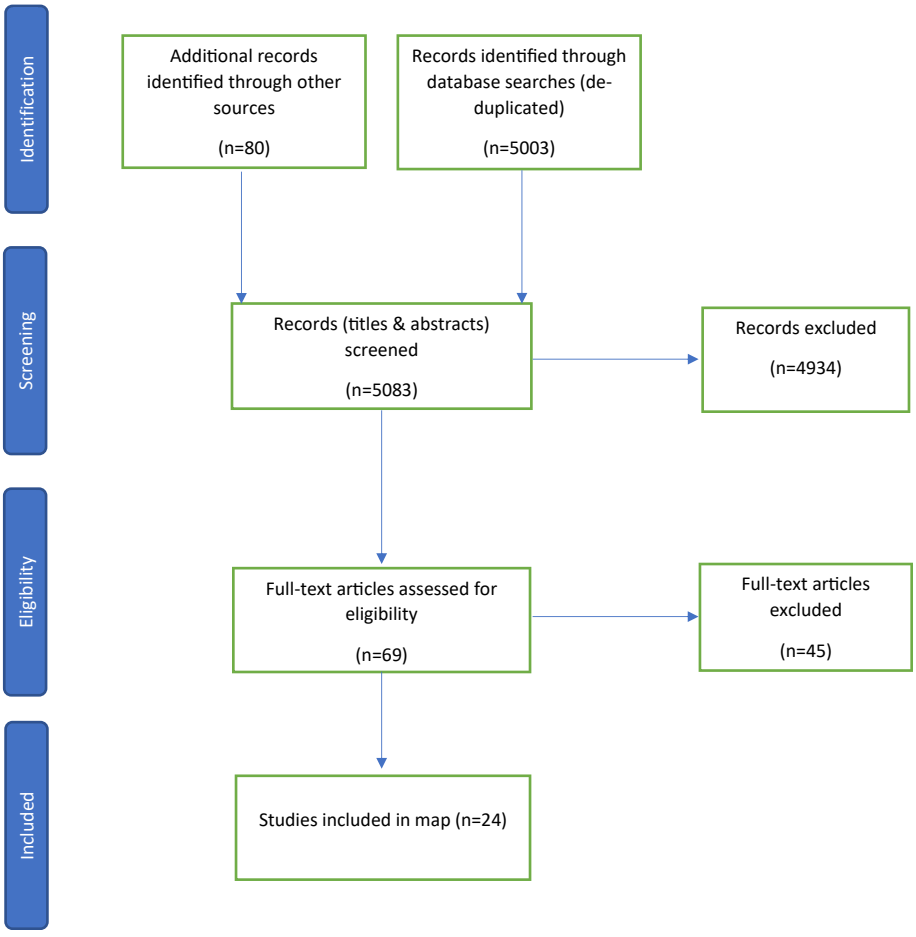

Fig. 1. PRISMA Study Selection flow chart.

Table 1
Data charting summary.

Bibliographic details	Type of paper	Issue	Intervention	Activities	Intervention type	Process measures	Health outcomes (individual)	Health outcomes (community)	Well-being (individual)	Well-being (community)	Economic or financial assessment
Cantaragiu R (2019)[31]	Research paper	Food waste & poverty	'The Food Bank' project	Co-financing project and goods donation.	Strengthening communities	✓					✓
Carley M et al. (2001)[24]	Report	Regeneration & sustainability	Multiple e.g. Borough Market Partnership, Kwik Save & Healthy Castlemilk pensioners voucher scheme, Seacroft Tesco Partnership	Employment schemes, voucher schemes, childcare programs, local business support.	Strengthening communities	✓		✓		✓	✓
Casanas B et al. (2011)[32]	Conference paper	Elderly Influenza	Vaccination program	In-store pharmacy resources for vaccine administration.	Public health	✓	✓	✓			✓
Colls R and Evans B (2008)[45]	Discussion paper	Child obesity	Exploration of in-store healthy eating strategies	Nutritional signposting and healthy eating in-store guided tours.	Public Health						
Cummins et al. (2005)[25]	Research paper	Deprivation - diet and psychological health	Store development	Introduction of large-scale food retailing.	Multiple: strengthening communities; public health	✓	✓	✓		✓	✓
Cummins et al. (2008)[26]	Research paper	Deprivation - diet, psychological health and local regeneration	Store development & local partnership	Introduction of large-scale food retailing & associated local employment scheme	Multiple: Strengthening communities; public health	✓	✓	✓	✓	✓	✓
Gittelsohn J et al. (2006)[47]	Research paper	Obesity & related chronic disease	Healthy Stores Program	In-store cooking demonstrations, recipe cards, mass media support.	Public health	✓					
Gore R et al. (2020)[33]	Research paper	Evaluation of hypertension prevention program	REACH FAR intervention, including 'Shop Healthy' Program	In-store healthy food promotion combined with local health education and screening.	Public health						
Hepburn P and Thompson M (2018)[27]	Report	Deprivation	Hattersley & Mottram regeneration partnership.	Introduction of large-scale food retailing, long-term unemployment scheme and funding for community hub.	Strengthening communities				✓	✓	✓
Imrie R and Dolton M (2014)[28]	Discussion paper	Urban regeneration	Store development and local partnerships	Introduction of large-scale food retailing, building affordable housing and infrastructure investment.	Strengthening communities	✓					
KPMG LLP 2018[34]	Report	Tesco's economic & social contribution to the UK	Multiple local and national interventions	Funding community champions, charity	Multiple: Public health;					✓	✓

				partnerships, funding community projects, food donation, community spaces.	strengthening communities					
Lee R M et al. (2015)[35]	Research Paper	Obesity & related chronic disease amongst an African American community	Eat Right-Live Well! campaign	Stock changes, labelling, advertisements and price reductions; in-store taste tests and recipe cards; community events; staff training.	Public health	✓			✓	
Marques F et al. (2010)[43]	Research Paper	Sustainability and inequality	Community initiatives and environmental preservation	Food bank donations and funding neighbourhood initiatives and seed donations.	Strengthening communities					
McEachern MG, Warnaby G. (2019)[41]	Discussion Paper	Health promotion and community development	Health, community and employment initiatives	Blood pressure checking, apprenticeships, community education, seasonal events.	Strengthening communities					
McQuaid R et al. (2005)[29]	Research Paper	Unemployment	'Alloa Initiative' partnership programme i.	Employment programme - teaching personal presentation, teamwork, retailing skills and customer care.	Strengthening Communities			✓	✓	
Onemanchester (2017)44	Website (case study)	Food poverty and social stigma	Support for a community shop	Goods donations by supermarkets and cooking classes.	Strengthening communities					
Price C et al. (2004)[36]	Research paper	Ageing in place	University-community-retail partnership to facilitate community education	In-store community workshops.	Public Health	✓	✓			
Reilly M (2017)[37]	Website (case study ×3)	Community development	Multiple local community case studies	In-store community holistic space; yoga classes; bird feeding community education and festival sponsorship.	Multiple: strengthening communities and public health					
Rybaczewska M and Sparks L (2020)[42]	Research paper	Community development	Multiple local community interventions	Funding local projects, breakfast clubs, free food delivery	Strengthening communities				✓	
Surkan PJ et al. (2016)[46]	Research Paper	Obesity & related chronic disease amongst an African American community	Eat Right-Live Well! campaign	Stock changes, labelling, advertisements and price reductions; in-store taste tests and recipe cards; community events; staff training.	Public health	✓	✓			

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Table 1 (*continued*)

Bibliographic details	Type of paper	Issue	Intervention	Activities	Intervention type	Process measures	Health outcomes (individual)	Health outcomes (community)	Well-being (individual)	Well-being (community)	Economic or financial assessment
Tesco and Groundwork 2021[38]	Report	COVID-19 pandemic	National charity partnership	Funding for community groups	Strengthening communities			✓		✓	
The Co-operative (2019)[39]	Report	Corporate social responsibility	Multiple local and national interventions	Steel Warriors Partnership repurposing confiscated knives into gym equipment, funding community groups etc.	Multiple: Strengthening communities and public health					✓	✓
The National Charity Partnership, 2018[40]	Report	Diabetes	National Charity Partnership	Fundraising; event facilitation; and education and awareness raising	Public health	✓	✓	✓			
Wrigley N et al. (2002)[30]	Discussion paper	Deprivation	Seacroft Partnership	Introduction of large-scale food retailing, long-term unemployment scheme.	Strengthening communities					✓	

Strengthening communities

Table 1 shows that the majority of studies corresponded to 'strengthening communities' actions. Within these, seven papers covered actions which were part of a broader *community regeneration* programme.[24–30] Specific actions included: store support to affordable housing; local employment initiatives; and funding the creation of a community 'hub' intended to bring community groups together. Inputs often involved collaborations or partnerships between supermarkets and local authorities, local or national charities, employment or educational training providers, educational institutions, housing associations, community groups and faith groups.[24–40] Resource inputs included funding for community spaces and new job opportunities or job training.[27,30,33,40]

A subcategory included activities we interpreted as fostering *community cohesion*, with food shops offering shared space in-store, in one example for educational activities on 'ageing in place', or well-being activities and classes.[33,36,37,41,42] Inputs included the free usage of store space; and/or staff time to host groups and events. One report highlighted the role of 'Community Champions', dedicated staff whose role is to assist and enable local projects.[34]

A final subcategory related to supporting *community infrastructure*.[31,34,38,39,43,44] Actions included grant funding or donations to support communities in running emergency services, such as food banks, and assisting with the development of outdoor activity spaces. Environmental protection was a common theme, e.g. waste reduction and sustaining the natural environment, e.g. connecting individuals to wildlife or promoting sustainable practices through the funding or facilitation of educational events and activities.[34,37,41] Typically, inputs predominately involved goods (food donation), and financial resources, assigned either through charity partnerships, direct donations to groups or project-based funding, but they could also include donations of staff time and store space.

Public health promotion and prevention

A second approach to supporting communities are actions aligned with health promotion or prevention. Those with a promotion focus included healthy lifestyles work delivered through in-store events, such as food tours, tastings and educational events, and supporting fitness and sports.[34,35,37,39,44,45] Inputs included: financial resources for promotional material; training and equipment; direct grants to community groups; and staff time and training for in-store healthy eating tours.

Those focusing on prevention or control of specific health conditions or diseases[32-34,39-31,47] included: in-store vaccination programmes; awareness and educational programmes for conditions like hypertension; in-store blood-pressure monitoring; and campaigns on the heart or circulatory diseases, or loneliness. Inputs included donations of space (both for storage of medical equipment and store-space for demonstrations), funding for training and resources (educational material and medical equipment) and staff time to assist with programmes.[32,34,36,37,46] Also included here were financial donations towards cause-specific awareness campaigns and collaborations and partnerships on a specific prevention strategy, for example, the Tesco/British Heart Foundation and Diabetes UK charity partnership.[40]

Reported outcomes and impact

The extent to which outcomes were formally assessed reflects the breadth and type of literature included, and potentially also the duration of the study and intervention (Tables 1 and 3). Indeed some – predominantly discussion papers and small case studies –

Table 2
Data charting of inputs, partnerships, and location.

Bibliographic details	What?	Who?	Where?	Duration
Cantaragiu R (2019)[31]	Collaborations and Partnerships, community resources	Lidl and Junior Chamber International	Romania	2 years (at time of publication)
Carley M et al. (2001)[24]	Collaborations and Partnerships, community resources	Various – Sainsbury's, Tesco, Kwik Save, Borough Market, local businesses, local community groups and local councils	UK-wide (various locations)	Various/unspecified
Casanas B et al. (2011)[32]	Community resources, collaborations and partnerships	Publix supermarkets, Publix Pharmacy and University of South Florida	Florida, USA	1 year
Colls R and Evans B (2008)[45]	Community resources	Tesco, Sainsbury and Asda	UK-wide	Unspecified
Cummins et al. (2005)[25]	Collaborations and partnerships, community resources	Tesco, Glasgow Chamber of Commerce, a local training college, and regeneration companies	Springburn, Glasgow, UK	1 year
Cummins et al. (2008)[26]	Collaborations and partnerships, community resources	Tesco, Glasgow Chamber of Commerce, a local training college, and regeneration companies	Springburn, Glasgow, UK	1 year
Gittelsohn J et al. (2006)[47]	Community resources	Supermarket and local media	Republic of the Marshall Islands	10 weeks
Gore R et al. (2020)[33]	Collaborations and partnerships, community resources	REACH FAR programme involving supermarkets, faith-based sites, restaurants, New York City Department of Health and Mental Hygiene	New York and New Jersey, USA	24 months
Hepburn P and Thompson M (2018)[27]	Collaborations and partnerships, community resources and community infrastructure	Tesco, Tameside MBC, Jobcentre Plus, Work Solutions, The Skills Funding Agency, and Peak Valley Housing Association	Hattersley and Mottram, Greater Manchester, UK	11 years (plus further 10 post-paper publications)
Imrie R and Dolton M (2014)[28]	Community infrastructure, community resources, collaborations and partnerships	Planners from Lambeth, local councillors, the architects of Tesco's scheme, Collado Collins, Tesco's planning consultants, GL Hearn, and other development organisations, such as London Thames Gateway Development Corporation (LTGDC) and Leaside Regeneration Company (LRC)	Bromley-by-Bow, East London, UK	length of study 12 months, intervention unspecified
KPMG LLP (2018)[34]	Community resources, collaborations and partnerships	British Heart Foundation, Diabetes UK, Cancer Research, Groundwork, FareShare, Trussel Trust and local community groups, local community stakeholders, local community groups	UK-wide	1 year
Lee et al. R M (2015)[35]	Community resources, collaborations and partnerships	Johns Hopkins Bloomberg School of Public Health (and student assistance), local community groups, registered dietitian	Baltimore, USA	9 months
Marques F et al. (2010)[43]	Community resources	None specified	Sao Paulo, Brazil (various cities)	Unspecified
McEachern M G and Warnaby G (2019)[41]	Community resources	Independent cooperative retailers, local schools and community groups	Greater Manchester, UK	Interviews carried out between 2015 and 2016, intervention lengths unspecified
McQuaid R et al. (2005)[29]	Employment initiatives, collaborations and partnerships	Clackmannanshire Council, Jobcentre Plus, Scottish Enterprise Forth Valley (the Local Enterprise Company), and Triage Central	Alloa, Scotland, UK	8 weeks (length of Alloa Initiative Employability Training Course), total length of study unspecified
Onemanchester (2017)[44]	Community resources	One Manchester Community Fund, FareShare, Tesco, M&S, Healthy Me Healthy, Rainbow Haven project, University of Manchester	Anson, Manchester, UK	Unspecified
Price C et al. (2004)[36]	Collaborations and partnerships, community resources	Specialist university faculty, Ohio Dept of Aging, local area agency on aging, local AARP chapter, county extension agents and local students	Ohio, USA	1+ years

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Table 2 (*continued*)

Bibliographic details	What?	Who?	Where?	Duration
Reilly M (2017)[37]	Community resources, community infrastructure, collaborations and partnerships	Local festival and schools	Wisconsin, Texas and Colorado, USA	Unspecified
Rybaczewska M and Sparks L (2020)[42]	Community resources	None specified	Edinburgh, Glasgow and Falkirk, Scotland, UK	Unspecified
Surkan PJ et al. (2016)[46]	Community resources	Local organisations and faith groups	Baltimore, USA	9 months
Tesco and Groundwork (2021)[38]	Collaborations and partnerships, community resources	Groundwork	UK-wide	4 months
The Co-operative (2019)[39]	Collaborations and partnerships, community resources, community infrastructure	Various e.g. Steel Warriors, British Red Cross, Keep Britain Tidy	UK-wide	1 year
The National Charity Partnership (2018)[40]	Collaborations and partnerships, community resources	British Heart Foundation, Diabetes UK	UK-wide	3 years
Wrigley N et al. (2002)[30]	Community infrastructure, community resources and partnerships and collaborations	Seacroft Partnership, in association with Leeds City Council, property developers Asda St James, the employment services agency, the shop workers' union USDAW and the East Leeds Family Learning Centre	Seacroft, Leeds, UK	Unspecified

gave no account of outcomes.[37,41,43–45] Due to the diversity of actions covered by the literature, varied study designs, and no common or consistent measure of outcomes, a clear picture of effectiveness or concrete impact is not discernible.

The most commonly measured aspect of interventions related to implementation (n = 11), for example, of in-store healthy eating initiatives or of new retail development in a food 'desert';[25,26,35,47] community well-being outcomes (n = 10); and economic and job outcomes (n = 11). Individual health (n = 6) and community health outcomes (n = 6) were infrequently reported, with change to individual well-being (n = 2) the least cited. For public health promotion or prevention actions, studies measured outcomes both quantitatively and qualitatively. Two were natural experiments focused on the same healthy eating initiative.[25,26] These were the most comprehensive reports on outcomes and included bivariate analysis of dietary outcomes for fruit and vegetable intake, self-reported using the General Health Questionnaire (GHQ-12) and qualitative focus groups. Only marginal improvements in health were observed, however, and reported as not statistically significant.[25,26] This was also the case for studies interested in healthy eating, recording increases in sales of fruit and vegetables as a proxy for impact on customer health.[46]

Focus on outputs over outcomes

Whether the focus was more closely allied to health promotion or community development, studies fell short of reporting on effectiveness and impact and instead were limited to recounting outputs rather than outcomes. Commonly reported were counts of actions delivered (n = 14), such as high uptake and successful vaccine administration, and delivery of a waste reduction initiative.[29,31,32] This was similar in retailers' own reporting of CSR or Environment and Sustainability Goals (ESG).[34] For example, national charity partnerships and community grants schemes were largely evaluated according to amounts donated to community groups, the number of projects supported, groups reached, and by volunteer hours.[34,38,40,48] Some gave breakdowns by sub-group of beneficiaries, e.g. children and young people, older people, socially isolated people and people/households on a low income, and some used case studies to provide more insights into the impact on individuals or groups.

Even when striving to report on Social Return on Investment (SROI), assessment of the social return largely failed to pinpoint any difference made to health or well-being. While Cantaragiu estimated a positive SROI from a food waste initiative in Romania, the paper did not detail how changes in 'mentalities, community involvement, reduction of social exclusion' were assessed.[31, p. 509] Overall, the reporting of any difference made to community well-being lacked specificity, and consideration of 'success factors' tended to dominate the narrative. However, this did enable a number of common insights on implementation to be drawn out.

Community knowledge and insights

As well as social and economic value, one study emphasised the importance of knowledge and understanding of local challenges and context.[42, p. 4] Similarly, Surkan et al. highlighted the 'community driven' approach conceived by the store owner as influential in securing financial and in-kind support and flexibility,[46, p. 119] and Lee et al. the owner-initiation resulting in greater enthusiasm, commitment, and impetus for the intervention.[35, p. 855] Being a family business with a long community history was also felt also to be influential to the successful implementation of a 'culturally adapted' programme.[33, p. 1535]

Conversely, a failure to understand the community could reportedly result in unintended consequences. A study of a regeneration development, including a new supermarket, intentionally located on the periphery of a residential area to create a

Table 3
Type of outcome reported.

Type of outcome reported	Number of studies
Process outcomes	11
Health (individual) outcomes	6
Health (community) outcomes	5
Well-being (individual) outcomes	2
Well-being (community) outcomes	10
Economic or financial assessment	9

more outward-looking community and stimulate 'bridging' social capital'[49] in practice led to a 'hollowing out' of the community, both in a physical and a social sense.[27, p. 22]

Partnership and effective partnerships

Partnerships could be based on the sharing of knowledge or skills,[25–27,29–31] donation of financial resources,[28,34,37,38] or a combination of these.[40] They were also reportedly key to access and enabling community collaboration, particularly where partners were well embedded in their community.[33,39] Carley et al. highlighted the overall success of a 'strategic, participative approach' to ensure retail revival fostered long-term social and economic benefits, incorporating actors across different levels of decision-making.[24, p. 67] Whilst predominantly capturing employment outcomes, McQuaid et al.[29] also adopted frameworks to draw out features of successful partnerships to guide future practice, such as: having a clear strategy, incentives for collaboration, and making the best use of partners' resources and skills. Again, a partnership model was felt to be influential in enabling corporate resources to be mobilised for a vaccination programme,[32] and features such as 'flexibility, pragmatism and support for one another' were highlighted as important to success.[40, p. 19]

Community insights and partnership are both key features of Asset-Based Community Development (ABCD), a five-stage process, adapted by Price et al.[36] in their ageing in place community education study, beginning with the identification of partnerships and their strengths and closing with the embedding of more sustainable community outreach.[50]

Discussion

Food retailer initiatives towards local communities is an under-researched area that may nevertheless have the potential to support the broader public health effort in communities. 'Building back' from the global pandemic depends not only on the immediately pressing aspects of financial security and material well-being but also on whether we have the economic, social and environmental assets and infrastructures in place to foster well-being and build resilience.[51–53]

This review has shown, even within a relatively small body of literature, that food retailers are involved in diverse actions with a bearing both on community conditions and on health behaviours. We consider that these actions could contribute to the community conditions influential to well-being, as seen through the community-centred and asset-based lenses outlined in the introduction to this paper. Strengthening communities actions involved contributing resources (or assets) of time, money (large and small grants to local groups), goods and space, and were often underpinned by development of partnerships and collaborations. These have the potential to be felt locally in terms of improved civic infrastructure, built environment, better connections between people or groups, and increased capacity in the community and voluntary sector to provide support and activities. From time, space, goods and financial resources dedicated to health promotion and health care actions, changed behaviour amongst groups could cumulatively make a difference to dietary health or physical activity in the local population and/or protection from disease. Yet, we found that impact on community well-being was not actively captured in any of these studies, and reporting of health and well-being-related outcomes that might contribute to any change was generally weak. Intent to assess the impact of community oriented CSR actions is present, however, as observed in the growing attention to social value and social return on investment, e.g. in CSR/ESG impact reporting. Nevertheless, we have shown that to date, these have been 'high level', dominated by the presentation of 'counts' of outputs and not the evaluation of outcomes in the context of local areas. This is a significant barrier to understanding what works in what circumstances and where CSR strategies and actions of food retail and business more broadly can effectively support the local infrastructure for community resilience.

To this evidence gap, we add the challenge to food retailers as businesses. While philanthropic donations and ad hoc community investment is a feature of supermarket CSR, there is increasing pressure on companies to create 'shared value' by aligning business goals and competencies with the development priorities of local stakeholders.[17,54] The studies included in this review suggest there could be movement in this direction, in that incorporating community knowledge and resources is reportedly influential to the successful implementation of actions. Alongside the aforementioned influence of investment in partnerships, these are key aspects of community-centred asset-based working.

We argue, therefore, that the theoretical underpinning associated with these approaches (reflecting the human, physical and organisational resources), which includes consideration of context and community conditions, could be a useful framework for future study of food retailer community actions. We recommend that future research also focus in depth on identifying a subset of health and well-being outcomes most likely to be associated with such initiatives and attempt to identify where social value is accrued across local systems.

Limitations

This was a complex search across a broad literature and several disciplines. Pilot searches were conducted to test search string sensitivity, including in application to searches of grey literature. While care was taken to ensure the search strategy was as inclusive as possible within our parameters, it is possible that some literature of relevance was missed through indexing or other reasons.

Author statements

Ethical approval

Ethical approval was not required as this is a scoping review of extant literature.

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Competing interests

We have no conflicts of interest to declare.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.puhe.2021.09.029.

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Review Paper

Development of a critical appraisal tool for models predicting the impact of 'test, trace, and protect' programmes on COVID-19 transmission

J.W. Frank [a, *], G. Marion [b], A. Doeschl-Wilson [c]

[a] Usher Institute, University of Edinburgh, Teviot Hall, Edinburgh EH8 9DX, Scotland, UK
[b] Biomathematics and Statistics Scotland, James Clerk Maxwell Building, Edinburgh EH9 3FD, Scotland, UK
[c] The Roslin Institute, University of Edinburgh, Roslin Institute Building, Easter Bush EH25 9RG, Scotland, UK

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ABSTRACT

Objectives: To develop a critical appraisal tool for non-computational-specialist public health professionals to assess the quality and relevance of modelling studies about Test and Trace (and Protect – TTP) programmes' impact on COVID-19 transmission.
Study design: Decision-making tool development.
Methods: Using Tugwell et al.'s 1985 Health Care Effectiveness equation as a conceptual framework, combined with a purposive search of the relevant early modeling literature, we developed six critical appraisal questions for the rapid assessment of modeling studies related to the evaluation of TTP programmes' effectiveness.
Results: By applying the critical appraisal tool to selected recent COVID-19 modeling studies, we demonstrate how models can be evaluated using the six questions to evaluate internal and external validity and relevance.
Conclusions: These six critical appraisal questions are able to discriminate between modeling studies of higher and lower quality and relevance to evaluating TTP programmes' impact. However, these questions require independent validation in a larger and systematic sample of relevant modeling studies which have appeared in later stages of the pandemic.

Introduction

Decision-making related to the COVID-19 pandemic has made extensive use of information from studies using complex mathematical models. Specialist technical and contextual knowledge is necessary for detailed 'critical appraisal' of such studies. However, public health professionals lacking relevant technical knowledge are often required to evaluate quality and relevance of modelling studies.[1] It would be useful for non-specialists, especially public health professionals with only standard (i.e. MPH level) training in epidemiology, to be able to quickly assess when to bring new COVID-19 modeling papers (appearing in large numbers since the start of the pandemic) to the attention of modeling specialist colleagues.

Several authors[2–6] have developed approaches to assess internal and external validity for modeling studies. However, these tools are generic and encompass a broad range of models, spanning clinical diagnostic/prognostic decision tools through to burden-of-illness estimates and cost-effectiveness analyses.

We address this gap by developing a "critical appraisal" tool, for non-specialists to efficiently screen COVID-19 modeling studies for quality and relevance to COVID-19 test trace and protect (TTP) programmes. TTP programmes test individuals, track or trace potential contacts of positive cases and then protect public health by providing advice regarding isolation or quarantine to both cases and contacts (We would cite Grantz et al.[7] as providing a particularly clear and generalizable pictorial description of precisely how TTP programmes work.). Specifically, we devise a critical appraisal question checklist to address the question: "*What are the key indicators of modeling study quality and relevance, for evaluation of TTP programme overall effectiveness in reducing COVID-19 transmission?*"

* Corresponding author. 40 East Barnton Avenue, Edinburgh EH4 6AQ, UK. Tel: +44 0 7515198002.
E-mail addresses: john.frank@ed.ac.uk (J.W. Frank), glenn.marion@bioss.ac.uk (G. Marion), andrea.wilson@roslin.ed.ac.uk (A. Doeschl-Wilson).

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Methods

Our objectives were to 1) identify the key modifiers affecting TTP programme effectiveness in reducing COVID-19 transmission; 2) generate less than ten easy-to-use critical appraisal (CA) questions that allow non-modelers, with only basic epidemiological training, to assess the quality and relevance of modelling studies for evaluating such effectiveness; and 3) demonstrate application of the proposed CA questions using purposively identified modelling studies.

We applied *Iterative Measurement Loop* methodology (see Tugwell et al.[8]), an established critical appraisal (CA) tool for analyzing the population-level effectiveness and efficiency of competing healthcare interventions, to evaluate TTP programme effectiveness in reducing COVID-19 transmission. This led to a comprehensive list of factors affecting TTP programme effectiveness, based on the 'Healthcare Effectiveness Equation' (see Box 1).[8]

We adopt the standard CA tool approach (see CASP and Oxford CEBM websites[9,10]) of identifying a checklist of questions that, in sequence:

1. Screen out studies not directly relevant, i.e. determine whether the study in question *addresses key aspects*, identified through *Iterative Measurement Loop* methods[8] *that co-determine TTP programme overall effectiveness.*
2. Assess *internal validity*, i.e. are study findings logically derived from the data presented and analysed?
3. Assess *external validity*, i.e. are the findings applicable to the reader's *particular decision-making situation*? In this case, the evaluation of a specific COVID-19 TTP programme (e.g. as currently deployed in UK and most HICs.)

To generate specific CA questions, we performed a *purposive* review of modeling papers that assess TTP programme effectiveness, to identify *key shortcomings* with respect to the three criteria earlier. This was limited to studies of high-income countries (HICs), and papers published (or listed on relevant pre-print archives) from early 2020 to May 1, 2021. The review was purposive, rather than systematic or narrative, in that modeling papers fitting the inclusion criteria were sampled until no further generic shortcomings were being identified – so-called 'saturation.'[11] We were unable to validate against an independent sample of relevant TTP modelling papers, because we exhausted the most widely cited studies published during the study period in developing the CA questions. Such validation, in particular for low- to middle-income countries (LMICs), has therefore been left to other investigators, who will need to use a representative sample of suitable modelling papers published later in the pandemic.

Results

Critical appraisal question conceptual framework: How do COVID-19 TTP programmes work, and what are the key modifiers of their effectiveness?

Fig. 1 provides a schematic description of the rather complex string of processes involved in TTP programme implementation. These can be distinguished by direct effects ('A' in Fig. 1) associated with the positive-tested (index) case and by indirect effects ('B') associated with the contacts of that case. Box 1 shows the key modifiers of any TTP programme's effectiveness that can potentially diminish its overall impact on COVID-19 transmission, as derived from the Iterative Measurement Loop associated with the factors in Fig. 1, based on the 'Healthcare Effectiveness Equation'.[8]

Purposive literature search

The most relevant modelling studies for generating checklist questions were identified through targeted search in Google Scholar and widely used pre-print servers (e.g. bioRxiv, medRxiv), using the keywords 'COVID* AND model* AND test* AND trace/tracing AND protect/quarantine/isolate AND effect,' and by hand-

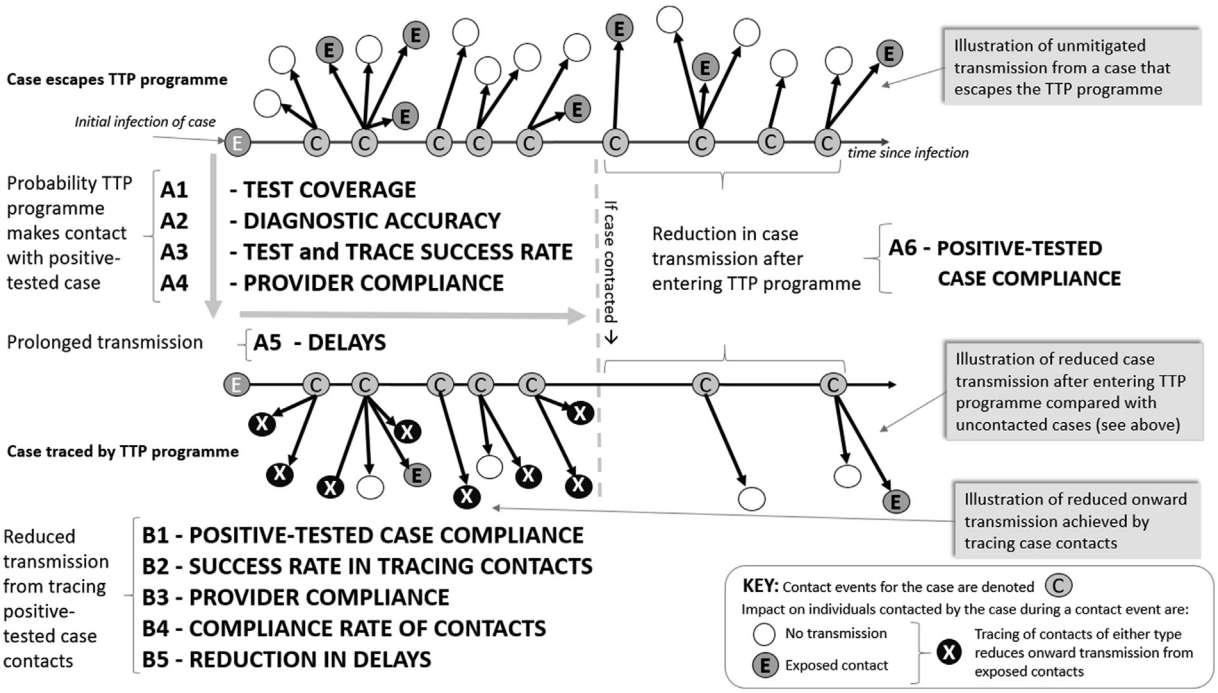

Fig. 1. Key Modifiers of TTP Programme Effectiveness. TTP, test trace and protect.

Text Box 1: Key Modifiers Affecting test trace and protect (TTP) Programmes' Overall Effectiveness

A. DIRECT EFFECTS ON SECONDARY CASES* FROM ISOLATING *TEST-POSITIVE (INDEX) CASES*.

1. **TEST COVERAGE:** % of all transmitting cases obtaining a COVID-19 test result within the time window required for potential impact from TTP actions
2. **DIAGNOSTIC ACCURACY:** % of truly infectious cases correctly identified by testing = test sensitivity under real-world conditions (including swab technique), potentially varying by time since infection
3. **TEST and TRACE SUCCESS RATE:** % of positive-tested persons notified by TTP staff of test result/need to act (e.g. isolate)
4. **PROVIDER COMPLIANCE FOR CASES:** proportion of advice given to test-positive cases (e.g. re isolation) which is scientifically accurate
5. **TTP PROGRAMME DELAYS**% of total infectiousness potential averted in those testing positive, considering all relevant delays
6. **COMPLIANCE WITH ISOLATION:** % of test-positive cases who comply with the isolation advice, prorated by degree of compliance and effectiveness of recommended isolation measured in terms of remaining % of total infectiousness potential averted

COMBINED WITH:

B. INDIRECT EFFECTS ON ONWARD TRANSMISSION BY *CONTACTS* OF INDEX (TEST-POSITIVE) CASES*: all the analogous factors affecting the effectiveness of interruption of further transmission by the contacts of the test-positive case:

1. **CONTACTS LISTING COMPLIANCE:** combining willingness and ability to name all relevant contacts since infectiousness began, including adequate identifiers for typical tracing success
2. **CONTACT TRACING RATE OF TTP**
3. **PROVIDER COMPLIANCE FOR CONTACTS:** proportion of advice given to contacts of test-positive cases (e.g. re-isolation) which is scientifically accurate
4. **CONTACTS' COMPLIANCE WITH QUARANTINE**
5. **CONTRACT TRACING DELAYS:** delays in tracing the contacts of index cases could have highly non-linear effects. This is because rapid tracing could limit cascade of subsequent transmission along whole branches of the network of contacts of the case, their contacts etc., whereas delays make it more likely that such cascades are set in motion leading to exponential growth in case numbers.

* Both asymptomatic (including pre-symptomatic and symptomatic cases are meant by this term – see text under Question #2 in the Results section for commentary on this point).

Explanatory Note: Each of these steps should be assessed in terms of the accuracy with which each element in the process is modelled. Studies that make an effort to assess uncertainty are in general to be preferred over those that offer false certainty e.g. a range of rates of compliance or effectiveness of isolation advice offer a more realistic representation of the state of knowledge than point estimates.

Source: modified from Tugwell et al.[8]

Note: Based on original healthcare effectiveness models, multiplication of the aforementioned identified modifiers for cases and contacts, respectively, would yield a crude estimate for the overall actual programme effectiveness, comprising effects from actions involving: A. (index) cases; B. contacts of cases. If the probability of 'success,' in terms of percentage-correct-completion, for each of the six modifiers of overall programme effectiveness for test-positive cases is, say 50%, then the overall proportion of potential optimum impact on transmission by programme action involving such cases is: [0.5 X 0.5 X 0.5 X 0.5 X 0.5 X 0.5] = 1/64 = 1.6% – i.e. the programme impact on transmission from actions taken regarding index cases is only 1.6% of the overall potential reduction in such transmission. At some points in the UK's national Test and Trace Programme, some of these modifiers are now thought to have had levels of success even lower than 50% (House of Parliament, 2021).

It should be noted however that the assumption of multiplicativity, representing independent probabilities for the effects of each of the diverse modifiers of effectiveness, is not necessarily warranted and may underestimate actual programme success, emphasizing the need for more sophisticated mathematical models.

searching the citations in those studies and published reviews of COVID-19 TTP effectiveness modelling (sometimes compared with other control measures). The range of identified issues regarding internal or external validity was fully captured by twelve original studies,[7,11–22] published between early 2020 (effectively the first such studies after the pandemic began) and May 2021. No additional issues compromising internal or external validity were identified from other modelling studies published during that the time period. As a result, the authors were able to identify six major sorts of shortcoming affecting such modeling, which were then integrated into the critical appraisal questions listed below.

Critical appraisal questions for screening modeling studies potentially relevant to COVID-19 TTP effectiveness evaluation

QUESTION#1. KEY MODIFIERS: Does the study incorporate or account for the effects, on COVID-19 transmission, of variation in the full set of key modifiers of overall TTP programme effectiveness identified in Text Box 1? (If not, stop here: study not likely to be useful)

It is important to note that a modeling study may not explicitly mention each individual modifier of effectiveness listed in Box 1, as it may 'bundle' several modifiers into one or more model parameters or process. For example, Grantz et al.[7] bundled 'coverage' (effectiveness modifier #A1) and 'test diagnostic accuracy (i.e. sensitivity)' (#A2) with modifier #A6 'compliance with advice to isolate,' into a single parameter – 'isolation completeness' – representing the probability that an infection in the community is detected and isolated by a TTP programme. This also illustrates that studies may use different terminology for key modifiers. To enable assessment of internal and external validity definition and underlying assumptions for each modifier must be stated.

QUESTION #2. STRUCTURE AND SCALE: Are models used in the study employing a structure and scale appropriate for evaluating the impact on COVID-19 transmission of TTP programmes operating at the scale of interest, e.g. national or regional?

Identifying appropriate model structure and scale to assess COVID-19 TTP programme effectiveness is challenging, and the twelve studies identified were found to be heterogeneous in this respect. In terms of structure, for example one might expect strong dependence of model results on assumed between-individual contact patterns, but some models simply assume homogeneous mixing (e.g. Contreras et al.[18]). Similarly, accounting for asymptomatic or pre-symptomatic carriers of SARS-CoV-2[23,24] affects testing coverage of potential transmitters (#A1 in Text Box), but only some in-scope studies do so (e.g. again, not Contreras et al.)[18] Caution is advised when considering models that employ coarse scales or overly simplistic structures for contact patterns. Such models may only be able to provide useful predictions of a qualitative nature (e.g. relative importance of specific modifiers on overall predictions). Internal and external validity of model results should be carefully examined in relation to such scope and scale considerations.

For example, generalising from an early study of the local COVID-19 TTP programme (including a widely downloaded mobile phone app) on the Isle of Wight just off the southern English coast[19] may be problematic; its small study population size, and perhaps even more so its unique geography, surely limit its applicability to large nation states.

QUESTION #3. PARAMETERISATION: Are key inputs (e.g. values for COVID-19's key transmission parameters and modifiers of effectiveness of TTP programmes, as listed in Box 1) credibly derived (i) using models fitted to representative data or (ii) from suitable peer-reviewed studies, and ideally systematic reviews and meta-analyses?

This criterion would probably have constituted an unreasonably high bar during the first year of the pandemic, where datasets were just starting to get assembled and modelers were unlikely to be granted full access to raw data. Furthermore, too few primary studies, and certainly systematic reviews of them, had been completed until very recently, with many key studies awaiting final peer-review available only through 'pre-print' archives, such as medRxiv. Even as late in the pandemic as the end of 2020, Quilty et al.[20] tally publications relevant to estimating quarantine-duration reduction, under rapid antigen testing, with 59 papers on PubMed and 1934 on medRxiv. However, it is now entirely reasonable to demand critical inputs be derived from high-quality sources and analyses, ideally accounting for multiple sources, appropriately vetted for quality and statistically summarized where appropriate, such as two recent syntheses of incubation period data.[25,26]

QUESTION #4. UNCERTAINTY QUANTIFICATION: Does the study account for a credible range of values for key input parameters, by executing comprehensive *sensitivity analyses*, showing resulting uncertainty, e.g. credible intervals or distributions, for key model outputs?

A key issue is the level of uncertainty associated with best estimates of key parameters. The fewer high-quality primary studies providing suitable data, and the narrower the range of relevant settings in which they were conducted, the more important a comprehensive sensitivity analysis becomes. Both Grantz et al.[7] and Contreras et al.[18] appear to meet this criterion, with sensitivity analyses across a wide range of input parameter values.

QUESTION #5. CONSISTENCY WITH OTHER STUDIES [EXTERNAL VALIDITY]: Are key results arising from the model(s) consistent with other high-quality evidence on impact and performance of TTP programmes?

Assessing external validity is not only a matter of looking explicitly for consistency of results across comparable studies and identifying outliers; it also involves noting entire categories of substudies (e.g. estimating key model inputs' distributions in particular settings – see above) where there is virtually no replication available. This a particular problem with COVID-19 research, simply because no study was possible until about February/March 2020. As a specific example of good practice in this regard, we would point to the work of the UK's Modeling Sub-Advisory Group (SPI-M) who have carefully issued consensus statements based on a variety of diverse modeling approaches.[27]

QUESTION #6. SENSE CHECK (EXTERNAL VALIDITY): What specific questions/settings does the appraiser wish to address? Is the model being appraised credibly applicable to these (e.g. the UK in 2021)?

This final question provides the opportunity to ask "Do I have any remaining doubts (not covered above) about applicability of this study to the particular TTP programme I want to evaluate?" Potential sources of non-generalisability should be assessed along with issues related to the intended application. For example, the agent-based modelling study of Aleta et al.[22] utilises detailed contact structures, based on pre-pandemic mobility data from Boston, USA, and models effects of applied COVID-19 interventions on these assumptions. This study may provide useful guidelines for developing comparable models; however, direct application to other countries is problematic because of likely differences in the pre-pandemic contact patterns and deployment of social distancing measures.

Discussion (and practical lessons learned)

Here we describe the lessons learned to guide those embarking on a literature (or systematic) review of modeling studies to inform evaluation of TTP programmes:

Relative timing of the modelling study to events. Particularly in the context of CA questions 2 (STRUCTURE AND SCALE) and 3 (PARAMETERISATION), it is important to consider the timing of the study in relation to data and knowledge available at the time of publication, compared to when the critical appraisal is conducted. For example, in early studies the proportion asymptomatic cases may be based on purely cross-sectional studies whereas, due latent period, only cohort studies provide a clear picture of the true percentage of cases which are fully asymptomatic.[23,24] Models based on such early estimates of key parameters can therefore be expected to have a 'limited shelf life' and must be interpreted with caution.

Demographic context. Key parameters vary within and between settings. For example, the secondary attack rate within a household (or household attack rate) is likely to vary considerably within and across populations, but only some models explicitly account for such heterogeneity. Furthermore, households are not of consistent size, age–sex composition, and crowdedness across societies (let alone comparable with respect to cross-reactive immunocompetence arising from previous exposure to other coronaviruses.[28] Secondary attack rates based on household data will not be fully generalizable from one society – e.g. China, with low birth rates but many households which include older relatives,[29] to another – e.g. in sub-Saharan Africa, with high birth rates, a very young population overall, and many communities with extremely crowded housing, such as large low-income informal settlements.[12]

Geographical, cultural, or political features. A further caveat to external validity is that some input parameters may be contextualized by other important but often unstated local geographical, cultural, or political features. For example, isolated islands (either physically isolated, such as Iceland, New Zealand, and the Faroe Islands) or politically distinct 'islands' with historically strong border controls (such as Hong Kong, Singapore and Taiwan) have in some cases introduced strict COVID-19 control measures, including gradations of social distancing through to full 'lock-down,' while at the same time enforcing draconian inbound-traveler restrictions.[14] The effect of such imported-case exclusion measures can be large[15] and may influence observed impacts of TTP programmes because transmission is rendered entirely internal to the population in question. Such issues are most apparent in studies of closed 'institutional/cruise-ship' settings, such as the well-known Diamond Princess outbreak early in the pandemic.[16] Such extreme settings may hold advantages for estimating key transmission parameters; however, such estimates may be confounded by atypical features, such as population-age profiles or saturation of air-circulation systems by aerosols, leading to more of a 'point (or common) source' epidemic curve, rather than a 'person-to-person' transmission curve.[30] Thus, generalizing from 'island' settings to societies with more porous borders should be undertaken with extreme caution.

Nuances of TTP programmes. TTP programmes may appear to be similar between jurisdictions, but in fact may be quite different in important respects. For example, TTP programmes with strong legal sanctions against cases or their contacts, who are non-compliant with advice to isolate/quarantine (including mandatory 'quarantine hotel' stays under armed guard), would be expected to achieve high rates of transmission interruption, compared to more voluntary programmes, relying entirely on 'self-isolation at home.'[17] There are many such features of TTP programmes that powerfully influence case and contact *compliance* with advice to isolate/quarantine (see Box 1), such as concerns about data security, and they may or may not be fully described in a given published account.

Shortcomings of modelling study reporting. We note, as have other commentators[1–3] that inconsistent and often incomplete reporting was common among the dozen key modelling studies we examined in detail. Standard guidance for such reporting has been published and is constantly being refined.[1,3]

Degree of compliance. When using models to evaluate any TTP programme, a key concern is how that programme is executed on the ground, as well as the full context of other societal behavioural patterns relevant to COVID-19 transmission e.g. compensatory behaviours, and the extent to which the study accounts for such factors, especially via proper reporting practices (see earlier discussion).

In summary, 'the devil is in the details'. Anyone reviewing modeling studies which make use of model inputs from settings likely affected by these peculiarities should exercise extreme caution in extrapolating the results to settings which are fundamentally different.

The major strength of this study is that it utilized a purposive sample of about a dozen highly cited early modeling studies of COVID-19 TTP programmes' effectiveness to generate CA questions suitable for use by non-modelers, with only MPH-level training in epidemiology, for screening such studies for more detailed attention by trained modelers.

The major weakness of this study is that it did not attempt a systematic review of this exploding literature (as of spring 2021), but instead relied on the likely saturation of identifiable weaknesses, based on a purposive sample of early studies. This limitation may have resulted in bias and also limit the applicability of these CA questions to later modelling studies utilizing novel and improved methods and/or higher-quality input data. A second major weakness is that the authors did not attempt to validate the CA questions developed on an independent sample of modeling studies, simply because they had already used all the most highly cited studies of this kind in developing the questions. We leave that important task to others, now that many more pertinent modeling studies have been published.

This study has used a systematic process to develop a brief decision tool – involving creation of a bespoke conceptual framework, a purposive search to identify potential modelling study shortcomings, and the subsequent creation of six CA questions. The tool is intended to allow non-modelers to critically assess modelling studies that aim to address the impact on COVID-19 transmission of TTP programmes, a major global intervention to reduce viral transmission. Only by others' attempts to use these questions can we learn how useful they are. To that end, we invite public health professionals who are involved in evidence reviews on this topic to write to us, in care of the corresponding author, about their experiences with this tool.

Author statements

Ethical approval

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Competing interests

None declared.

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Original Research

Estimating influences of unemployment and underemployment on mental health during the COVID-19 pandemic: who suffers the most?

J.O. Lee [a, *], A. Kapteyn [b], A. Clomax [a], H. Jin [b]

[a] Suzanne Dworak-Peck School of Social Work, University of Southern California, Los Angeles, CA, USA
[b] Center for Economic and Social Research, University of Southern California, Los Angeles, CA, USA

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ABSTRACT

Objectives: The aim of the study was to evaluate whether unemployment and underemployment are associated with mental distress and whether employment insecurity and its mental health consequences are disproportionately concentrated among specific social groups in the United States during the COVID-19 pandemic.
Study design: This is a population-based longitudinal study.
Methods: Data came from the Understanding America Study, a population-based panel in the United States. Between April and May 2020, 3548 adults who were not out of the labor force were surveyed. Analyses using targeted maximum likelihood estimation examined the association of employment insecurity with depression, assessed using the 2-item Patient Health Questionnaire, and anxiety, measured with the 2-item Generalized Anxiety Disorder scale. Stratified models were evaluated to examine whether employment insecurity and its mental health consequences are disproportionately concentrated among specific social groups.
Results: Being unemployed or underemployed was associated with increased odds of having depression (adjusted odds ratio [AOR] = 1.66, 95% confidence interval [CI] = 1.36–2.02) and anxiety (AOR = 1.50, 95% CI = 1.26, 1.79), relative to having a full-time job. Employment insecurity was disproportionately concentrated among Hispanics (54.3%), Blacks (60.6%), women (55.9%), young adults (aged 18–29 years; 57.0%), and those without a college degree (62.7%). Furthermore, Hispanic workers, subsequent to employment insecurity, experienced worse effects on depression (AOR = 2.08, 95% CI = 1.28, 3.40) and anxiety (AOR = 1.95, 95% CI = 1.24, 3.09). Those who completed high school or less reported worse depression subsequent to employment insecurity (AOR = 2.44, 95% CI = 1.55, 3.85).
Conclusions: Both unemployment and underemployment threaten mental health during the pandemic, and the mental health repercussions are not felt equally across the population. Employment insecurity during the pandemic should be considered an important public health concern that may exacerbate pre-existing mental health disparities during and after the pandemic.

Introduction

With a death toll of 678,815 in September 2021,[1] the COVID-19 pandemic has triggered massive employment insecurity[2,3] in the United States. Nationwide, the unemployment rate climbed to 14.7% in April from 3.9% in February,[4] marking the steepest month-over-month increase in unemployment in US history.[4] Rising employment insecurity has strong potential to threaten mental health during and after the pandemic.[5–8] Early evidence has reported substantial deterioration of mental health during the pandemic.[9] The prevalence of depression symptoms early in the pandemic was 27.8%, more than three times higher than before the pandemic (8.5%).[10] However, little is known about whether the nation's plummeting mental health is attributable to rising employment insecurity during the pandemic in the United States, with few notable exceptions.[9,11] Yet a prior study[11] focused on adults aged ≥55 years, limiting the field's ability to accurately estimate the full scope of the mental health repercussions of rising employment insecurity at a national level. Furthermore, as with

* Corresponding author. Suzanne Dworak-Peck School of Social Work, University of Southern California, 669 West 34th St., Los Angeles, CA 90089, USA. Tel.: +213 740 7822; fax: +213 740 3301.
E-mail address: lee363@usc.edu (J.O. Lee).

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most existing studies,[12,13] a prior study[9] made a simple distinction between having a job vs not having a job; therefore, another critical type of employment insecurity, that is, underemployment, has been overlooked. Underemployment occurs when people are employed but worked fewer hours than desired (e.g. involuntarily part-time).[12] Relevant studies have generated mixed findings regarding whether underemployment mirrors unemployment[14–16] or secure employment[17,18] regarding effects on mental health.[12] We are not aware of studies that have examined this question during the COVID-19 pandemic. Underemployment rates have been consistently rising,[13,19] and even more so during COVID-19,[20] in the United States, warranting an urgent systematic inquiry to accurately estimate the breadth of its triggered mental health burden.

Further, the field has not reached a consensus on the nature of the association between employment insecurity and mental health.[21,22] The debate is between social causation (i.e. employment insecurity undermines mental health) vs social selection (i.e. pre-existing mental health problems threaten employment insecurity).[22,23] Because existing empirical evidence supports both social causation[24,25] and social selection,[26] it is critical to investigate the impact of employment insecurity on mental health while minimizing the potential for social selection.[27,28]

Importantly, less is known about whether employment insecurity generates differential impacts on mental health across the population.[29] Belonging to historically disadvantaged social groups may condition the association between employment insecurity and mental health.[30–32] Specifically, less privileged social groups (e.g. racial and ethnic minorities,[33] women,[34] young adults,[15,35] and people with low socio-economic status[31,32]) may be more likely to experience stressors, such as employment insecurity (i.e. differential exposure).[31,32,36] In addition, the detrimental impact of a given stressor will be more activated for less privileged social groups, resulting in worse consequences, because of their limited financial resources[33] and access to social resources that can mitigate the mental health repercussions of stressors (i.e. differential vulnerability).[31,32,37] Supporting such conceptual speculation, early evidence on unemployment rates during the pandemic shows that the economic turmoil most affected workers who are racial and ethnic minorities,[38–40] women,[38,41] young adults,[38] and people with low socio-economic status.[38] It remains unclear whether these social groups also experienced disproportionately higher rates of underemployment. Furthermore, no identified studies have examined differential vulnerability. Consequently, it is unknown whose mental health has been most threatened by employment insecurity during the pandemic.[9,42]

To address these gaps, the present study focused on three central research aims. First, it assessed the association between employment insecurity, including both unemployment and underemployment, and depression and anxiety, using nationally representative data in the United States. We used the targeted maximum likelihood estimation (TMLE) method,[43,44] a well-established statistical method designed to estimate causal effects in observational data. The estimation controlled for mental health status before the pandemic, further minimizing the possibility of social selection (i.e. compromised mental health threatens employment security). Second, we evaluated whether employment insecurity was disproportionately concentrated among specific race and ethnicity, gender, age, and education (a key indicator of socio-economic status that is applicable across varying ages[43]) groups (i.e. differential exposure). Third, we conducted stratified analyses by race and ethnicity, gender, age, and education level to evaluate whether the mental health consequences of employment insecurity are worse for certain social groups (i.e. differential vulnerability). These stratified analyses will advance the field's ability to locate segments of population with heightened risk exposure and vulnerabilities and enhance our capacity to allocate public health resources adequately to disrupt the escalation of pre-existing mental health disparities in the United States.

Methods

Study population

Data for this study came from the Understanding America Study (UAS), a nationally representative probability-based internet panel in the United States.[45] Participants are randomly selected from the US postal delivery sequence files and recruited by an elaborate process using a sequence of postal mailings.[45] Eligible participants are adults aged ≥18 years in contacted households. Following the established protocol in the UAS, selected households were first notified through mail, followed with a priority mail invitation letter in English and Spanish providing the study overview, a brief survey asking about sociodemographic information, and $5 compensation for reviewing the packet, with a promise of a $15 incentive for completing the sociodemographic survey. Those who completed the sociodemographic survey received a phone call, identity verification, informed consent form, the $15 incentive, a brochure, a tablet and broadband internet connection mechanisms when needed (provided at no cost), and instructions to login into the UAS internet interface for an additional $20 incentive for completing a more extensive "my household" sociodemographic survey. Household survey completers are considered UAS panel members.

Since March 10, 2020, the UAS has instituted a tracking survey asking COVID-19-related questions biweekly. Respondents are asked to respond on a specific day of the 14-day cycle with 2 weeks to respond. Approximately 81% of respondents answered questions on their assigned day, so the vast majority of responses are realized during the first 2 weeks of the survey period. A description of the data and links for download are available at https://uasdata.usc.edu/covid19.

The current analysis used data from early waves of the UAS tracking surveys: UAS235 (April 1 to April 28, 2020; response rate = 97.04%; 5645 invited to participate, 5478 completed the survey) and UAS242 (April 29 to May 26, 2020; response rate = 91.46%; 7002 invited to participate, 6403 completed the survey). These periods of data collection paralleled the peak period of employment insecurity during the pandemic in the United States.[44] Of all participants invited to at least one of these two COVID-19 surveys (n = 7008), 5262 participants completed these two COVID-19 surveys. Because employment insecurity was the focal predictor, participants who were retired, full-time students, or not in the labor force for any other reasons were excluded from the analyses, bringing the final analysis sample to 3548 participants. We augmented these two COVID-19 waves with two prepandemic UAS data sources to establish a robust set of covariates, including the first wave of UAS taken by all new respondents and the most recent biannual regular assessment taken by all respondents, before the pandemic. The affiliated university's institutional review board approved this study.

Measurements

Depression and Anxiety (UAS Wave 242, May 2020)

Depression was assessed using the 2-item Patient Health Questionnaire[46] that measures the frequency of two core depressive symptoms in the fourth edition of the *Diagnostic and Statistical Manual of Mental Disorders* (i.e. anhedonia and depressed feeling) in the last 2 weeks ("not at all," "several days," "more than half the days," and "nearly every day"). Anxiety was measured with the 2-item Generalized Anxiety Disorder scale,[47] which includes similar

4-point Likert scales for anxious feeling and non-stop worrying. Following the established guideline,[46,48] these two measures were dichotomized, using a total score of 3 or higher as the threshold to classify clinically meaningful depression and anxiety.

Employment Security (UAS Wave 235, April 2020)

Insecure employment status included unemployment and hour-related underemployment[47] (i.e. involuntary reduction in number of working hours). Secure employment represents having a job without any reduction in working hours during the pandemic.

Covariates

Covariates included earlier depressive symptoms assessed in the most recent biannual regular assessment before the pandemic, measured by the Center for Epidemiologic Studies Depression Scale (8 items).[49] COVID-19-related symptoms were assessed using a 9-item survey. COVID-19-related discrimination was measured by a 4-item survey (e.g. being threatened or harassed due to others thinking the participant has COVID-19). Personality was assessed by the big-five personality traits (e.g. extroversion and conscientiousness).[50,51] Health insurance was assessed by whether participants currently had health insurance. Sociodemographic covariates included (1) race and ethnicity (Latino or Hispanic, non-Hispanic Black, non-Hispanic Asian, non-Hispanic White, and other), (2) gender (female or male), (3) age group (18–29, 30–44, and ≥45 years), (4) education level (high school or below, some college, college graduate, and postgraduate), and (5) married (yes or no).

Statistical analysis

First, we clustered COVID-19-related symptoms into a symptomatic group and an asymptomatic group using the k-mean clustering algorithm,[52] which reduced the dimensions of covariates and avoided the potential collinearity problem caused by the intercorrelations among COVID-19-related symptoms. Second, we derived double-robust estimation using the TMLE method[53,54] to evaluate the associations between employment insecurity and two mental health measures. The covariates include the clusters of COVID-19-related symptoms derived from the analysis in step one and all other covariates. Under standard assumptions, the estimates derived using TMLE can be interpreted as causal effects[53,54] (for more technical details, see the online supplement). Third, we evaluated the possibility of differential exposure across race and ethnicity, gender, age, and education levels using Chi-squared tests. We then conducted stratified TMLE models by race and ethnicity, gender, age, and education level to evaluate differential vulnerability across social groups. Sampling weights were calculated using a two-step approach established in UAS[45] and incorporated in all analyses, including TMLE that followed the procedure established in a prior study,[53] maintaining the sample representativeness and addressing missingness. The analysis was conducted using the "tmle" package in R.[57]

Results

Table 1 summarizes the descriptive statistics; 50.7% of participants were female, and the weighted mean age was 44.95 years. TMLE results are summarized in Table 2, which show that insecure employment (unemployment and underemployment combined) was significantly associated with increased depression (adjusted odds ratio [AOR] = 1.66, 95% confidence interval [CI] = 1.36, 2.02) and anxiety (AOR = 1.50, 95% CI = 1.26, 1.79). We conducted an additional TMLE analysis, evaluating whether effects for underemployed people were similar to the effects for unemployed people. The results revealed that underemployed and unemployed people were similar regarding depression (AOR = .91, 95% CI = .71, 1.17) and anxiety (AOR = 1.26, 95% CI = .99, 1.60). With no significant observed differences between underemployment and unemployment, these two categories remained combined in subsequent analyses.

Next, we evaluated whether employment insecurity was disproportionately concentrated among specific social groups (i.e. differential exposure). As shown in Table 3, exposure to insecure employment was significantly associated with race and ethnicity, gender, age, and education. Specifically, 54.3% of Hispanics and 60.6% of non-Hispanic Blacks compared with 48.3% of Whites, 55.9% of women compared with 45.7% of men, 57.0% of young adults (aged 18–29 years) compared with 44.4% of those in the 30–44 years age group; and 62.7% of people who completed high school or lower compared with 29.1% of those with an advanced degree experienced either unemployment or underemployment during COVID-19.

Furthermore, as shown in Table 2, stratified TMLE analyses revealed that coefficients representing the impacts of employment insecurity were statistically significant in most stratified subgroups except for non-Hispanic Blacks, non-Hispanic others, and young adults for both mental health measures and women and those with some college education for anxiety. However, the results also indicate heightened odds of experiencing depression or anxiety or both among certain subgroups—Hispanics (depression: AOR = 2.08, 95% CI = 1.28–3.40; anxiety: AOR = 1.95, 95% CI = 1.24–3.09), men (depression: AOR = 2.15, 95% CI = 1.50–3.08; anxiety: AOR = 2.05, 95% CI = 1.48–2.83), those aged ≥45 years (depression: AOR = 1.90, 95% CI = 1.39–2.62), and those who completed high school or lower (depression: AOR = 2.44, 95% CI = 1.55–3.85).

Discussion

Confirming speculation,[5,6] data from this nationally representative panel revealed that employment insecurity has threatened mental health in the United States during the pandemic, and mental health repercussions are not felt equally across the population.

Unemployment, underemployment, and mental health

Our study results corroborate that underemployed people mirror unemployed people, rather than those who kept their full-time job, regarding their mental health. The current findings are consistent with some prior studies[14,15] and contradict others.[11,17] However, contradictory prior studies[17] operationalized underemployment in relation to workers' overqualification for jobs and was conducted in macroconditions without any major economic contraction or focused on workers aged ≥55 years.[11] The discrepancies in findings may stem from differences in the operationalization of underemployment, macroeconomic context, or target age group, hinting at the importance of examining varying dimensions of underemployment across different economic contexts and age groups.

The similarity between unemployed and underemployed people regarding mental health observed in the present study suggests that the widely used operationalization of employment insecurity as a simple distinction between unemployment and any employment likely underestimates the breadth of mental health problems attributable to employment insecurity. In April 2020, 10.9 million Americans were underemployed.[55] Our study findings highlight the importance of drawing attention to underemployed people who suffer the mental health consequences of employment insecurity, yet have been largely overlooked in empirical studies and practice discussions. The general upward trend of underemployment[13,19] further highlights the importance of examining underemployment as a public health and mental health concern. Employment insecurity may negatively affect mental health for

Table 1
Descriptive statistics of the study sample ($n = 3548$).

Constructs	Unweighted	Weighted
	M (SD) or *n* (%)	M (SD) or *n* (%)
Employment security		
Secure employment	1790 (50.5)	1790 (49.1)
Insecure employment		
Unemployment	1229 (34.6)	1303 (35.8)
Underemployment	529 (14.9)	549 (15.1)
Depression (PHQ-2 ≥ 3)	442 (12.5)	447 (12.4)
Anxiety (GAD-2 ≥ 3)	550 (15.6)	538 (14.9)
Race and ethnicity		
Hispanic	590 (16.6)	671 (18.4)
Non-Hispanic White	2414 (68.0)	2245 (61.6)
Non-Hispanic Black	326 (9.2)	508 (13.9)
Non-Hispanic other	218 (6.1)	219 (6.0)
Gender[a]		
Female	2050 (57.8)	1847 (50.7)
Male	1497 (42.2)	1794 (49.3)
Age group[a]		
18–29	355 (10.0)	409 (11.2)
30–44	1227 (34.6)	1479 (40.6)
≥45	1963 (55.4)	1753 (48.1)
Education level		
High school or less	779 (22.0)	1384 (38.0)
Some college education	1254 (35.3)	964 (26.5)
Bachelor's degree	907 (25.6)	723 (19.9)
Advanced degree	608 (17.1)	571 (15.7)
Health insurance (no)	359 (10.1)	444 (12.2)
Marital status (yes)	1902 (53.6)	1956 (53.7)
Depressive symptoms before pandemic (CES-D)[b]	1.78 (2.20)	1.84 (2.19)
Presence of COVID-related symptoms	1102 (31.3)	1115 (30.9)
COVID-related discrimination		
Received poorer service	87 (2.5)	102 (2.8)
Threatened or harassed	54 (1.5)	62 (1.7)
Treated with less courtesy and respect	163 (4.6)	161 (4.4)
Other people acted afraid of you	340 (9.6)	334 (9.2)
Personality scores		
Extroversion	25.51 (6.37)	25.42 (6.21)
Conscientiousness	35.68 (5.71)	35.33 (5.82)
Neuroticism	21.88 (6.44)	22.03 (6.37)
Agreeableness	35.33 (5.67)	35.16 (5.75)
Openness	35.48 (6.33)	35.16 (6.11)

[a] Sum of frequencies in subcategories not equal to the total sample size due to missing values.
[b] Minimum: 0; 1st quartile: 0; median: 1; 3rd quartile: 3; maximum: 8.

years, known as "scarring effects,"[24,56,58] warranting the activation of mental health services for unemployed and underemployed people to alleviate the mental health repercussions of employment insecurity during the pandemic, including long-term follow-up.

Differential exposure and differential vulnerability

Supporting the differential exposure hypothesis[31,32,36] and earlier evidence on unemployment rates during the pandemic,[38–41] the present study revealed that employment insecurity, including both unemployment and underemployment, hits those who hold a less privileged social status the most—employment insecurity was disproportionately concentrated among Hispanic and non-Hispanic Blacks, women, young adults (aged 18–29 years), and those without a college degree. This unequal burden among these segments of the population reflects the virus's differential impact on sectors with a higher percentage of workers from historically marginalized communities.[59,60] Furthermore, our stratified analyses show that certain disadvantaged social groups suffered worse consequences (i.e. differential vulnerability) in addition to experiencing more job loss or work-hour reduction (i.e. differential exposure). Hispanic workers, in addition to their higher probability of experiencing employment insecurity, experienced worse effects on their mental health when experiencing employment insecurity compared with any other racial or ethnic group. Similarly, those who completed high school or less reported higher odds of experiencing depression subsequent to employment insecurity, along with a heightened risk of employment

Table 2
Targeted maximum likelihood estimates of the relationships between insecure employment and depression and anxiety in the full and stratified samples.

Group	Depression (PHQ-2 ≥ 3)		Anxiety (GAD-2 ≥ 3)	
	AOR (95% CI)	*P*	AOR (95% CI)	*P*
Full sample	1.66 (1.36–2.02)	<.001	1.50 (1.26–1.79)	<.001
Stratified				
Race and ethnicity				
Hispanic	2.08 (1.28–3.40)	.003	1.95 (1.24–3.09)	.004
Non-Hispanic White	1.63 (1.29–2.07)	<.001	1.42 (1.15–1.75)	.001
Non-Hispanic Black	1.20 (.63–2.28)	.58	1.38 (.69–2.79)	.36
Non-Hispanic other	1.22 (.62–2.41)	.57	1.25 (.62–2.51)	.53
Gender				
Male	2.15 (1.50–3.08)	<.001	2.05 (1.48–2.83)	<.001
Female	1.46 (1.15–1.86)	.002	1.19 (.96–1.47)	.12
Age				
18–29	1.45 (.86–2.45)	.16	1.14 (.71–1.84)	.59
30–44	1.54 (1.14–2.09)	.005	1.58 (1.20–2.07)	.001
≥45	1.90 (1.39–2.62)	<.001	1.59 (1.20–2.10)	.001
Education				
High school or less	2.44 (1.55–3.85)	<.001	1.71 (1.12–2.62)	.01
Some college	1.45 (1.05–1.99)	.02	1.15 (.85–1.55)	.37
Bachelor's degree	1.81 (1.20–2.75)	.005	1.68 (1.20–2.35)	.003
Advanced degree	1.78 (1.08–2.95)	.02	1.58 (1.01–2.48)	.05

Table 3
Weighted frequency and proportion of insecure employment stratified by age group, gender, race and ethnicity, and education.

Subgroup	Insecure employment (Weighted $n = 1852$)		Secure employment (Weighted $n = 1790$)
	Unemployment	Underemployment	
	n (%)	n (%)	n (%)
Race and ethnicity*[a]			
Hispanic	263 (39.2)	101 (15.1)	307 (45.8)
Non-Hispanic White	743 (33.1)	340 (15.2)	1161 (51.7)
Non-Hispanic Black	240 (47.2)	68 (13.4)	200 (39.4)
Non-Hispanic other	57 (26.0)	41 (18.7)	121 (55.3)
Gender[a]			
Male	551 (30.7)	269 (15.0)	974 (54.3)
Female	752 (40.7)	280 (15.2)	815 (44.1)
Age group*[a]			
18–29	163 (39.9)	70 (17.1)	176 (43.0)
30–44	419 (28.3)	245 (16.6)	814 (55.1)
≥45	720 (41.1)	234 (13.4)	798 (45.5)
Education level*[a]			
High school or less	700 (50.6)	168 (12.1)	516 (37.3)
Some college education	384 (39.8)	167 (17.3)	413 (42.8)
Bachelor's degree	155 (21.4)	113 (15.6)	455 (62.9)
Advanced degree	65 (11.4)	101 (17.7)	406 (71.0)

*$P < .01$.
[a] The sum of weighted frequencies in subcategories is not equal to the total weighted sample size due to rounding.

insecurity. Taken together, the current findings suggest that Hispanics and those with low education levels will likely suffer the most because both mechanisms driving health disparities, differential exposure and vulnerability, are patterned unfavorably for these two groups. Considering that upward mobility in employment (i.e. securing a new job or adequate employment) are harder for these groups,[61,62] the confluence of differential exposure and differential vulnerability likely further deepen the existing disparities in mental health for racial and ethnic minorities and those with low socio-economic status.[63,64] Strengthening mental health services for unemployed and underemployed people, particularly workers from historically marginalized backgrounds,[65] such as Hispanic workers and those with low education levels, is imperative to avert the possible "perfect storm" of mental health challenges that is poised to hit the vulnerable members of our society the most.

Limitations

This study relied on self-reports, possibly introducing reporting bias.[66] Second, the present study focused on hours-based underemployment. As such, other forms of underemployment—income- or skills-based underemployment[15]—were not considered, which is likely to underestimate the scope and effects of underemployment on health.[67] Considering other types of underemployment and examining unique and joint impacts of varying underemployment status on mental health may be a fruitful future direction to further clarify the impacts of this ever-rising type of employment insecurity on mental health and identify which specific type of underemployment should be prioritized as a means to curb rising mental health problems. Third, although the present study contributed to the debate between social selection vs social causation by implementing TMLE and controlling for earlier mental health status before the pandemic, it is not our intention to claim that the possibility of reverse causality has been completely eliminated. Mental health problems in childhood, for example, could not be included as a covariate because such information was not available in the UAS data. Although the incorporation of mental health measures before the pandemic ease the concern of not having childhood mental health measure, the unique influence of childhood mental health problems could not be controlled. Relatedly, causal interpretation of the results from stratified analyses warrants particular caution because the smaller sample size may threaten the assumptions needed to interpret coefficients from TMLE as causal effects.[53,54]

Conclusions

The present study expands the body of literature concerning mental health consequences during the pandemic in four important ways. First, the study used nationally representative data that were collected during the peak period of employment insecurity during the pandemic in the United States.[44] Second, by leveraging a novel statistical method and rich prospective data, the study contributes to the ongoing debate regarding social causation vs social selection. Third, the present study revealed that being underemployed is similar to being unemployed in terms of their effects on mental health, clarifying the existing mixed findings and advocating for the mental health needs of underemployed people. Finally, the present study systematically evaluated differential exposure (i.e. who experienced more employment insecurity) and differential vulnerability (i.e. who experienced worse consequences subsequent to employment insecurity), revealing the possibility of worsening disparities in mental health triggered by the recent economic turmoil. No other identified studies appear to integrate these unique strengths.

In conclusion, the present study findings reveal that employment insecurity, not just unemployment but also underemployment, threatens the public's mental health during the pandemic. In the domain of social policies, providing a more generous unemployment benefit package is likely to reduce economic hardship and distress and thus mitigate the impact of employment insecurity on mental health.[7] A recent study reported that receiving unemployment insurance was associated with decreased mental health problems among those who experienced job loss during the pandemic.[68] Furthermore, the study findings suggest a needed shift in policy and service targets from an exclusive focus on unemployed people to include underemployed people.

Currently, rules for underemployed workers' eligibility for unemployment insurance benefits vary across states. Adjusting the eligibility criteria during the pandemic and providing additional support for underemployed people who do not meet a given state's eligibility criteria will likely ease mental distress in this group. Importantly, our study findings indicate that the economic upheaval was not felt evenly across social groups. Particularly, Hispanics and those with low education levels will likely confront worse mental health repercussions subsequent to employment insecurity during the pandemic, further exacerbating prepandemic disparities in mental health. Policies and interventions that make mental health services more affordable and accessible to low-resourced members of our society will be critical because Hispanics[69] and people with low education levels[70] tend to have fewer resources. Smartphone-based interventions, for example, have shown promising effects on depression.[71] Providing such an intervention to those experiencing employment insecurity, particularly those who lost health insurance along with their job or do not have a sufficient financial reservoir to cover treatment, may alleviate the deleterious impacts of employment insecurity on mental health and avoid deepening existing disparities in mental health during and after the pandemic.

Author statements

Ethical approval

The study followed the principles outlined in the Declaration of Helsinki, and the University of Southern California's institutional review board approved the study.

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Competing interests

None.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.puhe.2021.09.038.

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Original Research

Excess mortality in Glasgow: further evidence of 'political effects' on population health

L. Schofield [a], D. Walsh [b, *], N. Bendel [c], R. Piroddi [d, e]

[a] Public Health Scotland, Gyle Square, 1 South Gyle Crescent, Edinburgh EH12 9EB, Scotland, UK
[b] Glasgow Centre for Population Health, Olympia Building, 2-16 Orr Street, Bridgeton Cross, Glasgow G40 2QH, Scotland, UK
[c] Manchester City Council, Town Hall Extension, Manchester M60 2LA, England, UK
[d] Department of Public Health Policy and Systems, University of Liverpool, Waterhouse Building, Block B, Brownlow Street, Liverpool L69 3GF, England, UK
[e] Business Intelligence Team, NHS Liverpool Clinical Commissioning Group, The Department, Lewis's Building, Renshaw Street, Liverpool L1 2SA, England, UK

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ABSTRACT

Objectives: The aim of the study was to update previous analyses of 'excess mortality' in Glasgow (Scotland) relative to the similar postindustrial cities of Liverpool and Manchester (England). The excess is defined as mortality after adjustment for socio-economic deprivation; thus, we sought to compare changes over time in both the deprivation profiles of the cities and the levels of deprivation-adjusted mortality in Glasgow relative to the other cities. This is important not only because the original analyses are now increasingly out of date but also because since publication, important (prepandemic) changes to mortality trends have been observed across all parts of the United Kingdom.

Study design and methods: Replicating as far as possible the methods of the original study, we developed a three-city deprivation index based on the creation of spatial units in Glasgow that were of similar size to those in Liverpool and Manchester (average population sizes of approximately 1600, 1500 and 1700 respectively) and an area-based measure of 'employment deprivation'. Mortality and matching population data by age, sex and small area were obtained from national agencies for two periods: 2003–2007 (the period covered by the original study) and 2014–2018. The rates of employment deprivation for each city's small areas were calculated for both periods. Indirectly standardised mortality ratios (SMRs) were calculated for Glasgow relative to Liverpool and Manchester, standardised by age and three-city deprivation decile. For context, city-level trends in age-standardised mortality rates by year, sex and city were also calculated.

Results: There was evidence of a stalling of improvement in mortality rates in all three cities from the early 2010s. After adjustment for area deprivation, all-cause mortality in Glasgow in 2014–2018 was c.12% higher than in Liverpool and Manchester for all ages (SMR 112.4, 95% CI 111.1–113.6) and c.17% higher for deaths under 65 years (SMR 117.1, 95% CI 114.5–119.7). The excess was higher for males (17% compared with 9% for deaths at all ages; 25% compared with 5% for 0–64 years) and for particular causes of death such as suicide and drug-related and alcohol-related causes. The results were broadly similar to those previously described for 2003–2007, although the excess for premature mortality was notably lower. In part, this was explained by changes in levels of employment deprivation, which had decreased to a greater degree in the English cities: this was particularly true of Manchester (a reduction of −43%, compared with −38% in Liverpool and −31% in Glasgow) where the overall population size had also increased to a much greater extent than in the other cities.

Conclusions: High levels of excess mortality persist in Glasgow. With the political causes recently established – the excess is a 'political effect', not a 'Glasgow effect' – political solutions are required. Thus, previously published recommendations aimed at addressing poverty, inequality and vulnerability in the city are still highly relevant. However, given the evidence of more recent, UK-wide, political effects on mortality – widening mortality inequalities resulting from UK Government 'austerity' measures – additional policies at UK Government level to protect, and restore, the income of the poorest in society are also urgently needed.

* Corresponding author.
E-mail address: David.Walsh.2@glasgow.ac.uk (D. Walsh).

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Introduction

The 'fundamental causes' of poor health and health inequalities are established as being socio-economic.[1–3] However, some populations exhibit notably higher mortality than their socio-economic profile would predict.[4–8] A prominent example in the United Kingdom is the case of excess mortality in Scotland's largest city, Glasgow[9–12] – unhelpfully described in the media as a 'Glasgow effect'.[13] Much of the discussion of this topic stemmed from a 2010 publication, which compared socio-economic disadvantage and mortality in Glasgow and in two postindustrial cities in England, Liverpool and Manchester.[9] The study showed that although the socio-economic profiles of all three cities were very similar, all-cause mortality in Glasgow was c.14% higher than in the two English cities, with premature mortality (<65 years) c.30% higher (after adjustment for any remaining differences in neighbourhood-level 'income deprivation'). This study generated considerable debate and hypothesising of potential causes of this excess[14–22] and resulted in a vast investigative research programme,[23] which ultimately led to an evidence-based explanation of the most likely causes.[11,12] Although complex and multifactorial, at its heart was a toxic combination of historical poor living conditions and adverse political decision-making, which, over time, had conferred greater disadvantage on Glasgow than in the comparator cities. The results, endorsed by numerous academics and key figures across the United Kingdom,[12] thereby emphasised that rather than being a 'Glasgow effect', excess mortality in the city instead represented a 'political effect'.

The role of political determinants of health is of course well understood.[24–29] Importantly, since the publication of the 2010 paper, the United Kingdom has experienced further such political effects on health: widening inequalities across the United Kingdom attributed to UK Government 'austerity' measures that have slashed the income of, and consequently increased death rates among, the poorest and most vulnerable in society.[30–36] Postindustrial parts of the United Kingdom (including Glasgow, Liverpool and Manchester) have been shown to have been most affected by these policies.[37,38] This, alongside other changes that have taken place since 2010, for example, to national and local governments, begs a number of questions regarding the extent to which the findings of the original 2010 research may have now changed. The aim of this project, therefore, was to update those analyses and thereby answer three research questions: to what extent have levels of deprivation changed over time; how does mortality in Glasgow compare with Liverpool and Manchester, after adjustment for area deprivation; and to what extent have levels of such excess mortality changed over time?

Methods

To maximise comparability, as far as possible, we replicated the original methodology used in the 2010 study (which analysed mortality data for 2003–2007 in relation to area deprivation in 2005).[11,12]

Geographical units of analysis

Cities were defined by their current local authority boundaries. The spatial units used in the measurement of neighbourhood deprivation in Scotland and England (so-called 'datazones' and 'lower-layer super output areas' [LSOAs], respectively) differ in size, with the average population of datazones being approximately half of LSOAs. As this is problematic in comparing neighbourhood disadvantage levels, a new set of spatial units for Glasgow, of a similar size to those in Liverpool and Manchester, was created by merging neighbouring, similarly deprived, areas using specialist software, the AZ Tool:[39,40] this has been used previously in related research.[4] Note that the spatial units created for this purpose in the 2010 study could not be used because an updated version of datazones (2011 datazones) has since been produced. Similarly, a new set of LSOAs (2011 LSOAs) was introduced in England following the 2011 census. Thus, the units of analysis for this study were merged 2011 datazones and 2011 LSOAs.

Creation of a three-city area deprivation index

The previous three-city research used a measure of 'income deprivation', based on UK Government Department of Work & Pensions (DWP) data. However, because of recent social security changes, that measure cannot be compared over time. Instead, we used the similar measure of 'employment deprivation', also derived from DWP data, and included in both the 2004 and 2016 versions of the Scottish Index of Multiple Deprivation (SIMD).[41,42] A measure of exclusion from work, it is calculated as the percentage of the working-age population in each area in receipt of either unemployment-related or sickness-related social security payments. Although the definition has changed slightly between the 2004 and 2016 SIMD, it is comparable between those time points.[4,42] Nationally, it is also highly correlated with both the overall SIMD score and the overall English Index of Multiple Deprivation score.[4,9] We repeated the original analyses of 2003–07 all-cause mortality using this measure of deprivation, and there was very little difference in the results compared with those based on the original income deprivation measure. The online appendix contains further details of these comparisons, alongside full definitions of the measures of deprivation.

For Glasgow, employment deprivation data were obtained from the 2004 and 2016 SIMD; for the English cities, identical data for the same periods were obtained directly from DWP. A three-city deprivation index was thereby created based on levels of employment deprivation in each small area (merged datazone or LSOA) and from which population-weighted deciles were derived.

For additional context, employment deprivation data for other UK cities (three largest in Scotland, four largest in England with the exception of London) were also obtained from DWP.

Mortality and population data

For the main updated analyses, mortality data (by sex, 5-year age group, cause of death and small area) for 2014–2018, and matching population denominator data for 2016 (the period mid-point), were obtained from the National Records of Scotland for Glasgow and from the Office for National Statistics for Liverpool and Manchester. The same causes of death as before were examined (defined by the same ICD codes): these are listed in online appendix Table A1.

To assess the impact of the different measures of deprivation in the earlier period, all-cause mortality data (2003–2007) and population data (2005) were also accessed from the same sources. To provide context to the main mortality analyses, city-level all-cause mortality data (and matching population data) by sex and age were obtained for 1981–2018.

Statistical analyses

Indirectly standardised mortality ratios (SMRs) were calculated for Glasgow relative to Liverpool and Manchester combined, standardised by 5-year age group and three-city deprivation decile, for all-cause deaths for the period 2003–2007 (to assess the impact of using the different measure of deprivation) and for all-cause and cause-specific deaths in 2014–18. Analyses were stratified by sex

and age group: all ages, 0–14 years, 15–44 years, 45–64 years, 65+ years and 0–64 years.

For background/context to the main mortality analyses, trends in directly age-standardised mortality rates per 100,000 population by year and city were also calculated, using the 2013 World Health Organisation standard population.[43]

Results

Population/spatial units

In the 2010 study, the average population sizes of the small area units of analysis (merged 2001 datazones/2001 LSOAs) in Glasgow, Liverpool and Manchester were 1626, 1502 and 1717, respectively. In the updated analyses, the equivalent sizes for merged 2011 datazones and 2011 LSOAs were 1662, 1626 and 1919. Further details are included in the online appendix (Table A2).

Between 2005 and 2016 (the original and new analyses mid-points), the estimated populations of all three cities increased – but more substantially in Manchester. Glasgow's total population increased by approximately 8% and Liverpool's by approximately 11%; however, the equivalent increase in Manchester was approximately 22% (Table A2).

Deprivation

Reflecting the income deprivation–based analyses published previously, overall levels of 2004 employment deprivation were very similar in the three cities, with between 22% (Manchester) and 24% (Liverpool) of the working-age population classed as employment deprived; the figure for Glasgow was 23%. However, Fig. 1 shows that employment deprivation levels had fallen considerably in all three cities by 2016: to 12.5% in Manchester, 15% in Liverpool and 16% in Glasgow. In relative terms, the decrease was greatest in Manchester: the change between the two periods represents a –43% decline, compared with –38% (Liverpool) and –31% (Glasgow).

Fig. 1 also shows that employment deprivation decreased across all parts of Great Britain; however, Glasgow, Liverpool and especially Manchester saw the greatest relative reductions.

Mortality analyses

To contextualise the main mortality analyses, Fig. 2 shows trends in male and female all-cause mortality rates between 1981 and 2018 for all ages and 0–64 years, presented as 3-year rolling averages. The two periods covered in the main analyses presented below (2003–07 and 2014–2018) are highlighted/shaded. In contrast to previous trends, there has been a stalling of improvement in male all-age mortality rates since 2012/2014 in all three cities (but especially in Glasgow and Liverpool); this has been demonstrated and quantified previously.[36] For females of all ages, there has been no improvement in Glasgow rates since 2009/2011; although the same is broadly true of the English cities, the greater fluctuation in rates makes this more difficult to discern. For premature mortality (deaths <65 years), changes in male trends from 2012/2014 are particularly noticeable in Glasgow and Manchester. There is much more fluctuation in female rates, although rates in Liverpool have increased consistently since 2011/2013.

Of relevance to the analyses presented below is that the gap in female premature mortality rates between Glasgow and both English cities reduced between the two periods of analysis (2003/2007 and 2014/2018); this is also true in comparing male premature rates between Glasgow and Liverpool (but not Manchester).

Fig. 3 examines in more detail the all-cause mortality gap between Glasgow and the two English cities for the 2014–18 period, showing SMRs for Glasgow relative to Liverpool and Manchester combined, adjusting not only for age but also for employment deprivation. All-age mortality in Glasgow for males in the period 2014–18 was approximately 17% higher after adjustment (SMR: 116.7; 95% confidence intervals [CIs] 119.6–123.5); for females, the equivalent figure was approximately 9% (SMR 108.5, 95% CI 106.8–110.2). For deaths under the age of 65 years, the excess in Glasgow was approximately 25% for males (SMR 125.1, 95% CI 121.6–128.7) and c.5% for females (SMR 105.4, 95% CI 101.5–101.5).

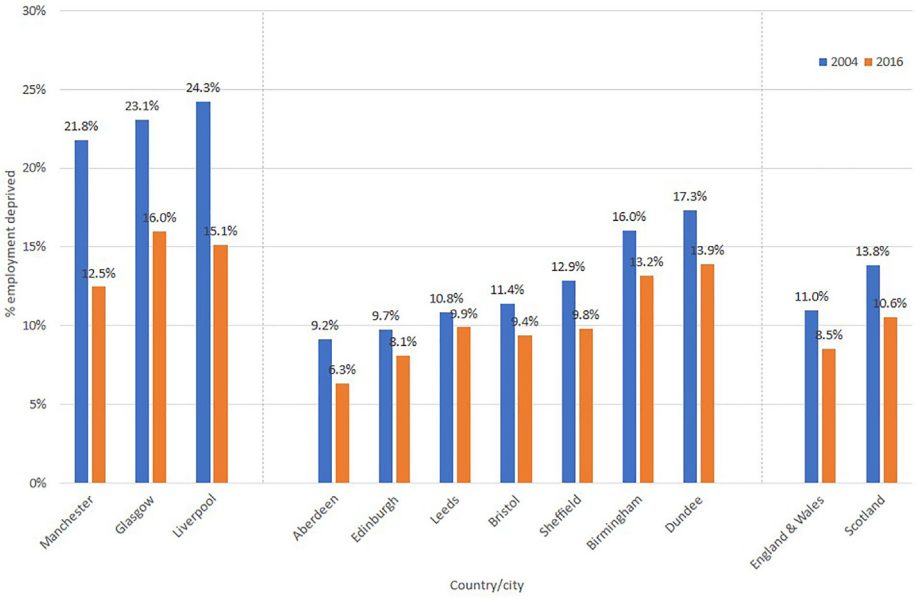

Fig. 1. Percentage of working-age population classed as 'employment deprived' in 2004 and 2016: Glasgow, Liverpool and Manchester compared with Scotland, England and Wales and selected UK cities.

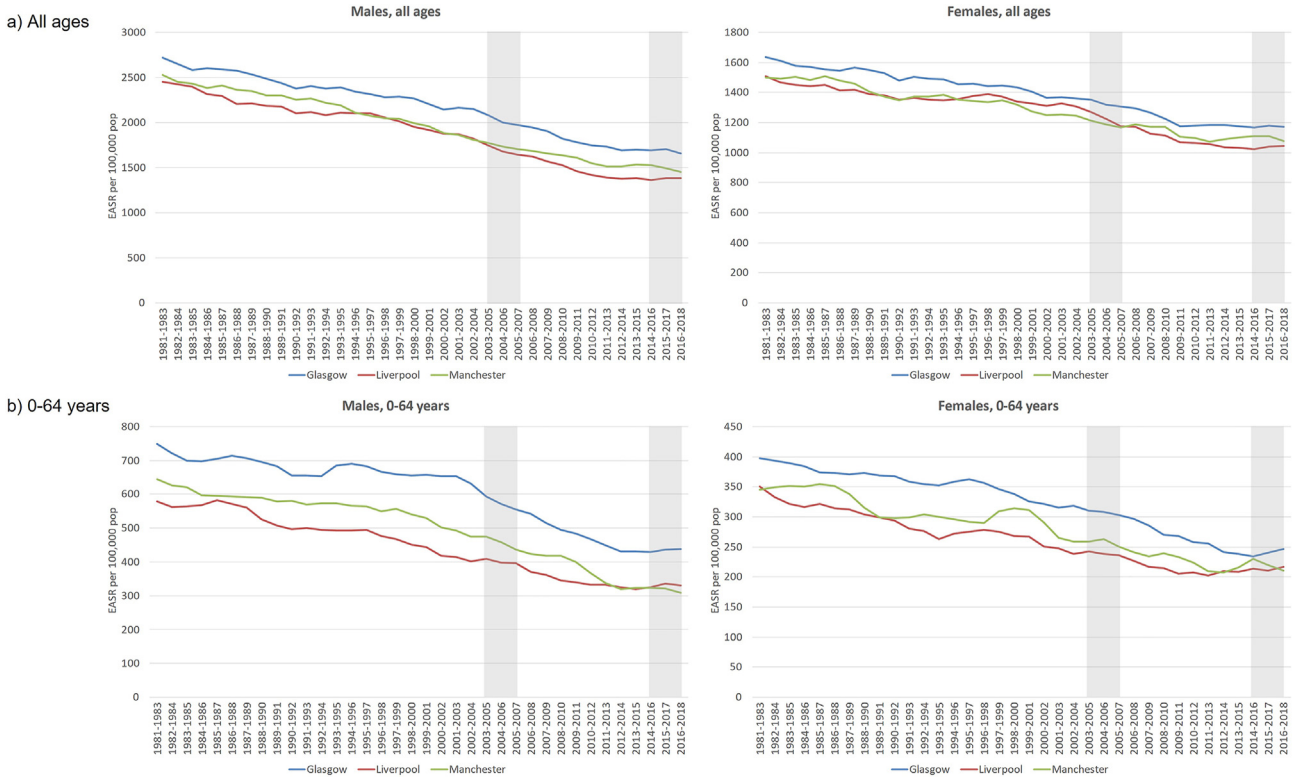

Fig. 2. European age-standardised mortality rates (EASRs) per 100,000 population, 3-year rolling averages, for all-cause deaths, Glasgow, Liverpool, Manchester, 1981–2018. Shaded areas denote periods covered by previous (2003–2007) and current (2014–2018) analyses. Note different y-axis scales on each chart.

Across different age groups, the excess in Glasgow was greatest among those of working age, principally among males: mortality was approximately 53% and 20% higher for males aged 15–44 years and 45–64 years, respectively. However, childhood mortality (age <15 years) was approximately 20% lower in Glasgow than in the English cities (with similar figures for males and females).

The online appendix (Table A3) presents data for males and females combined, showing overall excess figures of c.12% for all ages and c.17% for 0–64 years.

The results for 2014–18 are *broadly* similar to those for 2003–2007 (Table A3), with comparable all-age excess: 15% (2003–2007) and 12% (2014–2018). The major difference is a notable reduction in the excess for *premature* mortality (from 30% to 17% overall), especially for females (from 23% to 5%). This is partly explained by the narrower gap between the cities shown in Fig. 1 – but also by differences in deprivation: for the 2003–07 period, the cities' deprivation profiles were very similar, and thus, adjustment for deprivation made little difference to the results. In the most recent period, this was no longer the case: for example, for premature mortality, adjustment for deprivation reduces the excess for males from c.37% higher to 25%, and for females from c.13% to c.5%.

Comparisons between Glasgow and Liverpool and Manchester separately (rather than combined) showed similar results, although the excess tended to be lower in comparison with Manchester (online appendix Table A4).

Fig. 4 shows the SMRs for Glasgow by three-city deprivation decile for all ages and 0–64 years. The results for 2014–18 are compared with 2003–2007. For all-age deaths, the higher mortality in Glasgow is observed fairly evenly across deciles – especially in the most recent period. Note that the higher mortality in Decile 2 in the first period was not seen in the original study (i.e. based on income deprivation rather than employment deprivation); otherwise, the results are very similar. For 0–64 years, the excess is higher among more, rather than less, deprived deciles. Again, this pattern is clearer in the most recent period. The higher excess in deciles 2 and 3 in the early period was again not observed in the original study based on income deprivation.

Finally, Fig. 5 presents – for all ages and both sexes – age-, sex- and deprivation-adjusted mortality (2014–2018) for Glasgow, relative to Liverpool and Manchester combined, for the different causes of death examined. The excess was lowest for all cancers (c.12%), including lung cancer (c.16%), and diseases of the circulatory system (c. 18%). However, in absolute terms, these causes obviously account for most deaths. In relative terms, however, the excess in Glasgow was greatest for drug-related poisonings (approximately 2.3 times higher), alcohol-related causes and suicide, both of which are approximately 50% higher. Comparing males and females (online appendix Figure A1), with the exception of suicide, the excess was higher for male deaths for each cause, especially for alcohol-related causes and drug-related poisonings. The levels of excess are broadly similar to those shown in the 2010 study; the main exception is alcohol-related causes, where the excess has fallen considerably.[9] This is discussed further below.

Discussion

Summary of main results and implications

These analyses of mortality and deprivation in three UK post-industrial cities update previous, impactful, research. They provide further evidence of worrying recent mortality trends, not just in Glasgow, but in the English comparator cities as well. The overall level of 'excess mortality' in Glasgow in 2014–18 was, at c.12%, broadly similar to that shown by previous analyses. However, the excess for premature mortality (<65 years) reduced from c.30% to 17%, partly influenced by changes in the employment deprivation profiles of the

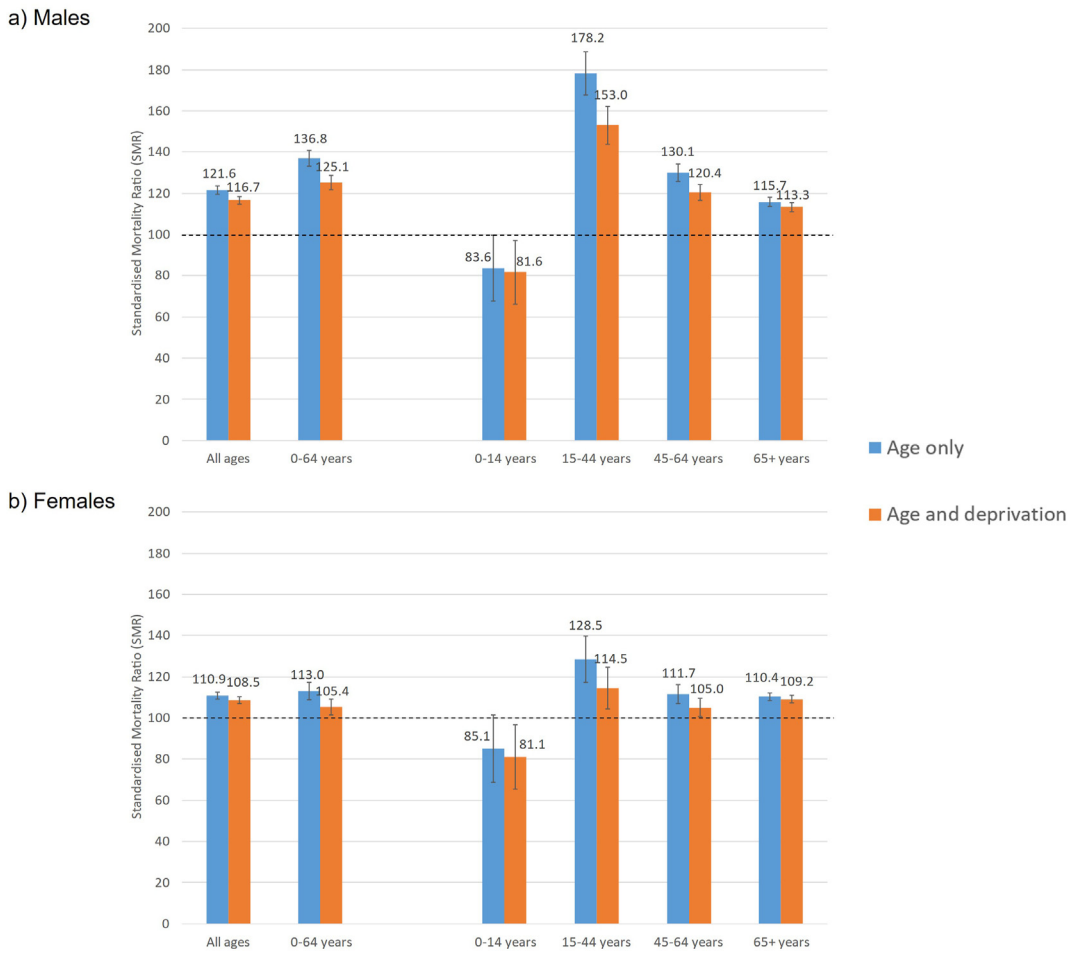

Fig. 3. All-cause standardised mortality ratios (SMRs), Glasgow relative to Liverpool and Manchester, standardised by (1) five-year age group and (2) 5-year age group and three-city deprivation decile, for (a) males and (b) females, 2014–2018.

cities: the latter is particularly true of Manchester, where the overall population size has also increased to a much greater extent.

The implications of this work are multiple. The overall 'stalling' of improvement in mortality rates in the cities is known to mask *increasing* death rates among the more deprived populations across the United Kingdom.[36] These have been linked to UK Government austerity measures, which have had a particularly detrimental effect on the poorest in society and therefore signal an urgent need for appropriate policy responses, including reversing previous cuts to social security payments for those most in need.[31–36]

The study suggests Manchester has, on average, become much less socioeconomically disadvantaged recently (potentially linked to population increases primarily in the city centre[44]); therefore, it is perhaps a less valid comparator city for these analyses than before. However, we should be cautious in this interpretation, for the work also highlights important limitations in how area deprivation is currently measured in the United Kingdom. The previously used measure of income deprivation has been criticised for several reasons, including a 'ceiling effect' (whether social security payments match the level of need).[9,12] Employment deprivation is similarly limited; in addition, it does not reflect levels of *in-work* poverty, which has risen in recent years,[45] and also fails to account for income reductions caused by UK Government austerity measures: indeed, those no longer eligible to claim particular benefits following these reforms are excluded from this definition of deprivation. More fundamentally, however, indicators derived from such administrative sources fail to capture the multifaceted experiences of living in poverty in the United Kingdom: there is a clear need, therefore, to better understand such 'unmeasured' differences between populations.

Strength and weaknesses

This study has several strengths. The analyses are based on the total populations of the cities, rather than survey samples. We have updated previous influential research. The analyses are based on the creation of similar-sized spatial units of analysis and have used an identical measure of deprivation – thus overcoming the problem of different measures of deprivation being used at different geographical scales in the different UK countries. That said, for reasons articulated previously, the use of employment deprivation is also one of the study's key limitations. In focussing on Glasgow's excess levels of mortality, we have also not analysed rates by deprivation decile *within* each city: this would be an important area for future research, given that we know the overall 'stalling' of improvement in mortality masks increasing death rates among the most deprived. This has been shown for UK nations and for Scottish (but not yet English) cities.[36] The analyses also predate the COVID-19 pandemic: further research would be required to explore whether impacts differed across the cities.

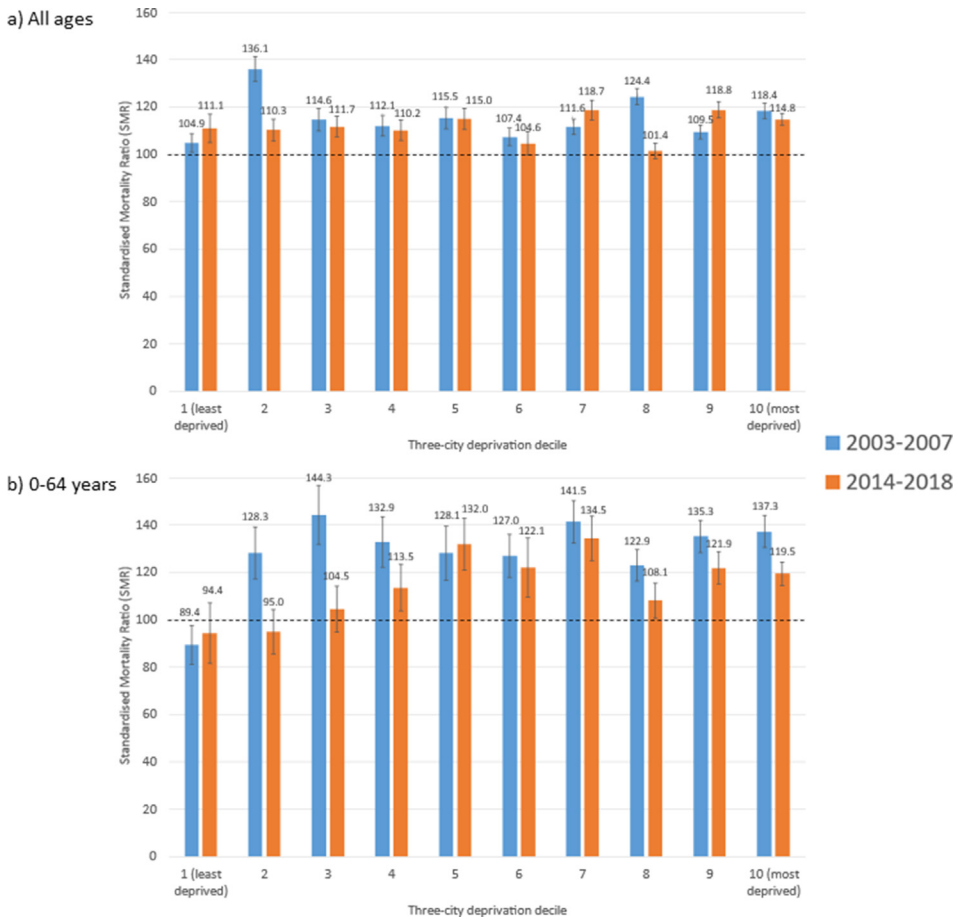

Fig. 4. All-cause age/sex standardised mortality ratios (SMRs), Glasgow relative to Liverpool and Manchester, by three-city deprivation decile for (a) all ages and (b) 0–64 years, 2003–2007 and 2014–2018.

Relevance to other studies

Stalling improvement in mortality rates in all three cities has been demonstrated recently. For example, male mortality rates in Manchester reduced by approximately −5% in the 1980s, −8% in the 1990s and 2000s, but only by −1% in the 2010s (up to 2017). Similar slowdowns were observed in the majority of UK cities.[36]

For all-age deaths, the level of excess mortality shown here for Glasgow is similar to previous studies, but lower for deaths under 65 years.[9,12,13,46–48] The higher excess for suicide and alcohol- and drug-related mortality is consistent with the previous research into the causes of Glasgow's excess mortality, with evidence of a greater vulnerability in Glasgow's population caused by a series of adverse historical and political events.[11,12] In addition, all three causes of death were recently explored in a study of birth cohorts in UK countries and cities: for drug-related deaths and suicide, particular cohorts in all three cities were at greater risk of death – but these 'cohort effects' were much more pronounced in Glasgow. Period effects were shown to be important in the analysis of deaths from alcohol-related causes; however, birth cohorts in Glasgow also had the highest mortality rates from these causes.[49] Despite that, the present study has shown that Glasgow's excess mortality for this cause of death has reduced considerably: from approximately 2.3 times higher in 2003–07 to less than 50% higher in 2014–2018. This reflects changing trends in alcohol-related deaths across the cities. Rates among males increased dramatically in Glasgow from the early 1990s, peaking in the early to mid-2000s (the period covered by the original analyses), before falling sharply in subsequent years; in contrast, rates in Liverpool and Manchester increased steadily over three decades until the early 2010s. A similar picture was observed for females, although rates in all three cities were much lower.[36]

The notably higher drug-related death rate in Glasgow (and Scotland) has been much discussed, including within two recent UK Government Parliamentary enquiries;[50,51] unfortunately, key policy recommendations to address the issue have been rejected by the UK Government.[52]

Although deaths from suicide have been shown here to be considerably higher in Glasgow, the rates of death from this cause have fallen notably in all three cities over the last three decades.[36] It has previously been suggested that lower rates of suicide in Liverpool may be influenced by the religious profile of its population, potentially conferring a protective effect.[53,54] Other such protective effects for population health in both the English cities were included as part of the 2016 explanation of the causes of Glasgow's excess mortality: in Liverpool's case, this related primarily to higher social connectedness, and in Manchester's case, this related primarily to its greater levels of ethnic diversity (linked to so-called 'healthy migrant' effects).[11,12] The influence of the latter has since been quantified with one study showing that in the years 2001–2010, excess mortality among 35- to 74-year-olds in Glasgow (relative to Manchester) reduced by one-fifth after adjustment for ethnicity and country of birth.[46] The effect may be plausibly greater now, given that a large proportion of the recent population increase

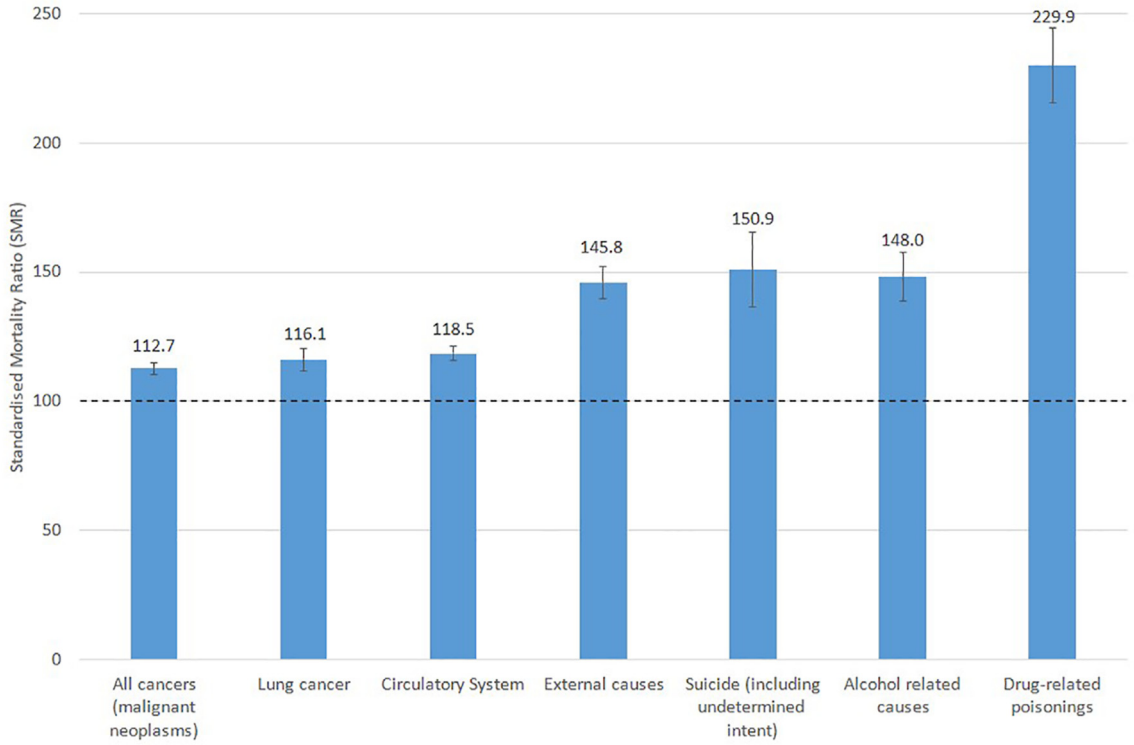

Fig. 5. Age, sex and three-city deprivation decile standardised mortality ratios (SMRs), Glasgow relative to Liverpool and Manchester, by cause of death, all ages, 2014–2018.

in Manchester is attributable to international immigration.[55] That greater population change in Manchester (compared with the other two cities) may be relevant more generally, given the previously demonstrated association between population change and mortality trends: linked to the aforementioned healthy migrant effect, mortality can decline in areas experiencing population increase, and rise in places experiencing population loss.[56–60] The increasing size of the student population – and younger residents more generally – in Manchester[44] may be relevant, although further comparative research across all three cities would be required to try to quantify its potential impact.

Conclusion

Taken in its entirety, all the evidence of excess levels of, and changing trends in, mortality in Glasgow emphasises that there is no such thing as a 'Glasgow effect': rather it is a political effect and therefore requires a political response. As the present study still demonstrates pronounced levels of excess mortality in Glasgow, previously published policy recommendations to address poverty, inequality and vulnerability in the city remain highly relevant.[12] However, given evidence of the impact of UK Government austerity measures affecting all UK cities, additional measures at UK Government level to protect, and restore, the income of the poorest in society are also urgently needed.

Author statements

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Ethical approval

Not required.

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Competing interests

None declared.

Authors' contributions

D.W. originally conceived the study. The research questions and analysis plan were agreed by all authors. Data were extracted by D.W., N.B. and R.P. L.S. undertook the analyses. D.W. drafted the article. All authors provided substantial critical input to improve the article, and all authors approved the final draft.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.puhe.2021.10.004.

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Short Communication

Psychotropic medications sales during COVID-19 outbreak in Italy changed according to the pandemic phases and related lockdowns

B. Farina [a], C. Massullo [a], E. De Rossi [a], G.A. Carbone [a], R. Serraino [b], C. Imperatori [a, *]

[a] Cognitive and Clinical Psychology Laboratory, Department of Human Sciences, European University of Rome, Italy
[b] Pharma Experience, Rome, Italy

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ABSTRACT

Objectives: We have investigated the psychotropic medications sales (i.e. benzodiazepines, mood stabilisers and selective serotonin reuptake inhibitors) during the COVID-19 pandemic in the period from March 2020 to February 2021 compared with the same period in the preceding year.
Study design: This was a retrospective and observational study.
Methods: Data were obtained from five pharmacies located in a working-class zone populated by approximately 150,000 people in the urban area of Rome (Italy).
Results: A general slight increase in psychotropic medications sales was observed during the whole pandemic period compared with the previous year.
Conclusion: Our data showed that (1) the percentage of sales seems to vary according to the pandemic phases and related lockdowns and (2) the sales differ between the classes of medications considered.

Introduction

Epidemiological studies, reviews and meta-analyses demonstrate the worsening of mental health status during the COVID-19 pandemic compared with previous periods.[1,2] Indeed, it has been reported an increased prevalence of mood-, anxiety-, sleep- and stress-related disorders due to an interplay of several factors such as worry about becoming infected, worsening living conditions caused by forced quarantine and nationwide lockdowns, social isolation, reduced income, school and university closures, dramatic changes in work life.[1–3]

Nevertheless, data on psychotropic medications consumption during COVID-19, as a possible effect of the increased burden of psychological suffering, are still scarce and controversial. Some national and government agencies worldwide report a global growth of prescriptions of benzodiazepines (BZDs), mood stabilisers (MSs) and selective serotonin reuptake inhibitors (SSRIs) during the COVID-19 pandemic,[4,5] but it is still unclear the role of the different factors involved in this increase.

For example, Armitage[4] attributes the increased rate of antidepressant prescribing during the first COVID-19 lockdown measured by the National Health Service in England to the negative psychological impact of the pandemic, whereas Walker et al.[6] contested this hypothesis considering this increase as a consequence of the ongoing upward trend in antidepressants prescribing over the last years, independently from the COVID-19.

The official government Italian National Pharmaceutical Agency (AIFA)[7] detected an increase (+7.96%) in sales of 'anxiolytics' in the pandemic period compared with the preceding year. Nevertheless, the AIFA does not specify which pharmacological classes of 'anxiolytics' were considered.

To extend available data on psychotropic drugs consumption during COVID-19 pandemic, we assessed the monthly sales of BZDs, MSs and SSRIs in a working-class zone populated by about 150,000 people in the urban area of Rome (Italy) in the period from March 2020 to February 2021 compared with the same period in the preceding year.

Methods

Database and study outcome

According to the aims of the present study, the sales of three classes of psychotropic medications used in the treatment of anxiety-depressive spectrum have been investigated: BZDs, MSs and SSRIs. The therapeutic classes have been selected according to the European Pharmaceutical Market Research Association. Data

* Corresponding author. Department of Human Sciences, European University of Rome, Via degli Aldobrandeschi 190, 00163 Roma, Italy. Tel.: +6 66 54 38 73.
E-mail address: claudio.imperatori@unier.it (C. Imperatori).

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were obtained from five pharmacies located in a working-class zone populated by approximately 150,000 people in the urban area of Rome (Italy). The average monthly number of customers (i.e. the number of individuals who bought at least one medication or another non-pharmaceutical health-related product) in these pharmacies is approximately 28,000 people. Considering the cyclical nature of COVID-19 being characterised by peaks and waves,[8] we focused on three time points of the pandemic in Italy corresponding to lockdown periods: (1) March to May 2020 (i.e. the first wave and first lockdown, T1), (2) June to September 2020 (i.e. reopening phase, T2) and (3) October 2020 to February 2021 (i.e. the second wave and lockdown, T3). These time points were compared (i.e. percentage change) to the same ones in the previous year (i.e. non-pandemic period): (1) March to May 2019 (T1), (2) June to September 2019 (T2) and (3) October 2019 to February 2020 (T3).

Results

As expected, the first result detected was the decrease in the number of pharmacy customers during the first and the second COVID-19 waves compared with the same period in the previous year (Fig. 1A). Specifically, compared with the previous year, during the pandemic period, a significant decrease in pharmacy customers was observed at T1 (344,699 vs 422,743; i.e. −18.46%) and at T3 (696,350 vs 752,386; i.e. −7.45%). Conversely, a slight increase (i.e. +0.21%) was observed at T2 (503,792 vs 502,726).

Despite this, taking into account all considered psychotropic medications, a slight increase (59,987 vs 59,928; i.e. +0.10%) was observed during the pandemic period compared with the previous year. Specifically, an increase in SSRIs (16,844 vs 16,412; i.e. +2.63%) and MSs (9,794 vs 9,129; i.e. +7.28%) sales was observed during all the pandemic period compared with the previous year. Conversely, a decrease in BZDs sales (33,349 vs 34,387; i.e. −3.02%) was detected during all the pandemic period compared with the previous year.

Focusing on the considered time points, compared with the previous year, an increase in all considered psychotropic medications sales (20,574 vs 19,432; i.e. +5.88%) was observed during the pandemic period at T2 (Fig. 1B). Conversely, a decrease was observed during the pandemic period at T1 (14,410 vs 15,259; i.e. −5.56%) and T3 (25,003 vs 25,237; i.e. −0.93%).

Considered separately (Fig. 1C–E), an increase in BDZs (11,307 vs 11,094; i.e. +1.92%), MSs (3,385 vs 2,967; i.e. +14.09%) and SSRIs (5,882 vs 5,371; i.e. +9.51%) sales was observed during the pandemic period at T2. An increase in SSRIs (7,177 vs 6,879; i.e. +4.33%) and MSs (4,076 vs 3,798; i.e. +7.32%) sales was also observed during the pandemic period at T3. Conversely, a decrease in BDZs (13,750 vs 14,560; i.e. −5.56%) sales was detected during the pandemic period at T3. Finally, a decrease in BDZs (8,292 vs 8,733; i.e. −5.05%), SSRIs (3,785 vs 4,162; i.e. −9.06%) and MSs (2,333 vs 2,364; i.e. −1.31%) sales was observed during the pandemic period at T1.

Discussion

The aim of this study was to investigate the BDZs, SSRIs and MSs consumption during COVID-19 outbreak in a sample of the urban area of Rome (Italy). As official government data are still not available in detail, to the best of our knowledge, this is the first study conducted in Italy on psychotropic medications consumption during the first year of the COVID-19 pandemic.

The most relevant results of our study are that (1) the percentage of sales seems to vary according to the pandemic phases and related lockdowns and (2) the sales differ between the classes of medications considered.

Indeed, even if we observed a general increase in SSRIs (+2.63%) and MSs (+7.28%) sales during the COVID-19 year (March 2020 to February 2021) compared with the previous one (March 2019 to February 2020), this growth varies according to the restriction phases with an initial decrease in T1 and an upsurge in T2 and T3. The initial decrease can be explained by both the substantial reduction of pharmacy customers (−18.46%) observed at the first lockdown period (T1) and the disruption of mental health services during COVID-19 lockdown.[9] We should recall that the acute outbreak of March 2020 induced the Italian government to enforce the first total lockdown in the Western world. People were not allowed to circulate, and the most of non-essential public and private health services were closed to avoid the spread of the infection. Unavailability of health services and prescriptions, as well as the worry of being infected, can explain the initial reduction of medication consumptions. On the contrary, in T2 (summertime), the situation was temporarily normalised, and the restrictions were discontinued. In

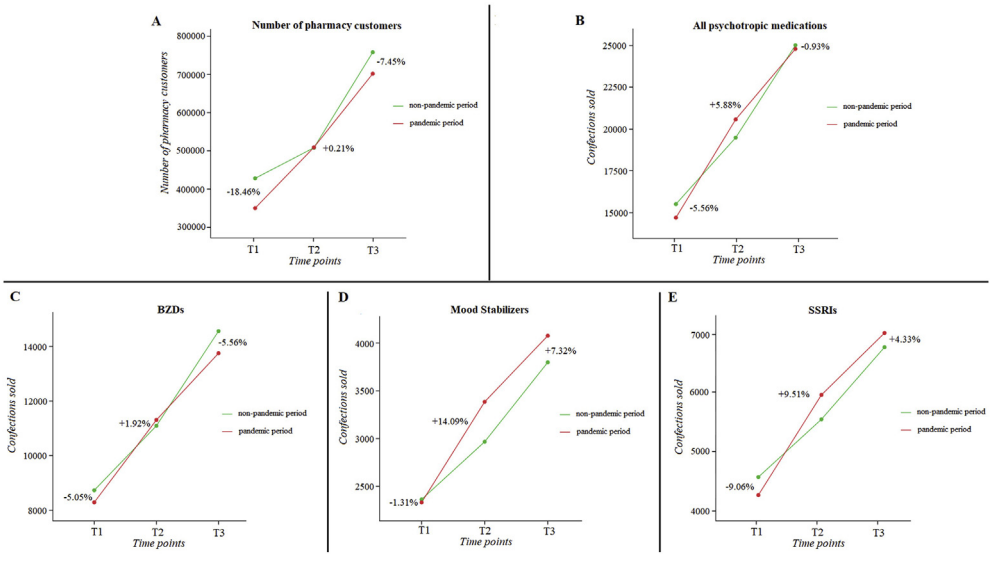

Fig. 1. (A) Number of pharmacy customers during the different time points. (B–E) Confections of psychotropic medications sold across the three time points. BZDs, benzodiazepines; SSRIs, selective serotonin reuptake inhibitors; T1, time point n°1 (i.e. March to May); T2, time point n°2 (June to September); T3, time point n°3 (i.e. October to February).

T2, we do not observe relevant differences with the same period of 2019 in the number of pharmacies customers, but the consumption of the psychotropic medications raised for all the classes considered (BDZs +1.92%, MSs +14.09% and SSRIs +9.51%). In the second Italian lockdown (T3), which in Italy has been experienced with much more discouragement than the first, even if the customers number decreased (−7.45%), we detected an increase in SSRIs (+4.33%) and MSs (+7.32%) consumptions. We can, thus, hypothesise that reduced mental health resources and growth of distressing conditions[1–3] led to an increase in consumption of SSRIs and MSs.

This research has several limitations: (1) our sample is small and not representative of the entire Italian population; (2) despite a strong relationship between medications sales and their consumption is supposed, this relationship is not fully demonstrated; (3) we measured only the three most common classes of psychotropic medications used in the treatment of anxiety-depressive spectrum but not other antidepressant or antipsychotic medications; and (4) we recorded only medication rate sales, and we do not know if the surge is due to an increase in new cases, the worsening of pre-existing sufferings or both. Because of these limitations and the rapidly evolving nature of COVID-19 pandemic psychological burden, our results must be considered preliminary.

Overall, our findings are in line with previous reviews and meta-analyses[1–3] that suggest an increased prevalence of mental burden due to the COVID-19 pandemic and recommend the urgent need of investments on preventive measures and health-promoting interventions (e.g. psychotherapies) to buffer negative effects of COVID-19 on mental health.[10]

Author statements

Author contributions

B.F. conceptualization; methodology; analysis and interpretation; writing—original draft.

C.M. conceptualization; data curation; methodology; writing—review and editing.

E.D.R. conceptualization; data curation; methodology; writing—review and editing

G.A.C conceptualization; data curation; methodology; writing—review and editing

R.S. conceptualization; data curation; methodology; C.I. conceptualization; supervision; methodology; analysis and interpretation; writing—original draft.

Ethical approval

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Conflicts of interest

None declared.

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Retraction notice

Retraction notice: Effect of educational interventions on health in childhood: a meta-analysis of randomized controlled trials [Public Health Volume 164, November 2018, Pages 134-147]

X. Wang [a, d], G. Zhou [d], J. Zeng [a, b, c], T. Yang [a, b, c], J. Chen [a, b, c], T. Li [a, b, c, *]

[a] Children's Nutrition Research Center, Children's Hospital of Chongqing Medical University, Chongqing 400014, China
[b] Ministry of Education Key Laboratory of Child Development and Disorders, Children's Hospital of Chongqing Medical University, Chongqing 400014, China
[c] Chongqing Key Laboratory of Translational Medical Research in Cognitive Development and Learning and Memory Disorders, Chongqing 400014, China
[d] Third Affiliated Hospital of Zunyi Medical College, Guizhou 563000, China

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The article is a duplicate of a paper that has already been published in Medicine, 97 (2018) e11849 https://doi.org/10.1097/MD.0000000000011849. Redundant publications overweigh the relative importance of published findings and distort the academic record of the authors. One of the conditions of submission of a paper for publication is therefore that authors declare explicitly that the paper has not been previously published and is not under consideration for publication elsewhere. As such this article represents a misuse of the scientific publishing system.

The scientific community takes a very strong view on this matter and apologies are offered to readers of the journal that this was not detected during the submission process.

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* Corresponding author. Children's Nutrition Research Center, Children's Hospital of Chongqing Medical University, Chongqing 400014, China.
E-mail address: tyli@vip.sina.com (T. Li).

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Original Research

The detection of the epidemic phase of COVID-19 and the timing of social distancing policies in Korea

Woohyeon Kim*

Korea Institute of Public Finance, 336, Sicheong-daero, Sejong 30147, Republic of Korea

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ABSTRACT

Objectives: Observing cumulative and new daily confirmed cases of COVID-19, disease control authorities respond to a surge in cases with social distancing measures or economic lockdown. The question in this article is whether we can gather more useful information from a readily available time series data set of day-to-day changes in confirmed cases of COVID-19.
Study design: Time-series data analysis was done using a hidden Markov model.
Methods: Day-to-day differences in confirmed cases of COVID-19 in Korea from February 19, 2020, to July 13, 2021, were modeled via a hidden Markov model. The results from the model were compared with the effective reproduction number and the Korean government's response.
Results: The model reports that Korea was in an epidemic phase from August 2020 and from mid-November 2020, the second and third epidemic waves. The government's response, represented by the Government Response Stringency Index, was not timely during the epidemic phases. The results from the model may also be more helpful to detect the onset of the epidemic phase of an infectious disease than the effective reproduction number.
Conclusions: The model can reveal a hidden epidemic phase and help disease control authorities to respond more promptly and effectively.

Introduction

The unprecedented COVID-19 pandemic has thrown the world into crisis. The numbers of cumulative or newly confirmed cases or deaths are released by the media, with the information provided by research centers or websites, such as Johns Hopkins University or Worldometer. Governments respond to surges in confirmed cases with social distancing measures or economic lockdowns. However, the up-to-date case numbers may not be sufficient for health authorities to judge whether or not a serious epidemic phase is underway, requiring tougher action. People may not understand the implicit meaning of the daily fluctuation of the time series data of confirmed cases. A surveillance system with scientific support should process an up-to-date data set and share its understanding of pandemic risk with the public.

South Korea has repeatedly imposed different levels of social distancing measures and partial economic lockdowns, and the government has produced guidelines on easing or tightening these measures. For example, as of December 2020, the Korea Disease Control and Prevention Agency (KDCA) tightened social distancing from level 2 (rapid local transmission, initial phase of national transmission) to level 3 (national epidemic) when the weekly average number of confirmed cases exceeded 800–1000.[a] However, the threshold of 800–1000 cases seems to be unsubstantiated. Even when the actual number of cases did exceed the threshold, KDCA was often reluctant to implement a tougher lockdown policy.[b] Understandably, KDCA assesses a variety of different economic and social factors in addition to the pandemic risk. However, hesitation also comes about because KDCA is not able to detect the true risk of an epidemic phase from the daily number of cases and

* Tel.: +82-44-414-2338; fax: +82-44-414-2309.
E-mail addresses: 7bumblebees@gmail.com, whkim@kipf.re.kr.

[a] The KDCA website, http://ncov.mohw.go.kr/en, Accessed: January 26, 2021. The guidelines of KDCA have changed throughout the pandemic. However, the number of confirmed cases remains as the important determinant in adjusting social distancing measures.

[b] For example, Korea suffered 900 confirmed daily cases during the third week of December 2020, arguably meeting the requirement for social distancing level 3. However, KDCA decided to remain at level 2+ at that time.

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deaths. This hesitation may confuse the public who have to live their daily lives under social distancing rules.

To help with this situation, established statistical methods are available to detect the early onset of an epidemic. Regression models and other statistical treatments based on historical data sets, from simple summary statistics to cumulative sum statistics, have been actively used for early detection.[1–4] The seminal research introduced a periodic regression to model a fluctuation of weekly pneumonia-influenza deaths in the United States.[5] The model fitted the regular pattern of death cases with the historical data to identify an irregular surge of cases over a predetermined threshold. Several drawbacks have been pointed out, including the need for non-epidemic data to model a normal trend[6] or the independent observations assumption.[7] The need for a long-term non-epidemic data set to model the baseline is particularly vulnerable to a newly discovered infectious disease. ARIMA(Autoregressive Integrated Moving Average)-type time series modeling can also be used to model a fluctuation and detect an irregular perturbation.[8] However, time series modeling may depend on stationarity and single distribution assumptions, which are hard to satisfy in many cases, including epidemics.[9]

Some researchers have paid attention to a hidden Markov model to relax the strong assumptions above.[6,9] Epidemiological data can be readily separated and modeled with different states, an epidemic and a non-epidemic phase underlying the Markov chain. Martínez-Beneito et al.[7] further developed the idea by modeling the week-to-week differences in influenza incidence rate in Spain. They identified an epidemic phase, the period when strong containment measures would be needed to curb the spread of the virus.

This article models the daily confirmed cases of COVID-19 in Korea following the model suggested by Martínez-Beneito et al.;[7] this information is readily available to the public as well as to disease control authorities. The model becomes particularly helpful in understanding when and where an epidemic breaks out in each country or region with an estimated probability of being in an epidemic phase. The epidemic phases of COVID-19 are identified from the daily confirmed cases in Korea from February 2020 to mid-2021. It is then considered how well the epidemic phases correlate with the timing of social distancing and lockdown policies.

The COVID-19 situation and social distancing policies in Korea

The first case of COVID-19 in Korea was reported on January 20, 2020. Since then, it is believed that Korea has been relatively successful in curbing the spread of the virus compared with many other countries. Korean people have conformed to COVID-19 prevention measures, wearing face masks, supporting the aggressive "trace, test, and treat" strategy, and following social distancing rules.[10]

However, efforts to contain the spread of coronavirus have not always been successful. Panel (a) in Fig. 1 illustrates the daily change in confirmed cases in Korea from mid-February 2020 to mid-July 2021. It can be seen that there were at least three distinct outbreaks of COVID-19. Because COVID-19 is a highly contagious disease, the momentary carelessness of a small group of people can lead to widespread exposure to the virus. It is believed that the first two surges of the virus originated exclusively from activities in some local churches.[c] On the other hand, the cause of the third nationwide outbreak starting in November 2020 is unclear.

Whenever the virus has surged, KDCA has taken infectious disease prevention and control measures. In addition, different levels of social distancing have been applied for people in local outbreak areas or nationwide as needed. Because social distancing measures and the related lockdown of small businesses hurt the economy, KDCA has a difficult task in maintaining a balance between preventing outbreaks and sustaining the economy. Therefore, KDCA carefully defined some rules, ranging from mild distancing in daily life to enhanced social distancing. As of December 2020, Korea had five different levels of social distancing, depending on the severity and scale of virus transmission and the pandemic (Table 1).

From KDCA's standpoint, determining when to intervene and adjust social distancing measures is very important. According to the rules in Table 1, changes in daily confirmed cases are the determining factor for imposing social distancing measures. According to the rules, KDCA should tighten restrictions from level 2 (regional) to level 2.5 or 3 (national) when the 7-day average of daily cases peaks at or exceeds 400–500 or when there is a sudden surge in confirmed cases (e.g. doubling or a sudden increase in daily confirmed cases). However, it is not obvious what an average of over 400–500 daily cases means in terms of virus control or how to determine whether a doubling in cases is sudden enough to provoke a shift to the next level of rules.

The effective reproduction number (R_t) provides important information for health authorities.[d] By definition, the number of infected people increases when $R_t > 1$. Much of the literature on epidemiology and economics considers the R_t rate when constructing modeling for the COVID-19 pandemic.[13,14] KDCA reports that it refers to the effective reproduction number as one of the subindicators used to adjust levels of social distancing.[15] However, it is not clear how KDCA incorporates information about R_t into the criteria shown in Table 1. Therefore, some experts in Korea recommend that KDCA should actively use the reproduction number rather than just tracing changes in confirmed cases.[16] The reproduction number has an intuitive meaning. The condition when $R_t > 1$ indicates that a virus is spreading and action is required to contain it. However, R_t is time-lagged information because the information represents a delayed dynamics of transmission.[17] Furthermore, crucial information, including the serial interval and time of symptom onset, may not be readily available to correctly estimate R_t, especially for a newly emerging infectious disease.[17] Authorities may run the risk of releasing biased estimation results without credible prior information.

This study exploits the advantages of the hidden Markov modeling in the context of contagious diseases as suggested by Martínez-Beneito et al.[7] The hidden Markov model has several advantages over other information, including the effective reproduction number. First, the model only requires information that is readily available publicly, that is, daily changes in confirmed cases. This simplicity enables us to generate relevant information in a timely manner, even for a newly infectious disease. Second, the model contemporaneously sheds light on the hidden status of a current epidemic. This information would help authorities to base their decisions to implement painful social distancing and economic lockdown on more complete evidence. The estimation results effectively complement the frequently referenced metrics of the COVID-19 era, including R_t.

[c] On February 18, 2020, a super-spreader was identified in the Shincheonji Daegu branch of the Church, leading to 5212 cases nationwide, particularly in the Daegu-Gyeongbuk area of Korea.[11] On August 3, 2020, Sarang Jeil Church in Seoul became another outbreak epicenter, resulting in 1163 cases nationwide according to KDCA.

[d] The reproduction number represents the average number of subsequent cases from a primary case.[12]

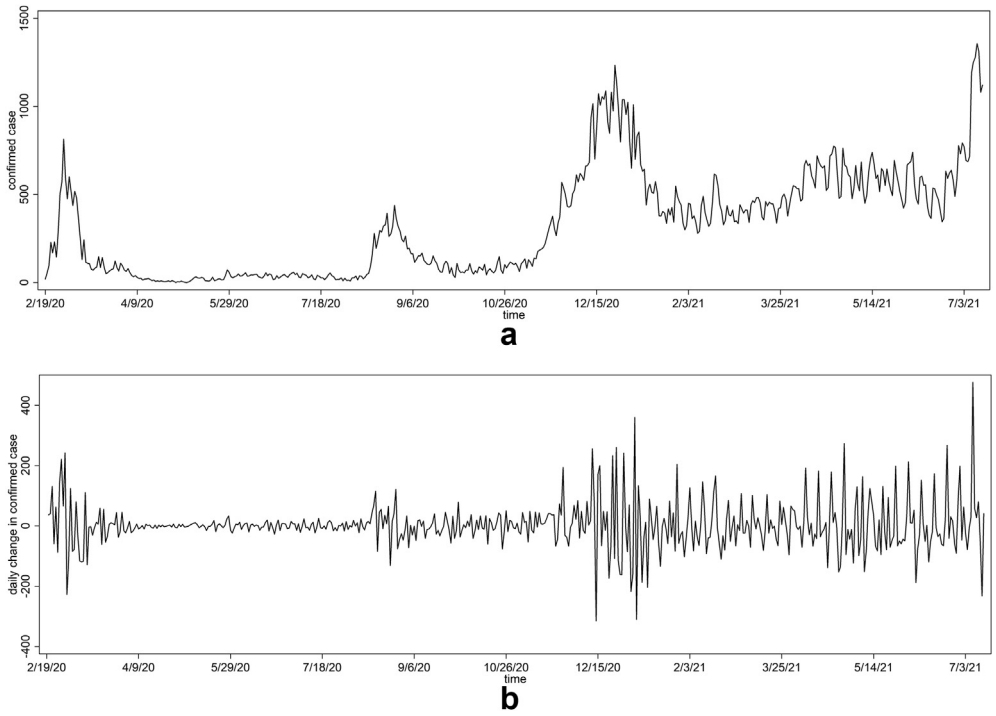

Fig. 1. Daily COVID-19 confirmed case, South Korea, February 19, 2020, to July 13, 2021.

Methods

The question in this article is whether we can gather more useful information from a readily available time series data set: day-to-day changes in confirmed cases of COVID-19. Specifically, the question is how we can determine whether we are in an epidemic phase (the onset of an epidemic) from changes in daily confirmed cases of COVID-19. The hidden Markov model can systematically analyze information on an infectious disease. The model distinguishes the epidemic phase, in which an infectious virus spreads rapidly and the variance in the number of cases increases from a non-epidemic phase with a narrow range of changes in daily case numbers. Indeed, we observe large variations in day-to-day differences in cases at a time when episodes of COVID-19 in Korea were waxing and waning, as shown in panel (b) in Fig. 1. Accordingly, it is reasonable to identify epidemic and non-epidemic phases by observing variations in day-to-day differences in confirmed cases.

Day-to-day differences in cases—$Y_{i,j}$—are modeled on the observations above, where i represents 17 first-tier administrative divisions (metropolitan areas and provinces) in Korea, and j stands for days from February 19, 2020, to July 13, 2021, which is the period of the data set analyzed.

$$Y_{i,j} \mid (Z_{i,j} = 0) \sim \mathrm{N}(0,\ \sigma^2_{0,i})$$

$$Y_{i,j} \mid (Z_{i,j} = 1) \sim \mathrm{N}(\rho Y_{i,j-1},\ \sigma^2_{1,i})$$

The model shows that if we are in a non-epidemic phase—that is, $Z_{i,j} = 0$—$Y_{i,j}$ follows a normal distribution with mean 0 and variance $\sigma^2_{0,i}$. Once we are in an epidemic phase—that is, $Z_{i,j} = 1$—the variance in the distribution increases to $\sigma^2_{1,i} > \sigma^2_{0,i}$, which indicates that the variance in the day-to-day differences in cases is larger in an epidemic phase than in a non-epidemic phase. In addition, in an epidemic phase, it is reasonable to model the difference in cases today as correlated with the difference in cases yesterday through the parameter ρ, given the characteristics of infectious diseases that spread from an infected person to a healthy person. The hidden daily epidemic status $Z_{i,j}$ is assumed to follow a Markov process through $P_{k,m} = P(Z_{i,j+1} = m \mid Z_{i,j} = k)$, where $k = 0, 1,\ m = 0, 1$. Therefore, the daily epidemic phase transition is governed by the four parameters, $P_{0,0}$, $P_{0,1}$, $P_{1,0}$, and $P_{1,1}$.

A Bayesian framework is used to obtain posterior distributions with appropriate prior distributions for the parameters in the model, $P_{0,0}$, $P_{0,1}$, $P_{1,0}$, $P_{1,1}$, ρ, $\sigma^2_{0,i}$, $\sigma^2_{1,i}$. Following the previous study,[7] hyper-prior distributions are used to represent the condition $\sigma^2_{0,i} < \sigma^2_{1,i}$. More specifically, four ordered statistics $(\theta_{(1)},\ \theta_{(2)},\ \theta_{(3)},\ \theta_{(4)})$ are drawn from a uniform distribution $U(a,b)$, and let $\sigma^2_{0,i}$ and $\sigma^2_{1,i}$ come from $U(\theta_{(1)}, \theta_{(2)})$ and $U(\theta_{(3)}, \theta_{(4)})$, respectively.[e] The condition $\sigma^2_{0,i} < \sigma^2_{1,i}$ in the model is satisfied in this way. The parameters $P_{0,0}$ and $P_{1,1}$ depend on the $beta(0.5,\ 0.5)$ priors; ρ starts from a prior $U(-1, 1)$. After fitting the model, all posterior distributions for parameters are obtained along with samples of daily epidemic status, $Z_{i,j}$, through Gibbs sampling. The posterior average of samples of $Z_{i,j}$ represents the posterior daily probability of being in an epidemic phase for region i at time j.

[e] The parameters of the precedent uniform distribution a, b are assigned according to the variance of the day-to-day differences, $Y_{i,j}$.

Table 1
Social distancing in Korea, basic rules.

Level	Level 1 Distancing in daily life	Level 1.5 Regional level	Level 2	Level 2.5 National level	Level 3
Concept	Distancing in daily life	Local transmission	Rapid transmission, starting phase of national transmission	National transmission	National epidemic
Situation	Daily disinfection and social distancing/control of disease under the medical capacity	Transmission lasts equal to or over 7 days in a specific region threatening the medical system's capacity	Shows increases in transmission despite of Level 1.5 actions/observations of national transmission	National transmission lasts equal to or over 7 days exceeding the capacity of current medical system/surge in number of confirmed cases nationwide and threat of collapse of current medical system	
Criteria	- Average of daily confirmed cases per week • Seoul metro region: below 100 • Chungcheong, Honam, Gyeongbuk, Gyeongnam: below 30 • Gangwon, Jeju: below 10	- Average of daily confirmed cases per week • Seoul metro region: equal to or over 100 • Chungcheong, Honam, Gyeongbuk, Gyeongnam: equal to or over 30 • Gangwon, Jeju: equal to or over 10 - Average of daily confirmed cases per week of ages equal to or above 60 • Seoul metro region: equal to or over 40 • Chungcheong, Honam, Gyeongbuk, Gyeongnam: equal to or over 10 • Gangwon, Jeju: equal to or over 4	When applied to one of the following criteria ① Increase of confirmed cases by 200% lasts after the Level 1.5 actions in epidemic regions ② Level 1.5 actions last for 7 days or longer in two or more regions ③ Number of national daily confirmed cases surpasses 300 for 7 days or longer	- Average of daily confirmed cases per week peaks to or over 400–500 **OR** doubling or sudden increase in confirmed cases during Level 2 ※ The ratio of new confirmed cases of 60 or older, accommodation capability of severe patients, etc. will be considered when increasing the level to 2.5	-Average of daily confirmed cases hits 800–1000 or over **OR** doubling or sudden increase in confirmed cases during Level 2.5 ※ The ratio of new confirmed cases of 60 or older, accommodation capability of severe patients, etc. will be considered when increasing the level to 3
Core Message	Comply with COVID-19 precautionary acts in normal daily/social/economic lives	Regional transmission, thorough social distancing in high-risk regions	Rapid regional transmission, refrain from outings and gathering in high-risk regions and using public facilities	National transmission, stay at home if possible, and refrain from outings and using public facilities	- National epidemic - Stay at home - Minimize contact with others

Ministry of Health and Welfare in Korea, Social Distancing Basic Rules, translated in George Mason University, Mason Korea https://masonkorea.gmu.edu/corona/national-regulations-in-korea/social-distancing, updated: December 11, 2020.

The daily time series of confirmed cases for the 17 administrative divisions[f] of Korea compiled by Statistics Korea were collected for the period February 19, 2020, to July 13, 2021. It is interesting to see how the estimated daily probability of being in an epidemic phase is correlated with other relevant information, namely, day-to-day changes in confirmed cases and the effective reproduction number R_t. The advantages of the new information from the hidden Markov model are presented by comparing the regional population-weighted average of the probabilities with other measures. The corresponding daily effective reproduction number for Korea was extracted from Our World in Data.[12] In addition, a critical policy question in terms of disease control is how the government of Korea actually responded to the COVID-19 situation by adjusting social distancing levels. It is difficult to clearly determine how local governments and KDCA reacted over time. Notwithstanding the current national rules from KDCA, shown in Table 1, rules were constantly revised in line with the ever-changing nature of the pandemic. Furthermore, the local government in each region can tighten or loosen the social distancing level at their discretion. The Government Response Stringency Index[g] is a standardized measure showing how a government's policies and responses evolve.[18] Albeit an imperfect measure, the index can be used to understand how the Korean government reacted on the whole and whether its responses can be considered appropriate in the light of the estimated probabilities of being in an epidemic phase according to the model. The Government Response Stringency Index is also available in Our World in Data.

Results

The posterior distribution of parameters in the model is shown in Table 2, where $\widehat{\rho}$ is estimated to be negative, probably reflecting the serrate-shaped time series data of day-to-day differences in confirmed cases in panel (b) in Fig. 1. This itself may not represent the dominant characteristics of the data flows shown in Fig. 1. On the contrary, the daily transition probabilities $\widehat{P_{0,0}}$ and $\widehat{P_{1,1}}$ are estimated to be extremely high, at 98.7% and 95.7%, respectively, exhibiting the path-dependent tendency of an infectious disease. Therefore, the estimates have the potential to fit the data flows well along with the differences in variances, $\widehat{\sigma_{0,i}^2} < \widehat{\sigma_{1,i}^2}$ coming from $\widehat{\theta_{(1)}} \sim \widehat{\theta_{(4)}}$.

After estimating the probability of being in an epidemic phase for each region i at time j, it is informative to see how the flows of the probabilities and the actual numbers of cases are correlated. The daily number of cases was plotted, and circles were overlaid for the days when the estimated probability of being in an epidemic phase was greater than 50%. Although there may be other ways of interpreting and using the results, it seems reasonable to regard a probability of greater than 50% as a warning sign, following previous studies.[7]

[f] The administrative divisions comprise eight special or metropolitan cities (Seoul, Busan, Daegu, Incheon, Gwangju, Daejeon, Ulsan, and Sejong) and nine provinces (Gyeonggi, Gangwon, Chungbuk, Chungnam, Jeonbuk, Jeonnam, Gyeongbuk, Gyeongnam, and Jeju).

[g] The Government Response Stringency Index, part of the Oxford COVID-19 Government Response Tracker, is a composite measure, which uses nine metrics to measure a government's strictness of policy response. The metrics are school closures, workplace closures, cancellation of public events, restrictions on public gatherings, closures of public transport, stay-at-home requirements, public information campaigns, restrictions on internal movement, and international travel controls. The index ranges from 0 (the least strict response) to 100 (the most strict response).[18]

Table 2
The posterior distribution of parameters.

Parameters	Mean	Standard deviation	25%	median	75%
$\widehat{P_{0,0}}$	0.987	0.002	0.985	0.987	0.988
$\widehat{P_{1,1}}$	0.957	0.006	0.953	0.957	0.961
$\widehat{\theta_{(1)}}$	5.002	0.001	5.000	5.001	5.002
$\widehat{\theta_{(2)}}$	5.006	0.004	5.002	5.004	5.008
$\widehat{\theta_{(3)}}$	6.770	1.339	5.688	6.582	7.602
$\widehat{\theta_{(4)}}$	64.813	6.211	60.433	63.873	68.557
$\widehat{\rho}$	−0.316	0.022	−0.331	−0.316	−0.303

The plots for two regions, the city of Daegu and the Gyeongbuk province, are shown in Fig. 2. As explained in Section 2, the first outbreak in Korea occurred in these two areas during February and March 2020. The model performs well in the sense that the probabilities of being in an epidemic phase capture the onset and decline of the pandemic in February and March 2020. More helpfully, the epidemic probabilities beneath the actual confirmed cases distinguish an epidemic from a non-epidemic in a more scientific manner.

Fig. 2 also illustrates the relatively strong performance of the model for other periods of the pandemic in Korea. The second wave of the pandemic, in August 2020, occurred mostly in Seoul, the capital city of Korea, and nearby metropolitan areas, Incheon city and Gyeonggi province. From mid-August 2020, the model warns of the onset of the pandemic in these areas. The model provides alerts again for Seoul and Incheon from early- or mid-November 2020 during the nationwide third wave of the pandemic. For the third wave, it is interesting that the model flags warnings for Gangwon and Gyeongnam provinces, which show upward trends of confirmed cases from mid-November 2020. These two areas did not previously suffer from the pandemic during the first and second waves. On the other hand, Sejong city and Jeonnam province, for example, do not show upward trends in the number of confirmed cases during the third epidemic wave; these two areas are known to be successful in containing the outbreak because of their population size and density, showing relatively stable case numbers over the period. The model hardly gives any warning for Sejong city and Jeonnam province.

As each regional epidemic probability is effective in analyzing and detecting the early onset of the epidemic locally, a local population-weighted average of the probability of being in an epidemic phase illustrates another way of viewing the national pandemic. Panel (a) in Fig. 3 shows daily confirmed cases and the hidden local population-weighted average of epidemic probabilities. The average probabilities stand out during the second and third waves of the pandemic in Korea and beyond. Although the numbers of confirmed cases in the first pandemic were greater than those in the second, the model is silent for the first period. This result indicates that a locally severe outbreak in the first period may not have been serious at the national level, meaning that locally intensive disease controls were appropriate at that time. On the other hand, there was a need for KDCA to focus on social distancing and other control measures nationwide during the second and third waves. The model helps to understand the real-time epidemic situation locally and nationally and to ensure that appropriate measures are taken.

The effective reproduction number and the hidden Markov model exhibit quite different patterns in some periods. Again, a reproduction number greater than 1 is a warning sign of being in an epidemic phase. Panel (b) in Fig. 3 uses circles to identify the days where $R_t > 1$. Although the time series of the effective reproduction number corresponds fairly well with the first, second, and third waves of the pandemic in Korea, the numbers are also greater than 1 for most of May, June, and July 2020. The changes in confirmed cases

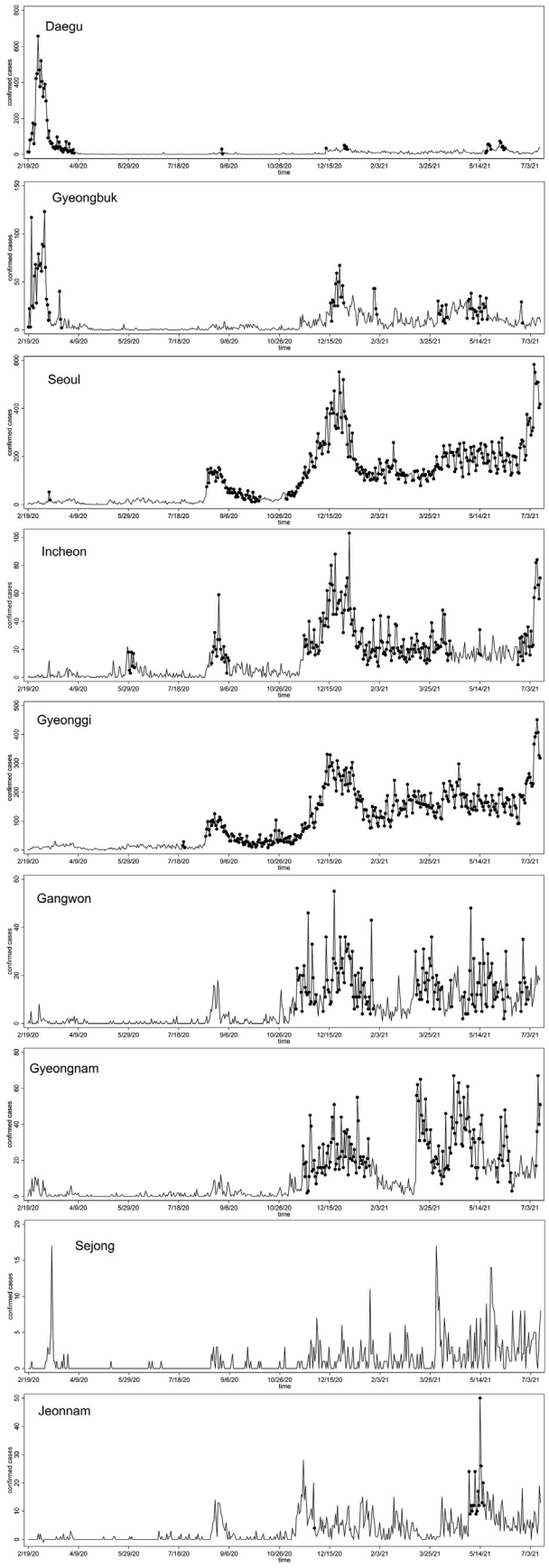

Fig. 2. Numbers of confirmed cases and the probabilities of being in an epidemic phase in different regions.

remained stable during this period when KDCA lowered the level from social distancing (level 2) to distancing in daily life (level 1). The figure shows that the effective reproduction number may be excessively sensitive for correctly detecting the onset of infectious disease. From a public policy point of view, the hidden Markov model more clearly distinguishes epidemic and non-epidemic phases.

An additional distinction is that the hidden Markov model presents a more conservative identification of onset compared with the effective reproduction number. For example, the reproduction number produces a warning sign until August 30, 2020, three days after the number of cases reached the peak during the second wave. However, the hidden Markov model remains cautious until September 9, 2020, when the time series of confirmed cases appears to be completely back to normal. For the third wave and beyond, the distinction is more pronounced, as the hidden Markov model consistently flags warnings, whereas the effective reproduction number does not.

Finally, a central policy question is whether the actual government responses in Korea correspond to the hidden status of the epidemic. Panel (c) in Fig. 3 shows the Government Response Stringency Index of Korea.[18] The index does not seem to be highly correlated with the probability of being in an epidemic phase according to the model. Therefore, from a policy point of view, this implies that the Korean government could have been more aggressive in its response in the periods with warning signs, that is, the second and third waves of the pandemic.

Discussion

Since 2020, the world has faced the highly contagious disease COVID-19. In Korea, adopting an aggressive "trace, test, and treat" strategy with tough social distancing and economic lockdown rules has been considered relatively successful in containing the spread of the epidemic.[19,20] However, local lockdowns and social distancing policies have taken a heavy toll on the economy, particularly on vulnerable economic groups, such as small business owners. According to Korea Credit Data,[h] retail sales in 2020 were lower than 2019 almost every week. Therefore, the assessment of the risk of pandemic locally and nationally in an accurate and timely manner is more important than ever before.

This study has shown how a hidden Markov model can be used to understand real-time COVID-19 situations. The model reports that Korea was in an epidemic phase during August 2020 and in the period from mid-November onward, the second and third waves. The results can help both the authorities and the public understand the current spread of the virus and take appropriate action. According to the results of the model, the policy responses in Korea may not have been as timely as they could have been. Finally, the effective reproduction numbers appear to represent different information compared with the results of the model. The hidden Markov model clearly separates epidemic and non-epidemic phases, which, from a policy point of view, is more useful for detecting the onset of an infectious disease and adjusting relevant disease control measures.

To evaluate whether the model performs well in other settings, COVID-19 cases in five other countries (the United States, the United Kingdom, India, New Zealand, and Brazil) were analyzed with the same model.[i] The model continuously raises a warning

[h] Korea Credit Data (KCD) is a for-profit financial technology company that collects and provides business transaction information. It compares changes in sales in the year 2020 with the same weeks in the previous year. See the online supplemental material.

[i] The results are available in the online supplemental material.

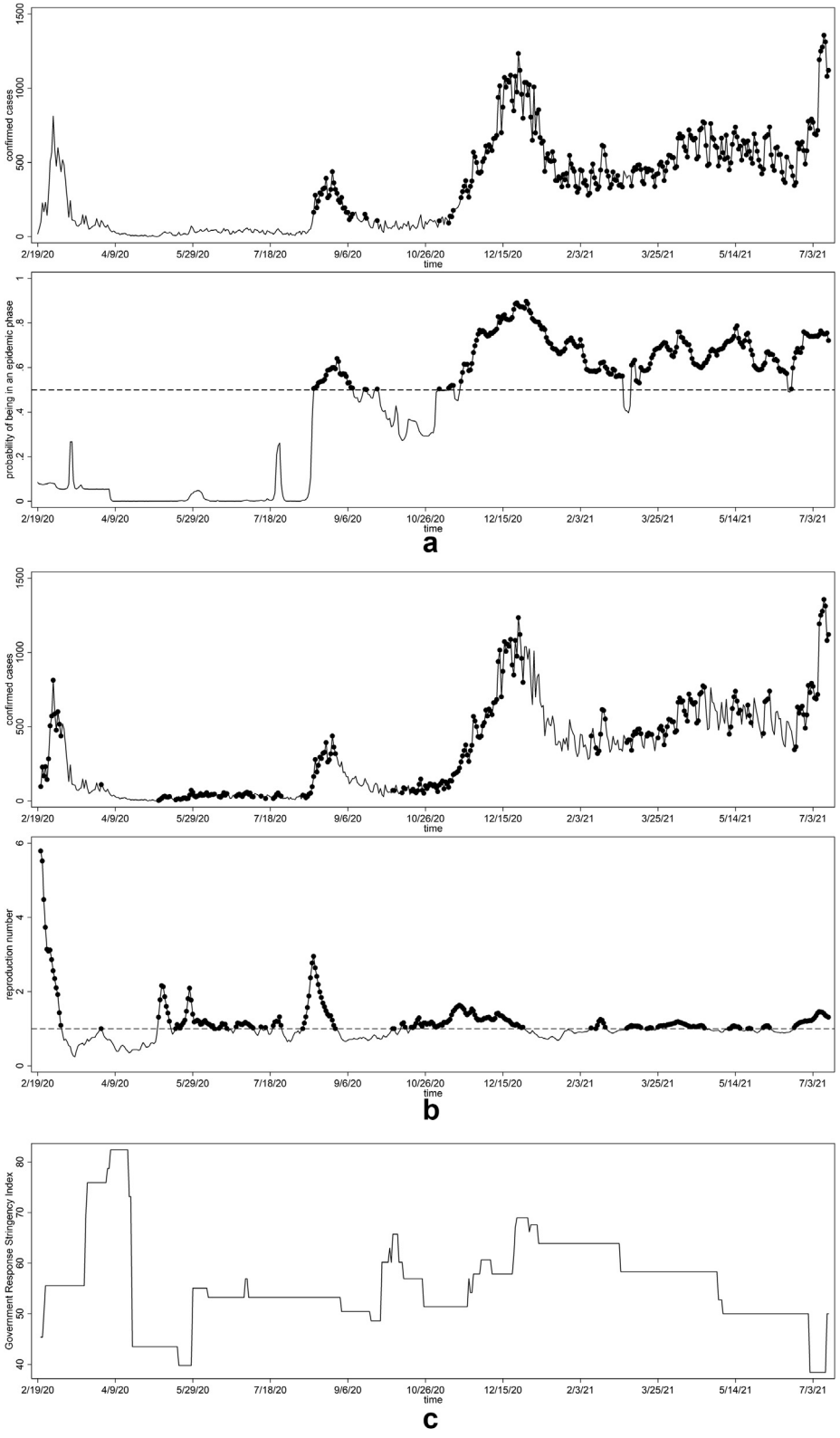

Fig. 3. Population-weighted averages of the probability of being in an epidemic phase, the effective reproduction numbers, and Government Response Stringency Index for Korea.

flag for the United States, India, and Brazil, who have suffered from a high number of cases of COVID-19 throughout the pandemic, whereas it stays relatively silent for New Zealand and during some calm periods for the United Kingdom.

Compared with other established models, the model has some attractive features for identifying the outbreaks of infectious diseases. The hidden Markov model itself fits quite naturally with the mixture of distributions explaining different states of

epidemic and non-epidemic periods. Furthermore, conventional Serfling-type classical regression models usually require long series of historical epidemic data to perform well.[3] When it comes to a newly emerging infectious virus such as COVID-19, this means its performance for surveillance, monitoring, and evaluation may be weaker. The model introduced in this study was estimated via Bayesian framework, an intuitive way to understand the current status in the absence of sufficient data.[21] A priori knowledge of infectious disease is combined with gradually updating new daily information, which resembles the way we process newly available information.

In addition, the effective reproduction number, a well-known measure for understanding the intensity of an infectious disease outbreak in epidemiology, may not be sufficient to capture the dynamics of disease spread, especially from the public health policy point of view. As shown in Fig. 3, during the period under study, the reproduction number turns out to be sensitive with respect to the threshold $R_t > 1$. Specific and timely warning and social distancing implementation may be difficult if depending solely on the observation of changes in the reproduction numbers. The model in this study successfully differentiates epidemic and non-epidemic phases amid extreme fluctuations in confirmed cases.

From a quarantine perspective, the model can provide informative answers on how to prepare to treat COVID-19 patients with respect to medical resources, such as hospital beds, staff, and so on. This is because the model in this study models daily differences in confirmed cases, not the number of cases itself. Therefore, the probability of being in an epidemic phase itself is related to the differences in confirmed cases locally and nationally by model construction. The disease control and prevention agencies who have responsibility to distribute the resources to hospitalize and treat patients may benefit from the scientific results by modeling the daily differences in confirmed cases locally and nationally.

In addition, the epidemic probability from the model may be used to perform a cost-benefit analysis of social distancing policies. As mentioned, social distancing policies and economic lockdowns have been painful, especially for small business owners. The government should measure the total benefits and costs of strengthening or weakening lockdown policies when needed. The probability of the severity of virus spread can be a readily available component for measuring the benefits and costs of those policies in cost-benefit quantitative analysis.

There are limitations to the model which should be explored in future research. First, the model gives a warning during a period of a rapid decline of confirmed cases by construction because it is designed to recognize a large variation of differences as an epidemic phase. In Fig. 3, we can observe a clear difference of warning signs between the hidden Markov model and the effective reproduction numbers in the winter of 2020. The reproduction numbers explain the decline of number of cases in a timely manner, whereas the hidden Markov model displays a more conservative attitude and continues to give a warning until a stationary time series of confirmed cases is observed. This study did not analyze how to evaluate and determine how conservative we should be in terms of quarantine policy. Both methods have their own pros and cons, but these may need to be explored.

In relation to the limitation mentioned previously, some may point out that the model can become silent during a plateau in the time series of confirmed cases. Theoretically, it is possible for the model to stay calm when a high number of cases continues with little fluctuation. This is a possible limitation of the model and should be further examined, although, considering the nature of infectious disease, the situation of a high constant plateau in a series of confirmed cases may be unlikely.

The model estimates a daily probability of being in an epidemic phase but does not directly show when to adjust the level of social distancing. This research follows previous studies regarding the period when an epidemic probability becomes greater than 50% as an epidemic phase.[7] In a real setting, the threshold for detecting an epidemic phase may not apply for all related authorities or the public. Future research should scrutinize the relationship between social distancing measures and the probability of being in an epidemic phase during the COVID-19 outbreak. Understanding this relationship is essential in an ex-ante social distancing and lockdown policy simulation.

Although disease control authorities set social distancing and lockdown measures based on the information observed, tracing daily changes in confirmed cases may not tell them directly what to do. The main contribution of the model in this article is that it can reveal a hidden epidemic phase and guide disease control authorities to respond in a more scientific manner. Although authorities have their own disease control guidelines (see, for example, Table 1), it may be difficult for the authorities to take persuasive action against vocal complaints from the public who are suffering from prolonged lockdown and social distancing measures. Therefore, evaluating the real-time level of pandemic risk becomes more important for communicating with the public and taking appropriate action.

Author statements

Ethical approval

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Competing interests

None declared.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.puhe.2021.10.002.

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Original Research

Understanding and addressing vaccine hesitancy in the context of COVID-19: development of a digital intervention

H. Knight [a], R. Jia [a], K. Ayling [a], K. Bradbury [b, c], K. Baker [b], T. Chalder [d], J.R. Morling [a, e], L. Durrant [a], T. Avery [a], J.K. Ball [f], C. Barker [b], R. Bennett [g], T. McKeever [a], K. Vedhara [a, *]

[a] University of Nottingham, School of Medicine, Nottingham, UK
[b] National Institute for Health Research (NIHR) ARC Wessex, UK
[c] University of Southampton, Department of Psychology, Southampton, UK
[d] Kings College London, Department of Psychological Medicine, London, UK
[e] National Institute for Health Research (NIHR) Nottingham Biomedical Research Centre (BRC), Nottingham University Hospitals NHS Trust and the University of Nottingham, Nottingham, UK
[f] University of Nottingham, School of Life Sciences, Nottingham, UK
[g] Rehab Studio LTD, London, UK

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ABSTRACT

Objectives: Severe Acute Respiratory Coronavirus 2 (SARS-CoV-2) was identified in late 2019, spreading to over 200 countries and resulting in almost two million deaths worldwide. The emergence of safe and effective vaccines provides a route out of the pandemic, with vaccination uptake of 75–90% needed to achieve population protection. Vaccine hesitancy is problematic for vaccine rollout; global reports suggest only 73% of the population may agree to being vaccinated. As a result, there is an urgent need to develop equitable and accessible interventions to address vaccine hesitancy at the population level.
Study design & Method: We report the development of a scalable digital intervention seeking to address COVID-19 vaccine hesitancy and enhance uptake of COVID-19 vaccines in the United Kingdom. Guided by motivational interviewing (MI) principles, the intervention includes a series of therapeutic dialogues addressing 10 key concerns of vaccine-hesitant individuals. Development of the intervention occurred linearly across four stages. During stage 1, we identified common reasons for COVID-19 vaccine hesitancy through analysis of existing survey data, a rapid systematic literature review, and public engagement workshops. Stage 2 comprised qualitative interviews with medical, immunological, and public health experts. Rapid content and thematic analysis of the data provided evidence-based responses to common vaccine concerns. Stage 3 involved the development of therapeutic dialogues through workshops with psychological and digital behaviour change experts. Dialogues were developed to address concerns using MI principles, including embracing resistance and supporting self-efficacy. Finally, stage 4 involved digitisation of the dialogues and pilot testing with members of the public.
Discussion: The digital intervention provides an evidence-based approach to addressing vaccine hesitancy through MI principles. The dialogues are user-selected, allowing exploration of relevant issues associated with hesitancy in a non-judgmental context. The text-based content and digital format allow for rapid modification to changing information and scalability for wider dissemination.

Introduction

Severe Acute Respiratory Coronavirus 2 (SARS-CoV-2) was identified in late 2019. At the time of writing, the latest estimates suggest that it has spread to over 200 countries and has resulted in the deaths of almost two million people.[1] The resulting global pandemic has seriously affected the social and economic fabric of societies everywhere and the physical and mental health crisis continues.[2] Safe and effective vaccines provide a route out of this crisis, but the development of these vaccines, while necessary, is not sufficient. For vaccines to achieve their full potential, the public also needs to be willing to be vaccinated. Recent data suggest this cannot be assumed. A recent survey of United Kingdom (UK) households indicated that approximately 82% of the population would agree to be vaccinated.[3] This estimate should be viewed

* Corresponding author. School of Medicine, University of Nottingham, University Park Nottingham, NG7 2RD, UK.
E-mail address: kavita.vedhara@nottingham.ac.uk (K. Vedhara).

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0033-3506/

against a backdrop of declines in vaccine intent overall and the fact that it masks large variations in intent between demographic groups. Vaccine hesitancy, defined as a 'delay in acceptance or refusal of vaccines despite availability of vaccine services'[4] may significantly impact the uptake of COVID-19 vaccines, particularly amongst ethnic minorities, women, and those with less education.[3,5,6] If, as has been suggested, 75–90% of a population will need to be vaccinated for community protection to be achieved,[7] then there is an urgent need to develop equitable and accessible interventions to address vaccine hesitancy at the population level within the United Kingdom.

Attempts to improve vaccine uptake are not new and have focussed traditionally on approaches such as information/education, incentives[8–10] and reminders. However, results from successive reviews suggest that the evidence-based support of any one approach remains limited.[8–11] Furthermore, much of the work has been conducted in the context of adults making decisions for their dependents, rather than adults making decisions for themselves. The generalisability of these findings to COVID-19 vaccines in adults is, therefore, unclear. Nonetheless, much can be gleaned from the existing evidence: information, while necessary, is unlikely to improve vaccine uptake on its own, and interventions need to engage with individuals' reasons for hesitancy, i.e. their hesitancy cognitions.[12]

We report here a roadmap for the development of a scalable digital intervention, which seeks to address the concerns of individuals who are vaccine-hesitant, with a view to enhancing the uptake of COVID-19 vaccines. We report the process we followed in developing a digital vaccine hesitancy intervention suitable for adults considering a COVID-19 vaccination. While primary data were collected within the United Kingdom, we also drew from global evidence on vaccine hesitancy. In view of the urgency of the public health need, our approach to intervention development was pragmatic and took advantage of existing data where possible and appropriate. Evaluation of the intervention is underway and will be the focus of future work.

Methods and results

Our development involved four main stages and included the involvement of public and patient partners throughout:

Stage 1: In order to understand and identify common reasons for COVID-19 vaccine hesitancy and acceptance, we carried out (a) an analysis of existing survey data collected within the United Kingdom during the pandemic, (b) a rapid systematic literature review drawing from international literature and (c) an examination of qualitative findings from a series of public engagement workshops regarding views of the public to immune challenges and vaccines.

Stage 2: We synthesised evidence from independent experts. This entailed qualitative interviews with experts from a range of relevant disciplines to identify evidence-based responses to the most common vaccine concerns raised by the public identified in stage 1.

Stage 3: We developed 'therapeutic dialogues' to address common vaccine hesitancy concerns. These were developed in a workshop bringing together experts in psychological and digital behaviour change interventions.

Stage 4: The digital intervention was developed.

As this was a linear process, with each stage informing the next, we present the methods and results from each stage consecutively.

Stage 1. Understanding and identifying common reasons for hesitancy & acceptance.

Analysis of existing survey data

As part of a separate study into the UK population's mental and physical health over the course of the pandemic, we collected data regarding COVID-19 vaccination intention between 11th–30th November 2020 during the second national lockdown and prior to the rollout of the vaccines (3rd December 2020). During this period, daily case rates peaked at 24,962 (15th November 2020).[14] A detailed description of this study and the recruitment processes has been published previously.[13] But in relation to vaccine intention, respondents were asked 'If you were offered a COVID-19 vaccine, would you take it?' and also asked, through a free text response, to elaborate on their main reason(s) for this intention. This item gave participants space to provide single or multiple responses, all of which were coded and analysed for common themes. One researcher (RJ) conducted a preliminary review of the free text data, allowing the generation of initial themes. To enhance reliability, a second researcher (KA) independently examined the emerging themes, allowing further refinement. The frequency at which these themes appeared was quantified. Where vaccine hesitancy was indicated, themes were categorised within the WHO 3Cs model of vaccine hesitancy, which proposes that three main factors influence the decision to accept vaccines: confidence, complacency, and convenience.[4] All coding and categorisation was conducted with high levels of initial agreement (91% for reasons associated with vaccine hesitancy and 85% for reasons associated with the agreement to vaccination). All discrepancies were resolved by discussion.

A total of $n = 762$ individuals provided data (22% of whom indicated they were hesitant about receiving a COVID-19 vaccination); 93% ($n = 709$) of respondents also provided a free-text response indicating their reasons for vaccine acceptance or hesitancy, of which 96% ($n = 683$) provided sufficient detail for reasons to be categorised into themes. For those who expressed vaccine hesitancy, the most common concerns were found to map on to the WHO 3C category of 'confidence' (e.g. concerns related to long-term complications, side effects and insufficient testing of the vaccines). The second most common concern related to 'complacency' (e.g. beliefs of low personal risk of COVID-19, beliefs in the ability to fight off the infection naturally). Concerns related to the 'convenience' category were the least common, but where they occurred, they centred on a lack of information about the vaccines and altruism (i.e. other people needing the vaccines more) (see Table 1a). In contrast, in respondents who indicated they would be willing to receive a COVID-19 vaccine, common reasons given related to 'self-protection', followed by 'hope to end the pandemic/wish for normal life' and a desire to 'protect the population or unspecified others and control the virus' (see Table 1b).

Rapid systematic literature review

For identifying additional themes/reasons for COVID-19 vaccine hesitancy that may have not been captured in our survey, a rapid systematic literature review was conducted. Four electronic databases (Medline, PsychInfo, Medrxiv, PsyAxiv) were searched to identify peer-reviewed journal articles and pre-prints, which examined reasons for COVID-19 vaccine hesitancy dated between 01/01/2020 and 03/12/2020: using the following search terms: (COVID-19 vaccine hesitancy) OR ((COVID-19) AND (vaccine hesitancy)). Randomised controlled trials (RCTs), mixed methods trials, cohort, and qualitative studies with adult participants were included. One researcher (RJ) conducted abstract and full-text screening to determine eligibility, and a second cross-checked all eligibility decisions (KA). Following title and abstract screening, 49 articles remained for full-text screening, with 10 ultimately deemed suitable for inclusion summarised in Table 2.[15–24] The

Table 1a
Common reasons for vaccine hesitancy and acceptance: survey findings.

WHO 3C category	Themes	Count	Examples of free text responses
Confidence	Concerns about unknown long-term effects	39	'It hasn't been long enough to see if there are any long-term risks' 'Uncertainties around long-term effects' 'Unknown long term side effects'
	Concerns about side effects	39	'I don't have full information about its side effects' 'Undiscovered side effects/uncertainty of the side effects' 'Unknown long-term side effects'
	Concerns there is an insufficien t testing/evidence base	37	'Not sure it has been tested thoroughly' 'Unclear rigour of the testing/clinical trial results/statistics, etc.' 'It has not been tested at a scale'
	Concerns the development of the vaccine has been rushed	27	'Its development and production has been rushed through' 'Feels rushed compared to normal vaccine standards' 'I don't think there has been sufficient time to know fully the effects of it'
	Concerns about the safety of the vaccine (but not explicitly side effects)	21	'I'm concerned about its safety' 'Would want to be 100% sure it was safe' 'Would only take it if I was convinced it was 100% safe'
	Unsure about vaccine effectiveness	14	'I would like the research evidence about its effectiveness rate (in different age groups especially 60+)' 'Not sure about how effective are they, especially as if you get COVID you can get it again. The vaccines antibodies are not as effective as getting the virus itself' 'Would prefer a vaccine that stops transmission, not just stop me showing symptoms'
	Concerns around vaccine interactions/ effectiveness with existing conditions	10	'I'm pregnant/breastfeeding so unsure about the effects on my child' 'I have auto immune disease' 'I have a chronic condition/treatment/operation so unsure about effects of the vaccine will have on me'
	Lack of trust in the manufacturer/government/ scientists etc.	9	'It is not in Government or manufacturers' interests to tell the truth about side effects and adverse reactions' 'The poor management of the pandemic by the government reduces my confidence in the safety and efficacy of a vaccination programme' 'Don't trust it/an American vaccine'
Complacency	Believe they are not at high risk of COVID-19	7	'I'm not in a risk category' 'I don't want it at this stage as I'm not at high risk of getting COVID'
	Believe they are in good health/Their body can fight off the virus	6	'I prefer my body to deal with it in its own way' 'I believe maintaining strong immune system is best defence' 'I am not in a risk category and I limit my vaccinations to things that potentially have very serious consequences for me'
	Have already had COVID-19	3	'I've had COVID already so should be okay for a few months at least' 'Would like to know more about antibodies and the likelihood of getting COVID twice' 'I'd want to know if I have the antibodies already'
Convenience	Other people need it more	7	'More at-risk people need it first' 'It should be delivered to needy first, I'll have to wait for offer' 'I'm fit and healthy that there are more vulnerable people who need it before I do'
	Lack of knowledge about the vaccine	18	'I would like to know more about it' 'I need to be educated about it first' 'I want more information and I need to research about it before accepting it'
	Don't like injections/vaccine experience	2	'I have been told it is very uncomfortable' 'The fear of the injection. I have always avoided them'
	Inconvenience	1	'Inconvenient'
	Freedom of choice	1	'If it were a requirement by law, I would not want it, freedom of choice is important'

primary reason for excluding articles at the full-text screening stage were that many studies looked at vaccine intention only, not reasons for vaccine hesitancy (see Fig. 1). Three of the studies were conducted in the United States, and two in the United Kingdom. The remaining five studies were conducted in Nigeria, Mainland China, Hong Kong, France and Malta, respectively. Six studies identified reasons for vaccine hesitancy based on survey questions where a pre-selected list of potential reasons was given. Three studies coded free-text responses to survey questions, and one study analysed participant interviews. Six of the studies collected data from a general population sample, three collected data from health care workers and one did both.

Findings from both the quantitative and qualitative studies included in the review were categorized according to the 3C model. The most common themes identified in this review mirrored those identified in our survey. However, the following additional themes were identified: (1) general vaccine scepticism (i.e. mistrust of pharmaceutical industry); (2) cost of vaccines; (3) concerns relating to vaccine contents; (4) timing of vaccination in relation to the state of the pandemic and (5) concern that the vaccine might result in COVID-19 disease (see Table 2).

Additional insights from public and patient involvement (PPI)

Of the initial survey sample, 9.5% were from ethnic minority groups. To supplement the views of ethnic minorities captured in the survey, we also consulted PPI findings available through the University Hospital Southampton NHS Foundation Trust PPI team regarding the acceptability of vaccines. Several PPI meetings were held on this broad area between July–October 2020, including

Table 1b
Common reasons for vaccine acceptance: survey findings.

Themes	Count	Example of responses
Self-protection	208	'To protect me from getting COVID-19' 'I'm in a vulnerable group' 'It would make mee feel safer'
Protect specific others (e.g. family, friends, colleagues etc.)	57	'I want myself, my loved ones, and my community to be safe' 'Don't want to catch the virus and give it to my family' 'Want to protect myself and my family'
Protect the population/non-specific others and control the virus	139	'Vaccines are important not just to protect ourselves but others and essential to stop the spread' 'To protect the vulnerable who can't take the vaccine' 'It may save many lives' 'The need for herd immunity via vaccine is very important and there needs to be a critical mass of people taking this up'
Confidence in SARS-Cov-2 vaccine	87	'It has been clinically tested and I trust the process' 'I don't believe a vaccine once approved would be unsafe' 'It has shown to be effective'
Hope to end the pandemic/wish for normal life	185	'I want to be able to resume my life' 'So that life can get back to normal' 'I just want to be able to hug my daughters' 'Truly get on top of this virus and get all our lives and the economy and health service back in action'
Civil duty/Requirement	21	'Everyone who can, should have it. Vaccines are our best chance of eradicating it' 'It's my social responsibility' 'I would feel it was my duty, to help to protect other people'
Non-specific pro-vaccine/pro-science statement	49	'I believe in science' 'Vaccine works' 'I would take any vaccine at this point' 'Can't think of a good reason why not to take it'

meetings that specifically sought the views of Black, Asian and Minority Ethnic (BAME) individuals.

The feedback from all the consultation meetings was reviewed and was found to reveal considerable overlap in the vaccine concerns identified in these meetings, with those identified as part of our survey and literature review. The only additional concerns related to whether vaccines had been tested on people from different ethnic groups and issues of trust in the medical and scientific communities. These issues were, therefore, prioritised for inclusion in our intervention.

Synthesising findings from Stage 1 to identify the most common reasons for vaccine hesitancy

The evidence emerging from the survey, rapid literature review and PPI findings were then triangulated through discussion between the two behavioural scientists (RJ, KA) contributing to this stage of the work. The aim of these discussions was to identify the most common COVID-19 vaccine concerns. This was based in part on the frequency with which concerns were identified in the survey, review, and PPI findings, ensuring that all three domains of the WHO 3C model were represented and that any unique perspectives raised by ethnic minority participants were also captured.

This led to the identification of nine core COVID-19 vaccine concerns. Concerns that were endorsed by fewer than 0.5% of the sample and did not align with concerns identified within the literature and PPI groups were not included within the intervention (i.e. vaccination is 'inconvenient'; Table 1a.). In keeping with the most frequently cited concerns being related to 'confidence', 5/9 concerns related to 'confidence' (i.e. generalisability of evidence on vaccine safety and effectiveness to diverse populations; side-effects; rapid nature of vaccine development; clinical effectiveness and vaccine scepticism). Two out of nine concerns related to 'complacency' (i.e. low perceived risk of COVID-19 and belief in the ability to fight off the infection naturally). A further two concerns related to 'convenience' (i.e. perceived lack of knowledge about COVID-19 vaccine and altruistic beliefs regarding others having a greater need). A tenth concern was subsequently added when the UK government decided to alter the dosing schedule from 3/4 weeks to up to 12 weeks between the two doses recommended for the Astra Zeneca and Pfizer vaccines. In keeping with the WHO 3C model, this latter issue is also related to the issue of 'confidence'. Each theme/concern was given equal weighting within the subsequent development process.

Stage 2. Synthesising the evidence-based views of independent experts.

Following the identification of 10 core vaccine concerns (Table 3) we sought to gather evidence-based responses to these concerns. This was achieved through semi-structured interviews with six academic and clinical experts from the fields of public health, general medicine, respiratory medicine and immunology with particular expertise in COVID-19 and/or COVID-19 vaccines. Each expert was presented with the list of 10 concerns and asked to provide an evidence-based response to each concern based on their knowledge of the scientific literature at that time. Interviews with experts were subjected to rapid thematic and content analysis after each interview, and interviews continued until saturation in responses was achieved (i.e. no new responses emerged).[25]

The expert responses demonstrated significant thematic overlap and consistency. Table 3 summarises the areas of evidence cited by experts in response to each concern.

Stage 3. Developing therapeutic dialogues to address common vaccine hesitancy concerns.

Our approach to developing the intervention was predicated on two main observations of the existing evidence. First that psycho-education alone (i.e. provision of information gathered in Stage 2) is unlikely to be an effective way to address COVID-19 vaccine concerns. Second that a central pillar of our approach should be to acknowledge and engage with individuals' concerns in a supportive context. To achieve this, we sought to develop 'therapeutic

Table 2
Summary of studies included in rapid literature review.

Author	Region	Study design	Population	Sample size	Themes or responses with frequencies[a]
Adebisi et al., 2020[15]	Nigeria	Survey question with listed answers	General public	N = 517 (*n* = 132 provided reasons for vaccine hesitancy)	Unreliability of the clinical trials (37.1%); immune system is sufficient (27.3%); the vaccine is not safe (16.7%); COVID-19 vaccine is likely to be expensive (6.8%); other reasons (12.1%)
Fisher et al., 2020[16]	US	Open ended question	General public	N = 1003 (*n* = 303 provided reasons for vaccine hesitancy)	Specific concerns about the vaccine (82.6%, side effects/safety, efficacy, newness, including not wanting to be the first to get the vaccine, rigour of testing, vaccine contents). Need additional information (24.7%, compatibility with personal health conditions e.g. allergies, comorbid conditions, recommendation from doctor or official, timing regarding state of pandemic, personal immunity, need more information unspecified). Anti-vaccine attitudes, beliefs, and emotions (76.6%, don't need the vaccine e.g. not at risk, religious beliefs, don't believe the vaccine will work informed by reference to other bad vaccine experiences/flu shots not working/ vaccine won't work against mutation organism, general statements about not getting vaccines, not comfortable with vaccines, fear about vaccines, misconceptions/incorrect information about vaccines). Lack of trust in vaccines, government and Centers for Disease Control and Prevention (CDC), pharmaceutical companies, vaccine development or testing process, reference to specific conspiracy theories, distrust unspecified (45.2%). Other (9.8%, altruism i.e. wanting higher risk individuals to get first, cost, dislike of needles).
Fu et al., 2020[17]	Mainland China	Survey question with listed answers	Health care workers and general population	N = 541 (*n* = 445 provided responses in relation to vaccine hesitancy)	Concerns about vaccine safety: newness of vaccine, effectiveness of the vaccine. Cost of the vaccine
Gadoth et al., 2020[18]	US	Free-text question	Health care workers	N = 1069 (*n* = 609 provided responses in relation to vaccine hesitancy)	'I'm confident there will be other effective treatments soon' (1%) 'I don't yet know enough about the vaccine to make a decision' (14%) 'I want to gain natural immunity to the virus that causes covid-19' (2%) 'Development of the vaccine may be rushed/the vaccine may not be thoroughly tested prior to approval' (15%) 'I believe vaccines may give you the disease they are designed to protect against' (1%) 'I don't know' (1%)
Grech et al., 2020[19]	Malta	Survey question with listed answers	Family physicians and trainees	N = 350 (*n* = 123 provided responses in relation to vaccine hesitancy)	The majority of the COVID-19 vaccine-related concerns were long-term side effects and insufficient knowledge about the vaccine. Other concerns included: short-term side effects (e.g. fever), vaccine effectiveness and general anti-vaccine attitudes.
Hacquin et al., 2020[20]	France	Interviews	General public	N = 5028 (*n* = 1004 provided responses in relation to vaccine hesitancy)	General opposition to vaccines; concerns that the vaccine would not be effective; not personally required (don't need to get vaccinated); lack of trust in government and pharmaceutical industries.
Kwok et al., 2020[21]	Hong Kong	Survey question with listed answers from a scale	Nurses	N = 1205 (*n* = 1205 provided responses in relation to vaccine hesitancy)	Confidence in safety; effectiveness; and trust in other authorities. Complacency regarding whether the disease is common; that the immune system is sufficient to fight off the disease and the disease is not severe. Constraints to getting vaccinated such as everyday stress; inconvenience; visiting the doctors; discomfort. Calculations involving weighing up benefits and risks; needing to closely consider whether it is personally useful; needing to understand more about vaccines and vaccination.

Table 2 (*continued*)

Author	Region	Study design	Population	Sample size	Themes or responses with frequencies[a]
					Collective responsibility including, it not being necessary to get the vaccine when everyone is vaccinated; getting vaccinated can enable an individual to protect people with weaker immune systems; vaccination is a collective action to prevent the spread of diseases.
Pogue et al., 2020[22]	US	Survey question with listed answers	General public	N = 316 (33.5% provided responses in relation to vaccine hesitancy)	Concerns about vaccine safety (45.5%); lack of trust in the source that encouraged them to receive the vaccine (13.5%); other e.g. need more testing on the vaccines
Sherman et al., 2020[23]	UK	Survey question with listed answers from a scale	General public	N = 1500 (*n* = 1448 provided responses in relation to vaccine hesitancy)	Concerns about safety and side effects of the vaccine; newness of the vaccine; needing sufficient information to make an informed decision; afraid of needles; not at risk of serious illness from COVID; trust in manufacturers/ government/health care professionals;
Williams et al., 2020[24]	UK	Free text question	General public	N = 527 (*n* = 158 provided reasons for vaccine hesitancy)	Concerns about vaccine safety (100%) centred on the newness of the vaccine and its safety (e.g. long-term effect, side effects) and effectiveness.

[a] Themes or responses were based on participants who provided information on vaccine hesitancy.

dialogues' based on the communication principles of motivational interviewing (MI), including:

- *Expressing empathy:* cultivating an empathic space with which to explore hesitancy
- *Developing discrepancy:* identifying areas in which a person's actions are misaligned with their personal values and goals
- *Embracing resistance:* working collaboratively with an individual to foster change and recognising when that resistance and motivation are intricately tied

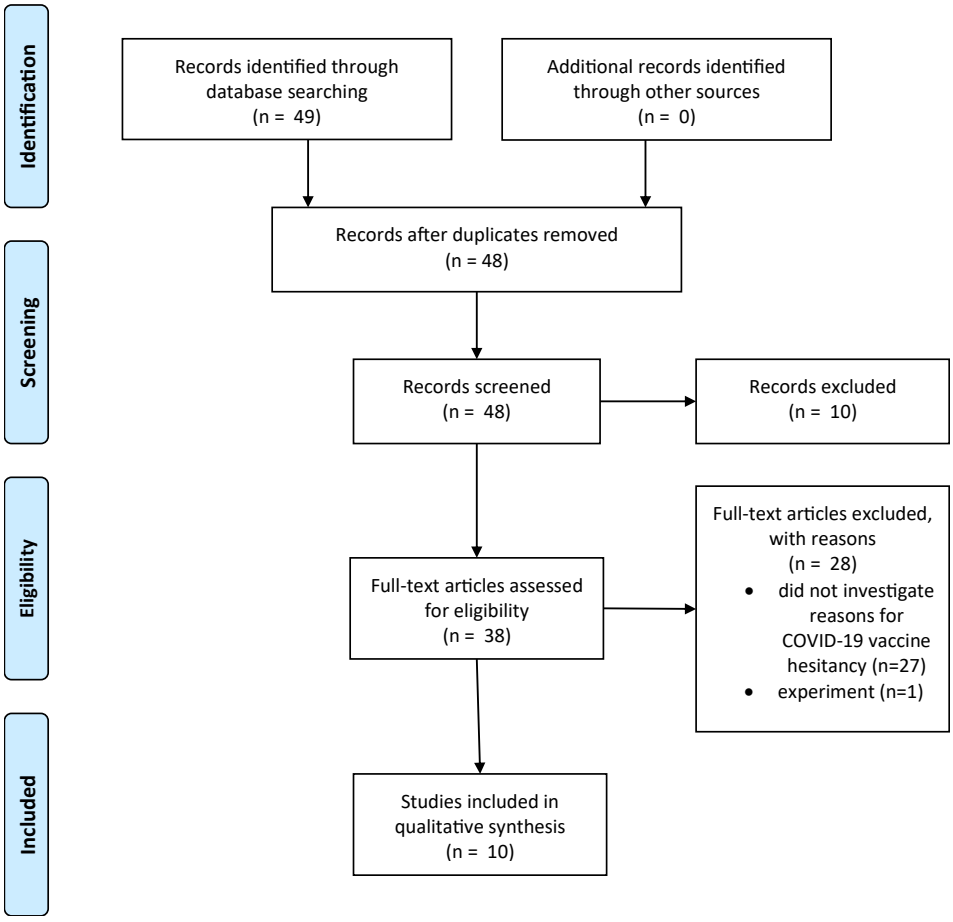

Fig. 1. PRISMA summary of search procedure.

Table 3
Expert responses to 10 most common reasons for vaccine hesitancy.

Concern	Key responses
'I don't know if the vaccines have been tested on people like me: • *By age, ethnicity, and comorbid health condition*'	• The vaccines have been trialled in 10s of 1000s of people across many countries and ethnicities • No discernible difference in response to the vaccine across ethnic groups or age groups • Researchers included individuals with common chronic health conditions in the trials to ensure any risks to this population were identified • Pregnant and breastfeeding women were not included in the trials
'*I don't think we know enough about the side-effects of the vaccines*'	• All COVID-19 vaccines have undergone very robust testing, including pauses to trials to explore whether adverse events or allergic reactions were as a result of the vaccine itself • These vaccines follow the same trial protocols for reporting adverse events to the medical advisory boards that all other vaccines must follow • All vaccines come with the chance of immediate side effects, such as a sore arm, fever etc. This shows the immune system has responded to the vaccine • Short-term side effects are similar to all other vaccines • Although there is less safety data available, MRNA vaccines have been studied for years
'*I think the whole process has been rushed*'	• The vaccines have followed the same development criteria that all vaccines must undergo • Many other vaccines are developed in a similar time frame, such as the flu vaccine. • The difference in timeframes has resulted in the concerted channelling of funds into the development of these vaccines, with governments, manufacturers, and scientific bodies providing substantial and rapid funding, expediting the researchers' ability to test the vaccines • Some vaccines, such as the Oxford AstraZeneca vaccine, were developed quickly because the researchers utilised an existing vaccine formula and inserted in an inert form of the COVID-19 virus. • New technology also allowed us to identify the genetic make-up of the virus much more quickly • Evaluation of the safety of the vaccine by independent regulators (MRHA) was expedited as the regulators prioritised reviewing the trial data
'*I don't know if they will work*'	• The data suggests short-term protection of at least 3 months • Pfizer vaccines is highly effective in the short term – approximately 95% • Oxford-AstraZeneca rates varied, but were approximately 70% effective • However, long-term data has yet to be reported • We don't know yet if the vaccines prevent transmission
'*I don't think I am at risk of getting COVID-19*'	• While many people experience mild symptoms, COVID-19 is unpredictable; we are not able to predict who will be adversely affected. • Although COVID-19 affects older people most severely, a significant proportion of those hospitalised are under the age of 60. • We know that you can contract COVID-19 more than once and are unsure how long any immunity to the virus lasts after exposure. • The vaccines offer protection against the virus and prevent the risk of experiencing a severe form of the disease. • Receiving a vaccine could prevent you from requiring hospitalisation. • Vaccination reduces the volume of the population who can contract and spread the virus, reducing the disease burden in the community.
'*I think my body can fight the virus on its own*'	• Younger individuals are less likely to experience severe COVID-19, however there is still the risk of this happening. • It is also possible to get re-infected with the virus, although evidence suggests the reinfection results in less severe illness. • The immune system can exhibit extreme reactions to the COVID-19 virus, but it is very unlikely to react in such a way to the vaccines. • Reducing your risk of contracting and therefore spreading COVID-19 helps to protect others. • Reducing your risk of contracting COVID-19 also means you are much less likely to need to self-isolate.
'*I just don't know enough about it: Safety and effectiveness concerns*'	• The vaccines all significantly reduce the risk of contracting severe COVID-19. • Effectiveness has been shown in individuals of all ages, ethnic backgrounds, and with other health conditions. • No serious side effects have been reported; participants in the early trials have now been monitored for almost 12 months. • The MHRA have been monitoring the vaccines' safety extremely carefully, as they do with all other vaccines.
'*Other people need it more than me*'	• The Joint Committee for Vaccines and Immunisations (JCVI) has identified a priority list for vaccine dissemination. • If someone is offered a vaccine, it means they have been identified as being in a priority group. • Receiving a vaccine does not detract from someone else receiving a vaccine.
'*I don't believe in vaccines: Safety and effectiveness concerns*'	• Vaccines save millions of lives every year and there is no evidence for adverse effects of the COVID-19 vaccines.
'*I'm worried I would have to wait 12 weeks before I get my second dose*'	• This decision was taken because it allows twice as many people to get some protection against the virus, offering the greatest opportunity to save lives. • The first vaccination offers short-term protection, while the second booster dose provides long-term protection. • Delaying the second dose from 3 to 12 weeks also gives the immune system longer to develop immunity. • In the Oxford-AstraZeneca vaccine trials, a longer gap between doses offered better protection.

- *Supporting self-efficacy:* enhancing confidence that an individual can embark on change.[26]

MI was considered an appropriate approach because individuals who are vaccine-hesitant are, by definition, not ready to, or ambivalent about, changing their cognitions and behaviour and MI is known to be effective in such contexts.[27,28] Thus, for each of the most common vaccine concerns identified in Stage 1 we developed a therapeutic dialogue, which would both impart information relevant to the individual concern, but do so using the communication principles of MI with a view to facilitating cognitive and, in turn, behaviour change, i.e. reduce hesitancy and improve vaccine uptake.

Table 4
Exemplars of how MI principles were included within the therapeutic dialogues.

Concern	Motivational interviewing concept	Concept example utilised in the dialogue
'*I don't know if the vaccines have been tested on people like me*'	Expressing empathy: • Including reflective listening to concerns and integration of follow up questions to engage user	These are brand new vaccines and it is completely understandable that you would ask about their safety
'*I don't believe I am at risk of getting COVID-19*'	Developing discrepancy: • Identifying potential areas of conflict between vaccine hesitancy and personal values	So when you choose to have a vaccination you are also choosing to protect others, to take the pressure off the NHS, and helping us all get back to normal.
'*I don't think we know enough about the side-effects of the vaccines*'	Embracing resistance: • Recognising resistance and helping to move forward collaboratively	And you are not alone in wondering about this. Scientists, doctors, the independent regulator who decide on which medicines can be offered to the public (the Medicines and Health care Products Regulatory Agency) all want to know how well the vaccines work.
'*I don't know if the vaccines have been tested on people like me*'	Supporting self-efficacy • Enhancing confidence to make an informed decision about whether to receive a vaccine	We hope we have been able to help with your concerns about the safety of the vaccines. To sum up, they have all been monitored very closely to find side effects. But if you did experience a side effect it is most likely to be very minor and much less severe than catching COVID-19.

An online format was chosen to deliver the therapeutic dialogue to maximise audience reach and engagement, supported by substantial evidence based on the use of this modality to promote vaccine uptake.[29,30]

Development of the therapeutic dialogues occurred through several expert workshops with behavioural scientists with expertise in MI, therapeutic interventions, digital interventions, behaviour change and COVID-19. First, key themes identified in the expert interviews (Stage 2) were discussed and translated into conversational language. The investigators chose a conversational approach to align with the online delivery format and ensure inclusivity for all reading/English levels (see stage 4 below). Second, the dialogues were reviewed to identify points at which MI techniques could be integrated throughout. This process drew on contributors' experience in behaviour change research and adopted the approach proposed by Rollnick and colleagues.[26] This included *expressing empathy* through the use of accepting and non-judgemental language. By *developing discrepancy* by simultaneously providing information related to the concern and presenting a rationale for vaccine uptake. The latter were derived from survey respondents willing to accept a COVID-19 vaccine (see Table 1b) and sought to develop a discrepancy between the individual's cause for concern and their wider personal values and goals. By *embracing resistance* by acknowledging that their concerns are shared by others and are legitimate and supporting *self-efficacy* by reinforcing the individual's personal agency in making their decision to accept a vaccine or not. See Table 4 for illustrative examples of how MI principles were embedded within the therapeutic dialogues.

Finally, we hosted a PPI workshop to discuss the resulting dialogues. Participants were members of the general public recruited through the University Hospital Southampton NHS Foundation Trust PPI team. The workshop was advertised as an opportunity to provide feedback about an online tool designed to answer the public's questions about the COVID-19 vaccines. Four individuals responded to the advertisement and attended the workshop. The group, while small, included two adults less than 30 years (two greater than 50 years); three women and one man and all reported interest in vaccine hesitancy and had some experiences of it among friends and family. All participants were paid for their time. The feedback obtained through this workshop fostered changes to their readability, along with an expansion of the information conveyed and greater consideration of specific groups within the population (i.e. those who have allergies or specific religious and cultural needs). No additional vaccine concerns were identified by the group.

Stage 4. The digital intervention.

The script from each of the 10 therapeutic dialogues provided the architecture for our digital, web-based vaccine hesitancy intervention. Given high rates of internet usage throughout the Uunited Kingdom (92% of adults)[31] and other similar developed countries, it was felt that the use of a digital platform would maximise reach and accessibility. The research team worked with a digital development company to design and build a conversational interface through which individuals identify the issue that most closely underpins their reason for being hesitant (from the issues stated above, e.g. concerns about side effects). This identification triggers an MI driven therapeutic dialogue relevant to the selected concern, with opportunities for the individual to further explore the content as they progress through the dialogue, as well as to access responses to more than just their initial concern.

Once developed, the digital intervention was piloted with 18 members of the public (nine male/nine female) who had no previous experience with the dialogues. Participant feedback on the dialogue content, user interface, accessibility, and general presentation led to a final iteration of the intervention, which can be viewed here: www.covidvaxfacts.info. For illustrative screenshots, see Supplementary Figs. 1 and 2.

Discussion

The development of safe and effective vaccines against SARS CoV-2, while necessary, will not be sufficient to contain COVID-19 unless we also achieve high vaccine uptake. We have described here the rapid development of an evidence-based digital intervention, which draws on the communication principles of MI and is in keeping with many of the recommendations made in a recent review of approaches to increasing vaccine uptake, e.g. focus on the concerns of the population.[32] Our aim is to provide the end-user with an intervention that is individualised to their specific concerns, acknowledges the legitimacy of these concerns, provides up to date information related to these concerns while also providing an accepting non-judgemental context in which they can explore their reasons for hesitancy. The text-based content and digital format mean it can be readily scaled-up for wider dissemination and rapidly modified for implementation in different languages and to respond to changing information.

Although this intervention, like much else to do with COVID-19, has been developed at a pace, we think the process highlights some potential issues regarding intervention development worthy of discussion. First, the development of our digital, behavioural intervention followed a fairly conventional path as outlined in the Medical Research Council's (MRC) best practice guidance. This involved evaluating the evidence base and theory, as well as incorporating the views of target users (i.e. members of the general public).[33] This was possible partly because we had timely access to PPI findings available through the University Hospital Southampton NHS Foundation Trust regarding the acceptability of vaccines, allowing rapid comparison of the PPI findings with the concerns identified through our existing survey data and literature review.

A critical step in digital intervention development is the optimisation of intervention content since digital intervention content cannot be adjusted 'in the moment', like in a practitioner delivered intervention. We were able to conduct optimisation work with PPI, albeit with a smaller sample ($N = 4$) than might usually be employed in digital intervention development. Computer science methodology states that during an intervention, optimisation around 80% of views can be captured with five target users, and we were close to this threshold.[34] However, best practice guidance from digital health psychology suggests including larger, diverse samples is important to ensure views of people from different backgrounds are considered.[33] Despite having a smaller sample, our optimisation with PPI did help us to improve the persuasiveness and accessibility of the key messages within the intervention. It is possible that we may have found other important ways of optimising our content by including a larger, more diverse group of PPI at this stage. However, it is important to note that this intervention is quite simple; it targets only one behaviour, draws on a very well-established behavioural technique, which guided content design (MI), and it addressed barriers that were thoroughly identified using existing evidence in the intervention planning stage. Therefore, in this particular context, it is possible that sufficient optimisation was achieved with a smaller sample. Following launching the intervention, we were able to remain responsive to changes in the vaccine guidance by seeking expert advice in relation to the risk of blood clots, protection against emergent variants, pregnancy, and vaccination during Ramadan. Expert responses on these topics were compiled into a breaking news section and updated within the dialogues in line with government recommendations. Delivering the intervention digitally provides a rapid means of evaluating and evolving the intervention as reasons for hesitancy change, allowing real-time collection of both analytics and usage data alongside data that might answer specific research questions.

The MRC highlights the importance of making use of existing data and evidence wherever possible. In this work, we were able to benefit from data collected as part of another study[13] where we were able to identify specific concerns related to vaccine hesitancy. We also drew on evidence kindly shared with us by others. This allowed acceleration of the intervention development and improved the economic efficiency of research.

In view of the urgency of the public health issue, we conducted a rapid review. Given the rapid evolution of the scientific landscape, we acknowledge that new work may have since emerged. However, to the author's knowledge, recent work provides evidence on the persistence of the primary concerns underpinning this intervention within the general public.[23,35,36] Indeed, COVID-19 has most likely led to an unprecedented number of rapid reviews, as the scientific community have clamoured to understand the available evidence as quickly as possible. Although it is clear that rapid reviews take many forms (e.g. limited by language, dates, databases etc.), they do vary in the quality of their reporting and the methodological shortcuts they take.[37] The implications of these inconsistencies for the quality and validity of these reviews is, however, unclear as there is thus far limited evidence comparing the results of different review approaches. The provision of such evidence in future research would undoubtedly inform the contexts in which it is appropriate to conduct rapid reviews and the methods that should be employed. Such guidance now exists for scoping reviews.[38] and would appear to be in development for rapid reviews by the Equator network.[39]

While we have attempted to create an intervention that is scalable, limitations to our work are noted. Although the development of the intervention was predicated on findings from the international literature and incorporated feedback from an ethnically diverse PPI group, the survey data used in Stage 1 was collected from a predominantly white sample (90.3%) within the East Midlands.[13] Given elevated rates of vaccine hesitancy amongst ethnic minority groups, a targeted approach to the development and rollout of future interventions is warranted. Additionally, participants were asked to report their own concerns about receiving a vaccine; however, these concerns may have changed over the course of vaccine rollout and be influenced by an individual's social networks and the media. Exploring temporal changes to vaccine hesitancy and the impact of external factors on intrinsic concerns is a worthwhile avenue for future research. Finally, while the utility of delivering an intervention digitally is relevant for countries with high internet usage, the mechanism for delivery in less developed countries requires careful consideration. However, it is hoped that this paper provides a framework for future iterations of rapid behavioural interventions, which can be adapted to meet the unique needs of the population and behaviour of choice.

Conclusion

In summary, for COVID-19 vaccines to achieve their full public health potential, the public need to be willing to be vaccinated. Recent data suggest this cannot be assumed. We have reported here on the development of a scalable digital intervention that seeks to address the concerns of individuals who are vaccine-hesitant with a view to enhancing their confidence in COVID-19 vaccines, and in turn, their uptake. The effects of the intervention on these outcomes will be the subject of future work.

Author statements

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Ethical approval

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Competing interests

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Authorship contribution statement

HK, KV, KB, KB, TC: conceptualisation, data analysis, writing original draft, reviewing and editing. RJ, KA: Conducted rapid literature review, writing of original draft, reviewing and editing. JRM, LD: conceptualisation, expert contributions through qualitative interviews, reviewing and editing. TA, JKB, CB, RB, TMK: reviewing and editing.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.puhe.2021.10.006.

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