ONLINE SUPPLEMENTARY MATERIALS: FILE 1

Clinical care pathways using chlamydia and gonorrhoea tests are evolving: point of care nucleic acid amplification tests may reduce genitourinary medicine service delivery costs

Supplementary Methods

A) Clinical pathways and steps

Each of the pathways comprises a number of steps; each step has a number of elements which have costs associated with them or are used to scale the costs (e.g. the proportion of patients who go through that step). These elements are:

Step components:

- Proportion of patients who go through the step (activity)
- Length of time (minutes) to complete the step
- Grade of staff/staff blend
- Non-staff resources required: consumables, drugs and pathology
- Proportion of the time, if the step is delivered in conjunction with another pathway

For most steps in the pathway a blend of staff is likely to be involved, for example, any grade of nurse. These were explicitly modelled and such combinations were taken from the Integrated London Sexual Health Tariff [1,2].

If two pathways are delivered at the same time, one would be considered as the primary pathway and the other as an additional pathway, in terms of costing. Efficiencies with staff time are generated when more than one pathway is delivered during a consultation, but the full amount of non-staff inputs are still needed as these are specific to the pathway being delivered. For example, the initial registration or health promotion steps would not occur twice, but any non-staff consumables would be required at 100%.

B) GUM Clinic Workshops

We chose a variety of clinics for the workshops to obtain as wide a range of opinions as possible given a small sample size. These included a traditional GUM clinic, a fully integrated sexual health clinic with STI and contraception offered, and one with a large proportion of individuals from high-risk groups. A lead clinician at each clinic was asked to invite his or her coworkers, and to encourage a wide range of participation. These workshops were organized during allocated staff training sessions so as not to interfere with normal working hours. Staff were all made aware of the purpose of the workshop, that detailed notes would be taken on what was said during the workshops, and that the information would be used to build consensus pathways and cost them out. All staff were made aware that the goal was to present our findings as a peer reviewed publication; consent

was implicitly given by attendance. Workshops were attended by a range of clinical and administrative staff including, at a minimum, one consultant, one nurse (Band 7/8), one health advisor, and one administrator. Each workshop lasted between 60-90 minutes.

C) Building chlamydia and gonorrhoea clinical pathways

The pathways were created using an iterative methodology. First, the research team reviewed the current pathways from the published Integrated London Sexual Health Tariff [1] and proposed new patient pathways using a chlamydia/gonorrhoea POCT to prompt discussions at the first workshop. During each workshop we asked open-ended questions about the clinic's current care pathways and possible modifications if a chlamydia/gonorrhoea POC NAAT were available. Questions considered patient flow, time from test to treatment, and the total number of clinical steps or time which would be reduced by using POC NAAT. We also captured the benefits and limitations of using and implementing a chlamydia/gonorrhoea POC NAAT in clinical practice. Subsequent workshops built on the pathways generated at previous workshops, refining them or creating new ones if their care delivery varied significantly. Costs were not considered during the workshops. We returned all of the pathways to the study team and workshop participants at the end of the study, asking for any final comments and to obtain consensus around the pathway detail.

C) Cost model

The total pathway cost = (Cost Step 1) + (Cost Step 2) + … + (Cost Step N).

$$Cost\ Step\ N_{Primary} = A \times \left(M \times ((C_{s1} \times Q_{s1}) + (C_{s2} \times Q_{s2}) + \cdots + (C_{sN} \times Q_{sN})) + \sum C_{Cons} \times Q + \sum (\right.$$

If the proportion additional is 0, then Cost Step $N_{Additional} = 0$, else

$$Cost\ Step\ N_{Additional} = A \times \left(Add \times M \times ((C_{s1} \times Q_{s1}) + (C_{s2} \times Q_{s2}) + \cdots + (C_{sN} \times Q_{sN})) + \sum C_{Cons} \times Q \right.$$

Where A is the activity, M is the number of minutes, C is the cost, Q is the quantity/proportion, s_1, s_2 … s_N are the different staff grades/blends, Cons is consumables, Path is pathology and Add is the proportion additional.

We made some general assumptions about the pathways when information was not available from the focus groups. This was done to ensure some consistency in the pathways. There were:

- Patient registration step – 5 minutes, 100% admin clerical, 0% as an additional pathway. The cost of patient registration is included in the total pathway cost, but is not shown in Figure 1 for simplicity.
- Both standard care and POCT testing pathways require sample collection instructions, gloves, urine pot and vulvo-vaginal swab.
- For asymptomatic patients, 70% would be a urine sample and 30% would be a vulvo-vaginal swab. This is based on 100% of men providing urine, and 60% of women providing a urine sample.
- The health promotion step always includes the consumables: KY lubricant (x2), STI literature (x3), male condoms (x10). Where no health promotion step is included, we added the same consumables to the consultation.
- For standard care pathways, the results management step is done by a 5/6 Nurse (6 minutes), 95% SMS text message, 2% letter notification, 3% telephone notification.
- For POCT pathways, the results management step is done by a 5/6 Nurse (6 minutes), with all patients receiving results by SMS text message, and of those 2% and 3% also receive results by letter or telephone notification, respectively.
- For standard care and POCT pathways, the step for contacting those with a positive or equivocal test results requires 90% SMS text message, 5% letter notification, 5% telephone notification.
- Microscopy is done for all symptomatic patients and is 10 minutes of a 5/6 Nurse, using blotting paper, gloves, gram stain, immersion oil, loops and a slide.
- Blood tests all include bandages/plaster, blood tube, cotton wool, gloves, needle, sterets/antiseptic wipe, syringe, transport tube and vacutainer.
- The proportion additional time was taken from pathways in the Integrated London Sexual Health Tariff [1] as this was not specifically discussed in the focus groups.

Table A: Cost inputs used in the model; taken from the Integrated Sexual Health Tariff [1,2]

Type	Item	Cost	Unit
Staff	Blend Doctor - N7/8	1.45	Minute
Staff	Blend Nurse 7/8	1.10	Minute
Staff	Blend all com SRH N2 - Dr	1.06	Minute
Staff	Blend Health Adviser	1.03	Minute
Staff	Blend Nurse 5/6/7/8	0.89	Minute
Staff	Blend Nurse 5/6	0.75	Minute
Staff	Admin/clerical	0.53	Minute
Pathology	Cepheid PoC CT/GC Test	18.00	Sample
Pathology	Chlamydia & Gonorrhoea NAAT	12.51	Sample
Pathology	GC Culture/typing - lab processing	7.55	Sample
Pathology	GC NAAT	12.00	Sample
Pathology	Gonorrhoea Culture	4.54	Sample
Pathology	HIV Serology	52.80	Sample
Pathology	HIV Serum test (4th Generation)	12.78	Sample
Pathology	Syphilis Immunoassy - Total antibody (IgG & IgM)	16.50	Sample
Consumables	Bandages/ plasters	0.07	Item
Consumables	Blood tube	0.12	Item
Consumables	Blotting paper	0.05	Item
Consumables	Chlamydia - Local Leaflet	0.06	Item
Consumables	Chlamydia - National Leaflet	0.06	Item
Consumables	Cotton Wool	0.01	Item
Consumables	Cover Slip	0.65	Item
Consumables	CT/GC Swab (cervical/endocervical)	1.56	Item
Consumables	Culture plate	1.04	Item
Consumables	Culture swab- GC	1.04	Item
Consumables	Dark ground microscopy kit	0.21	Use
Consumables	Gloves	0.05	Pair
Consumables	Gonorrhoea Leaflet	0.06	Item
Consumables	Gram Stain	0.20	Procedure
Consumables	Immersion oil	0.02	Sample
Consumables	Kit assembly costs - Chlamydia	3.22	Item
Consumables	KY Lubricant	0.30	Application
Consumables	Lab Request form with bag	0.10	Item
Consumables	Laboratory/pathology request form	0.26	Item
Consumables	Letter notification	0.58	Item
Consumables	Literature (STI)	0.06	Item
Consumables	Loops	0.60	Item
Consumables	Male Condom	0.06	Item
Consumables	Microscope slide (qty 1)	0.07	Item
Consumables	Needle	0.03	Item

Type	Item	Cost	Unit
Consumables	Paper	0.02	Item
Consumables	pH paper	0.10	Item
Consumables	Phone call	0.07	Minute
Consumables	PN slip	0.05	Item
Consumables	Saline	0.20	Item
Consumables	Sample Collection Instructions	0.05	Item
Consumables	Slide	0.05	Item
Consumables	SMS Text message	0.10	Item
Consumables	Speculum	0.82	Item
Consumables	Stains for microscopy	0.65	Item
Consumables	Sterets/antiseptic wipe	0.02	Item
Consumables	Swab	0.02	Item
Consumables	Syringe 10ml Luer Slip Syringe	0.11	Item
Consumables	Transport tube	0.26	Item
Consumables	Urine Pot, sterile collection	0.23	Item
Consumables	Urine Specimen Container (PCR Tube and Pipette)	1.04	Item
Consumables	Vacutainer	0.02	Item
Consumables	Vulvo-vaginal swab	0.16	Sample
Drugs	Azithromycin (1000 mg)	4.50	Treatment Course
Drugs	Ceftriaxone (500 mg)	5.09	Treatment Course

Table B: Descriptions of clinical steps involved in chlamydia / gonorrhoea testing and treatment pathways.

Step name	Activity
Consultation	Meet with clinician, discuss reason for attendance and any other issues, e.g. risk behaviour.
Contact positives	For patients with a positive or equivocal test result, extra time is allocated to ensure that they receive their result and attend for treatment, e.g. extra phone calls and follow-up.
Exam	Clinical examination including physical genital exam, with swabs or samples taken as appropriate.
Health Promotion	Discussion around safer sex and reducing risk behaviours.
Microscopy	Samples (genital swabs) prepared and read in the clinic laboratory.
Off-site sample processing	External step – sample is sent off-site for laboratory processing.
Partner notification	Discussion around importance of having partners notified and treated, and whether patients need assistance in reaching partners.
Patient registration	The patient registers, either face to face with a receptionist/administrator, or using an electronic kiosk or computer, and asked about reason for attendance, symptoms, risk factors, etc. A pro forma is often used. This step includes time to retrieve patient notes.
POCT	Chlamydia/gonorrhoea point of care test: staff process urine sample or swab, prepare cartridge for POC NAAT machine, and retrieve and review results.
Prepare test kits	Make the test kits for the self-service machines in clinics.
Receive samples	Process and prepare self-collected samples to be sent for off-site sample processing or processed in POC test.
Results	Consultation with patients about their positive results (negative result generally does not require a consultation).
Results management	Managing the results when they come in from the laboratory (e.g. inputting on IT system) or the POCT if patients have already left the clinic, notifying patients of their results by text message (~95%), letter or by telephone call, and requesting that positive patients return for treatment
Sample collection	Urine or vaginal swab samples taken for chlamydia and gonorrhoea NAAT testing, and/or blood samples obtained for HIV and syphilis testing, and/or swabs taken for gonorrhoea culture. Staff process samples and prepare for testing (either sent to an off-site laboratory or POCT in the clinic).
Supported partner notification	Clinic staff will notify partners for patients requesting assistance.
Treatment	Drugs given in clinic, along with advice on safer sex.

Table C: Additional chlamydia and gonorrhoea testing and treatment pathways.

Pathway	Clinical steps	As Primary Pathway		As Additional Pathway	
		Cost per patient	Time (min)	Cost per patient	Time (min)
A) Rapid sexual health screening for asymptomatic patients.					
Asymptomatic Rapid SHS (current)	Consultation / Sample collection*,† → Off-site sample processing (1-2 weeks) → Results management → Contact positives	£62.16	21.2	£54.17	11.1
B) Current and proposed self-service pathways for asymptomatic patients.					
Asymptomatic Self-service (current)	Prepare kits → Receive sample → Off-site sample processing (1-2 weeks) → Results management → Contact positives	£24.37	14.9	£23.70	14.2
Asymptomatic Self-service POC (proposed)	Prepare kits → Receive sample → POCT (90 min) → Results management → Contact positives	£32.60	14.9	£31.94	14.2
C) Gonorrhoea follow up visit for second line treatment after failure of initial treatment.					
2nd Gonorrhoea treatment (current)	Exam → Treatment → Health promotion / Partner notification	£41.07	35.0	£33.97	25.0

Table C: Additional chlamydia and gonorrhoea testing and treatment pathways. Pathway steps, cost per patient, and health care professionals' time is shown. The first step, patient registration, is common to all pathways and is not shown. Detailed descriptions of all clinical steps are provided in Table B. **(A) Rapid sexual health screening for asymptomatic patients.** After registration, patients have a combined short consultation and blood test for syphilis and HIV, provide a self-collected sample for chlamydia and gonorrhoea (urine for men and self-taken vaginal swab for women), and then leave the clinic. In some cases, a rapid HIV test would be given instead of the standard HIV laboratory test if deemed appropriate and available, such as in high-risk groups like men who have sex with men or those with multiple partners. *Urine/vulvo-vaginal swab collected for chlamydia and gonorrhoea testing. †Blood sample collected for HIV and syphilis testing. **(B) Current and proposed self-service pathways for asymptomatic patients.** In self-service testing, patients register at a machine, and if no symptoms are reported, they are offered a chlamydia/gonorrhoea test and/or pregnancy test. Patients then drop off a self-provided sample in the clinic and leave, with no direct clinical contact. Results management follows, in which most patients would receive a text message (SMS) of their results, with extra time allowed to ensure positives are contacted and attend for treatment. **(C) Gonorrhoea follow up visit for second line treatment after failure of initial treatment.** In the case of primary treatment failure, a follow-up visit is necessary for second-line gonorrhoea treatment with cefixime and azithromycin.

Table D: Potential benefits and limitations of a POC NAAT for chlamydia and gonorrhoea in a GUM clinic.

Benefits	Concerns/considerations
Same day diagnosis and treatment for positive patients, improving treatment rates and preventing onward transmission, reducing the risk of complications	Staff time would be diverted from patient contact to running the test
Quicker results for patients, alleviating anxiety	Staff would need to be trained in running the test and reporting results
One clinic visit for positive patients rather than two visits (one for the test and one for treatment)	Changes in how services are managed and workflow
Reducing overtreatment from presumptive treatment, to minimise development of antimicrobial resistance	Some patients may get results in two hours, others may have to wait longer if capacity has not been planned properly, although capacity is very flexible and can be changed easily
Potential to reduce the number of clinic visits, which means more time available to other patients	Implications of reducing the number of samples sent to laboratories, e.g. clinics may have contracts in place, and loss of business to central laboratories
Greater confidence for clinicians in providing quick and appropriate treatment	Clinics may need to assume responsibility for quality assurance of testing and reporting
Attracting new clients who would not normally come in for a test	Other tests may become available in the near future, yet clinics would be tied into a contract if they are early adopters
Reduces the number of people lost to follow up i.e. test positive but do not return for treatment	Could result in loss of income to clinic in standard first / follow up tariff payment system
Fast track testing service for partners reducing the need for presumptive treatment	Patients may need to wait in the clinic for their results for 2 hours
Efficiencies realised in clinic enable capacity to be released and utilised elsewhere	

References

1. Pathway Analytics. Sexual Health Tariff. http://www.pathwayanalytics.com/sexual-health/about-the-tariff Last accessed: 25/06/2014

2. London Sexual Health Programme. The Sexual Health Tariff. http://www.londonsexualhealth.org/projects/tariffs.html Last accessed: 18/1/2013