By: Graham Gibbens, Cabinet Member Adult Social Care & Public Health

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To: Social Care and Public Health Cabinet Committee – 14 September 2012

Subject: Changing contract arrangements for Chlamydia Screening testing in the

laboratories for Kent and Medway

Classification: Unrestricted

Summary

This is a service that will be the responsibility of the County Council from April 2013. The PCT cluster will consult the council on any changes proposed to services that will become the responsibility of the council.

Part of the chlamydia screening programme is paying for the costs of the tests in Laboratories that meet national standards. Chlamydia screening testing is commissioned from the four hospitals in Kent and Medway with prices ranging from £7.50 to £16.40. Cost savings could be made by streamlining the cost, tendering the service and reducing the number of laboratories who provide the service.

Introduction

The purpose of this paper is to set out the reasons and rationale for the re-tendering of the chlamydia screening testing service.

Report contents

1. Background

The National Chlamydia Screening Programme (NCSP) is a control and prevention programme targeted at sexually active young people less than 25 years of age. Chlamydia is the most common bacterial sexually transmitted infection (STI) in the UK; affecting both men and women. Most people with chlamydia have no symptoms, but if left untreated, chlamydia, can lead, in women, to infertility, ectopic pregnancy and chronic pelvic pain. In men it may cause urethritis and epididymitis. In both sexes it can cause arthritis.

In the financial year 2011/12 a total of 48037 chlamydia screens were carried out as part of the Chlamydia screening programme across Kent and Medway. The total target population for this programme across Kent and Medway is 213,332 of which 35% (74,666) need to be screened to achieve the target.

Pathology is a crucial element of almost all patient pathways and is the foundation for high quality diagnosis, treatment and care. Commissioning pathology is not, in principle, different from commissioning any other service. It is driven by the same priorities and information by the same set of skills and methodologies. It is not more complicated than other services, but nor is it simpler. As with all commissioning processes, it is important to have a sound basic understanding of the nature of the service and the value that it offers.

Drivers relevant to determining the appropriate commissioning approach to community pathology services are:

- The need to ensure a high quality, safe and compliant service
- The need to improve effectiveness
- The need to improve affordability
- The need to improve value for money
- The need to evidence a quality service

Table 1 Chlamydia screening activity for 15-24 year population in 2011/12

PCT	Chlamydia screening coverage for 2011/12
West Kent	19004 (24%)
Eastern and Coastal Kent	20638 (20.7%)
Medway	8395 (24.4%)
Total tests	48037

2. Key issues

Chlamydia tests generated as a result of the Chlamydia screening programme are processed in 4 laboratories in Kent and Medway. These being

- Maidstone and Tunbridge Wells NHS Trust lab
- Dartford and Gravesham NHS Trust lab
- East Kent Hospitals University NHS Foundation Trust lab
- Medway NHS Foundation Trust lab

There is considerable variation in price charged per test. This variation is as following

Table 2 Tariff for Chlamydia testing according to each laboratory

NHS Trust	Tariff per test
Maidstone and Tunbridge Wells NHS Trust lab	£7.50
Dartford and Gravesham NHS Trust lab	£16.66
East Kent Hospitals NHS Trust lab	£10.96
Medway NHS Trust lab	£ 16.40

Table 3 Total expenditure per year for Chlamydia testing according to each laboratory

NHS Trust	Total cost per year
Maidstone and Tunbridge Wells NHS Trust lab	£188,500
Dartford and Gravesham NHS Trust lab	£153,000
East Kent Hospitals NHS Trust lab	£240,000
Medway NHS Trust lab	£138,000
Total cost	£719,500.

- The cost of processing chlamydia samples in DVH is a block contract irrespective of the activity.
- The cost of processing samples in MTW also includes the cost of all Chlamydia samples generated from GUM clinic and the transportation cost of all pathology samples other than chlamydia.

3. Implications

Chlamydia screening has been an NHS target for 3 years. The new Public Health Outcomes Framework for Local Authorities from April 2013 recommends a Chlamydia screening diagnosis indicator i.e. at least 2,400 Chlamydia diagnosis per 100,000 15-24 year olds per annum including Genito Urinary Medicine (GUM). This translates to 35% coverage of the eligible population. If all three PCTs (West Kent, East Kent and Medway) were to achieve the target of 35% at the current tariff it will inflate the cost of testing in the labs even further.

4. Risk analysis
Table 4 Risk Analysis of Tendering Chlamydia Testing Services across Kent and Medway

What could go wrong	Cause (why)	Consequences	Mitigation
(1)	(2)	(3)	(4)
Samples are not collected within the right timeframe.	1.The lab does not have any arrangements in place for a drop off point. 2. The lab does not have arrangements in place for transportation of samples.	All the samples need to be destroyed as they can't be processed.	Tender award will be subject to assurances on planned collections at nominated sites and provision in place for issues arising. Score highly on tender award.
The lab does not have the capacity to process all the samples.	1.There is a drive by the screening office to increase the number of screens. 2. The NAAT platform is not large enough to process the screens. 3. The lab only processes samples at day time.	Only some of the samples can be processed at any given time resulting in loss of the non-processed samples. This will result in an inability to meet target and potentially positive patients left untreated.	

	4. the lab cannot cope with seasonal variation of work load.		
The quality of lab testing is poor.	The lab equipment is out of date and does not meet NCSP standards.	1.A large number of screens are identified as equivocal. 2.This has an impact on the positivity rate of the chlamydia screening programme.	NAAT testing (or implementation of future testing requirements) to latest platform standards to be core criteria for contract being awarded as specified in 3.2.1 of the service specification.
Results are not reported within NCSP Core Requirement timeframe (90% to programme staff in 7 working days).	The lab does not realise the importance of reporting within the timescale. There are no agreed arrangements in place to report results from the lab to the screening office. The electronic system used to report results	There is a delay in notification and treatment.	Current arrangement is that the lab reports direct to CSO. Service level agreement provides for this in the Summary of Requirements and in 4.3.
There are inadequate facilities for storage of samples	does not work. 1.The processing lab is outside Kent and has no arrangements in place with labs in Kent to act as holding points for samples. Security? 2.There are designated points for storage of samples but there are no refrigeration facilities available 3. The storage facilities are not available over the weekend.	A large number of screens are lost because of inadequate storage facilities.	Service specification (5.3) states that prenegotiated nominated sites must have a pathway in place for receiving samples and the means to refrigerate samples.
Agreed number and type of screening kits are not provided	1.The screening team has to spend time pipetting urine into the kit. 2.There are infection control implications.	Staff unable to perform test in an outreach capacity.	Service specification in the Summary of Requirements is explicit in stating that urine samples do not require pipetting. Volume of kits provided for in Service Specification at 5.5.
The data cannot be transferred electronically in a secure manner to the screening programme data base.	The IT system in the lab does not talk to the IT system in the screening programme office	There are breaches in information governance	Needs to be in SLA with high criteria scoring for contract award. CTAD compliance Service Specification 6.3.
Calls cannot be taken by the provider from the screening	Insufficient staffing levels to handle screening	Client not receiving results in time.	Text and phone contact in place at

office.	administration.		present. Service specification provides for Service Availability criteria at 7.2 and 7.3.
Performance monitoring reports are not provided to the chlamydia screening office.	Insufficient staffing levels to handle screening administration.	Screening office and commissioners unable to gauge progress and react accordingly.	Service specification provides for Performance and Monitoring reports at 8.1.
The cost of transporting the samples makes the service more expensive.	Increase in distance to be travelled between new lab locations and existing/new collection points.	Any costs saved on the unit costs will be absorbed in transportation costs.	Transportation costs will be capped
The cost of chlamydia screens generated from the GUM clinic becomes more expensive.	Current providers do not win tender and the overheads burden of cost for providing GUM screens remains the same.	This results in the service becoming more expensive.	Renegotiate the cost of GUM screens outside the block contract
The existing service providers decide not to process the chlamydia screens and other screens originating from GUM clinic.	Current providers and commissioners cannot agree a mutually agreeable compensating tariff for GUM screens.	There is a gap in service provision for GUM.	All GUM screens to be considered for re tender.
Confidential data is leaked	The lab staff don't have the required training in information governance and other confidentiality policies.	Adverse publicity. Patients lose confidence in the service and screening numbers drop significantly. Potential for fines.	Point 9.1. in Service Specification and SLA will state explicitly the requirements in terms of systems, processes and staff training expectations. Awarded tender will need to score highly on this criteria.

5. Options appraisal

Table 5 options appraisal

Options	Advantages	Disadvantages
1.Do nothing	No disruption to current	If the target for testing were to be
	service	met the cost of the service will
		become more expensive
2.Offer Chlamydia testing in	There will be no need to go	Current providers from whom
partnership between providers and	out to tender and the	chlamydia testing activity is diverted
reduce number of testing sites	desired savings can be	may challenge the decision in the
	made by renegotiating the	competition commission
	price of the tests	
3.Go out to tender	A more cost effective	The cost of the service may go up if
	service	an external bidder (outside Kent)
		were to be awarded the tender

6. Financial consequences

In the year 2011/12 the budget for processing Chlamydia tests in the labs was £719,500 across the cluster. If the service is tendered out to less than four providers it will lead to cost reduction and improvement in the standards of the service. It is estimated that the savings made by tendering the service could be in the range of £100,000 to 150,000.

7. Recommendations

- (1) The Cabinet Member for Adult Social Care and Public Health will be asked to make a decision on Chlamydia testing service being put out to tender with the potential for savings made being reinvested in the chlamydia screening service (as set out in option 3 of this report).
- (2) Members of the Social Care & Public Health Cabinet Committee are asked to consider and either endorse or make recommendations on the proposed decision to be taken by the Cabinet Member for Adult Social Care & Public Health.

8. Contact details

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Background Documents:none

Appendix A

NHS Kent and Medway

Chlamydia Screening Guidance & Service Specification

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1. Background

The National Chlamydia Screening Programme (NCSP) is a control and prevention programme targeted at sexually active young people aged under the age of 25. In 2010/11 the Vital Sign target was to screen 35% of the 15-24 year old population.

The number of screens this translates into for each area of NHS Kent and Medway is outlined below along with what the actual activity was for the year.

Table 1 NCSP Chlamydia testing activity for 2010/11

NHS Kent and Medway	15-24 year	Number of	Last year's	Deficit in	
	population	pulation screens required		numbers	
	(2010/11	to meet 35%			
	screening year)	target			
West Kent	79200	27720	19004	8716	
East Kent	99600	34860	20638	14222	
Medway	34400	12040	8395	3645	
Total	213200	74620	48037	26583	

The New Chlamydia target differs from the old target in that GUM screens will be included in the overall coverage. The number of Chlamydia screens that were performed in the GUM clinics is as shown in table 2. This number has been deducted from the total number of screens required to meet each of the percentage coverage. The screens generated from GUM will more or less remain the same irrespective of what Chlamydia screening activity is performed in the NCSP.

Table 2 Total number of Chlamydia screens performed in GUM clinics 2010/11

	Chlamydia GUM screens		
NHS West Kent	4519		
NHS East Kent	7323		
NHS Medway	3015		
Total	14857		

Table 3 Total number of tests in Kent based on achieving a sliding scale target

	15-24 year	10% to 15% of	15%+1 to 20%	20%+1 to 25%	25%+1 to 30%	30%+1 to 35%
	population	population	of population	of population	of population	of population
		less GUM	less GUM	less GUM	less GUM	less GUM
		* screens	screens	screens	screens	screens
		Screens				
NHS	77,641	7764 to 11646	11647 to 15528	15529 to 19410	19411 to	23293 to 27174
West		(647 to 970 per	(971 to 1294	(1295 to 1617	23292	(1942 to 2264
Kent		month)	per month)	per month)	(1618 to 1941	per month
					per month)	
		271 to 594	595 to 918	919 to 1241	1242 to 1565	1566 to 1888
NHS	100,028	10002 to 15004	15005 to 20005	20006 to 25007	25008 to	30009 to 35009
East		(833 to 1250	(1251 to 1667	(1668 to 2083	30008	(2501 to 2917
Kent		per month)	per month)	per month)	(2084 to 2500	per month)
					per month)	
		223 to 640	640 to 1057	1057 to 1473	1474 to 1890	1890 to 2307
Total	177669	494 to 1234	1235 to 1975	1976 to 2714	2716 to 3455	3456 to 4195
number						
of tests						
for NHS						
East						
Kent &						
NHS						
West						
Kent						

Table 4 Total number of tests in Medway based on achieving a sliding scale target

	15-24 year	10% to 15% of	15%+1 to 20%	20%+1 to 25%	25%+1 to 30%	30%+1 to 35%
	population	population	of population	of population	of population	of population
		less GUM	less GUM	less GUM	less GUM	less GUM
		screens *	screens	screens	screens	screens
NHS	35,663	3566 to 5349	5350 to 7132	7133 to 8915	8916 to 10698	10699 to 12482
Medway		(297 to 445 per	(446 to 594 per	(595 to 742 per	(743 to 891per	(892 to 1040 per
		month)	month)	month)	month)	month)
		46 to 194	195 to 343	344 to 491	492 to 640	641 to 789

Table 5 Total number of tests per month (excluding GUM) for NHS West Kent, NHS East Kent and NHS Medway

10% to 15% of	15%+1 to 20%	20%+1 to 25%	25%+1 to 30%	30%+1 to 35%
population	of population	of population	of population	of population
less GUM	less GUM	less GUM	less GUM	less GUM
screens	screens	screens	screens	screens
'				
540 to 1428	1429 to 2318	2319 to 3205	3206 to 4095	4096 to 4984
r /	oopulation ess GUM screens	ess GUM less GUM screens	oppulation of population less GUM less GUM screens screens	oppulation of population of population less GUM less GUM less GUM screens screens

*

GUM screens have been deducted from the totalnumber of screens tested every month because all Chlamydia screens originating from GUM are paid through the block contract.

NHS Kent and Medway is committed to continuing to provide a Chlamydia screening programme, with the focus on core services undertaking the majority of screening. Coverage at 35% will now be expected to be reached from a combination of screens carried out under the NCSP and GUM (15-24 population).

NHS Kent and Medway currently use four different pathology services to meet the demands of the programme. NHS Kent & Medway is now inviting potential pathology providers to tender to provide Chlamydia screening pathology services for the whole of NHS Kent and Medway from April 2013

2. Summary of Requirements

NHS Kent and Medway is looking for a single pathology provider to provide a diagnostic service for the detection of Chlamydia trachomatis as part of the National Chlamydia Screening Programme (NCSP). Providers are invited to tender on a basis of no minimum number of screens being guaranteed by NHS Kent and Medway.

Any potential provider must fulfil the NCSP Core Requirementsstandards (see Appendix A) including the quality standard of at least 90% of results reported by the laboratory to the programme staff within 7 working days.

Any successful provider must also meet the appropriate service and quality standards as defined within the Kent and Medway Pathology Service Specification for Pathology/Laboratory Medicine 2012/2013.

We require the provider to offer screening by the testing of male urines, female urines and self-taken vaginal swabs. It is a condition of the tender that urine samples must **NOT** require pipetting into a UPT at the screening/testing site. We do **NOT** require dual testing of Chlamydia and Gonorrhoea.

3. Service Specification

3.1.1 Aim of service

To provide a full end to end laboratory service for the transportation, receipt, testing and reporting for the Chlamydia Screening Programme for under 25 year olds in NHS Kent and Medway. This shall include the provision of all screening kits, the delivery and collection of both kits and samples, sample and reporting data entry and the reporting of the result by electronic transfer of data.

3.2 Pathology service

- 3.2.1 To provide a full diagnostic service for the detection of Chlamydia trachomatis in appropriate specimens submitted for testing using NAATS (Nucleic Acid Amplification Test), or any future nationally agreed testing methodology for its detection.
- 3.2.2 To provide screening, by means of testing of male urines, female urines, and self-taken vaginal swabs.

- 3.2.3 To test and report on all appropriate samples that are submitted. It is the responsibility of the screen taker to ensure Fraser competence is assessed and to respond to any safeguarding concerns.
- 3.2.4 To have sufficient capacity to process up to 170.samples per day with systems to cope with variable demand throughout the year with significant seasonal peaks. However, it is important to note that this specification is based on no minimum number of screens being guaranteed by the commissioner.
- 3.2.5 To store samples for a specified period of time (within manufacturer's recommendations) to allow complaints/queries/request for further testing to be acted upon. This applies in particular to untested samples and samples that result in positive / equivocal results rather than samples that give a negative result.
- 3.2.6 To provide a full Chlamydia end to end testing service including the preanalytical, analytical, post-analytical phases plus the interpretation and reporting of results as well as clinical advice on further investigation and treatment of patients.

4. Accreditation and standards

- 4.1 To ensure the service is compliant with all relevant legislation and codes of practice.
- 4.2 To maintain full or conditional accreditation by Clinical Pathology Accreditation UK Ltd (CPA) (or any replacement body), meet the regulatory requirements of MHRA, and HTA for the provision of microbiological services and demonstrate adherence to quality management systems.
- 4.3 To meet the National Chlamydia Screening Programme Core Requirements as detailed in NCSP Core Requirements Fifth Edition.
- 4.4 To meet all other appropriate service and quality standards of the Kent and Medway Pathology Network Service Specification forPathology/LaboratoryMedicine 2012/13.

4.5 To undertake regular audits to ensure quality standards are being achieved. Audit results are to be shared with the service commissioners and the provider is to ensure any changes and improvements in service delivery identified as part of the audit are implemented. Screening kits – supply, distribution and collection.

5. Screening kits – supply, distribution and collection

- 5.1 To supply to Chlamydia Screening Office (CSO) sites across NHS Kent and Medway, as part of the overall cost, screening kits for use for urine samples and self-taken swabs.
- 5.2 To supply, as part of the overall cost, Home Testing Kits to CSO sites across Kent and Medway.
- 5.3 Timely planned collection of kits from a minimum number of nominated sites across West Kent, East Kent and Medway, to be agreed upon by commissioner and provider and to be arranged and coordinated by provider. Nominated sites must have means to refrigerate samples and agree for samples to be received from screening personnel at out-of-hours, and/or at weekends.
- 5.4 In the event of a leaked or damaged sample, the laboratory will inform the relevant CSO office who will request a repeat sample.
- 5.5 An agreed minimum number of screening kits to be made available directly to the Chlamydia screening teams on a monthly basis.

6. Data inputting and transfer

- 6.1 To input a minimum dataset to a database for each sample received, with option to input full dataset.
- 6.3 Meet national CTAD requirements.
- 6.4 To transfer data (including results) in a secure, electronic manner to NHS Kent and Medway and/ or Local Authority Chlamydia Screening Programme database.

7. Service availability

- 7.1 To be able to receive samples between 8am and 5pm Monday Friday, excluding Public Holidays.
- 7.2 To deal with day-to-day telephone or email enquiries from the central screening team for each of the three geographical areas within NHS Kent and Medway (East Kent, West Kent and Medway) with regards to screening queries within one working day. A telephone number and email contact address is to be provided to each screening office for use in these situations. The laboratory is to nominate a dedicated person to deal with these queries and to advise the screening offices of holiday/sickness cover arrangements for this person. The laboratory will not be expected to deal with queries from the public or from individual screening sites.
- 7.3 To provide the screening offices with a full list of all key laboratory staff to assist with the smooth delivery of service.

8. Performance monitoring reports

- 8.1 To provide monthly performance reports to each of the three NHS Kent and Medway Chlamydia screening offices, providing information on number of samples received, number of positives, number of negatives, number equivocal, number not processed and performance against delivery times/
- 8.2 To meet with the NHS Kent and Medway Chlamydia commissioners on a quarterly basis to review service delivery and performance.

9. Confidentiality, Data Protection and Information Governance

9.1 To ensure there are systems and processes in place, including staff training, to ensure patient confidentiality is maintained as detailed in the NCSP Core Requirements document.

10. Geographic coverage

10.1 To provide screening for clients within NHS Kent and Medway

11. Contract start date

11.1 To provide a full service from April 2013