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A Rapid Realist Review of the Role of Community Pharmacy in the Public Health Response to COVID-19

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9 2 the Public Health Response to COVID-19
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3 18 Introduction
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6 19 Community pharmacists and their teams have remained accessible to the public providing essential
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8 20 services despite immense pressures during the COVID-19 pandemic. They have successfully
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10 21 expanded the influenza vaccination programme and are now supporting the delivery of the COVID-
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12 22 19 vaccination roll-out.
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15 23 Aim
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18 24 This rapid realist review aims to understand how community pharmacy can most effectively deliver
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20 25 essential and advanced services, with a focus on vaccination, during the pandemic and in the future.
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23 26 Method
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26 27 An embryonic programme theory was generated using four diverse and complementary documents
27
28 28 along with the expertise of the project team. Academic databases, preprint services and grey
29
30 29 literature were searched and screened for documents meeting our inclusion criteria. The data was
31
32 30 extracted from 103 documents to develop and refine a programme theory using a realist logic of
33
34 31 analysis. Our analysis generated 13 context-mechanism-outcome configurations explaining when,
35
36 32 why and how community pharmacy can support public health vaccination campaigns, maintain
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38 33 essential services during pandemics, and capitalise on opportunities for expanded, sustainable public
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40 34 health service roles. The views of stakeholders including pharmacy users, pharmacists, pharmacy
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42 35 teams and other healthcare professionals were sought throughout to refine the 13 explanatory
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44 36 configurations.
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49 37 Results
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52 38 The 13 context-mechanism-outcome configurations are organised according to decision makers,
53
54 39 community pharmacy teams and community pharmacy users as key actors. Review findings include:
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56 40 supporting a clear role for community pharmacies in public health; clarifying pharmacists' legal and
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58 41 professional liabilities; involving pharmacy teams in service specification design; providing suitable
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3 42 guidance, adequate compensation and resources; and leveraging accessible, convenient locations of
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5 43 community pharmacy.
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8 44 Discussion

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11 45 Community pharmacy has been able to offer key services during the pandemic. Decision makers
12
13 46 must endorse, articulate and support a clear public health role for community pharmacy. We
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15 47 provide key recommendations for decision makers to optimise such a role during these
16
17 48 unprecedented times and in the future.
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22 23 50 Strengths and limitations of this study

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26 51 A diverse group of professional and public stakeholders validated our findings from the literature.
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31 53 By using a realist approach, we were to use broad range of data, including grey literature.
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35 55 To enable us to develop recommendations in a timely manner the focus of the review was
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37 56 deliberately narrow.
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41
42 58 The topic could have been informed by other sources of evidence in particular empirical interviews
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44 59 with key stakeholder.
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49 61 COVID-19 vaccination is a rapidly evolving area and this research was based on the best available
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51 62 evidence at the time.
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For peer review only

66 Introduction

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68 Community pharmacy teams have continued to provide essential services during the coronavirus
69 disease 2019 (COVID-19) pandemic. They offer accessibility and medicines expertise to the public,
70 even in challenging times.^{1 2 3} However, COVID-19 creates extra workload demands, such as
71 medication dispensing with increases of up to 33% in prescription numbers.⁴ To cope with this
72 demand community pharmacies have increased their opening hours and hired additional staff.⁴
73 Alongside this additional workload, they have managed widening coverage of the influenza vaccines
74 programme.⁵

75 Evidence suggests that community pharmacy can successfully provide diverse vaccination services
76 including seasonal and pandemic influenza, travel vaccinations and hepatitis B for at-risk groups,
77 within the provisions of the UK National Health Service (NHS) or privately.⁶ They have successfully
78 provided influenza vaccines as an NHS commissioned advanced service since 2015.⁵ One service
79 evaluation found that of 485 patients asked, 99% expressed confidence in their pharmacist to
80 provide additional vaccinations.⁷ Community pharmacy can also support influenza and other
81 vaccinations to combat the significantly higher COVID-19 related mortality in the non-white
82 community.^{8 9}

83 The COVID-19 pandemic has stretched NHS capacity to safely and efficiently meet public health
84 demands. A role for community pharmacy in the national vaccination service requires an
85 understanding of what pharmacy teams require to successfully deliver essential and advanced
86 services during the pandemic. Such knowledge is timely, given the roll-out of COVID-19 vaccines
87 across the community.¹⁰

88 Delivering a vaccine is a complex process and successful delivery is context-dependent. A realist
89 review helps make sense of complex situations^{11 12}, such as how community pharmacy can most

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3 90 effectively address the challenges presented by COVID-19. A rapid review can generate guidance for
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5 91 decision makers to assist with roll-out of COVID-19 vaccinations to community pharmacy.
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8 9 92 **Methods**

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12 93 A rapid realist review of academic and other literature, supplemented by input from key actors, was
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14 94 undertaken to understand how and when community pharmacy can effectively support the public
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16 95 health agenda during pandemics such as COVID-19. Rapid reviews aim to ensure findings are
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18 96 generated and disseminated in response to the urgent nature of the situation. To produce this
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20 97 knowledge at pace, we truncated the following review processes:

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24 98 - Programme theory development was undertaken within 1 month with input from the
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26 99 project team.
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28 100 - Searching was expedited using broad search terms and using a limited number of key data
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30 101 sources.
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33 102 - Data analysis and context-mechanism-outcome configuration (CMOC) development
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35 103 focussed on where the programme theory was considered most important during COVID-19.

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38 104 This realist review was undertaken within six-months (August 2020 - January 2021), the protocol was
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40 105 published on PROSPERO¹³ and, where relevant, follows the RAMESES quality and publication
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42 106 standards.¹⁴

43 44 45 107 **Stage 1: Programme Theory Development**

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48 108 The project team met virtually to develop an embryonic programme theory using four diverse
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50 109 documents from an initial search representing a professional journal¹⁵, a research journal¹⁶, a policy
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52 110 document (Royal Pharmaceutical Society)¹⁷ and a practical influenza briefing.¹⁸ The team identified
53
54 111 the need for (i) enabling guidance for community pharmacy (to achieve legitimisation)¹⁶; (ii) practical
55
56 112 direction for community pharmacy practices (to ensure feasibility)^{15 16}; and (iii) user assurance of
57
58 113 appropriate, safe, feasible and timely intervention (relative advantage).¹⁵ The resultant embryonic
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3 114 theory, patterned on a COM-B behavioural model of capability, opportunity, and motivation leading
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5 115 to behaviour¹⁹, was used to inform searching and initial analyses.
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8 9 116 Stage 2: Literature Searching

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11 117 Searches were conducted (July-August 2020) using MEDLINE, EMBASE, CINAHL, Web of Science, and
12
13 118 Scopus for search concepts relating to Pharmacy and COVID by AB (see Appendix 1 for search
14
15 119 strategy). Reference checking and citation searching of all included references on Google Scholar
16
17 120 (using the Publish or Perish tool) were also carried out. Given the novelty of the virus, we searched
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19 121 the contents of preprint services and the World Health Organisation (WHO) COVID Register. Grey
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21 122 literature searches included social media (e.g. blogs, facilitated Twitter® discussion [#Cpharmchat]),
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23 123 community pharmacy websites, and emails from relevant regulators and professional organisations
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25 124 (e.g., Royal Pharmaceutical Society [RPS], Pharmaceutical Services Negotiation Committee [PSNC],
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27 125 General Pharmaceutical Council [GPhC]).
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32 126 Key inclusion criteria were high or middle-income countries, community pharmacy and infectious
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34 127 disease management (see Appendix 2). The search covered January 2003-July 2020 to include SARS,
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36 128 a comparable condition first identified in 2003. There were no restrictions on study designs eligible
37
38 129 for inclusion.
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42 43 130 Stage 3: Data Selection and Extraction (selection and coding)

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46 131 Selection and appraisal of documents followed a two-step procedure:

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48 132 1). EY screened the title, abstract and keywords of potentially relevant documents against inclusion
49
50 133 criteria. A 10% random sample was checked by two research team members (AB and MM) for
51
52 134 consistency.
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56 135 2). EY obtained and screened full texts of all documents meeting the eligibility criteria.
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3 136 Relevant data from the included full text documents was coded into NVivo by EY, MM and JB. Some
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5 137 codes came from the data (i.e. inductive coding); others were derived from the programme theory
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7 138 (i.e. deductive coding) and some were derived using retroduction (i.e. by interpretation of what
8
9 139 might be functioning as mechanisms).²⁰ No assessment was made of the rigour of the data within
10
11 140 included documents, however global judgements were made of the quality of the explanations
12
13 141 provided by the CMOCs and programme theory using the criteria of consilience, simplicity and
14
15 142 analogy.²¹

19 143 Stage 4: Data Synthesis

20 144 The data analysis/synthesis was conducted by EY, MM and JB with input from the rest of the project
21
22 145 team to develop and refine the programme theory using a realist logic of analysis. Our analysis
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24 146 generated 13 realist CMOCs, explaining when, why and how community pharmacy can support
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26 147 public health vaccination campaigns, maintain essential services during pandemics, and capitalise on
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28 148 opportunities for expanded, sustainable public health service roles. Actor conversations generated
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30 149 further CMOCs related to care for diverse and vulnerable populations, including the Black and
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32 150 Minority Ethnic (BAME) community.

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39 151 Our realist logic of analysis centred on the following questions:

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42 152 • Interpretation of meaning: Do the contents coded by the team provide data that may be
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44 153 interpreted as CMOCs?
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46 154 • Interpretations and judgements about CMOCs: How do the CMOCs relate to the programme
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48 155 theory?
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50 156 • Interpretations and judgements about programme theory: How do the programme theory and
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52 157 its CMOCs correspond with key actor perspectives of reality?
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3 158 Data to answer our questions was iteratively sought across documents. Interpretive cross-case
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5 159 comparison was used to identify and to explain the “success” of pandemic community pharmacy
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7 160 interventions delivered in different settings or to different population groups.
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10 11 161 Key Stakeholders

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14 162 Key stakeholders, including community pharmacists and support staff (including representatives
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16 163 from large and smaller chains, sole independent pharmacies and primary care), other healthcare
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18 164 professionals and members of the public were consulted on four occasions. The meetings took place
19
20 165 over Microsoft Teams and each lasted about one hour.
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23 166 Patient and Public Involvement

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26 167 Members of the public were drawn from The University of Sheffield’s Patient and Public Involvement
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28 168 database and contacts of the core project team. Groups numbered between 11 and 13 members,
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30 169 with ages ranging from 22 to 74 years, from diverse locations and ethnicities including Black African,
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32 170 Black Caribbean, British Asian, British Chinese, White Irish and White British. Collectively,
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34 171 stakeholders provided feedback and advice on their real-world experience of working in or using
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36 172 community pharmacy.
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48 176 103 documents were included in this rapid review and were coded to develop and refine our CMOCs
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50 177 and programme theory (PRISMA diagram in Appendix 3). The final programme theory is summarised
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52 178 in Appendix 4—from abstract visioning to actual patient uptake of the COVID-19 vaccine. Although
53
54 179 the programme theory is outlined in a linear fashion, steps within it are not necessarily linear and
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56 180 may occur simultaneously. The CMOCs are organized according to key actors, or individuals and
57
58 181 groups with a vested interest in community pharmacy delivery of a COVID-19 vaccination
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182 programme. “Actor” derives from sociology and is synonymous with “stakeholder”; we privileged
 183 this term to differentiate programme theory/CMOC organization from project stakeholder
 184 participants.²² Table 1 briefly describes the three actor groups with their respective CMOCs and
 185 corresponding steps in Appendix 4. Tables 2-4 show the final 13 CMOCs.

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187 Table 1: Programme Theory Actors with corresponding CMOCs and steps

Programme Theory Actors	Description	CMOCs*	Steps in Programme Theory**
Decision Makers	The UK government, regulatory and professional bodies, the public.	CMOC 1 - 4	Steps 1 - 4
Community Pharmacists and their Teams	Community pharmacists are health care professionals registered by the General Pharmaceutical Council and supported by teams made up of counter assistants, dispensers and registered technicians. They work in high street locations, in local communities and in supermarkets. Employers range from large chains to small individually owned community pharmacies.	CMOC 5 – 9	Steps 5 – 7 and 9 – 11
Pharmacy Users	Members of the public who use any community pharmacy services including prescription dispensing, minor ailment advice/treatment or vaccination services.	CMOC 10 - 13	Step 8

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189 *see Table 2-4

190 **See Appendix 4

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192 The following sections summarise the CMOCs related to each of the three actor groups. Illustrative
 193 examples of the supporting evidence from review documents are presented (Tables 2-4).

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195 *Decision makers*

196 Decision maker and public endorsement (CMOC 1) are essential first steps in enlisting community
 197 pharmacy for COVID-19 vaccination programmes. Regulators must ensure pharmacists have the
 198 legal scope to do so (CMOC 2), with community pharmacy input during the development of policies
 199 and protocols (CMOC 3), so that final service specifications are flexible and do-able within local
 200 settings (CMOC 4).

201 Table 2 - Decision Makers (CMOCs 1-4)

<p>CMOC 1 –</p> <p>Support a public</p> <p>health role^{23 24 25}</p> <p><small>26-32</small></p>	<p>When the government, pharmacy regulators, professional bodies and the public endorse and support a clear role for community pharmacy in public health services (C), community pharmacists will be more likely to adopt vaccination services (O) because they see it as their professional role and duty (M).</p> <p><i>“Distribution and administration of the COVID-19 vaccination programme will require concerted action across the NHS. With unique insight and expertise in medicines and the delivery of vaccination programmes, pharmacists have a clear role in contributing to the success of this programme.” (Great Britain)²⁴</i></p> <p><i>“55% of the public have visited a pharmacy during the COVID19 crisis...89% of people believe pharmacies are playing an essential role in the COVID19 crisis.” (UK National Pharmacy Association)²³</i></p>
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	<p><i>“Pharmacists...have been called on to coordinate the administration of COVID-19 tests...providing ongoing COVID-19 surveillance to communities by allowing walk-in testing at community pharmacies...[This] might be more sustainable and convenient than the large-scale public screening being done as of the summer of 2020.” (USA)²⁵</i></p> <p><i>“Given the past success of community pharmacists with increasing annual seasonal influenza uptake and their accessibility, pharmacists will need to be central in administering COVID-19 vaccines in order to achieve rapid population-wide coverage.” (Canada)²⁶</i></p>
<p>CMOC 2 –Clarify legal and professional liabilities^{24 31 33-40}</p>	<p>When pharmacy regulators and the NHS clarify community pharmacists’ legal and professional liabilities arising from the administration of a novel and potentially unlicensed COVID-19 vaccine (C), community pharmacists are more willing to give the vaccination (O) because they feel reassured regarding liability (M).</p> <p><i>“The role of pharmacists in the COVID-19 vaccination programme must be made clear to the pharmacy profession itself. Professional and representative pharmacy bodies have an important role to play in providing the right level of information to the profession to support their roles in the vaccination programme.” (Great Britain)²⁴</i></p> <p><i>“Indemnity insurance for individual healthcare professionals needs to be amended to cover this activity and be state-funded. There also needs to be clear communication to healthcare professionals, so they clearly understand</i></p>

	<i>that they are covered and under which circumstances this applies.” (Great Britain)⁴¹</i>
CMOC 3 – Co-develop feasible service specifications^{1 38} <i>42-48</i>	When COVID-19 vaccination policy and service specifications have been developed with input from diverse community pharmacists and staff tasked with administering and supporting the administration of the vaccine (C), community pharmacies are more likely to deliver the service (O) because they believe the service specification is feasible (M). <i>“Pharmacists ideally want input into future policy changes before they are finalized, so that these can reflect capacity and preparedness on the ground and be publicized accurately.” (Great Britain)¹</i>
CMOC 4 – Issue clear, relevant and timely guidance^{25 27 31 34} <i>48-62</i>	When government, pharmacy regulators and professional bodies provide consistent, clear, relevant, and timely guidance for the delivery of the COVID-19 vaccines (C), community pharmacies are more likely to deliver the service (O), because the guidance is helpful and simplifies implementation (M). <i>“... it is good to see that NHSE/I have provided the information we have been waiting for to review the resources we have nationwide and decide how we can bring them to bear to help the NHS defeat this virus.” (Great Britain)⁴⁹</i>

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In England community pharmacies have government contracts and partnerships to deliver vaccinations and other essential services during emergencies, including the COVID-19 pandemic.^{25 31}

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³² Pharmacies in the USA and Canada have also been identified as having a substantive role in

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vaccine administration (CMOC1).^{25,26} The idea of harnessing UK community pharmacy capacity

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enjoys widespread public support (CMOC2).²³ However, appropriate service delivery is hampered by

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unfeasible operational conditions (CMOC3)¹; for example, medication deliveries are funded by the

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UK government for “vulnerable people”, but this category of service users is defined narrowly by the

210 government and misunderstood by the public, creating unrealistic expectations of community
 211 pharmacy and generating additional work.¹

212 In contrast, when clear options for community pharmacy involvement in COVID-19 vaccination
 213 programmes were issued through the NHS (CMOC4), the chief executive of the Association of
 214 Independent Multiple Pharmacies commented positively on members' engagement in delivering
 215 vaccines.⁴⁹

216 *Community Pharmacists and Team*

217 Community pharmacies have had to manage ongoing essential services, in addition to supporting
 218 COVID vaccination delivery during the pandemic (CMOC6), including delivery of necessary
 219 medications (CMOC7). Given fears and anxieties related to COVID-19 and changes to service
 220 delivery, community pharmacies have had to deal with inappropriate behaviours from the public,
 221 including emotional abuse and threats of physical abuse (CMOC8). As an integral public health
 222 service, community pharmacy capacity to meet NHS needs will be enhanced through use of IT and
 223 collaboration with other service providers (CMOC9).

224 Table 3 - Community Pharmacists and Team (CMOCs 5-9)

CMOC 5 – Receive adequate compensation and resources^{1 63-77}	When community pharmacies receive adequate compensation and resource support for COVID-19 vaccines (C), they are more likely to deliver the service (O), because they feel recognised for their service contributions (M).
	<i>“Pharmacists...have been incredible in supporting patients throughout COVID-19 and rightly deserve recognition for the work they do. We know that teams were already under pressure and that colleagues in community pharmacy are feeling added financial strain.” (Great Britain).⁶³</i>

	<p><i>“In the community, mitigating the impact of COVID-19 has...focused largely on general practitioners (GPs). This is unsurprising to those in the pharmacy profession who have long considered policy makers to overlook them.” (Great Britain)¹</i></p>
<p>CMOC 6 – Sustain capacity and facility to adapt essential services^{16 17 30 34 68 70 71}</p>	<p>When a community pharmacy has the capacity and permission to manage and adapt existing essential services during COVID-19 (C), they are more likely to effectively deliver and sustain these services (O) because it’s feasible for them to do so (M).</p>
<p>78-91 92</p>	<p><i>“Virtual and telephone consultations have become commonplace, particularly to vulnerable patients. Pharmacists have implemented systems to dispense medications in advance of need to minimise wait times and duplicate visits. In case-by-case examples...there has been anticipatory management of medication-related needs.” (Ireland)⁹²</i></p> <p><i>“Pharmacists who had comfort and confidence in managing electronic communication reported feeling greater control over workflow and the ability to triage and queue patients more effectively based on priority and need.” (Canada)⁶⁰</i></p>
<p>CMOC 7 – Inform users of essential service availability/continuity</p>	<p>When community pharmacies have processes in place to inform pharmacy users about the availability of essential services (C), pharmacy users are less likely to become anxious (O), because they feel reassured about access to what they need (M).</p>

<p>92 16 28 31 32 51 60 65 71 80 81</p> <p>85 93-101</p>	<p><i>“Access to medications is a main concern expressed by our patients... The CDC and SAMHSA offer guidance on ways to reduce stress and anxiety in this time of uncertainty.”⁹⁵</i></p> <p><i>“As a result of the power dynamics at play, it is ultimately up to pharmacists to be able to reassure patients and provide care, all while taking into account their mental health. Currently, guidelines regarding patient interaction during a pandemic are needed”.⁵¹</i></p> <p><i>“In addition, there is ongoing work in liaison with pharmacists, general practitioners, and state and territory authorities to enable therapeutic substitution by pharmacists in the event of a shortage. This will allow community pharmacists to substitute dose strength or form without prior approval from the prescriber, if a prescribed medicine is not available at the time of dispensing. These measures highlight the important role pharmacists can play in enabling and maintaining access to medicines for people in need throughout the COVID-19 outbreak.” (Australia)⁸⁵</i></p> <p><i>“Access to medications is a main concern expressed by our patients... The CDC and SAMHSA offer guidance on ways to reduce stress and anxiety in this time of uncertainty.” (USA)⁹⁵</i></p>
<p>CMOC 8 – Protect the health and safety of staff ^{24 31 51 71 77 81 102-108}</p>	<p>When community pharmacies have the means to protect the health of pharmacists and staff (C), they are more likely to deliver essential services and COVID-19 vaccination services (O), because they feel safe to do so (M).</p>

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	<p><i>“...Given high levels of public anxiety and uncertainty regarding the integrity of the drug supply chain in Canada, many participants reported difficult, sometimes frightening, interactions with members of the public and their desire for dedicated security to provide support and conflict management” (Canada).³¹</i></p> <p><i>“An additional burden Asian pharmacists face, on top of pharmacist harassment, is the rise of anti-Asian racism that has come about due to COVID-19. Verbal and even physical abuse has been reported to happen in various countries, such as the UK, France, and the USA, to those of Chinese descent...” (UK, France, USA)⁵¹</i></p> <p><i>“The survey found that although more than a third (37%) of pharmacists said they felt unsafe at some point working during the pandemic, concerns over PPE have eased. This is due, in part, to the supply problems being eased and community pharmacists being finally allowed to order from the national online PPE portal in an emergency, after calls for access from the RPS.” (Great Britain)⁷⁷</i></p>
<p>CMOC 9 – Enhance collaboration across services, including IT¹⁸ <i>26 47 56 57 69 78 80 85 109-114</i></p>	<p>When systems needed for COVID-19 vaccination, including IT and remuneration, support collaboration by various service providers (e.g. general practitioner surgeries and community pharmacies: (C), a coordinated response is more likely (O), because reduced effort is needed from everyone (M).</p>

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“Planning and delivery should be undertaken across a consistent, pre-agreed footprint. It may be more efficient and cost effective to provide immunisation across a number of providers, pooling resources and sites to deliver the best service possible, and working in coordination with other local stakeholders such as directors of public health and local government.” (Great Britain)⁴⁷

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“For many community pharmacists, a lack of connected IT is a huge problem. Kieran Eason, who runs an independent pharmacy in Tamworth, Staffordshire, says lack of intra-operability makes it more difficult to do relatively simple things, like sending prescription requests to GPs. “Pharmacy IT is just a complete disaster,” he says, suggesting the COVID-19 crisis has highlighted flaws, such as the number of different systems pharmacists use.” (Great Britain)⁶⁹

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226 Although attention is focused on a COVID-19 vaccine, community pharmacies offer diverse essential
227 services. In the UK and other high-income countries, community pharmacy services also provide
228 advanced services such as vaccinations.¹¹⁵ Pharmacists consider it a professional responsibility to
229 provide essential services during the pandemic, despite clear financial risks to themselves.⁶³

230 Despite pharmacists’ professional and moral obligations to provide essential services, ongoing
231 persistent ‘under-recognition’ can jeopardize their ability to contribute to COVID-19 vaccinations
232 (CMOC5) as well as maintain a usual service. Under-recognition has been an issue in previous UK
233 vaccination campaigns; respondents to a survey of Welsh community pharmacists after the 2016
234 influenza season described providing a “mop up” service for general practitioners (GPs).^{59 68}

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3 235 Multiple required community pharmacy service adaptations have been reported by the UK
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5 236 Pharmaceutical Journal, including changeover in retail space to medication preparation and
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7 237 dispensing, and call-in shopping services for other retail items (CMOC6). Service adaptations have
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9 238 been affected by hours of operation, available staff, and cancellations of contracted services, such as
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11 239 blood pressure testing and smoking cessation support—all with financial implications for
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13 240 pharmacists.⁸⁰

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17 241 Before COVID-19, community pharmacies globally were offering “valued-added services” (VAS) such
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19 242 as drive-thru services, online ordering and communications services (e.g., prescription reminders) to
20
21 243 stay competitive. Many VAS services have helped pharmacies adapt more quickly to pandemic
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23 244 restrictions.⁸¹

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27 245 During the pandemic, ensuring access to needed medications has been a critical pharmacy service,
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29 246 to allay public concerns (CMOC7).¹⁶ Potential and actual disruptions in expected services and needed
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31 247 supplies (e.g., medications) have resulted in tensions, threats and verbal/physical abuse by the
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33 248 public to community pharmacists (CMOC 8).^{51 80 116} Safety policies, protocols and safety-related
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35 249 supplies (e.g., PPEs) must in place to ensure community pharmacy teams’ safety.⁸⁰

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39 250 The UK COVID-19 vaccination campaign borrows heavily from previous, successful collaborative
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41 251 influenza vaccination programmes using community pharmacy and GPs (CMOC9).⁴⁸ Pooling
42
43 252 resources improves service delivery.¹¹⁷ For example, the UK Pharmaceutical Journal reported how a
44
45 253 greater collaborative approach has resulted in successful influenza vaccination of home care staff
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47 254 and domiciliary workers during the pandemic.¹¹⁷

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49
50 255 The pandemic has clearly demonstrated the importance of interoperable, connected IT systems
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52 256 across services.¹¹⁸ Getting access to reliable information is important for tracking supplies and
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54 257 deliveries related to the COVID-19 vaccination programme.⁶⁹ A pandemic silver lining is raised
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56 258 awareness of IT functions for enhanced delivery of essential services (e.g., medication planning,
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3 259 prescribing and dispensing between pharmacies and GPs) and advanced services, including
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5 260 vaccinations.⁶⁹
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9 261 *Pharmacy Users*

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11 262 Pharmacy users trust community pharmacies as a reliable source of information (CMOC10) about
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13 263 vaccines, and pharmacies' local accessibility and convenience increases the likelihood of users
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15 264 obtaining COVID-19 vaccines through them (CMOC11). Community pharmacy relationships with
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17 265 vulnerable populations in their local settings may enhance uptake of the vaccine by these groups
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19 266 (CMOC12). Provision for privacy is an important user consideration. Pharmacy users expect private
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21 267 consultations to preserve their confidentiality (CMOC13).
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269 Table 4 - Pharmacy Users (CMOCs 10-13)

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<p>COMC 10 – Trust the pharmacist as reliable information source^{32 53 119-122}</p>	<p>When pharmacy users receive information about the COVID-19 vaccine from their community pharmacy (C), they are more likely to get the vaccine (O), because they trust community pharmacy as a source of reliable, accurate information (M).</p> <p><i>“When patients were educated about influenza, herpes zoster, and pneumococcal vaccines as a result of a pharmacist-driven intervention in community pharmacies, they were influenced to receive the vaccination.” (USA)¹¹⁹</i></p> <p><i>“Being able to address the public enquiries with accurate up-to-date information about the local situation and the overall infection progress is the key to build trustful relationship with them at troubled times.” (Macau)³²</i></p>
<p>CMOC 11 – Trust the pharmacist to deliver responsive services^{7 18 23 26 34 37 43 51 54 59 63 70 84 85 123-135}</p>	<p>When community pharmacies are trusted to make necessary service adaptations to ensure services are flexible, convenient and accessible (C), COVID-19 vaccine uptake is likely to be higher among pharmacy users (O) because the service is responsive to local needs (M).</p> <p><i>“Pharmacists have always been the most accessible health care provider; this is especially true in the era of COVID-19.... While other professionals have closed their doors to patients, community pharmacies remained open to the public despite stricter lockdown restrictions. As highly trusted healthcare clinicians, community pharmacists play a vital role in closing the gaps that are exacerbated by the additional strain on the system and reduced access to healthcare providers.” (Canada)⁵¹</i></p>

	<p><i>“Pharmacy flu vaccination services complement those provided by general practitioners to help improve overall coverage and vaccination rates for patients in at-risk groups. These services are highly accessed by patients from all socio demographic areas, and seem to be particularly attractive to carers, frontline healthcare workers, and those of working age.” (Great Britain)¹³⁵</i></p>
<p>CMOC 12 –</p> <p>Access culturally-sensitive services</p> <p><small>27 78 80 92 136</small></p>	<p>When community pharmacies leverage their community location and community-staff relationships (C), vulnerable populations, such as Black, Asian and Minority Ethnic groups are more likely to use their services, including COVID-19 vaccination services (O), because they trust their local community pharmacies to provide culturally sensitive service. (M)</p> <p>“Research continues to highlight that patients who are medically underserved have poorer inequitable access to health care due to them experiencing greater physical barriers to accessibility, encountering poorer patient-professional communication and are significantly disadvantaged where a service is not tailored to their unique needs or preferences.” (Great Britain)¹³⁷</p> <p><i>“I think over the years what’s happened is nationally it’s almost like everything has to be the same, which then doesn’t work because it doesn’t accommodate all the little variations...So we need to go back and in each individual pharmacy, gear it towards the population that it is meant to be meeting the needs of” (Pharmacist caring for BAME community-Great Britain)¹³⁷</i></p>

<p>CMOC 13 –</p> <p>Receive private and confidential services^{7 50 65 129}</p> <p>138-140</p>	<p>When community pharmacies make provisions for privacy (C), pharmacy users are more likely to use their services (O), because they are reassured about confidentiality (M).</p> <p><i>“If there was something not right...the first thing I would do is make an appointment with a doctor. I wouldn’t do and talk to somebody over a pharmacy counter.” (Great Britain)⁶⁵</i></p> <p><i>“Privacy, confidentiality and dignity are all vital elements of a trusting relationship between healthcare professionals and their patients.... In terms of privacy, the quality was perceived by the participants to include a confidential room that enabled private consultations.” (Great Britain)⁷</i></p>
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272 Public trust in community pharmacists is high—similar to doctors and nurses.³⁸ Trust between
 273 pharmacists and users can be leveraged to overcome scepticism about the COVID-19 vaccine.
 274 Providing reliable information about the disease and the vaccine, as pharmacies have done with
 275 other infections, can enhance public uptake of the COVID-19 vaccine.¹¹³ In the USA, 90% of the US
 276 population lives within 5 miles of a community pharmacy. Given their convenience and accessibility,
 277 consumers have visited their community pharmacists 12 times more frequently than their GPs.²¹ A
 278 UK study found that consumers who were eligible for a free influenza vaccine through their GPs
 279 were willing to pay for pharmacy service because of convenience and ease of access.¹²⁷ Established,
 280 trusting relationships are especially important for providing culturally sensitive services to
 281 marginalized and vulnerable communities.¹²⁹ Community pharmacists, often members of local
 282 communities are specially positioned to understand the culturally contextual factors that impact
 283 their pharmacy users.⁸⁹ Trusting relationships are founded on privacy, confidentiality and dignity,

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3 284 and COVID-19, public health protocols and limited space must be considered—in order to maintain
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5 285 vital trust among pharmacy users.⁶⁵
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8 286 Discussion

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12 287 This realist review sought to understand how community pharmacy can contribute to the public
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14 288 health agenda during the COVID-19 pandemic, particularly continuation of essential services and
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16 289 engagement in vaccination services.¹¹⁵ As the COVID-19 vaccination service continues to evolve, our
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18 290 recommendations for decision makers highlight opportunities for community pharmacy to promote
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21 291 safe, efficient and effective service delivery.
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26 293 Summary of key Findings

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29 294 To optimise community pharmacy service during the pandemic, decision makers must endorse and
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31 295 articulate a clear role for these healthcare professionals. The public already endorses advanced roles
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33 296 for community pharmacy (e.g., vaccinations, minor ailment scheme), but public awareness depends
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36 297 on what decision makers do and say. Practical decision maker measures include adequate
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38 298 reimbursement to help cover the cost for time, staff and PPE (particularly for a sustainable long-term
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40 299 service); legal (including indemnity), regulatory coverage for advanced roles; and clear and
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42 300 consistent guidance for vaccination preparation and for adaptation of essential services. When given
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44 301 the opportunity, the permissions and resources to do so, community pharmacies have been able to
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46 302 adapt quickly to continue essential services and whenever possible, to offer critical advanced
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49 303 services. Historically, community pharmacies have significantly increased vaccination uptake (e.g.,
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51 304 influenza vaccinations) given their accessibility and convenience and capacity to adapt to local needs
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54 305 for the general population and marginalized groups (e.g., BAME).
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4 307 Compare to other similar or related studies discussing important differences in
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7 308 results
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10 309 At the time of this realist review, there were no similar reviews on community pharmacy roles with
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12 310 respect to COVID-19 vaccinations. COVID-19 represents an unprecedented situation with limited
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14 311 direct evidence to guide decision-making. However, realist approaches engage with a wider evidence
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16 312 base, including research on past pandemics (e.g., SARS)^{60 141 142}, mass vaccination campaigns (e.g.,
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18 313 influenza)¹⁴³, and community pharmacies' capacity pre-COVID-19 to deliver essential and advanced
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20 314 services.^{19 144 145} Key factors previously include a lack of leadership, a lack of guidance and an
21
22 315 increasing reliance on professional judgement and experience.⁶⁰ Research from the UK and other
23
24 316 economically developed countries supports the 13 CMOCs and decision maker recommendations in
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26 317 this review (see tables 2-4 and table 5). However, limitations continue to surround the direct policy
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28 318 relevance of much of the community pharmacy evidence base.¹⁴⁶
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35 320 Study strengths and limitations
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38 321 The realist approach uses diverse data, including grey literature. This feature is especially important
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40 322 given a novel and rapidly evolving topic area, such as COVID-19. Multiple researchers with subject
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42 323 matter expertise participated in screening the literature and extracting and coding data, which
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44 324 maximised opportunities to discuss and debate the plausibility of the inferences made. The CMOCs
45
46 325 were developed and refined through regular discussions within a team with varied academic and
47
48 326 clinical backgrounds. Professional and public stakeholder consultation further refined the CMOCs.
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52 327 All rapid reviews operationalise coverage versus expediency. Other sources of evidence could have
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54 328 informed the review; however, potential gaps were mitigated by stakeholder engagement and
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56 329 expertise within the team. The evidence supporting the CMOCs was based on available time for
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58 330 document review, and during the review period, research, directives and policy related to COVID-19
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331 vaccination rapidly evolved. The programme theory and its CMOCs, however, are expressed in such
 332 a way that they can be further confirmed, refuted or refined in the future using additional data.

333 **Meaning of the study: possible explanations and implications for decision makers**

334 Although there are multiple actors involved in pandemic response, for brevity, recommendations
 335 (Table 5) are directed towards decision makers who possess the formal authority to implement the
 336 recommendations.

337
 338 Table 5 - Recommendations for Decision Makers to Increase Community Pharmacy Engagement in
 339 Pandemic Response (for further details check: <https://www2.aston.ac.uk/lhs/research/periscope>).

Recommendations	Derived from CMOC
Articulate a clear public health agenda role for community pharmacy (e.g., COVID-19 testing and vaccination)	1
Ensure pharmacy regulations for advanced roles, such as novel vaccine administration, are in place to legally protect community pharmacists and their teams	2
Involve local community pharmacies in policy and service specification development	3
Provide timely guidance with sufficient details for community pharmacies to quickly adapt to local needs	4
Provide adequate funding and reimbursement for community pharmacy services to deliver COVID-19 vaccines	5
Equip community pharmacies with the necessary permissions to manage and adapt essential services	6

Ensure community pharmacies have the means to adequately protect the health of themselves, their staff and pharmacy users	8
Facilitate collaboration and coordination of COVID-19 vaccination services across providers (e.g., GPs, community pharmacies) and systems (e.g., IT)	9

340

341 As the CMOCs were refined, ‘tensions’ were uncovered with implications for decision makers,
 342 particularly: community pharmacists as healthcare professionals versus retailers^{43 106 145 147};
 343 community pharmacies’ capacity to remain financially viable while managing essential and advanced
 344 services.^{19 148 149} and; pharmacists’ capacity to provide off-site services while maintaining physical
 345 premises.¹⁵⁰ These tensions stem from lack of awareness of community pharmacists as healthcare
 346 professionals.

347

348 Along the continuum of healthcare from community to hospital, community pharmacy is often the
 349 first point of contact for the public. Community pharmacies contribute to primary care services
 350 through essential services (e.g., medication dispensing) and expanded roles (e.g., vaccinations),^{115 147}
 351 often decreasing workload pressures on other providers, such as GPs.¹⁵¹ Public surveys demonstrate
 352 high levels of satisfaction with community pharmacy services, and vaccination uptake is increased
 353 when pharmacies deliver these services.¹⁴⁹ Nevertheless, lack of public and decision maker
 354 awareness of community pharmacy primary care roles has slowed uptake and integration of these
 355 services.¹²¹ A recent UK public survey found that community pharmacies are seen as “a medicine
 356 supply shop by 48.3% of people, as a place to purchase medicines by 22%, and a place to purchase
 357 non-medicinal products by 17.7%.”²⁸

358

359 In Ireland and Canada community pharmacies are an integral part of national vaccination
 360 campaigns.¹⁴⁹ In both instances, community pharmacists participate in vaccination planning,
 361 pharmacy regulators provide clear guidance on vaccination management, and vaccinations are

1
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3 362 equitably refunded through public health systems. The removal of barriers, such as economic
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5 363 pressures on pharmacies has resulted in impressive national vaccine uptake, even in large countries,
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7 364 such as Canada.¹⁴⁹ Globally, there is an emerging trend for governments, health insurance companies
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10 365 and consumers to remunerate community pharmacies for services that contribute to improved
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12 366 health outcomes.¹⁵⁰

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16 368 Community pharmacies tend to be defined as premises where medications are dispensed, which
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18 369 compounds the confusion (by the public and decision makers) of professional primary care services
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20 370 versus retailers.¹⁵⁰ Instead, pharmacies should be defined with respect to actions or services that
21
22 371 require specialised health knowledge to optimise health outcomes. For example, a retail approach to
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24 372 over-the-counter (OTC) medications is to permit consumers to make their own choices, similar to
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26 373 supermarket choices. Pharmacy input for into OTC purchases could potential decrease adverse
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28 374 medication interactions or unnecessary allergic reactions.¹⁴⁷ The 'value-add' of community
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30 375 pharmacies, evidence-informed engagement with consumers, can decrease morbidity and mortality
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32 376 outcomes and increase medication regimen adherence.^{150 152}

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37 377 Although community pharmacists can provide professional services off premises (e.g.,
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39 378 immunizations in community and religious centres), they need to maintain their physical premises
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41 379 and staff for financial reasons. In addition, pharmacy users seek out community pharmacy services
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43 380 due to their accessibility and convenience, and without a physical space to engage regularly with
44
45 381 pharmacy users, trust-building between pharmacists and users is compromised.¹⁵³

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51 383 As evidenced by public media, many countries, including the UK are declaring service specifications
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53 384 for COVID-19 vaccinations. Community pharmacists can potentially provide vaccination services in
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55 385 two locations.¹⁵⁴ They can collaborate with GPs in Primary Care Networks (PCN) to support PCN
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57 386 vaccination sites. Alternatively, they can provide a COVID-19 vaccination service from their premises
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3 387 if they meet service specifications. The described tensions create difficult choices for pharmacists
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5 388 that can be ameliorated through the decision maker recommendations in Table 5.
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10 390 Unanswered questions and future research

13 391 A future realist evaluation involving primary data collection from key actors will inform refinement
14
15 392 of the programme theory, CMOCs and decision maker recommendations. This empirical research
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17 393 will address the tensions identified above. Future research will also address issues identified through
18
19 394 the stakeholder groups, such as vaccination hesitancy, outside the scope of this review. While this
20
21 395 work touched upon unique issues for marginalised populations including BAME groups, those of
22
23 396 lower socioeconomic status and those with disabilities, further exploration is needed.
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31 398 Conclusion

34 399 The COVID-19 pandemic is a worldwide health emergency. Vaccination is key to combatting the
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36 400 pandemic. The role of community pharmacy may be both short and long term; with a potential need
37
38 401 for regular annual vaccines. This rapid realist review offers recommendations for decision makers to
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40 402 enable community pharmacy to play a key role, both during these unprecedented times and into the
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42 403 future.
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412 Contributorship statement

413 IM conceived and led the project and had overall responsibility for PERISCOPE. All team members
414 developed develop the embryonic programme theory. AB conducted the searches. AB and GW
415 advised on realist methods. GW also advised on primary care implications and provided
416 methodological oversight. EY screened documents at title, abstract and full-text with support from
417 AB and MM. EY, MM and JB coded relevant data into NVivo. EY, MM and JB conducted the data
418 analysis/synthesis. HZ and AH advised on pharmacy aspects and policy implications. TK led PPI. TK
419 and HZ advised on implications in BAME communities. All team members contributed drafting the
420 final report for publication and approved the final draft for submission.

421 Data Sharing Statement

422 No additional data available.

423 Competing Interests

424 Geoff Wong is Deputy Chair of the NIHR HTA Prioritisation Committee: Integrated Community Health
425 and Social Care (A) and Member of the NIHR HTA Prioritisation Committee: Integrated Community
426 Health and Social Care (A) Methods Group.

427 Andrew Booth is a member of the National Institute for Health Research Health Services and
428 Delivery Research Funding Board, the National Institute for Health Research Evidence Synthesis

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3 429 Programme Advisory Group and the National Institute for Health Research School for Social Care
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5 430 Research Commissioning Panel.
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For peer review only

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Appendix 1 – Search terms
 Search log – 28th August 2020

Source	Date searched	Search strategy	Hits (or records obtained from searches)
Publish or Perish (Google Scholar)	31/07/2020	Pharmacy[titl] AND Covid*	715
Publish or Perish (Google Scholar)	31/07/2020	Pharmacist[titl] AND Covid*	225
Ovid MEDLINE	31/07/2020	exp Coronavirus/ OR exp Coronavirus Infections/ OR (coronavirus* OR 2019-nCoV OR 2019 nCoV OR nCov OR Covid-19 OR Covid19 OR SARS-CoV-2 OR novel coronavirus OR novel corona virus OR covid* or coronavirus 2 OR coronavirus infection* OR coronavirus disease OR corona virus disease OR new coronavirus OR new corona virus OR new coronaviruses OR novel coronaviruses OR wuhan) AND (Community pharmacy OR community pharmacies OR community pharmacist OR community pharmacists OR retail pharmacy OR retail pharmacist OR retail pharmacists OR dispensing chemist OR dispensing chemists OR [(Pharmacist OR pharmacy) AND (community OR "primary care")]) OR dispensary OR apothecary OR druggist)	61
28 th August 2020	EMBASE	<ol style="list-style-type: none"> exp Coronavirus/ or exp Coronavirus Infections/ or (coronavirus* or "2019-nCoV" or " 2019 nCoV" or nCov or "Covid-19" or Covid19 or "SARS-CoV-2" or "novel coronavirus" or "novel corona virus" or covid* or "coronavirus 2" or "coronavirus infection*" or "coronavirus disease" or "corona virus disease" or "new coronavirus" or "new corona virus" or "new coronaviruses" or "novel coronaviruses" or wuhan).mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword, floating subheading word, candidate term word] 78202 ("Community pharmacy" or "community pharmacies" or "community pharmacist" or "community pharmacists" or "retail pharmacy" or "retail pharmacist" or "retail pharmacists" or "dispensing chemist" or "dispensing chemists" or dispensary or apothecary or druggist).mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug 	52 hits

		<p>manufacturer, device trade name, keyword, floating subheading word, candidate term word] 15896</p> <p>3. ((Pharmacist or pharmacy or pharmacies) and (community or "primary care")).mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword, floating subheading word, candidate term word] 26928</p> <p>4. 2 or 3 29215</p> <p>5. 1 and 4 89</p> <p>6. limit 5 to medline 37</p> <p>7. 5 not 6</p>	
28 th August 2020	CINAHL	<p>(((("Community pharmacy" or "community pharmacies" or "community pharmacist" or "community pharmacists" or "retail pharmacy" or "retail pharmacist" or "retail pharmacists" or "dispensing chemist" or "dispensing chemists" or dispensary or apothecary or druggist)) OR (((Pharmacist or pharmacy or pharmacies) and (community or "primary care"))))) AND exp Coronavirus/ or exp Coronavirus Infections/ or (coronavirus* or "2019-nCoV" or " 2019 ncov" or nCov or "Covid-19" or Covid19 or "SARS-CoV-2" or "novel coronavirus" or "novel corona virus" or covid* or "coronavirus 2" or "coronavirus infection*" or "coronavirus disease" or "corona virus disease" or "new coronavirus" or "new corona virus" or "new coronaviruses" or "novel coronaviruses" or wuhan)</p>	24 hits
28 th August 2020	Web of Science	<p># 4 14 #1 AND #2</p> <p>Refined by: [excluding] Databases: (MEDLINE)</p> <p>Databases= WOS, BCI, BIOSIS, CCC, DRCI, DIIDW, KJD, MEDLINE, RSCI, SCIELO, ZOOREC Timespan=All years</p> <p># 3 102 #1 AND #2</p> <p>Databases= WOS, BCI, BIOSIS, CCC, DRCI, DIIDW, KJD, MEDLINE, RSCI, SCIELO, ZOOREC Timespan=All years</p> <p># 2 32,714 TS=((("Community pharmacy" or "community pharmacies" or "community pharmacist" or "community pharmacists" or "retail pharmacy" or "retail pharmacist" or "retail pharmacists" or "dispensing chemist" or "dispensing chemists" or dispensary or apothecary or druggist)) OR (((Pharmacist or pharmacy or pharmacies) and (community or "primary care")))))</p> <p>Databases= WOS, BCI, BIOSIS, CCC, DRCI, DIIDW, KJD, MEDLINE, RSCI, SCIELO, ZOOREC Timespan=All years</p>	14 hits

		# 1 95,896 TS=(coronavirus* or "2019-nCoV" or " 2019 ncov" or nCov or "Covid-19" or Covid19 or "SARS-CoV-2" or "novel coronavirus" or "novel corona virus" or covid* or "coronavirus 2" or "coronavirus infection*" or "coronavirus disease" or "corona virus disease" or "new coronavirus" or "new corona virus" or "new coronaviruses" or "novel coronaviruses" or wuhan) Databases= WOS, BCI, BIOSIS, CCC, DRCI, DIIDW, KJD, MEDLINE, RSCI, SCIELO, ZOOREC Timespan=All years	
28 th August 2020	Scopus	(TITLE-ABS-KEY (coronavirus* OR "2019-nCoV" OR " 2019 ncov" OR ncov OR "Covid-19" OR covid19 OR "SARS-CoV-2" OR "novel coronavirus" OR "novel corona virus" OR covid* OR "coronavirus 2" OR "coronavirus infection*" OR "coronavirus disease")) AND (((("Community pharmacy" OR "community pharmacies" OR "community pharmacist" OR "community pharmacists" OR "retail pharmacy" OR "retail pharmacist" OR "retail pharmacists" OR "dispensing chemist" OR "dispensing chemists" OR dispensary OR apothecary OR druggist)) OR ((pharmacist OR pharmacy OR pharmacies) AND (community OR "primary care")))))	591 hits
28 th August 2020		Search of the contents of preprint services and the WHO Covid register: pharmacy OR pharmacist OR pharmacists or pharmacies	(402 hits)
28 th August 2020		e.g. the curated BioRxiv/MedRxiv dataset (connect.medrxiv.org/relate/content/181).	10 hits and 19 hits – none relevant
28 th August 2020		Social media (e.g. blogs) including facilitated twitter® discussion (#Cpharmchat) on the Impact of COVID-19 on community pharmacy.	Twitter 8 hits
28 th August 2020		Web-sites/emails from relevant regulators and professional organisations including RPS (https://www.rpharms.com/), PDA (https://www.the-pda.org/), PSNC (http://psnc.org.uk/), and GPhC (https://www.pharmacyregulation.org/).	Completed
28 th August 2020		Pharmaceutical Journal web-site https://www.pharmaceutical-journal.com/ . No language restrictions at title and abstract stage selection stage. Separated high and low/middle income countries at sift stage.	Completed
28 th August 2020		Local Pharmaceutical Committees (LPC)	Completed

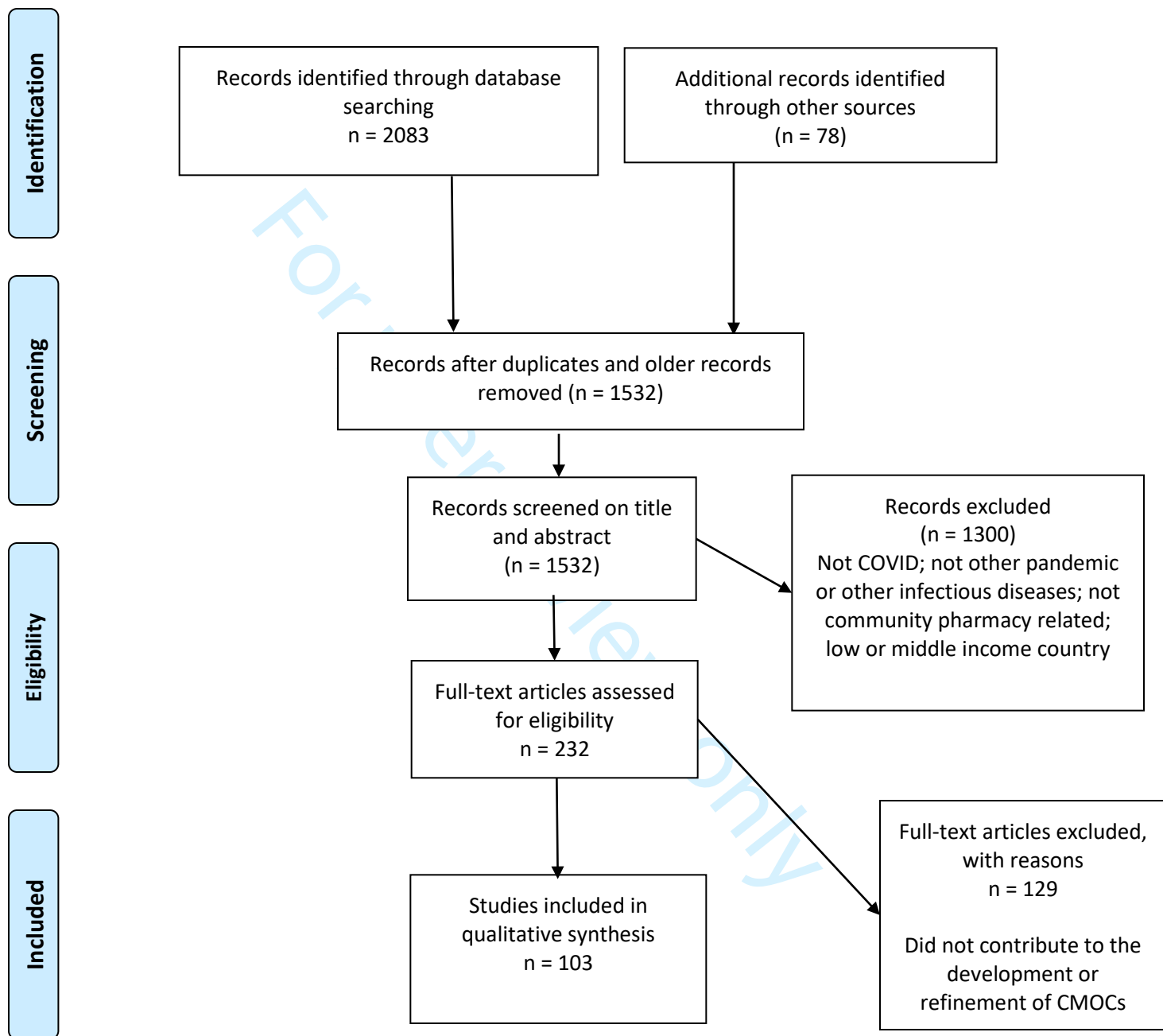
Appendix 2 - Literature inclusion criteria

Published after January 2003 AND
COVID-19 or other pandemic or other infectious diseases
OR vaccination programmes
OR expanded/extended roles
AND Community Pharmacy
AND High- or middle-income country

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PRISMA 2009 Flow Diagram

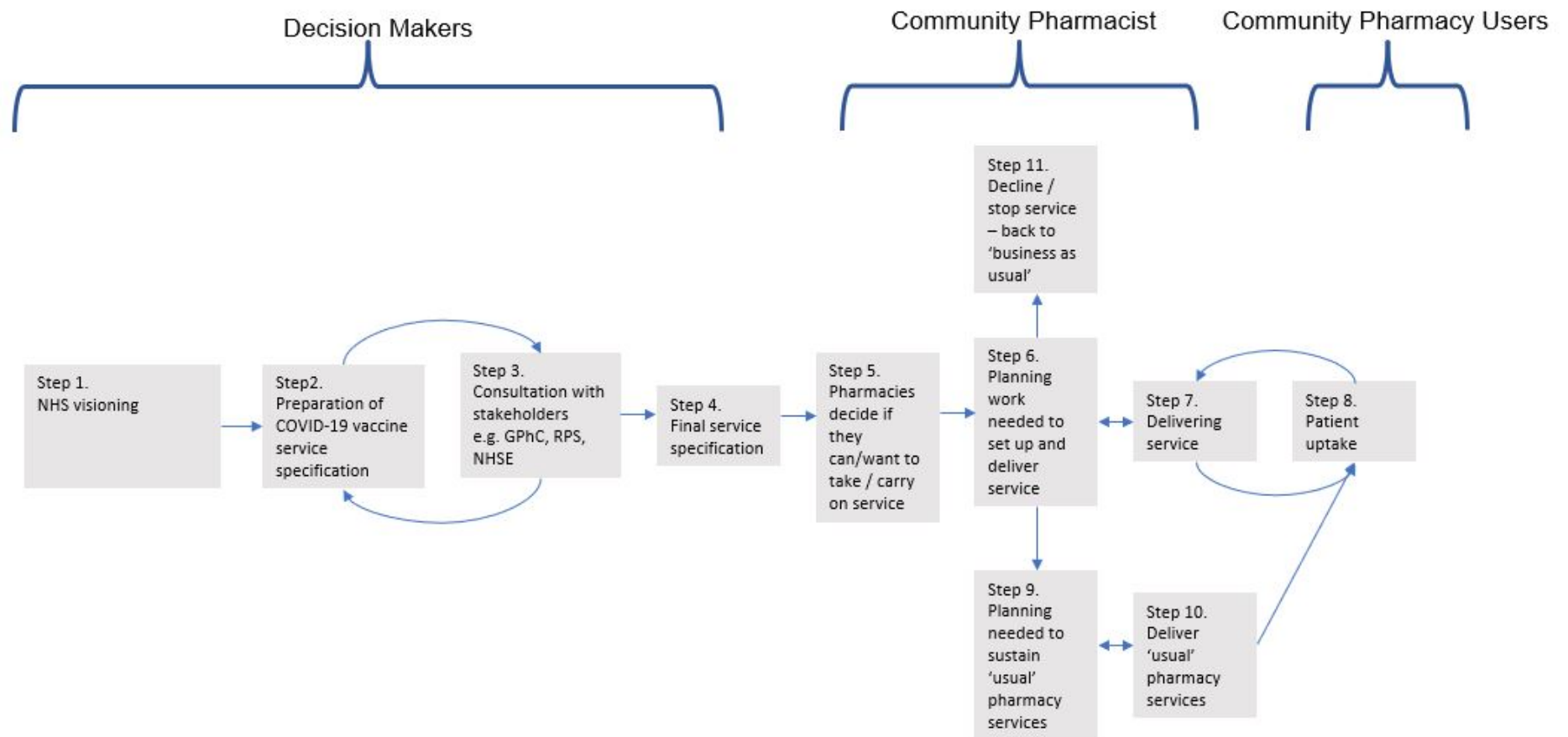


From: Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement. PLoS Med 6(7): e1000097. doi:10.1371/journal.pmed1000097

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Appendix 4 - A simplified diagram of the programme theory of a COVID-19 vaccination programme provided by community pharmacies



BMJ Open

A Rapid Realist Review of the Role of Community Pharmacy in the Public Health Response to COVID-19

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2021-050043.R1
Article Type:	Original research
Date Submitted by the Author:	24-Mar-2021
Complete List of Authors:	Maidment, Ian; Aston University Young, Emma; The University of Sheffield MacPhee, Maura; The University of British Columbia Booth, Andrew; The University of Sheffield, School of Health & Related Research (SchARR) Zaman, Hadar; University of Bradford Breen, Juanita; University of Tasmania Hilton, Andrea; University of Hull, FHSC Kelly, Tony; Aston University, PPI Lead on Project Wong, Geoff; University of Oxford, Primary Care Health Sciences
Primary Subject Heading:	Health services research
Secondary Subject Heading:	General practice / Family practice, Infectious diseases
Keywords:	COVID-19, QUALITATIVE RESEARCH, Organisation of health services < HEALTH SERVICES ADMINISTRATION & MANAGEMENT

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Manuscripts



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29 10 Keywords: COVID-19, SARS-CoV-2, Community Pharmacy Services, Vaccination
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33 12 Word count: 3,744
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18 Abstract

19 Introduction

20 Community pharmacists and their teams have remained accessible to the public providing essential
21 services despite immense pressures during the COVID-19 pandemic. They have successfully
22 expanded the influenza vaccination programme and are now supporting the delivery of the COVID-
23 19 vaccination roll-out.

24 Aim

25 This rapid realist review aims to understand how community pharmacy can most effectively deliver
26 essential and advanced services, with a focus on vaccination, during the pandemic and in the future.

27 Method

28 An embryonic programme theory was generated using four diverse and complementary documents
29 along with the expertise of the project team. Academic databases, preprint services and grey
30 literature were searched and screened for documents meeting our inclusion criteria. The data was
31 extracted from 103 documents to develop and refine a programme theory using a realist logic of
32 analysis. Our analysis generated 13 context-mechanism-outcome configurations explaining when,
33 why and how community pharmacy can support public health vaccination campaigns, maintain
34 essential services during pandemics, and capitalise on opportunities for expanded, sustainable public
35 health service roles. The views of stakeholders including pharmacy users, pharmacists, pharmacy
36 teams and other healthcare professionals were sought throughout to refine the 13 explanatory
37 configurations.

38 Results

39 The 13 context-mechanism-outcome configurations are organised according to decision makers,
40 community pharmacy teams and community pharmacy users as key actors. Review findings include:

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3 41 supporting a clear role for community pharmacies in public health; clarifying pharmacists' legal and
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5 42 professional liabilities; involving pharmacy teams in service specification design; providing suitable
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7 43 guidance, adequate compensation and resources; and leveraging accessible, convenient locations of
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9 44 community pharmacy.

12 45 Discussion

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15 46 Community pharmacy has been able to offer key services during the pandemic. Decision makers
16
17 47 must endorse, articulate and support a clear public health role for community pharmacy. We
18
19 48 provide key recommendations for decision makers to optimise such a role during these
20
21 49 unprecedented times and in the future.

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27 51 Strengths and limitations of this study

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30 52 A diverse group of professional and public stakeholders validated our findings from the literature.

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35 54 By using a realist approach, we were to use broad range of data, including grey literature.

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40 56 To enable us to develop recommendations in a timely manner the focus of the review was
41
42 57 deliberately narrow.

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46
47 59 The topic could have been informed by other sources of evidence in particular empirical interviews
48
49 60 with key stakeholder.

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54 62 COVID-19 vaccination is a rapidly evolving area and this research was based on the best available
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56 63 evidence at the time.

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For peer review only

66 Introduction

67

68 Community pharmacy teams have continued to provide essential services during the coronavirus
69 disease 2019 (COVID-19) pandemic. They offer accessibility and medicines expertise to the public,
70 even in challenging times.^{1 2 3} However, COVID-19 creates extra workload demands, such as
71 medication dispensing with increases of up to 33% in prescription numbers.⁴ To cope with this
72 demand community pharmacies have increased their opening hours and hired additional staff.⁴
73 Alongside this additional workload, they have managed widening coverage of the influenza vaccines
74 programme.⁵

75 Evidence suggests that community pharmacy can successfully provide diverse vaccination services
76 including seasonal and pandemic influenza, travel vaccinations and hepatitis B for at-risk groups,
77 within the provisions of the UK National Health Service (NHS) or privately.⁶ They have successfully
78 provided influenza vaccines as an NHS commissioned advanced service since 2015.⁵ One service
79 evaluation found that of 485 patients asked, 99% expressed confidence in their pharmacist to
80 provide additional vaccinations.⁷ Community pharmacy can also support influenza and other
81 vaccinations to combat the significantly higher COVID-19 related mortality in the non-white
82 community.^{8 9}

83 The COVID-19 pandemic has stretched NHS capacity to safely and efficiently meet public health
84 demands. A role for community pharmacy in the national vaccination service requires an
85 understanding of what pharmacy teams require to successfully deliver essential and advanced
86 services during the pandemic. Such knowledge is timely, given the roll-out of COVID-19 vaccines
87 across the community.¹⁰

88 Delivering a vaccine is a complex process and successful delivery is context-dependent. A realist
89 review helps make sense of complex situations^{11 12}, such as how community pharmacy can most

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2
3 90 effectively address the challenges presented by COVID-19. A rapid review can generate guidance for
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5 91 decision makers to assist with roll-out of COVID-19 vaccinations to community pharmacy. This rapid
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7 92 realist review aimed to understand how community pharmacy can most effectively deliver essential
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9 93 and advanced services, with a focus on vaccination, during the pandemic and in the future.
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13 94 **Methods**

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16 95 A rapid realist review of academic and other literature, supplemented by input from key actors, was
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18 96 undertaken to understand how and when community pharmacy can effectively support the public
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20 97 health agenda during pandemics such as COVID-19. Rapid reviews aim to ensure findings are
21
22 98 generated and disseminated in response to the urgent nature of the situation. To produce this
23
24 99 knowledge at pace, we truncated the following review processes:

- 25
26 100 - Programme theory development was undertaken within 1 month with input from the
27
28 101 project team.
- 29
30 102 - Searching was expedited using broad search terms and using a limited number of key data
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32 103 sources.
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34 104 - Data analysis and context-mechanism-outcome configuration (CMOC) development
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36 105 focussed on where the programme theory was considered most important during COVID-19.

37
38 106 This realist review was undertaken within six-months (August 2020 - January 2021), the protocol was
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40 107 published on PROSPERO¹³ and, where relevant, follows the RAMESES quality and publication
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42 108 standards.¹⁴
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45 109 **Stage 1: Programme Theory Development**

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47 110 The project team met virtually to develop an embryonic programme theory using four diverse
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49 111 documents from an initial search representing a professional journal¹⁵, a research journal¹⁶, a policy
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51 112 document (Royal Pharmaceutical Society)¹⁷ and a practical influenza briefing.¹⁸ The team identified
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53 113 the need for (i) enabling guidance for community pharmacy (to achieve legitimisation)¹⁶; (ii) practical

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3 114 direction for community pharmacy practices (to ensure feasibility)^{15 16}; and (iii) user assurance of
4
5 115 appropriate, safe, feasible and timely intervention (relative advantage).¹⁵ The resultant embryonic
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7 116 theory, patterned on a COM-B behavioural model of capability, opportunity, and motivation leading
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9
10 117 to behaviour¹⁹, was used to inform searching and initial analyses.
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13 118 Stage 2: Literature Searching

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16 119 Searches were conducted (July-August 2020) using MEDLINE, EMBASE, CINAHL, Web of Science, and
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18 120 Scopus for search concepts relating to Pharmacy and COVID by AB (see Appendix 1 for search
19
20 121 strategy). Reference checking and citation searching of all included references on Google Scholar
22
23 122 (using the Publish or Perish tool) were also carried out. Given the novelty of the virus, we searched
24
25 123 the contents of preprint services and the World Health Organisation (WHO) COVID Register. Grey
26
27 124 literature searches included social media (e.g. blogs, facilitated Twitter® discussion [#Cpharmchat]),
28
29 125 community pharmacy websites, and emails from relevant regulators and professional organisations
30
31 126 (e.g., Royal Pharmaceutical Society [RPS], Pharmaceutical Services Negotiation Committee [PSNC],
32
33 127 General Pharmaceutical Council [GPhC]).
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36
37 128 Key inclusion criteria were high or middle-income countries, community pharmacy and infectious
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39 129 disease management (see Appendix 2). The search covered January 2003-July 2020 to include SARS,
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41 130 a comparable condition first identified in 2003. There were no restrictions on study designs eligible
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44 131 for inclusion.
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47 132 Stage 3: Data Selection and Extraction (selection and coding)

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50 133 Selection and appraisal of documents followed a two-step procedure:

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53 134 1). EY screened the title, abstract and keywords of potentially relevant documents against inclusion
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55 135 criteria. A 10% random sample was checked by two research team members (AB and MM) for
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57 136 consistency.
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3 137 2). EY obtained and screened full texts of all documents meeting the eligibility criteria.
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6 138 Relevant data from the included full text documents was coded into NVivo by EY, MM and JB. Some
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8 139 codes came from the data (i.e. inductive coding); others were derived from the programme theory
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10 140 (i.e. deductive coding) and some were derived using retroduction (i.e. by interpretation of what
11
12 141 might be functioning as mechanisms).²⁰ No assessment was made of the rigour of the data within
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14 142 included documents, however global judgements were made of the quality of the explanations
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16 143 provided by the CMOCs and programme theory using the criteria of consilience, simplicity and
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18 144 analogy.²¹

145 Stage 4: Data Synthesis

146 The data analysis/synthesis was conducted by EY, MM and JB with input from the rest of the project
147 team to develop and refine the programme theory using a realist logic of analysis. Our analysis
148 generated 13 realist CMOCs, explaining when, why and how community pharmacy can support
149 public health vaccination campaigns, maintain essential services during pandemics, and capitalise on
150 opportunities for expanded, sustainable public health service roles. Actor conversations generated
151 further CMOCs related to care for diverse and vulnerable populations, including the Black and
152 Minority Ethnic (BAME) community.

153 Our realist logic of analysis centred on the following questions:

- 154 • Interpretation of meaning: Do the contents coded by the team provide data that may be
155 interpreted as CMOCs?
- 156 • Interpretations and judgements about CMOCs: How do the CMOCs relate to the programme
157 theory?
- 158 • Interpretations and judgements about programme theory: How do the programme theory and
159 its CMOCs correspond with key actor perspectives of reality?

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3 160 Data to answer our questions was iteratively sought across documents. Interpretive cross-case
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5 161 comparison was used to identify and to explain the “success” of pandemic community pharmacy
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7 162 interventions delivered in different settings or to different population groups.
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10 163 Key Stakeholders

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14 164 Key stakeholders, including community pharmacists and support staff (including representatives
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16 165 from large and smaller chains, sole independent pharmacies and primary care), other healthcare
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18 166 professionals and members of the public were consulted on four occasions. The meetings took place
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20 167 over Microsoft Teams and each lasted about one hour.
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23 168 Patient and Public Involvement

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26 169 Members of the public were drawn from The University of Sheffield’s Patient and Public Involvement
27
28 170 database and contacts of the core project team. Groups numbered between 11 and 13 members,
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30 171 with ages ranging from 22 to 74 years, from diverse locations and ethnicities including Black African,
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32 172 Black Caribbean, British Asian, British Chinese, White Irish and White British. Collectively,
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34 173 stakeholders provided feedback and advice on their real-world experience of working in or using
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36 174 community pharmacy.
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48 178 103 documents were included in this rapid review and were coded to develop and refine our CMOCs
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50 179 and programme theory (PRISMA diagram in Appendix 3). The final programme theory is summarised
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52 180 in Appendix 4—from abstract visioning to actual patient uptake of the COVID-19 vaccine. Although
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54 181 the programme theory is outlined in a linear fashion, steps within it are not necessarily linear and
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56 182 may occur simultaneously. The CMOCs are organized according to key actors, or individuals and
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58 183 groups with a vested interest in community pharmacy delivery of a COVID-19 vaccination
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184 programme. “Actor” derives from sociology and is synonymous with “stakeholder”; we privileged
 185 this term to differentiate programme theory/CMOC organization from project stakeholder
 186 participants.²² Table 1 briefly describes the three actor groups with their respective CMOCs and
 187 corresponding steps in Appendix 4. Tables 2-4 show the final 13 CMOCs.

189 Table 1: Programme Theory Actors with corresponding CMOCs and steps

Programme Theory Actors	Description	CMOCs*	Steps in Programme Theory**
Decision Makers	The UK government, regulatory and professional bodies, the public.	CMOC 1 - 4	Steps 1 - 4
Community Pharmacists and their Teams	Community pharmacists are health care professionals registered by the General Pharmaceutical Council and supported by teams made up of counter assistants, dispensers and registered technicians. They work in high street locations, in local communities and in supermarkets. Employers range from large chains to small individually owned community pharmacies.	CMOC 5 – 9	Steps 5 – 7 and 9 – 11
Pharmacy Users	Members of the public who use any community pharmacy services including prescription dispensing, minor ailment advice/treatment or vaccination services.	CMOC 10 - 13	Step 8

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191 *see Table 2-4

192 **See Appendix 4

193

194 The following sections summarise the CMOCs related to each of the three actor groups. Illustrative
 195 examples of the supporting evidence from review documents are presented (Tables 2-4).

196

197 *Decision makers*

198 Decision maker and public endorsement (CMOC 1) are essential first steps in enlisting community
 199 pharmacy for COVID-19 vaccination programmes. Regulators must ensure pharmacists have the
 200 legal scope to do so (CMOC 2), with community pharmacy input during the development of policies
 201 and protocols (CMOC 3), so that final service specifications are flexible and do-able within local
 202 settings (CMOC 4).

203 Table 2 - Decision Makers (CMOCs 1-4)

<p>CMOC 1 – Support a public health role^{23 24 25} <small>26-32</small></p>	<p>When the government, pharmacy regulators, professional bodies and the public endorse and support a clear role for community pharmacy in public health services (C), community pharmacists will be more likely to adopt vaccination services (O) because they see it as their professional role and duty (M).</p> <p><i>“Distribution and administration of the COVID-19 vaccination programme will require concerted action across the NHS. With unique insight and expertise in medicines and the delivery of vaccination programmes, pharmacists have a clear role in contributing to the success of this programme.” (Great Britain)²⁴</i></p> <p><i>“55% of the public have visited a pharmacy during the COVID19 crisis...89% of people believe pharmacies are playing an essential role in the COVID19 crisis.” (UK National Pharmacy Association)²³</i></p>
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	<p><i>“Pharmacists...have been called on to coordinate the administration of COVID-19 tests...providing ongoing COVID-19 surveillance to communities by allowing walk-in testing at community pharmacies...[This] might be more sustainable and convenient than the large-scale public screening being done as of the summer of 2020.” (USA)²⁵</i></p> <p><i>“Given the past success of community pharmacists with increasing annual seasonal influenza uptake and their accessibility, pharmacists will need to be central in administering COVID-19 vaccines in order to achieve rapid population-wide coverage.” (Canada)²⁶</i></p>
<p>CMOC 2 –Clarify legal and professional liabilities^{24 31 33-40}</p>	<p>When pharmacy regulators and the NHS clarify community pharmacists’ legal and professional liabilities arising from the administration of a novel and potentially unlicensed COVID-19 vaccine (C), community pharmacists are more willing to give the vaccination (O) because they feel reassured regarding liability (M).</p> <p><i>“The role of pharmacists in the COVID-19 vaccination programme must be made clear to the pharmacy profession itself. Professional and representative pharmacy bodies have an important role to play in providing the right level of information to the profession to support their roles in the vaccination programme.” (Great Britain)²⁴</i></p> <p><i>“Indemnity insurance for individual healthcare professionals needs to be amended to cover this activity and be state-funded. There also needs to be clear communication to healthcare professionals, so they clearly understand</i></p>

	<i>that they are covered and under which circumstances this applies.” (Great Britain)⁴¹</i>
CMOC 3 – Co-develop feasible service specifications^{1 38} <i>42-48</i>	When COVID-19 vaccination policy and service specifications have been developed with input from diverse community pharmacists and staff tasked with administering and supporting the administration of the vaccine (C), community pharmacies are more likely to deliver the service (O) because they believe the service specification is feasible (M). <i>“Pharmacists ideally want input into future policy changes before they are finalized, so that these can reflect capacity and preparedness on the ground and be publicized accurately.” (Great Britain)¹</i>
CMOC 4 – Issue clear, relevant and timely guidance^{25 27 31 34} <i>48-62</i>	When government, pharmacy regulators and professional bodies provide consistent, clear, relevant, and timely guidance for the delivery of the COVID-19 vaccines (C), community pharmacies are more likely to deliver the service (O), because the guidance is helpful and simplifies implementation (M). <i>“... it is good to see that NHSE/I have provided the information we have been waiting for to review the resources we have nationwide and decide how we can bring them to bear to help the NHS defeat this virus.” (Great Britain)⁴⁹</i>

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In England community pharmacies have government contracts and partnerships to deliver

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vaccinations and other essential services during emergencies, including the COVID-19 pandemic.^{25 31}

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³² Pharmacies in the USA and Canada have also been identified as having a substantive role in

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vaccine administration (CMOC1).^{25,26} The idea of harnessing UK community pharmacy capacity

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enjoys widespread public support (CMOC2).²³ However, appropriate service delivery is hampered by

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unfeasible operational conditions (CMOC3)¹; for example, medication deliveries are funded by the

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UK government for “vulnerable people”, but this category of service users is defined narrowly by the

212 government and misunderstood by the public, creating unrealistic expectations of community
 213 pharmacy and generating additional work.¹
 214 In contrast, when clear options for community pharmacy involvement in COVID-19 vaccination
 215 programmes were issued through the NHS (CMOC4), the chief executive of the Association of
 216 Independent Multiple Pharmacies commented positively on members' engagement in delivering
 217 vaccines.⁴⁹

218 *Community Pharmacists and Team*

219 Community pharmacies have had to manage ongoing essential services, in addition to supporting
 220 COVID vaccination delivery during the pandemic (CMOC6), including delivery of necessary
 221 medications (CMOC7). Given fears and anxieties related to COVID-19 and changes to service
 222 delivery, community pharmacies have had to deal with inappropriate behaviours from the public,
 223 including emotional abuse and threats of physical abuse (CMOC8). As an integral public health
 224 service, community pharmacy capacity to meet NHS needs will be enhanced through use of IT and
 225 collaboration with other service providers (CMOC9).

226 Table 3 - Community Pharmacists and Team (CMOCs 5-9)

CMOC 5 – Receive adequate compensation and resources^{1 63-77}	When community pharmacies receive adequate compensation and resource support for COVID-19 vaccines (C), they are more likely to deliver the service (O), because they feel recognised for their service contributions (M).
	<i>“Pharmacists...have been incredible in supporting patients throughout COVID-19 and rightly deserve recognition for the work they do. We know that teams were already under pressure and that colleagues in community pharmacy are feeling added financial strain.” (Great Britain).⁶³</i>

	<p><i>“In the community, mitigating the impact of COVID-19 has...focused largely on general practitioners (GPs). This is unsurprising to those in the pharmacy profession who have long considered policy makers to overlook them.” (Great Britain)¹</i></p>
<p>CMOC 6 – Sustain capacity and facility to adapt essential services^{16 17 30 34 68 70 71}</p>	<p>When a community pharmacy has the capacity and permission to manage and adapt existing essential services during COVID-19 (C), they are more likely to effectively deliver and sustain these services (O) because it’s feasible for them to do so (M).</p>
<p>78-91 92</p>	<p><i>“Virtual and telephone consultations have become commonplace, particularly to vulnerable patients. Pharmacists have implemented systems to dispense medications in advance of need to minimise wait times and duplicate visits. In case-by-case examples...there has been anticipatory management of medication-related needs.” (Ireland)⁹²</i></p> <p><i>“Pharmacists who had comfort and confidence in managing electronic communication reported feeling greater control over workflow and the ability to triage and queue patients more effectively based on priority and need.” (Canada)⁶⁰</i></p>
<p>CMOC 7 – Inform users of essential service availability/continuity</p>	<p>When community pharmacies have processes in place to inform pharmacy users about the availability of essential services (C), pharmacy users are less likely to become anxious (O), because they feel reassured about access to what they need (M).</p>

<p>92 16 28 31 32 51 60 65 71 80 81</p> <p>85 93-101</p>	<p><i>“Access to medications is a main concern expressed by our patients... The CDC and SAMHSA offer guidance on ways to reduce stress and anxiety in this time of uncertainty.”⁹⁵</i></p> <p><i>“As a result of the power dynamics at play, it is ultimately up to pharmacists to be able to reassure patients and provide care, all while taking into account their mental health. Currently, guidelines regarding patient interaction during a pandemic are needed”.⁵¹</i></p> <p><i>“In addition, there is ongoing work in liaison with pharmacists, general practitioners, and state and territory authorities to enable therapeutic substitution by pharmacists in the event of a shortage. This will allow community pharmacists to substitute dose strength or form without prior approval from the prescriber, if a prescribed medicine is not available at the time of dispensing. These measures highlight the important role pharmacists can play in enabling and maintaining access to medicines for people in need throughout the COVID-19 outbreak.” (Australia)⁸⁵</i></p> <p><i>“Access to medications is a main concern expressed by our patients... The CDC and SAMHSA offer guidance on ways to reduce stress and anxiety in this time of uncertainty.” (USA)⁹⁵</i></p>
<p>CMOC 8 – Protect the health and safety of staff ^{24 31 51 71 77 81 102-108}</p>	<p>When community pharmacies have the means to protect the health of pharmacists and staff (C), they are more likely to deliver essential services and COVID-19 vaccination services (O), because they feel safe to do so (M).</p>

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	<p><i>“...Given high levels of public anxiety and uncertainty regarding the integrity of the drug supply chain in Canada, many participants reported difficult, sometimes frightening, interactions with members of the public and their desire for dedicated security to provide support and conflict management” (Canada).³¹</i></p> <p><i>“An additional burden Asian pharmacists face, on top of pharmacist harassment, is the rise of anti-Asian racism that has come about due to COVID-19. Verbal and even physical abuse has been reported to happen in various countries, such as the UK, France, and the USA, to those of Chinese descent...” (UK, France, USA)⁵¹</i></p> <p><i>“The survey found that although more than a third (37%) of pharmacists said they felt unsafe at some point working during the pandemic, concerns over PPE have eased. This is due, in part, to the supply problems being eased and community pharmacists being finally allowed to order from the national online PPE portal in an emergency, after calls for access from the RPS.” (Great Britain)⁷⁷</i></p>
<p>CMOC 9 – Enhance collaboration across services, including IT¹⁸ <i>26 47 56 57 69 78 80 85 109-114</i></p>	<p>When systems needed for COVID-19 vaccination, including IT and remuneration, support collaboration by various service providers (e.g. general practitioner surgeries and community pharmacies: (C), a coordinated response is more likely (O), because reduced effort is needed from everyone (M).</p>

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“Planning and delivery should be undertaken across a consistent, pre-agreed footprint. It may be more efficient and cost effective to provide immunisation across a number of providers, pooling resources and sites to deliver the best service possible, and working in coordination with other local stakeholders such as directors of public health and local government.” (Great Britain)⁴⁷

“For many community pharmacists, a lack of connected IT is a huge problem. Kieran Eason, who runs an independent pharmacy in Tamworth, Staffordshire, says lack of intra-operability makes it more difficult to do relatively simple things, like sending prescription requests to GPs. “Pharmacy IT is just a complete disaster,” he says, suggesting the COVID-19 crisis has highlighted flaws, such as the number of different systems pharmacists use.” (Great Britain)⁶⁹

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228 Although attention is focused on a COVID-19 vaccine, community pharmacies offer diverse essential
229 services. In the UK and other high-income countries, community pharmacy services also provide
230 advanced services such as vaccinations.¹¹⁵ Pharmacists consider it a professional responsibility to
231 provide essential services during the pandemic, despite clear financial risks to themselves.⁶³

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232 Despite pharmacists’ professional and moral obligations to provide essential services, ongoing
233 persistent ‘under-recognition’ can jeopardize their ability to contribute to COVID-19 vaccinations
234 (CMOC5) as well as maintain a usual service. Under-recognition has been an issue in previous UK
235 vaccination campaigns; respondents to a survey of Welsh community pharmacists after the 2016
236 influenza season described providing a “mop up” service for general practitioners (GPs).^{59 68}

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3 237 Multiple required community pharmacy service adaptations have been reported by the UK
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5 238 Pharmaceutical Journal, including changeover in retail space to medication preparation and
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7 239 dispensing, and call-in shopping services for other retail items (CMOC6). Service adaptations have
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9 240 been affected by hours of operation, available staff, and cancellations of contracted services, such as
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11 241 blood pressure testing and smoking cessation support—all with financial implications for
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13 242 pharmacists.⁸⁰

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17 243 Before COVID-19, community pharmacies globally were offering “valued-added services” (VAS) such
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19 244 as drive-thru services, online ordering and communications services (e.g., prescription reminders) to
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21 245 stay competitive. Many VAS services have helped pharmacies adapt more quickly to pandemic
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23 246 restrictions.⁸¹

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27 247 During the pandemic, ensuring access to needed medications has been a critical pharmacy service,
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29 248 to allay public concerns (CMOC7).¹⁶ Potential and actual disruptions in expected services and needed
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31 249 supplies (e.g., medications) have resulted in tensions, threats and verbal/physical abuse by the
32
33 250 public to community pharmacists (CMOC 8).^{51 80 116} Safety policies, protocols and safety-related
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35 251 supplies (e.g., PPEs) must in place to ensure community pharmacy teams’ safety.⁸⁰

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39 252 The UK COVID-19 vaccination campaign borrows heavily from previous, successful collaborative
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41 253 influenza vaccination programmes using community pharmacy and GPs (CMOC9).⁴⁸ Pooling
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43 254 resources improves service delivery.¹¹⁷ For example, the UK Pharmaceutical Journal reported how a
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45 255 greater collaborative approach has resulted in successful influenza vaccination of home care staff
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47 256 and domiciliary workers during the pandemic.¹¹⁷

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50 257 The pandemic has clearly demonstrated the importance of interoperable, connected IT systems
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52 258 across services.¹¹⁸ Getting access to reliable information is important for tracking supplies and
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54 259 deliveries related to the COVID-19 vaccination programme.⁶⁹ A pandemic silver lining is raised
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56 260 awareness of IT functions for enhanced delivery of essential services (e.g., medication planning,
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3 261 prescribing and dispensing between pharmacies and GPs) and advanced services, including
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5 262 vaccinations.⁶⁹
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9 263 *Pharmacy Users*

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11 264 Pharmacy users trust community pharmacies as a reliable source of information (CMOC10) about
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13 265 vaccines, and pharmacies' local accessibility and convenience increases the likelihood of users
14
15 266 obtaining COVID-19 vaccines through them (CMOC11). Community pharmacy relationships with
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17 267 vulnerable populations in their local settings may enhance uptake of the vaccine by these groups
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19 268 (CMOC12). Provision for privacy is an important user consideration. Pharmacy users expect private
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21 269 consultations to preserve their confidentiality (CMOC13).
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271 Table 4 - Pharmacy Users (CMOCs 10-13)

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<p>COMC 10 – Trust the pharmacist as reliable information source^{32 53 119-122}</p>	<p>When pharmacy users receive information about the COVID-19 vaccine from their community pharmacy (C), they are more likely to get the vaccine (O), because they trust community pharmacy as a source of reliable, accurate information (M).</p> <p><i>“When patients were educated about influenza, herpes zoster, and pneumococcal vaccines as a result of a pharmacist-driven intervention in community pharmacies, they were influenced to receive the vaccination.” (USA)¹¹⁹</i></p> <p><i>“Being able to address the public enquiries with accurate up-to-date information about the local situation and the overall infection progress is the key to build trustful relationship with them at troubled times.” (Macau)³²</i></p>
<p>CMOC 11 – Trust the pharmacist to deliver responsive services^{7 18 23 26 34 37 43 51 54 59 63 70 84 85 123-135}</p>	<p>When community pharmacies are trusted to make necessary service adaptations to ensure services are flexible, convenient and accessible (C), COVID-19 vaccine uptake is likely to be higher among pharmacy users (O) because the service is responsive to local needs (M).</p> <p><i>“Pharmacists have always been the most accessible health care provider; this is especially true in the era of COVID-19.... While other professionals have closed their doors to patients, community pharmacies remained open to the public despite stricter lockdown restrictions. As highly trusted healthcare clinicians, community pharmacists play a vital role in closing the gaps that are exacerbated by the additional strain on the system and reduced access to healthcare providers.” (Canada)⁵¹</i></p>

	<p><i>“Pharmacy flu vaccination services complement those provided by general practitioners to help improve overall coverage and vaccination rates for patients in at-risk groups. These services are highly accessed by patients from all socio demographic areas, and seem to be particularly attractive to carers, frontline healthcare workers, and those of working age.” (Great Britain)¹³⁵</i></p>
<p>CMOC 12 –</p> <p>Access culturally-sensitive services</p> <p><small>27 78 80 92 136</small></p>	<p>When community pharmacies leverage their community location and community-staff relationships (C), vulnerable populations, such as Black, Asian and Minority Ethnic groups are more likely to use their services, including COVID-19 vaccination services (O), because they trust their local community pharmacies to provide culturally sensitive service. (M)</p> <p>“Research continues to highlight that patients who are medically underserved have poorer inequitable access to health care due to them experiencing greater physical barriers to accessibility, encountering poorer patient-professional communication and are significantly disadvantaged where a service is not tailored to their unique needs or preferences.” (Great Britain)¹³⁷</p> <p><i>“I think over the years what’s happened is nationally it’s almost like everything has to be the same, which then doesn’t work because it doesn’t accommodate all the little variations...So we need to go back and in each individual pharmacy, gear it towards the population that it is meant to be meeting the needs of” (Pharmacist caring for BAME community-Great Britain)¹³⁷</i></p>

<p>CMOC 13 –</p> <p>Receive private and confidential services^{7 50 65 129}</p> <p>138-140</p>	<p>When community pharmacies make provisions for privacy (C), pharmacy users are more likely to use their services (O), because they are reassured about confidentiality (M).</p> <p><i>“If there was something not right...the first thing I would do is make an appointment with a doctor. I wouldn’t do and talk to somebody over a pharmacy counter.” (Great Britain)⁶⁵</i></p> <p><i>“Privacy, confidentiality and dignity are all vital elements of a trusting relationship between healthcare professionals and their patients.... In terms of privacy, the quality was perceived by the participants to include a confidential room that enabled private consultations.” (Great Britain)⁷</i></p>
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274 Public trust in community pharmacists is high—similar to doctors and nurses.³⁸ Trust between
 275 pharmacists and users can be leveraged to overcome scepticism about the COVID-19 vaccine.
 276 Providing reliable information about the disease and the vaccine, as pharmacies have done with
 277 other infections, can enhance public uptake of the COVID-19 vaccine.¹¹³ In the USA, 90% of the US
 278 population lives within 5 miles of a community pharmacy. Given their convenience and accessibility,
 279 consumers have visited their community pharmacists 12 times more frequently than their GPs.²¹ A
 280 UK study found that consumers who were eligible for a free influenza vaccine through their GPs
 281 were willing to pay for pharmacy service because of convenience and ease of access.¹²⁷ Established,
 282 trusting relationships are especially important for providing culturally sensitive services to
 283 marginalized and vulnerable communities.¹²⁹ Community pharmacists, often members of local
 284 communities are specially positioned to understand the culturally contextual factors that impact
 285 their pharmacy users.⁸⁹ Trusting relationships are founded on privacy, confidentiality and dignity,

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3 286 and COVID-19, public health protocols and limited space must be considered—in order to maintain
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5 287 vital trust among pharmacy users.⁶⁵
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8 288 Discussion

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12 289 This realist review sought to understand how community pharmacy can contribute to the public
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14 290 health agenda during the COVID-19 pandemic, particularly continuation of essential services and
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16 291 engagement in vaccination services.¹¹⁵ As the COVID-19 vaccination service continues to evolve, our
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18 292 recommendations for decision makers highlight opportunities for community pharmacy to promote
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20 293 safe, efficient and effective service delivery.
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26 295 Summary of key Findings

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29 296 To optimise community pharmacy service during the pandemic, decision makers must endorse and
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31 297 articulate a clear role for these healthcare professionals. The public already endorses advanced roles
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33 298 for community pharmacy (e.g., vaccinations, minor ailment scheme), but public awareness depends
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35 299 on what decision makers do and say. Practical decision maker measures include adequate
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37 300 reimbursement to help cover the cost for time, staff and PPE (particularly for a sustainable long-term
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39 301 service); legal (including indemnity), regulatory coverage for advanced roles; and clear and
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41 302 consistent guidance for vaccination preparation and for adaptation of essential services. When given
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43 303 the opportunity, the permissions and resources to do so, community pharmacies have been able to
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45 304 adapt quickly to continue essential services and whenever possible, to offer critical advanced
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47 305 services. Historically, community pharmacies have significantly increased vaccination uptake (e.g.,
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49 306 influenza vaccinations) given their accessibility and convenience and capacity to adapt to local needs
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51 307 for the general population and marginalized groups (e.g., BAME).
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4 309 Compare to other similar or related studies discussing important differences in
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7 310 results
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10 311 At the time of this realist review, there were no similar reviews on community pharmacy roles with
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12 312 respect to COVID-19 vaccinations. COVID-19 represents an unprecedented situation with limited
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14 313 direct evidence to guide decision-making. However, realist approaches engage with a wider evidence
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16 314 base, including research on past pandemics (e.g., SARS)^{60 141 142}, mass vaccination campaigns (e.g.,
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18 315 influenza)¹⁴³, and community pharmacies' capacity pre-COVID-19 to deliver essential and advanced
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20 316 services.^{19 144 145} Key factors previously include a lack of leadership, a lack of guidance and an
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22 317 increasing reliance on professional judgement and experience.⁶⁰ Research from the UK and other
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24 318 economically developed countries supports the 13 CMOCs and decision maker recommendations in
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26 319 this review (see tables 2-4 and table 5). However, limitations continue to surround the direct policy
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28 320 relevance of much of the community pharmacy evidence base.¹⁴⁶
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35 322 Study strengths and limitations
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38 323 The realist approach uses diverse data, including grey literature. This feature is especially important
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40 324 given a novel and rapidly evolving topic area, such as COVID-19. Multiple researchers with subject
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42 325 matter expertise participated in screening the literature and extracting and coding data, which
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44 326 maximised opportunities to discuss and debate the plausibility of the inferences made. The CMOCs
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46 327 were developed and refined through regular discussions within a team with varied academic and
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48 328 clinical backgrounds. Professional and public stakeholder consultation further refined the CMOCs.
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52 329 All rapid reviews operationalise coverage versus expediency. Other sources of evidence could have
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54 330 informed the review; however, potential gaps were mitigated by stakeholder engagement and
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56 331 expertise within the team. The evidence supporting the CMOCs was based on available time for
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58 332 document review, and during the review period, research, directives and policy related to COVID-19
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3 333 vaccination rapidly evolved. The programme theory and its CMOCs, however, are expressed in such
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5 334 a way that they can be further confirmed, refuted or refined in the future using additional data.
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8 335 For this rapid review, given our short timeline of six months, we initially decided to focus on
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10 336 community pharmacy roles and pandemic response in middle to high-income countries. Whilst we
11
12 337 identified data from higher-income countries such as Canada, USA, Australia and France, there was
13
14 338 very little published from middle-income countries. As such, it is likely that our findings and
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16 339 recommendations are most applicable to high-income countries, although, the lessons learned from
17
18 340 high-income countries can serve as an initial reference point for best practice for other countries.
19
20 341 The recommendations are "how to's" for other countries to consider within their own cultural and
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22 342 healthcare settings.
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27 343
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30 344 **Meaning of the study: possible explanations and implications for decision makers**
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33 345 Although there are multiple actors involved in pandemic response, for brevity, recommendations
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35 346 (Table 5) are directed towards decision makers who possess the formal authority to implement the
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37 347 recommendations.
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42 349 Table 5 - Recommendations for Decision Makers to Increase Community Pharmacy Engagement in
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44 350 Pandemic Response (for further details check: <https://www2.aston.ac.uk/lhs/research/periscope>).
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Recommendations	Derived from CMOC
Articulate a clear public health agenda role for community pharmacy (e.g., COVID-19 testing and vaccination)	1

1 2 3 4 5 6 7 8 9	Ensure pharmacy regulations for advanced roles, such as novel vaccine administration, are in place to legally protect community pharmacists and their teams	2
10 11	Involve local community pharmacies in policy and service specification development	3
12 13 14 15	Provide timely guidance with sufficient details for community pharmacies to quickly adapt to local needs	4
16 17 18 19 20	Provide adequate funding and reimbursement for community pharmacy services to deliver COVID-19 vaccines	5
21 22 23 24 25	Equip community pharmacies with the necessary permissions to manage and adapt essential services	6
26 27 28 29	Ensure community pharmacies have the means to adequately protect the health of themselves, their staff and pharmacy users	8
30 31 32 33 34	Facilitate collaboration and coordination of COVID-19 vaccination services across providers (e.g., GPs, community pharmacies) and systems (e.g., IT)	9

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352 As the CMOCs were refined, 'tensions' were uncovered with implications for decision makers,

353 particularly: community pharmacists as healthcare professionals versus retailers^{43 106 145 147};

354 community pharmacies' capacity to remain financially viable while managing essential and advanced

355 services.^{19 148 149} and; pharmacists' capacity to provide off-site services while maintaining physical

356 premises.¹⁵⁰ These tensions stem from lack of awareness of community pharmacists as healthcare

357 professionals.

358

359 Along the continuum of healthcare from community to hospital, community pharmacy is often the

360 first point of contact for the public. Community pharmacies contribute to primary care services

361 through essential services (e.g., medication dispensing) and expanded roles (e.g., vaccinations),^{115 147}

362 often decreasing workload pressures on other providers, such as GPs.¹⁵¹ Public surveys demonstrate

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2
3 363 high levels of satisfaction with community pharmacy services, and vaccination uptake is increased
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5 364 when pharmacies deliver these services.¹⁴⁹ Nevertheless, lack of public and decision maker
6
7 365 awareness of community pharmacy primary care roles has slowed uptake and integration of these
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9 366 services.¹²¹ A recent UK public survey found that community pharmacies are seen as “a medicine
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11 367 supply shop by 48.3% of people, as a place to purchase medicines by 22%, and a place to purchase
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13 368 non-medicinal products by 17.7%.”²⁸
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18 370 In Ireland and Canada community pharmacies are an integral part of national vaccination
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20 371 campaigns.¹⁴⁹ In both instances, community pharmacists participate in vaccination planning,
21
22 372 pharmacy regulators provide clear guidance on vaccination management, and vaccinations are
23
24 373 equitably refunded through public health systems. The removal of barriers, such as economic
25
26 374 pressures on pharmacies has resulted in impressive national vaccine uptake, even in large countries,
27
28 375 such as Canada.¹⁴⁹ Globally, there is an emerging trend for governments, health insurance companies
29
30 376 and consumers to remunerate community pharmacies for services that contribute to improved
31
32 377 health outcomes.¹⁵⁰
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35 378
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37 379 Community pharmacies tend to be defined as premises where medications are dispensed, which
38
39 380 compounds the confusion (by the public and decision makers) of professional primary care services
40
41 381 versus retailers.¹⁵⁰ Instead, pharmacies should be defined with respect to actions or services that
42
43 382 require specialised health knowledge to optimise health outcomes. For example, a retail approach to
44
45 383 over-the-counter (OTC) medications is to permit consumers to make their own choices, similar to
46
47 384 supermarket choices. Pharmacy input for into OTC purchases could potential decrease adverse
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49 385 medication interactions or unnecessary allergic reactions.¹⁴⁷ The ‘value-add’ of community
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51 386 pharmacies, evidence-informed engagement with consumers, can decrease morbidity and mortality
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53 387 outcomes and increase medication regimen adherence.^{150 152}
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3 388 Although community pharmacists can provide professional services off premises (e.g.,
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5 389 immunizations in community and religious centres), they need to maintain their physical premises
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7 390 and staff for financial reasons. In addition, pharmacy users seek out community pharmacy services
8
9 391 due to their accessibility and convenience, and without a physical space to engage regularly with
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11 392 pharmacy users, trust-building between pharmacists and users is compromised.¹⁵³
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16
17 394 As evidenced by public media, many countries, including the UK are declaring service specifications
18
19 395 for COVID-19 vaccinations. Community pharmacists can potentially provide vaccination services in
20
21 396 two locations.¹⁵⁴ They can collaborate with GPs in Primary Care Networks (PCN) to support PCN
22
23 397 vaccination sites. Alternatively, they can provide a COVID-19 vaccination service from their premises
24
25 398 if they meet service specifications. The described tensions create difficult choices for pharmacists
26
27 399 that can be ameliorated through the decision maker recommendations in Table 5.
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32 33 401 Unanswered questions and future research 34

35
36 402 A future realist evaluation involving primary data collection from key actors will inform refinement
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38 403 of the programme theory, CMOCs and decision maker recommendations. This empirical research
39
40 404 will address the tensions identified above. Future research will also address issues identified through
41
42 405 the stakeholder groups, such as vaccination hesitancy, outside the scope of this review. While this
43
44 406 work touched upon unique issues for marginalised populations including BAME groups, those of
45
46 407 lower socioeconomic status and those with disabilities, further exploration is needed.
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48
49 408 We had initially focused the review on community pharmacy roles and pandemic response in middle
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51 409 to high-income countries, but found limited data in middle-income countries. The findings are thus
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53 410 more likely to be applicable to high-income countries but may serve to inform practice elsewhere.
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55 411 Empirical research, using for example a realist evaluation approach, should be conducted to extend
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3 412 our findings on the role of community pharmacy in COVID vaccination programmes to middle to low
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5 413 income countries.
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12 415 Conclusion

15 416 The COVID-19 pandemic is a worldwide health emergency. Vaccination is key to combatting the
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17 417 pandemic. The role of community pharmacy may be both short and long term; with a potential need
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19 418 for regular annual vaccines. This rapid realist review offers recommendations for decision makers to
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21 419 enable community pharmacy to play a key role, both during these unprecedented times and into the
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23 420 future.
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426 Research Ethics Approval

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431 Contributorship statement

432 IM conceived and led the project and had overall responsibility for PERISCOPE. All team members
433 developed develop the embryonic programme theory. AB conducted the searches. AB and GW
434 advised on realist methods. GW also advised on primary care implications and provided
435 methodological oversight. EY screened documents at title, abstract and full-text with support from
436 AB and MM. EY, MM and JB coded relevant data into NVivo. EY, MM and JB conducted the data
437 analysis/synthesis. HZ and AH advised on pharmacy aspects and policy implications. TK led PPI. TK
438 and HZ advised on implications in BAME communities. All team members contributed drafting the
439 final report for publication and approved the final draft for submission.

440 Data Sharing Statement

441 Data is available upon reasonable request to the lead author.

442 Competing Interests

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3 443 Geoff Wong is Deputy Chair of the NIHR HTA Prioritisation Committee: Integrated Community Health
4
5 444 and Social Care (A) and Member of the NIHR HTA Prioritisation Committee: Integrated Community
6
7 445 Health and Social Care (A) Methods Group.
8

9
10 446 Andrew Booth is a member of the National Institute for Health Research Health Services and
11
12 447 Delivery Research Funding Board, the National Institute for Health Research Evidence Synthesis
13
14 448 Programme Advisory Group and the National Institute for Health Research School for Social Care
15
16 449 Research Commissioning Panel.
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Appendix 1 - OVID MEDLINE – Search Strategy

1. exp Coronavirus/ or exp Coronavirus Infections/ or (coronavirus* or "2019-nCoV" or "2019 ncov" or nCov or "Covid 19" or Covid19 or "SARS CoV 2" or novel coronavirus or novel corona virus or covid* or "coronavirus 2" or coronavirus infection* or coronavirus disease or corona virus disease or new coronavirus or new corona virus or new coronaviruses or novel coronaviruses or wuhan).mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]

2. (Community pharmacy or community pharmacies or community pharmacist or community pharmacists or retail pharmacy or retail pharmacist or retail pharmacists or dispensing chemist or dispensing chemists or (((Pharmacist or pharmacy) and (community or primary care)) or dispensary or apothecary or druggist)).mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]

3. 1 and 2

NB. No Date or Language Limits were applied.

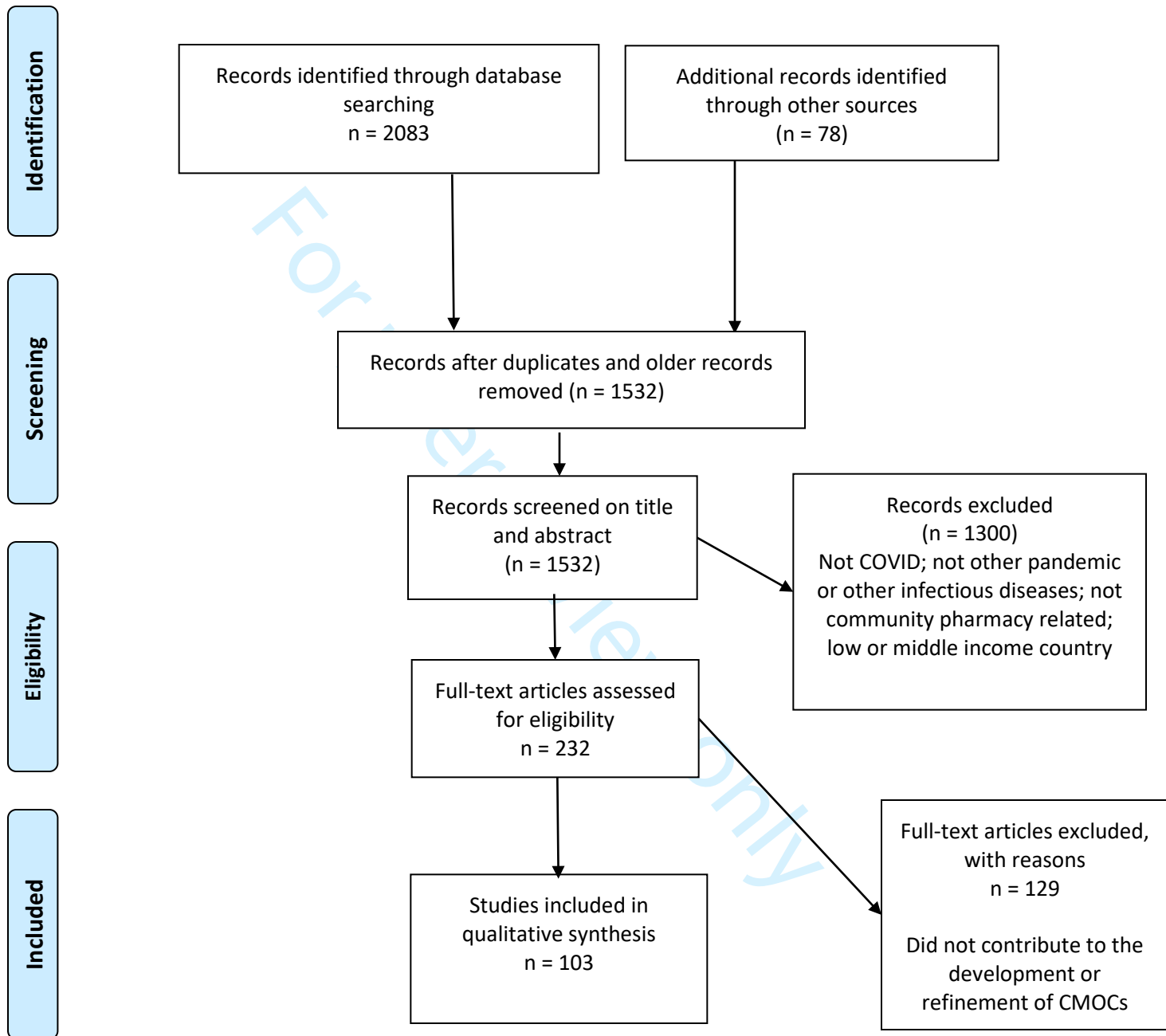
Appendix 2 - Literature inclusion criteria

Published after January 2003 AND
COVID-19 or other pandemic or other infectious diseases
OR vaccination programmes
OR expanded/extended roles
AND Community Pharmacy
AND High- or middle-income country

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PRISMA 2009 Flow Diagram

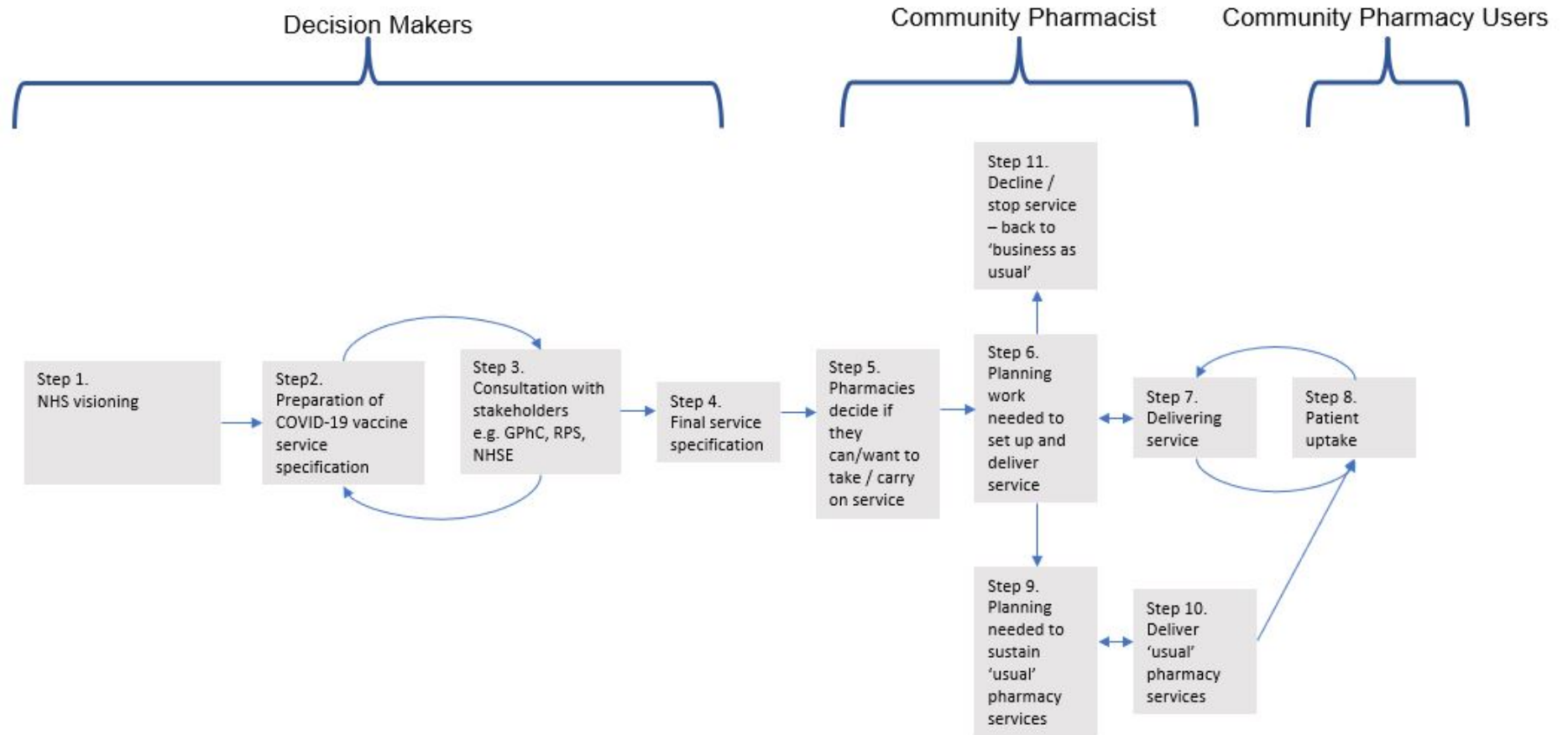


From: Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement. PLoS Med 6(7): e1000097. doi:10.1371/journal.pmed1000097

For more information, visit www.prisma-statement.org.

For peer review only - <http://bmjopen.bmj.com/site/about/guidelines.xhtml>

Appendix 4 - A simplified diagram of the programme theory of a COVID-19 vaccination programme provided by community pharmacies



BMJ Open

A Rapid Realist Review of the Role of Community Pharmacy in the Public Health Response to COVID-19

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2021-050043.R2
Article Type:	Original research
Date Submitted by the Author:	13-Apr-2021
Complete List of Authors:	Maidment, Ian; Aston University Young, Emma; The University of Sheffield MacPhee, Maura; The University of British Columbia Booth, Andrew; The University of Sheffield, School of Health & Related Research (SchARR) Zaman, Hadar; University of Bradford Breen, Juanita; University of Tasmania Hilton, Andrea; University of Hull, FHSC Kelly, Tony; Aston University, PPI Lead on Project Wong, Geoff; University of Oxford, Primary Care Health Sciences
Primary Subject Heading:	Health services research
Secondary Subject Heading:	General practice / Family practice, Infectious diseases
Keywords:	COVID-19, QUALITATIVE RESEARCH, Organisation of health services < HEALTH SERVICES ADMINISTRATION & MANAGEMENT

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Manuscripts



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21 7 Breen, University of Tasmania, Hobart; Andrea Hilton, University of Hull, Hull, UK; Tony Kelly, PPI
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29 10 Keywords: COVID-19, SARS-CoV-2, Community Pharmacy Services, Vaccination
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33 12 Word count: 3,744
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18 Abstract

19 Introduction

20 Community pharmacists and their teams have remained accessible to the public providing essential
21 services despite immense pressures during the COVID-19 pandemic. They have successfully
22 expanded the influenza vaccination programme and are now supporting the delivery of the COVID-
23 19 vaccination roll-out.

24 Aim

25 This rapid realist review aims to understand how community pharmacy can most effectively deliver
26 essential and advanced services, with a focus on vaccination, during the pandemic and in the future.

27 Method

28 An embryonic programme theory was generated using four diverse and complementary documents
29 along with the expertise of the project team. Academic databases, preprint services and grey
30 literature were searched and screened for documents meeting our inclusion criteria. The data was
31 extracted from 103 documents to develop and refine a programme theory using a realist logic of
32 analysis. Our analysis generated 13 context-mechanism-outcome configurations explaining when,
33 why and how community pharmacy can support public health vaccination campaigns, maintain
34 essential services during pandemics, and capitalise on opportunities for expanded, sustainable public
35 health service roles. The views of stakeholders including pharmacy users, pharmacists, pharmacy
36 teams and other healthcare professionals were sought throughout to refine the 13 explanatory
37 configurations.

38 Results

39 The 13 context-mechanism-outcome configurations are organised according to decision makers,
40 community pharmacy teams and community pharmacy users as key actors. Review findings include:

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3 41 supporting a clear role for community pharmacies in public health; clarifying pharmacists' legal and
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5 42 professional liabilities; involving pharmacy teams in service specification design; providing suitable
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7 43 guidance, adequate compensation and resources; and leveraging accessible, convenient locations of
8
9 44 community pharmacy.

12 45 Discussion

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15 46 Community pharmacy has been able to offer key services during the pandemic. Decision makers
16
17 47 must endorse, articulate and support a clear public health role for community pharmacy. We
18
19 48 provide key recommendations for decision makers to optimise such a role during these
20
21 49 unprecedented times and in the future.

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27 51 Strengths and limitations of this study

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29
30 52 A diverse group of professional and public stakeholders validated our findings from the literature.

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35 54 By using a realist approach, we were to use broad range of data, including grey literature.

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40 56 To enable us to develop recommendations in a timely manner the focus of the review was
41
42 57 deliberately narrow.

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47 59 The topic could have been informed by other sources of evidence in particular empirical interviews
48
49 60 with key stakeholder.

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54 62 COVID-19 vaccination is a rapidly evolving area and this research was based on the best available
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56 63 evidence at the time.

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For peer review only

66 Introduction

67
68 Community pharmacy teams have continued to provide essential services during the coronavirus
69 disease 2019 (COVID-19) pandemic. They offer accessibility and medicines expertise to the public,
70 even in challenging times.^{1 2 3} However, COVID-19 creates extra workload demands, such as
71 medication dispensing with increases of up to 33% in prescription numbers.⁴ To cope with this
72 demand community pharmacies have increased their opening hours and hired additional staff.⁴
73 Alongside this additional workload, they have managed widening coverage of the influenza vaccines
74 programme.⁵

75 Evidence suggests that community pharmacy can successfully provide diverse vaccination services
76 including seasonal and pandemic influenza, travel vaccinations and hepatitis B for at-risk groups,
77 within the provisions of the UK National Health Service (NHS) or privately.⁶ They have successfully
78 provided influenza vaccines as an NHS commissioned advanced service since 2015.⁵ One service
79 evaluation found that of 485 patients asked, 99% expressed confidence in their pharmacist to
80 provide additional vaccinations.⁷ Community pharmacy can also support influenza and other
81 vaccinations to combat the significantly higher COVID-19 related mortality in ethnic minorities
82 (excluding White minorities).^{8 9}

83 The COVID-19 pandemic has stretched NHS capacity to safely and efficiently meet public health
84 demands. A role for community pharmacy in the national vaccination service requires an
85 understanding of what pharmacy teams require to successfully deliver essential and advanced
86 services during the pandemic. Such knowledge is timely, given the roll-out of COVID-19 vaccines
87 across the community.¹⁰

88 Delivering a vaccine is a complex process and successful delivery is context-dependent. A realist
89 review helps make sense of complex situations^{11 12}, such as how community pharmacy can most

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3 90 effectively address the challenges presented by COVID-19. A rapid review can generate guidance for
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5 91 decision makers to assist with roll-out of COVID-19 vaccinations to community pharmacy. This rapid
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7 92 realist review aimed to understand how community pharmacy can most effectively deliver essential
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9 93 and advanced services, with a focus on vaccination, during the pandemic and in the future.
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13 94 **Methods**

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16 95 A rapid realist review of academic and other literature, supplemented by input from key actors, was
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18 96 undertaken to understand how and when community pharmacy can effectively support the public
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20 97 health agenda during pandemics such as COVID-19. Rapid reviews aim to ensure findings are
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22 98 generated and disseminated in response to the urgent nature of the situation. To produce this
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24 99 knowledge at pace, we truncated the following review processes:

- 25
26 100 - Programme theory development was undertaken within 1 month with input from the
27
28 101 project team.
- 29
30 102 - Searching was expedited using broad search terms and using a limited number of key data
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32 103 sources.
- 33
34 104 - Data analysis and context-mechanism-outcome configuration (CMOC) development
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36 105 focussed on where the programme theory was considered most important during COVID-19.

37
38 106 This realist review was undertaken within six-months (August 2020 - January 2021), the protocol was
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40 107 published on PROSPERO¹³ and, where relevant, follows the RAMESES quality and publication
41
42 108 standards.¹⁴
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50 109 **Stage 1: Programme Theory Development**

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53 110 The project team met virtually to develop an embryonic programme theory using four diverse
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55 111 documents from an initial search representing a professional journal¹⁵, a research journal¹⁶, a policy
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57 112 document (Royal Pharmaceutical Society)¹⁷ and a practical influenza briefing.¹⁸ The team identified
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59 113 the need for (i) enabling guidance for community pharmacy (to achieve legitimisation)¹⁶; (ii) practical

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3 114 direction for community pharmacy practices (to ensure feasibility)^{15 16}; and (iii) user assurance of
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5 115 appropriate, safe, feasible and timely intervention (relative advantage).¹⁵ The resultant embryonic
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7 116 theory, patterned on a COM-B behavioural model of capability, opportunity, and motivation leading
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9
10 117 to behaviour¹⁹, was used to inform searching and initial analyses.
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13 118 Stage 2: Literature Searching

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16 119 Searches were conducted (July-August 2020) using MEDLINE, EMBASE, CINAHL, Web of Science, and
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18 120 Scopus for search concepts relating to Pharmacy and COVID by AB (see Appendix 1 for search
19
20 121 strategy). Reference checking and citation searching of all included references on Google Scholar
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23 122 (using the Publish or Perish tool) were also carried out. Given the novelty of the virus, we searched
24
25 123 the contents of preprint services and the World Health Organisation (WHO) COVID Register. Grey
26
27 124 literature searches included social media (e.g. blogs, facilitated Twitter® discussion [#Cpharmchat]),
28
29 125 community pharmacy websites, and emails from relevant regulators and professional organisations
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31 126 (e.g., Royal Pharmaceutical Society [RPS], Pharmaceutical Services Negotiation Committee [PSNC],
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33 127 General Pharmaceutical Council [GPhC]).
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37 128 Key inclusion criteria were high or middle-income countries, community pharmacy and infectious
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39 129 disease management (see Appendix 2). The search covered January 2003-July 2020 to include SARS,
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41 130 a comparable condition first identified in 2003. There were no restrictions on study designs eligible
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44 131 for inclusion.
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47 132 Stage 3: Data Selection and Extraction (selection and coding)

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50 133 Selection and appraisal of documents followed a two-step procedure:

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53 134 1). EY screened the title, abstract and keywords of potentially relevant documents against inclusion
54
55 135 criteria. A 10% random sample was checked by two research team members (AB and MM) for
56
57 136 consistency.
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3 137 2). EY obtained and screened full texts of all documents meeting the eligibility criteria.
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6 138 Relevant data from the included full text documents was coded into NVivo by EY, MM and JB. Some
7
8 139 codes came from the data (i.e. inductive coding); others were derived from the programme theory
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10 140 (i.e. deductive coding) and some were derived using retroduction (i.e. by interpretation of what
11
12 141 might be functioning as mechanisms).²⁰ No assessment was made of the rigour of the data within
13
14 142 included documents, however global judgements were made of the quality of the explanations
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16 143 provided by the CMOCs and programme theory using the criteria of consilience, simplicity and
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18 144 analogy.²¹
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23 145 Stage 4: Data Synthesis

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26 146 The data analysis/synthesis was conducted by EY, MM and JB with input from the rest of the project
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28 147 team to develop and refine the programme theory using a realist logic of analysis. Our analysis
29
30 148 generated 13 realist CMOCs, explaining when, why and how community pharmacy can support
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32 149 public health vaccination campaigns, maintain essential services during pandemics, and capitalise on
33
34 150 opportunities for expanded, sustainable public health service roles. Actor conversations generated
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36 151 further CMOCs related to care for diverse and vulnerable populations, including ethnic minorities.
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40 152 Our realist logic of analysis centred on the following questions:
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- 43 153 • Interpretation of meaning: Do the contents coded by the team provide data that may be
44
45 154 interpreted as CMOCs?
- 46
47 155 • Interpretations and judgements about CMOCs: How do the CMOCs relate to the programme
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49 156 theory?
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51 157 • Interpretations and judgements about programme theory: How do the programme theory and
52
53 158 its CMOCs correspond with key actor perspectives of reality?
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3 159 Data to answer our questions was iteratively sought across documents. Interpretive cross-case
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5 160 comparison was used to identify and to explain the “success” of pandemic community pharmacy
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7 161 interventions delivered in different settings or to different population groups.
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10 11 162 Key Stakeholders

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14 163 Key stakeholders, including community pharmacists and support staff (including representatives
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16 164 from large and smaller chains, sole independent pharmacies and primary care), other healthcare
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18 165 professionals and members of the public were consulted on four occasions. The meetings took place
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20 166 over Microsoft Teams and each lasted about one hour.
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23 167 Patient and Public Involvement

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26 168 Members of the public were drawn from The University of Sheffield’s Patient and Public Involvement
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28 169 database and contacts of the core project team. Groups numbered between 11 and 13 members,
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30 170 with ages ranging from 22 to 74 years, from diverse locations and ethnicities including Black African,
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32 171 Black Caribbean, British Asian, British Chinese, White Irish and White British. Collectively,
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34 172 stakeholders provided feedback and advice on their real-world experience of working in or using
35
36 173 community pharmacy.
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41 42 43 175 Results

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48 177 103 documents were included in this rapid review and were coded to develop and refine our CMOCs
49
50 178 and programme theory (PRISMA diagram in Appendix 3). The final programme theory is summarised
51
52 179 in Appendix 4—from abstract visioning to actual patient uptake of the COVID-19 vaccine. Although
53
54 180 the programme theory is outlined in a linear fashion, steps within it are not necessarily linear and
55
56 181 may occur simultaneously. The CMOCs are organized according to key actors, or individuals and
57
58 182 groups with a vested interest in community pharmacy delivery of a COVID-19 vaccination
59
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183 programme. “Actor” derives from sociology and is synonymous with “stakeholder”; we privileged
 184 this term to differentiate programme theory/CMOC organization from project stakeholder
 185 participants.²² Table 1 briefly describes the three actor groups with their respective CMOCs and
 186 corresponding steps in Appendix 4. Tables 2-4 show the final 13 CMOCs.

187

188 Table 1: Programme Theory Actors with corresponding CMOCs and steps

Programme Theory Actors	Description	CMOCs*	Steps in Programme Theory**
Decision Makers	The UK government, regulatory and professional bodies, the public.	CMOC 1 - 4	Steps 1 - 4
Community Pharmacists and their Teams	Community pharmacists are health care professionals registered by the General Pharmaceutical Council and supported by teams made up of counter assistants, dispensers and registered technicians. They work in high street locations, in local communities and in supermarkets. Employers range from large chains to small individually owned community pharmacies.	CMOC 5 – 9	Steps 5 – 7 and 9 – 11
Pharmacy Users	Members of the public who use any community pharmacy services including prescription dispensing, minor ailment advice/treatment or vaccination services.	CMOC 10 - 13	Step 8

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190 *see Table 2-4

191 **See Appendix 4

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193 The following sections summarise the CMOCs related to each of the three actor groups. Illustrative
 194 examples of the supporting evidence from review documents are presented (Tables 2-4).

195

196 *Decision makers*

197 Decision maker and public endorsement (CMOC 1) are essential first steps in enlisting community
 198 pharmacy for COVID-19 vaccination programmes. Regulators must ensure pharmacists have the
 199 legal scope to do so (CMOC 2), with community pharmacy input during the development of policies
 200 and protocols (CMOC 3), so that final service specifications are flexible and do-able within local
 201 settings (CMOC 4).

202 Table 2 - Decision Makers (CMOCs 1-4)

<p>CMOC 1 – Support a public health role^{23 24 25} <small>26-32</small></p>	<p>When the government, pharmacy regulators, professional bodies and the public endorse and support a clear role for community pharmacy in public health services (C), community pharmacists will be more likely to adopt vaccination services (O) because they see it as their professional role and duty (M).</p> <hr/> <p><i>“Distribution and administration of the COVID-19 vaccination programme will require concerted action across the NHS. With unique insight and expertise in medicines and the delivery of vaccination programmes, pharmacists have a clear role in contributing to the success of this programme.” (Great Britain)²⁴</i></p> <p><i>“55% of the public have visited a pharmacy during the COVID19 crisis...89% of people believe pharmacies are playing an essential role in the COVID19 crisis.” (UK National Pharmacy Association)²³</i></p>
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	<p><i>“Pharmacists...have been called on to coordinate the administration of COVID-19 tests...providing ongoing COVID-19 surveillance to communities by allowing walk-in testing at community pharmacies...[This] might be more sustainable and convenient than the large-scale public screening being done as of the summer of 2020.” (USA)²⁵</i></p> <p><i>“Given the past success of community pharmacists with increasing annual seasonal influenza uptake and their accessibility, pharmacists will need to be central in administering COVID-19 vaccines in order to achieve rapid population-wide coverage.” (Canada)²⁶</i></p>
<p>CMOC 2 –Clarify legal and professional liabilities^{24 31 33-40}</p>	<p>When pharmacy regulators and the NHS clarify community pharmacists’ legal and professional liabilities arising from the administration of a novel and potentially unlicensed COVID-19 vaccine (C), community pharmacists are more willing to give the vaccination (O) because they feel reassured regarding liability (M).</p> <p><i>“The role of pharmacists in the COVID-19 vaccination programme must be made clear to the pharmacy profession itself. Professional and representative pharmacy bodies have an important role to play in providing the right level of information to the profession to support their roles in the vaccination programme.” (Great Britain)²⁴</i></p> <p><i>“Indemnity insurance for individual healthcare professionals needs to be amended to cover this activity and be state-funded. There also needs to be clear communication to healthcare professionals, so they clearly understand</i></p>

	<i>that they are covered and under which circumstances this applies.” (Great Britain)⁴¹</i>
<p>CMOC 3 – Co-develop feasible service specifications^{1 38}</p> <p>42-48</p>	<p>When COVID-19 vaccination policy and service specifications have been developed with input from diverse community pharmacists and staff tasked with administering and supporting the administration of the vaccine (C), community pharmacies are more likely to deliver the service (O) because they believe the service specification is feasible (M).</p> <p><i>“Pharmacists ideally want input into future policy changes before they are finalized, so that these can reflect capacity and preparedness on the ground and be publicized accurately.” (Great Britain)¹</i></p>
<p>CMOC 4 – Issue clear, relevant and timely guidance^{25 27 31 34}</p> <p>48-62</p>	<p>When government, pharmacy regulators and professional bodies provide consistent, clear, relevant, and timely guidance for the delivery of the COVID-19 vaccines (C), community pharmacies are more likely to deliver the service (O), because the guidance is helpful and simplifies implementation (M).</p> <p><i>“... it is good to see that NHSE/I have provided the information we have been waiting for to review the resources we have nationwide and decide how we can bring them to bear to help the NHS defeat this virus.” (Great Britain)⁴⁹</i></p>

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In England community pharmacies have government contracts and partnerships to deliver

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vaccinations and other essential services during emergencies, including the COVID-19 pandemic.^{25 31}

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³² Pharmacies in the USA and Canada have also been identified as having a substantive role in

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vaccine administration (CMOC1).^{25,26} The idea of harnessing UK community pharmacy capacity

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enjoys widespread public support (CMOC2).²³ However, appropriate service delivery is hampered by

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unfeasible operational conditions (CMOC3)¹; for example, medication deliveries are funded by the

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UK government for “vulnerable people”, but this category of service users is defined narrowly by the

211 government and misunderstood by the public, creating unrealistic expectations of community
 212 pharmacy and generating additional work.¹

213 In contrast, when clear options for community pharmacy involvement in COVID-19 vaccination
 214 programmes were issued through the NHS (CMOC4), the chief executive of the Association of
 215 Independent Multiple Pharmacies commented positively on members' engagement in delivering
 216 vaccines.⁴⁹

217 *Community Pharmacists and Team*

218 Community pharmacies have had to manage ongoing essential services, in addition to supporting
 219 COVID vaccination delivery during the pandemic (CMOC6), including delivery of necessary
 220 medications (CMOC7). Given fears and anxieties related to COVID-19 and changes to service
 221 delivery, community pharmacies have had to deal with inappropriate behaviours from the public,
 222 including emotional abuse and threats of physical abuse (CMOC8). As an integral public health
 223 service, community pharmacy capacity to meet NHS needs will be enhanced through use of IT and
 224 collaboration with other service providers (CMOC9).

225 Table 3 - Community Pharmacists and Team (CMOCs 5-9)

CMOC 5 – Receive adequate compensation and resources^{1 63-77}	When community pharmacies receive adequate compensation and resource support for COVID-19 vaccines (C), they are more likely to deliver the service (O), because they feel recognised for their service contributions (M).
	<i>“Pharmacists...have been incredible in supporting patients throughout COVID-19 and rightly deserve recognition for the work they do. We know that teams were already under pressure and that colleagues in community pharmacy are feeling added financial strain.” (Great Britain).⁶³</i>

	<p><i>“In the community, mitigating the impact of COVID-19 has...focused largely on general practitioners (GPs). This is unsurprising to those in the pharmacy profession who have long considered policy makers to overlook them.” (Great Britain)¹</i></p>
<p>CMOC 6 – Sustain capacity and facility to adapt essential services^{16 17 30 34 68 70 71}</p>	<p>When a community pharmacy has the capacity and permission to manage and adapt existing essential services during COVID-19 (C), they are more likely to effectively deliver and sustain these services (O) because it’s feasible for them to do so (M).</p>
<p>78-91 92</p>	<p><i>“Virtual and telephone consultations have become commonplace, particularly to vulnerable patients. Pharmacists have implemented systems to dispense medications in advance of need to minimise wait times and duplicate visits. In case-by-case examples...there has been anticipatory management of medication-related needs.” (Ireland)⁹²</i></p> <p><i>“Pharmacists who had comfort and confidence in managing electronic communication reported feeling greater control over workflow and the ability to triage and queue patients more effectively based on priority and need.” (Canada)⁶⁰</i></p>
<p>CMOC 7 – Inform users of essential service availability/continuity</p>	<p>When community pharmacies have processes in place to inform pharmacy users about the availability of essential services (C), pharmacy users are less likely to become anxious (O), because they feel reassured about access to what they need (M).</p>

<p>92 16 28 31 32 51 60 65 71 80 81</p> <p>85 93-101</p>	<p><i>“Access to medications is a main concern expressed by our patients... The CDC and SAMHSA offer guidance on ways to reduce stress and anxiety in this time of uncertainty.”⁹⁵</i></p> <p><i>“As a result of the power dynamics at play, it is ultimately up to pharmacists to be able to reassure patients and provide care, all while taking into account their mental health. Currently, guidelines regarding patient interaction during a pandemic are needed”.⁵¹</i></p> <p><i>“In addition, there is ongoing work in liaison with pharmacists, general practitioners, and state and territory authorities to enable therapeutic substitution by pharmacists in the event of a shortage. This will allow community pharmacists to substitute dose strength or form without prior approval from the prescriber, if a prescribed medicine is not available at the time of dispensing. These measures highlight the important role pharmacists can play in enabling and maintaining access to medicines for people in need throughout the COVID-19 outbreak.” (Australia)⁸⁵</i></p> <p><i>“Access to medications is a main concern expressed by our patients... The CDC and SAMHSA offer guidance on ways to reduce stress and anxiety in this time of uncertainty.” (USA)⁹⁵</i></p>
<p>CMOC 8 – Protect the health and safety of staff ^{24 31 51 71 77 81 102-108}</p>	<p>When community pharmacies have the means to protect the health of pharmacists and staff (C), they are more likely to deliver essential services and COVID-19 vaccination services (O), because they feel safe to do so (M).</p>

	<p>“...Given high levels of public anxiety and uncertainty regarding the integrity of the drug supply chain in Canada, many participants reported difficult, sometimes frightening, interactions with members of the public and their desire for dedicated security to provide support and conflict management” (Canada).³¹</p> <p>“An additional burden Asian pharmacists face, on top of pharmacist harassment, is the rise of anti-Asian racism that has come about due to COVID-19. Verbal and even physical abuse has been reported to happen in various countries, such as the UK, France, and the USA, to those of Chinese descent...” (UK, France, USA)⁵¹</p> <p>“The survey found that although more than a third (37%) of pharmacists said they felt unsafe at some point working during the pandemic, concerns over PPE have eased. This is due, in part, to the supply problems being eased and community pharmacists being finally allowed to order from the national online PPE portal in an emergency, after calls for access from the RPS.” (Great Britain)⁷⁷</p>
<p>CMOC 9 – Enhance collaboration across services, including IT¹⁸ <small>26 47 56 57 69 78 80 85 109-114</small></p>	<p>When systems needed for COVID-19 vaccination, including IT and remuneration, support collaboration by various service providers (e.g. general practitioner surgeries and community pharmacies: (C), a coordinated response is more likely (O), because reduced effort is needed from everyone (M).</p>

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“Planning and delivery should be undertaken across a consistent, pre-agreed footprint. It may be more efficient and cost effective to provide immunisation across a number of providers, pooling resources and sites to deliver the best service possible, and working in coordination with other local stakeholders such as directors of public health and local government.” (Great Britain)⁴⁷

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“For many community pharmacists, a lack of connected IT is a huge problem. Kieran Eason, who runs an independent pharmacy in Tamworth, Staffordshire, says lack of intra-operability makes it more difficult to do relatively simple things, like sending prescription requests to GPs. “Pharmacy IT is just a complete disaster,” he says, suggesting the COVID-19 crisis has highlighted flaws, such as the number of different systems pharmacists use.” (Great Britain)⁶⁹

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227 Although attention is focused on a COVID-19 vaccine, community pharmacies offer diverse essential
228 services. In the UK and other high-income countries, community pharmacy services also provide
229 advanced services such as vaccinations.¹¹⁵ Pharmacists consider it a professional responsibility to
230 provide essential services during the pandemic, despite clear financial risks to themselves.⁶³

231 Despite pharmacists’ professional and moral obligations to provide essential services, ongoing
232 persistent ‘under-recognition’ can jeopardize their ability to contribute to COVID-19 vaccinations
233 (CMOC5) as well as maintain a usual service. Under-recognition has been an issue in previous UK
234 vaccination campaigns; respondents to a survey of Welsh community pharmacists after the 2016
235 influenza season described providing a “mop up” service for general practitioners (GPs).^{59 68}

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3 236 Multiple required community pharmacy service adaptations have been reported by the UK
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5 237 Pharmaceutical Journal, including changeover in retail space to medication preparation and
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7 238 dispensing, and call-in shopping services for other retail items (CMOC6). Service adaptations have
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9 239 been affected by hours of operation, available staff, and cancellations of contracted services, such as
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11 240 blood pressure testing and smoking cessation support—all with financial implications for
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13 241 pharmacists.⁸⁰

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17 242 Before COVID-19, community pharmacies globally were offering “valued-added services” (VAS) such
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19 243 as drive-thru services, online ordering and communications services (e.g., prescription reminders) to
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21 244 stay competitive. Many VAS services have helped pharmacies adapt more quickly to pandemic
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23 245 restrictions.⁸¹

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27 246 During the pandemic, ensuring access to needed medications has been a critical pharmacy service,
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29 247 to allay public concerns (CMOC7).¹⁶ Potential and actual disruptions in expected services and needed
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31 248 supplies (e.g., medications) have resulted in tensions, threats and verbal/physical abuse by the
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33 249 public to community pharmacists (CMOC 8).^{51 80 116} Safety policies, protocols and safety-related
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35 250 supplies (e.g., PPEs) must in place to ensure community pharmacy teams’ safety.⁸⁰

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39 251 The UK COVID-19 vaccination campaign borrows heavily from previous, successful collaborative
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41 252 influenza vaccination programmes using community pharmacy and GPs (CMOC9).⁴⁸ Pooling
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43 253 resources improves service delivery.¹¹⁷ For example, the UK Pharmaceutical Journal reported how a
44
45 254 greater collaborative approach has resulted in successful influenza vaccination of home care staff
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47 255 and domiciliary workers during the pandemic.¹¹⁷

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50 256 The pandemic has clearly demonstrated the importance of interoperable, connected IT systems
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52 257 across services.¹¹⁸ Getting access to reliable information is important for tracking supplies and
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54 258 deliveries related to the COVID-19 vaccination programme.⁶⁹ A pandemic silver lining is raised
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56 259 awareness of IT functions for enhanced delivery of essential services (e.g., medication planning,
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3 260 prescribing and dispensing between pharmacies and GPs) and advanced services, including
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5 261 vaccinations.⁶⁹
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9 262 *Pharmacy Users*

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11 263 Pharmacy users trust community pharmacies as a reliable source of information (CMOC10) about
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13 264 vaccines, and pharmacies' local accessibility and convenience increases the likelihood of users
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15 265 obtaining COVID-19 vaccines through them (CMOC11). Community pharmacy relationships with
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17 266 vulnerable populations in their local settings may enhance uptake of the vaccine by these groups
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20 267 (CMOC12). Provision for privacy is an important user consideration. Pharmacy users expect private
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22 268 consultations to preserve their confidentiality (CMOC13).
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270 Table 4 - Pharmacy Users (CMOCs 10-13)

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<p>COMC 10 – Trust the pharmacist as reliable information source^{32 53 119-122}</p>	<p>When pharmacy users receive information about the COVID-19 vaccine from their community pharmacy (C), they are more likely to get the vaccine (O), because they trust community pharmacy as a source of reliable, accurate information (M).</p> <p><i>“When patients were educated about influenza, herpes zoster, and pneumococcal vaccines as a result of a pharmacist-driven intervention in community pharmacies, they were influenced to receive the vaccination.” (USA)¹¹⁹</i></p> <p><i>“Being able to address the public enquiries with accurate up-to-date information about the local situation and the overall infection progress is the key to build trustful relationship with them at troubled times.” (Macau)³²</i></p>
<p>CMOC 11 – Trust the pharmacist to deliver responsive services^{7 18 23 26 34 37 43 51 54 59 63 70 84 85 123-135}</p>	<p>When community pharmacies are trusted to make necessary service adaptations to ensure services are flexible, convenient and accessible (C), COVID-19 vaccine uptake is likely to be higher among pharmacy users (O) because the service is responsive to local needs (M).</p> <p><i>“Pharmacists have always been the most accessible health care provider; this is especially true in the era of COVID-19.... While other professionals have closed their doors to patients, community pharmacies remained open to the public despite stricter lockdown restrictions. As highly trusted healthcare clinicians, community pharmacists play a vital role in closing the gaps that are exacerbated by the additional strain on the system and reduced access to healthcare providers.” (Canada)⁵¹</i></p>

	<p><i>“Pharmacy flu vaccination services complement those provided by general practitioners to help improve overall coverage and vaccination rates for patients in at-risk groups. These services are highly accessed by patients from all socio demographic areas, and seem to be particularly attractive to carers, frontline healthcare workers, and those of working age.” (Great Britain)¹³⁵</i></p>
<p>CMOC 12 –</p> <p>Access culturally-sensitive services</p> <p><small>27 78 80 92 136</small></p>	<p>When community pharmacies leverage their community location and community-staff relationships (C), vulnerable populations, such as ethnic minorities, are more likely to use their services, including COVID-19 vaccination services (O), because they trust their local community pharmacies to provide culturally sensitive service. (M)</p> <p>“Research continues to highlight that patients who are medically underserved have poorer inequitable access to health care due to them experiencing greater physical barriers to accessibility, encountering poorer patient-professional communication and are significantly disadvantaged where a service is not tailored to their unique needs or preferences.” (Great Britain)¹³⁷</p> <p><i>“I think over the years what’s happened is nationally it’s almost like everything has to be the same, which then doesn’t work because it doesn’t accommodate all the little variations...So we need to go back and in each individual pharmacy, gear it towards the population that it is meant to be meeting the needs of” (Pharmacist caring for ethnic minority community-Great Britain)¹³⁷</i></p>

<p>CMOC 13 –</p> <p>Receive private and confidential services^{7 50 65 129}</p> <p>138-140</p>	<p>When community pharmacies make provisions for privacy (C), pharmacy users are more likely to use their services (O), because they are reassured about confidentiality (M).</p> <p><i>“If there was something not right...the first thing I would do is make an appointment with a doctor. I wouldn’t do and talk to somebody over a pharmacy counter.” (Great Britain)⁶⁵</i></p> <p><i>“Privacy, confidentiality and dignity are all vital elements of a trusting relationship between healthcare professionals and their patients.... In terms of privacy, the quality was perceived by the participants to include a confidential room that enabled private consultations.” (Great Britain)⁷</i></p>
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273 Public trust in community pharmacists is high—similar to doctors and nurses.³⁸ Trust between
 274 pharmacists and users can be leveraged to overcome scepticism about the COVID-19 vaccine.
 275 Providing reliable information about the disease and the vaccine, as pharmacies have done with
 276 other infections, can enhance public uptake of the COVID-19 vaccine.¹¹³ In the USA, 90% of the US
 277 population lives within 5 miles of a community pharmacy. Given their convenience and accessibility,
 278 consumers have visited their community pharmacists 12 times more frequently than their GPs.²¹ A
 279 UK study found that consumers who were eligible for a free influenza vaccine through their GPs
 280 were willing to pay for pharmacy service because of convenience and ease of access.¹²⁷ Established,
 281 trusting relationships are especially important for providing culturally sensitive services to
 282 marginalized and vulnerable communities.¹²⁹ Community pharmacists, often members of local
 283 communities are specially positioned to understand the culturally contextual factors that impact
 284 their pharmacy users.⁸⁹ Trusting relationships are founded on privacy, confidentiality and dignity,

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3 285 and COVID-19, public health protocols and limited space must be considered—in order to maintain
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5 286 vital trust among pharmacy users.⁶⁵
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8 287 Discussion

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12 288 This realist review sought to understand how community pharmacy can contribute to the public
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14 289 health agenda during the COVID-19 pandemic, particularly continuation of essential services and
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16 290 engagement in vaccination services.¹¹⁵ As the COVID-19 vaccination service continues to evolve, our
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18 291 recommendations for decision makers highlight opportunities for community pharmacy to promote
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20 292 safe, efficient and effective service delivery.
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24 294 Summary of key Findings

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29 295 To optimise community pharmacy service during the pandemic, decision makers must endorse and
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31 296 articulate a clear role for these healthcare professionals. The public already endorses advanced roles
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33 297 for community pharmacy (e.g., vaccinations, minor ailment scheme), but public awareness depends
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35 298 on what decision makers do and say. Practical decision maker measures include adequate
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37 299 reimbursement to help cover the cost for time, staff and PPE (particularly for a sustainable long-term
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39 300 service); legal (including indemnity), regulatory coverage for advanced roles; and clear and
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41 301 consistent guidance for vaccination preparation and for adaptation of essential services. When given
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43 302 the opportunity, the permissions and resources to do so, community pharmacies have been able to
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45 303 adapt quickly to continue essential services and whenever possible, to offer critical advanced
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47 304 services. Historically, community pharmacies have significantly increased vaccination uptake (e.g.,
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49 305 influenza vaccinations) given their accessibility and convenience and capacity to adapt to local needs
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51 306 for the general population and marginalized groups.
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4 308 Compare to other similar or related studies discussing important differences in
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7 309 results
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10 310 At the time of this realist review, there were no similar reviews on community pharmacy roles with
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12 311 respect to COVID-19 vaccinations. COVID-19 represents an unprecedented situation with limited
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14 312 direct evidence to guide decision-making. However, realist approaches engage with a wider evidence
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16 313 base, including research on past pandemics (e.g., SARS)^{60 141 142}, mass vaccination campaigns (e.g.,
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18 314 influenza)¹⁴³, and community pharmacies' capacity pre-COVID-19 to deliver essential and advanced
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20 315 services.^{19 144 145} Key factors previously include a lack of leadership, a lack of guidance and an
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22 316 increasing reliance on professional judgement and experience.⁶⁰ Research from the UK and other
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24 317 economically developed countries supports the 13 CMOCs and decision maker recommendations in
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26 318 this review (see tables 2-4 and table 5). However, limitations continue to surround the direct policy
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28 319 relevance of much of the community pharmacy evidence base.¹⁴⁶
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35 321 Study strengths and limitations
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38 322 The realist approach uses diverse data, including grey literature. This feature is especially important
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40 323 given a novel and rapidly evolving topic area, such as COVID-19. Multiple researchers with subject
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42 324 matter expertise participated in screening the literature and extracting and coding data, which
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44 325 maximised opportunities to discuss and debate the plausibility of the inferences made. The CMOCs
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46 326 were developed and refined through regular discussions within a team with varied academic and
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48 327 clinical backgrounds. Professional and public stakeholder consultation further refined the CMOCs.
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52 328 All rapid reviews operationalise coverage versus expediency. Other sources of evidence could have
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54 329 informed the review; however, potential gaps were mitigated by stakeholder engagement and
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56 330 expertise within the team. The evidence supporting the CMOCs was based on available time for
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58 331 document review, and during the review period, research, directives and policy related to COVID-19
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3 332 vaccination rapidly evolved. The programme theory and its CMOCs, however, are expressed in such
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5 333 a way that they can be further confirmed, refuted or refined in the future using additional data.
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8 334 For this rapid review, given our short timeline of six months, we initially decided to focus on
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10 335 community pharmacy roles and pandemic response in middle to high-income countries. Whilst we
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12 336 identified data from higher-income countries such as Canada, USA, Australia and France, there was
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14 337 very little published from middle-income countries. As such, it is likely that our findings and
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16 338 recommendations are most applicable to high-income countries, although, the lessons learned from
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18 339 high-income countries can serve as an initial reference point for best practice for other countries.
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24 341 Our recommendations can be viewed as "how tos" for other countries to consider within their own
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26 342 cultural and healthcare environments. A number of European and North American countries have
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28 343 introduced legislative changes to extend the role of community pharmacy and thus reduce pressure
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30 344 on other parts of their healthcare systems.^{145 147} Our findings can be used by community pharmacy
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32 345 and decision makers, from countries other than the UK, when mapping out similar services
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34 346 particularly in the context of changes in the legislation.
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41 348 **Meaning of the study: possible explanations and implications for decision makers**
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44 349 Although there are multiple actors involved in pandemic response, for brevity, recommendations
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46 350 (Table 5) are directed towards decision makers who possess the formal authority to implement the
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48 351 recommendations.
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53 353 Table 5 - Recommendations for Decision Makers to Increase Community Pharmacy Engagement in
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55 354 Pandemic Response (for further details check:
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57 355 [https://publications.aston.ac.uk/id/eprint/42310/1/Guidance_for_Policy_Makers_on_the_role_of_C](https://publications.aston.ac.uk/id/eprint/42310/1/Guidance_for_Policy_Makers_on_the_role_of_Community_Pharmacy_in_COVID.pdf)
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59 356 [ommunity_Pharmacy_in_COVID.pdf](https://publications.aston.ac.uk/id/eprint/42310/1/Guidance_for_Policy_Makers_on_the_role_of_Community_Pharmacy_in_COVID.pdf)).
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Recommendations	Derived from CMOC
Articulate a clear public health agenda role for community pharmacy (e.g., COVID-19 testing and vaccination)	1
Ensure pharmacy regulations for advanced roles, such as novel vaccine administration, are in place to legally protect community pharmacists and their teams	2
Involve local community pharmacies in policy and service specification development	3
Provide timely guidance with sufficient details for community pharmacies to quickly adapt to local needs	4
Provide adequate funding and reimbursement for community pharmacy services to deliver COVID-19 vaccines	5
Equip community pharmacies with the necessary permissions to manage and adapt essential services	6
Ensure community pharmacies have the means to adequately protect the health of themselves, their staff and pharmacy users	8
Facilitate collaboration and coordination of COVID-19 vaccination services across providers (e.g., GPs, community pharmacies) and systems (e.g., IT)	9

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358 As the CMOCs were refined, ‘tensions’ were uncovered with implications for decision makers,

359 particularly: community pharmacists as healthcare professionals versus retailers^{43 106 145 148};

360 community pharmacies’ capacity to remain financially viable while managing essential and advanced

361 services.^{19 149 150} and; pharmacists’ capacity to provide off-site services while maintaining physical

362 premises.¹⁵¹ These tensions stem from lack of awareness of community pharmacists as healthcare

363 professionals.

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5 365 Along the continuum of healthcare from community to hospital, community pharmacy is often the
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7 366 first point of contact for the public. Community pharmacies contribute to primary care services
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10 367 through essential services (e.g., medication dispensing) and expanded roles (e.g., vaccinations),^{115 148}
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12 368 often decreasing workload pressures on other providers, such as GPs.¹⁵² Public surveys demonstrate
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14 369 high levels of satisfaction with community pharmacy services, and vaccination uptake is increased
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16 370 when pharmacies deliver these services.¹⁵⁰ Nevertheless, lack of public and decision maker
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18 371 awareness of community pharmacy primary care roles has slowed uptake and integration of these
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20 372 services.¹²¹ A recent UK public survey found that community pharmacies are seen as “a medicine
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22 373 supply shop by 48.3% of people, as a place to purchase medicines by 22%, and a place to purchase
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24 374 non-medicinal products by 17.7%.”²⁸

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30 376 In Ireland and Canada community pharmacies are an integral part of national vaccination
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32 377 campaigns.¹⁵⁰ In both instances, community pharmacists participate in vaccination planning,
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34 378 pharmacy regulators provide clear guidance on vaccination management, and vaccinations are
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36 379 equitably refunded through public health systems. The removal of barriers, such as economic
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38 380 pressures on pharmacies has resulted in impressive national vaccine uptake, even in large countries,
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40 381 such as Canada.¹⁵⁰ Globally, there is an emerging trend for governments, health insurance companies
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42 382 and consumers to remunerate community pharmacies for services that contribute to improved
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44 383 health outcomes.¹⁵¹

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48 385 Community pharmacies tend to be defined as premises where medications are dispensed, which
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50 386 compounds the confusion (by the public and decision makers) of professional primary care services
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52 387 versus retailers.¹⁵¹ Instead, pharmacies should be defined with respect to actions or services that
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54 388 require specialised health knowledge to optimise health outcomes. For example, a retail approach to
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56 389 over-the-counter (OTC) medications is to permit consumers to make their own choices, similar to
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3 390 supermarket choices. Pharmacy input for into OTC purchases could potential decrease adverse
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5 391 medication interactions or unnecessary allergic reactions.¹⁴⁸ The 'value-add' of community
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7 392 pharmacies, evidence-informed engagement with consumers, can decrease morbidity and mortality
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10 393 outcomes and increase medication regimen adherence.^{151 153}

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13 394 Although community pharmacists can provide professional services off premises (e.g.,
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15 395 immunizations in community and religious centres), they need to maintain their physical premises
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17 396 and staff for financial reasons. In addition, pharmacy users seek out community pharmacy services
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19 397 due to their accessibility and convenience, and without a physical space to engage regularly with
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21 398 pharmacy users, trust-building between pharmacists and users is compromised.¹⁵⁴

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27 400 As evidenced by public media, many countries, including the UK are declaring service specifications
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29 401 for COVID-19 vaccinations. Community pharmacists can potentially provide vaccination services in
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31 402 two locations.¹⁵⁵ They can collaborate with GPs in Primary Care Networks (PCN) to support PCN
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33 403 vaccination sites. Alternatively, they can provide a COVID-19 vaccination service from their premises
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36 404 if they meet service specifications. The described tensions create difficult choices for pharmacists
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38 405 that can be ameliorated through the decision maker recommendations in Table 5.

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41 42 43 407 **Unanswered questions and future research**

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45
46 408 A future realist evaluation involving primary data collection from key actors will inform refinement
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48 409 of the programme theory, CMOCs and decision maker recommendations. This empirical research
49
50 410 will address the tensions identified above. Future research will also address issues identified through
51
52 411 the stakeholder groups, such as vaccination hesitancy, outside the scope of this review. While this
53
54 412 work touched upon unique issues for marginalised populations including ethnic minorities, those of
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57 413 lower socioeconomic status and those with disabilities, further exploration is needed.

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3 414 We had initially focused the review on community pharmacy roles and pandemic response in middle
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5 415 to high-income countries, but found limited data in middle-income countries. The findings are thus
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7 416 more likely to be applicable to high-income countries but may serve to inform practice elsewhere.
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10 417 Empirical research, using for example a realist evaluation approach, should be conducted to extend
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12 418 our findings on the role of community pharmacy in COVID vaccination programmes to middle to low
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14 419 income countries.
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21 421 **Conclusion**
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24 422 The COVID-19 pandemic is a worldwide health emergency. Vaccination is key to combatting the
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26 423 pandemic. The role of community pharmacy may be both short and long term; with a potential need
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28 424 for regular annual vaccines. This rapid realist review offers recommendations for decision makers to
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30 425 enable community pharmacy to play a key role, both during these unprecedented times and into the
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32 426 future.
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432 Research Ethics Approval

433 This research did not involve human participants and therefore ethical approval was not required.

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437 Contributorship statement

438 IM conceived and led the project and had overall responsibility for PERISCOPE. All team members
439 developed develop the embryonic programme theory. AB conducted the searches. AB and GW
440 advised on realist methods. GW also advised on primary care implications and provided
441 methodological oversight. EY screened documents at title, abstract and full-text with support from
442 AB and MM. EY, MM and JB coded relevant data into NVivo. EY, MM and JB conducted the data
443 analysis/synthesis. HZ and AH advised on pharmacy aspects and policy implications. TK led PPI. TK
444 and HZ advised on implications in ethnic minorities. All team members contributed drafting the final
445 report for publication and approved the final draft for submission.

446 Data Sharing Statement

447 Data is available upon reasonable request to the lead author.

448 Competing Interests

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3 449 Geoff Wong is Deputy Chair of the NIHR HTA Prioritisation Committee: Integrated Community Health
4
5 450 and Social Care (A) and Member of the NIHR HTA Prioritisation Committee: Integrated Community
6
7 451 Health and Social Care (A) Methods Group.
8

9
10 452 Andrew Booth is a member of the National Institute for Health Research Health Services and
11
12 453 Delivery Research Funding Board, the National Institute for Health Research Evidence Synthesis
13
14 454 Programme Advisory Group and the National Institute for Health Research School for Social Care
15
16 455 Research Commissioning Panel.
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Appendix 1 - OVID MEDLINE – Search Strategy

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2. (Community pharmacy or community pharmacies or community pharmacist or community pharmacists or retail pharmacy or retail pharmacist or retail pharmacists or dispensing chemist or dispensing chemists or (((Pharmacist or pharmacy) and (community or primary care)) or dispensary or apothecary or druggist)).mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]

3. 1 and 2

NB. No Date or Language Limits were applied.

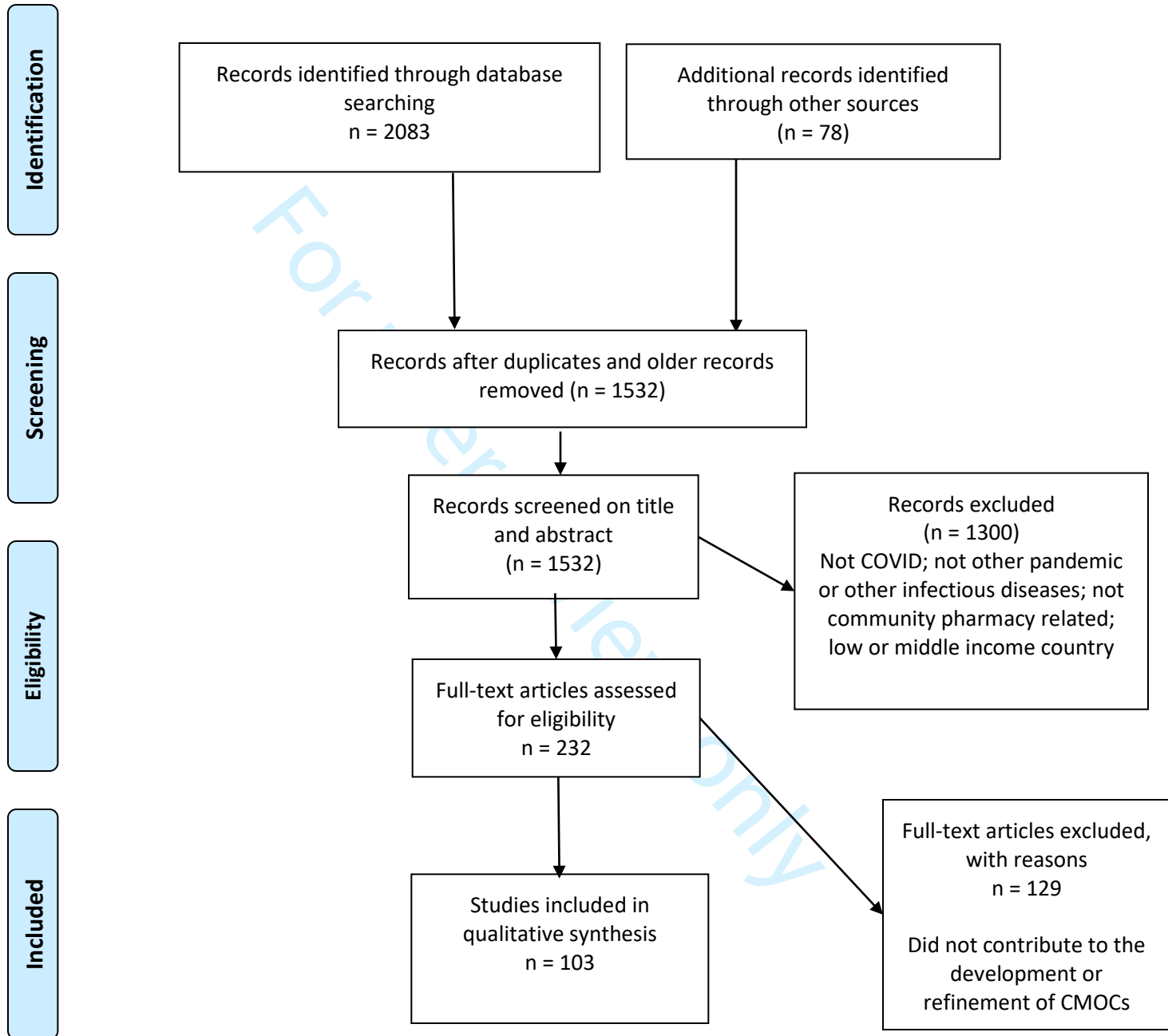
Appendix 2 - Literature inclusion criteria

Published after January 2003 AND
COVID-19 or other pandemic or other infectious diseases
 OR vaccination programmes
 OR expanded/extended roles
AND Community Pharmacy
AND High- or middle-income country

For peer review only



PRISMA 2009 Flow Diagram



From: Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement. PLoS Med 6(7): e1000097. doi:10.1371/journal.pmed1000097

For more information, visit www.prisma-statement.org.

For peer review only - <http://bmjopen.bmj.com/site/about/guidelines.xhtml>

Appendix 4 - A simplified diagram of the programme theory of a COVID-19 vaccination programme provided by community pharmacies

