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1 **Improving HIV Pre Exposure Prophylaxis (PrEP) uptake and initiation:**
2 **process evaluation and recommendation development from a national PrEP**
3 **programme.¹**

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30 **Abstract**

31 **Background:** HIV pre-exposure prophylaxis (PrEP) is key to HIV transmission elimination but
32 implementation is challenging and under-researched. We undertook a process evaluation of the
33 first two years of a national PrEP programme to explore barriers and facilitators to implementation
34 and to develop recommendations to improve implementation, focussing on PrEP uptake and
35 initiation.

36 **Methods:** Stage 1 involved semi-structured telephone interviews and focus groups (09/2018-
37 07/2019) with geographically and demographically diverse patients
38 seeking/using/declining/stopping PrEP (n=39), sexual healthcare professionals (n= 54),
39 community-based organisation service users (n=9) and staff (n=15) across Scotland. We used
40 deductive thematic analysis, to derive and then map key barriers and facilitators to priority areas
41 that experts agreed would enhance uptake and initiation. In Stage 2 we used analytic tools from
42 implementation science to systematically generate evidence-based, theoretically-informed
43 recommendations to enhance uptake and initiation of PrEP.

44 **Results:** Barriers and facilitators were multi-levelled and interdependent. Barriers included the
45 rapid pace of implementation without additional resource, and a lack of familiarity with PrEP
46 prescribing. Facilitators included opportunities for acquisition of practice-based knowledge and
47 normalisation of initiation activities. We refined our 68 “long-list” recommendations to 41 using
48 expert input and the APEASE criteria. Examples include: provision of PrEP in diverse settings to
49 reach all in need; co-produced, culturally sensitive training resources for healthcare professionals,
50 with focused content on non-daily dosing; meaningful collaborative working across all
51 stakeholders.

52 **Conclusions:** These evidence-based, theory informed recommendations provide a robust
53 framework for optimising PrEP uptake and initiation in diverse settings to ensure PrEP reaches all
54 who may benefit.

55 **Keywords:** HIV/AIDS, Pre-Exposure Prophylaxis, PrEP, process evaluation, implementation
56 study, recommendation-development, Behaviour Change Wheel, HIV Prevention.

57

58 **Summary for table of contents**

59 Zero new HIV infections could become a reality if HIV pre-exposure prophylaxis (PrEP)
60 programmes are successfully implemented but the World Health Organization recognizes that
61 large scale roll out is challenging.

62 We used implementation science research tools in novel ways to evaluate one of the world's first
63 national PrEP programmes, to develop evidence-based recommendations for use across a range
64 of settings to improve PrEP uptake and initiation.

65 Adopting these recommendations could enable governments and societies to better address HIV
66 prevention goals.

67

68 **Background**

69 HIV pre-exposure prophylaxis (PrEP), in which people take antiretroviral medication to prevent HIV
70 acquisition, is a major advance in biomedical prevention of HIV. In clinical trials, orally administered
71 PrEP has been shown to reduce the risk of HIV acquisition by 44-97% (1-4). Although PrEP is
72 becoming increasingly available, research drawing on implementation science to specifically
73 enhance its implementation is relatively limited (5-7). The World Health Organization and others
74 acknowledge the importance of making PrEP available for safe, effective prevention outside clinical
75 trial settings as key to realising its potential to end HIV epidemics (8,9). Implementation science
76 tools, with their specific focus on understanding and enhancing implementation, could help unlock
77 the full potential of PrEP (10) to assist with the elimination of HIV transmission (9).

78

79 Scotland became one of the first countries worldwide to implement a national PrEP programme
80 (11). At the time, there were around 4600 people living with HIV attending specialist care in
81 Scotland (12) and 228 people newly diagnosed with HIV each year, half of whom were gay,
82 bisexual, and other men who have sex with men (GBMSM) (13). From July 2017, oral PrEP and all
83 associated medical monitoring were made available free at point of access, as part of broader HIV
84 combination prevention and sexual health care, almost exclusively through sexual health clinics, to

85 those at greatest risk of HIV acquisition (14). Prescribing followed specialist association guidance
86 (15), but services developed their own local models of delivery, largely within existing budgets.
87 These broadly involved: [1] identifying a patient as a PrEP candidate; [2] provision of PrEP
88 information, baseline screening for HIV and other blood borne viruses (BBVs), sexually transmitted
89 infections (STIs), and renal function; [3] prescribing and dispensing PrEP; and [4] regular in person
90 reviews for HIV, BBV, and STI testing, renal monitoring, adherence support, wider sexual health
91 promotion, and PrEP prescribing (15). Quantitative outcomes from the national PrEP Programme
92 have been reported as part of routine surveillance (12-14) and through detailed epidemiology (6).

93

94 We conducted a process evaluation of the first two years of Scotland's PrEP programme. Our
95 approach divided the PrEP care cascade into three sections; awareness and access (16), uptake
96 and initiation, and adherence and retention in care (17). Here we focussed on uptake and initiation
97 of PrEP.

98

99 We addressed the following research questions:

- 100 1. Within PrEP care pathways where exactly should we intervene (priority areas) to optimise
101 uptake and initiation?
- 102 2. What are the barriers and facilitators to optimising implementation within these priority
103 areas?
- 104 3. Which evidence-based and theoretically informed recommendations could improve the
105 implementation of PrEP uptake and initiation?

106

107 **Methods**

108 As described elsewhere (16,17), Stage 1 is a retrospective qualitative process evaluation within a
109 larger natural experimental design study evaluating PrEP implementation in Scotland (research
110 questions 1 and 2). Stage 2 involves development of recommendations to improve PrEP uptake
111 and initiation, using systematic intervention development approaches (research question 3).

112

113 **Data collection**

114 *Participants*

115 We used multi-perspective purposive sampling to understand the implementation of PrEP uptake
116 and initiation from diverse viewpoints. In total, 117 participants took part in individual semi-
117 structured telephone interviews (n=71) or in one of 10 group discussions (n=46) (September 2018-
118 July 2019). The sample comprised: 39 patients; 54 healthcare professionals; nine non-
119 governmental organisation (NGO) service users; and 15 NGO staff from across Scotland. All
120 NGOs had an HIV prevention remit and served GBMSM, trans, and/or Black African communities.
121 Group discussions included one type of stakeholder at a time.

122

123 Patients were either using PrEP (n=23, 59%) or had declined (n=5, 13%), stopped (n=6, 15%), or
124 been assessed as ineligible (n=5, 13%) for PrEP. PrEP users included those who took PrEP daily,
125 event-based or both ways. They ranged in age from 20-72 years with just over half (n=21, 54%)
126 between 25-34 years. All self-identified as gay or bisexual men, the majority of whom (n=34, 87%)
127 were cisgender. Almost all were of 'White British' (n=31, 80%) or 'Other White' (n=7, 18%)
128 ethnicity. Two thirds had a university degree (n=26, 67%) and the majority were in employment
129 (n=34, 87%). The patient areas of residence reflected a mix of relative affluence and deprivation
130 although the most (n=5, 16.7%) and least (n=3, 10%) deprived quintiles (according to Scottish
131 Index of Multiple Deprivation (SIMD), which divides areas into five subgroups according to the
132 extent to which an area is "deprived" (18)) were under-represented and patients predominantly
133 resided in the middle three quintiles (73%) (data missing for 9 participants). Healthcare
134 professionals were all involved in PrEP implementation in a mix of rural (n=12, 22%), semi-
135 rural/urban (n=8, 15%), or urban (n=34, 63%) settings, largely reflecting the wider Scottish
136 population distribution. They included specialist sexual health doctors and nurses of various
137 grades, some with national PrEP roles, PrEP prescribing general practitioners (who prescribed
138 PrEP on the Scottish islands), health promotion officers, a midwife, and a clinical secretary
139 responsible for PrEP-related administration. NGO service users were all of Black African ethnicity,
140 predominantly cis-gender women, and not using PrEP.

141

142 *Recruitment*

143 Healthcare professionals offered patients the opportunity to take part in the study during routine
144 consultations taking place in four of the 14 regional health boards (responsible for the protection
145 and improvement of their population's health) providing over 90% of PrEP related care in Scotland.
146 NGO service users who were either engaged with NGOs *and* attending sexual health clinics
147 (classed as patients above) or only engaged with NGO services (classed as NGO service users
148 above) were invited to participate via interactions with NGO staff. We recruited these and other
149 NGO staff and healthcare professionals across all of Scotland's 14 regional health boards by email
150 invitation.

151

152 *Procedure*

153 All participants provided informed verbal or written consent immediately prior to the interviews
154 /group discussions. We collected data with the aid of a topic guide that included open-ended
155 questions designed to explore participants' experiences and perceptions of uptake and initiation of
156 PrEP, rather than questions based on any theoretical concepts anticipated to influence
157 implementation. Where possible within the group discussions, dialogue between participants was
158 encouraged rather than between facilitators and participants. All participants talked from their own
159 and others' perspectives. Patients were offered a £30 shopping voucher as reimbursement for their
160 time.

161

162 Data collection was led by JM, with input from experienced qualitative researchers, PF, IY, and JF.
163 JM, PF, IY, and JF reviewed and discussed early transcripts for quality assurance purposes. All
164 interviews and group discussions were audio recorded, transcribed verbatim, anonymised, and
165 imported into NVivo software for analysis.

166

167 **Data analysis**

168 Stage 1

169 *Research Question 1: Within PrEP care pathways where exactly should we intervene (priority*
170 *areas) to optimise uptake and initiation?*

171 Firstly, we used the Action, Actor, Context, Target, Time framework (19) to conceptualise the
172 sequential actors, actions, settings, and processes that constituted PrEP uptake and initiation.
173 Secondly, we iteratively created a series of visualisations of the overall behavioural system of PrEP
174 uptake and initiation using available UK guidance on best clinical practice in PrEP provision (12)
175 and transcripts of early interviews and group discussions. Thirdly, we comprehensively assessed
176 the breadth and depth of data relating to the patient pathway through PrEP uptake and initiation.
177 Finally, we (PF, JM) ranked the most important areas which were considered to be amenable to
178 change to create priority areas for intervention. Then research team members with real-world
179 clinical experience of providing PrEP services in assorted settings (CSE, RN, JS) provided further
180 input resulting in the identification of nine final priority areas for recommendation development.

181

182 *Research Question 2: What are the barriers and facilitators to implementing the priority areas for*
183 *PrEP uptake and initiation?*

184 We (JM and PF) conducted deductive thematic analysis (20) of the qualitative data concerning
185 barriers and facilitators for each priority area. We used the relative frequency of barriers and
186 facilitators to manage the volume of findings and to ensure we focussed only on those that were
187 deemed most important. This stage ended with the identification of the major barriers and
188 facilitators for the priority areas.

189

190 Stage 2

191 *Research question 3: Which evidence-based and theoretically informed recommendations could*
192 *improve PrEP uptake and initiation?*

193 We treated each of the priority areas independently and analysed each separately. Firstly, we
194 entered the key barriers and facilitators into a matrix. Secondly, we used the Behaviour Change

195 Wheel (BCW) approach (21), and systematically coded the key barriers and facilitators for each
196 priority area using the Theoretical Domains Framework (TDF) (22). Finally, we specified
197 corresponding Intervention Functions (broad ways of intervening relevant to the theoretical
198 domains) and used the Behaviour Change Technique (BCT) and corresponding Taxonomy
199 (BCTTv1) (23) to describe, in detail and using a standardised language, potential intervention
200 content that may be helpful to operationalise the Intervention Functions, address key barriers and
201 facilitators, and enhance future PrEP implementation. This created an initial “long-list” of
202 recommendations. The cluster of related-approaches used here (BCW, TDF, BCTTv1) stem from
203 the intersection of the behavioural and implementation sciences. Each approach was developed
204 from the systematic syntheses of multiple prior concepts, constructs and theories and the use of
205 consensus-building amongst interdisciplinary behaviour change and implementation science
206 experts. These approaches can be thought of as offering ‘meta-perspectives’ within behavioural
207 and implementation research and provide a systematic process for, and a standardised language
208 to describe, the development of interventions (i.e., BCW), the theoretical influences on behaviour
209 (i.e., TDF) and the particular techniques used to change behaviour (BCTTv1). All coding and
210 drafting of recommendations were completed by JM and double-checked for accuracy, validity, and
211 credibility by PF. Any disagreements were discussed until consensus was reached.

212

213 Finally, clinical expert team members (CE, RN, JS) scrutinised, sense-checked, and shortlisted the
214 long list of initial recommendations using the APEASE criteria (24). This resulted in the introduction
215 of some new recommendations, in addition to minor amendments to or merging/deleting of existing
216 recommendations.

217

218 **Ethical considerations**

219 The Glasgow Caledonian University Research Ethics Committee (HLS/NCH/17/037,
220 HLS/NCH/17/038, HLS/NCH/17/044) and the South East Scotland National Health Service
221 Research Ethics Committee (18/SS/0075, R&D GN18HS368) provided ethical approval.

222

223 **Results**

224 *Research Question 1: Within PrEP care pathways where exactly should we intervene (priority*
225 *areas) to optimise uptake and initiation?*

226 Nine priority areas for intervention (black) were identified from the wider range of potential areas of
227 focus (Figure 1). Each potential area forms part of a typical patient pathway at the start of PrEP care.
228 The priority areas involve two actors (sexual healthcare professionals (HCPs) and potential PrEP
229 users (patients)).

230

231 *Research Question 2: What were the barriers and facilitators to optimising implementation within*
232 *these priority areas?*

233 In general, facilitators to implementing the priority areas in one service directly matched
234 corresponding barriers in others (Table 1). Even before systematically generating
235 recommendations, the analysis began to directly highlight useful lessons learned about
236 implementation.

237

238 Here we provide a brief narrative overviewing the details in Table 1 for each of the nine priority
239 areas along with indicative quotations from participants for context.

240

241 [1] Engaging HCPs with PrEP as an HIV prevention approach:

242 Whilst structural issues related to capacity within the sector, "*We're having to squeeze this*
243 *extra work into the same resource.*" (HCP), psychosocial issues encompassed factors such
244 as staff attitudes. Facilitators included collegiality, peer-fostered support, and the use of
245 existing networks to actively share innovation.

246 *"We were all able to share things like protocols, and how we were all working...so*
247 *that nurses will be able to prescribe. These are all things that are being worked on*
248 *together, so that each health board doesn't need to do things individually, and I think*
249 *that helped hugely."* (HCP)

250

251 [2] PrEP users accurately reporting their own HIV risk behaviour and/or other factors placing them
252 at higher risk of HIV acquisition:

253 Several psychosocial issues were identified including the importance of sexual and sexual health
254 literacy and expectations of staff being approachable and non-judgmental.

255 *“There’s a moral judgement that comes with clinical risk assessment, and patients*
256 *can pick up on that, and they pick up on it really, really quickly, and that just wrecks a*
257 *patient’s consultation.” (HCP)*

258 *“It’s a question of just listening a little bit more. Not having a dismissive attitude. I*
259 *think everybody likes to be listened to. And it’s really important, when people, even if*
260 *they are speaking with an accent, to try and listen, and try to understand where they*
261 *are coming from.” (NGO staff working with Black African communities)*

262

263 [3] HCPs correctly identifying PrEP candidates:

264 HCPs were comfortable raising PrEP with GBMSM but experienced difficulties with women and
265 some minoritised groups. This was partly because HCPs felt that the PrEP eligibility criteria (12)
266 aligned with question areas they would not necessarily ask non-GBMSM.

267 *“Through years of experience. I make it [assessing GBMSM patients’ HIV risk] so*
268 *matter of fact as if it’s conversation and I think a lot of my colleagues do the same.”*
269 *(HCP)*

270 However, supportive IT systems, which highlighted eligibility criteria were felt to facilitate PrEP
271 conversations.

272

273 [4] HCP determining the safety of prescribing:

274 Issues such as familiarity with HIV medication, training and peer support were important.

275 *"It's definitely a learning process. Experience, really, and the more exposure to it*
276 *[PrEP] has definitely changed the way that I think, and assess people. And what the*
277 *follow-up is as well."* (HCP)

278

279 [5] Communicating eligibility decisions:

280 Knowledge, skills and experience were key.

281 *"I think that terminology makes patients really angry. And I think that is probably one*
282 *of the biggest problems, is telling people, you're 'not eligible'. I think that people*
283 *really don't like being told that."* (HCP)

284 *"It's not that you're making that decision, so I would sit with the guidelines and go*
285 *through them one by one with like the criteria, and go through them and say 'you*
286 *don't fit any of them'."* (HCP)

287

288 [6] Patients taking up the offer of PrEP:

289 The way HCP present choices around PrEP was important, as were the beliefs of others (e.g.,
290 peers, partners) and PrEP users' own beliefs about PrEP efficacy and the perceived
291 consequences of PrEP.

292 *"I think her words were, have you thought about PrEP? She [doctor] sort of prompted*
293 *it, prompted the conversation but didn't push it and then I continued the*
294 *conversation."* (PrEP user)

295 *"He [clinic nurse] was kind of telling me about all the good things about PrEP, but I*
296 *wasn't...I don't know. I didn't want to buy it, if this is a phrase, because he was*
297 *almost saying that it's the best thing ever, because he was using it, he was using it*
298 *and he told me that. So, I don't know, I kind of stopped using the [clinic]."* (PrEP user)

299

300 [7] HCPs adequately explaining the different PrEP regimens:

301 Some staff struggled because of their lack of experience with on-demand dosing in particular.

302 *“I don’t know how good I would be if they were saying so I’m going to have sex on a*
303 *Saturday and then I’m going to have sex on a Thursday, when do I actually start and*
304 *stop it, you know? So, it’s case-by-case and I probably still need to refresh my*
305 *memory a little bit and read up a bit on that still if I was doing that because most of*
306 *the people are just taking it every day.” (HCP)*

307

308 [8] Potential PrEP users choosing their preferred regimen:

309 The importance of choosing a dosing regimen that was tailored to their life circumstances was felt
310 to be key.

311 *“It has to be based on their reality. So some men think event based dosing will never be for*
312 *them. It’ll never work for them. And then when you actually unpick, oh actually you’re right.*
313 *The only time I really have sex is when I go out on a Friday night. And we’re saying, well*
314 *you could prepare for that.” (HCP)*

315

316 [9] Potential PrEP users getting their first prescription:

317 The practicalities of where PrEP was dispensed were particularly important.

318 *“It [hospital pharmacy] is not the easiest place to get to if you don’t have your own*
319 *transport.” (HCP)*

320

321 *Research Question 3: Which evidence-based and theoretically informed recommendations should*
322 *improve future PrEP uptake and initiation?*

323 Analysis of the main barriers and facilitators to each priority area enabled us to systematically
324 theorise what was working well in relation to implementation, and also what was not. We were then
325 able to formulate specific tailored recommendations to enhance the future implementation of each
326 of the priority areas in both general terms (Intervention Functions) and highly specific terms

327 (operationalised BCTTV1s) (Table 2). Full details of our underpinning analysis are provided within
328 supplementary files.

329

330 **Discussion**

331 Complex multi-levelled factors shaped PrEP implementation. Nine specific areas of the PrEP care
332 cascade involved in uptake and initiation of PrEP were both amenable to change and prioritised for
333 improvement. The corresponding barriers and facilitators were multi-levelled and interdependent.
334 Many were psychosocial, relating directly to the way staff or patients thought and felt; others
335 related to the organisation of services, wider issues of access to support and training, and factors
336 relating to the environmental infra-structure of services. Using tools from implementation science,
337 we systematically generated highly specific, theoretically informed and evidence-based ways of
338 optimising PrEP implementation in the future. Examples include: provision of PrEP in diverse
339 settings to reach all in need; co-produced, culturally sensitive training resources for healthcare
340 professionals, with focused content on non-daily dosing (25,26); meaningful collaborative working
341 across all stakeholders.

342

343 To date, several attempts have been made to conceptualise the implementation of PrEP but these
344 have been largely broad and descriptive, typically categorising the whole of PrEP care into four or
345 five large steps within a continuous, linear care cascade (27-30). Published studies have tended to
346 focus on using these high-level steps to audit or quantify PrEP implementation, seeking to identify
347 and understand key points of attrition within particular populations and associated health care
348 systems (31). There are numerous examples of PrEP prescribing guidance (15,32-33), but fewer
349 published studies specifically address the implementation of PrEP routine care pathways and
350 services. A scoping review of PrEP delivery models (34) created a comprehensive inventory of
351 existing models, but did not specifically focus on delivery of the detailed steps of the PrEP cascade
352 within the models described. A review of PrEP implementation identified multiple barriers to PrEP
353 uptake, some of which mirrored those we described (35). The authors proposed multilevel
354 interventions to target these barriers but acknowledge that proposed interventions do not always
355 align to specific barriers.

356

357 In contrast, no work to date has used conceptualisations of the care cascade as a starting point for
358 systematic, focussed service improvement whilst explicitly using theory and evidence to enhance
359 implementation. We directly addressed this gap by taking a single key step of the PrEP care
360 cascade, the uptake and initiation of PrEP, and focussed on it as an area in need of intervention
361 development to enhance future implementation. We derived recommendations (interventions)
362 directly from the barriers and facilitators at each priority area.

363

364 Some recommendations warrant additional comment. In relation to ‘engaging HCPs with PrEP as
365 an acceptable approach to HIV prevention’, we highlight the need to address both structural *and*
366 psychosocial issues. We also emphasise the importance of considering financial and other
367 resources as well as the timescale for implementation (36). These factors are likely to be central to
368 HCP engagement which in turn is central to patient uptake. We also recommend a multileveled
369 national infrastructure to promote, coordinate, and monitor HCP engagement with PrEP and
370 highlight how these structural initiatives could be bolstered by a range of local initiatives such as
371 engaging staff through local “PrEP champions”. The barriers these recommendations are designed
372 to overcome were strikingly similar to those reported in a number of studies within Pinto et al’s
373 recent review (35).

374

375 In relation to ‘potential PrEP users accurately reporting their HIV risk behaviour’, we found that
376 depending on the cultural context, it may be important to educate and persuade HCP about the
377 ‘bigger picture’ of PrEP provision (37) and overcome any residual moralism and stigma relating to
378 sex, homophobia, or racism which has also been described in other studies (35,38,39). Stigma is
379 well recognised as a potent barrier to accessing HIV testing, prevention and care (40) and it also
380 might inhibit the full disclosure of HIV acquisition risk factors such as stigmatised sexual
381 behaviours or partner numbers relevant to PrEP offer and uptake. Stigma may also apply to and
382 inhibit the taking of PrEP itself (41-44). We recommend close partnership work between sexual
383 health services, NGOs and PrEP users to enable sensitive, culturally appropriate conversations
384 around PrEP, and to help HCPs improve their cultural competencies (39,45,46). The strongly

385 supported health care and community-level “PrEP-positive” ethos described by our participants
386 seems highly appropriate (45) and would need to be extended to all settings in which PrEP may be
387 provided in the future, particularly those in which sexual health is less familiar.

388

389 Our findings suggest that the ‘PrEP eligibility criteria’ which were used by HCPs to help identify
390 people who might benefit most from PrEP (28), should be reframed and understood as needs-
391 based approaches to HIV prevention, conveying the pros and cons of PrEP so that it can be
392 extended to all who could benefit. This could largely remove the issue that criteria are less
393 sensitive for identifying people from certain groups or racial backgrounds as also reported in other
394 countries (47).

395

396 A large epidemiological analysis published after this study showed that Scottish implementation
397 models strongly favour GBMSM and have limited reach into other key vulnerable populations
398 (6,14). In parallel, the characteristics of people newly diagnosed with HIV in Scotland have
399 changed since the introduction of PrEP and now people are more likely to have acquired HIV
400 though heterosexual sex and to be non-white indigenous than in the pre-PrEP era (14,48), similar
401 to findings from Australia (49). As noted in our recommendations and by others, reaching all
402 groups that could benefit from PrEP is essential (9). Several studies provide explanations for low
403 PrEP uptake in some key vulnerable populations. Among women of colour in the UK, important
404 factors were low awareness of PrEP, feelings of stigma related to HIV itself and attending sexual
405 health clinics, and a preference for trusted community settings for discussion about HIV testing and
406 prevention (41,50). Among people who inject drugs in Scotland, awareness of PrEP was low but
407 some would find PrEP appealing if provided within familiar settings such as outreach drug services
408 (51). Very few trans people have accessed PrEP in Scotland (12). International studies suggest
409 that the need for PrEP among this group is high but important barriers to access preclude uptake
410 (42,52). Restricting PrEP provision to sexual health clinics probably deters some trans people who
411 could benefit (53). Additional or tailored recommendations to enhance PrEP uptake and initiation
412 for people from vulnerable populations are needed as evidence accrues.

413

414 We used a novel, rigorous approach to developing recommendations which is not typical of
415 approaches to enhancing implementation. The resulting recommendations are anchored in
416 evidence (like many studies) but are also uniquely theory-driven (22) and are specified using a
417 standardised language to describe intervention content in detail (i.e., Intervention Functions and
418 Behaviour Change Techniques (23)). Together they highlight the need for improving
419 implementation systemically, and at multiple levels simultaneously.

420

421 Typically, the initial stages of the PrEP care cascade involve a complex patient journey, marked by
422 setting-specific interactional dynamics and a series of interdependent joint and individual
423 behaviours. Our adoption of a behavioural lens, and the subsequent systematic development of
424 highly specific ways to enhance implementation, meant we re-conceptualised this patient journey
425 as a series of distinct and sequential behaviours.

426

427 We focussed on one national context and although findings are likely to be generalisable to similar
428 settings, it is uncertain how recommendations might apply in very different contexts. In particular,
429 as all PrEP care was free of charge, participants did not face the financial barriers reported from
430 some settings (54). Very few people in Scotland on PrEP are not GBMSM (13) and our findings
431 lack specificity for other groups. A high proportion of PrEP user participants had a university
432 qualification and while representative of those on PrEP in Scotland, the sample under-represents
433 those with lower health and PrEP literacy who may have other needs and preferences for
434 accessing PrEP care. Furthermore, the COVID-19 pandemic led to a reconfiguration of some
435 sexual health and PrEP services and our findings may be more or less relevant as a result. Our
436 evaluation took place relatively early in the PrEP programme which probably magnifies early stage
437 issues which become less important as familiarity increases.

438

439 To support individuals and populations to fully benefit from PrEP we must overcome the
440 considerable challenges of large-scale implementation (33). Here, we combined qualitative data
441 from multiple viewpoints and used multiple analytic tools to systematically detail useful insights

442 concerning uptake and initiation from the first two years of Scottish PrEP implementation. To our
443 knowledge, we present the first evidence-based and theory-informed recommendations which can
444 be used flexibly across a range of settings to improve PrEP uptake and initiation. Our findings will
445 inform future Scottish implementation of PrEP (55) and could usefully contribute to the global
446 public health priority of elimination of HIV transmission by 2030 (33,56).

447

448 **Declarations**

449 **Ethics approval and consent to participate**

450 The study received ethical approval from the Glasgow Caledonian University Research Ethics
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453

454 **Consent for publication**

455 Not applicable.

456

457 **Data Availability Statement**

458 Due to the sensitive nature of the questions asked in this study, survey respondents were assured
459 raw data would remain confidential and would not be shared.

460

461 **Conflicts of interest**

462 CSE reports research grants from National Institute of Health Research UK, Chief Scientist Office
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488

489 **Authors' contributions**

490 All authors contributed to the conception and design of the studies, interpretation of findings,
491 revision of the manuscript and approved the final version. Specific additional contributions are as
492 follows and marked where appropriate in the manuscript: CSE was principal investigator and
493 involved in all stages of the research and wrote the initial draft of the manuscript. PF
494 conceptualised the design of the process evaluation and led the behavioural analyses. JM led the
495 study day to day and undertook all research activities including data collection and analysis under
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507

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699

700 **Tables & Figures**

701 **Figure 1: Steps in the uptake and initiation of PrEP illustrating where to intervene to improve implementation.**

702 **Legend:** Shaded boxes depict areas for recommendation development. (1) HCPs engaging with PrEP as an acceptable approach
 703 to HIV prevention; (2) Potential PrEP users accurately reporting HIV risk behaviour; (3) HCPs identifying PrEP candidates based on
 704 risk of HIV acquisition; (4) HCPs determining safety of prescribing and medical suitability for PrEP; (5) HCPs communicating
 705 eligibility/ineligibility for PrEP; (6) Potential PrEP users taking up PrEP; (7) HCPs adequately explaining different PrEP regimens; (8)
 706 Potential PrEP users choosing their preferred regimen; and (9) Potential PrEP users obtaining their first PrEP prescription. Steps in
 707 clear boxes were not selected as priority areas. Pointed Boxes highlight the interactions between the steps. Connected boxes
 708 highlight the associated nature of those steps.

709

710 **Table 1: The major barriers and facilitators to each of the nine priority areas within uptake and initiation of PrEP**

Agreed priority area for intervention (i.e., recommendation development)	Key barriers	Key facilitators
1) HCPs engage with PrEP as an approach to HIV prevention	-lack of dedicated budget, pace of implementation and competing service innovations (e.g., HPV vaccination of GBMSM) -beliefs about being de-skilled by PrEP initiation due to its repetitive nature	-collegiality, team work, and peer-support fostered formal and informal networks and relationships at multiple levels -enhanced job role and job satisfaction associated with PrEP initiation reinforced the work

	<p>-moral views on PrEP, condom use, STIs and homophobic attitudes</p>	<p>-staff understood the bigger picture and understood the efficacy and cost-effectiveness of PrEP relative to care costs associated with people living with HIV.</p> <p>-staff had insight into the social and emotional consequences of HIV and PrEP for the individual</p> <p>-staff recognized the role PrEP has in bringing people whose behaviours and/or behaviours of others put them at highest risk of HIV to specialist services</p>
<p>(2) Potential PrEP users accurately report their HIV risk behaviour</p>	<p>-patient concerns over meeting eligibility criteria confounds accurate reporting</p> <p>-patient expectations of being judged by HCPs constrains accurate reporting</p> <p>-low levels of sexual, sexual health and HIV literacy make frank conversations about HIV risk very hard</p>	<p>-the very availability of PrEP enables worthwhile frank conversations about actual HIV risks</p> <p>-expectations that HCPs will be approachable, culturally sensitive and non-judgmental</p>
<p>(3) HCPs identify PrEP candidates based on risk of HIV acquisition</p>	<p>-difficulties operationalising eligibility criteria</p> <p>-there were doubts concerning veracity of patient accounts of their HIV risks (e.g., inflating their reported risk to meet eligibility criteria)</p>	<p>-they could build on prior expertise around HIV risks particularly amongst GBMSM</p> <p>-peer support and discussions about eligibility are useful and added new skills</p> <p>-longstanding competencies in communication skills around sexual/drug histories could be employed</p> <p>-beliefs that PrEP can enable open and honest disclosures of HIV risk behaviours</p>

		-supportive IT systems and documentation enable identification of PrEP candidates
(4) HCPs determine safety of prescribing and medical suitability for PrEP	<p>-HCPs worried about making the wrong decisions around prescribing and some believed that PrEP prescribing should be consultant (specialist medic)-led</p> <p>-there were limited opportunities to take up education and training</p> <p>-conflicting advice and mixed messages from senior colleagues made the situation unclear</p> <p>-prescribing PrEP was sporadic and not routine</p>	<p>-HCPs felt comfortable with prescribing given their previous experience with post exposure prophylaxis (PEP) and HIV care</p> <p>-formal and informal training and learning opportunities at local-, regional-, and national-levels were available</p> <p>-formal and informal opportunities for peer support were available (e.g., to seek advice, check and share decision-making, and discuss more medically complex cases, at local-, regional-, and national-levels)</p> <p>-frequent opportunities to prescribe PrEP and on the job experience</p> <p>-booked PrEP appointments provide the opportunity to prepare for interactions by reviewing electronic patient records</p>
(5) HCPs communicate eligibility/ineligibility for PrEP	<p>-they felt under pressure from patients to provide PrEP</p> <p>-they lacked knowledge, skills and experience to convey risk/benefits of PrEP effectively</p>	<p>-they could make explicit reference to the eligibility criteria to shape their decisions</p> <p>-they could discuss ineligibility in a positive light and use it as a teachable moment for wider HIV risk reduction</p> <p>-they could suggest self-sourcing PrEP online and the offer of monitoring within the sexual health service as an alternative to free NHS prescription</p> <p>-they can focus on risk/benefits for given individuals</p>

(6) Potential PrEP users take up offer of PrEP	<p>-they are reticent to take daily medication</p> <p>-they are put-off by the perceived health and social consequences (e.g., side effects and perceived potential reputational damage)</p> <p>-HCP are perceived to push PrEP</p> <p>-they are dubious about the effectiveness of PrEP</p>	<p>-they can tailor regimes flexibly (i.e., daily and or event based)</p> <p>-they want to take PrEP because of the perceived health and social consequences (e.g., HIV risks and better sex)</p> <p>-PrEP use is reinforced by significant others (peers, partners, friends)</p> <p>-HCPs provide a balanced narrative and enable informed tailored choices around PrEP</p> <p>-they are confident in the efficacy of PrEP</p>
(7) HCPs explain the different PrEP regimens	<p>-they lack familiarity with on-demand dosing</p>	<p>-they can use information booklets and illustrations to show how to follow on-demand dosing to structure conversations</p>
(8) Potential PrEP users choose their preferred regimen	<p>-HCPs offer limited dosing regimens not suited to patients' life circumstances</p>	<p>-HCPs offer a range of appropriate regimen choices in a balanced manner</p> <p>-there is considerable information of PrEP dosing available on-line</p>
(9) Potential PrEP users get their first PrEP prescription	<p>-there are delays to starting PrEP whilst waiting for baseline HIV test results</p> <p>-PrEP is only available through off-site dispensing</p>	<p>-there is on-site dispensing</p>

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713 **Table 2: Specific recommendations to improve the implementation of uptake and initiation using the Behaviour**
714 **Change Wheel approach, incorporating Behaviour Change Techniques**

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Agreed priority area for intervention (i.e., recommendation development)	Key recommendations to enhance the implementation of uptake and initiation (Numbers in brackets relate to the BCT from the BCTTv1)
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<p>1) HCPs engage with PrEP as an approach to HIV prevention</p>	<p>1.1 Ensure those that fund sexual health services provide the resource to match the costs of the programme</p> <p>1.2 Ensure a realistic timescale for PrEP implementation that allows for critical planning activities, such as estimating the likely demand for PrEP, conducting a full service review to determine capacity and how PrEP will fit into existing practices, and working in partnership across the whole HIV sector to develop and deliver an ‘official’ national PrEP training package (9.1), including examples of how to deliver PrEP services (4.1, 6.1), to prepare the workforce (12.1, 12.2). Such training should also focus on enhancing the cultural competencies of all staff to work with diverse communities (4.1, 6.1, 8.1, 2.2)</p> <p>1.3 Ensure a multileveled national infrastructure has a clear remit to promote, coordinate, and monitor HCP engagement with PrEP (12.2, 2.1)</p> <p>1.4 In the early stages of PrEP roll-out, national PrEP coordination groups and local PrEP leaders should organise shared learning events and ensure formal and informal peer support systems are in place (e.g., real-time/email support from senior staff, team meetings, ‘phone a friend’, clinical network arrangements) to strengthen working relationships among HCPs (12.2, 3.1, 3.2, 6.2)</p> <p>1.5 Use local, regional, and national infrastructures to foster a team-oriented, ‘open-source’ approach to PrEP-related work (e.g., share protocols, training materials, service innovations and adaptations, insights into how to engage HCPs with PrEP) (12.2, 3.1, 3.2, 6.1, 6.2)</p> <p>1.6 Identify HCPs with a strong belief in and commitment to PrEP to act as local champions and inspire and engage other HCPs with PrEP (12.2)</p> <p>1.7 Educate HCPs on the economic and wider benefits and value of PrEP for the healthcare system, local sexual health services, communities, and individual clients, for example, by informing of the positive health, cost/ financial, service engagement, social, and emotional impacts of PrEP (e.g., talks from leading clinicians in favour of PrEP, positive testimonials of PrEP users) (5.1, 5.3, 5.6, 9.1)</p>
<p>(2) Potential PrEP users accurately report their HIV risk behaviour</p>	<p>2.1 Sexual health services could ask NGO staff who have high levels of cultural competency in delivering sexual health promotion interventions to Black Africans, trans people, and cis women to share their tailored vocabularies and co-produce a stock of key phrases and scenarios to enable HCPs to sensitively probe clients when taking a sexual/ drug history (4.1, 6.1, 7.1)</p>

	<p>2.2 Ensure HCPs are educated (5.1), trained (4.1, 6.1, 8.1, 8.7), and appraised in their skills (2.2) in explaining the risk-benefit of PrEP and mandate this activity in a formal protocol (4.1, 5.1)</p> <p>2.3 Ensure PrEP information and communications (e.g., sexual health service and NGO staff-client interactions, national patient information booklets, sexual health service, NGO, and HIV/PrEP activists' websites and social media, marketing campaigns) avoid using the term 'eligibility criteria' and instead adopt 'needs-based' terminology that explicitly conveys the risks and benefits of PrEP (5.1, 13.2)</p> <p>2.4 HCPs should actively promote PrEP to clients as one of several sexual health promotion methods (5.1) and emphasise their own and other experts and credible sources' support for it (e.g., government, public health agencies, NGO staff) (9.1)</p> <p>2.5 Facilitate and maintain (e.g., via training, clinical supervision, reflective practice) a warm, welcoming, and friendly atmosphere wherein HCPs communicate with clients in a non-judgemental manner, using active listening and inclusive, sex- and PrEP-positive, and destigmatising language to establish trust and ensure an open dialogue (12.2, 5.3)</p>
<p>(3) HCPs identify PrEP candidates based on risk of HIV acquisition</p>	<p>3.1 Ensure PrEP information and communications (e.g., sexual health service and NGO staff-client interactions, national patient information booklets, sexual health service, NGO, and HIV/PrEP activists' websites and social media, marketing campaigns) avoid using the term 'eligibility criteria' and instead adopt 'needs-based' terminology that explicitly conveys the risks and benefits of PrEP (5.1, 13.2)</p> <p>3.2 Adopt a protocolled approach to PrEP that includes advice (e.g., clear statements and nuanced examples) regarding the eligibility criteria (4.1, 13.2)</p> <p>3.3 Ensure HCPs maintain their knowledge of the HIV risks among different groups, and skills in conducting culturally sensitive clinical risk assessments (e.g., ongoing professional development, clinical supervision) (5.1, 2.2, 2.3, 8.1)</p> <p>3.4 Ensure a range of peer-support systems are in place (e.g., real-time/email support, team meetings, 'phone a friend', clinical network arrangements) to assist HCPs in making complex eligibility decisions (12.2, 3.1, 3.2, 6.2)</p> <p>3.5 HCPs should actively but sensitively promote PrEP to clients as a method for HIV prevention (5.1) and emphasise their own and other experts and credible sources' support for it (e.g., government, public health agencies, NGO staff) (9.1) so clients feel comfortable to disclose their HIV risks</p>

<p>(4) HCPs determine safety of prescribing and medical suitability for PrEP</p>	<p>4.1 Produce national guidelines to promote and instruct HCPs on safe prescribing of and medical suitability for PrEP, review and update the guidelines to reflect new information and lessons learned over time (5.1, 4.1)</p> <p>4.2 Use national infrastructure to facilitate discussion among senior clinicians and reach a consensus on best practice for a range of scenarios to promote consistency in decisions on the safety of prescribing and medical suitability for PrEP (12.2, 3.1. 3.2)</p> <p>4.3 Ensure HCPs are educated about PrEP via a comprehensive and ongoing training package that covers HIV testing, the HIV window period, and risk of antiretroviral resistance, common side-effects and their typically transient nature, the likelihood of toxic effects and role of monitoring to prevent long-term issues, and contraindications (5.1)</p> <p>4.4 Ensure there are formal and informal peer-support systems at local-, regional-, and national-level (e.g., real-time/email support, team meetings, 'phone a friend', clinical network arrangements) to assist HCPs in making complex decisions on medical suitability for PrEP (12.2, 3.1, 3.2, 6.2)</p> <p>4.5 Demystify PrEP and build HCPs confidence by presenting PrEP as a drug that can be prescribed by any qualified prescriber or supplied via agreed protocols (e.g., PGD) within sexual health service settings (13.2)</p> <p>4.6 National coordinated PrEP training should include inter-disciplinary online PrEP learning resources for HCPs which can be broken down into short modules on specific topics (e.g., covering safe prescribing of and medical suitability for PrEP) and spread out over a period of time (5.1, 4.1). These could be aligned with professional development for many job roles (12.2)</p> <p>4.7 Introduce a shadowing scheme across different sexual health services to enable HCPs from services with few PrEP users to become familiar with PrEP processes, including ensuring safe prescribing of and medical suitability for PrEP (12.2, 6.1)</p> <p>4.8 Train HCPs on how to conduct adequate assessments of any underlying health conditions and interpret the results of new tests required to establish medical suitability for PrEP (4.1, 6.1), share example cases for HCPs to discuss and work through (8.1, 8.7), provide feedback (2.2), and allow opportunities for ongoing reflections on skill acquisition (2.3)</p>
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	<p>4.9 Inform HCPs that they can easily access up-to-date and evidence-based online information on interactions between PrEP and other drugs (e.g., www.hiv-druginteractions.org) (4.1)</p>
<p>(5) HCPs communicate eligibility/ineligibility for PrEP</p>	<p>5.1 Adopt a protocolled approach to PrEP that includes advice (e.g., clear statements and nuanced examples) regarding the eligibility criteria (4.1, 13.2)</p> <p>5.2 Throughout PrEP provision and promotion (e.g., during HCP and NGO staff-client interactions, in national patient information booklets, on sexual health service, NGO, and HIV/ PrEP activists' websites and social media, in marketing campaigns) avoid using the term 'eligibility criteria' and instead adopt 'needs-based' terminology that explicitly conveys PrEP decisions as a function of the individual risk-benefit of PrEP for each client (12.2, 13.2)</p> <p>5.3 Ensure HCPs are educated, trained, and appraised in their skills in discussing the risks and benefits of PrEP (e.g., through online modules, peer support, clinical supervision), for example, by giving information on PrEP health consequences (5.1), producing a 'how to' script for common PrEP scenarios based on the lessons learned of SHCPs with general medicine expertise (4.1, 7.1), and providing opportunities to shadow (6.1), practice with (8.1, 8.7), and receive feedback (2.2) from more experienced HCPs</p> <p>5.4 HCPs should reassure clients that they are at low risk for HIV by educating them (e.g., verbally, directing to reputable websites) on the facts of HIV transmission and effectiveness of alternative sexual health promotion methods (5.1)</p> <p>5.5 HCPs need to be aware of the option to self-source PrEP and could consider directing clients who do not meet the eligibility criteria but would still like to access PrEP to reputable online sources of information about where to buy PrEP (e.g., provision of national patient information booklets, signpost to appropriate websites (3.1)</p> <p>5.6 HCPs should explore the root cause(s) of HIV-related anxieties among clients who do not have an identified need for PrEP and work with them to problem solve solutions (1.2)</p>
<p>(6) Potential PrEP users take up of PrEP</p>	<p>6.1 All sectors involved in PrEP should consider a range of approaches (e.g., via HCP-/NGO-client interactions, sexual health service, NGO, and HIV/PrEP activists' websites and social media, national patient information booklets, marketing campaigns) to: normalise PrEP by drawing parallels to the use of daily preventive medicine in other areas of health (e.g., contraceptive pill to protect against pregnancy, blood thinners to reduce the risk of heart attack and stroke) (13.2); and educate</p>

	<p>potential PrEP users on the flexibility of PrEP by informing them of the idea of ‘seasons of risk’ (i.e., unlikely to be on PrEP forever, can start and stop as circumstances dictate) and the various dosing options (i.e., can opt for less intensive on-demand dosing, if appropriate) (5.1, 13.2)</p> <p>6.2 HCPs should draw on research evidence and what they know about other patients’ decision-making and experiences to inform patients of the health, social, and emotional benefits of PrEP (5.1, 5.3, 5.6, 16.3) but also stress that PrEP is a choice and discuss the pros and cons of taking up PrEP compared to not taking up PrEP with respect to clients’ individual interests (9.2)</p> <p>6.3 HCPs should educate clients about the potential side-effects of PrEP and their typically transient nature (5.1), share management strategies for the most common side-effects (1.2), and reassure against concerns about longer-term toxic effects by drawing attention to the tests undertaken at regular reviews (5.1)</p> <p>6.4 Co-produced PrEP information and communications (e.g., HCP-/NGO staff-client interactions, national patient information booklets, sexual health service, NGO, and HIV/PrEP websites and social media, posters in sexual health service and NGO settings, marketing campaigns) should provide an accessible, scientific explanation of what PrEP does (i.e., how it works inside the body) and describe PrEP efficacy and safety with reference to key research and ‘real world’ studies and regional or national HIV incidence data (5.1, 9.1)</p>
<p>(7) HCPs explain the different PrEP regimens</p>	<p>7.1 Use a variety of ways to educate HCPs about on-demand dosing (4.1) and assist them during consultations (7.1). For example:</p> <ul style="list-style-type: none"> • Develop a range of resources (e.g., brief fact sheet, PrEP provider pocket guide, national patient information booklets) with clear written instructions and diagrams that depict how to take PrEP on-demand, including examples of when to start and stop for various scenarios, which can be used to educate HCPs (4.1) and assist them during consultations (7.1). Such resources should ideally be co-produced by a range of diverse organisations and the communities who will use them) • Provide HCPs with laminated copies of the on-demand dosing diagrams that they can pin to their wall as a quick reminder of how to take PrEP on-demand (4.1, 7.1) • Record a short video or soundbite that explains on-demand dosing for different scenarios that HCPs may watch or listen to at a future date (4.1)

	<ul style="list-style-type: none"> • Include an online or paper-based quiz with questions about on-demand dosing as part of HCPs PrEP training and ongoing professional development and ensure that there is opportunity to discuss answers (2.7)
(8) Potential PrEP users choose their preferred regimen	<p>8.1 HCPs should inform clients of their options for how to take PrEP by way of a balanced narrative (5.1) and then jointly, with each individual client, facilitate a decisional balance weighing up the pros and cons per option, taking into account lifestyle and/or the availability of evidence to support it (i.e., dependent on gender and whether oral, anal, or vaginal/frontal sex) (9.2)</p> <p>8.2 HCPs and NGO staff could direct clients to reputable online sources of information on the various ways to take PrEP (e.g., sexual health service, NGO, and HIV/PrEP activists' websites and social media) (3.1, 9.1) in addition to the information they provide (e.g., verbally, via provision of national patient information booklet)</p>
(9) Potential PrEP users get their first PrEP prescription	<p>9.1 Ensure services establish a PrEP supply chain (12.2) and maintaining agreed stock levels (12.5) to enable HCPs to dispense PrEP as soon as possible</p> <p>9.2 Work with pharmacy leads to extend the role of community pharmacists to enable clients to obtain PrEP via a range of settings (12.1)</p>

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Legend: Full details of our underpinning analysis are provided within supplementary files. Details of the operationalisation of Behaviour Change Techniques are shown in brackets.