GOING TO LAW FOR PREP: A CASE STUDY FROM ENGLAND

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TRANSFORMING THE UK'S RESPONSE TO HIV

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BACKGROUND:

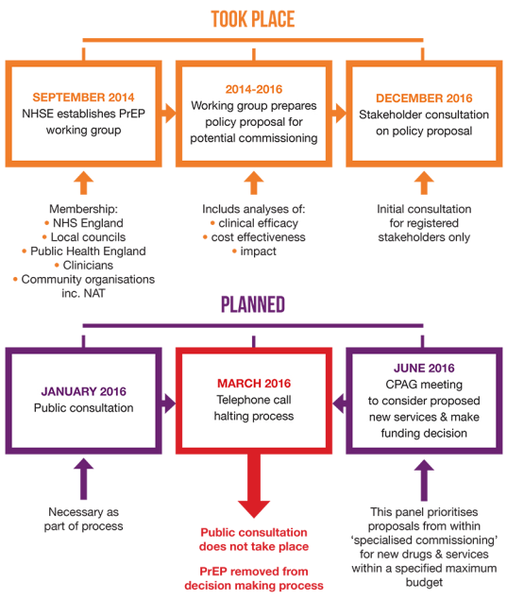
The National Health Service in England (NHS England) commissions HIV services at the national level within its 'specialised commissioning' functions. This has historically included provision of anti-retrovirals (ART) for preventive purposes such as Post-exposure Prophylaxis (PEP). In 2014 NHS England made clear that it would similarly have responsibility to commission the drug used in PrEP (tenofovir/emtricitabine), should PrEP be assessed as an appropriate intervention. The clinical service to prescribe PrEP and support patients would be delivered in sexual health clinics and so would need to be commissioned by the 151 England local councils with public health responsibilities.

PROPOSED TIMETABLE FOR NHSE COMMISSIONING OF PREP

The first stage in considering the case for commissioning PrEP was the establishment by NHS England (NHSE) of a working group in September 2014. The final proposal should have been presented to the Clinical Priorities Advisory Group (CPAG), which met once a year (in June 2016) to consider all new proposals for 'specialised commissioning' funding and place them in order of prioritisation for a final NHS England decision on which of the proposals to commission.

On 21 March 2016, NHS England announced unexpectedly that it was not going to continue the work on PrEP because it had received legal advice that commissioning PrEP was outside its powers since it was a preventive intervention and NHS England's powers only extended to delivery of treatment.

Faced with the decision by NHS England to abandon at the last minute its decision-making on PrEP, with no alternative commissioning process agreed or proposed, just a wholly inadequate further trial for an additional 500 gay and bisexual men, the community was united in protest.



LEGAL ACTION FOR PREP:

THE PROCESS

It is highly unusual for a judicial review of this kind to be considered by High Court and then Court of Appeal so quickly. The main reason for this was that the uncertainty as to whether or not PrEP was to be included in the CPAG process meant that CPAG were unable to come to a final view on the other policy proposals put to it in 2016 – thus a number of other treatments for other conditions were being delayed. The re-started public consultation process received the largest ever public response to a policy proposal for specialised commissioning. Following the CPAG decision, NHS England announced that it would commission a three-year implementation study (the 'PrEP IMPACT trial') for at least 10,000 people with £10m funding. This would be followed by 'wider national roll-out'.

THE RISKS

Taking legal action is a significant step for any NGO, especially a small one such as NAT. There are reputational risks, relational risks and financial risks. In particular, the possibility of losing and having to pay not just one's own legal costs but also the costs of the winning side poses a real threat to financial stability.

The reputational risks were mitigated by ensuring that the organisation accessed expert legal advice, had a clear media strategy, and worked closely in an alliance with a wide range of stakeholders including other HIV NGOs, activists and clinicians.

Relational risks were born out, with NAT's well established positive working relationship with NHS England significantly affected. During the legal action period, all work with NHSE on a very wide range of issues of concern was put on hold. Rebuilding trust and collaboration has been a painstaking process, however good will on both sides has enabled progress in this area.

Financial risks were mitigated in this instance by two factors. First, the lawyers working for NAT agreed to work simply for whatever NAT was able to raise via crowdfunding (inevitably substantially below their commercial rates), and secondly NAT's lawyers negotiated an agreement with NHSE which meant that in the event of NAT losing the case there would be no requirement on NAT to pay NHS England's costs (though this came with the agreement of a significantly lower threshold on costs paid to NAT's lawyers should NAT win). The legal action was thus made possible both through the goodwill of NAT's lawyers with whom we had built supportive relationships over a number of years, but also the goodwill of NHS England's legal team who implicitly accepted the public interest in NAT taking the case.

THE ARGUMENTS

The legal question related to the powers of the NHS to commission preventive interventions and it is therefore quite specific to England. The key legal conclusions are found in the Court of Appeal judgment.

A central conclusion relied on the fact that NHS England already commissioned PEP. The Court rejected the claim that PEP and PrEP were fundamentally different. They work in similar ways biologically, with both making a difference only if initial infection with HIV has taken place. Powers relied on to commission PEP must therefore apply to PrEP also. Importantly the Court held that they can both be considered as treatment and that the law's definition of treatment included prevention.

The Court also relied on the powers in law for the NHS 'to do anything which is calculated to facilitate … the discharge of any function … conferred by this Act'. The Court held that commissioning PrEP which prevented HIV and the costs of its treatment clearly facilitated the NHS in its function to treat HIV.

A couple of quotations from the judgment illustrate the preference of the Court for a construction of the law which supports integrated and practical frontline delivery of healthcare:

> "THIS SEEMS TO BE ALTOGETHER TOO TECHNICAL AND LEGALISTIC AN APPROACH TO A REGULATION WHICH MUST BE INTENDED TO BE READ AND APPLIED NOT BY LAWYERS BUT BY HEALTH SERVICE MANAGERS AND DOCTORS IN THEIR DAILY LIVES."

> "ONCE IT IS APPRECIATED THAT THE FACT THAT TREATMENT IS PREVENTATIVE TREATMENT DOES NOT AUTOMATICALLY MEAN THAT IT IS TO BE ASSIGNED TO THE PUBLIC HEALTH SIDE OF THE BOUNDARY, IT IS MUCH MORE SENSIBLE TO REGARD ALL TREATMENT ASSOCIATED WITH HIV AS BEING A 'NON-PUBLIC HEALTH FUNCTION' SINCE, OTHERWISE, RESPONSIBILITY WILL BECOME FRAGMENTED."

WIDER CAMPAIGNING:

The legal case for PrEP was part of a wider movement of activism and protest, policy and media work which created an environment in which PrEP became a politically hot topic. This work included the launch of two community websites in October 2015. Prepster focussed on supporting and promoting community activism to secure PrEP access, as well as provision of information on PrEP to affected communities. IWantPrepNow enabled people to buy generic PrEP cheaply from overseas. It was estimated that by mid-2017 about 8,000 people were accessing PrEP via IWantPrepNow.

Alongside these websites, an informal alliance of activists, NGOs and clinicians was formed, eventually under the banner United4PrEP. This alliance coordinated a range of activity including social media assets and campaigning, media lines, and lobbying of politicians. NAT and other organisations, particularly Terrence Higgins Trust, ensured that politicians kept the issue of PrEP on the political agenda. The PrEP legal case received a very high level of press coverage, and was the leading story in most broadcast, print and online media. Together this work created an environment in which, having lost the legal case, it would have been politically very difficult for NHSE not to commission PrEP.

CONCLUSIONS AND NEXT STEPS:

Litigation can be an effective intervention to force a national health system to consider the case for PrEP.

Previously established good relationships with eminent lawyers and with health system officials can support community sector organisations in taking the serious step of going to law (especially around the cost implications).

The argument that PrEP is not just 'prevention' but also 'treatment' can be effective and convincing, and allows for a broader and flexible view as to how PrEP might be planned, funded and delivered within a health system.

Provision of PrEP in England involves a number of possible statutory bodies – there was a helpful instinct in the court judgments in favour of a commonsense approach which would maximise the chance of securing the public health benefits of PrEP – rather than a narrow silo-based interpretation of duties.

The legal action had a wider impact on PrEP awareness, with extensive media reporting and observed spikes in demand for generics linked to this reporting. It fed back into community demand and pressure for PrEP on the NHS.

Litigation was accompanied by a wide range of community actions including public protest, media work, facilitation of generics access and parliamentary lobbying. All were essential to the successful outcome of PrEP provision.

The three-year PrEP IMPACT trial began in October 2017 and currently after just nine months has already recruited over 8,000 participants. It is likely that the numbers on the trial will be increased from 10,000 to 13,000 but this will still not meet demand to 2020. HIV sector stakeholders and community organisations are now calling for the roll-out of a national PrEP programme, without any cap on numbers, as soon as possible, alongside a better approach to understanding and meeting the need for PrEP amongst key populations other than gay and bisexual men.

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