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Chapter 7: Implementation Science or 'Show' Trial?: England's PrEP Impact study

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Abstract

England's PrEP Impact Trial ran between 2017 and 2020. This chapter centres first on the policy events that first gave rise to the trial underpinned the trial's genesis. Interviews with key stakeholders demonstrate that rather than achieving its aims as practical implementation trial that might have enabled and shared learning on the best ways to roll out PrEP, instead the Impact trial was designed and maintained as a 'show trial' to help manage a policy and financial impasse. Those interviewed tended to observe that because Impact's power dynamics were rooted in traditional hierarchies about the production of evidence, this undermined its use as anything more than a stop-gap. Ultimately, rather than enabling the sharing of lessons for those planning the immanent launch of England's future PrEP services, this trial's legacy will instead be largely about the divisions and inequalities that it has exacerbated.

7.1 Introduction

The efficacy and effectiveness of Pre Exposure Prophylaxis (PrEP) was first established globally through successive randomised (Molina et al. 2015; Grant et al. 2010) and non-randomised trials (McCormack et al. 2016) focussed primarily on its capacity to reduce the risk of sexual transmission among men who have sex with men. Alongside the development of HIV Treatment as Prevention over the past two decades, this work has underpinned a triumphal global narrative about how preventive uses of HIV antiretroviral treatments would mean new HIV infections would soon be a thing of the past. However, just as we witnessed

with the introduction of HIV antiretroviral treatment in the 1990s, evidence that PrEP worked did not mean that accessible services would be implemented to reach all those in need.

This chapter focuses on how PrEP policy in England has played out vis-à-vis the launch of England's PrEP Impact trial in 2017 as the world's 'largest single PrEP implementation trial'. It purportedly aimed to address 'significant outstanding implementation questions that should be answered prior to using PrEP in a sustained way on a substantial scale in England' (NHS England 2016). These included: understanding how many sexual health clinic attendees need PrEP, willingness to take it, and duration – in order to inform an orderly roll-out of PrEP services in England (Public Health England and Chelsea and Westminster Hospital NHS Foundation Trust 2020). On paper, the PrEP Impact Trial existed in order to provide answers about how to best provide PrEP through England's health service, by filling an apparent gap between existing scientific knowledge and practical application.

Behind the scenes, however, there were other reasons for the initiation of the Impact trial: the trial rhetoric offered an expedient, low cost solution to a political deadlock. This chapter offers first-hand insights into these backstage processes, revealing how the questionable motives of the PrEP Impact trial have resulted in troubling contradictions throughout its progress, which themselves create challenging implications for future PrEP policy in England.

7.2 Trials and tribulations

Social scientists of medicine have pointed to profound challenges arising from a knowledge hierarchy that has prioritised the randomised control trial (RCT) as the pinnacle of acceptable health evidence-making (Wahlberg and McGoey 2007; Deaton and Cartwright 2018). This critique argues that the persistence of RCTs as the 'gold standard' of knowledge creation fails to recognise the ways in which strictly standardised conditions silence the complex social dynamics within which all health technologies are ultimately embedded. HIV provides exemplary evidence to support this critique, given the widely demonstrated inadequacy of focussing disproportionately on the outcomes of experimental research regimes to address an epidemic defined by its complex and particularised social, political, moral and economic disparities (Fassin 2007; Kingori and Sariola 2015; Kippax and Stephenson 2016; Camlin and Seeley 2018). This body of work closely examines how 'evidence' and its mode of

production often becomes entrenched in systems designed to protect and benefit the interests of those organising the trial, at the cost of producing meaningful learning outcomes. As such, the HIV response has been profoundly impacted by biomedicalisation that renders the 'social issues (both carried and revealed by AIDS) practically inexpressible' (Fassin 2007 p. 189).

In response to these critiques of knowledge production, the emergent field of *implementation science* might appear to be a remedy. Implementation research is meant to examine how new interventions or technologies that proved efficacious in the controlled setting of the RCT might be made effective in 'real world' contexts. 'The basic intent of implementation research is to understand not only what is and isn't working, but how and why implementation is going right or wrong, and testing approaches to improve it' (Peters et al. 2013). This kind of approach is meant to pick up on contextual cues (including process issues, but also social inhibitors) which can then be acted upon in real time through pragmatic research design. Therefore, good implementation research is intended to be reliant upon open and iterative learning with rich data collected from stakeholders and users across the life of the project with regard not only to medical technologies, but also the messier processes and procedures of access and activation which are impacted by social interaction, diverse cultures of expectation and exchange, systems of meaning and structures of inequality.

However, the PrEP Impact Trial was not designed in a way that could enable it to promote this sort of advance through iterative learning. Perhaps this is because practitioners of implementation science can find it difficult to escape the habits of power and control that are embedded in the scientific knowledge hierarchy. In addition, these habits may have become entrenched as the trial practitioners sought to obliviate the trial's own genesis, given it was hastily developed to resolve a financial impasse between key health policy agencies. It could also be the case that the trial was simply a means of rationing access to the costly medicines being used for PrEP (at a time when they were still under patent), while funding for sexual health services across England simultaneously faced serious decline (Nagington and Sandset 2020). In examining these possibilities, this study provides evidence that the PrEP Impact trial was less an implementation trial and more of a 'show trial', a term traditionally associated with criminal or political trials that are arranged to satisfy public demands or purge opposition, rather than to achieve its nominal purpose.

7.3 Methods

Using my longstanding network of professional HIV contacts in England, I generated an opportunistic (and subsequently snowballed) list of key stakeholders to invite for interview between May and August 2019 near the mid-point of the Impact trial. I knew many across years of working relationships, including membership of United4PrEP - an activist coalition demanding government provision of PrEP. I am therefore embedded in the processes that I am analysing.

Table 7.1 Roles of potential and actual study participants

Role Description	**Invited (n=)**	**Interviewed (n=)**
Clinician/IMPACT trialist	4	1
Community activist/organiser/HIV organisation (paid and unpaid)	14	10
Public Health England (PHE) staff	4	0
Local Authority staff/elected council member	7	2
NHS England (NHSE) staff	2	0
Other	2	0
Total	33	13

The invitation to take part was emailed by a research administrator, and included information explaining the aim of undertaking a policy analysis of the Impact's political and social context. Those who agreed to take part included: key PrEP activists some of whom had paid roles connected to PrEP activism, and others who did not (including those representing women, people in the sex work industry and Black African heterosexuals); senior staff in national and local HIV organisations; and Local Authority commissioners of sexual health services. Many study participants were members of the trial's Community Advisory Board, alongside one member of the trial's Programme Oversight Board. Trial clinicians and PHE/NHSE staff were invited to take part but almost universally declined, saying things like: "Sharing personal views at this point could place me in a conflicted position." In addition, as fieldwork got underway, tensions had been reignited between NHSE and Local Authorities regarding proposals to expand the trial, making it a "sensitive time" according to a further invitee. While interviews with more clinical and health infrastructure stakeholders may have

provided wider perspectives, the data from this sample offer sharp, front-line insights into the drivers and responses to PrEP policy in England unavailable elsewhere. Although it is important to acknowledge the limited account afforded by these data, the acute reticence among particular groups to engage in the study indicates why investigating this trial in light of its political and social contexts (rather than from a hegemonic, scientific perspective) is essential. The matter of anonymisation was initially left open so that participants could exercise a choice to be named – however, as it turned out, very few wanted to be named, so the decision has been taken to anonymise all quotes. This study was granted ethical approval by the School for Policy Studies' Ethics Committee at the University of Bristol.

7.4 Why was a 'show' trial needed?

Following the earliest efficacy studies that showed PrEP worked, a wide array of volunteer PrEP activists self-organised, finding unique ways to disseminate unbiased information and to strategically build demand for public provision. These efforts were particularly notable among those working in sex industries, within networks of gay men, and among others with a particular stake in preventing HIV. A working group on PrEP had already been established by the National Health Service in England (NHSE) as early as September 2014 to work out costings and service design in anticipation of the results from the PROUD trial. So the focus of all of these volunteer efforts from many quarters was to provide information and support to help meet an interim gap in reliable information sources, to sustain support for public provision, and to support those who were already privately buying PrEP online[1].

There was therefore a universal expectation among all stakeholders that national roll-out would take place as soon as England's own PROUD trial had concluded. However, on 21 March 2016 NHSE made a surprise announcement that commissioning PrEP was outside its powers. They argued that because the 2012 Health and Social Care Act had conferred responsibility on England's 343 elected Local Authorities (comprising boroughs, counties and municipalities) for public health services, NHSE said they were not in a legal position to take responsibility for PrEP provision. This policy backdrop set the stage for a serious impasse between Local Authorities and NHSE over who was responsible for considering

[1] Notable organisations involved nationally and internationally include: Porn4Prep, I Want PrEP Now, Prepster ActUp London, Sophia Forum and United4PrEP.

provision of these costly medicines which remained under patent, and their associated clinical services – for the purposes of HIV prevention. It was a conflict that once again enabled a space for divergent accounts of morality to be debated in public, academic and policy narratives, frequently playing on supposed uncertainties in the PrEP evidence base (Sandset and Wieringa, 2019).

The National AIDS Trust took NHSE to court, and NHSE's refusal to consider PrEP funding was overturned on appeal (Azad et al. 2018). However, this 'victory' was rapidly followed by defeat when, in late 2016, NHSE's annual review of treatments needing specialised commissioning did not approve PrEP. Thus, despite widespread clinical and community agreement that PrEP would play an important role in HIV prevention in England, the funding impasse remained. The PrEP Impact trial emerged as means of temporarily resolving uncertainty about whether any publicly funded PrEP could be accessed by those who needed it. Participants in my research overwhelmingly and independently identified that the trial was primarily set up to enable the legal use of generic formulations of medications (tenofovir and emtricitabine) rather than patented Truvada, thereby reducing PrEP's costs.

> [the decision to run the Impact study was driven by] the impact of budget. And it was the expedient way to deliver this innovation, umm…within a budget they could manage. Doing it under the umbrella of a research project allowed them to use generic drugs, which obviously is a fraction of the price of the real PrEP, and therefore allowed them to enrol a much larger number than they could have done for the budget they felt they could manage. (HIV clinician) #11

> If they were going to call it a trial, then they were able to use generic drugs instead of branded drugs. (member of staff in local HIV organisation) #4

> The kind-of activist discussion was: "If it's a trial you can get generic drugs and what we need is access, and if this is the offer on the table then we should take it". (PrEP advocate) #7

Having been widely understood from the outset as the only opportunity of getting anyone on to publicly-funded PrEP in the near future, most stakeholders from the HIV sector said they and their colleagues had initially regarded their role in sustaining the pretence of this 'show

trial' as a fair trade off for PrEP access. This open secret was said to have been widely acknowledged among those in PrEP activist networks who had closely followed events.

> Nobody really wanted a trial, and nobody could really see – actually, no, that's not true. Some people could see there will be some benefit in terms of the objectives of the trial, but to be frank, it was a just a vehicle: to enable as many people as possible to access PrEP in the quickest possible way. (member of staff in national HIV organisation) #8

When asked what they felt the ultimate outcome or legacy of the IMPACT Trial was likely to be, half of all participants felt that the single gain provided by the study was that it had been the only strategy for enabling tens of thousands of people in England to get PrEP without having to pay for it privately.

> I think undoubtedly it will have stopped hundreds of people sero-converting, in spite of all of its problems and it has got PrEP to lots of folk. Is it good enough? No. But I think that's its legacy, other than that I can't really think of [its legacy] to tell you the truth. (member of staff in local HIV organisation) #9

However, despite several respondents acknowledging their initial attraction to this short-term solution, many described how their perspective on the value of this expedient solution had changed as the trial progressed. At the half-way stage of the Impact trial, when our interviews were taking place, many said they were no longer able to keep up the pretence that this was a real trial, because the duplicity had pushed them towards burnout. These participants said they felt increasingly debased by the particular performance required by the trial narrative as a study to support and inform future roll out, when the reality was that it had only ever been a managerialist mechanism designed to mitigate costs.

> We have for the longest time been colluding with each other that we need this trial for these reasons and the reasons really are about finance. It's that kind of disingenuous, dishonest process that has absolutely worn me down. (sexual health commissioner for a Local Authority) #12

Those most directly involved in trial governance described being surprised by the 'rules of engagement' during formal trial meetings, including unspoken hierarchies of power which aimed to silence those who might pull back the curtain between the trial's front-stage and back-stage.

> One of my key questions [during official trial meetings] has always been what does he or she think? Does he or she know that this is a crock of shit? Could we have that conversation privately? I've come to realise we can never have it publicly.
> (member of staff in national HIV organisation) #5

While most continued to adhere to 'rules' governing what should and should not be publicly expressed about the true nature of the trial, three interviewees (each involved in different ways) said they had openly critiqued the trial's façade. In each case, these individuals mentioned the personal costs of raising their concerns within and beyond the trial's own structures. While the conclusions of this chapter emphasise structural and population-level implications of this trial, it's the personal and intra-personal toll for advocates and others working closely in and around PrEP Impact was at times considerable. Most of the stakeholders interviewed for this study had been closely involved in England's HIV landscape for a number of years, so they are not strangers to the political realities of compromise and pragmatism. However, most described the Impact trial as a particularly troubling and exhausting conflict zone which served to further alienate those who hold different understandings of what constitutes valuable 'evidence' from one another, while simultaneously driving wedges between stakeholder groups, organisations and individuals.

7.5 The trial as an expression of power

As one would expect of a clinical trial, governance and oversight were held centrally by those in PrEP Impact's uppermost structures (including the trial team and senior figures in Public Health England and NHSE who chaired the Programme Oversight Board – or POB - which managed the trial's externally-facing narrative). Framed as an 'implementation trial' to help answer real world questions of uptake and access in order to test and inform future service design, around half of interviewees pointed out that the inflexibility of the trial structure, meant that no space was created for iterative learning. It appears that the sanctity of following prescribed process, inherited from practices common in RCTs rather than implementation

studies, seriously inflected this project. Stakeholders described how their recommendations to: better promote Impact to diverse audiences, help simplify patient management, support the sharing of live information about clinic spaces, monitor the impact of PrEP on the mental health and wellbeing of diverse users, and to better support the user experience, were ignored. Community stakeholders consistently reported gaining the impression from the outset that their suggestions were regarded as meddlesome and irrelevant. Some reflected on other implementation studies where the relationships between triallists and their stakeholders were more engaging, ongoing and meaningful, with inbuilt opportunities to implement iterative learning throughout a trial's progress.

> [The trial leads] could have had community representation, and they chose to keep that separate as a Community Advisory Board [CAB]. (HIV clinician) #11

While this interviewee said that the trial team had tried to engage with community stakeholders, all other interviewees who sat on the trial's CAB consistently described it as a distinctly arms-length mechanism for disseminating updates from the centre. Some felt the CAB was a site for playing out community disputes, and had become consumed by 'busy-work' – rather than having their diverse forms of expertise meaningfully valued and incorporated. It remains unclear the extent to which the POB might have played a role in establishing these patterns, and to what extent it functioned on a different premise to the trial team.

A prevalent theme from the majority of interviewees was that those leading the trial sought to enforce the concept of *data integrity* as a disciplining tool, arguing that all trial outcomes would be tainted if strict adherence to the protocol was spoiled[2]. The argument that strict control of data flow was essential to maintain its integrity was, according to many, a key means the trial committee centralised its power by restricting access to meaningful interim data. What they described instead was Impact's own failure to function as an implementation trial, because it had disabled its own capacity to learn iteratively, study its own processes and procedures, adapt accordingly and study the ensuing effects. By the half-point stage of the

[2] A few of those interviewed did note that a change in the clinical leadership part way through the study had brought some renewed opportunity for dialogue.

trial, information about the demographic features of trial participants remained strictly confidential and cynicism was widespread among almost all of those interviewed. A high proportion of participants expressed considerable concern that it would only be at the end of the trial that it would become apparent how few people other than men who have sex with men had been enrolled (with concerns about limited diversity even among this group), meaning the trial had curtailed its own capacity to learn what might have been done differently in order to understand and best meet the diverse needs of potential PrEP users.

Most interviewees drew links between controls on data-sharing and the trial protocol's stated intent not to promote PrEP, but instead to use a non-interventionist trial design that assessed and offered PrEP to eligible individuals already attending sexual health clinics. As a result - they argued - marginalised MSM, Black African migrant men and women, trans people, and workers in the sex industry remained at increased HIV risk because of their experience of barriers in accessing traditional sexual health services. There was concern that because many were not tuned in to the social media channels of most PrEP activism, it was even less likely that marginalised people would find out about PrEP – even despite the considerable efforts of dedicated volunteer sex workers, women and trans people who sought to help overcome these types of obstacles. Ultimately, what concerned these interviewees was that the 'show trial' would ultimately broaden those same gaps because of the trial team's determination to only enable access for existing users of sexual health services, while simultaneously not supporting any form of promotion.

> We need to understand what Black-African women need to uptake this, so we need to build that into the trial, it wasn't about that. It was like, "All communities that are at risk will understand their risk in the same way". (PrEP advocate) #2

Despite early assurances of 'ringfenced' trial allocations for groups at high risk of HIV beyond MSM, at the trial half-way point participants broadly agreed that the ringfencing strategy had failed, and that this was in part because the trial did not allocate funds for campaigns to support the promotion of information about PrEP or for trial recruitment.

> For those other communities we needed some investment and that wasn't done, that's a huge failing of the trial. (PrEP advocate) #2

Outside of the trial, Public Health England subsequently funded a few community groups to provide PrEP awareness interventions for targeted populations through its HIV Prevention Innovation Fund. Some other community organisations provided information about PrEP and the Impact trial from their own resources. However, stakeholders made it clear that these piecemeal arrangements did not amount to anything like the required national coordination or scale to ensure that news of PrEP's availability through the trial might reach a sufficiently diverse range of people in need in ways that would help ensure that the sample it gained could adequately and fully inform future services across England. Despite repeating their concerns at successive CAB meetings, stakeholders were deeply concerned that the sharing of trial evidence that had been promised was subsequently sequestered. This meant that collective learning would be delayed until the formal publication of results, long after such lessons could pragmatically be implemented into service plans.

> Is PrEP reaching the people that need it now, is it reaching people in their diversity? No. Is this trial going to lead to routine commissioning? Not necessarily. Is it gonna lead to equitable access? Almost certainly not, because they are I think going to conclude from this trial that some people just don't need or want PrEP. (PrEP advocate) #7

Ultimately, most stakeholders expressed frustration that despite the time and energy they had committed to supporting and enabling the Impact trial, they had come to realise it had been organised as a means of rationing PrEP demand via the trial's highly managerialist structures. At the outset, maximum trial allocations were dispensed to each of the 139 clinic sites, and 20% of the trial's 10,000 spaces were ringfenced for members of high-risk groups beyond MSM. Early demand was predictably strongest in urban locations with high MSM density, and as trial sites started to open in late 2017 some allocations filled rapidly. A new section of the trial website was quickly developed with the intention of directing (primarily MSM) users to clinics that still had available spaces for different user groups. In the summer of 2018, the 'non MSM' ringfence was dropped from 20% to 10% due to purportedly low demand among those who were not cis-gendered men who have sex with men. Some asserted that the posture of restraint about trial recruitment and promotion was a purposeful tactic to rein in spending not only for the trial itself, but as a means of rationing demand for the commissioned service that might follow.

> Places for getting homosexual men [were getting] filled up so then the solution was to say, “Well we overestimated the number of women that might use PrEP”. No you didn’t because you didn’t estimate, you just came up with a number. It was never an estimate and it was never calculated properly. (PrEP advocate) #7

There was a real concern that this focus on demand management had not only pitted people against one another within the HIV sector, but among communities in need.

> I know there were people who are involved in the process who are quite annoyed. If a gay man who is really genuinely at risk goes somewhere and it’s full. And then you say, ‘oh, we have 1000 places reserved for Blacks’. And when they are not accepted, they are thinking, ‘it’s not right. It's not right’. I honestly think that inadvertently, they are really making people feel very bad. (member of staff at a local HIV organisation) #4

A tiered set of inequalities had emerged, described by the participant above, with well-informed gay and bisexual men facing increasingly unpredictable access to trial places, accompanied by vanishingly low figures for more diverse men who have sex with men, and people having heterosexual sex. With so much ongoing change, community organisations and potential PrEP users they were supporting were increasingly unclear which clinics were accepting what categories of people into their remaining trial places.

Despite the strict expectations attached to the confidentiality of all trial data, it was notable during these interviews just how frequently some details and figures appeared to have leaked out among those on the CAB and those playing a role in other trial committees. However, such figures could never be formally acknowledged or built into future planning, they essentially only held ‘hearsay’ status.

> You know, only four percent of these places have been taken up by non-MSM people, and that’s really crazy! (member of staff at a local HIV organisation) #4

There was a lot of discontent about the inequalities of access that had become apparent through these informal knowledge networks.

> I think still a lot of people will have misunderstood it as a medical study [ie. RCT with placebo]. That inherently will have put so many communities off, particularly communities that often feel like they are not cared for and won't be cared for if the medical study is wrong. Particularly Black communities and even a lot of sex worker communities can feel like they'll all just be the lab rats. (PrEP advocate) #13

> It was a trial that was designed for and about gay men, and particular gay men. (PrEP advocate) #7

This concern therefore added to many participants' disquiet about ways in which the PrEP Impact trial had further entrenched existing bias in HIV prevention services towards urban, middle class white gay men who tend to disproportionately use the sexual health clinics through which the trial exclusively operated. During our interviews, participants had begun to predict how the failure to recruit and learn about PrEP needs amongst diverse populations would directly imprint itself onto future service design, built primarily around 'ideal users' who are already routinely attending sexual health services (Holt, 2015; Young et al. 2020).

Adding to the complexity of this 'show trial' was NHSE's announcement that they would support additional medication costs that could enable the trial to expand first to 13,000 in June 2018, and then to 26,000 places in the spring of 2019 (NHS England n.d.). The latter announcement to double the trial size created significant conflicts with Local Authorities who carry responsibilities for running all of the sexual health clinics where the Impact trial was sited. Most balked at the match-funding needed to support the additional clinical caseloads and follow-on screening that would accompany trial expansion. Uneven and protracted negotiations ensued, with many local commissioners arguing that they could not afford the costs within a context of extensive funding cuts driven by a national politics of austerity. These conflicts were reported widely in the gay, local and national press, further compounding confusion about trial places for those who might want to enrol. Then, in the midst of the fieldwork for this study, on 5th July 2019, the NHS National Director of Special Commissioning released a letter via Twitter that said he was "asking the trial researchers to support open ended additional places where any clinic and their local authority commissioner would like them" (Stewart 2019). Therefore, not only were the earlier attempts to ration trial places widely regarded as causing divisions and entrenching inequalities among those most impacted by HIV, but these calls for expansion then became a site for open conflict to be

played out between NHSE and Local Authorities. These developments also raised questions about the inherent contradictions built into Impact's trial structure. Each time the NHSE made an unexpected announcement supporting trial expansion, this further deepened the rifts which had opened between these large institutional players. The vastly different working cultures between the highly centralised structures represented by Public Health England and the National Health Service, contrasted with hundreds of Local Authorities run by publicly-elected representatives came sharply into focus through the way the Impact trial had been managed.

> So privately [among local authority commissioners] for example, there is lots of, 'We can never trust NHS England again'. […] there's been an ugly fraught process, but that will be its legacy. (sexual health commissioner for a Local Authority) #12

This same individual described the impossible position in which they had been placed, being expected gain approval for even more of their Local Authority's funds to support clinical provision for further trial expansion, while still having no access to interim trial data.

> I've got to take this back to a whole range of people and sell it, so throw me a fish for Christ's sake! Throw me something that can help me sell this back at base. (sexual health commissioner for a Local Authority) #12

All participants expressed frustration about the continual conflicts between NHS and Local Authorities on responsibilities for additional running costs as the trial progressed and grew. The 'show trial' had been constructed in order to overcome conflicts about who would pay for PrEP but became the new location where that disagreement played out. Many participants took the view that the Impact trial was unable to resolve weaknesses caused by longer term disinvestment in sexual health service provision and HIV prevention, and that it could not be expected to resolve broader infrastructure challenges. The 'show' trial was devised as a means of squaring the circle, finding what appeared to be an ingenious way to keep down the costs of high-priced patent protected medicine by gaining legal access to generics instead. However, its carefully rationed access served to further entrench the structural determinants of health, which for many participants had become a more relevant issue than attempting to maintain the 'show' trial's façade.

> The Impact trial will finish with some limited data that will help us in our future planning and it's not going to solve the rest of the problems that still exist because of political and economic and cultural disinvestment in our sexual health services. (PrEP advocate) #1

> The reason why a lot of London clinics have not taken up the new places is because of capacity. So they don't have capacity in terms of seeing more patients. So I think that will be a kind of big impact. I think that, in terms of the trial itself, I think that one of the challenges they have is that they don't want to acknowledge some of the challenges they are facing. (clinic staff member) #3

Some participants reflected on the way that these wider frustrations were ultimately directed into disputes over the machinations of the trial itself with the fall-out of these conflicts resonating across the sector. They described how this situation had dramatically increased internal competition between actors for funds, attention and recognition, thereby deflecting attention away from the under-resourced structures in which in which all actors were situated. All of this was understood to have resulted from careful PrEP rationing which had been crafted as part of the trial design. As a result of these combined factors, few of those interviewed expressed any confidence that the Impact trial could meet its goal of meaningfully shaping how England could deliver PrEP in the future.

> Interviewer: What kind of legacy will we end up with as a result of the Impact trial?
> Participant: In terms of what will we know?
> Interviewer: Sure.
> Participant: What will we know that we don't know now?
> Interviewer: Yes.
> Participant: I don't know, because it's difficult to…[long pause]… I'm really struggling with that question, I'm afraid, I really am.
> Interviewer: That's fine.
> Participant: I'm not sure how to answer that because there are still so many questions. (sexual health commissioner in a Local Authority) #14

Most tended to agree with this sentiment, because in their view, Impact had neither pursued meaningful questions that would provide the answers that Local Authorities required for

service design, nor had it shared any of what it had learned. In addition to this, along the way the trial's managerialist control functions had helped to sow discontent, distrust and conflict between groups were meant to be working towards the joint goal of HIV prevention.

7.6 The Impact study and PrEP's future in England

The PrEP Impact trial was framed as an implementation study but stakeholder accounts demonstrate the ways in which it is best regarded as a 'show' trial - concocted not as a genuine implementation study but an inherently flawed attempt to bypass conflicts between national and local government actors. While this compromise solution did enable access to generic PrEP for thousands who would have either had to pay for it privately or do without, even that element of the trial's success is mitigated by a range of associated harms.

Rather than celebrating the trial's 'gains', the majority of interviewees felt exhausted and personally complicit with a trial infrastructure that had actually served to deepen conflict and distrust between the very agencies who would need to co-commission the PrEP services of the future (NHSE alongside hundreds of Local Authorities), and also between some voluntary organisation actors. Furthermore, the vast majority of participants expressed profound concern that the implementation trial had actively functioned as a mechanism of healthcare rationing (Nagington and Sandset 2020), creating an expansion of barriers to PrEP's accessibility among the socially and economically marginalised. This trial was structured in ways that disabled many in need from learning about or receiving PrEP. The costs of the inequalities fostered by and woven into the fabric of PrEP provision in England through the Impact trial are inestimable. The feature of the trial that is most culpable for this state of affairs was its ongoing attachment to a hierarchy of evidence-making that prioritised process and 'purity' over functional outcomes.

Central to the stated outcomes of Impact was that it was meant to inform good commissioning practice when PrEP services were finally rolled out. To this end, in June 2018 the trial's Programme Oversight Board established a Short Term PrEP Commissioning Planning Group which was tasked with devising a set of recommendations for future PrEP Commissioning in England. These would be informed by trial outcomes and interim learning gained up to that point and shared for dissemination among key stakeholders. However, the report developed by that group was never allowed into the public domain. At the time of

writing, England's Department of Health and Social Care has released commissioning directions and PrEP treatment budget allocations for Local Authorities which needs to be implemented within an extremely short timeframe, (personal communication, 2020) while the Short Term PrEP Commissioning Planning Group's report and recommendations, commissioned by the Impact POB, remain suppressed.

With Local Authority sexual health commissioners expected to pull together a PrEP service in the four months between the release of commissioning directions and the conclusion of the Impact trial, there is no expectation that there will be any sharing of insight from those holding the trial data during this short planning period. This is perhaps one of the most potent demonstrations of this trial's particular performance of the making of evidence from before the start of the trial to beyond its finish (Rhodes & Lancaster 2019). Rather than working in collaboration to share information that will benefit the design of immanent service, the evidence remains in the hands of the actors closest to the centre of this show. Presumably that evidence will be packaged and prepared for future academic publication in esteemed scientific journals, but this does not meet the practical needs of planner and implementers who are rapidly having to design England's new PrEP service, with no functional insights to glean from the Impact trial. The only thing that has been made clear to current planners, is that when this service launches, state-funded PrEP will still only be accessible to those already using sexual health clinics. As with other 'show' trials, the final conclusions of the PrEP Impact trial will contain few surprises, and once all the final reports are written there is small chance of anything being done to address the way this trial has further entrenched structural injustices and inequalities in England's PrEP provision.

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