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#### **ABSTRACT**

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#### Introduction

- 11 Shielding aimed to protect those predicted to be at highest risk from COVID-19 and was
- uniquely implemented in the United Kingdom during the first year of the pandemic, from
- 13 March 2020. As the first stage in the EVITE Immunity evaluation, we generated a logic
- model to describe the programme theory underlying the shielding intervention.

# **Design and participants**

- 16 We reviewed published documentation on shielding to develop an initial draft of the logic
- model. We then discussed this draft during interviews with 13 key stakeholders involved in
- putting shielding into effect in Wales and England. Interviews were recorded, transcribed and
- analysed thematically to inform a final draft of the logic model.

# 21 Results

- 22 The shielding intervention was a complex one, introduced at pace by multiple agencies
- 23 working together. We identified three core components: agreement on clinical criteria;
- 24 development of the list of people appropriate for shielding; and communication of shielding
- advice. In addition, there was a support programme, available as required to shielding
- 26 people, including food parcels, financial support, and social support. The predicted
- 27 mechanism of change was that people would isolate themselves and so avoid infection, with
- 28 the primary intended outcome being reduction in mortality in the shielding group.
- 29 Unintended impacts included negative impact on mental and physical health and wellbeing.
- 30 Details of the intervention varied slightly across the home nations of the UK, and were
- 31 subject to minor revisions during the time the intervention was in place.

# Conclusions

- 34 Shielding was a largely untested strategy, aiming to mitigate risk by placing a responsibility
- on individuals to protect themselves. The model of its rationale, components, and outcomes
- 36 (intended and unintended) will inform evaluation of the impact of shielding and help us to
- 37 understand its effect and limitations.

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#### Strengths and limitations

- This paper presents the first description of the rationale for shielding which was an internationally unique and untested public health intervention implemented in the UK during the COVID 19 pandemic
- Our paper combines formal documentation on the shielding programme in the UK
  with interviews with those with those involved in creating and implementing it, so
  allowing for an exploration of how the rapidly implemented policy was
  operationalised on the ground
- This logic model provides the first step in undertaking the EVITE Immunity study, a
  population-scale national assessment of effects of shielding on COVID-19 infection
  rate, mortality, serious illness, use of NHS resources, health-related quality-of-life
  and behaviour.
- While we collected views from policy makers in England and Wales, the majority of interview participants were based in Wales, so their experience may not be representative of all other parts of the UK.
- Developing this logic model within EVITE Immunity study has involved people with direct experience of shielding from the outset, with public contributors represented across all aspects of research development and implementation, reflecting strong views that evidence about effects of shielding is needed.

60 Main text: 3892 words

- 62 Background
- 63 As an early response to the COVID-19 pandemic, the four UK nations introduced a policy of
- 'shielding' for clinically extremely vulnerable (CEV) people. Those identified as being at the
- 65 highest risk from COVID-19 infection, due to pre-existing conditions such as lung disease or
- current immunosuppressant medications, were strongly advised to strictly self-isolate, not
- leaving the home unless it was vital. The policy was the subject of rapid development and
- 68 implementation. It was first discussed by SAGE (UK's Scientific Advisory Group for
- 69 Emergencies) on 13<sup>th</sup> March 2020, and put into place within ten days. To support the
- shielding policy, a programme of practical and financial support was made available by a
- 71 range of statutory, commercial and third sector partners.
- 72 The shielding intervention was in place for a total of 10 months over two periods, before
- being suspended in the spring of 2021. It eventually included over 4 million people across
- 74 the UK [1].
- 75 Shielding was introduced as a novel precautionary response to an unprecedented situation,
- vith no underpinning empirical evidence about its effectiveness at reducing SARS-CoV-2
- 77 infections, serious illness or deaths.
- 78 We undertook an evaluation of shielding in Wales (EVITE Immunity), where records for the
- 79 130,000 people who were identified for shielding are already anonymously linked with
- other integrated data sources, utilising the MRC funded ConCOV project in the Secure
- 81 Anonymised Information Linkage (SAIL) Databank [2]. Initial findings show that people were
- more likely to have been identified for inclusion in the shielding intervention with increasing
- age, frailty and residence in deprived areas; and that reported infection rate was higher in
- 84 the shielded cohort than the non-shielded general population, though testing rates were
- higher and infection rates amongst those not tested in each cohort were unknown [3]. We
- 86 will also report how shielding affected deaths, health care utilisation, immunity status, NHS
- costs, and quality-of-life, and how people complied with guidance [4].
- 88 In line with the latest MRC guidelines on evaluating complex interventions [5], the first stage
- 89 of the EVITE Immunity study aimed to develop a programme theory to explain the
- 90 intentions of the policy, making explicit all components of the intervention (defined here as

being the shielding policy plus support programme), and representing these in a logic model, presented in this paper. Logic models can have a particular value in helping to articulate causality in the evaluation of public health interventions [6]. We will use this logic model to guide the analysis and interpretation of evaluation findings.

# Methods

Our study was designed as case study research. Based on published information, we prepared a draft logic model describing the components of the intervention, the mechanisms by which it was assumed to work, outcomes, intended impact, risks, and relevant contextual factors. We conducted individual interviews (n=3) and group interviews (n=4) online with a total of 13 key stakeholders: senior policymakers and clinicians from Public Health and Chief Medical Officers' teams, and representatives from local government and the voluntary and community sector, in Wales (n=12) and England (n=1). Respondents were recruited to provide a range of relevant perspectives. Interviews were conducted by experienced qualitative researchers from Swansea University. In advance of the interview, we shared an information sheet on the study with participants and they completed written consent forms.

Rationale for shielding March 2023 Appendix Interview questions.docx (v1.0)] to explore the rationale for shielding, steps undertaken to create and implement the intervention, and individual/organisational roles. We showed participants the draft logic model and invited comments and discussion. Data collection took place between March and May 2021.

We recorded and transcribed interviews, with participants' consent. We analysed the data using a framework approach to thematic analysis, incorporating a tabular data summary of cases/codes and data extracts [7], and refined the logic model into a final version. Each transcript was reviewed and coded by two members of the study team; findings and implications were discussed by the whole study team, including public participants.

We used a semi-structured interview schedule [Supplementary file EVITE Immunity

#### Patient and public involvement

People affected by the shielding policy have been directly involved throughout development of the research design [8-10]. Two were co-applicants on the funding proposal and are members of the Research Management Group overseeing study implementation (LG, LD). They work with six more public contributors via a Patient Advisory Panel. An independent Study Steering Committee includes two further public contributors. Our public contributors and some academic co-applicants were personally, directly or indirectly, affected by the implementation of the shielding policy. Results The final version of the logic model describing the shielding intervention is shown in Figure 1. This incorporates some changes made following analysis of the interviews, including reduced deaths among the shielding population being highlighted as the primary intended impact, while the proximate outcome of 'avoided infection' was changed to 'reduced infection'. Small additions were made to inputs, context and unintended impacts. Below, we present and discuss the key aspects of the logic model and report the experience and reflections of the stakeholders we interviewed. [Figure 1 Logic Model describing the shielding intervention] *Inputs: components of the intervention* The intervention was complex. There were three core processes relevant to all people advised to shield: the Chief Medical Officers of the four nations reaching agreement on the clinical criteria for inclusion on the CEV list; identification of people to be added to the list; and communication with those identified. Identifying and communicating with CEV people took place in phases, with batches of individuals being added to the list over the time the shielding programme was 'live' and much smaller numbers being removed. Across the UK, CEV people were identified through searches of centralised databases (which produced the majority of names for the list in Wales), and through primary and secondary care records, in conjunction with doctors' clinical judgement [11]. This mixed approach was described as 'build the list nationally first

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and then ask GPs to review' (Participant 2 Policy Maker). Some GPs and practice managers

responded to people requesting to be removed from, or added to, the list. As one 149 respondent noted, this was more significant than a mere administrative process: 150 'The GP had the authority to put people on and off, but a lot of the GPs hadn't 151 realised... what the implication of that was for the individual about going back to 152 153 work, back to school, or actually getting access to the food box or not.' (Participant 9 Local government) 154 The development of the QCovid risk prediction tool, which identified clinical and 155 demographic risk factors for COVID-19-related hospitalisations and deaths [12, 13] led to 156 substantial numbers being added to CEV lists in the summer of 2020. 157 158 The 'binary' nature of inclusion on the list was seen by one respondent as problematical: 'It didn't reflect the spectrum of risk. So you were selecting a group of people for 159 160 really quite an austere set of advisory statements, but actually nothing for the rest.' 161 (Participant 1 Policy Maker) Letters were sent to CEV people strongly advising them to shield from 23<sup>rd</sup> March 2020, 162 initially for 12 weeks [14]. Respondents reported considerable thought going into the exact 163 wording of the letters, with an emphasis on them giving advice, not instruction: 164 We were telling people they could rather than telling people they must. .... It was 165 strong advice, but it was set in advisory terms.' (Participant 7 Policy maker) 166 Where telephone numbers were available, reinforcement of the advice was sent by text 167 168 message. The other aspect of the intervention was the support programme, a range of components 169 170 experienced by some CEV people as required. These included eligibility (achieved through a change in legislation) for Statutory Sick Pay for CEV people, even if they were not ill, to allow 171 172 them to take time off work if their job could not be done at home. For those who needed 173 them, the UK government contracted with commercial providers to deliver weekly food parcels. CEV people could also access delivery of medications and were given priority by 174 supermarkets for food delivery. 175 176 Other forms of support were available through local government and partner organisations, and CEV people were invited to register to access this. Welsh local government respondents 177

described taking a proactive approach to contacting CEV people who might be in need of 178 help, through welfare telephone calls: 179 'trying to keep [CEV people] linked into their society, their communities. So it was 180 very much a kind of social response to it... Most of the people doing the calling were 181 182 our librarians.' (Participant 10 Local government) Although changes to data sharing rules allowed lists of CEV people to be supplied to local 183 government, significant challenges were reported with using the shared data: 184 185 'It was incomplete. It wasn't accessible...It wasn't transferable. It didn't match any of the other datasets. We couldn't identify individuals through it. I think the first lot 186 187 didn't even have people's names. It just had their NHS number.' (Participant 11 Local government) 188 189 Voluntary and community sector (VCS) organisations often worked in co-ordination with local 190 and central government, running telephone helplines offering advice and emotional support 191 for isolated people: 'We switched from a Monday to Friday, nine to five operation, to a seven day a week 192 operation. ... We were even doing things like contacting very local suppliers, and 193 shops, to see if we could get deliveries put in place for people.' (Participant 3 194 Voluntary and community sector) 195 196 197 Predicted mechanisms of change and outcome The predicted mechanism of change was that people would isolate themselves, with the 198 199 outcome of avoiding infection. Some respondents expressed anxiety about the loss of liberty this represented, even though 'it was really quite an honourable aim' (Participant 1 200 201 Policy Maker). Initially, shielding people were advised to avoid all contact with others, even 202 within the home. Respondents were aware that this was problematical: 'Everybody realised that wasn't realistic for ninety per cent of people, who don't live 203 in houses with west wings and east wings. And so... it then became a household 204 205 isolation, which was even worse.' (Participant 1 Policy Maker)

206	Equally, some of those shielding would require care at home, with care workers a potential	
207	source of infection:	
208	'A number of these people were vulnerable, they had comorbidities, they required	
209	support to manage that, and therefore contact would occur'. (Participant 5, Policy	
210	Maker)	
211	Respondents were aware that adherence to shielding advice would vary between	
212	individuals, and also over time, but felt that overall risk would still be reduced:	
213	'It's not an all or nothing, it's not if you break it once, you've broken the law, like with	
214	the legislative regulations.' (Participant 2 Policy Maker)	
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216	Intended impact	
217	The primary intended impact was a reduction in mortality among CEV people. This was	
218	emphasised strongly by most respondents.	
219	'The idea is that if we isolate them they're less likely to get it, because if they get it	
220	they're probably going to be really, really poorly and die.' (Participant 5, Policy	
221	Maker)	
222	Some respondents described a broader range of beneficial impacts, including limiting the	
223	burden on the NHS, engendering of community spirit, and more social and voluntary	
224	support for isolated vulnerable people.	
225	'It's about protecting the NHS, because that's in all our interests, isn't it, but actually	
226	on a local level, it was very much about supporting our communities.' (Participant 10,	
227	Local government)	
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229	Risks/unintended impact	
230	All participants described potential risks or unintended impact of shielding, and in particular	
231	the impact which it might have on mental health, through isolation and anxiety:	
232	'Some people who are shielding are still able to be effectively engaged somehow with	
233	society. They're working from home or whatever. But others have suffered, probably	

234	a lotIt created a whole lot of knock-on anxiety and everybody who was related in
235	any way with the shielded person [was] put in a state of heightened awareness and
236	heightened anxiety.' (Participant 1 Policy Maker)
237	Concerns about the long-term mental health impact were reported as a factor in the
238	decision to pause shielding advice in July 2020:
239	'The effect on mental health started to outweigh the benefit once the prevalence was
240	low enough.' (Participant 2 Policy Maker)
241	In addition, concerns were widely expressed about the impact of shielding on physical
242	health, including muscle wastage:
243	'The debilitation from not leaving the house …this was not just that you were telling
244	ninety- year-olds and eighty-year-olds, you were telling this to often quite fit young
245	people who just had another condition to stay in the house.' (Participant 4, Policy
246	Maker)
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248	Other unintended impacts included that on the workforce, as CEV people whose jobs could
249	not be done from home were no longer available to work.
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251	Contextual factors
252	The shielding policy was based on the assumption that the CEV group would have enhanced
253	protection over that of the general population. Almost as soon as shielding started, a
254	lockdown was introduced for the wider population, imposing legally mandated restrictions
255	on spending time outside the home except for certain exemptions. The national lockdown
256	also brought certain whole-population initiatives, such as the 'furlough scheme' to subsidise
257	wages for staff on temporary leave.
258	Respondents reflected that although lockdown was likely to have slowed the spread of the
259	virus in the wider population, continuing steady rates of infection meant that shielding
260	needed to continue to run in parallel:
261	'It went on an awful lot longer than was envisaged in the first instance.' (Participant
262	4 Policy Maker)

Since the shielding policy was developed in the context of a crisis, it - along with the associated shielding programme - was devised and implemented at an unusually fast rate, and participants spoke of a clear shared purpose:

'We all had to make decisions differently and quickly, and we all had to use a bit more common sense than the traditional waiting for somebody else to come up with a strategy.' (Participant 8 Local government)

Local government respondents reported that there was a blurring around the edges of the population receiving their input, as they added people they knew to be vulnerable to their lists for this type of support, in addition to CEV people on the shielding list.

'Our proactive calling quickly extended to older people who were not necessarily shielding, but we felt they were also vulnerable – a number of them were... in effect shielding themselves.' (Participant 10 Local government)

In addition to the formal social support available from local authorities and third sector organisations, many CEV people were likely to have been able to access a wide range of other resources within the community, which enabled shielding to happen, especially informal support from family and friends. However, some would have lacked informal support from family, friends, and neighbours and may have become increasingly isolated.

#### Discussion

# Principal findings

Our logic model provides a visual presentation of our understanding of the programme theory underlying the shielding intervention introduced across the UK to protect the most vulnerable people doing the early phases of the COVID-19 pandemic. It captures the key components of the shielding intervention (policy plus support programme), and identifies the mechanism by which it might make a difference, potential impacts, both unintended and intended, and key contextual factors. The logic model will underpin our evaluation of the impact of the shielding intervention, and we will continue to review it as the evaluation is finalised, in order to provide a structure to evaluating an intervention which to an extent was fluid and extemporised.

Our interviews with the key stakeholders add three main areas of insight: into the iterative and fluid process of developing and implementing shielding; into the range of activities which local government and the third sector introduced to support shielding people, outside the formal bounds of the programme; and into the feelings of many of those involved in the process, who revealed uncertainty about not only the logic but also the justice of shielding. The shielding policy, like many other aspects of the UK government's response to SARS-CoV-2, was introduced at pace. This left those involved in implementing the policy and delivering the shielding programme to work out the details at speed, once the decision had been made. The policy implementation and support programme were designed and iteratively refined by the many different parties collaborating on the work across the four nations of the UK – not just SAGE, civil servants and clinicians, but also those involved in providing services at local and community level. In the delivery of the shielding support programme, there was some blurring, as the formal shielding policy ended up being delivered alongside support interventions for those regarded as vulnerable for social rather than clinical reasons. This does not undermine the programme theory, but instead is integral to it. The nature of implementation as a process over time could also be observed. Although the basic principle of shielding remained the same throughout the time period of the intervention, the details evolved significantly – in terms of the nature of the advice, the definition of who should be on the shielding list, and in turn, the numbers of those included. As the pandemic continued, the evolution of the innovative attempts to deal with its impact were obvious, with new ways of working emerging between national government, local government and the voluntary and community sector. There was some ambiguity about who was doing the shielding: the use of the term 'Shielded Patient List' in guidance from the Department of Health and Social Care [15] implies that those at risk were being shielded by the state; yet the advisory nature of the guidance suggests that people were being asked to actively shield themselves – shielding rather than

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being shielded.

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# Context of other literature

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usual support [26].

The changes in the intervention over time noted in our study reflect the evolving nature of the shielding list, and the slippage between guidance and advice in public discourse, has been tracked in detail by Herrick [16]. Emerging evidence suggests that, despite the shielding intervention, there were still high rates of infection, hospitalisation and mortality in the shielding group [3,17] casting doubt on the mechanism proposed. This may in part be due to the impracticality of truly isolating people, particularly those who were in contact with clinical care providers and carers due to their vulnerability. Modelling has suggested that under an 'imperfect' but realistic shielding strategy, in which contacts for those shielding were reduced by 80%, would still allow high rates of infection of high risk individuals, with deaths estimated at 150% -300% higher than under an implausible 'perfect' shielding model in which contacts were reduced to zero [18]. High rates of nosocomial COVID-19 infection have been identified, likely to disproportionately affect CEV people [19-21]. Our findings confirm previous studies which have identified the crucial role of local government and VCS organisations in supporting the implementation and operationalisation of the shielding policy [22], and previous work discussing local variation in how the CEV list was created and the proportion and make-up of population on it [1], in particular associated with the addition of people to the list by local clinicians [23]. Communication with CEV people to inform them of the support available has been reported elsewhere as missing thousands of people, as records were incomplete [23]. A rapid evaluation in Scotland concluded that while the principle of shielding was valid, the intervention should not be repeated in exactly the same format [24]. The concerns expressed in our interviews about potential negative impacts of shielding reflect suggestions from other studies that people advised to shield may have experienced increased anxiety and mental ill-health and struggled to access routine healthcare [1,25],

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and there may have been an additional strain on unpaid carers who were left without their

#### Strengths and limitations

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This is the first study to develop a logic model examining all components of the UK COVID-19 shielding policy and programme, and to report the perspective of those involved in operationalising it.

In this phase of the EVITE Immunity evaluation, we did not record the perspective of CEV people themselves, who will have adhered to a greater or lesser extent, with adherence perhaps changing over time [11]; later phases of EVITE Immunity will explore the experience of this group.

# *Implications*

The UK's response to the pandemic of advising shielding for the most vulnerable was an unusual one, paralleled most closely in Europe by Ireland and by Sweden, where a policy of shielding people aged over 70 contrasted with the general population lock downs of its Nordic neighbours [27]. Although initial modelling in the UK explored a similar community level, age-based approach to shielding [28,29], the adoption instead of an approach based on identifying and targeting individual clinical vulnerability was substantially more complex, and perhaps was regarded as more acceptable to the public. The emphasis in the UK on a mitigation approach – reducing the peak of infection while protecting the vulnerable – was soon overtaken by the imposition of general population lockdowns, but the two policy approaches continued to run in parallel, at least initially. Modelling early in the pandemic had identified a potential trade-off between increasing protection of the vulnerable and relaxing restrictions on the non-vulnerable [11]. However, the overlapping lockdown and shielding restrictions in the UK, together with the 'leakage' of shielding through necessary personal contacts, along with rates of full compliance reported as down to less than two thirds of those on the list by early summer 2020 [30] make it hard to measure how this has played out. The impact of shielding will have depended in part on people's willingness to comply with guidance, shaped in turn by media narrative and social norms. There was no equivalent guidance on second level shielding, for those essential close contacts of the shielded population, and measures to control infection within the wider population were imperfect.

Over time, there has been an evolution of risk within the shielded population resulting from subsequent waves of coronavirus infection, along with the vaccination programme. Shielding has now formally ended in both England and Wales. The most recent government guidance to previously shielding people in England reassured that, with protection from the vaccine, they would no longer be at substantially greater risk than the rest of the population [31], though new mutations challenge the efficacy of existing vaccines. A now much better defined core high risk subset remains, consisting of those unable to respond to vaccination appropriately [32]. In terms of both infection rates and mortality in the UK, the pandemic has been identified as having an unequal impact on the population, reflecting health inequalities ultimately rooted in social inequalities [32]. The shielding policy may have exacerbated these, as those living in more crowded accommodation would have found it more challenging to maintain isolation from others. Conclusion The shielding intervention was introduced to save lives by protecting the most vulnerable to SARS-COV-2 infection. The shielding programme of support was introduced particularly rapidly and involved novel collaborations between various agencies. Components varied slightly but were broadly similar across the UK. It was a hitherto largely untested strategy based on 'common sense' risk mitigation rather than evidence based interventions. Naturally, this large scale initiative created challenges both for those attempting to implement the policy and for those meant to benefit from it. Our logic model allows us to understand the different impacts (intended and unintended) of the shielding programme on organisations and populations, and spells out its rationale, components, and mechanisms.

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Ethics:

Developing the logic model with input from key stakeholders has given additional insight to

help us understand the causal links which will inform our evaluation of the impact of

shielding and help us to understand its effect and limitations.

The EVITE Immunity study has received approval from the Newcastle North Tyneside 2 409 Research Ethics Committee (IRAS 295050). 410 411 **Transparency statement:** 412 Alison Porter is the manuscript's guarantor and affirms that the manuscript is an honest, 413 accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as originally 414 planned (and, if relevant, registered) have been explained. 415 416 **Contributorship statement:** 417 418 AP contributed to the conception and design of the study, to data acquisition, analysis and interpretation, and led the drafting of the paper. BE and VW contributed to the conception 419 and design of the study, to data acquisition, analysis and interpretation, and critically 420 reviewed the draft paper. LD and LG contributed to the conception and design of the study, 421 contributed to data analysis and interpretation, and critically reviewed the draft paper. AA, 422 AC-S, JD, AE, AJ, SJ, MK, RL, JM, BS, AW contributed to the conception and design of the 423 424 study and critically reviewed the draft paper. HS led the study, contributed to the 425 conception and design of the study and critically reviewed the draft paper. 426 **Competing interests:** 427 Ronan Lyons, Stephen Jolles, Ann John and Adrian Edwards are members of the Welsh 428 429 Government COVID-19 Technical Advisory Group. Ann John is also co-Chair of the Scientific Pandemic Insights Group on Behaviours (SPI-B) which is a subgroup of the Scientific Advisory 430 Group for Emergencies (SAGE) advising the UK government. Stephen Jolles is also a member 431 of the Welsh Government Testing TAG and Cardiff University COVID Strategic Advisory Board 432 (SAB). No other authors have competing interests. 433 434 **Funding statement:** 435 This work is supported by the National Core Studies Immunity (NCSi4P) Programme. 436 437

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439 No additional data available.

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