GOING TO LAW FOR PREP: A CASE STUDY FROM ENGLAND

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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 historically included provision of antiretrovirals (ART) for HIV treatment and as a post-exposure prophylaxis (PEP). In 2014, NHS England made clear that it would similarly have responsibility to commission the drug used in PEP (pre-exposure prophylaxis), should PEP be assessed as an appropriate intervention. The clinical service to prescribe PEP and support patients would be delivered in sexual health clinics and should be commissioned by the 153 England local councils with public health responsibilities.

PROPOSED TIMETABLE FOR NHS COMMISSIONING OF PREP

The first stage in considering the case for commissioning PEP was the establishment by NHS England (NHS) of a working group in September 2014. The final proposal should have been presented to the Clinical Priorities Advisory Group (CPAG) in the spring of 2015 and 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 PEP because it had received legal advice that commissioning PEP was outside its powers since it was a preventive intervention and NHS England’s powers only extended to delivery of treatment.

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 PEP 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 2015 — thus a number of other recommendations 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) of at least 10,000 people with £13m funding. This would be followed by “wider national roll-out.”

THE RISKS

Taking legal action is a significant step for any NSO, especially a small one such as NAT. There are reputational risks, relational 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 winning provides 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 public, technical and policy network. The public and political response to the decision was clear, with all NHS organisations very widely involved in issues of concern. Rebuilding trust and collaboration has been a painstaking process, however good all sides on both sides has engaged in this area.

Financial risks were mitigated in this instance by two factors. First, the lawyers working for NAT agreed to work mainly for an upfront payment of £22,000 plus hourly rate via a legal aid funding route (costs are normally paid by the other commercial side), and secondly NAT’s lawyers negotiated an agreement with NHS which meant that in the event of NAT losing the case there would be no requirement on NAT to pay NHS England’s costs (through 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 initially accepted the public interest in NAT taking the case.

CONCLUSIONS AND NEXT STEPS:

The legal case for PEP was part of a wider movement of activism and protest, political and media work which created an environment in which PEP became a politically hot topic. This work included the launch of a public petition to the UK government to make PEP widely available; supporting and promoting community activism to secure PEP access, as well as provision of information on PEP to affected communities.

This work paved the way for legal action, particularly in England, where the legal case worked in an environment in which, having lost the legal case, it would have been politically very difficult for NHS to not commission PEP.

LITIGATION AND NEXT STEPS

Litigation can be an effective intervention to bring about a national health system to consider the case for PEP.

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

The argument that PEP is not just ‘prevention’ but ‘treatment’ can be effective and convincing, and allows for a broader and more focused case for PEP, how PEP might be planned, funded and delivered within a health system.

PEP in England involves a number of possible statutory bodies. — there was a helpful instinct in the court judgments in favour of a commercial approach which would make the case for securing the public health benefits of PEP rather than a more narrow-based test of public interest.

The legal action had a wider impact on PEP awareness, with extensive media reporting and received queries in demand for generalised legal aid for PEP on the NHS.

Litigation was accompanied by a wide range of community actions including public protests, media work, the circulation of derogated access and parliamentary lobbying. All were essential to the successful outcome of PEP provision.

The three-year PREP IMPACT trial began in October 2017 and currently after just nine months has already recruited over 6,000 participants. It is likely that the numbers on the trial will increase from 10,000 to 12,000 but this will not meet demand to 2020. HIV sector stakeholders and community organisations are now calling for the roll out of a national PEP programme, without any cap on numbers, as soon as possible, with a broader approach to understanding and making the case for PEP among key populations other than gay men and bisexual men.

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