

Request to vary the contract with Leeds Community Healthcare NHS Trust for the Integrated Sexual Health Service to include additional investment for the provision of Pre-exposure prophylaxis (PrEP)

Date: 19th January 2022

Report of: Head of Public Health

Report to: Director of Public Health

Will the decision be open for call in? Yes No

Does the report contain confidential or exempt information? Yes No

What is this report about?

Including how it contributes to the city's and council's ambitions

- Leeds City Council commissions Leeds Community Healthcare NHS Trust (LCH) to deliver the city's Integrated Sexual Health Service (ISHS). It provides contraception, sexually transmitted infection (STI) testing and treatment, and genitourinary medicine
- The Department for Health and Social Care has given additional funding through the Public Health grant to provide Pre-exposure prophylaxis (PrEP), a drug that prevents HIV infection, with the stipulation that it should be provided through existing commissioned services.
- Approval is therefore being sought to vary the contract with LCH to include an additional £265,815 for the 2021/22 financial year.
- This decision supports the Best Council Plan priority of supporting healthy, physically active lifestyles.

Recommendations

- a) The Director of Public Health is recommended to approve a variation to the contract price for the Integrated Sexual Health Service, which is delivered by Leeds Community Healthcare NHS Trust, to include up to an additional £265,815 for the provision of PrEP for the period 1st April 2021 to 31st March 2022.
- b) The Director of Public Health is recommended to approve the automatic transfer of any further PrEP allocations from the Department for Health and Social Care until the end of the contract term, 31st March 2023, as part of this variation.

Why is the proposal being put forward?

- 1 Under the terms of the Health and Social Care Act 2012, local authorities are responsible for the commissioning of:
 - comprehensive sexual health services including most contraceptive services and all prescribing costs, but excluding GP additionally-provided contraception
 - sexually transmitted infections (STI) testing and treatment, chlamydia screening and HIV testing
 - specialist services, including young people's sexual health, teenage pregnancy services, outreach, HIV prevention, sexual health promotion, services in schools, college and pharmacies.
- 2 In 2015 contraception provision, sexually transmitted infection (STI) testing and treatment, and genitourinary medicine was brought together into one, integrated service. The contract is with Leeds Community Healthcare NHS Trust (LCH) and is in place until March 2023.
- 3 The service is delivered mainly from the city centre base in the Merrion Centre, along with community clinic sessions in Armley, Beeston Hill, Chapeltown and Burmantofts. There is also an outreach team, working with those who find it hard to access care in the usual way, whether through chaotic lifestyles or not wishing to disclose their sexual behaviour for fear of judgement or outing. This includes sex workers, men who have sex with men, Black African communities, those who are trans or non-binary, and young people. The outreach is largely carried out in partnership with services who are already working with, and are trusted by, these groups.
- 4 The UK is one of the first countries to meet the UNAIDS 90-90-90 targets. In 2018 Public Health England estimated that 92% of people living with HIV in the UK had been diagnosed, 98% of those diagnosed were on treatment, and 97% of those on treatment were virally suppressed. The UK Government has set out a commitment to end transmission of HIV in England by 2030.
- 5 Leeds is a high rate city for HIV with a diagnosis rate of 11.4 per 100k population (15-59), compared with the national average of 8.1 per 100k and a late diagnosis rate of 57.1% compared with the national average of 43.1%.
- 6 Pre-exposure prophylaxis, or PrEP, is a way for people who do not have HIV to prevent infection by taking a pill every day (daily dosing), or before and after likely exposure (event-based dosing). It works by preventing the virus from establishing a permanent infection. When taken in accordance with recommended use, PrEP has been shown to significantly reduce the risk of HIV infection in people who are at high risk, for example those in a relationship with someone who is HIV-positive.
- 7 PrEP is also important for broader sexual health. It provides an opportunity for individuals at higher risk of HIV and sexually transmitted infection (STIs) – some of whom will not have been accessing prevention services previously – to regularly engage with sexual health and health promotion services.
- 8 Following a national trial to assess demand, the government made funding available to provide PrEP between October 2020 and March 2021 through existing commissioned sexual health services. The contract with LCH was therefore varied to include this provision. During this period, the service supported 205 people, over 156 first and 252 follow up appointments.
- 9 A new allocation was made for the 2021/22 financial year, which has been transferred to LCC through the Public Health Grant. Leeds has been allocated £276,172 of which 12.5% will be ringfenced to pay for Leeds residents who access services in other areas, through reciprocal charging arrangements with the other local authorities within the Yorkshire and Humber region. The remaining budget of £265,815 will be used to fund the distribution of PrEP through the Integrated Sexual Health Service, including to out of area clients for which we will be reimbursed.

- 10 Therefore, approval is being sought to change the contract value to include an additional £265,815 for 2021/22. The scope and nature of the service is not affected. The total contract value to date is £47,074,913. The addition of £265,815 therefore equates to an increase of 0.6%.
- 11 Approval for this variation is being sought retrospectively. It was not possible to seek approval in advance because the allocation was not confirmed until March 2021. Given that the provision was established at short notice, it was then necessary to undertake a review of the expenditure of the initial delivery period (October 2020 to March 2021) to ensure that the unit price was sufficient to cover all costs. This led to the negotiation of a new unit price with the contractor. Service delivery has had to continue in the meantime, in order that medical treatment is not interrupted. This has been paid for from the budget set aside for this variation. Therefore there has been no pressure placed on any other budget, and total expenditure for PrEP in 2021/22 will not exceed £265,815.
- 12 It is anticipated that the funding allocation from DHSC will continue to be confirmed on an annual basis each March. Given that this precludes seeking approval for further variations in advance, it is therefore proposed that this variation includes the provision to automatically transfer any further allocation that are made until the end of the contract term, which is 31st March 2023. It is anticipated that funding in future years will be of a similar value to that of 2021/22, when it was recalculated to more accurately reflect the level of need in the city. Additional funding of similar level for 2022/23 will be permissible under the Public Contracts Regulations 2015. Should LCC not receive this funding for 2022/23, the variation would automatically come to an end, and the contract value and level of PrEP activity would resume to their original level.
- 13 The requirements for this provision are contained in an annex to the specification, which has been reviewed and amended slightly in light of learning following the initial delivery phase.

What impact will this proposal have?

Wards affected:

Have ward members been consulted? Yes No

- 14 The service will contribute to the reduction in HIV transmission rates in the city and will monitor:

No. of people assessed for PrEP, broken down by:

- age
- gender
- ethnicity
- sexual orientation
- gender identity.

No. and % of people starting PrEP who are:

- new Leeds residents
- returning Leeds residents*
- new Out of Area residents*
- returning Out of Area residents

No. of people supplied PrEP, broken down by:

- age
- gender
- ethnicity
- sexual orientation
- gender identity.

No. of attendees who are on:

- event-based dosing
- daily dosing

No. and % of attendees who:

- have stopped PrEP
- are still on PrEP at 6 months
- are still on PrEP at 12 months;

No. and % of those diagnosed with HIV who report previous PrEP use

What consultation and engagement has taken place?

- 15 The Executive Member for Public Health and Healthy Lifestyles was consulted on the proposal on 14th October and 14th December 2021, and was supportive.
- 16 The provider has been consulted and has been confirmed that the provision can be managed within existing staffing capacity. This is based on a projection of the number that can be supported through the funding available.
- 17 Procurement and Commercial Services have been consulted and confirmed that this approach is permissible under the Public Contracts Regulations 2015.

What are the resource implications?

- 18 Funding for this additional provision has been transferred to LCC by the Department for Health and Social Care (DHSC) through the Public Health Grant.
- 19 LCH will be paid on a quarterly basis, based on the actual number of people supported, in order to monitor the level of demand. It is possible, therefore, that the level of spend will be less than the amount allocated. Although it has not been confirmed as yet, it is anticipated that any underspend will be returned to DHSC, as was the case last year.

What are the legal implications?

- 20 This is a Key Decision and will be subject to call-in. It was published on the List of Forthcoming Key Decisions on 15th December 2021.
- 21 There are no grounds for treating the contents of this report as confidential within the Council's Access to Information Rules.
- 22 The variation is being requested in accordance with the provisions of Regulation 72 (1b) (i) & (ii) of the Public Contracts Regulations 2015.
- 23 The modification of contracts is governed under the Public Contracts Regulations 2015 at regulation 72 which permits certain types of modifications. The regulation considers the extent to which a contract may be modified before it should be considered so substantially changed as to necessitate a new procurement. Permissible grounds for modification include a need for additional services due to unforeseen circumstances (subject to 50% maximum increase in initial contract value). It also requires the consideration of the effect of cumulative variations. Therefore this needs to be considered in taking this decision.
- 24 The figures set out at paragraph 11 and 12 of this report show the value of the initial contract, and the proposed increase due to the request to vary the contract and is within the realms of the regulation.
- 25 The provisions of Regulation 72 (1b) (i) & (ii) provide an exception "where all of the following conditions are fulfilled:
 - (b) for additional works, services or supplies by the original contractor that have become necessary and were not included in the initial procurement, where a change of contractor:

- (i) cannot be made for economic or technical reasons such as requirements of interchangeability or interoperability with existing equipment, services or installations procured under the initial procurement; and
- (ii) would cause significant inconvenience or substantial duplication of costs for the contracting authority, provided that any increase in price does not exceed 50% of the value of the original contract.

26 In making this variation, the above conditions of Regulation 72 (1b) (i) & (ii) are deemed to be satisfied for the following reasons:

- the funding was not available at the time of the procurement and has been allocated on the basis that the activity be delivered through our mainstream commissioned service
- the additional activity will make use of the staffing capacity already provided through the original contract – creating a new delivery mechanism would result in duplicating staffing and management costs and reduce the amount available to be spent on delivery. Furthermore, the short timescale in which the money can be spent means that it would not be possible, nor would it stimulate interest from the market for a low value service.

27 There is no overriding legal obstacle preventing the variation of this contract under Regulation 72 of the Public Contracts Regulations 2015. The percentage uplift is within the range permitted under Regulation. In making the final decision, the Director of Public Health should be satisfied that the course of action chosen, as to varying the contract, is the best course of action for the Council and should be satisfied that in doing so it represents best value for the Council.

What are the key risks and how are they being managed?

28 Client numbers will be monitored to ensure that the caseload does not exceed the funding available. This cap is based on the amount spent, rather than absolute client numbers, since it will depend on the demand for initial and / or follow-up appointments within this period. This will be detailed in the specification.

29 The contract will continue to be managed by officers in Adults and Health. Officers will continue to work with LCH to monitor the cost and quality of service provision and provide support and guidance in managing associated risks. This includes regular reviewing of performance information and quarterly contract management meetings with the provider at which any service delivery issues will be discussed.

30 If this decision is not approved, the city will not benefit from an allocation of external funding and will lose an opportunity to reduce HIV transmission rates, and the funding will be returned to the DHSC.

31 Requirements relating to information governance and the processing of personal data will be included in the specification and monitored through contract management processes.

32 In addition, the service is subject to inspection by the Care Quality Commission. At the last inspection, in May 2019, the service was rated Outstanding.

Does this proposal support the council's three Key Pillars?

- Inclusive Growth Health and Wellbeing Climate Emergency

33 This service will contribute to Best Council Plan's health priority of Supporting healthy, physically active lifestyles.

34 Furthermore, it will support the Leeds Health and Wellbeing Strategy priority of "A stronger focus on prevention".

- 35 This provision relates to the 'prevention' strand of the 'Leeds Health and Care Plan', supporting the development of a more integrated healthy living model in Leeds in order to maximise the health outcomes that can be achieved through sustained behaviour change and healthy living.
- 36 The service operates primarily from a city centre base, which ensures easy access for service users, and encourages the use of public transport. There are also a number of local clinics, which reduces travel further. This helps to reduce carbon emissions and environmental pollution which contributes to city actions to better manage air quality.
- 37 The preventative nature of this initiative aims to improve health and well-being and thus reduce hospital admissions, which helps ensure we better manage our use of resource intensive (and high footprint) health and care services.
- 38 The service specification requires that the service meets all legislation, guidance and good industry practice in environmental management and the objectives of the Council's sustainability policies. Officers from Adults and Health work with LCH through the established contract management process to ensure the service is proactively seeking to minimise its carbon footprint and thereby support the Council in achieving its ambition to be carbon neutral by 2030.

Options, timescales and measuring success

What other options were considered?

- 39 It is not suitable to undertake a procurement exercise for this provision, since it has been stipulated by the government that it should be delivered through existing commissioned services.
- 40 There is no need to award a separate contract to LCH, since there is justification for varying the existing the contract to include this provision.
- 41 The remaining option would be to not use the allocation from the government. However, this would significantly affect the Council's ability to address HIV transmission in the city

How will success be measured?

- 42 The contract will include a Performance Framework for the purpose of monitoring service delivery and outcomes. This will reflect the aims listed in paragraph 13 above.

What is the timetable for implementation?

- 43 The contract variation will be issued as soon as possible after approval is granted.

Appendices

- 44 None

Background papers

- 45 Equality Diversity Cohesion Integration Impact Screening