Evaluation of the Greater Manchester RU Clear? Chlamydia and Gonorrhoea Screening Programme

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Executive Summary

Background

Diagnosis rates of sexually transmitted infections (STIs) have been increasing in the UK since the mid-1990s (Health Protection Agency 2008b). The total number of new STI diagnoses reported by GUM clinics in the UK in 2008 (including chlamydia, gonorrhoea, herpes, warts and syphilis) was 399,738 and there were 268,109 "other STI diagnoses" (such as recurrent presentations) in 2008. While HIV and STIs are acknowledged as an important public health problem in the UK (Department of Health 2001), (Health Protection Agency 2007), most members of the public do not consider sexual health to be relevant to them (Duncan 2001). The asymptomatic nature of STIs and public denial means that often diagnosis and treatment for STIs are overlooked. Policy directed at improving accessibility of STI services, promoting HIV testing, and wider screening of STIs (DH 2005; DH 2004; DH 2001), along with the resurgence of STIs from the mid-1990s, has led to the diagnoses and management of STIs being more widely available in settings outside genitourinary medicine (GUM) clinics.

Aims

This report evaluates the impact of the *RU Clear? Chlamydia trachomatis* (CT) and *Neisseria gonorrhoea* (GC) Screening Programme on the sexual health of young people in Greater Manchester. Further, it seeks to inform future programme and policy development. It anticipates and recommends the benefits of rapid dual testing for the diagnoses of CT and GC in the community as well as examining the measured and client-perceived confidence of the testing being provided.

The effectiveness of the *RU Clear?* Programme was assessed in terms of CT and GC prevalence in key target populations in Greater Manchester. The objectives were to assess the contribution of the Programme to KC60 reporting by population demographics; its effectiveness by PCT, sex, sexual orientation, ethnicity, screening location and area; its appraisal by deprivation status; and whether, for those under 25 years of age, it is fit for purpose in terms of population STI prevalence and, for GC, testing accuracy (compared with microscopy and culture testing). This process intended to examine the experience of health care professionals working in screening clinics and those working in the GUM clinics.

We are mindful that GUM clinics deliver care to GC clients referred for confirmatory testing, antibiotic sensitive testing and treatment; whereas screening clinics only screen clients for initial diagnosis for referral to GUM clinics. Clients screened as part of the *RU Clear?* Programme were also examined with regard to their experience of the referral process (screening clinics) and GUM clinic attendance (post referral). The experiences of staff based at screening clinics and GUM clinics were examined in relation to dual testing, partner notification and the referral process.

Methodology

Data from a six month pilot period (from September 2007 to February 2008) and the preceding six month period (March to August 2007) were supplied by RU Clear?. The data were then quality assured and arranged into three datasets for analysis: (i) a six month dataset of all tests; (ii) a one year long dataset of all tests; (iii) a de-duplicated dataset of all individuals tested in the year period (since some individuals were recorded more than once). A fourth dataset comprising all GC positive individuals from the six month pilot period was collected at GUM clinics by researchers. This included additional information on demographics, further additional tests, treatment and partner tracing. The data collected for the March-August 2007 period included GC recall data and therefore also included dual tests. The data collected through September 2007-February 2008 from GC positive clients were analysed to define the proportion of clients with positive GC test results who underwent confirmatory testing and antibiotic sensitivity testing at GUM.

For the qualitative aspect of the study *RU Clear?* Programme staff, GUM clinic staff, and clients were recruited for telephone interview. *RU Clear?* and GUM clinic staff were recruited using contact lists that are kept for monitoring purposes. Clients were asked at screening if they would be willing to take part in the study by leaving their mobile telephone with staff for the researcher to contact them at a convenient time. Three *RU Clear?* Programme staff, three GUM clinic staff and five clients were interviewed.

Key findings

Screening coverage and positivity rates

In common with other UK studies of ethnicity and STI rates, rates of GC were higher in those of black African (1.8%), black Caribbean (1.7%) and mixed race (2.2%) ethnicity compared to those of white ethnicity (0.7%). However, while the positivity rate in persons defined as white was the lowest of all the ethnic groups described, approximately 85% of all persons tested were within this group. Enhancing the screening rate in minority ethnic groups is thus a priority in order to identify and treat persons predicted to test positive for CT and GC. New approaches to encourage an increase in uptake of screening in minority ethnic groups are clearly required.

Testing rates were higher in areas with higher levels of deprivation (6% of the population were screened in the area of in the highest quintile of deprivation compared to 3% in the least deprived). This shows that the programme has been successful at reaching those known historically to be most at risk of poor health. However, in this study, rates of CT were uniformly high across deprivation categories, with relatively little variation (from 10% in the second least deprived quintile to 12% most deprived quintile). This underlines the importance of giving all young people good access to screening for CT and GC, at all levels of deprivation.

Of those screened, CT positive diagnosis rates in males have a greater range (4.3% Heywood, Middleton and Rochdale Primary Care Trust (PCT) – 13.5% Ashton, Leigh and Wigan PCT) compared to females (10.1% Stockport PCT-14.4% Ashton, Leigh and Wigan PCT). Positivity rates for GC in males was lower (0.00%-1.25%) than in females (0.38%-1.53%).

The proportion of the population of young people aged 16-24 who were screened in the *RU Clear?* Programme varied across Greater Manchester. Screening rates in females in the best performing PCT (Manchester, 12%) were double those of other PCTs. Screening rates for females of the target age (15-24 years) were three times higher than that of males. Screening rates for males ranged from 1.4% (Stockport) to 3.3% (Heywood, Middleton and Rochdale). New approaches to encourage uptake of screening in males are required.

Significant achievements were made in identifying service use patterns of young people who attended testing. Differences in the uptake of testing and testing behaviours were identified between males and females. While it was found that young peoples' clinics were the most popular choice of testing location for both young females and males (40% and 33% respectively), the second most frequently used location for females was the Family Planning Clinics (22.5%) whilst Health Centres (18.6%) were

most popular for males. This shows overall that community testing was the most frequently used location of testing, but that females and males have different approaches to testing.

It was estimated from the total monies contributed by PCTs that the predicted 54 000 tests carried out between 2008 and 2009 that the cost per test would be £22.43. However, there was no comparable information from other PCTs (Lewisham PCT, City and Hackney PCT and Liverpool PCT) to comment on whether costs are similar across screening programmes as was originally intended.

Confirming and treating GC

The Nucleic Acid Amplification Test (NAAT) is used to test for GC. The specific type of NAAT used in Greater Manchester is the Gen-Probe APTIMA Combo 2 assay (AC2) which uses Transcription Mediated Amplification technology (TMA) to detect CT and GC nucleic acid. Samples that test positive are retested using a Gen-Probe APTIMA assay that detects a different target on the CT or GC nucleic acid (Aptima CT assay (ACT) and Aptima GC assay (AGC)). This combination of testing ensures a high degree of certainty that a reported reactive result indicates a true infection (Golden et al. 2004). However, guidelines state that NAATs should be confirmed by culture and that culture is the diagnostic method of choice in GUM (BASHH et al. 2005). Importantly, culture is required for testing antibiotic sensitivity. Nearly 1% (111 cases) of the screened population tested GC positive of whom 98 presented for treatment at GUM and 78 (14 males, 64 females) cases underwent culture/microscopy testing. Of the confirmed positives (confirmed on retest with culture and/or microscopy), 94% tested positive on culture, with 53% testing negative on microscopy. Microscopy was shown to capture fewer GC positive cases than culture; however, microscopy identified twelve cases missed by culture testing alone.

GUM culture/microscopy testing was able to confirm 69% of infections that were detected using AC2. All 14 males retested positive (100%); 40 females retested positive (63%), with partner information or limited retesting causing uncertainty in negative GC retests results in a further 21. In most female cases (72%), swabs were taken at fewer than three body sites, reducing the opportunity to confirm their positive GC result. When considering only those retested at all body sites (pharynx, cervix, urethra), 93% were found positive on culture and/or microscopy (13/14). In cases where swabs were not taken at all potential body sites, GC infection was less likely to be confirmed, suggesting that comprehensive swabbing is needed for accurate diagnosis. Overall, there was low uptake of pharyngeal swabbing (males 29% and females 27%) and a very low uptake of rectal swabbing (males 5% and females 14%). It was also reported that consistency in retest practice and swab site testing varied between clinics as well as within individual clinics. Clinics need to be consistent and comprehensive in their follow-up of clients screening positive for GC, to enable confirmation of GC diagnoses, and allow antibiotic sensitivity testing. Such data would add to the evidence base on the effectiveness of screening for GC alongside the national CT screening Programme.

Of 78 index patients, 46 (59%) were tested for drug resistance prior to treatment in accordance with the British Association for Sexual Health and HIV (BASHH) guidelines. Of the 46, five (11%) showed resistance to one or more GC antibiotic treatments, although all (100%) showed sensitivity to one or more of the most commonly prescribed treatments. The majority (96%) of patients tested were sensitive to Cefixime which was the most commonly prescribed medication for GC. For those referred and attending GUM, 75% took up the option of further STI testing (i.e. HIV and syphilis).

Perceptions/acceptability

Whilst perceived and actual confidence in testing methods was consistently high, improvements to partner identification and referral pathways are necessary to increase numbers of partners who uptake testing as a result of client positive diagnosis. This evaluation only considered partner traceability in relation to GC positive patients whose partners are traced and treated by GUM clinics. *RU Clear?* data on CT partner notification were not considered by this evaluation as the focus here is on the effectiveness of the dual test. The GC case note review found that partner traceability and subsequent partner treatment was low, and during interview GUM staff expressed some confusion about responsibilities.

Screening site staff viewed dual screening as positive, thought it acceptable for clients, and reported success with rapid referral systems. Staff reported that using such occasions to routinely test for all

STIs rather than just CT and GC would be beneficial since only testing for CT and GC could provide young people with false confidence in their sexual health status. Staff from GUM clinics also provided overall positive views, reported effective referral systems, and considered the Programme not to be a significant burden to work-load. GUM staff perceived that communication between *RU Clear?* Programme staff and GUM clinics could be improved as they felt that there were often duplicate requests for the same information.

Clients reported an overall positive experience of the screening Programme, found the test easy to take, and the staff helpful. Clients were pleased to have the opportunity to be tested and treated for two infections.

Clients reported being worried about CT testing but when offered dual testing for CT and GC, none of the GC tests were declined by clients. Clients thought that it was beneficial to test for both at once. It was found that there was little client resistance to this. It was felt by clients that ignoring other STIs and only testing for CT and GC could give young people false confidence in their status.

Recommendations

- This report recommends that the protocols for the *RU Clear?* Programme undergo appraisal. Policies and guidelines to ensure consistent testing procedures to reduce GUM clinic variability in testing are required. GUM clinic staff reported inconsistencies and confusion over who was responsible for partner notification for clients being referred by the *RU Clear?* Programme. For the screening programme to achieve a reduction in the rates of CT and GC, partners of index cases (the original patients presenting for testing) need to be tested and treated to reduce transmission. Protocols must clarify who is responsible for partner notification and staff ought to be made aware of the protocols.

- Retest practices varied across Greater Manchester GUMs and require greater consistency. It is suggested that greater attention is paid to following good clinical practice, especially regarding the swabbing of all relevant body sites at GUM. This may be facilitated by enhanced guidelines.

- Data quality needs to be improved for research and audit purposes. The most common errors were on dates of birth. This is a vital field for de-duplicating records (and thus determining repeat attendances, repeat infections etc.). It is not clear if data errors occurred in lab, testing site or at the *RU Clear?* Office; this will need investigating. A review of the training of data entry staff is also required. Processes for data input should be reviewed, for example, validation rules within the *RU Clear?* database should be used to set the possible parameters for each variable. It was also recommended by staff participating in interviews that the form could be simplified to provide more space as there is currently duplication of information on the form.

- For improvements to the service it was suggested that postal testing kits be made more widely available in community setting. Staff at screening sites suggested that the information materials about the screening tests should be made more effective and more young-person friendly and that a greater focus be aimed at this younger group.

- In the UK as a whole, the numbers of GC positive diagnoses have fallen. In this study, dual testing has resulted in the detection of cases that would otherwise have gone un-noticed. Consequently, rather than seeing a decrease in the number of GC positive diagnoses within Greater Manchester, this has resulted in the stabilisation of the number of positive cases detected. However, cases were generally asymptomatic and are likely to remain infected in the community without the screening programme. Efforts to obtain a consistently high level of testing, particularly amongst high-risk groups-are essential to control the spread of GC.

- Geodemographic tools such as P^2 People and Places, Health Acorn and Mosaic can be used to gain insight on the population, as well as attaining geographical locations of risk populations. The GC positive rate was highest in P^2's 'urban challenge' areas. These areas could be targeted for dual screening and primary prevention, and other social marketing

insights from these populations (e.g. purchasing habits, attitudes) can be used to inform interventions.

- Prevalence of GC was several times higher in black and mixed race communities, yet testing rates were low. Increasing the screening rates of these populations should be a priority.

- GC screening in a National Clamydia Screening Programme (NCSP)-targeted population is able to identify GC in a low-risk, asymptomatic population who may not access GUM services. However, positive diagnoses of GC in non-clinical settings require referral to sexual health services. Previous research has found low attendance at GUM sites for CT clients diagnosed in community clinics, suggesting that the proportion of GC positive individuals who do not present at GUM sites would be high. In this study 88% (98/111) attended for treatment. Enhanced referral between community settings and GUM sites is required. This could be facilitated by the use of common electronic appointment systems.

- Health centres have low screening rates; nevertheless, this is the second most popular location for males to take up testing. We would particularly recommend that that GPs and allied health services take a greater role in screening, recognising that this is an opportunity to access male clients.

- Sexual orientation or exposure through sex between men (MSM) is not recorded at initial screening as it is not required by the national programme. Without this information it is not possible to determine the prevalence of CT and GC in MSM who are screened in the community, or determine if this group is accessing the *RU Clear?* Programme. Although the programme is aimed at heterosexual young people MSM do participate so we recommend the initial screening form includes a question which will record if the infection was acquired through sex between men. This information can then be compared with KC60 and now Genitourinary Medicine Clinic Activity Data Set (GUMCAD), HIV, syphilis and other GUM data to examine use of services, prevalence and possible gaps in services in this vulnerable group.

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1. INTRODUCTION

1.1 Background to Project

Diagnosis rates of sexually transmitted infections (STIs) have been increasing in the UK since the mid-1990s (Health Protection Agency 2008b). The total number of new STI diagnoses reported by GUM clinics in the UK in 2008 (including chlamydia, gonorrhoea, herpes, warts and syphilis) was 399,738 and there were 268,109 "other STI diagnoses" (such as recurrent presentations) in 2008. While HIV and STIs are acknowledged as an important public health problem in the UK (Department of Health 2001), (Health Protection Agency 2007), most members of the public do not consider sexual health to be relevant to them (Duncan 2001). The asymptomatic nature of STIs and public denial means that often diagnosis and treatment for STIs are overlooked. Policy directed at improving accessibility of STI services, promoting HIV testing, and wider screening of STIs (DH 2005; DH 2004; DH 2001), along with the resurgence of STIs from the mid-1990s, has led to the diagnoses and management of STIs being more widely available in settings outside genitourinary medicine (GUM) clinics.

The *RU Clear?* Programme system was launched in September 2006. As part of the National Chlamydia Screening Programme (NCSP) the aim of the *RU Clear?* Programme is to screen sexually active young people under the age of 25. The target proportion tested was 17% of the under 25 year old population for 2007/08. The current target has been raised to 25% for 2009 -10 (National Chlamydia Screening Programme 2008b). Nucleic Acid Amplification tests (NAATs) facilitate easy and cost effective screening for CT (Low et al. 2007) and are routinely used in screening patient-collected urine samples and self-taken vaginal swabs. The UK National Chlamydia Screening Programme (NCSP), established to reduce the prevalence of CT in 16–24 year olds, can be used as an opportunity to exploit the dual screening potential of NAATs to opportunistically screen for GC on specimens taken for CT screens. The *RU Clear?* Programme collates data from the Chlamydia Screening Form and are informed of patient outcomes by GUM for those clients diagnosed *Neisseria gonorrhoeae* (GC) positive and referred to a GUM clinic for treatment and care.

The laboratory support was provided by the Manchester Medical Microbiology Partnership (MMMP) Virology Laboratory at Manchester Royal Infirmary. At the start of the programme the Gen-Probe TIGRIS DTS analyser was used at the microbiology laboratory to run the Gen-Probe APTIMA Combo 2® assay (AC2) which automatically tests every sample for both *Chlamydia trachomatis* (CT) and GC. The assay uses a member of the Nucleic Acid Amplification Tests (NAATs) family called transcription-mediated amplification (TMA) (Welte et al. 2000) to detect CT and GC nucleic acid. In February 2007 the same testing system was implemented at Pennine Acute Hospitals NHS Trust Microbiology Laboratory for its routine diagnostic work.

Several studies have previously explored the effectiveness of offering a dual test for the diagnosis of chlamydia and gonorrhoea in the community (Lavelle 2008; Lavelle et al. 2006; Stanley and Todd 2005). In addition, clinical studies have examined in detail the effectiveness of the different tests in comparison to the GUM clinic-based culture and microscopy tests (Hardwick et al. 2009; O'Mahoney et al. 2008) We aims to evaluate the effectiveness of the new AC2 dual test and compare it to the conventional GUM-based culture and microscopy-based tests.

The Centre of Public Health, Liverpool John Moores University (LJMU), was commissioned to evaluate the *RU Clear?* Programme. Maxwell's six dimensions of quality (Maxwell 1992; Maxwell 1984) were used in the tender document (Appendix 2) to specify the needs of the project.

1.2 Literature Review

1.2.1 Overview STI in UK and prevalence of infection

Diagnoses of sexually transmitted infections (STIs) have increased in the UK since the mid-1990s. In 2005, 790 443 diagnoses were made in sexual health clinics, with up to another quarter of the common infections in primary care (Cassell et al. 2006; Health Protection Agency 2006) Some 10.8% of males and 12.6% of females aged 16-44 reported that they have had an STI (Fenton et al. 2001). While HIV and STIs are acknowledged as an important public health problem in the UK (Department of Health 2001; Health Protection Agency 2006; Nicoll et al. 2001), most members of the public do not consider STIs to be relevant to them (Duncan et al. 2001). Due to public denial and the asymptomatic nature of STIs, diagnostic and treatment services are potentially overlooked. Policy has been established to promote improved accessibility of STI services, the promotion of HIV testing, and wider screening for STIs (Department of Health 2001, 2004). Diagnosis and management of STIs is becoming more widely available in settings outside the network of genitourinary medicine (GUM) clinics because of the resurgence of STIs, which began in the mid-1990s.

STIs present a complex problem for public health. For transmission, STIs like gonorrhoea and syphilis (Hethcote and Yorke 1978; Wasserheit and Aral 1996) and to a limited extent Chlamydia (LaMontagne et al. 2004) depend mainly on the small proportion of the population who have many sexual partners (the "core group"). Population transmission rates depend on the behaviour of individuals and on the use and availability of diagnostic tests and curative treatment (Wasserheit and Aral 1996). Early treatment reduces the period of time for which an individual is infectious (Anderson and Garnett 2000). Individuals with an STI are known to be at high risk of re-infection (LaMontagne et al. 2007), and an essential element in the prevention of re-infection is through partner notification and treatment (Cowan et al. 1996; Trelle et al. 2007). While GUM clinics have developed expertise in partner notification other forms of testing and diagnoses are less able (Trelle et al. 2007).

1.2.2 Chlamydia in the UK

Chlamydia trachomatis (CT) is the most prevalent bacterial sexually transmitted infection (STI) in the UK, comprising 31% of all new diagnoses made in GUM clinics in 2007 (Health Protection Agency 2008a). In 2007, 121,986 cases of CT were diagnosed in GUM clinics in the UK, giving a prevalence of 211 per 100,000 population. The North West (Girardet et al. 2009) has the highest CT prevalence in England (237 per 100,000) after London (303 per 100,000). Those at greatest risk for acquiring infection are sexually active young adults, specifically females aged 16-24 and males aged 18-29 (National Chlamydia Screening Programme 2008a). Prevalence rates in North West England are highest in males aged 20-24 (1,466 per 100,000) and females aged 16-19 (1,637 per 100,000), mirroring a trend throughout the UK (Health Protection Agency 2008a). In males who have sex with males (MSM), diagnoses of CT through GUM clinics rose from 387 to 3,239 in the past 10 years (1997-2006) (Department of Health 1998).

Of CT infected females and males, 70% and 50%, respectively, are asymptomatic. Left untreated, CT can lead to pelvic inflammatory disease (PID), infertility, ectopic pregnancy and tubal infertility in females, which are expensive to treat and have major lifetime consequences for those affected (Department of Health 1998).

Chlamydia, alone or with other microorganisms, has been found in between 5% to 50% of females seeking care for symptoms of PID. Diagnosis and treatment of PID is difficult and approximately 17% of females treated for PID will become infertile; 10% of those with PID who do conceive will have an ectopic pregnancy and 17% will experience chronic pelvic pain as a result of the infection

(Department of Health 1998). The annual cost of chlamydia and its consequences is currently estimated to exceed £100 million in the UK (Chief Medical Officer's Expert Advisory Group and Department of Health 1998).

CT screening has been shown to reduce the incidence of PID (Scholes et al. 1996). Of females assigned to CT screening plus treatment condition during a RCT, the incidence of PID in treated females was 8/10,000 per woman months compared with control females (who received no screening) suffering a PID incidence of 18/10,000, after controlling for confounding variables. Study participants were from a high risk register, limiting inferences on the true prevalence in the population.

1.2.3 Gonorrhoea in the UK

Neisseria gonorrhoeae (GC) is the second most common bacterial STI in the UK after chlamydia (Health Protection Agency 2007), and numbers of cases diagnosed in GUM clinics has increased by 42% in the past decade (from 13,212 in 1998 to 18,710 in 2007). The greatest incidence occurs in males, with a high proportion of diagnoses in young males aged 20-24 (174 per 100,000), 30% of which occurred in MSM. In MSM, diagnoses of GC through GUM clinics has risen in the past decade from 1,799 in 1998 to 3,868 in 2007 (115%) (Health Protection Agency 2008b).

Information on prevalence of GC in the general UK population is not available as national figures are based on the GUM KC60 returns data which only records information on patients presenting at GUM and therefore represents a clinical population. The KC60 data (Health Protection Agency 2007) cannot show the prevalence in the community and is more likely to represent a symptomatic, clinical population. Due to the simplicity of the KC60 aggregated data some information on individuals is not available (such as geographical location, repeat attendees and co-infections).

The Department of Health Sexual Health and HIV strategy (Department of Health 2001) set the target of a 25% reduction in newly acquired GC cases by 2007. This was not achieved, although there has been a 21% decrease, (from 23,705 in 2001 to 18,710 in 2007) in the number of cases of GC diagnosed at GUM since the target was set (Health Protection Agency 2008b).

1.2.4 STI co-infection

Understanding the epidemiology of STIs is essential for developing effective strategies for prevention and control. Routine testing for chlamydia in all patients testing positive for GC is recommended (BASHH et al. 2005). Creighton and colleagues (Creighton et al. 2003) reviewed clinical notes of 17,854 clients attending a South London GUM clinic in 1998 to examine the rates of CT, GC and dual infection. Of the clients attending, 3.8% tested positive for GC, 8.1% were CT positive and 1.5% were infected with both. They found much lower co-infection rates in MSM compared to heterosexual males. In the population studied, 24% of heterosexual men and 39% of heterosexual females with GC were also infected with CT, and 19% of heterosexual men and 13% of heterosexual females with CT were GC positive. Pelvic inflammatory disease among females was not significantly higher in those with dual infection (19.1%), compared with those diagnosed with GC alone (18.2%), but was higher than CT alone (12.8%) (Creighton et al. 2003). Co-infection with both CT and GC was more common in younger age groups, with more than half of females and a quarter of males aged 15-19 having co-infections, with risk of co-infection increasing with age. Higher rates of co-infection in young adults may be associated with more risky sexual acts: the National Survey of Sexual Attitudes and Lifestyles found 16-24 year olds were more like to have new sexual partners and concurrent partners compared to older people (Johnson et al. 2001).

Sociogeographic and demographic factors influence co-infection (Das et al. 2005). One study reviewing case notes in Coventry, found an annual co-infection incidence rate of 16.1/100,000 [95% confidence interval [CI] 9.9-22.3]. The infection rate was significantly higher in those of black ethnicity (rate: 82.6/100,000), relative rate 5.81, 95% CI [4.03-8.38], P=0.0001) than in those of other ethnicities. The highest incidence was in males aged 20-24 (n=81, 45.6%) years and in females aged 15-19 (n=66, 45.2%) years, living in the most deprived area of Greater Manchester. After controlling

for year of diagnosis, those aged 25-64 years had significantly lower incidence rates (0.13 [0.10-0.17], P=0.0001, Poisson regression) than those aged under 20 years. Increased incidence rates were also associated with high deprivation scores. Das and colleagues (Das et al. 2005) suggest a complex interaction between age, sex, ethnicity, geographic distribution, social deprivation and the risk of acquiring genital co-infection with GC and CT.

1.2.5 Screening tests

For screening tests to be considered appropriate they must have high sensitivity and specificity. Sensitivity and specificity are terms used in diagnostic tests that have only two outcomes; positive and negative.

The **sensitivity** measures the proportion of actual positives which are correctly identified as such (i.e. the proportion that test positive who actually have the disease). The **specificity** measures the proportion of negatives which are correctly identified (i.e. the percentage of people free from a disease who are identified as not having the condition). For full details of how these are calculated, see the methodology section (3.1.3.5).

The Genprobe APTIMA COMBO® 2 transcription mediated assays that are used to test for *Chlamydia trachomatis* and *Neisseria gonorrhoeae* in Greater Manchester have CT sensitivity of 98% and specificity of 98% and for GC sensitivity is 97.8% and specificity 99.2%. The positive predictive value (PPV, the proportion of clients with positive test results who are correctly diagnosed) is 71% when the GC prevalence is 2%. As estimates of UK prevalence are approximately 1% it is expected that the proportion of false positives on the GC results may be greater than 62% (Gen-Probe 2008). In contrast, the test for CT is expected to have a PPV of 85% based on a population prevalence of around 10%. Table 1.1 shows how the positive predictive value for the two tests is affected by different underlying prevalence in the population.

Table 1.1: Hypothetical positive predictive values and negative predictive values for various prevalence rates of CT and GC

	Prevalence Rate (%)	Sensitivity (%)	Specificity (%)	Positive Predictive Value (%)	Negative Predictive Value (%)
***Chlamydia trachomatis* (CT)**	1	96.1	98	33.1	100
	2	96.1	98	50	99.9
	5	96.1	98	72	99.8
	10	96.1	98	84.5	99.6
	15	96.1	98	89.6	99.3
	20	96.1	98	92.4	99
	25	96.1	98	94.2	98.7
	30	96.1	98	95.4	98.3
***Neisseria gonorrhoeae* (GC)**	1	97.8	99.2	55.3	100
	2	97.8	99.2	71.4	100
	5	97.8	99.2	86.6	99.9
	10	97.8	99.2	93.2	99.7
	15	97.8	99.2	95.6	99.6
	20	97.8	99.2	96.8	99.4
	25	97.8	99.2	97.6	99.2
	30	97.8	99.2	98.1	99

APTIMA COMBO 2® Assay (Gen-Probe 2008)

Stanley and Todd (Stanley and Todd 2005) conducted a small study in rural Cumbria and found a high proportion of false positives on the Nucleic Acid Amplification Tests (NAATs), using the Roche Cobas Amplicor amplification and detection system, when they tried to confirm the presence of GC in cultures grown from clinical samples. Of the GUM clinic samples, only ten out of 16 positive GC NAATs were confirmed by culture and only one out of 17 samples from primary care. From this they concluded that also screening for GC by NAAT, as well as screening for CT, is neither cost effective nor appropriate for the low prevalence population in rural North England. This research used a very small sample though so results should be viewed with caution.

Lavelle and colleagues (Lavelle et al. 2006), in a study of a dual screening programme in Liverpool, suggest that although culture is thought of as the 'gold standard' for GC testing they only found confirmatory evidence of GC on culture in 72% of those that tested positive on NAAT. Partner follow up revealed that three of the four clients that could not be confirmed on culture reported GC positive partners; this supports the original GC diagnosis on NAAT. Confirmatory culture was found at a variety of body sites in females suggesting the need for multiple swabs to be taken. They argue that without the additional supportive evidence estimates of PPV will be much lower than they actually are.

The recent UK-based audit on case notes of persons with CT, conducted in 193 clinics noted that half of all cases had no symptoms, and one-third attended for routine or asymptomatic screens (McClean et al. 2008a) emphasising the need for opportunistic screening on asymptomatic populations. Most (92%) clinics use NAATs for chlamydia diagnosis (Carne et al. 2008), with 93% of cases having genital NAATs (McClean et al. 2008b). Treatment favours azithromycin over doxycycline (54% vs. 37%). Most females had NAATs obtained from sites recommended by British Association for Sexual Health and HIV (BASHH) guidelines (BASHH et al. 2005), with 93% of females who had genital NAATs testing positive from cervical or vulvovaginal samples.

1.2.6 Dual Screening Programmes

The UK National Chlamydia Screening Programme (NCSP), established to reduce the prevalence of CT in 16–24 year olds, recognises the overlap between CT and GC (NCSP 2004). While combined screening for other STIs should not negatively impact on the implementation and monitoring of CT screening, it is recognised that dual detection using NAATs facilitates opportunistic screening of GC on CT specimens. Dual testing is considered effective if the prevalence of GC is greater than 2%. Among the NAATs, Transcription Mediated Assay (Welte et al. 2000) was chosen by Greater Manchester due to evidence suggesting the test is sensitive and specific for detecting both CT and GC.

Rao and colleagues (2008) report on a programme, similar to the *RU Clear?* Programme, that is running in Lewisham in South London. They conducted over 10,000 NAATs (BD ProbeTec *C. trachomatis/N. gonorrhoeae* Amplified DNA Assay Endocervical and Urethral Collection and Dry transport kits) in various community contraceptive clinics and general practices (GPs) in 2004/2005. The samples were tested using the strand displacement amplification assay (BD ProbeTec 2006). They found an overall GC prevalence of 4.1%: 5.7% in males and 3.8% in females. The highest rates were in older males, younger females and Black Minority Ethnic (BME) groups (specifically black Caribbean, black British/other and mixed). Odds ratios for GC positivity, compared to white individuals, were 2.44 (95% CI 1.82-3.27), for black Caribbean attendees and 2.33 (CI 1.74-3.13) for black British/other black attendees. Of the GC positive NAATs that Rao and colleagues report, only 67.2% were confirmed on culture, a proportion much lower than would be expected based on the sensitivity rate expected from these tests. The authors suggest that the large number of tests not confirmed on culture is a result of false negatives on the culture, not false positive results from the NAAT.

In the Netherlands further studies have been conducted on dual screening for CT and GC. The results differ from those conducted in the United Kingdom and show lower co-infection rates. Van Bergen and colleagues (van Bergen et al. 2006) conducted a large population-based CT screening programme in the Netherlands in 2003 and invited 21,000 people aged 15-29 (selected using

stratified area address density) to send in a urine sample (van Bergen et al. 2006). Overall, 8,383 samples were received and tested using polymerase chain reaction (PCR). They found an overall CT positive rate of 2% in females and 1.5% in males (it was highest in highly urbanised areas – 3.2% compared to 0.6% in rural areas). Positivity was strongly associated with ethnicity (and was especially high in those BME of Surinamese and Antillean decent), number of sexual partners and presence of symptoms. In the CT positive clients 2.4% (4/166) also tested positive for GC. This figure was initially nine out of 166 but five did not test positive on confirmatory PCR GC testing. Although 16/605 were reactive for GC initially none of these could be verified with the additional confirmatory test and the authors concluded that there were no GC cases in the CT negatives. Routine GC screening of the asymptomatic population was found to be inappropriate but all CT positive individuals should also be screened for GC (van Bergen et al. 2006). This study was the first screening programme of its kind in the Netherlands and although the initial study population was large (21,000) the actual number who tested CT positive was rather small (166) and of these only four tested GC positive. This small number testing positive does not allow us to examine risk factors or apply significance levels to the results. The 16 that initially tested positive for GC but could not be confirmed must also be looked at with caution as it appears the same test was used for the confirmation as was used for the diagnosis. The authors state that there is a need for confirmatory testing in a screening programme with a test that is more specific and at least as sensitive.

In Liverpool, Lavelle and colleagues (2007) identified the prevalence of Neisseria gonorrhoeae (GC) within a population screened for Chlamydia trachomatis (CT). Those testing positive for GC on the Aptima Combo2 assay (AC2) gonorrhoea screening test were referred to a local genitourinary medicine (GUM) department for confirmatory culture and microscopy, treatment, and partner notification. Of 4680 females and 473 males, approximately 1% had AC2 reactive gonorrhoea screening test. Of those clients who agreed to confirmatory testing using culture and microscopy and who were tested before any treatment, supportive evidence[1] for a gonorrhoea diagnosis was found in 37 (97%) of 38 females and all five males. In the population opportunistically screened for chlamydia, CT prevalence rates were 12% for females and 15.7% for males. Although both females and males showed a higher relative risk for GC if chlamydia positive, of the 47 females who were reactive for GC by AC2, 55% (26 females) were negative for chlamydia. It was concluded that AC2 tests were acceptable and accurate for testing gonorrhoea in asymptomatic populations and that AC2 had a higher positive predictive value than might be suggested by previous clinical trials in this low prevalence population. Although antibiotic sensitivity must be monitored, AC2 testing may offer a more acceptable alternative to microscopy and culture for GC in some populations.

The prevalence rates found in the Lewisham study (Rao et al. 2008) were higher than the rates found in the GUM clinic (1.04% in South London in 2004 – mapping the issues) again suggesting that calculating prevalence from a clinical, and likely symptomatic population (those seen at a GUM clinic), will dramatically underestimate true prevalence. Forty five percent of those with GC in Lewisham tested negative for CT, while in Liverpool 55% of those who tested positive for GC were negative for CT (Lavelle et al. 2007). With such a high proportion of those with GC being negative for CT, screening those with a CT diagnosis (as recommended in the Netherlands study; (van Bergen, 2006) or screening only those who are CT positive (as recommended by the NCSP) would miss a large proportion of the GC cases.

1.2.7 Partner notification

Partner notification is considered a vital part of treating sexually transmitted infections (Trelle et al. 2007). A recent UK-based national audit on information-giving, partner notification and follow-up, found good verbal information-giving but only half of cases received written information on chlamydia (McClean et al. 2008b). While 91% were given partner notification advice by a trained health

[1] Supporting evidence consisted of a positive confirmatory test result or evidence that the client's current or previous partner was GC positive.

professional partner outcome was not documented in a quarter, information about their chlamydia status, and treatment status was missed in 50% and 40% of cases sexual contacts.

1.2.8 Client information, advice, and follow-up

In a recent UK based audit of clinics, two-thirds followed the National Guideline recommended interval for providing a test of cure where indicated (Carne et al. 2008). Only 18% of clinics routinely ask clients to re-attend, with 40% having a policy of no routine follow-up and 62% using telephone or text follow-up (Carne et al. 2008).

Phone or text (43%) was as common as clinic-based (39%) follow-up but a quarter of cases received no follow up, and there was no recall in 60% of these cases (McClean et al. 2008b). Most (97%) clinics have information leaflets about chlamydia, although about 30% of clinics lack leaflets containing information about antibiotics and hormonal contraception (Carne et al. 2008).

1.2.9 Barriers to screening services

Few studies have investigated barriers to the use of STI screening services. One American study identified perceptions about barriers to STI services among young people (Tilson et al. 2004). Perceived barriers to care included lack of knowledge of STIs and available services, cost, shame associated with seeking services, long clinic waiting times, discrimination, and urethral specimen collection methods. Perceived features of ideal STI services included locations close to familiar places, extended hours, and urine-based screening. Television was perceived as the most effective route of disseminating STI information. Tilson and colleagues (Tilson et al. 2004) recommended further research to evaluate improving convenience, efficiency, and privacy of existing services, adding urine-based screening and new services closer to neighbourhoods; and using mass media to disseminate STI information to increase STI screening.

A follow-up study of American female adolescents (13-20 years old), treated for an STI, evaluates their attitudes regarding the use of home STI testing (Tebb et al. 2004). Home urine testing was the first choice for STI screening, particularly by those worried they had an STI, followed by the first void urine, self-obtained vaginal swab, and lastly endocervical swab collected in a clinical setting.

In the USA a study on female's opinions on ease and preferences for collecting their own vaginal swab and urine compared with depending on physician services found 90.4% considered it very easy to self-collect a vaginal swab (Chernesky et al. 2005). It was not influenced by age, education, or study site. Seventy-six percent preferred a vaginal swab over a pelvic examination, 60% over a urine collection, and 94% indicated that they would be tested more often if a vaginal swab was available.

In the UK a recent study of GUM clinics and potential future clients to determine their preference for obtaining test results, acceptability of including a named infection on contact slips and expectations about the acceptable length of an appointment (Brown et al. 2008). Three quarters felt it unacceptable to be only contacted if their results were positive ('no news is good news'). A clear preference was expressed to receive STI test results even if they are negative. A majority (68%) of GUM clients preferred a contact slip to be coded while the general public showed no preference. Telephone and face-to-face contact were most popular with relatively few choosing mobile telephone text messaging or email as their preferred option.

An invitation to provide a urine sample for testing CT in over 5,000 sexually active adults 16-44 years identified in the 2000 national survey of sexual attitudes and lifestyles (Johnson et al. 2001) prompted a 71% response rate (McCadden et al. 2005). Willingness to provide a urine sample was significantly higher among those reporting previous MSM, anal sex between males and females, and STI diagnosis and suggests those at highest risk are most likely to volunteer for screening which may have implications for prevalence statistic. In another study, proactive screening of 19,773 females and males 16-39 years on 27 GP lists for chlamydia using home-collected specimens (urine and vaginal swabs) was feasible and acceptable (Low et al. 2007). Uptake was 39.5% and 29.5% in females and

males, chlamydia prevalence rates in males and females in the general population were similar, and screening did not adversely affect anxiety, depression, or self-esteem and participants welcomed the convenience and privacy of home-sampling. A separate report on this study population described no evidence of a documented negative impact on overall psychological well-being following postal screening, and a decrease in anxiety levels among respondents (Campbell et al. 2006).

1.2.10 RU Clear? Greater Manchester Chlamydia and Gonorrhoea Screening Programme

As part of the Greater Manchester *RU Clear?* Programme, in addition to screening for CT, the programme tests and reports GC, using the Gen-Probe APTIMA Combo 2 assay NAAT. This is a urine-based test, taken in various community settings (including youth services, community contraceptive services and schools). Only a small minority of community clinics have the facilities to test and treat for GC so the screening protocol recommends clients who test positive for GC are referred to a genito-urinary medicine (GUM) clinic and fast-tracked for confirmatory testing, treatment, and antibiotic sensitivity testing, thus requiring effective referral pathways to be *in situ*. Figure 1.1 shows the care pathway for the *RU Clear* programme.

1.2.11 Referral to GUM Clinic

The *RU Clear?* Programme in Greater Manchester runs differently from other programmes in the UK in that treatment for GC is not routinely provided in the community and protocol states that any clients that test positive for GC are referred to a GUM clinic for confirmatory testing, treatment, and antibiotic sensitivity testing.

For the *RU Clear?* Programme to be effective all CT and GC clients need to be treated and their sexual contacts traced. For this to take place effective referral pathways are essential.

Wilkinson and Massil (2000) carried out a retrospective review of clinical notes to investigate how effective referral to a GUM clinic was for clients who tested CT positive in family planning clinics. They reviewed notes from 22 sites over a six month period and found 112 females who had a positive or equivocal result for CT but only 80% had been referred to a GUM clinic and only 52% had attended a GUM clinic. They also found long delays between testing and attendance at a GUM clinic (median of 20 days, range 11 – 118 days), a window where they may have transmitted the infection to partners. They conclude that this raises not the question of whether testing for CT should happen in the community but whether community sites should be undertaking treatment and partner notification. They suggest that there needs to be greater collaborative work between GUM clinics, family planning, and sexual and reproductive health services.

This is relevant to the work undertaken by the *RU Clear?* Programme because there are defined systems in place to ensure that all GC positive clients are referred to a GUM clinic, and part of this evaluation reports on whether these systems are fit for purpose.

1.2.13 Client Experience

Screening programmes ought to be patient-centred and underpinned with an understanding of patients' experience of being diagnosed with an STI. Qualitative research conducted by Duncan and colleagues (2001) indicated that information should be provided that normalises and de-stigmatises chlamydia and positively promotes genitourinary medicine services. Other anxieties include partner notification and uncertainty about future reproductive morbidity. Therefore, information on these issues needs to be easily available.

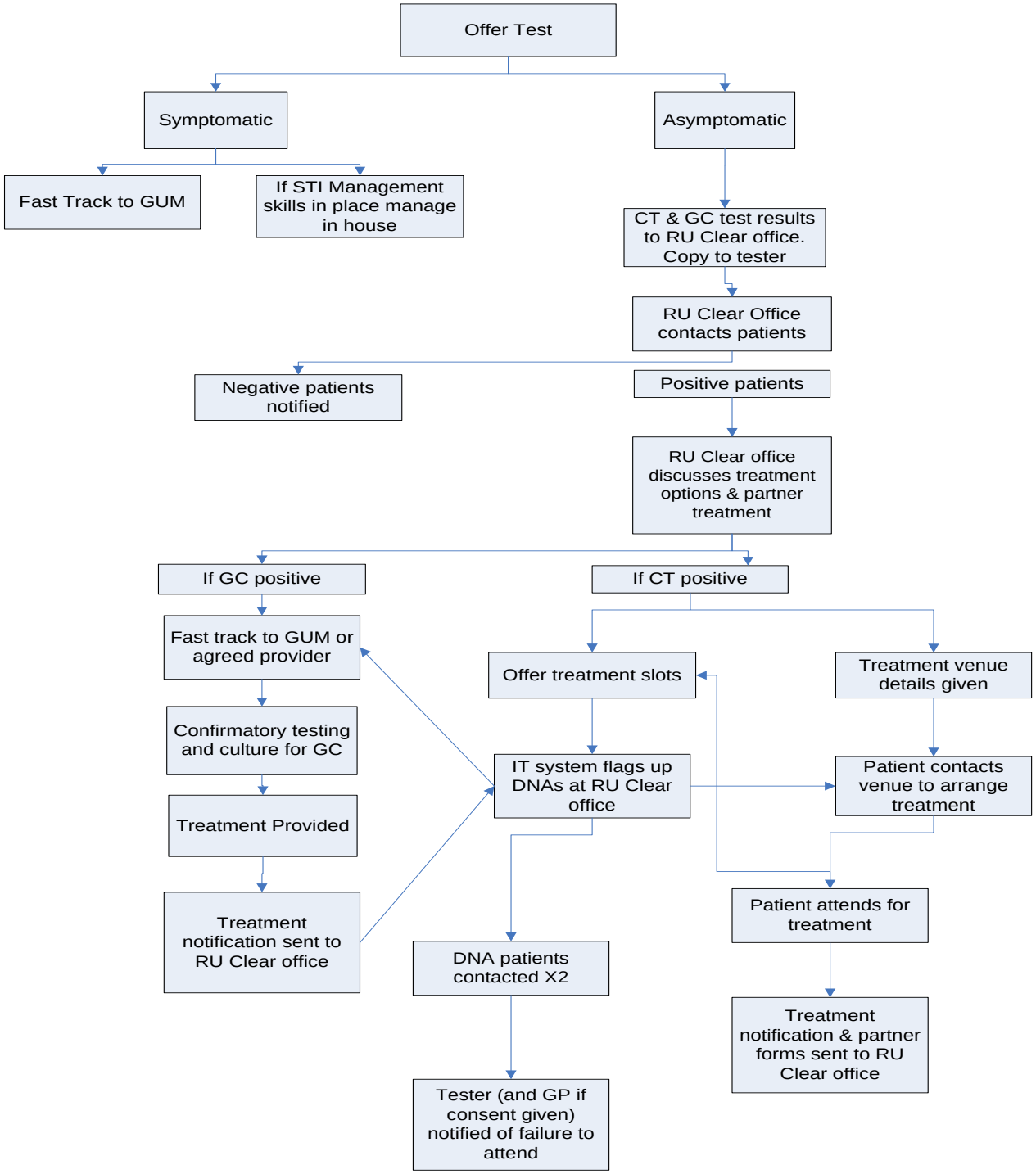


Figure 1.1: Care Pathway *RU Clear?* Programme Manchester

One study exploring client experience of CT screening (after having been sent a postal screening kit from the GP) found that clients reported a number of anxieties and concerns (Mills et al. 2006). Client anxiety arose primarily after receiving a positive test result and was particularly related to the partner notification process. Further concerns related to the possibility of having other undiagnosed sexually transmitted infections. In addition, Duncan and colleagues (2001) found that females feared infertility as a side-effect of chlamydia infection. Differences between the sexes in the reaction to a positive test

result were noted, with females appearing to be more upset by a positive diagnosis. Even though most participants reported some anxiety and discomfort related to the screening none regretted their choice to be screened. Findings show that those who had tested negative were no less likely to adopt healthy behaviours. All of these factors need to be taken into consideration, especially when delivering positive results to clients and making information and support available after result.

Evans and Cross (2007) evaluated client's experience of community STI testing in Lewisham. This area of London (which had the highest STI and teenage pregnancy rates at the time of the study) offers STI screening in community sexual and reproductive health services, the only service not offered is serology for HIV and syphilis which is done at GUM clinics. Evans and Cross interviewed users of the community sexual health service and found that the STI service was acceptable to those using it. Clients preferred the community service because it was easier to access, both geographically and because time waiting in the clinic was shorter. They also felt the environment of the sexual health clinic was important and viewed it as more comfortable compared to GUM clinics. Overall clients were satisfied with the service from the community STI clinics; relevant to our study they particularly liked that treatment was given within the clinic negating the need for referral elsewhere or the need to visit the pharmacy to pick up drugs. This system works differently to the service offered in Greater Manchester where gonorrhoea positive clients must be referred to a GUM clinic for treatment and further testing.

Duncan and colleagues (2001) and Mills and colleagues (2006) examined the social and psychological impact of screening but do not attempt to discuss client experience of the screening programme, the care pathway or the service received. Although Evans and Cross (2007) evaluate the client's experience of the Lewisham community STI service they were only able to interview people using the reproductive and sexual health service (i.e. those that have gone there especially to be screened) and were not able to evaluate the experience of those who did not specifically attend to be screened. Opportunistic screening in community settings allows screening of people who may not otherwise have volunteered for STI testing. For this reason, and because of the different care pathway employed in GM, we have been unable to find any relevant evidence of the experience of clients involved in opportunistic screening in the community and those that are then referred to a GUM clinic for GC treatment.

1.2.14 Provider Experience

Limited studies have explored staff views regarding community screening programmes. However, one study, conducted by Perkins, Carlisle & Jackson (2003) interviewed staff involved in the initial CT screening pilots within general practices in Portsmouth and Wirral. At this stage the programme was offering tests only to females aged under 25 years. Findings showed that they found the main problems with the programme were reported by receptionists who were handing the leaflets to clients and initially bringing up the programme at reception to save time in the consultation room. This caused issues with confidentiality and embarrassment in the waiting room and it was suggested that screening should only be brought up in the consultation room. GPs on the other hand reported that bringing up the screening initially in a consultation added 10 minutes to the consultation time which was viewed as unacceptable most of the time. Practices nurses felt that clients were more comfortable discussing screening with them rather than the GPs because they are less intimidating, have more time to talk and are usually female. GPs were reluctant to manage test results and treatment and reported usually referring all suspected STIs to a GUM clinic anyway as they have the diagnostic abilities and contact tracing skills that GPs lack. GPs and nurses also reported concern at only targeting females and suggested this would have a negative impact on some females' self esteem and cause problems when trying to get partners, especially those without symptoms, to be screened. Payment was also reported as an important component in making the test acceptable to GP's.

Joshi and Dixon (Joshi and Dixon 2000) conducted questionnaires with GPs in Yorkshire who provide chlamydia screening and found their main concern was their inability to conduct partner notification.

They were also concerned about the invasive nature of tests but most stated they would increase opportunistic screening if an effective (non-invasive) urine test became available. Since this study was conducted the NAATs test has become available and screening has been rolled out in general practices.

Most past research into the opinions of staff involved in screening from chlamydia has focussed on those working within general practices and was conducted prior to the nationwide distribution of the NCSP. We could find no research into the experience of staff offering screening in other community settings since the NSCP inception. There is also no evidence of the experience of those offering dual screening for GC and CT and no evidence of research looking at the opinion of staff with regard to the referral of clients to a GUM clinic for treatment.

2. AIM & OBJECTIVES

2.1. Aim

To evaluate the effectiveness of Dual Screening (*RU Clear? Programme*) to detect the prevalence of *Chlamydia trachomatis* and *Neisseria gonorrhoeae* in key target populations in Greater Manchester.

2.2. Objectives

- To assess the contribution of dual testing to KC60 reporting by population characteristics
- To evaluate deprivation status of the screened population
- To assess the effectiveness of dual screening on the National Chlamydia Screening Programme in Greater Manchester, by PCT, sex, sexual preference, ethnicity, screening locations, area deprivation classification
- To assess whether dual screening for *Chlamydia trachomatis* (CT) and *Neisseria gonorrhoeae* (GC), for people aged under 25 years, is fit for purpose, based on the current population prevalence of STIs in Greater Manchester
- To evaluate the accuracy of the dual test compared with microscopy and culture (gold standard)
- To examine the costs of the *RU Clear?* Programme in relation to other dual screening programmes
- To examine the experience of staff based at screening sites who offer the test to young people and staff based at GUM clinics who see the GC positive clients who are referred for confirmatory testing, antibiotic sensitivity testing and treatment
- To examine the experience of clients who are screened as part of the *RU Clear?* Programme, in relation to experience of the dual test, any referral process and experience at GUM clinics.

3. METHODOLOGY

The study was designed to evaluate the effectiveness of the *RU Clear?* Programme, both quantitatively and qualitatively. The quantitative methodology involved systematic analysis of retrospectively captured data on individuals screened and examines the effectiveness of the community-based test Gen-Probe APTIMA Combo 2® assay (AC2) which uses transcription-mediated amplification (TMA) (Welte et al.) technology to detect CT and GC nucleic acid. The evaluation examines quantitative data collected during a pilot period over six months as defined by *RU Clear?* Programme (from September 2007 to February 2008). The evaluation also includes examination of a full years' data that incorporates the six months prior to the pilot period. The qualitative methodology involved follow up of clients receiving the test, persons providing the test in the community and GUM clinic based health professionals providing care to GC positive referrals to determine their attitude towards the effectiveness and feasibility of the community test.

3.1. Quantitative Data

3.1.1 Data collection and security

Data were provided to Centre for Public Health from the start of the *RU Clear?* Programme via a secure web server to ensure security. All data were processed and stored under relevant protocols and laws pertaining to confidentiality and security. All data on GC positive clients and their contacts were followed up at treatment site (primarily GUM or young person's clinic) to complete additional information fields on sexuality, symptoms, number of attendances the client did not attend (DNA), additional tests, test results, treatment information and information on partners and partner notification. Wherever possible, additional information relating to partner testing and treatment were also followed up at clinics. All treatment sites were contacted by the CPH and a formal data request was submitted. Data transfer agreements were requested prior to the collection of additional data. Either clinic staff completed the data collection form or researchers from the CPH made an appointment and visited the clinic to collect the additional data from clinic files. The client's hospital number could not be used in place of identifiable data as the *RU Clear?* Programme did not record these numbers. A protocol was followed to ensure that no client identifiable data could be linked to the GC data collected within the clinic. A unique code for each of client was created to prevent external persons linking identifiable data. These data were then used in analysis for the positive predictive value of the dual test and to explore the different practices in clinic testing and treatment for GC positive clients across Greater Manchester.

3.1.2 Data Extraction and Validation

RU Clear? Programme data from the six month pilot period and the preceding six month period were provided by *RU Clear?*. Four datasets were defined for analysis: (i) a six month de-duplicated[2] dataset of all tests for the pilot period, (ii) a GC positive subset from the six month pilot period for follow up at GUM, (iii) a one year long dataset of all tests, and (iv) a year long de-duplicated dataset of all individuals tested in the year period.

[2] Where people attended for testing more than once in the period under investigation a single client record was created. In order to create this record a positive test was recorded if the client had tested positive for infection at any point in the 12 months under investigation. The maximum level of deprivation was recorded where the client had more than one residence in the period, along with the relevant PCT data. The number of tests taken within the 12 months was recorded as was whether the client had ever tested positive for CT and GC infections.

A total of 210 cases from the *RU Clear?* Programme data were deleted due to missing information on sex and date of birth and also where date of birth produced an age under-13 years. All cases where both test results were returned as 'insufficient' were also deleted (177 cases). After cleaning, a total of 25,960 individuals were identified. In the one year period from March 2007 to February 2008 a total of viable 28,887 tests were taken in these 25,960 individuals. A flow diagram of the numbers used in the quantitative analysis is given in Figure 3.1. The data from March–August 2007 included the GC recall data and therefore also included dual tests. Postcode information was used to map individuals to their Lower Super Output Areas (LSOA), Primary Care Trust (National Health Service and Manchester PCT) and national IMD quintile. Unless otherwise stated, analysis was restricted to those aged 15 to 24 years with valid postcode data – a total of 18,813 cases.

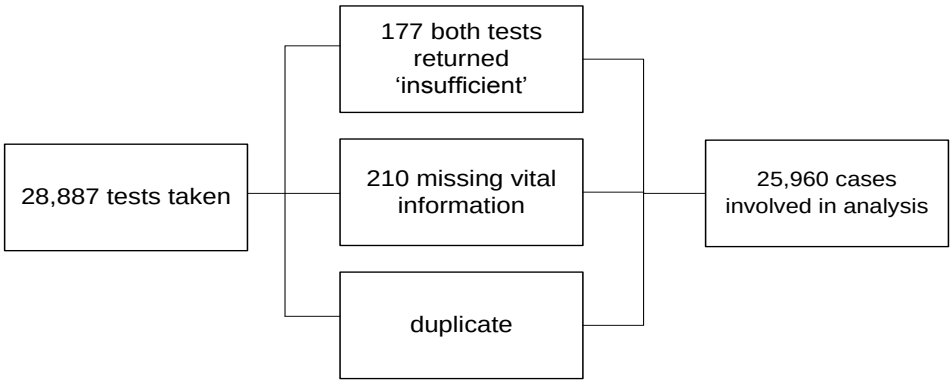


Figure 3.1: Flow diagram of data used for quantitative analysis

A total of 114 clients were diagnosed GC positive in the six month pilot period (September 2007-February 2008). Seven cases had no details of outcome and were assumed to be untreated. The remaining 107 cases were followed up at their reported treatment centres. Information on six cases was not available, 18 clients refused retests and were treated with antibiotics. A total of 83 clients were retested at GUM/sexual health clinics and additional data were collected from clinic files. Four clients were not defined as index cases according to the RU Clear?. Thus, retest practices and results were examined on 79 cases.

The process of matching 114 GC positive clients from *RU Clear?* Programme with their clinic records revealed unreliable data for the date of birth field in the *RU Clear?* Programme data, with many cases showing inverted day and month of birth. It was assumed that this problem existed throughout the datasets. This problem was corrected using date of birth recorded at the GUM/sexual health clinic wherever possible for the GC extract. For the full CT/GC datasets, date of birth was used to calculate age bands and for the purposes of finding duplicate records. The problem was partially addressed by calculating date of birth from a mid-month point for each person (e.g. 15/10/1985). Date of birth was calculated as age at date of test. Since analysis used age bands it was assumed that these errors did not bias the analysis.

3.1.3 Analysis

3.1.3.1 Contribution to national KC60 reporting

The *RU Clear?* Programme data from index clients and contacts, and Greater Manchester KC60 quarterly data (from quarter 1, 2006 to quarter 4, 2007 (the most recent data available at the time

from the Health Protection Agency) were analysed to determine the contribution of the dual screening programme to the national reporting system for STIs (KC60). The *RU Clear?* Programme data were charted from the fourth quarter 2007 since that was when the *RU Clear?* Programme screening began. The KC60 data are aggregated GUM clinic reports of STI diagnoses and as such ought to include all *RU Clear?* Programme referrals to a GUM clinic. However, *RU Clear?* Programme chlamydia positive cases are diagnosed and treated in the community and thus do not contribute to this dataset. This report presents charts on the number of diagnosed GC and CT cases, with analyses subdivided by infection and sex. Furthermore, the GC charts also show KC60 reports without the *RU Clear?* Programme contribution. This provides an opportunity to review the impact the *RU Clear?* Programme has had on routing reporting of GC.

3.1.3.2. Deprivation analysis

Data were examined to explore relationship between deprivation, chlamydia and gonorrhoea. A number of variables in the dataset provided indications of the relative wealth and deprivation of the population studied. Data on LSOA and PCT were matched to (i) national IMD (Indices of Multiple Deprivation) quintiles, and P^2 People & Places categories. The total number of people (aged 15-24 years) tested in a one year period (March 2007-February 2008) were stratified by national IMD quintile and the number and rate of positive CT and GC tests. The data related to Greater Manchester residents (age 15-24 years) that were tested through the *RU Clear?* Programme were evaluated alongside Greater Manchester population data (age 15-24 years) by national IMD quintile and P^2 People & Places categorisation (Box 1) to observe relationships between deprivation, test rates and positivity rates.

Box 1: P^2 People and Places definition

'P^2 People and Places' is a population segmentation tool based on 2001 Census data, Target Group Index data (TGI, which provides descriptive information), and geography to classify people by where they live. P^2 People and Places' classifications increase by level of deprivation from left to right, thus 'Mature Oaks' represent the least deprived and 'Urban Challenge' the most deprived (see appendix 3 for all definitions).

The relationship between each infection and deprivation positive CT and GC cases (resident in Greater Manchester) were analysed and charted by national IMD quintile and by P^2 People & Places categorisation per 100,000 people aged 15-24 years with 95% confidence intervals. The positive rate within the tested population was analysed by national IMD quintile and P^2 People & Places categorisation (age 15-24 years resident in Greater Manchester), with 95% confidence intervals.

3.1.3.3. Effectiveness of screening

The test rates and positivity rates of CT and GC were analysed using the 12 month deduplicated dataset (March 2007-February 2008) and data were matched to LSOA and PCT. These analyses were limited to all cases with full postcodes. Test rates and positivity rates were stratified by PCT of residence and sex of the individuals tested. The number of tests per PCT (age 15-25 years) were evaluated alongside Greater Manchester PCT population data 2007 (15-25 years) to determine the proportion of the population tested within the *RU Clear?* Programme. Positive tests were subdivided by PCT and the positive rate calculated for both infections.

The effectiveness of the programme in relation to different groups of people was explored. GUM clinic data from GC positive cases was the only dataset to contain information on sexuality. However it was limited and could only be used in a descriptive way to inform the report. The differences in the age of males and females tested within the *RU Clear?* Programme was examined using ANOVA. Differences in deprivation between males and females tested in the *RU Clear?* Programme were determined. Ethnicity breakdowns for Greater Manchester PCTs were provided for those aged 15-25 years. Differences between testing, infection and ethnicity were evaluated by sub-grouping the tested

population (GC positive cases and GC positive rate) and comparing proportions against the total tested population.

The difference in testing behaviour between the sexes was evaluated by analysing the number of tests by sex and test location. The numbers of tests were sub-grouped by date of diagnosis (March-August 2007, September 2007-February 2008, and the complete year). The evaluation was broken down by time to enable evaluation of test seeking over time as the screening service becomes more established these data show the services that have higher numbers of young males and females presenting for testing before and after the introduction of dual screening.

Effectiveness of screening coverage was analysed by mapping all testing locations and positive tests onto ordinance survey maps (see appendix 5 for maps). This illustrates the spread of screening sites and the positivity rate, highlighting areas with a high prevalence of positive cases

3.1.3.4. Acceptability of GC testing in the community

The acceptability of GC screening is considered by comparing the uptake of testing pre and post the introduction of dual screening. The number of screens and positive chlamydia and gonorrhoea results were stratified by month of test between March 2007 and February 2008. These data were used to evaluate the presence of seasonal fluctuations (classifying December-February as winter; March-May as Spring; June-August as Summer; September-November as Autumn). Secondary analysis by school/college term was conducted breaking down time periods by term times (e.g. February, April, May, October), and holiday periods (e.g. December/January, Christmas; June/July to September, summer holiday In addition data were examined for any relationship between screening advertising initiatives. Data were examined with a time lag of one to two months after seasonal / holiday / advertising occasions.

3.1.3.5. Confirmatory testing in GUM

The *RU Clear?* Programme pilot data (September 2007-February 2008) and data collected from GC positive client's treatment centre were analysed to define the positive predictive value (PPV, see table 3.1 for definitions) of the *RU Clear?* Programme test compared to the referral clinic's testing method.

Table 3.1: Definition table for positive predictive value, negative predictive value, sensitivity and specificity

Screening test result	**True status (gold standard defined)**		**Total**	**Predictive value**
	Positive	Negative		
Positive	*a*	*b*	$a + b$	**Positive predictive value =** $\frac{a}{a+b}$
Negative	*c*	*d*	$c + d$	**Negative predictive value =** $\frac{d}{c+d}$
	Sensitivity = $\frac{a}{a+c}$	**Specificity =** $\frac{d}{b+d}$		

The positive predictive value relates to the precision of the testing and the probability of correctly diagnosing a person with a condition.
The negative predictive value relates to the proportion of clients with a negative test result who are correctly diagnosed[3].

[3] Hart A. (2001) Making sense of statistics in healthcare. Radcliffe Medical Press Ltd., Oxton.

Sensitivity and specificity: Sensitivity is the measure of the probability of correctly diagnosing a case compared to the 'gold standard' of testing. Here the gold standard is as defined by the British Association for Sexual Health and HIV as tests using culture (BASHH et al. 2005). Specificity is the measure of the proportion of cases that are correctly defined as negative (see definition in table 3.1). In order for sensitivity and specificity to be determined, all samples would have to be re-tested using the gold standard. As only the clients who test positive on the initial screening test were then given a second confirmatory test at GUM clinic it was not possible to evaluate the sensitivity and specificity of the test in this population in this report.

Analysis of positive predictive value (PPV) was conducted on data from clients in the sample population (in the pilot period), who tested positive for GC, were treated for the condition and whose treatment centre provided additional data for analysis. The PPV was calculated for all cases, and then subdivided by sex. The PPV was only calculated for clients who had tested positive on AC2, had presented to a GUM clinic, and had undergone confirmatory culture and/or microscopy testing. The PPV calculations made use of all diagnostic indicators, including partner information collected from client files; previous CT diagnosis; and sample/swab sites. Inclusion criteria selecting the sample population for PPV analysis is presented as a flow chart (figure 4.10). A full description of the variables collected for GC positive cases is given in Appendix 4.

3.1.3.6. Effectiveness of GUM clinic referrals

GUM clinic data on clients testing GC positive were collated to determine partner reporting and notification, additional infections diagnosed, drug resistance and mode of treatment of GC positive cases, client non-attendance prior to treatment, and partner contact details. Different approaches to the management and treatment of clients by treatment centres were explored using the data collected on testing practices.

3.1.3.7. Predicting Gonorrhoea in a population screened for chlamydia

Characteristics of the GC positive population were explored using the six month dataset (September 2007-February 2008). Univariate data analysis consisted of cross tabulations and chi squared tests to investigate associations between relevant variables and their relationship to a positive test for gonorrhoea. Univariate variables included geo-demographics of the population; (i.e. ethnicity, age, sex, postcode for IMD, and P^2 People & Places), chlamydia test result, new sexual partner in the last three months and symptoms.

Multivariate analysis consisted of backwards stepwise logistic regression on the same population. Variables included sex, age, ethnicity, new sexual partner in last three months, symptoms, national IMD quintiles, and P^2 People & Places categorisation in the model in order to adjust for confounding factors. The sampling frame for analyses consisted of the 59% of selected cases where postcode, age, and sex, was available.

3.2 Qualitative Data

To evaluate the effectiveness and acceptability of a health intervention the experience of clients and staff involved in the programme were investigated. To increase screening coverage and encourage repeat testing clients need to have a positive screening experience. To effectively deliver appropriate services the experiences of staff involved in providing the screening need to be taken into account to ensure a suitable and successful service.

3.2.1 Design

Qualitative study design using in-depth telephone interviews to examine the impact of testing for GC within an opportunistic community CT screening programme

3.2.1.1 Tools

A semi-structured interview schedule was developed based on the key issues identified in the evaluation protocol. The interview design received input from a steering group (made up of sexual health managers and providers working with the *RU Clear?* Programme and in GUM clinic and stakeholders in sexual health in Greater Manchester). A semi-structured approach was chosen to ensure that all specific areas of importance (as defined by the steering group) were covered by all participants but the open ended nature of the questions and freedom to deviate from the set questions allowed the interviewees to discuss at length any areas they were particularly concerned or had particular interest in (Henson 2006).

At the end of the interview an opportunity was provided for the interviewee to discuss anything that had not already been covered by the structured questions. This allowed further investigation into any areas that were not anticipated by the research team and the steering group and allowed the participant to explore any other issues that had occurred to them during the interview.

Although there were a definite set of questions that were asked there was some degree of flexibility in the interview. The interviewer allowed the participant to talk at length about subjects if they wanted to. Furthermore, if the participant began to discuss a subject that was not covered by the structured questions the researcher allowed the area to be explored further by asking probing questions. Similarly if a question had already been discussed previous to it appearing on the interview schedule the researcher did not duplicate the conversation.

Telephone interviews were chosen as these are a quicker and more convenient method than face to face interviews as neither the researcher nor participant had to travel. Telephone interviews are appropriate when discussing less sensitive issues such as a service evaluation and not appropriate for exploring painful personal issues.

3.2.2 Study Population

3.2.2.1. RU Clear? Programme Clinic Staff

A list of all screening sites, including the name of the main contact at each site, was provided by *RU Clear?* Programme. This list contained approximately 40 sites though not all were currently offering screening and some of the contact names were listed at more than one site. Systematic sampling occurred initially (selecting every 10th name on the list) and these centres were contacted. If they were unable to take part or did not answer the phone after a couple of attempts the next name down was chosen. Initially 6 staff members agreed to take part in the interview and arranged a date for the interview. Two of the organised interviews did not take place because the researcher was unable to successfully contact one (getting through in small window period of calls at a GP practice) and one later declined to take part stating work issues. Four staff members at screening sites were interviewed. Unfortunately technical problems with the digital recorder meant that one interview was lost and was not retrievable. Thus analysis was carried out on three interviews.

The final sample consisted of one college Nurse, one sexual health Sister at a walk in centre and one Clinical Nurse Lead at a Brook Advisory Clinic.

3.2.2.2 GUM Clinic Staff

Contact details of all GUM clinics in Greater Manchester are maintained by the research team for monitoring purposes. The researcher contacted a number of sites either on the main reception number or through existing professional contacts. The researcher explained to the initial contact what the aim of the study was and asked who would be most appropriate to speak to. Four interviews were conducted and the same technical fault with the recorder resulted in one interview being lost.

Therefore analysis was carried out on three GUM clinic staff interviews. The final sample consisted of two Health Advisors, one GUM clinic Consultant.

3.2.2.3 Clients

Clients who had been screened at various sites around Greater Manchester were asked by *RU Clear?* Programme staff when they received their results whether they would be happy to be contacted for the evaluation. This sampling was done by convenience with a selection of details being passed on to the researcher and then once these options were exhausted the researcher requested *RU Clear?* Programme to collect some more names. Clients who agreed to be contacted provided a mobile telephone number and an indication of the best time to call. A large proportion of these were out of office hours. Names, mobile numbers and results were kept in a password protected file on a secure computer drive within the Centre of Public Health, LJMU. Only researchers working on the project had access to this information. All individuals who gave their details were contacted and asked if they would like to take part in an interview. Large proportions of individuals were not contactable; either because the number rang out, always went to answer phone or because a recorded message said the number was not available. One individual hung up the phone and the researcher felt it would be inappropriate and unethical to call her back. Young people who took part were offered £10 in high street vouchers to compensate them for their time. A postal address was requested at the end of the interview and written directly on to the envelope. The client's address was not recorded anywhere else and was not linked with any transcripts.

Clients fell into one of four categories based on the results of their *RU Clear?* Programme tests and followed different care pathways depending on these results (Figure 3.2)

3.2.3 Procedure

All persons interviewed were reminded their participation was voluntary, confidential, and would be recorded anonymously. No names, areas or clinical sites were included in the transcripts. Tape recordings were destroyed once transcribed. Interviews were conducted between September and December 2008.

3.2.3.1 Staff

Two types of staff were interviewed by telephone; those who offered tests at the screening venues and those who saw clients within GUM clinics who are referred from the screening programme. The purpose of the work was explained to all staff at initial telephone contact and a participant information sheet and consent form sent to individuals. At commencement of the interview participants were first read a detailed participant information sheet and given the opportunity to ask questions, or withdraw if they should so wish (including at any time during the interview). Interviews lasted between 20 – 55 minutes.

3.2.3.2 Clients

Clients who provided details to the screening programme and agreed to be contacted supplied a mobile telephone number and an indication of the best time to call. When a client answered the phone the aim of the study was briefly explained and each participant was asked if it was a convenient time and place to talk. If it was not convenient the researcher agreed to contact them at a specified time to reschedule or be in a confidential setting to converse. They were reminded all information was confidential and that no questions would be asked about past sexual history or behaviour. An information script was read to them and informed verbal consent was obtained. Clients were given the opportunity to withdraw after the initial introduction and reminded they had the right to end the interview at any point or skip any questions.

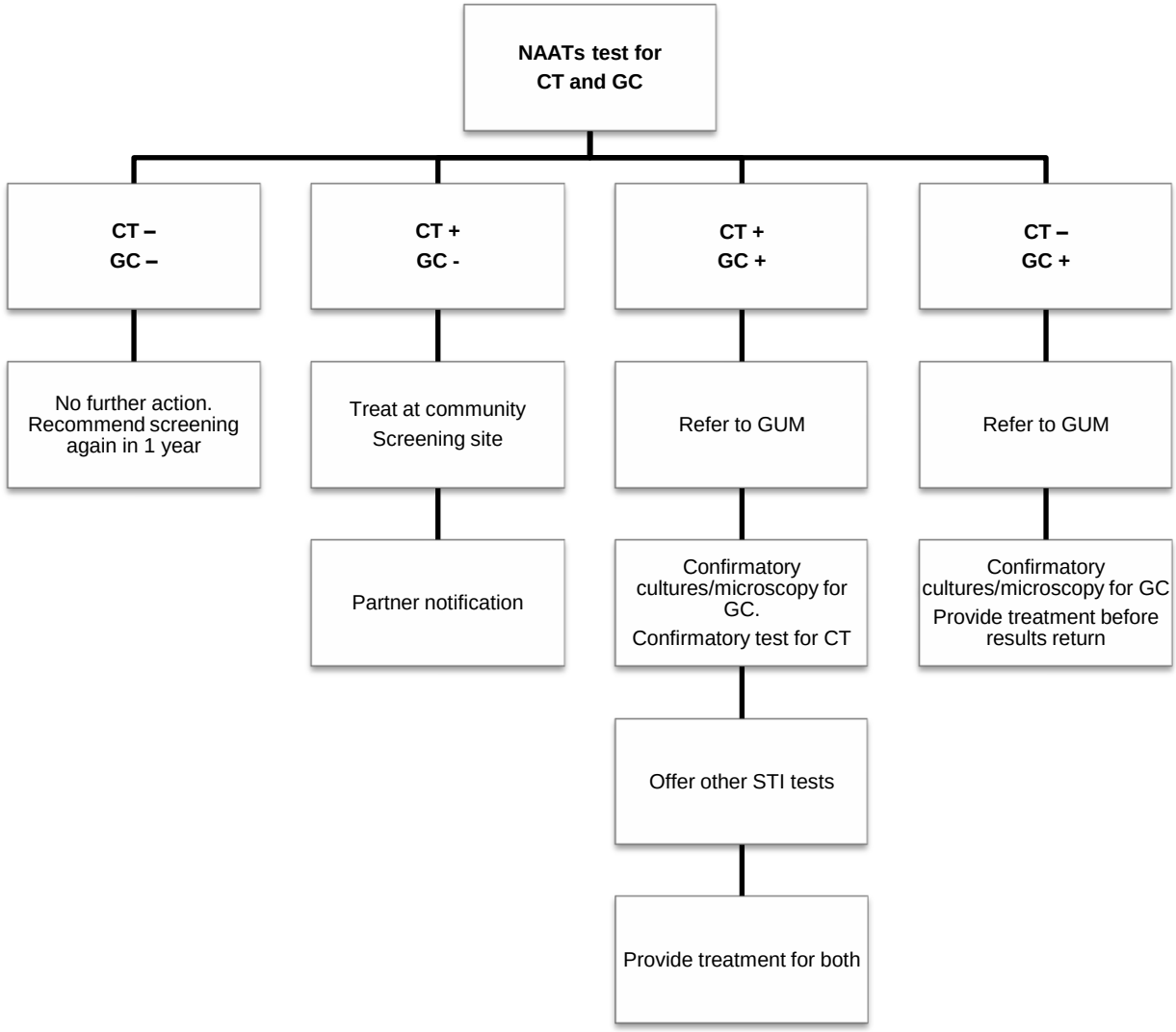


Figure 3.2: Care pathways for each client group

3.2.4 Analysis

Information gathered by telephone interview for both staff and clients were analysed using a similar methodology. Data were analysed in accordance with 'framework' thematic analysis which was developed specifically for applied and policy relevant qualitative research (Ritchie and Spencer 1994). A thematic framework was developed based on key emerging themes; this included question topics and other novel themes. Themes were applied to all data gathered (indexed) and then all individual transcripts divided on applicable themes (charting). When all data were sifted and charted the transcripts were interpreted based on these key categories. A second researcher independently reviewed transcripts and analysis to ensure accuracy of interpretation. No bias was found in the original results and both researchers agreed on key themes and results presented.

3.2.5 Ethical Considerations

Interviews were conducted with staff only after receipt of a signed consent. To maintain anonymity and confidentiality it was not possible to obtain written consent from clients. Instead informed verbal consent was obtained after a participant information script had been read to them. The vouchers that were sent to clients did not refer to the screening programme or STIs and only thanked participants

for helping with the evaluation. Contact details of the researcher were provided. Client names, mobile numbers and results were kept in a password protected file on a secure computer drive within the university department. Only researchers working on the project had access to this information.

Ethical approval was sought and granted from Liverpool John Moores University Ethics Committee. The proposal was also submitted to Salford and Trafford NHS Ethics Committee, who confirmed that full NHS ethics approval was not required because the study was part of a project classified as a service evaluation. The Manchester Primary Care Research Governance Partnership also acknowledged the study.

4. RESULTS

4.1. Contribution to national KC60 reporting

The KC60 data for males and females remained broadly stable between Q1 2006 and Q3 2007, with the majority of Chlamydia diagnoses being through GUM clinic (Figures 4.1 and 4.2). The number of male KC60 cases did not differ markedly from the number of female KC60 cases. The observed drop in quarterly reporting of female CT via KC60 in Q4 2007 (Figures 4.1 and 4.2) is likely to be due to a reporting delay.

A rise was observed in number of RU Clear? Chlamydia diagnoses, which in males increased from fewer than 100 in Q4 2006 to more than 200 in Q4 2007. The corresponding figures for females were approximately 200 in Q4 2006 and more than 700 in Q4 2007. More females were diagnosed in the community through the *RU Clear?* Programme in Q4 2007 than the total of those reported via KC60 for that quarter (Figure 4.2).

The GC positive cases detected by the *RU Clear?* Programme were referred to a GUM clinic, and their data directly fed into the KC60 data. Therefore it can be assumed that these cases would not have been detected in the absence of community screening. Figure 4.3 shows an additional line estimating what the KC60 figures would be without this contribution. Greater Manchester male cases may have contributed 42 cases from the screening programme to KC60 reporting (Figure 4.3). On average an additional 166 female cases were reported in the KC60 data in the first year of the *RU Clear?* Programme (Q4, 2006 – Q3, 2007; Figure 4.4). The additional dashed line shows that without these cases diagnosed in the community, the number of GC diagnoses in women would have shown a decrease.

Figure 4.1: Male KC60 and *RU Clear?* Programme Chlamydia reports and diagnoses for Greater Manchester

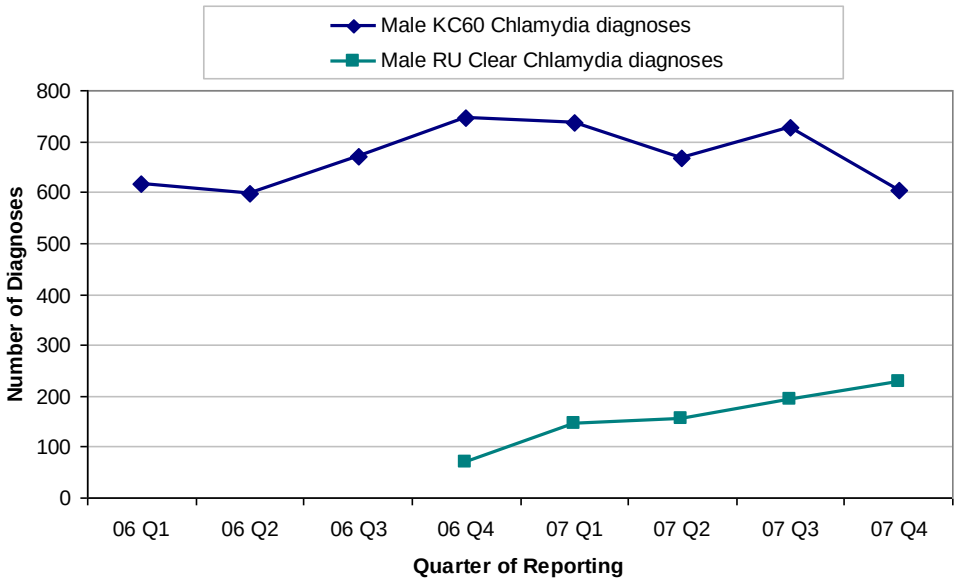


Figure 4.2: Female KC60 and *RU Clear?* Programme Chlamydia reports and diagnoses for Greater Manchester

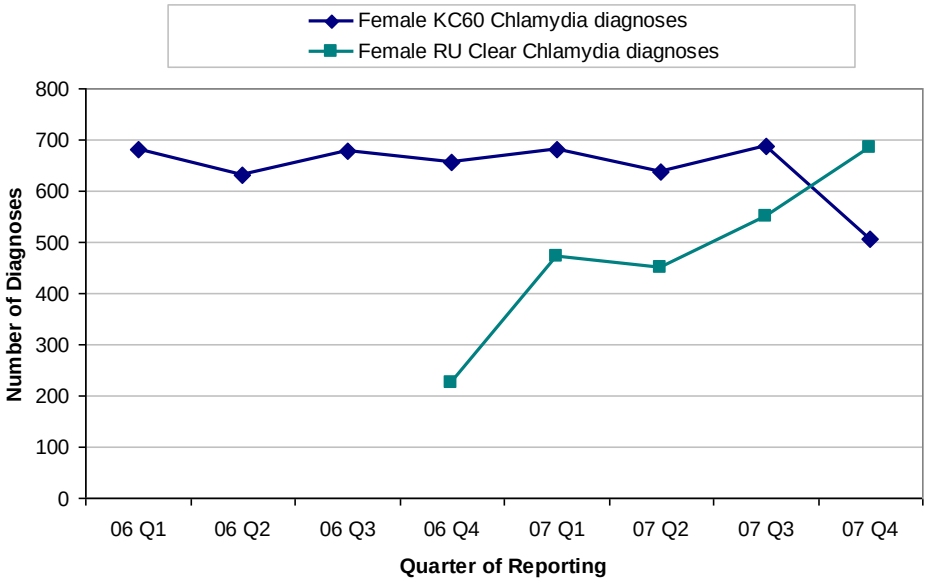


Figure 4.3: Male KC60 and *RU Clear?* Programme Gonorrhoea reports and KC60 data without *RU Clear?* Programme reporting for Greater Manchester

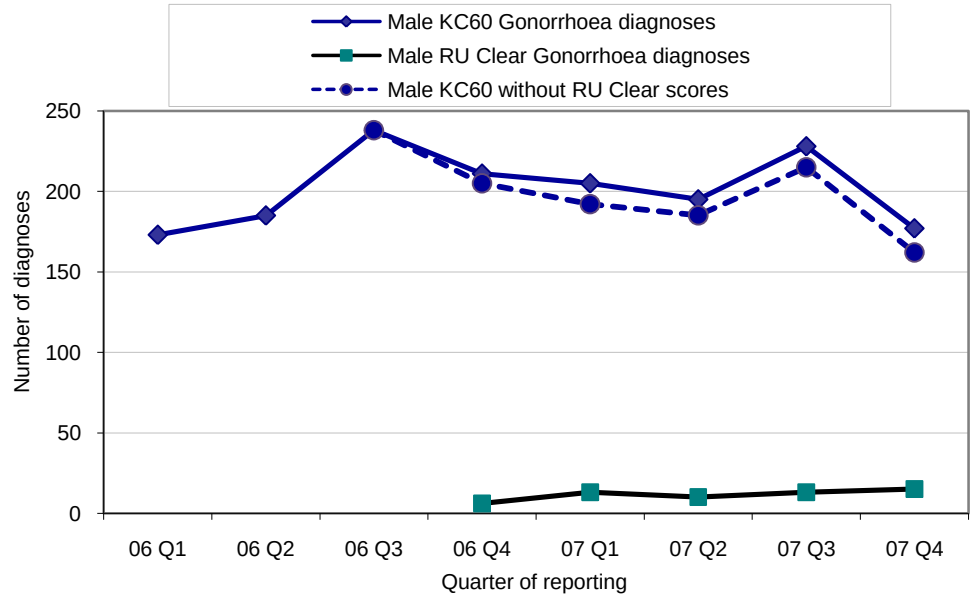
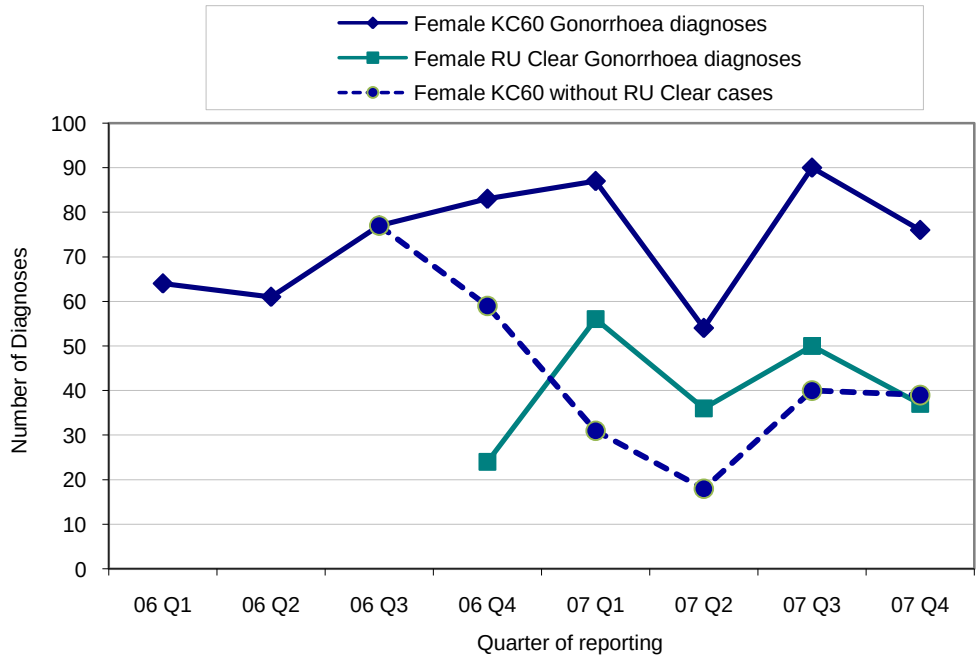


Figure 4.4: Female KC60 and *RU Clear?* Programme Gonorrhoea reports and KC60 data without *RU Clear?* Programme reporting for Greater Manchester



4.2. Deprivation

The deprivation status of Chlamydia positive clients aged 15-24 years was evaluated using national indices of multiple deprivation and the geodemographic tool P^2 People & Places (Beacon Dodsworth 2005) (appendix 3). The positivity rates for Chlamydia and Gonorrhoea (Table 4.1) show no statistically significant difference in prevalence among people belonging to different Index of Multiple Deprivation (IMD) Quintiles (as evidenced by the wide confidence intervals that overlap). However, it may be argued that there is a tendency for greater positivity among those residing in the more deprived quintiles. Positivity of Chlamydia ranged from 9.3% in the least deprived quintile to 10.8% in the most deprived quintile. For Gonorrhoea, positivity was lowest in the most deprived quintile (0.52%) and highest in the most deprived quintile (0.98%).

Table 4.1: Screening and positivity rates by quintile of Index of Multiple Deprivation (IMD) for all cases aged 15-24 years tested within the *RU Clear?* Programme (including those resident outside Greater Manchester)

IMD Quintiles	Total number of tests	CT positive tests	Percent CT positive (95%CI)	GC positive tests	Percent GC positive (95%CI)
Least deprived	967	90	9.3 (7.6-11.3)	5	0.52 (0.17-1.2)
Fourth	1963	179	9.1 (7.9-10.5)	8	0.41 (0.18-0.8)
Third	2922	271	9.3 (8.2-10.4)	18	0.62 (0.37-0.97)
Second	4991	519	10.4 (9.6-11.3)	30	0.60 (0.41-0.86)
Most deprived	10538	135	10.8 (10.2-11.4)	103	0.98 (0.8-1.18)

Testing rates were higher as level of deprivation increases. This relationship between deprivation and test rate was evident in those aged 15-24 year olds resident in Greater Manchester (Table 4.2); the more deprived the area, the greater the test rate.

Table 4.2: Population screening rates by Index of Multiple Deprivation in Greater Manchester (GM) residents aged 15 – 24 years

Indices of Multiple Deprivation	GM population 15<25	All GM tests 15<25	% Tested	CT positive tests	% CT positive (95%CI)	GC positive tests	% GC positive (95%CI)
Least deprived	27969	800	2.9	84	10.5 (8.5-12.8)	5	0.63 (0.2-1.45)
Fourth	44315	1690	3.8	166	9.8 (8.4-11.3)	7	0.41 (0.17-0.85)
Third	60268	2592	4.3	261	10.1 (8.9-11.3)	18	0.69 (0.41-1.1)
Second	90098	4462	5.0	506	11.3 (10.4-12.3)	29	0.65 (0.44-0.93)
Most deprived	152083	9269	6.1	1125	12.1 (11.5-12.8)	103	1.11 (0.91-1.35)

Figure 4.5 shows the positivity rate for the different P^2 People & Places classification system (for further details of this system see section 3.1.3.2 in the methods and for full descriptions, see appendix 3). The P^2 categories are ordered in increasing level of deprivation. There is some indication that a higher proportion of people (15-24 years) residing in more deprived areas in Greater Manchester were more likely to be CT positive with disadvantaged households showing the highest percentage of positive cases (Figure 4.5).

Figure 4.5: Percentage Chlamydia positive in the tested population resident in Greater Manchester by P2 People & Places Categorisation, age 15-24 years

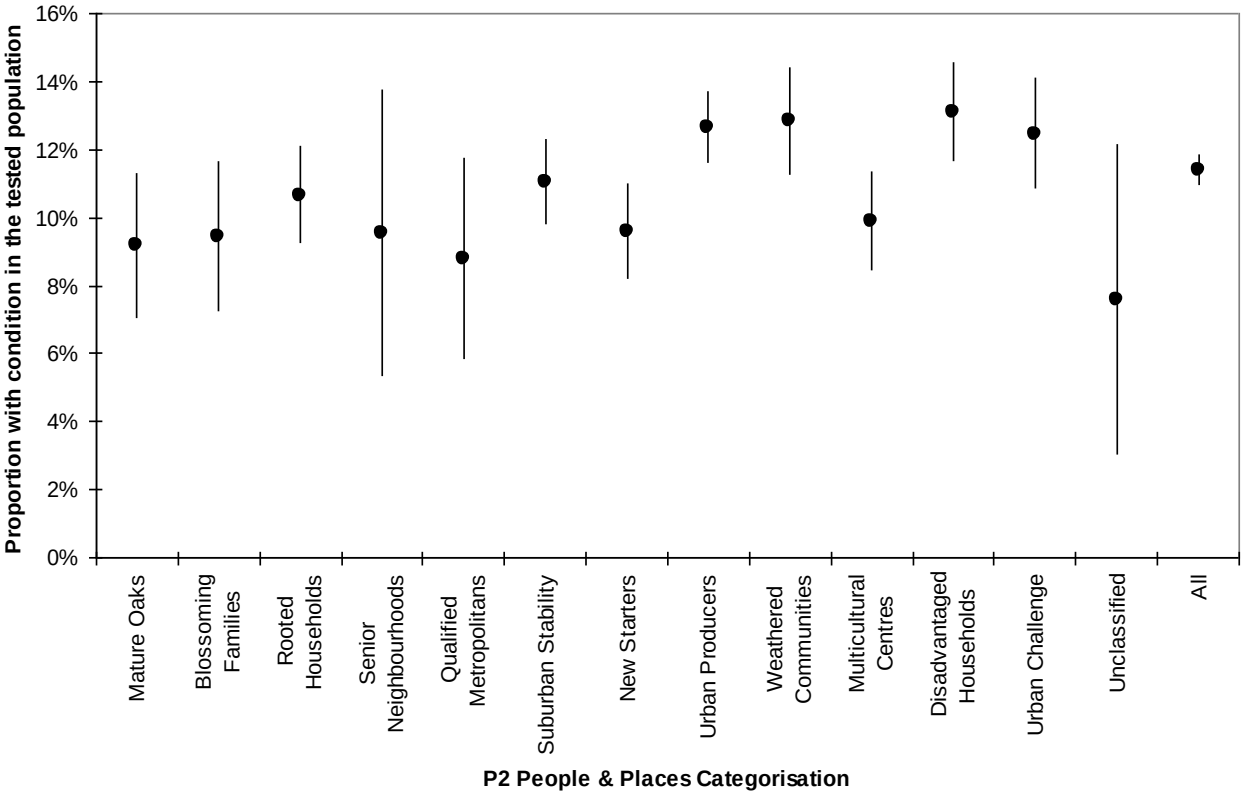


Figure 4.6: Percentage testing Gonorrhoea positive in the tested population resident in Greater Manchester by P2 People & Places Categorisation, age 15-24 years

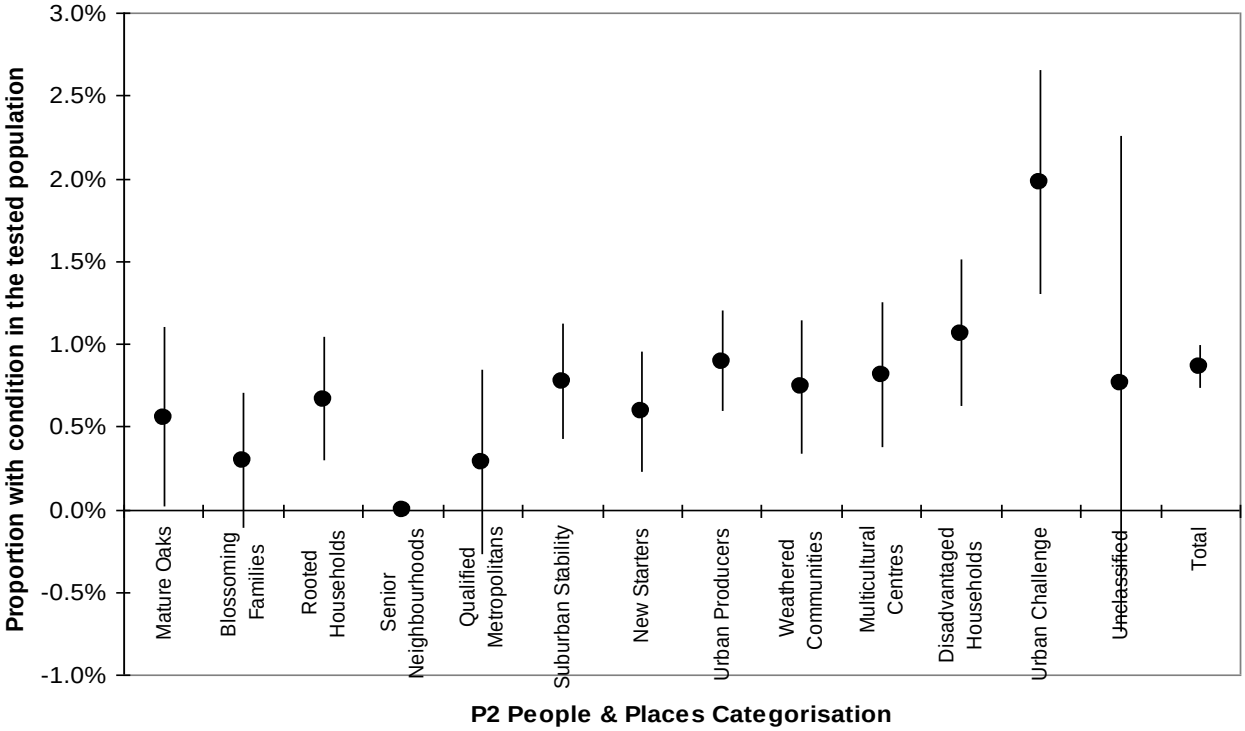


Figure 4.6 shows the relationship between deprivation and the proportion of those tested who were infected with GC among individuals aged 15-24 years. The P^2 People & Places group with the greatest proportion of GC positive clients within the tested population was the most deprived, 'Urban Challenge' group. This had a proportion of 2% GC positive compared to the total (overall) proportion of less than 1%, suggesting this is a target population for screening and health promotion.

Testing rates per P^2 People & Places category for persons aged 15-24 years who reside in Greater Manchester ranged from 2.8 to 9.0 (Table 4.3), showing that the groups with the highest test rates reside in the most deprived areas of Greater Manchester (Disadvantaged Households and Urban Challenge, 6.7% and 9.0% respectively). Test rates in Multicultural Centres, also one of the most deprived categories, were lower than other deprived groups (4%). CT positivity rates ranged from 9.2 ('Mature Oaks') to 13.1% ('Disadvantaged Households'), and GC positivity rates ranged from 0.28 ('Qualified Metropolitans') to 1.97% ('Urban Challenge').

Table 4.3: Greater Manchester population aged 15-24 years and tested population by P^2 People & Places Categorisation

Least Deprived ⇕ Most Deprived

P2 People & Places Categorisation*	GM total 15<25	All tests 15<25	% Tested	CT positive tests	% CT positive (95%CI)	GC positive tests	% GC positive (95%CI)
Mature Oaks	25310	721	2.8	66	9.2 (7.2-11.5)	4	0.55 (0.15-1.41)
Blossoming Families	18833	679	3.6	64	9.4 (7.3-11.9)	2	0.29 (0.04-1.06)
Rooted Households	45714	1811	4.0	193	10.7 (9.3-12.2)	12	0.66 (0.34-1.15)
Senior Neighbourhoods	4997	189	3.8	18	9.5 (5.7-14.6)		
Qualified Metropolitans	6773	354	5.2	31	8.8 (6-12.2)	1	0.28 (0.01-1.56)
Suburban Stability	54484	2464	4.5	272	11 (9.8-12.3)	19	0.77 (0.46-1.2)
New Starters	30097	1703	5.7	163	9.6 (8.2-11.1)	10	0.59 (0.28-1.08)
Urban Producers	65113	3695	5.7	467	12.6 (11.6-13.8)	33	0.89 (0.62-1.25)
Weathered Communities	31236	1763	5.6	226	12.8 (11.3-14.5)	13	0.74 (0.39-1.26)
Multicultural Centres	40237	1608	4.0	159	9.9 (8.5-11.5)	13	0.81 (0.43-1.38)
Disadvantaged Households	30728	2073	6.7	271	13.1 (11.7-14.6)	22	1.06 (0.67-1.6)
Urban Challenge	17939	1621	9.0	202	12.5 (10.9-14.2)	32	1.97 (1.35-2.78)
Unclassified	3257	132	4.1	10	7.6 (3.7-13.5)	1	0.76 (0.02-4.15)

*One of the P2 classifications, Country Orchard, does not occur in Greater Manchester, and therefore does not appear on this table

4.3 Effectiveness of screening for GC in a CT screening programme

4.3.1. Effectiveness of screening by PCT

The effectiveness of the screening programme was restricted to analyses involving the *RU Clear?* Programme target group aged 15-24 years. There are ten primary care trusts (PCTs) in Greater Manchester, caring for a total of 183,475 females and 191,243 males (Table 4.4).

During the study period, Manchester PCT had the highest test rate for females (11.8% of the female population) and Heywood, Middleton and Rochdale had the highest test rate for males (3.3% of the male population). The testing rate for females was lowest in Stockport and Trafford PCTs (both 6.1%) and for males in Stockport (1.4%) and Bolton (1.5%).

Table 4.4: Screening rates for Greater Manchester residents aged 15-24 by sex and PCT of residence

Greater Manchester PCTs	GM females 15<25	Female tests 15<25	Female test rate	GM Male 15<25	Male tests 15<25	Male test rate
Ashton, Leigh and Wigan	18482	1665	9.0	19945	613	3.1
Bolton	16803	1061	6.3	17345	252	1.5
Bury	11138	773	6.9	12245	188	1.5
Heywood, Middleton & Rochdale	13764	860	6.3	14669	488	3.3
Manchester	47386	5597	11.8	46758	1112	2.4
Oldham	14251	1310	9.2	15337	401	2.6
Salford	16561	1259	7.6	17873	535	3.0
Stockport	16677	1023	6.1	17288	237	1.4
Tameside and Glossop	16094	1298	8.1	16714	300	1.8
Trafford	12319	756	6.1	13069	202	1.6
Total	183475	15602	8.5	191243	4328	2.3

Table 4.5: CT positivity in Greater Manchester female residents aged 15-24 by PCT of residence

Greater Manchester PCTs	GM 15<25	Tests 15<25	CT positives	CT positive rate (95% CI)
Ashton, Leigh and Wigan	18482	1665	239	14.4 (12.7-16.1)
Bolton	16803	1061	135	12.7 (10.8-14.9)
Bury	11138	773	100	12.9 (10.7-15.5)
Heywood, Middleton and Rochdale	13764	860	88	10.2 (8.3-12.5)
Manchester	47386	5597	593	10.6 (9.8-11.4)
Oldham	14251	1310	177	13.5 (11.7-15.5)
Salford	16561	1259	173	13.7 (11.9-15.8)
Stockport	16677	1023	103	10.1 (8.3-12.1)
Tameside and Glossop	16094	1298	143	11.0 (9.4-12.8)
Trafford	12319	756	88	11.6 (9.4-14.1)
Total	183475	15602	1839	11.8 (11.3-12.3)

The CT positivity rate for females aged 15-24 tested through the *RU Clear?* Programme and resident in Greater Manchester was 11.8% (Total row of Table 4.5). Ashton, Leigh and Wigan, the PCT with the third highest testing rate, had the highest CT positive rate in Greater Manchester females (14.4%). Salford and Oldham PCTs had the second and third highest CT positive rates in females (13.7 and 13.5% respectively) with the lowest positive rate in Stockport (10.1%).

The CT positive rates for males aged 15-24 tested through the *RU Clear?* Programme and resident in Greater Manchester was 9.9% (Table 4.6). Ashton, Leigh and Wigan, one of the PCTs with the highest male test rates, had the highest CT positive male rate at 13.5%. Heywood, Middleton and Rochdale had the highest testing rates for males but had the lowest overall rate for CT, 4.3%.

Table 4.6: CT positivity in Greater Manchester male residents aged 15-24 by PCT of residence

Greater Manchester PCTs	GM 15<25	Tests 15<25	CT positives	CT positive rate (95% CI)
Ashton, Leigh and Wigan	19945	613	83	13.5 (10.9-16.5)
Bolton	17345	252	32	12.7 (8.9-17.5)
Bury	12245	188	14	7.4 (4.1-12.2)
Heywood, Middleton and Rochdale	14669	488	21	4.3 (2.7-6.5)
Manchester	46758	1112	115	10.3 (8.6-12.3)
Oldham	15337	401	35	8.7 (6.2-11.9)
Salford	17873	535	60	11.2 (8.7-14.2)
Stockport	17288	237	26	11 (7.3-15.7)
Tameside and Glossop	16714	300	23	7.7 (4.9-11.3)
Trafford	13069	202	21	10.4 (6.6-15.5)
Total	191243	4328	430	9.9 (9.1-10.9)

Table 4.7: GC positivity rates in Greater Manchester female residents aged 15-24 years by PCT of residence

Greater Manchester PCTs	GM females 15<25	female tests 15-24	Female GC positives	Female positive rate (95% CI)
Ashton, Leigh and Wigan	18482	1665	21	1.3 (0.8-1.9)
Bolton	16803	1061	4	0.4 (0.1-1.0)
Bury	11138	773	7	0.9 (0.4-1.9)
Heywood, Middleton and Rochdale	13764	860	5	0.6 (0.2-1.4)
Manchester	47386	5597	50	0.9 (0.7-1.2)
Oldham	14251	1310	20	1.5 (0.9-2.3)
Salford	16561	1259	14	1.1 (0.6-1.9)
Stockport	16677	1023	6	0.6 (0.2-1.3)
Tameside and Glossop	16094	1298	7	0.5 (0.2-1.1)
Trafford	12319	756	5	0.7 (0.2-1.5)
Total	183475	15602	139	0.9 (0.7-1.1)

Evaluation of GC positivity rates in female residents age 15-24 years in the different PCTs in Greater Manchester identified that positivity rates ranged from 0.4% in Bolton to 1.5% in Oldham (Table 4.7). Three PCTs (Oldham, Ashton, Leigh and Wigan, and Salford) had rates over 1%. GC positive rates

for males aged 15-24 residing in Greater Manchester ranged from 0% in two PCTs (Bolton and Bury) to 1.2% in Oldham (Table 4.8).

Table 4.8: GC positivity rates in Greater Manchester male residents aged 15-24 years by PCT of residence

GM PCTs	GM Male 15<25	Male tests	Male GC positives	Male positive rate (95% CI)
Ashton, Leigh and Wigan	19945	613	3	0.5 (0.1-1.4)
Bolton	17345	252		0.0 (0.0-1.5)
Bury	12245	188		0.0 (0.0-1.9)
Heywood, Middleton and Rochdale	14669	488	1	0.2 (0.0-1.1)
Manchester	46758	1112	11	1.0 (0.5-1.8)
Oldham	15337	401	5	1.2 (0.4-2.9)
Salford	17873	535	3	0.6 (0.1-1.6)
Stockport	17288	237	1	0.4 (0.0-2.3)
Tameside and Glossop	16714	300	2	0.7 (0.1-2.4)
Trafford	13069	202	2	1.0 (0.1-3.5)
Total	191243	4328	28	0.6 (0.4-0.9)

4.3.2. Effectiveness of screening by sex

While over fifteen and a half thousand females (8.5% of the total female target population) were tested through the *RU Clear?* Programme, fewer than five thousand males were screened (2.3% of the target population: Table 4.4). Males did not differ significantly from females in terms of their deprivation profile [4], suggesting that males came from similar areas to females. Males were significantly older than females (mean age 19.9 years compared to 19.6 years), and this age different was even more apparent when looking at those infected with Chlamydia (mean age for males 21 years; mean age for females 19.2 years) and Gonorrhoea (mean age for males of 21.1 years; mean age for females of 18.9 years)[5].

4.3.3. Effectiveness of screening by sexual orientation

Sexual orientation is inferred from information recorded in notes and is not necessarily self-defined. Ninety-five percent of the GC positive population in the six month pilot period were infected through heterosexual sex, four cases were MSM, and one case was undefined. Rectal self-taken swabs (and to a lesser extent) pharyngeal samples were not routinely collected (including for the *RU Clear?* Programme TMA test), nor is TMA designed to test rectal or pharyngeal samples. As such MSM may take a test but may not necessarily be certain that a negative test result means that they are free from infection. However these data do show that MSM are taking up the testing at available swab sites and are also testing positive in some cases.

We could not evaluate the effectiveness of the *RU Clear?* Programme by sexual orientation as this information is not collected at initial testing in the community. It is therefore not possible to evaluate uptake and calculate positive rates for the entire population screened in relation to sexual orientation. This is an area that still requires further exploration.

[4] Mean deprivation scores of males and females compared using ANOVA, P>0.05. Analyses used total tested population (all ages, 13-69 years) for a one year period.

[5] Mean ages compared between males and females using ANOVA, all P<0.001. Analyses used total tested population (all ages, 13-69 years) for a one year period.

4.3.4. Effectiveness of GC screening by ethnicity

Ethnicity data were not routinely collected at the onset of the programme but were 92% complete between March 2007 and February 2008. While only one third of the population aged 15-24 years in Greater Manchester are classified as white British or Irish (32%), 87% of all tests were carried out on this ethnic group. In contrast, although 30% of the 15-24 year olds in Greater Manchester are black or black British (African and Caribbean), only 4% of all tests were carried out on these groups. Between March 2007 and February 2008 the test rates and positivity rates for different ethnic groups differed substantially (Table 4.9). Thus, while 4.5% of all white young people were tested, screening rates were under 0.5% for all other groups apart from Asian or British Asian (1.6%). Prevalence of GC among those of white British/Irish ethnicity was 0.7%. As shown in previous studies (Low et al. 2001), prevalence of GC was higher in certain other ethnic groups, although only the mixed group (2.3%) was significantly higher than the white group.

Table 4.9: Chlamydia and gonorrhoea positive rate (March 07-Feb 08) by ethnicity for young people aged 15-24 years resident in Greater Manchester (where ethnicity is known)

Ethnicity	Greater Manchester population 15-24 years	Total tested (no.)	Test rate (%)	CT + (no.)	CT positive rate (95% CI)	GC + (no.)	GC positive rate (95% CI)
White British/Irish	356,336	16008	4.49	1848	11.5 (11.1-12)	118	0.7 (0.6-0.9)
Black or black British - Caribbean	183,475	449	0.24	72	16 (12.8-19.8)	7	1.6 (0.6-3.2)
Black or black British - African	152,933	362	0.24	36	9.9 (7.1-13.5)	7	1.9 (0.8-3.9)
Asian or Asian British	33,370	503	1.64	32	5.9 (4.0-8.2)	3	0.5 (0.1-1.6)
Mixed - white and other	209,625	741	0.35	118	15.9 (13.4-18.8)	17	2.3 (1.3-3.6)
Oriental/any other Asian	21,409	135	0.43	9	9.9 (4.6-17.9)	0	0 (0.0-4.0)
Any other ethnicity	162,677	268	0.16	26	9.7 (6.4-13.9)	3	1.1 (0.2-3.2)

CT + number of positive chlamydia tests, GC + number of positive gonorrhoea tests

4.3.5. Effectiveness of screening by testing location and the sexes

Testing uptake in the 15-24 year olds screened in the *RU Clear?* Programme, from different sexual health services (defined by *RU Clear?* Programme) varied over time (Table 4.10). The majority of tests were taken up through young people's sexual health clinics (38%), family planning (20%) and health centres (17%). There were different testing rates by sex, with fewer males accessing tests at family planning clinics, hospitals, walk-in, pharmacies and young people's sexual health clinics, and slightly more accessing tests through health clinics, youth centres, schools, colleges and PCTs. Notably, a large proportion of young males accessed tests via 'other' service locations such as outreach services. In the first six month period (March – August 2007) young males were more likely to be tested in 'other locations' (i.e. contact with outreach work), while in the later period (September 2007-February 2008) a greater proportion accessed testing via youth centres, health centres and PCT-based services in addition to an increased proportion of uptake in schools and colleges. This contrasted testing for females, who were relatively consistent throughout the year, and predominantly visited family planning services, and through youth services.

Table 4.10: Location of test by sex for those aged 15-24 years tested between March and August 2007, September 2007 – February 2008 and the total for the whole year period

	March-August 2007			September 2007 - February 2008			One year March 2007 - February 2008		
Type of Location	**Female**	**Male**	**Total**	**Female**	**Male**	**Total**	**Female**	**Male**	**Total**
Unknown	35 (0.4%)	12 (0.6%)	47 (0.4%)	21 (0.2%)	14 (0.3%)	35 (0.2%)	94 (0.4%)	20 (0.3%)	114 (0.4%)
Family Planning	2244 (25.6%)	197 (9.2%)	2441 (22.3%)	2732 (20.9%)	341 (8.8%)	3073 (18.1%)	5060 (22.5%)	512 (9%)	5572 (19.7%)
Health Centre	1199 (13.7%)	296 (13.8%)	1495 (13.7%)	2063 (15.8%)	800 (20.6%)	2863 (16.9%)	3629 (16.1%)	1060 (18.6%)	4689 (16.6%)
Hospital	344 (3.9%)	27 (1.3%)	371 (3.4%)	408 (3.1%)	82 (2.1%)	490 (2.9%)	790 (3.5%)	106 (1.9%)	896 (3.2%)
Pharmacy	97 (1.1%)	14 (0.7%)	111 (1%)	172 (1.3%)	32 (0.8%)	204 (1.2%)	286 (1.3%)	45 (0.8%)	331 (1.2%)
School/college	97 (1.1%)	105 (4.9%)	202 (1.8%)	468 (3.6%)	319 (8.2%)	787 (4.6%)	607 (2.7%)	423 (7.4%)	1030 (3.6%)
TOP	240 (2.7%)	(0%)	240 (2.2%)	612 (4.7%)	(0%)	612 (3.6%)	892 (4%)	(0%)	892 (3.2%)
Walk in	367 (4.2%)	83 (3.9%)	450 (4.1%)	374 (2.9%)	90 (2.3%)	464 (2.7%)	831 (3.7%)	165 (2.9%)	996 (3.5%)
Young person's clinic	3763 (42.9%)	790 (36.7%)	4553 (41.6%)	5475 (41.8%)	1259 (32.4%)	6734 (39.7%)	8961 (39.8%)	1876 (32.9%)	10837 (38.4%)
PCT	(0%)	(0%)	(0%)	91 (0.7%)	228 (5.9%)	319 (1.9%)	105 (0.5%)	228 (4%)	333 (1.2%)
Youth Centre	(0%)	(0%)	(0%)	11 (0.1%)	16 (0.4%)	27 (0.2%)	11 (0%)	16 (0.3%)	27 (0.1%)
Other	395 (4.5%)	628 (29.2%)	1023 (9.4%)	670 (5.1%)	703 (18.1%)	1373 (8.1%)	1252 (5.6%)	1256 (22%)	2508 (8.9%)
Total (100%)	**8781**	**2152**	**10933**	**13097**	**3884**	**16981**	**22518**	**5707**	**28225**

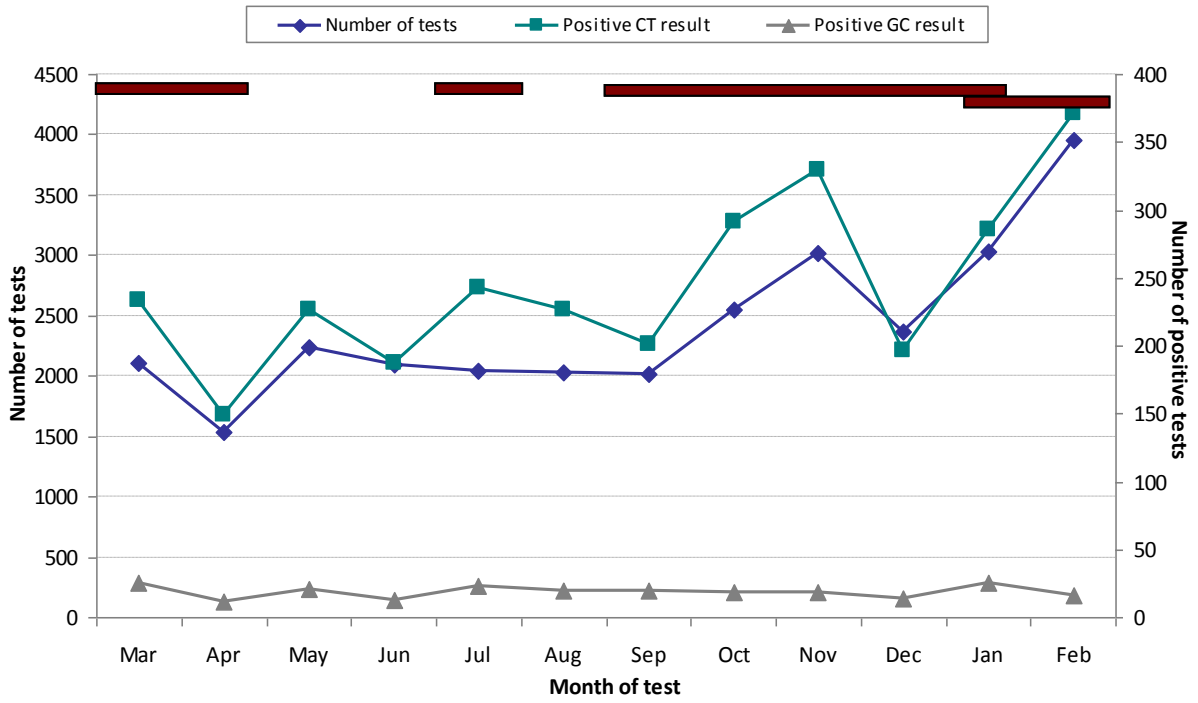
4.3.6. Effectiveness of screening by area

The location of the testing sites and the proportion of positive cases for the whole of Greater Manchester were mapped. The number of CT diagnoses and the proportion of Chlamydia positive cases per LSOA across Greater Manchester is shown in Map 1 (Appendix 5). Despite the diagnosis of 2269 CT cases in Greater Manchester, some areas contributed no cases diagnosed by the *RU Clear?* Programme. The overlay of Map 2, shows the location of *RU Clear?* Programme screening sites and indicates areas without CT diagnoses. These are mainly areas with limited or no screening sites. The exception seems to be Altrincham where there are plenty of clinics and no cases. Mapping of the number cases with a GC diagnoses made by the *RU Clear?* Programme illustrates the very low prevalence of GC (Map 3). Five LSOAs had three GC positive cases each; one juxtaposes another LSOA with four GC positive cases, suggesting a localised clustering. Map 4 overlays the GC positive map with the locations of the screening services, however the random nature of the GC positive distribution does not give a clear indication of diagnoses being related to the provision of testing sites.

4.4. Acceptability of dual testing in the *RU Clear?* Programme

The number of tests carried out through the *RU Clear?* Programme and the number and proportion of chlamydia and gonorrhoea positive tests are presented by month of test: for 15-24 year olds, Figure 4.7; for 13-18 year olds, Figure 4.8; for 19-24 year olds, Figure 4.9. These data were examined in conjunction with information relating to promotion campaigns (Appendix 6) to see if there was any relationship between promoting the screening service and an increase in tests. Dates when health promotion was made available has been added to the figures (the red bars across the top of the figures).

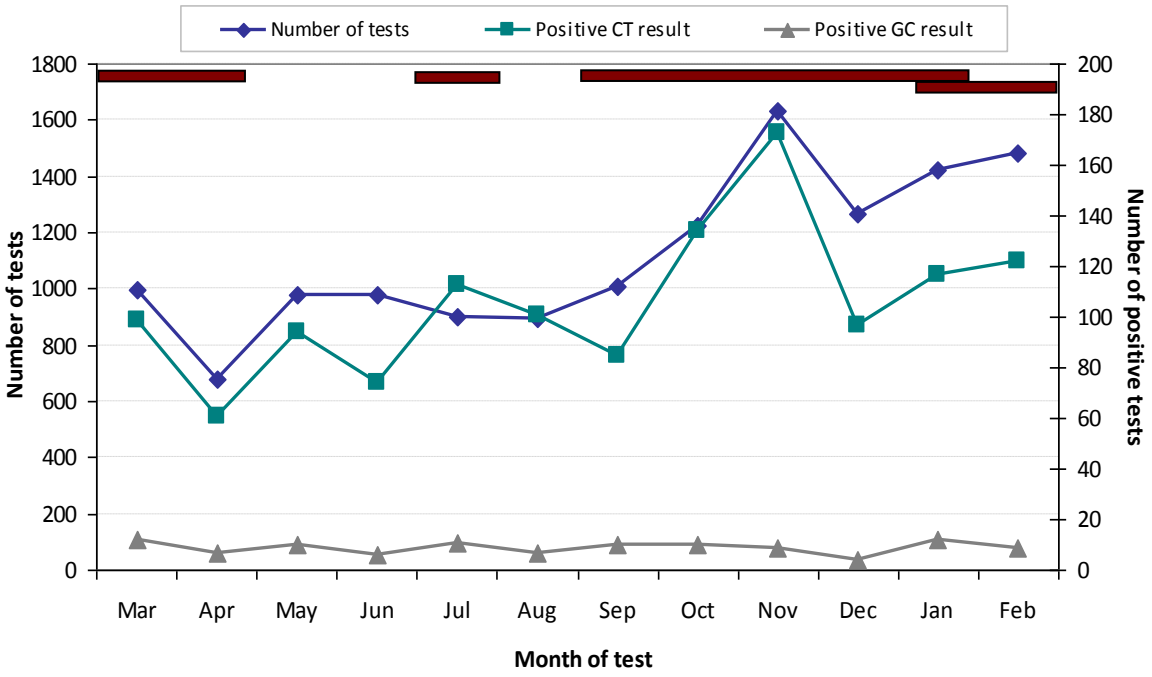
Figure 4.7: Number of tests, number of positive Chlamydia and gonorrhoea positive results by month of test, 15-24 year olds (red bars indicate provision of health promotion materials)



After commencement of the dual screening pilot in September there was an increase in the number of tests, with the greatest number of positive tests for 15-24 year olds occurring in February 2008

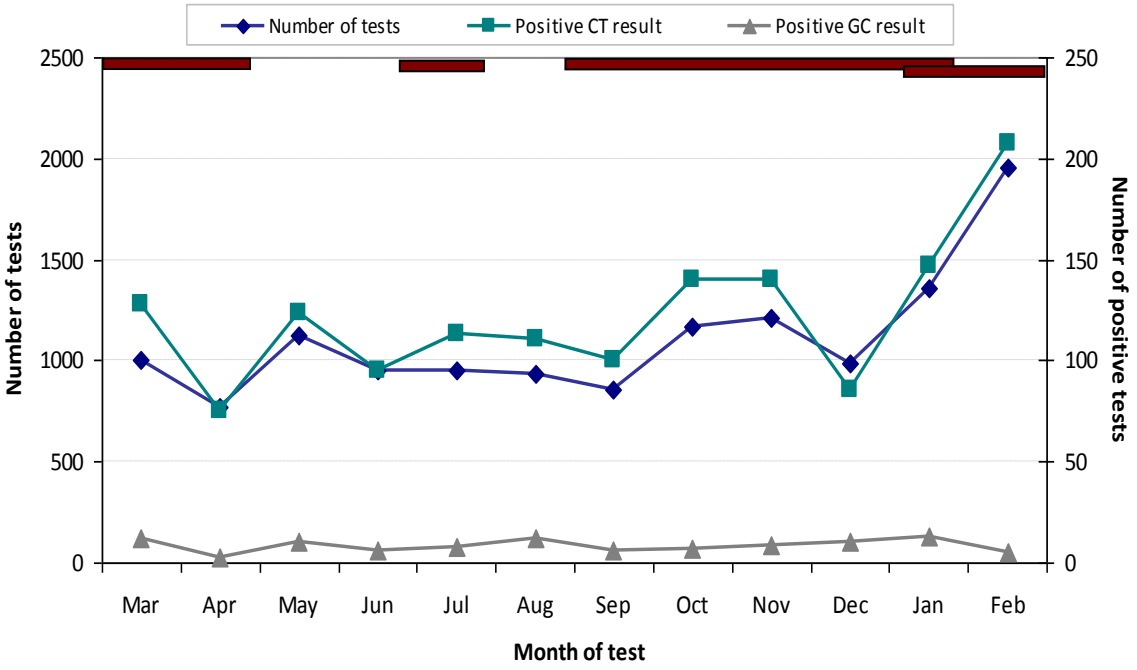
(Figure 4.7). There is no clear relationship between testing uptake and advertising for the *RU Clear?* Programme while the radio adverts (September 07 – January 08), Salford promotion, and the ADVAN promotion in colleges (January – March 2008) occur at the same time as an increased prevalence. There is a general increase in testing over the course of the year suggesting an increasing awareness and acceptability of screening.

Figure 4.8: Number of tests, number of positive Chlamydia and gonorrhoea positive results by month of test, 13-18 year olds (red bars indicate provision of health promotion materials)



The analysis was expanded to examine 13-14 year olds so that figure 12 shows data for all those aged 13 to 18 years. It was found that the main demand for testing was from October through to February and the highest recorded number of positive cases for 13-18 year olds was in October and November. The months with the highest CT positive rates in this age group were July and August (12.5% and 11.3% respectively) and October and November (11% and 10.6% respectively). For this age group the months with the highest GC positive rates were March, April and May (1.2% and 1% respectively); July (1.2%); September (1%).

Figure 4.9: Number of tests, number of positive chlamydia and gonorrhoea positive results by month of test, 19-24 year olds (red bars indicate provision of health promotion materials)



In young adults aged 19-24 years (Figure 4.9), the highest number of tests and positive results occurred in January and February (Figure 4.9). Peaks in positive CT cases were March (12.8%); May (Easter break; 11%); July to November (11.9% for July and August, 11.7%, 12% and 11.5% respectively); January and February (10.9% and 10.7% respectively). The months with the highest GC positive rates were March (1.2%); August (1.3%); December and January (1% respectively). Seasonal data are hard to interpret, since testing effort, advertising/promotions, demand and testing behaviour and risk behaviour can differ over the year. However, the autumn and winter months have the highest rates of testing and thus the highest number of positive tests overall.

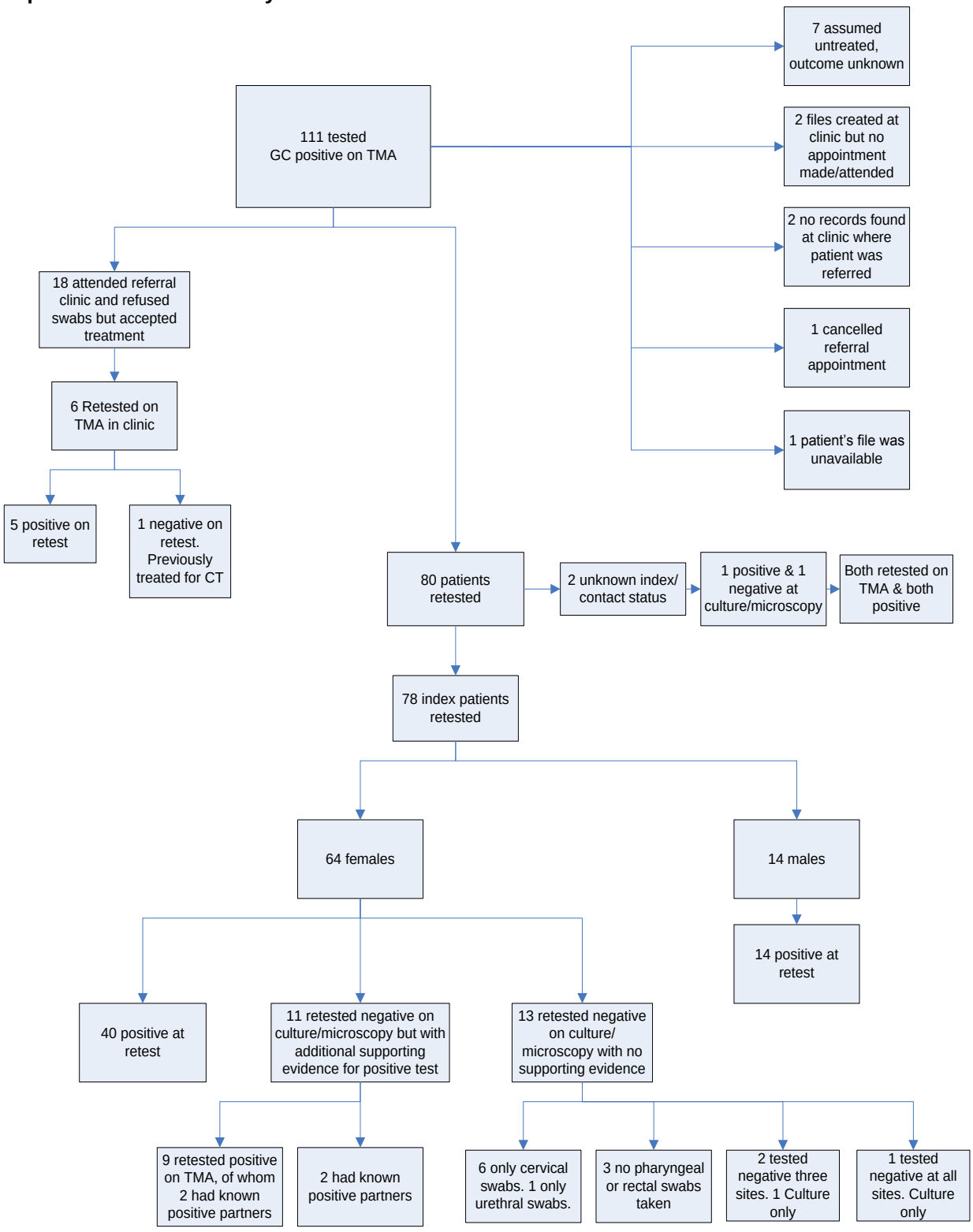
4.5 GC positive follow up

In the chlamydia screening programme, 114 people tested GC positive using TMA within the pilot period between September 2007 and February 2008. The positivity rate for GC within a chlamydia screening programme (Greater Manchester) from March 2007 to February 2008, was 0.7%. The majority of GC positive cases were female (66%), white British and Irish (78%), resident in Greater Manchester (89%), 90% of whom were within the target age group (15-24 years) of the chlamydia Screening Programme.

The 114 GC positive cases were followed up using the *RU Clear?* Programme data to explore their outcomes and to collect additional information on ethnicity, sexuality, sexual health screens, further culture/microscopy/TMA tests, treatment, resistance-testing and partner notification. Of the 114 GC positive cases identified for follow up, three were contacts of index clients, and thus excluded from these analyses (Figure 4.10). The 111 index cases represent 0.6% of the screened population. Of these, 44% also tested positive for CT. A total of 98 (88% of all GC positive cases) index clients were seen at GUM clinics and 80 (72% of all GC positive cases) agreed to have further tests taken. Of the thirteen cases who could not be followed up, seven were assumed to be untreated as they had no record of a GUM clinic referral, two had files created at GUM clinics but never attended, two were

referred to a GUM clinic but no file was found at the GUM clinic they were referred to, one cancelled the appointment, and one file was unavailable for checking (see Figure 4.10). Two of the 80 cases were removed from the analysis due to unresolved client status (index/contact).

Figure 4.10: Gonorrhoea positive cases tested on TMA in the six month pilot period, September 2007 – February 2008



4.5.1 Confirmation of GC using culture and microscopy

Figure 4.10 details the study population and outcomes for the GC retests. GC can only be confirmed for certain in those cases where the client has tested positive on TMA, has presented to GUM clinics and undergone confirmatory culture and/or microscopy testing.

Of 16,028 (76% females) persons tested using AC2 and AGC from the RU Clear programme, 18 males (0.5%) tested GC positive, 14 of whom underwent culture/microscopy tests at GUM and all were confirmed GC positive on culture/microscopy. Of the 78 females (0.6%) testing GC positive using AC2 and AGC, 64 agreed to confirmatory retests with 40 retesting positive. Thus if culture and microscopy are considered the gold standard, the overall positive predictive value (PPV) is only 69% (54/78).

Of the 24 females negative on culture/microscopy nine retested positive on NAAT at GUM, two of whom also reported known positive partners in their medical notes, and two others had positive partners. Of the 13 remaining negative retests, one case retested negative at all body sites, using culture only. Two cases retested negative at three body sites, with one retested using culture only. A further six cases were retested solely at the cervix, one only at the urethra, and three were not tested at the pharynx or rectum. A breakdown of tests by TMA sample site, swab site and retest result per site are displayed in tables 4.11 and 4.12. For females, swabs were collected from three or more sites in only 28% of cases. Of 64 female cases, 11 (17%) were retested at three body sites, of which 8 (73%) retested positive; 7 (28%) were retested at four body sites, of which 6 (86%) retested positive at one site or more. No partner information was available in 83% (20/24) of cases. Seven females (28%) were retested at all four body sites, of which 6 (86%) retested positive at one site or more. No partner information was available in 83% (20/24) of cases. All retested males were all confirmed positive.

Table 4.11: Males testing positive on TMA and having further confirmatory testing*

Number of cases	TMA Sample site	pharynx test	rectum test	urethra test
1	Urine	-	-	+
1	Urine	-	n/t	+
1	Urine	+	n/t	+
10	Urine	n/t	n/t	+
1	Unknown	-	n/t	+

* 5 cases refused further tests

No breakdown of data was available to examine microscopy and culture tests per swab site, but data were collected for overall positive or negative results. Of the 41 females re-tested only on culture, none were only tested on microscopy and 24 were tested on both (Tables 4.13-4.14). Microscopy was shown to miss more GC positive cases than culture (Table 4.13), although where both tests were conducted, microscopy identified cases missed by culture alone. Table 4.14 shows that 94% of those tested on both culture and microscopy tested positive on culture, with 53% testing negative on microscopy. Therefore 6% of cases would be missed without microscopy. These findings are consistent with those in previous studies (Lavelle et al. 2006; Low et al. 2001).

Table 4.12: Females originally testing positive on TMA and having further confirmatory testing*

Number of cases	TMA Sample site	pharynx test	rectum test	cervix test	urethra test
1	Urine	-	-	-	-
3	Urine	-	-	+	-
1	Urine	-	-	+	+
1	Urine	-	-	+	n/t
1	Urine	-	+	+	+
3	Urine	-	n/t	-	-
3	Urine	-	n/t	+	+
1	Urine	-	n/t	+	n/t
1	Urine	+	-	+	+
2	Urine	+	n/t	+	+
2	Urine	+	n/t	+	n/t
12	Urine	n/t	n/t	-	-
1	Urine	n/t	n/t	-	+
6	Urine	n/t	n/t	-	n/t
1	Urine	n/t	n/t	+	-
8	Urine	n/t	n/t	+	+
10	Urine	n/t	n/t	+	n/t
2	Urine	n/t	n/t	n/t	-
1	Cervix	n/t	+	+	+
1	Unknown	-	n/t	n/t	+
1	Unknown	n/t	-	+	+
1	Unknown	n/t	n/t	-	n/t
1	Unknown	n/t	n/t	+	+

*Fourteen cases refused further tests (13 on urine samples and 1 unknown). The shaded areas indicate the final three possible false positives. All other cases reveal supporting evidence, or were not tested on all likely sites, as shown in Figure 4.10.

Table 4.13: Female microscopy and culture test results in persons positive on TMA who were tested at GUM clinics

Test	Positive	Negative	Total
Tested only on culture	22	19	41
Tested only on microscopy	0	0	0
Tested for both	*17	7	24

* negative on culture in 1 case and on microscopy in 9 cases

Table 4.14: Female microscopy and culture test results, on the 17 cases where both tests were carried out and a positive result was provided by at least one testing method in persons positive on TMA who were tested at GUM clinics

Test	Positive	Negative
Culture	16	1
Microscopy	8	9

N.B. no information about specific swab sites were tests were carried out

4.5.2 Partner reporting and notification

Of the 80 clients retested at a GUM clinic in the pilot period (including two of unknown client status), 67 reported a total of 144 partners, and 13 provided no details of partners to be traced. Of those who did have partners to trace, client files documented 60 traceable partners, 44 of whom were already traced, 21 of whom had been treated. Clinic notes stated that 31 partners were untraceable. There was no information provided on the remaining partners. The majority of contact tracing was conducted by the index client. Of the 21 known to be treated we were only able to follow up information on 9 cases where contacts had attended for confirmatory testing and treatment based on their current or ex-partner's positive test. Seven cases tested positive for GC, one refused further tests and one tested negative. Therefore, the *RU Clear?* Programme was successful in identifying at least 135 GC cases and ensuring that others at risk of infection have been informed and advised to be tested. Overall, and where details were provided, 66% of contacts were from sexual relationships that were started less than three months prior to testing.

4.5.3 Resistance to antimicrobial therapy

Of 78 index patients, 46 (59%) were tested for drug resistance prior to treatment in accordance with the British Association for Sexual Health and HIV (BASHH) guidelines. Of the 46, five (11%) showed resistance to one or more GC antibiotic treatments, although all (100%) showed sensitivity to one or more of the most commonly prescribed treatments. The majority (96%) of patients tested were sensitive to Cefixime which was the most commonly prescribed medication for GC. The five clients were found to be resistant to Cefixime, Ciprofloxacin, Ofloxacin, Penicillin, or Tetracycline. In these cases a different course of medication was prescribed.

4.5.4 Uptake of testing for other co-infections

Referral to a GUM clinic from the *RU Clear?* Programme was effective at encouraging 75% (60/80) to take up the offer of screening for further infections. Although 59 (74%) took HIV tests and 58 (73%) agreed to syphilis tests, none were diagnosed as positive. Among the population tested for further infections, one (1.6%) was positive for Hepatitis B, and four (7%) were diagnosed with anogenital warts, three of whom were listed as symptoms and one as an additional infection. One (1.6%) case of *Trichomonias vaginalis*, four (7%) cases of bacterial vaginosis and four (7%) cases of candida were diagnosed.

4.5.5 Different approaches of clinics to referred GC positive clients

Of 17 clinics involved in client referrals during the pilot period, two clinics with one client each did not conduct additional tests and treated based on the TMA results alone. Generally, clinics had small numbers of GC positive people to treat. However, of the remaining 15 clinics Bolton, Salford and Central Youth had the highest proportion of index cases where further tests had not been carried out. This was between 38%-50% of cases (2-3 cases each).

Figure 4.10 shows that in many cases all body sites that could be tested for GC were not necessarily swabbed. Many health care professionals/guidance for testing promotes the swabbing of sites where the client's sexual history indicates that infection could be present. However evidence from Lavelle (Lavelle 2008) shows that testing all possible sites may provide more accurate results. Only 29% of males (4 individuals) and 27% of females who agreed to be swabbed had pharyngeal swabs taken for testing. Only one male (5%) and 11 females (14%) underwent rectal swabs; 82 % (63 cases) of females agreed to cervical swabs; and 76% of males (16 cases) and 58% of females (45 cases) agreed to urethral swabs.

Retest practices varied across all clinics and there were few clinics that showed consistent practice. Bury showed consistently good practice with swabs taken at all sites for all clients. 'Central Youth' swabbed male clients at both pharynx and urethra (although not rectum in one MSM client). Manchester Royal Infirmary consistently carried out urethral swabs on clients (except one) but was

less consistent with cervical swabs in females and pharyngeal swabs. This was also the case in Oldham and North Manchester General GUM. Data from Wigan showed a propensity to only swab clients at one site (cervix in females and urethra in males).

4.5.6 Predicting Gonorrhoea in a population targeted for chlamydia screening

The *RU Clear?* Programme has a target population of 15-24 years. We calculated the test rate for those people aged 15-24 years resident in Greater Manchester in the six month pilot period (Table 4.15). This represented 5.3% of the total Greater Manchester population of 15-24 year olds. As such 90% of the screens were in the target population. This group also contains 89% of all GC infections found, through the *RU Clear?* Programme, in the period under investigation.

Table 4.15: Sex, ethnicity, age group, chlamydia result, symptoms, history of partner change, national IMD quintiles by Gonorrhoea positivity, 15-24 year old

	GC Negative	GC Positive	Total	Chi square	df	P
Sex				**1.208**	**1**	**0.272**
Male	3406 (99.4%)	19 (0.6%)	3425			
Female	10834 (99.3%)	80 (0.7%)	10914			
Ethnicity				**4.480**	**1**	**0.034**
White	11553 (99.4%)	74 (0.6%)	11627			
BME	1949 (98.9%)	21 (1.1%)	1970			
Age Group				**0.909**	**1**	**0.340**
15-19	8829 (99.3%)	66 (0.7%)	8895			
20-24	5411 (99.4%)	33 (0.6%)	5444			
Chlamydia result				**176.093**	**1**	**0.000**
Negative	12771 (99.6%)	48 (0.4%)	12819			
Positive	1469 (96.6%)	51 (3.4%)	1520			
Symptom – discharge				**11.556**	**1**	**0.001**
Yes	1380 (98.6%)	20 (1.4%)	1400			
No	10925 (99.4%)	68 (0.6%)	10993			
Symptom – pelvic pain				**3.201**	**1**	**0.074**
Yes	1116 (98.8%)	13 (1.2%)	1129			
No	11125 (99.3%)	76 (0.7%)	11201			
Symptom – dysuria				**21.698**	**1**	**0.000**
Yes	960 (98.1%)	19 (1.9%)	979			
No	11329 (99.4%)	71 (0.6%)	11400			
New partner in past 3mts				**8.411**	**1**	**0.004**
Yes	7023 (99.1%)	65 (0.9%)	7088			
No	6097 (99.5%)	30 (0.5%)	6127			
National IMD Quintiles				**3.956**	**1**	**0.047***
Least & second least deprived	1786 (99.6%)	8 (0.4%)	1794			
Third most deprived	1696 (99.4%)	10 (0.6%)	1706			
Fourth most deprived	2901 (99.3%)	20 (0.7%)	2921			
Most deprived	5749 (99.1%)	50 (0.9%)	5799			

*Chi square linear P value, i.e. testing the assumption that the relationship between IMD and positivity is linear

Analysis of 15-24 year olds between September 2006-February 2007 (Table 4.15) showed that GC positive people were equally likely to be male (0.6% positive) as female (0.7% positive, p=0.272). BME groups (1.1% positive compared to white 0.6%, P=0.034), those testing positive for CT (3.4% compared to 0.4% testing CT negative, P<0.001), and those with a new sexual partner in the past three months (P=0.004), were significantly more likely to test GC positive. Furthermore, those with symptoms of dysuria and discharge were more likely to test positive for GC (p<0.001). There was no significant difference in prevalence between those aged under 20 years and those 20-24 years.

Multivariate analysis, using backwards stepwise logistic regression, was conducted in the same population of 15-24 year olds, on the following variables: sex, age, ethnicity, change in sexual partner in past 3 months, symptoms, and national IMD indices in the model. Of these, change in partner in the past three months, a positive CT diagnosis and symptoms for dysuria remained significant predictors of GC positivity.

These results are limited to those people where postcode information as well as accurate age and sex information was available (59% of cases from the pilot six month period). In those circumstances where a person has been tested more than once in the period symptoms were calculated if they were recorded at any time in that period.

4.6 Qualitative Study: Examining the Experience of Staff and Clients Involved in a Dual chlamydia and gonorrhoea Screening Programme

4.6.1 Screening Site Staff

4.6.1.1 Client's experience of the actual test

Interviewees were asked how they thought the clients found the actual test. Generally participants reported that clients found the test very easy and acceptable:

> *I think they find it acceptable. I think they're usually quite surprised that that's all it is. I think they expect it to be a lot more invasive. (E1)*

It was reported that the majority of tests are provided as a urine sample, and a minority by self taken vaginal swab. Participants believed that young people are not too embarrassed having the test and the postal kits are available for those who do not want to come in for testing:

> *I think the ones who find it embarrassing tend to go online and order a postal kit cos we do do treatment for quite a* few *people who've done postal tests (E2)*

One participant reported offering both urine sample and self taken vaginal swab if a client is particularly worried as this was seen to cover all bases and relieve any fears that it might be missed.

The only problem screening site staff reported with the actual test was nervousness about taking the test but this was very rare:

> *they get to the stage where they stress themselves out so they can't actually wee. It's the main problem they have, in which case we give them the swab (E1)*

4.6.1.2 Opinions of screening for both infections

Screening site staff were asked how they felt about screening for both infections and not just for chlamydia. Staff had a positive opinion of screening for both infections; they thought it was very acceptable for the clients and for the staff based at screening sites. It was viewed as an ideal opportunity to do two tests at once:

> *When you're doing one assessment may well test them for what we can… some of them it takes a lot for them to come for the test so to be able to offer them something else [is good] (E1)*

It was reported that as most of the publicity is about CT testing often clients have not considered themselves to be at risk of other infections. Dual screening was seen as a good opportunity to raise this issue. Screening for both infections provided an opportunity to discuss other STIs:

> *..there isn't a lot of publicity about the others [STIs] that are hitting them in the face. They tend to know about it if they have been to a sexual health tutorial or if they've actually taken note of it…but I think government campaigns about HIV and things are quite subtle really, they're not very hard hitting so they can ignore them quite easily (E1)*

Participants stated that clients seem eager to be tested for both infections as everyone chose to be tested for both even early on in the programme when it was opt out:

> *People come in very worried about chlamydia but when you explain that it's tested for gonorrhoea they think it's a very positive thing. And before we went onto the combined tests when it was an opt in, everybody opted for both anyway. We didn't have anyone that declined the gonorrhoea test (E2)*

Participants also believed there were financial benefits to testing for two infections as it provides a screening opportunity and it doesn't cost any more to test for GC:

> *I think it's a good idea as long as it's no extra cost. You're doing a test anyway for an STI why not? You know, so yes, I think it's a brilliant idea, and more people should, you know, do it. (E3)*

4.6.1.3 Confidence in the test results

Participants were asked how confident they were in the results of the combined CT and GC NAATs. Confidence in test results was generally high. One participant reported that experience with particular clients had showed how accurate the test is:

> *Very [confident]. Because…when we get people coming in for emergency contraception and they've just had unprotected sex with a new partner we will offer them the test but advise them to come back in three weeks for a repeat test and it's surprising in how many the first test is negative but the second test is positive. (E2)*

One participant reported occasional incidents of GC positive NAATs not being confirmed which caused them to be slightly suspicious of accuracy:

> *…we're finding that the confirmatory swab is coming back as negative for gonorrhoea, although it's been picked up on the urine sample…sometimes I doubt how accurate the*

gonorrhoea [NAAT] is and why there's so many obviously, false positives…[though it is only] very occasional.

4.6.1.4 Offering the test

Participants were asked how confident and comfortable they felt offering the combined test. All participants reported feeling comfortable and confident bringing it up and if clients come in for something else participants are happy to mention the test :

And if they don't come for that and they come for something else it's always mentioned. (E1)

One participant reported that staff at their centre have got used to offering the test after some initial uncertainty:

I think in the beginning they [staff] were a bit hesitant about offering it because they didn't want to offend people. But it's moved on now and it's kind of as a "first place let's do this test and then we know what its not". And that seems to be very acceptable to the public. (E2)

4.6.1.5 Feedback on clients referred to a GUM clinic

Participants were asked if they ever received feedback on gonorrhoea positive clients that are referred to GUM clinics and if they would like to:

Participants reported that they did not get any routine feedback from either *RU Clear? Programme* or the GUM clinic for any GC positives that were referred for treatment. The participants were satisfied with this and understood confidentiality meant that this information did not need to be routinely passed on. Two participants reported that when they do contact *RU Clear?* Programme or the treatment centre just to ensure clients have presented for treatment this information is always available.

One participant expressed that they would like to be sent client treatment information so they know people are being treated and would know to follow up an individuals that did not present for treatment.

So if they go straight to GUM and we may not know you see. But …it would be nice if we could get some correspondence to say this person was found to be positive for gonorrhoea and was fast tracked to GUM and was seen and you know treatment was given (E3)

4.6.1.6 Fast-tracking of clients to GUM clinic

Participants were asked about their experience of the fast tracking of gonorrhoea positive clients to GUM clinic for treatment. Participants reported this was a smooth and easy process and as most GUM clinics are achieving the Department of Health 48-hour access targets.

Participants reported a variety of systems for making GUM clinic appointments; either the clients, the screening site or *RU Clear?* Programme staff make the appointment. One reported they only make appointments for younger people or those they are particularly concerned about and other clients make the appointment themselves. All participants reported being happy with the system that was in place for them and that all clients are seen within 48 hours as per Department of Health access targets

One participant reported practical difficulties for clients attending GUM clinic services but this was a situation that the PCT was aware of and a new building was being sought:

The only difficulty with that is they are very young who have limited access to money and transport because there isn't a GUM locally…Older ones tend to go to [GUM], the younger ones tend to go to [another GUM] cos it's geographically closer. But it's still at least two buses for most people. But the PCT are aware of that and they have been trying to get GUM into this area. E2

4.6.1.7 Communication and paperwork

Participants were asked how they found communication and paperwork with *RU Clear?* Programme. Generally all paperwork was reported as being easy to use. Participants also reported they had a good working relationship with *RU Clear?* Programme and found it easy to get answers to queries as there is always someone on the phone who can help.

Two participants mentioned minor problems and delays or confusions in notification faxes from *RU Clear?* Programme that cause a small degree of inconvenience. One of these participants reported that *RU Clear?* Programme can be a little slow at sending notifications:

We occasionally get clients coming up for treatment before they've notified us. You know they'll speak to them in the morning and then they've arrived in the unit before.. the fax only comes through the day after. But it's not common – it's not something that we can't deal with. E2

And another participant reported that occasionally they will send information to *RU Clear?* Programme and then get a second request for the same information:

...Once they've been treated [the client] we fax a form over to say "yes they've attended and they've been treated". Sometimes, the RU Clear? Programme coordinators fax us over "did this person come on such a day she was asked to attend", so we might have to chase up the notes and say "yes she did attend" and we'll fax the forms or say "no this person did not attend".
R: So is that a case of sometimes missing things you've faxed over once already or..
E3: Yes, if it's not been faxed if it's a busy clinic or if the fax hasn't gone successfully.

This problem was also reported by one of the GUM clinics (see 4.8.4).

4.6.1.8 Improvements to the service

Participants were asked if they could think of any ways the *RU Clear?* Programme could be improved. One participant suggested that postal kits should be more easily available in other community settings such as supermarket pharmacies as this would increase numbers testing and make it easier for young people:

I think they would get more if maybe the postal kits were stocked in the pharmacies because sometimes people are in other settings such as supermarkets that have pharmacies you know if they were just there and the public could just access them.. (E2)

Another participant reported that they have problems encouraging young people to take away leaflets:

Well I'd say that the leaflets are quite user friendly really. I don't know whether people think they're a bit big cos they are, they're not huge but they're quite easy to read, they're just not interested in taking them. (E1)

They did not blame this on the actual leaflet design as they suggested that even if they were more young person friendly they believed clients probably wouldn't take them anyway:

> *The reason I do think it's a little bit of a waste of resources is that, I must admit when I first got my RU Clear? Programme pack when I started back ten months ago I was given all these other leaflets and I think I've probably still got most of them. I have offered them but one percent take it and the others are not interested. (E1)*

One participant reported that there needed to be an extra drive to capture the younger people but hoped that the HPV vaccination programme would encourage this:

> *I think we need to focus again and get it raised up more with school age kids but hopefully as the HPV rolls out that might flag up awareness again.*
> *R: Because there's opportunities to mention RU Clear? Programme…*
> *E2: Yes.*

4.6.1.9 Praise for the screening programme

Participants were asked if there is anything about *RU Clear?* Programme or the screening programme that they felt is done particularly well or anything positive they wanted to mention.

One participant praised their PCT and the programme for raising awareness and for various events that had been organised:

> *I think the events we've done; the launches and the promotion [have be good]. There's been a lot…our PCT has done quite a lot advertising in the local press and I think that's really raised awareness among college age students.*

Another participant praised the set up and good communication of the *RU Clear?* Programme team:

> *It appears to run well. Good communication. You always can get hold of someone if you have a query. Sometimes if you have a bit of a query and you're not sure what to do and there's always someone at the other end of the telephone that you can ask advice. They seem quite approachable. Yes, I think it's good at the moment, there's good communication and it's a good set up. (E3)*

4.6.1.10 Issues with Treatment

A number of participants reported some problems and issues with treatment, in particular treatment of the GC positives.

One participant (based at a CCS) reported that they would like to be more involved in treatment to enhance continuity of care for the clients:

> *I'd prefer it if they started to came back here to be treated for gonorrhoea because they're sort of familiar with our service… I feel if you're referring them to GUM then you're not fulfilling the full client care. I would prefer if they would be treated here. (E3)*

This participant worried that young people did not like to be referred to another service for treatment:

> *I don't think they...like...I think they're uncomfortable to have to go somewhere else [for treatment]. Obviously we're offering half a service so to speak cos we're doing the test and then we're saying "oh well, we can't actually do this for you so we'll send you*

somewhere else", which is a shame really. I think they would prefer if we could do that. (E3)

One participant (based at a centre that also provides treatment for GC and CT) reported their centre has found it is a problem when partners of GC positives either cannot or refuse to attend. They expressed a wish to be able, in extreme circumstances, to provide treatment to the contacts without having to see them – in the same way that the GUM clinic can. It was suggested that an amendment to the PGD (client group directive) may be needed. This was only mentioned by one centre that treats for both GC and CT:

…the only hiccup we come up against is if we get a female who comes for testing and back for treatment and she'll say the partner works away or he won't come. Very, very rare, and we have got round it in some people with liaising with GPs and you know to get them a prescription…I know it's difficult with PGDs but it would be better if we could issue that woman with two sets of drugs….They would always try to get them in. But I think, you know, it's a very small minority that's extreme but I think they can.

Maybe…they could amend the PGD to say that in an extreme case if you could have a telephone consultation with their partner just to check on allergies and things that you could then issue a pack of antibiotics to the partner. Cos if…I know it's the thing about prescriptions and the medication laws but it's a very very small minority and I don't think it would be abused because the public when they know they have to come in, 99% of them will come in it's that one who works on the oil rigs or has no access to other healthcare (E2).

4.6.1.11 Areas of Success

- Test was viewed as easy and acceptable to clients.
- Participants had positive opinion of screening for both infections. They viewed it as a good opportunity to discuss general sexual health and raise awareness of other STIs.
- Participants were very confident in the results of the NAATs, much more confident than the participants at GUM clinic sites.
- Participants reported being happy with the fast tracking and referral system they have in place.
- A good working relationship with *RU Clear?* Programme was reported. Participants at screening sites felt that communication was good and paperwork user-friendly.

4.6.1.12 Areas that need improvement or attention

- As problem of duplication of information requests was reported. Sites are often asked to fax same information more than once. This administrations process needs to be streamlined.
- Suggestions to improve uptake rates included stocking postal kits in pharmacies and encouraging testing in younger people.
- Some issues with treatment of GC positives mentioned – lack of continuity of care and difficulty of encouraging contacts to attend for screening.

4.6.2 Experience of GUM clinic staff

4.6.2.1 Referral from RU Clear? Programme

Staff were asked about their experience of the fast tracking of clients from the *RU Clear? Programme* service to GUM clinic. Staff reported that generally the system worked well. One participant reported initial problems with the system in place that caused delay and frustration (when the GUM clinic made

the appointments) but this has now been resolved and *RU Clear? Programme* will make the initial appointment:

> *Yes, it's quite often very frustrating because initially they were faxing referrals but then the clients were really hard to get hold of… Either they weren't answering their phone or by the time we'd got time to phone them back again sometimes two days had gone by which meant the clients weren't actually getting fast tracked at all they were being slow tracked. So we did speak to them [RU Clear? Programme] about it and what they do now is most of the time they make an appointment for the client …so we don't very often now have to contact the client nine times out of ten. Or probably more like the appointment is already made by the time we receive the referral fax, it's actually fairly straight forward now. (F1)*

Fast-tracking was reported by GUM clinic, like the screening sites, to be a fast process and to be within the 48-hour access targets:

> *Normally, they see a client today, they'll ring up, get an appointment tomorrow or maybe even today if we've got one this afternoon. So we can normally see people within 24 hours. It just depends what the availability is. (F1)*

Referral systems differed slightly between the GUM clinics with each having a different system to make appointments. All centres were happy with their current system:

> *…They give us client information,…but usually it is down to us to directly contact the client, which is our preference to be honest.*
> *R: Was that your choice originally or is that just how it ended up or?*
> *F5: No I think that's just how it ended up. Because [our GUM] was quite late in joining the RU Clear? Programme I think by the time it came to [our clinic] last year it had been working well in the rest of the Manchester area then so that was just the system they used.(F5)*

Participants reported that an additional system to speed up access to GUM clinic for *RU Clear? Programme* clients was not always necessary as access times are within 48-hours quick in Manchester anyway:

> *What I would say is we don't actually prioritise necessarily, I mean anyone either within or outside the RU Clear? Programme clinic, if they are found to have gonorrhoea or anything they are referred in but usually it will be the same appointment time. I am not aware that we have a specific fast track just for our RU Clear? Programme clients because our access is universally very good. (F2)*

One participant explained that referral of clients is especially quick and easy because of the common electronic appointment system:

> *In our area, […], we are lucky in that… the [centres] in the community are linked in very closely with the specialist clinic you see…appointments are done electronically…I am aware certainly that in others [areas] where there isn't such good networks between the GUM clinics and the young person's clinics or the community clinics perhaps is less good.*

This participant suggested that this system works particularly well and might be useful in other areas of Greater Manchester where referral systems don't seem to run as smoothly:

> *I think in [our area] we're unique in the sense that we have a ready made infrastructure that deals with it, sort of, off own our back so to speak*. (F2)

4.6.2.2 Tests and treatment at the GUM clinic

Participants were asked how they felt about the need to do a culture/swab at the GUM clinic to confirm the NAATs result. All participants reported that they were happy to do a confirmatory test as these were also needed to measure antibiotic resistance:

> *I think because of the problem with sensitivity, it has its place, although we don't have a lot of resistance in Manchester at the moment, but that's not to say that won't change. (F1)*

It was reported that testing for resistance is a very important issue for clinicians but the local surveillance system for GC resistance allows them to pick a first line antibiotic they can be confident in. The confirmatory testing was mentioned to be most important to pickup any resistant strains acquired elsewhere:

> *…if you get something coming back from the Far East, you know, with a multi resistance strain it may be diagnosed, picked up on with RU Clear? Programme, but if they're not confirmed by culture they won't really get to grips with that.*

It was also reported that a repeat culture would be done on a GUM clinic GC urine test anyway so did not add to the workload of inconvenience of the client:

> *F5: I think that's good practice and it's what we do if we had a positive urine with gonorrhoea we would still be doing cultures as their treatment so again… and I think it's what should be happening.*
> *R: You don't see it as duplication of efforts?*
> *F5: No because they're doing the initial urine and we're just seeing the client once for culture and treatment. (F5)*

One participant suggested the screening programme was a good opportunity to screen for other STIs:

> *And normally people when they come to us, they want further testing anyway. So we'll offer them* chlamydia*, most of the time we'll repeat the* chlamydia *anyway. We'll send off for an HIV test initially so it's a good way of getting people to take up other testing. So, you know, at the moment, it's serving a purpose because of offering additional screening. (F1)*

Participants were asked their opinion of presumptive treatment for the gonorrhoea at the GUM clinic before the cultures returned. All staff interviewed stated they were happy with this as this is standard procedure for any GC cases diagnosed in the GUM clinic:

> *The question is if you get someone coming into GUM you've got to make decision as to whether you treat them there and then anyway because you're not going to get a culture result back for another week. So I always say most of them are going to get treated*

empirically. Unless they have an objection to it in which case, yes you can wait for the culture result. So it seems to be that we are treating anyone on the basis of a positive RU Clear? Programme. In the main, as it happens, I suppose all we're doing is, doing the cultures to confirm it for audit purposes and seeing if we've got the right antibiotics sensitivity

One participant also reported the availability of local resistance information meant statutory prescribing was straightforward:

…We have a good working relationship with the microbiologist [in our area] so they can kind of keep us up to date you know on their resistance pathway you know. So I'm happy with that. (F5)

GUM clinic staff were asked about their confidence in the results of the original combined test. Two centres reported slight concerns about the sensitivity of the NAATs results with the tests showing more positives than the number confirmed on culture.

One participant believed the NAAT is more accurate than the cultures as they get these results at the same time:

*I mean, we've noticed here when we've done culture … the lab automatically test it for PCR for gonorrhoea as well. Although we're sending a culture so we get two tests back from every site for gonorrhoea. So if we see a gay man for example, and we do a rectal, throat and a urethral, we'll send those off for gonorrhoea tests. But with c*hlamydia *tests for those same sites will also contain a gonorrhoea result. So we can look at our gonorrhoea cultures and a lot of our gonorrhoea cultures are negative. I don't know what percent it is at the moment. It's not massive but there's certainly a difference between the positivity on the PCR gonorrhoea and the culture positivity. There is a difference, so, we feel that probably the PCR are more accurate. (F1)*

Specific issues with sensitivity and specificity were mentioned by one participant and referred to this being a concern for a number of their colleagues. They were aware that on paper the test has high sensitivity and specificity but worried that without a major audit this data is unclear:

I think the other issue is that I've experienced is that even though on paper, it's a good test for gonorrhoea, in terms of sensitivity and specificity and accuracy, anecdotally, certainly myself and a number of other clinicians are a bit worried about the number of false positives, potentially getting through. Unfortunately, without the proper audit, and comparison between culture and the Aptima test it's difficult to say…. But it slightly concerns me a little bit that we're maybe, you know, getting some false positives coming through. (F2)

The same participant continued and drew attention to possible bias in any audit as non-attenders, which may be more likely to be asymptomatic may skew the results:

… but the trouble with any kind of audit I think there's an element of bias because… they don't all turn up because there isn't a 100% attendance rate for those who are referred in. Particularly amongst the group of young people who tend to be poor attenders

anyway. [It may be biased because] clients who attend who are symptomatic, who are by definition more likely to have gonorrhoea. (F2)

This participant appreciated that some of the false positives will be genuine infection that are picked up very early after infection but this is a minority:

…it may be that because you pick it up…in the early part of the incubation period, where the actual load of gonococci is very low you might just be picking it up on the NAAT but missing it on the culture. It's a window period, isn't really. (F2)

But he cautioned against using NAATs for all diagnoses:

I think clinicians like myself would be slightly cautious about saying, you know, we can use it as a gonorrhoea screening test at wholesale within the general population, I do think we need a bit more information on that really. (F2)

One participant reported no problems with confidence in the NAATs test and believed it was as reliable as tests that are used at GUM clinic:

F5:…I'm very confident in that.
R: You've not heard any evidence of false positives?
F5: We have seen false positives but not just on the RU Clear? Programme. We've had false positives …or potential false positives in the GUM so it's no different to the ones we might be seeing in the clinic.
R: So your faith in them is the same as in any tests you'd do?
F5: Yes.

GUM clinic participants were asked how they manage informing clients that their GC cultures have returned negative. When there are concerns about the sensitivity of the NAATs this is a worry if there are more false positives that then need to be explained to the client

All participants reported they had no problems in passing on this information. They stated that the additional cultures are done mainly to test for antibiotic resistance anyway and treatment will already have been given by this point:

..But you know, if it comes out negative, the whole point of it is to try and make sure the antibiotics we're giving to the clients are the right antibiotics. If for some reason the test is negative, it may be a failure in the point of the test but once the client has been treated, there's no point in repeating it again….People generally understand what that means. We're saying it's not that you haven't got gonorrhoea, it's that the test is negative, which are two separate things…(F1)

One participant had concerns that contradictory culture results caused confusion for clients who were then unsure whether to notify their partners:

…Obviously for some clients it may cause issues with partner's identification, but at the end of the day, the client's given the choice. They're not forced to take the treatment. You know, this test has been positive, the culture is negative.. (F5)

Participants reported that they are likely to treat all cases presumptively even if they are not confirmed on cultures, especially if they have symptoms:

> *Obviously if there's other areas that have got symptoms or you know, we may find they've got a discharge we'll obviously treat them empirically anyway....Perhaps we'll offer them treatment. Purely on epidemiological grounds and if they don't want it then fine, if they decline then that's perfectly ok. It's one of those situations where it's very very difficult….So in essence; a lot will end up being treated anyway. (F2)*

4.6.2.3 Additional testing at GUM clinic

Staff were asked if many clients referred from *RU Clear? Programme* refuse to be swabbed or have a more invasive screen. All centres reported that a minority of clients who attend for GC treatment refuse to be swabbed for antibiotic sensitivity or have further STI tests. Although it was reported as only a very small number of clients it was felt to be a problem:

> *…what we're finding is that the people who won't be swabbed most of them won't have bloods done either. So I feel that something could be done around encouraging clients. If it was explained to them why they need testing or why a gonorrhoea test or culture should be performed, that would help us to get their cooperation. (F1)*

Two participants felt that clients had no expectation that they would need further swabs or tests when attend the GUM clinic. One participant felt that *RU Clear?* Programme did not ensure that the client was aware of this before attending and believed *RU Clear?* Programme should be doing more to ensure clients understand what will happen at GUM clinic:

> *…they come under the presumption that they're having treatment. So, I don't know what they're told at RU Clear?* Programme *…people are saying, "oh, we were just told we had to come here because they don't treat for gonorrhoea". That seems to be the understanding and I'm not saying that's what's been said, it's the understanding of the client that if you've got gonorrhoea you need to go to a GU clinic. I don't think it's been made clear to them why they're being asked to come here, not because of the treatment, the sensitivity issue. I think, just if they were trying to sell it (F1)*

Those that do refuse to have further swabs done when they attend cause difficulty for the GUMs as they have to treat for GC based on presumptions about the cultures:

> *…I mean you can, repeat it on a urine test but you're back to square one again cos you're going to be using the same test… So those kind of clients we often end up treating empirically without doing a swab if they've declined it. (F2)*

One participant worried that as the clients didn't expect further tests they felt like they were pressuring clients into procedures they weren't prepared for:

> *By the time you try to start to persuade them it almost feels like you're coercing them into something they don't want, and it's very difficult. I think I feel like they feel like they're being pushed into it and they get very defensive. Where as I feel if that was explained to them before they came, we still wouldn't obviously make them have it done, but I think we would feel they've been better informed and it was an informed choice rather than a knee jerk reaction. (F1)*

Participants acknowledged that this choice had to be left up to the client and if they still refuse to have swabs done they will still be given treatment:

> *Well at the end of the day, clients are adults and are able to make an informed choice. You know I think it's better that they receive treatment than not receive treatment (F5)*

One way that participants reported handling any unwavering refusals is by doing a another type of swab at the original screening site as many young people feel more comfortable with this:

> *…sometimes they will accept a swab only at the screening clinic. Then if we could do a Stuarts, which is a transport media swab that will then be plated out for gonorrhoea then ok, it may not be as accurate as doing a direct plating on to gonococcal culture media but it's a bit of a compromise… if someone's found positive on a screening at RU Clear?* Programme*, they can come out to the original screening clinic…have a swab taken which can then be sent for gonorrhoea culture and are then given treatment. (F2)*

The need for a more flexible approach and a second choice of ways to treat some clients who refuse to come into GUM clinic or be swabbed was emphasised by one participant:

> *We can hark on about best practice and policies, at the end of the day you sometimes have to be pragmatic about management it's this balance between…best clinical practice but being pragmatic. …you know we don't want people going around with untreated gonorrhoea, albeit someone who may well be false positive. I think our experience at [our clinic] is that we've had to veer a little bit towards adopting pragmatic measures in actually giving gonorrhoea treatment off a PGD within a community young person's clinic. Either with or without confirmatory swab there. (F2)*

This echoes what was stated by a participant that offers community screening who felt that only being able to treat GC in a GUM clinic can be impossible with a very small number of cases (see 4.7.8).

Participants were asked what extra tests they thought it is appropriate to offer to clients who attended as referrals from *RU Clear?* Programme. All staff reported they would offer a sexual health screen appropriate to the sexual history of the individual in the same way they would do with a client who did not come in via *RU Clear?* Programme:

> *Well we take a full sexual history off anybody who's been referred from RU Clear? Programme. And we would then offer tests appropriate to that history. So it does change form client to client. (F1)*

Male clients who report sex with males are offered other additional tests (for example rectal or pharyngeal culture). One participant raised that they should not need to offer full sexual health screens to any referred clients as they should be asymptomatic. Any clients who report symptoms should be referred straight to GUM clinic and not be screened by *RU Clear?* Programme:

> *I think we're talking here by definition talking asymptomatic clients aren't we? Because, I mean, obviously we r*efer *in symptomatic clients so they're going to get a full screen and blood and they'll be managed like a GUM client anyway. If you get woman who's got a discharge she shouldn't be having an RU Clear?* Programme*, those are the ones that should be filtered out from the outset and they'll be r*eferred *straight into us without having an RU Clear* Programme*?. (F2)*

Only one participant raised this issue and the comments made by the other participants imply that they do see symptomatic clients so it is not clear that symptomatic clients are being referred straight to GUM clinic before *RU Clear?* Programme screen them. Referring symptomatic clients, and not just testing for chlamydia and gonorrhoea, is important as many STIs have similar symptoms and only testing for chlamydia and gonorrhoea may not resolve these issues.

4.6.2.4 Working with RU Clear? Programme

Participants were asked if they thought the community screening service added to their or the GUM clinics workload. Generally staff felt that the screening programme didn't add to their workload in any noticeable way. The service offered by *RU Clear?* Programme was seen by some as serving a different client group than GUM clinic and actually relieving some of the workload of these simple cases from GUM clinic:

> *No it doesn't. Actually, it's a good thing because there is a niche market for that type of thing. People want to drop off a sample off and get the results. And that's fine…They're a different client group than clients who come to GUM. And that's good as it takes away some of the more routine stuff from the GU clinic, which allows us to get on with more complex work. So it has a really valuable role in the community. (F1)*

Any additional administrative responsibilities were viewed as minor and acceptable by all participants:

> *it hasn't impacted…I mean, they're treated as a standard client if you like. The only difference is that we have to fax back the information once you've got results and treatment outcomes….it's not a massive additional workload. (F5)*

The additional contacts of *RU Clear?* Programme clients who present at GUM clinic were reported to add a slight addition to the work load but this was viewed as an acceptable amount:

> *I think that we get a few coming in who are contacts of* chlamydia *into our service because at the end of the day, GUM is part of sexual health isn't it? So, they're going to fetch up in a variety of clinics including GUM. Some are under 25, some are over 25… it's not a vast number in comparison obviously to the volume of work we do in the GUM clinic. (F2)*

The low prevalence of gonorrhoea was cited as a reason that there was little additional workload. One participant raised concern about how it would affect their workload, if the proportion of young people screened increased dramatically this would have negative impact on the GUM clinic:

> *Bearing in mind, you know, if we suddenly went to 50% of population [screened] it would have a big impact on the rest of the work [nursing staff] are doing. They have a lot of other work in contraception, screening and pregnancy testing you know…So that has to be kept an eye on I think… (F2)*

Participants were asked what they thought about the *RU Clear?* Programme forms and paperwork for index clients and contacts. Most of the participants thought the forms were user friendly and self explanatory:

> *…they're fairly self-explanatory. It's fairly simple and it's in big block capitals ABC and I've not heard any problems with the actual forms. I think it's fairly clear, I think it's black and white (F2)*

One participant raised the issue of visually unclear forms but acknowledged this could have been a problem with their fax:

> *They're all right. They don't always fax very clearly, but it's usually, you know, whether it's their fax or our fax that's very grainy, but faxes are often like that. They're legible. (F5)*

Another participant reported some problems with the design of the actual form that made completion difficult and complicated for their centre. They thought the form was not designed to be faxed as the information is duplicated although when you send a fax the sender retains this information anyway. This participant suggested that with only minor changes the form would become much more user friendly:

> *I think the referral form is poor. It's been designed in such a way that it implies you cut off the bottom of the form and you are supposed to return part of an A4 sheet back to them. But it means that you then have to duplicate all the information from the top of the form onto the bottom of the form where you can send it. I don't understand because when you fax something you get a copy of what you fax through, you keep the original document don't you? So what there should have just been is a space at the bottom just for you to write information about the client when they attended, whether they brought a partner, was treatment was given, what other tests were given, then you fax that whole thing through when it's completed and then you put your original one, which was now completed in the case notes. But for some bizarre reason they've got some space at the bottom which with dotted lines above it which you have to enter all the information in (F1)*

The same participant had concerns as the form requests information that they thought was unnecessary which creates extra work:

> *..there's also a space to say who saw the client which I don't understand the relevance of. Why they would need to know who saw the client? I don't understand what that's about, because we don't always know when the clients come we obviously go back to look at the notes and see who saw them so I don't understand why they need that information either. (F1)*

Participants were asked how they found communications with *RU Clear?* Programme in general and any ways that this could be improved. Two of the three centres had a positive opinion of communications with *RU Clear?* Programme. They had found that *RU Clear?* Programme were very organised and efficient with communicating information:

> *I think the* f*eedback the overall organisation obviously is very good, it is very well coordinated, that I think they do get the results back speedily, and I think that it a very good thing. (F2)*

One participant had some concerns about communication with *RU Clear?* Programme and had some objections to the way that some of the information is handled and communicated:

> *Sometimes you fill them in and they email you and then you think you remember the names and I've done these before. But you'd go and get the notes put all the information in again and you email it back to them, and then they phone you up and say has such-*

and-such a person been? And it drives me mad and I don't understand… Where is this information going? Why are we being asked the same things three or four times? (F1)

This participant noted that problems they were experiencing reflect badly on the organisation and professionalism of *RU Clear?* Programme. This participant was disappointed that *RU Clear?* Programme could not improve this element of their service better as they viewed the programme as a missed opportunity to run a great service:

It irritates me that they are running this massive service and they think they could make it so fantastic and yet it doesn't give you much confidence if you then say "well I faxed that to you on Tuesday" and then there's this big sigh and shuffling of papers and people saying, "well, I don't know where it's gone" and they sound so hopeless and useless and it just makes you raise your eye [brow] *and think what's the point in me doing this if no one is going to retain this information? And you know it can be three times, you see the same names and you think 'I've just done this' (F1)*

This participant also talked about the difficulty of reaching *RU Clear?* Programme staff on the phone to have a conversation about these problems because phone messages don't get passed on:

you ring somebody up and it's a sort of adminy type person and they'll say they'll get someone to ring you back, and nobody ever does. That's the other irritation…I realise they're busy, we've all got client contact and we've all got lots of sets of notes sitting around that need phone calls. But we don't ring very often and if you do have an issue you try and ring up and see if you can sort things like this out. (F1)

This participant expressed disappointment about how their relationship with *RU Clear?* Programme had deteriorated. They felt as if there was no consistent working relationship as there was no continuity in the contact and help from the *RU Clear?* Programme office:

You get a different person each time you ring and nobody seems to want to take responsibility for it. No one says "gosh that's really bad, I'll look into it." It's like one person tried to blame another for the… like "I wasn't here yesterday", and that's not really the issue and I wouldn't want my staff to say, you know "I wasn't here yesterday". I think it needs addressing. (F1)

This individual initially felt they had a good working relationship with the *RU Clear?* Programme off but this has deteriorated over time and they now feel as if they have been abandoned by *RU Clear?* Programme. These difficulties in communication have resulted in this centre losing enthusiasm and motivation for the programme. She reported feeling demoralised and pessimistic about the work as a result of this:

And it's not good for relations when you think well I'll do it but I don't know why I'm bothering. Cos they'll only be ringing up on Friday asking for it again, it doesn't help the situation. (F1)

She suggested to improve this situation that the *RU Clear?* Programme office should try to keep regular contact with the site involved as this would resolve problems earlier and cultivate a feeling of partnerships:

I just think you do need to maintain contact with people…on a project like this. You know it wouldn't be a bad idea if you had annual site visits. Maybe not as formal as a site visit

but an annual point of contact even but it seems to trundle along now and it's becoming difficult, you know you don't hear anything from them…they ring occasionally and leave a message but you don't get to talk to anybody anymore. I think we envisaged that this was something like a partnership and it doesn't feel like a partnership anymore. (F1)

4.6.2.5 Contact tracing

Participants were asked their views of the contact tracing and partner notification carried out by the GUM clinic for the clients referred from *RU Clear?* Programme.

There were differences between how each centre deals with tracing the contacts of GC positive clients. One participant reported that their centre does the partner notification for a referred *RU Clear?* Programme client in the same way they do for any standard GUM clinic clients. But the other two participants reported confusion over whose responsibility it is and how the process works:

The one thing we might have issues with is sometimes we're not clear who's responsibility chasing up partners is - is it the RU Clear? Programme *coordinator or is it [our] nurses to do it? I think sometimes, particularly where we do it in [our area], where we've absorbed the RU Clear?* Programme *quite well into our community clinics, it often ends up that the nurse has to chase up the contacts. But I think this is more for gonorrhoea than for* chlamydia*. I think we'd expect that the responsibility for recalling and tracking of gonorrhoea positives is probably our nursing staff you know. The* chlamydia *side of it is the RU Clear?* Programme *coordinator.*

One participant raised concern about the confusion that contacts feel when they receive a text message from *RU Clear?* Programme telling them one of their sexual contacts has tested positive and they need to make an appointment at the GUM clinic. The participant was concerned as it is not obvious who the sender is and this can cause anxiety for the clients:

… clients ring us, somebody's given the client our number to book an appointment…there's no text number to reply back to. So we've had a few now and we're assuming it's RU Clear? Programme who've done it or some sort of community screening…The only problem…they're not sure about the information because it looks a bit anonymous. They would like something a bit more tangible….they're usually quite grateful they've been contacted…they think it's somebody winding them up. (F1)

The same participant had concerns about the anonymous nature of the contact tracing (both by test message and phone call) that she thinks *RU Clear?* Programme does. She did state she was not sure these messages were definitely coming from *RU Clear?* Programme as the GUM clinic they have been advised to call does not always correspond with where they live:

I'm not 100% sure it's RU Clear? Programme because we've never got to the bottom of which organisation it is but it's something Manchester wide because sometimes have been ringing up from far away, they see it as their nearest clinic. Which makes me think it's somebody who's not very good either on Manchester geography…(F1)

4.6.2.6 Giving young people false confidence and ignoring other STIs

One participant raised the concern that *RU Clear?* Programme may suggest to young people that chlamydia and gonorrhoea are the only infection that they could acquire:

> *…the problem that I've always had with the* chlamydia *screening is that worry that STIs don't stop at* chlamydia *and gonorrhoea…my worry is that people, especially younger people, have had a screen think 'I'm alright' when in fact they've not given any consideration to the other infections, especially syphilis and HIV…I worry there are lots of people who remain untested for these infections when really we should be trying to increase the numbers of HIV tests that are done. (F5)*

But this participant was eager to stress that HIV testing should not necessarily be carried out in the community and needed specialist skills and consideration:

> *I don't think that that [HIV testing] is best done necessarily in the community. It's ok when things are all negative, difficulties arise when people have got positive results, and how they're handled and you know, dealing with the fall out of that. That worries me sometimes. (F5)*

The *RU Clear?* Programme screening programme was regarded mentioned as a good opportunity to raise the general issue of sexual health and other tests:

4.6.2.7 Young people not attending

One participant felt client non- non-attendance was a serious problem for their GUM clinic:

> *I think the attendance rate, because you know it's been brought to my attention, of clients who will have an appointment because they've been found to have gonorrhoea at RU Clear?* Programme *but they have not attended our clinic. And then we have to action that, and very often we cannot…get the client in. And that causes difficulties. (F1)*

It was estimated by this participant that a large proportion of *RU Clear?* Programme referrals did not attend their initial or reschedule appointments:

> *…we haven't really audited, but I would say anecdotally, possibly upwards of 50% of clients who are found to be gonorrhoea positive from the RU Clear?* Programme*, given appointments then don't attend [the first appointment] and… I wouldn't have thought we get as many as 75% of clients in from the…source of screening. (F1)*

This links in with the issues raised earlier and in the screening site interviews about treating those who refuse to attend the GUM clinic in the community (see 4.8.4)

4.6.2.8 Reaching other clients

The *RU Clear?* Programme and the NCSP were praised as they screen clients that would not normally access sexual health services:

> *I do think it's a very acceptable for the client… there's no doubt that RU Clear?* Programme *reaches clients that probably otherwise wouldn't access the healthcare services…I think a lot of it, never mind how sceptical we are initially, [has worked] (F1)*

One area that was highlighted as needing attention is the low levels of screening in general practice which this participant expected but have still not been addressed:

I suppose the big question was 'was it going to pick up in general practice' and it hasn't. I think that a very small proportion has been done in primary care which is what we expected. It pretty much has fallen on, already with services with a bit of an infrastructure, like young person's sexual health clinics, like the Brook, like family planning. I think we expected that in all honesty. So...improvements, well in long term, again in GPs to do a bit more.

4.6.2.9 Successful areas

- Referral to GUM clinic is a quick process as GUM clinics are generally making their 48 hours targets
- *RU Clear?* Programme great opportunity to raise issue of other STIs
- Screening reaches niche client group that are not otherwise accessing GUM clinic

4.6.2.10 Improvements needed

- Communication issues and duplication of efforts repeat requests for the same info. There seem to be some duplication of information requests – asked to fax same information more than once.
- Suggest one named point of contact and annual visits/check ups to GUM clinics to ensure continuous relationship between GUM and *RU Clear?*
- Clarify how partner notifications/contact tracing should work.
- Clients often arrive at GUM clinic unaware they will be asked to have extra swabs etc. This needs to be spelled out by *RU Clear?* Programme when they are given the results
    - Pragmatic ways of getting round this have been developed (ie swabbing in community) – develop this further into official guidance as it seems a bit *ad hoc*
- Non-attendees is a real issue, any way this can be reduced?
- Increase screening in GPs

4.6.3 Clients

Of 43 clients listed as willing to participate, attempted contact with each of them facilitated interview in only five clients. The low response rate (5/43=12%) was due to an inability to procure direct telephone communication with the sample, who did not answer their mobile phone, or their mobile went to answer phone, or because a recorded message said the number was unavailable. Two individuals hung up. Of 11 clients who the researcher spoke with directly, five were interviewed.

Clients interviewed were aged between 16 and 25, all were female and had been tested in a variety of venues including at a hospital, at a community contraceptive clinics and at a family planning clinic. Interviews were conducted within one month of receiving results.

Participants were quiet and did not spontaneously offer much information other than positive or negative affirmations, even with friendly prompting and encouragement. All but one was GC negative and two tested CT positive. One participant tested GC and CT positive and was referred to GUM clinic for treatment. This participant was more conversational and provided further details about the test procedures.

Overall, participants had a positive experience of the programme. They found the 'pee in the pot' test easy and reported that staff at the screening sites were helpful and welcoming:

…[they were] really friendly and understanding. (A2)

Participants understood about the dual test and were happy to be screened for both. Participants all received their results by phone, rather than by text message or by letter, and were satisfied with this way of receiving the results:

> *I'd much rather it come through a telephone call than obviously a text message or a letter….Because you find out straightaway don't you?* (A1)

Participants were content with the amount of time between their test and when they received their result and estimated it was between one and two weeks. Each stated they had been upset and shocked by the result but said the individual who gave them the result was helpful and kind:

> *…I was gutted that I had it, so I was very upset yeah…. They just said oh well…like if you want, I can make you an appointment to go have the treatment for it now. And I said yeah and she was helpful, helped me yeah*. (B1)

The one client who attended a GUM clinic for treatment did so on the same day as she received the result. She could not attend her nearest GUM clinic that day as they had no appointments. Despite the distance she was happy to travel as it meant she was treated quickly. She had a positive experience of the additional tests at GUM clinic and was given a full sexual health screen including blood test for HIV. She reported that partner notification was not necessary as she attended the GUM clinic with her male partner from whom she had contracted the infection.

Each participant, including the young woman referred to GUM clinic, stated that they would recommend the screening programme to their friends. They reported it was easy to do and thought it was good to find out if they had an infection and get treatment:

> *…just to make sure like everything's alright because you never know do you? Things like the pain you might have in your stomach might just be like cramps but it might be something else.* (B1)

4.7 Costings and other similar projects

*All cost data provided by RU Clear? Programme Screening Coordinator July **2008.***

4.7.1 Direct RU Clear? Programme Costs

The majority of the costs that are in the *RU Clear?* Programme budget come from laboratory expenditure (£633,775) paid to Manchester Medical Microbiology Partnership (MMMP) Virology Laboratory at Manchester Royal Infirmary (Table 4.16). These costs cannot be broken down to reveal how the addition of reporting the GC result impacts upon this. The other major expenditure to the programme is staff costs (£330,950) which are likely to remain the same whether or not GC is included. In fact, most of the expenses, for example recruitment, IT equipment, advertising and publicity, rental/leases and travel, will remain the same even if they programme was only screening for CT.

Table 4.16: Direct costs to the *RU Clear?* Programme

Description	2008/9
	£
Staff Costs. WTE = 9.50	**330,950**
Project Office	
Recruitment	*3000*
Training/ conferences	*10000*
Travel	*8000*
Medical Equipment	*2000*
Medical Consumables	*5000*
IT Equipment	*5000*
Axsys annual fee	*23000*
Office Equipment	*1000*
Rental/Leases	*9000*
Printing and Stationery	*31000*
Heating, Lighting, Power	*3000*
Telephones & SMS	*3000*
Maintenance	*1000*
Advertising/Publicity	*32000*
Postage	*14300*
Audit	*5000*
Drug Costs	*20000*
Transport	*20000*
Project Office Total	**195,300**
Laboratory	
Screening & confirmation. MMMP - MRI	**633,775**
Additional Screening & Confirmation	**50,950**
Non-Salary Sub-total	**880,025**
GM Chlamydia Screening Programme - Total	**1,210,975**
Income - PCT Contribution	**1,211,000**

Data provided by RU Clear? Programme *Screening Co-ordinator July 2008*

Table 4.17: Cost of providing results, PN, advice and treatment booking service

Results, partner notification, advice & treatment booking service cost		
	WTE	**Cost 08/9 (£)**
Staff costs	*3.2*	*87,636*
Telephony		*5,000*
postage		*1,872*
IT maintenance		*22,000*
Total		**116,508**

Data provided by RU Clear? Programme *Screening Co-ordinator July 2008*

Estimated costs (Table 4.17) for results, partner notification and treatment booking service (i.e. liaising with GUM clinic to organise an appointment) are given below and are unlikely to change if GC screening was not being offered. Partner notification costs for GC positives are borne by the GUM clinic they are referred to and not by *RU Clear?* Programme.

Clients that need to be referred to GUM clinic are time consuming because *RU Clear?* Programme has to spend time contacting the GUM clinic for outcome information. This is also true of clients with complicated CT that need to be referred to GUM clinic. In terms of budget it is estimated that the only additional costs that screening for GC incurs is the confirmatory test (£12.80 per test) and an additional information leaflet.

Table 4.18: additional cost incurred from GC testing.

Additional GC costs	£	
Leaflet	*1,118*	(40,000 copies)
confirmation test	*2,560*	(£12.80 per test)
	£3,678	

Data provided by RU Clear? Programme *Screening Co-ordinator July 2008*

Based on the information from 2007/2008 *RU Clear?* Programme predict they will offer 54,000 tests in 2008/2009. Approximately 10% will test CT positive and 140 cases (0.26% of all those tested) will be positive for only gonorrhoea.

Table 4.19: Result and projected number of tests

Results given	**2007/8**
Total tests	*31,862*
CT + (any GC status)	*3,383*
GC + CT -	*104*
Projected	**2008/9**
Total tests	*54,000*
CT + (any GC status)	*5,400*
GC + CT -	*140*

Data provided by RU Clear? Programme *Screening Co-ordinator July 2008*

Based on a predicted 54,000 tests being carried out in 2008/2009 it is estimated, based on the total monies contributed by the PCTs, to cost £22.43 per test.

4.7.2 Costs to GUM clinic

Payment by Results (PbR) deems the cost of each attendance at GUM clinic as £146 for a first visit (based on 07/08 PbR tariff for a first GUM clinic attendance and excluding MFF. DH_073121). The GUM clinic that sees the referred clients will bear this additional cost. There will also be additional costs for any clients who DNA their appointments but the cost of this is not quantifiable.

4.7.3 Costs of similar projects

Other English PCTs that are also screening for both infections were contacted in an attempt to compare *RU Clear?* Programme costs to similar programmes. No other PCTs could provide such information specifically for dual screening. Reasons for this included: the programme had not been running long enough for the information to be available; and the screening costs were embedded in the Sexual and Reproductive Health (S&RH) services and the specific cost information could not be extracted. One PCT commented that testing for CT as well as GC is only an extra 50p to £1 but the cost of the repeat visit, treatment, and two cultures (cervix and urethra, urethra only in males) to

check sensitivities have to be added, and these depend on local lab costs and are embedded in the general Sexual and Reproductive Health services costs.

4.7.4 Other similar screening programmes

Other programmes were contacted to request other reports, journal articles or documents were available. Again no official reports were available about the programme specifically or because the programmes were rolled out in Phase 3 so were not long established. Peer reviewed journal articles about similar programmes are included in the literature review and come mainly from Lewisham PCT and Liverpool PCT.

Three PCTs provided some information informally which is included below.

City & Hackney PCT have been running a dual screening service since Phase 3 and were able to provide a small amount of information about their service. They had not published any data yet. They use the BD Viper Strand Displacement Amplifier test and all clients are informed the test is for both infections. Between April and November 2008 conducted 6971 screens (all dual NAATs), 573 (8%) tested CT positive, 135 (2%) positive for GC and 61 (1%) were coinfected. The chlamydia screening lead in the PCT said that there was no evidence to suggest that also screening for GC has had a detrimental effect on recruitment to the screening programmes.

Lewisham PCT, as well as publishing information in peer reviewed journals (Roa et al 2008), were able to provide some additional information about their screening programme (personal correspondence). Overall they have a GC positively rate of approximately 3% with some of these testing CT negative. Further research is being undertaken but they have found that most of the specimens that tested GC positive and CT negative on NAAT do grow on culture so are not false gonorrhoea positives. Prevalence is highest in females under 19 and males 19-24. In terms of ethnicity, between January 2004 and June 2008 over 50% of those testing positive were black, 22% white and 14% mixed race.

The care pathway for those tested in Lewisham is different to clients in Greater Manchester. Approximately 90% of NAATs tests are done in S&RH–as are all CT and GC services. Those who test CT positive are only referred on if there is evidence of other gynaecological problems. If someone tests GC positive, urethral and cervical swabs are taken and these are sent to be culture and antibiotic sensitivity tested. Only if a GC culture comes back as being resistant to antibiotics is a client referred to GUM clinic. This differs from *RU Clear?* Programme where all GC positives must be referred to GUM clinic for treatment and cultures. S&RH services in Lewisham offer all services except serology for HIV and syphilis. The decision to treat and do cultures on all cases within the community, and not refer on, was taken as a result of Wilkinson et al (2000) who found that only 50% of clients who tested positive for CT in S&RH never got treated at GUM clinic after they were referred to GUM clinic. Lewisham PCT have found that their clients want a one-stop-shop.

Liverpool PCT has a very similar screening programme to *RU Clear?* Programme. They have found CT prevalence of 12% for females and 16% for males and gonorrhoea positivity of 1% in males and in females. They found supportive evidence (either confirmed on culture or known positive partner), for GC in 98% of cases that tested positive on NAATs. They have found that only 2 of the 47 females who tested GC positive declined any follow up at GUM clinic and had to be treated for GC in the community. No research has been conducted that explored how clients feel about having to attend a GUM clinic for treatment and further testing.

5. Discussion

In this section we discuss the screening coverage for Greater Manchester's screening programme for Chlamydia. We further discuss the effectiveness of testing for Gonorrhoea in the community as a dual test with Chlamydia. The acceptability of the screening programme among staff and service users is also assessed.

5.1 Coverage of screening and positivity rates

Findings show that testing rates were higher in areas with higher levels of deprivation (3% of the population were screened in quintile of least deprivation compared to 6% in the most deprived). This shows that the programme has been successful at reaching those known historically to be most at risk of poor sexual health (Department of Health 2001). However, although there was a tendency for the more deprived areas to have greater rates of positivity of both CT and GC (note that the confidence intervals were wide, table 3), positivity was generally high across all areas for CT reinforcing the need for all young people to have access to screening. In the case of GC infection, one particular category of area with high deprivation ('urban challenge' using the P^2 People and Places categorisation system) showed higher rates (Figure 4.6), and commissioners should consider targeting the screening programme in areas with this classification.

In common with the Chlamydia screening programme in the rest of England (National Chlamydia Screening Programme 2008a) testing rates are far lower for males compared to females (ranging from 1.4% of the eligible population in Stockport to 3.3% in Heywood, Middleton and Rochdale). In order to achieve the current target of 25% of young people screened per April 2010 (National Chlamydia Screening Programme 2008b), and to ensure equality of access, the programme urgently needs to increase the number of young men accessing screening.

Significant achievements were made in identifying service use patterns of young people who attended testing. Differences in uptake of testing and testing behaviours were identified between males and females. While it was found that young peoples' clinics were the most popular choice of testing location for both young females and males (40% and 33% respectively), the second most frequently used location for females was the Family Planning Clinics (22.5%) whilst Health Centres (18.6%) were the second most popular for males. This shows overall that community testing was the most frequently used location of testing, but that females and males have different approaches to testing.

In common with other UK studies of ethnicity and STI rates (Low et al. 2001), rates of GC were higher in those of black African (1.8%), black Caribbean (1.7%) and mixed race (2.2%) ethnicity compared to those of white ethnicity (0.7%). However, while the positivity rate in persons defined as white was the lowest of all the ethnic groups described, approximately 85% of all persons tested were within this group. Enhancing the screening rate in minority ethnic groups is thus a priority in order to identify and treat persons predicted to be more likely to test positive for CT and GC. New approaches to encourage an increase in uptake of screening in minority ethnic groups are clearly required.

The proportion of the population of young people aged 16-24 who were screened in the *RU Clear?* Programme varied across the region. Screening rates in females in the best performing PCT (Manchester, 12%) were double those of other PCTs. The rate of CT positivity among females was at least 10% in all PCTs studied (10.1% Stockport PCT-14.4% Ashton, Leigh and Wigan PCT),

suggesting that across Greater Manchester screening is appropriately targeted at those at risk of infection. CT positive diagnosis rates in males have a greater range (4.3% Heywood, Middleton and Rochdale PCT – 13.5% Ashton, Leigh and Wigan PCT) suggesting that low risk males are being tested in some areas. Similarly, positivity rates for GC in males was lower (0.00%-1.25%) than in females (0.38%-1.53%).

5.2 Costs of the dual testing programme

Costing information was provided the RU Clear Screening Coordinator in July 2008. Costs were estimated from the total monies contributed by PCTs to the predicted 54 000 tests carried out between 2008 and 2009 that the cost per test would be £22.43. The majority of monies used for laboratory services and salary costs. The majority of all costs would have been incurred anyway if the programme was only screening for CT. The only additional costs incurred by the programme were £12.80 per confirmatory GC test (£2560 in total), another leaflet promoting GC screening (£1118) and minor staff costs for liaising with GUM for GC treatment. However, there was no comparable information from other PCTs (Lewisham PCT, City and Hackney PCT and Liverpool PCT) to comment on whether costs are similar across screening programmes.

5.3 Referral and treatment of GC positive patients

Previous research suggests that a high proportion of those testing positive with Chlamydia in a community setting may not attend GUM services (Wilkinson et al. 2000), and for this reason one of the few other dual screening programmes (Lewisham) has opted to test and treat both CT and GC in the community. In Greater Manchester, CT positive cases who are negative for GC are treated in the community, with GC positive cases being referred to GUM. It is therefore important to assess the success of the referral process. Of the 111 index cases testing positive for GC, 98 (88%) attended the GUM. Thus it appears that follow-up rates in Greater Manchester are reasonably high. Liverpool PCT operates a similar programme and found a similar rate (85%) of GC cases did attend GUM for follow-up.

5.4 Confirmation of community GC positive test results

Once tested positive for GC, an *RU Clear?* patient's treatment and care is transferred to GUM. Examination of GC patient confirmatory retests at GUM showed that the screening test for GC has high sensitivity (96%) and specificity (98%). However, in a low prevalence population, even such high sensitivity and specificity rates can generate a large proportion of false positives. In evaluating the dual screening programme, it is therefore useful to consider the positive predictive value (the proportion of those initially testing positive for GC in the community who are confirmed to have the infection), as well as to review the most up to date published data on the performance of the dual test. The specific type of Nucleic Acid Amplification Test (NAAT) used in Greater Manchester is the Gen-Probe APTIMA Combo 2 assay (AC2) which uses Transcription Mediated Amplification technology (TMA) to detect CT and GC nucleic acid. Samples that test positive are retested using a Gen-Probe APTIMA assay that detects a different target on the CT or GC nucleic acid. This combination of testing ensures a high degree of certainty that a reported reactive result indicates a true infection (Basavaraj et al. 2008; Golden et al. 2004; O'Mahoney et al. 2008). Although national guidelines state that NAATs should be confirmed by culture and that culture is the diagnostic method of choice in GUM (BASHH et al. 2005), it is now well recognised that culture is less sensitive than TMA (Golden et al. 2004; Mahto et al. 2009), making it unsuitable to use as a gold standard against which to assess

positive predictive value. Testing by culture alone would have missed four probable GC positives (based on their partner history: 5% of the 78 index cases) and failure to test at all possible sites of infection may have led to a further 12% of cases (9/78) being undetected.

Of the 18 males initially screened as GC positive (0.5% of those screened), 14 underwent culture/microscopy tests at GUM and all were confirmed GC positive. Of the 78 females (0.6% of the screened population) testing GC positive using AC2, 64 agreed to confirmatory retests with 40 retesting positive. Overall, 69% (54/78) of cases were confirmed by culture/microscopy. This is a lower proportion of confirmed cases compared with findings from an area of similar prevalence of GC (Liverpool, 1%) using the same test (89%; Lavelle et al. 2006). In Liverpool, all cases were swabbed at all potential sites of infection (if relevant to sexual history): the cervix, urethra, rectum and pharynx. While the Liverpool study followed-up all those found positive in the community, this study aimed to retrospectively evaluate testing practice across multiple clinic locations across Greater Manchester, and found that in actuality swabbing practice was less consistent. National guidance on testing and treating gonorrhoea emphasises the need for comprehensive testing at all target body sites where symptoms are present, when a partner has reported gonorrhoea or sexual history indicates a risk (BASHH et al. 2005). In Greater Manchester, swabbing was found to be less consistent. Swabbing at the pharynx was found to be relatively uncommon, yet 25% of male and female patients swabbed at the pharynx retested positive on culture/microscopy at this site. Further, we noted inconsistent swabbing practice whereby cervical sites were not swabbed when the urethra was (and vice versa). The Liverpool data show that if only culture at an equivalent site had been used, the number of cases confirmed by culture would have been found to be lower (82% compared to 89%: Lavelle et al. 2006). For the Liverpool study, evidence of a GC positive partner was considered supportive evidence of for GC infection, even in the absence of positive culture results, bringing the total proportion of confirmed or probable cases to 98%. In Greater Manchester, collection of data on partners was limited, but showed that four of the 24 cases retesting positive had GC positive partners. Consistent swabbing not only provides a greater probability of confirming a NAATs test, but, critically, provides the opportunity to test for antibiotic sensitivity and thus enables the provision of appropriate treatment at GUM for GC infection.

5.5 Acceptability of the screening programme among staff and service users

Screening data shows the number of tests increasing over the duration of the pilot study, suggesting that the test was acceptable to the target audience. The qualitative element of this study was designed to investigate the experience of staff and patients involved in the Greater Manchester Chlamydia screening programme. Staff, in general, reported a positive experience of the dual screening programme. GUM staff found the tests acceptable and considered the programme was not a significant burden to their work-load. Testing for both infections was viewed positively and thought to attract those who would not have attended under normal circumstances. Rapid referral has been facilitated by local efforts to achieve the national policy targets stating that all patients must be offered an appointment within 48 hours (Department of Health, 2008). One GUM staff participant was concerned because he perceived that 25% of referrals never attended, although this evaluation shows that across Greater Manchester, the actual figure was lower: 15% did not attend (see above).

We believe this is the first documentation of the experiences of patients of an opportunistic community screening programme that offers GC and CT tests to young people, and referral to GUM for treatment, in a variety of clinical and non-clinical settings. A variety of research studies have investigated the emotional and psychological effects of a CT diagnosis (Duncan, et al., 2001; Mills, et al., 2006; and one study (Evans and Cross, 2007) focused on patient experience of a community STI screening service. The Evans and Cross study examined experiences of those seeking screening but did not include people screened opportunistically in non-clinical community settings. In our study, of the

patients available for interview, each reported a positive experience of the screening programme, finding the test easy, and all staff friendly and helpful. Participants reported being pleased that they had been tested, and if necessary treated, for two infections.

Individuals with an STI are known to be at high risk of re-infection, and an essential element in the prevention of re-infection and of further transmission is through partner notification and treatment (LaMontagne, et al, 2007; Trelle S et al., 2007). Partner notification decreases the number of re-infections in index cases and increases the number of partners coming forward to be tested. While GUM clinics have developed expertise in partner notification, other testing venues are less able (Trelle, et al., 2007). In our study, GUM staff reported inconsistencies and confusion over who is responsible for partner notification for patients referred by the screening programme. For the screening programme to achieve a reduction in the rates of CT and GC, partners of index cases need to be tested and treated to reduce transmission (Cowan, et al., 1996; Trelle, et al., 2007).

Using telephone interviews was an effective way for health staff to participate in this study. This may reflect healthcare employees' confidence in discussing professional issues by phone. Staff were accessible and motivated to discuss the programme and provide their opinions on its strengths and weaknesses. While additional interviews could have enhanced the data, many issues were repeated by different staff suggesting saturation of the subject matter was achieved. It is not known if the two lost interviews would have provided additional perspectives. Despite random selection of staff, it is likely that staff with a strong interest in the screening programme were more likely to participate, causing some selection bias.

The low response rate in patients was a limitation to this study. A total of 43 patients provided their mobile phone numbers to screening programme coordinators, suggesting an agreement in principle to participate. In practice, only 11 could be contacted, five of whom could be interviewed despite multiple attempts to make contact. While we can rationalise on reasons for non-response, the low response rate suggests that telephone interviews with young people about STI testing is not an appropriate research methodology. A review of similar studies found no evidence to suggest telephone interviews are poorly effective as a research tool. This flaw may have reduced the breadth of patient opinion about the dual screening method. Face-to-face interviews organised at the time of screening may have generated greater participation however, the distribution of the sample population around Greater Manchester and the wide variety of services accessed, often only for one-off contact, meant face-to-face interviewing would be extremely difficult. The subject matter (STIs) may still have caused a low response rate as this is an uncomfortable topic for many people. We thus present our results as an exploratory contribution towards the opinions of patients experiencing dual testing, and recognise, as with all qualitative research, their limitation for generalising across all service users.

In summary, our qualitative results suggest that in an urban area of higher prevalence of GC, dual testing in clinical and non-clinical settings is acceptable and perceived to be effective. Thus, public and professional perceptions may not be a barrier to setting up dual testing screening programmes in other locations. However, positive diagnoses in non-clinical settings require referral to sexual health services. Protocols must clarify who is responsible for partner notification. In general, across the UK, while rapid access to GUM has improved following a government defined target of 48-hour appointments for all patients, enhanced referral between community settings and GUM is required. This could be facilitated by the use of common electronic appointment systems. Additional research on the experience of patients in screening programmes may further inform policy makers of potential barriers to use, selection biases, and issues which need to be addressed to enhance use at community level. Investigating young people's sexual behaviour after dual testing may indicate whether young people assimilate health promotion messages about other infections. Research comparing the experience of patients treated for GC in the community against those referred to GUM

for treatment would inform policymakers of limitations in, and facilitate development of, current care pathways.

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Appendices

Appendix 1

Abbreviations List

AC2 - Aptima Combo 2 dual test for *Chlamydia trachomatis* and *Neisseria gonorrhoeae*

ANOVA – Analysis of variance

CT – Chlamydia trachomatis

DNA – Did not attend

GC – Neisseria gonorrhoea

IMD – Indices of Multiple Deprivation

LSOA – Lower Super Output Area

MSM – Males who have sex with males

MSF – Males who have sex with females

FSM – Females who have sex with males

NAATs – Nucleic Acid Amplification Tests

NCSP – National Chlamydia Screening Programme

PPV – Positive predictive value

TMA – Transcription-mediated amplification

S&RH – Sexual and reproductive health

Appendix 2

Aims and objectives in conjunction with Maxwell's six dimensions of quality:

Effectiveness

The effectiveness of the dual testing system was evaluated to assess whether it is producing the desired effect by examining:

- 12 months of data from opportunistically screened people (for CT and GC) to determine proportions testing positive for GC in CT positive and CT negative clients.
- All positive GC tests from the pilot six months were followed up to determine effectiveness of referral to a GUM clinic, subsequent testing, treatment and contact tracing. These were used to determine the positive predictive value of the NAATs test.
  - Number of referrals to GUM clinics for confirmatory GC testing.
  - Number of referrals who refused confirmatory testing (GUM clinic data).
  - Number of GC cases that tested positive on confirmatory testing at GUM clinics (GUM clinic data).
  - Number of GC cases that underwent treatment (GUM clinic data).
  - Number of GC cases that were screened for other STIs (GUM clinic data).
  - Number of GC cases whose contacts were successfully traced, followed up and treated where appropriate (GUM clinic data).
  - Total number of partners reported and contacted, who receive screening CT and GC (GUM clinic data).
  - Number of partners accepting testing and number of partners receiving treatment (GUM clinic data).
  - DNA rate for GC case management (GUM clinic data).
  - Antibiotic sensitivity patterns of those cases confirmed on culture (GUM clinic data).

- Details of any additional costs incurred for dual screening, including referrals to GUM clinics for GC test (*RU Clear?* Programme workload) positive cases, treatment, and contact tracing (GUM clinic workload).
- Comparisons were made with similar screening programmes in other regions.
- KC60 trends were modelled in the absence of dual testing and compared with KC60 data during the pilot period to determine the impact of the dual testing pilot.

Efficiency

The efficiency of the dual testing system was examined to see if the number of correctly diagnosed cases of GC were maximised for a given level of resource input. This was done by:

- Gathering data on the cost of follow up and partner treatments.
- Comparing the cost to other similar pilots
- Collating data on index client and partner refusal rates
- Comparisons with other similar screening services

Acceptability

The acceptability of the dual screening system to staff and staff was explored. This was done through:

- Phone interviews with staff
- Phone interviews with staff
- Comparing the rates of CT uptake in Greater Manchester before and after the introduction of dual testing to see if it has had a negative, positive or negligible effect on screening uptake rates.

Access

The impact of GC positive referral pathways on the 48hr waiting time targets for GUM clinic consultants was examined by:

- Comparing the 48 hour waiting time audit data before and after the introduction of dual testing.
- Data on the additional number of people referred and the number of extra hours they would have added to GUM clinic workload and potential effect of additional demand for GUM clinic services.

Equity

Data was collected and analysed to determine whether dual testing favours some population sub groups whilst discouraging others. This was done by:

- Collecting GUM clinic data regarding perceived sexual orientation (behaviour) and ethnicity (where available).
- Analysing the data to see if access if biased against any subgroup.
- Residency data were also mapped to national Indices of Multiple deprivation (IMD) and a market segmentation tool to determine differences in attendance rate.

Relevance

The appropriateness of the dual testing system was examined for the population that is eligible for CT screening. This was done by:

- Pulling the findings together to look at efficiency and effectiveness and compare them to other similar screening programmes.
- Examining the acceptability to the client population
- Exploring the effect on overall gonorrhoea figures for Greater Manchester
- Analysing basic cost information.

Appendix 3
Description of the P^2 People and Places Category

Adapted from Beacon Dodsworth Ltd, www.p2peopleand places.co.uk

1. ***Mature Oaks***
    - *Older, prosperous adults. May include pensioners;*
    - *Tend to live in large detached houses which they own outright having finished paying mortgage;*
    - *Live as married couples, grown up children who have moved away;*
    - *Tendency for them to have a car each, generally powerful;*
    - *Read broadsheet and black top newspapers and have keen interest in politics;*
    - *Use leisure time to go on holiday;*
    - *Tend to shop in Sainsbury's;*
    - *Likely to have worked as managers, professionals or employers, many work from home;*
    - *Likely to hold academic qualifications and command a good income.*
2. ***Country Orchards***
    - *People working in agriculture in rural areas;*
    - *Older adults, mostly as part of family units;*
    - *Each household has two cars, which are likely to have powerful engines;*
    - *Keen interest in politics and read broadsheet newspapers;*
    - *Tesco supermarket of choice;*
    - *Split between land owners and less wealthy farmers and agricultural workers;*
    - *Many work from home on their own farms. Can have a high income and many also well educated.*
3. ***Blossoming families***
    - *Young families with the parents being young adults aged 25-34 with young infants;*
    - *Parents likely to be a married couple;*
    - *Still paying a mortgage on their homes which tend to be detached properties or semi-detached or terraced;*
    - *These families have at least two cars. Majority have large powerful engines. Family cars with mid-sized engines also popular;*
    - *Black top newspapers are read and shopping mainly done in Sainsbury's, although Tesco is popular;*
    - *Adults well qualified and well paid. Tend to be professionals, managers or employers;*
    - *A large proportion of the* females *in this category work.*
4. ***Rooted households***
    - *Made up of older adults, generally aged 45 and over. Also includes some young families where the parents are aged 25-34;*
    - *Generally semi-detached properties and mortgages are still being paid though some will own their houses outright;*
    - *Typically will have two or more cars, predominantly family cars with mid-sized engines;*
    - *Generally not interested in politics and read black top newspapers;*
    - *Tend to do grocery shopping at Tesco;*
    - *Tend to be skilled manual workers on high wages.*
5. ***Qualified metropolitans***
    - *Mainly single, highly qualified adults living in cities, predominantly London;*
    - *Live in single households, mainly flats and bedsits and tend to rent their homes;*
    - *Tend not to have cars and use public transport to get to work, mainly trains;*
    - *Extremely interested in politics and read broadsheet newspapers;*
    - *Majority shop in Sainsbury's;*
    - *Hold higher qualifications and work as professionals in well paid jobs;*
    - *Also includes some cultural diversity*
6. ***Senior neighbourhoods***
    - *Live in detached houses that they own, having finished off paying their mortgages. Some may own a second home;*
    - *Likely to have one car, varying sizes and power;*
    - *Very interested in politics and read broadsheet and black top newspapers;*
    - *Grocery shopping varies from Aldi and Lidl to Tesco, Morrisons and Somerfield;*
    - *Contains pensioners, incomes generally low. However, for some affluence comes from assets rather than income.*
7. ***Suburban stability***
    - *The average group encompassing all ages living in the suburbs;*
    - *Families common with parents aged between 25 and 34. Also co-habiting couples in same age group and older adults up to pensionable age;*
    - *Tend to be buying the houses and will still have mortgages to pay. Some also live in rental accommodation, housing association and council properties. Mostly semi-detached or terraced properties;*
    - *Households likely to have one car, generally with a small engine;*
    - *Adults tend not to be interested in politics and read tabloids. Grocery shopping generally done in Asda but also Aldi, Lidl, Morrisons and Somerfield;*
    - *Tend to be skilled manual workers with some being in routine and semi-routine occupations and use cars, bus or foot to get to work.*

8. ***New starters***
    - *Young adults aged between 16 and 34. Include students and young working adults;*
    - *Live mainly in single households and women are well represented amongst them;*
    - *Accommodation rented and tends to be bedsits and purpose built flats. Though many live in single households, also a high proportion of couples co-habiting;*
    - *New starters likely to not have a car;*
    - *Very interested in politics and read broadsheet newspapers;*
    - *Likely to smoke;*
    - *Shopping done cheaply in Aldi and Lidl;*
    - *Predominantly students with high levels of qualifications but do not work.*
9. ***Multicultural centres***
    - *Predominantly families and includes a broad ethnic mix and includes those of different ethnicity and religion;*
    - *This category includes some richer and some poorer families;*
    - *Live mostly in terraces housing that is housing association or council property. Many also live in bedsits or purpose built flats;*
    - *Generally do not have a car, commuting by train;*
    - *Quite interested in politics and predominantly read tabloid newspapers, although some read broadsheets;*
    - *Some likely to be smokers. Shopping is split between Aldi and Lidl and Sainsbury's;*
    - *Tend to be employed as semi-skilled manual and unskilled workers.*
10. ***Urban producers***
    - *Younger adults between the ages of 16 and 34, many with children. A lot of families are single parent households;*
    - *Tend to live in terraced housing, many of these homes can be without central heating;*
    - *Likely to have one car with a small engine per household;*
    - *Not interested in politics and tend to read tabloid newspapers;*
    - *Likely to be smokers and to shop in Asda;*
    - *Do not hold academic qualifications and tend to work as in routine and semi-routine occupations as well as skilled manual, semi-skilled manual or unskilled labour;*
    - *Incomes are low and unemployment and long-term unemployment are high, as is long-term illness.*
11. ***Weathered communities***
    - *Contains mostly pensioners but also some young adults, aged 16-24 years with children who tend to be single parent families;*
    - *The pensioners in these communities tend to live alone;*
    - *Housing likely to be housing association or council housing, small, semi-detached or purpose build flats;*
    - *Households unlikely to have a car;*
    - *Uninterested in politics and likely to read tabloid newspapers and likely to shop in Asda, Aldi and Lidl;*
    - *Mostly made up of retired adults but some work in routine and semi-routine as well as semi-skilled manual and unskilled jobs which tend to be in manufacturing;*
    - *Unemployment also high as is unemployment due to long-term illness.*
12. ***Disadvantaged households***
    - *Conventional and single parent families. Young adults between the ages of 25 and 34 with children;*
    - *Live in council and housing association properties which are mainly purpose built flats and terraced houses which are unlikely to have central heating;*
    - *Unlikely to have a car;*
    - *Not interested in politics, read tabloid newspapers.*
    - *Extremely likely to smoke and do their shopping at Asda;*
    - *Unlikely to have qualifications and employed in routine and semi-routine as well as semi-skilled manual and unskilled labour.*
    - *Many in this category are unemployed and also a lot of long-term illness preventing employment.*
13. ***Urban challenge***
    - *Mainly pensioners, particularly aged over 75. Also some young adults between 16 and 24 years, centred mainly in urban areas;*
    - *Tend to be purpose built flats. Accommodation tends to be small and council or housing association owned;*
    - *A lot of these households are pensioners who live alone;*
    - *Very unlikely to own a car;*
    - *Unlikely to be interested in politics and tend to read tabloid newspapers;*
    - *Tend to be smokers and shop at Asda;*
    - *Very unlikely to have any qualifications. Those with jobs work in routine and semi-routine occupations;*
    - *Unemployment, including long term unemployment is high, as are incidences of long term illness.*

Notes:

Unclassified: *these describe people whose characteristics are too different for them to fall into another category;*
Occupations*: routine occupations include jobs such as machine operators, packers, cleaners, labourers, sales assistants, HGV drivers and bar staff. Semi-routine occupations include jobs such as salesmen, agricultural workers, those working in childcare and service industries.*
Newspapers: *Broadsheet sinclude The Times, The Telegraph, The Guardian, The Independent, Financial Times. Black tops include The Daily Mail and The Daily Express. Tabloids include The Sun, The Mirror, The Daily Star and The Daily Record.*

Appendix 4

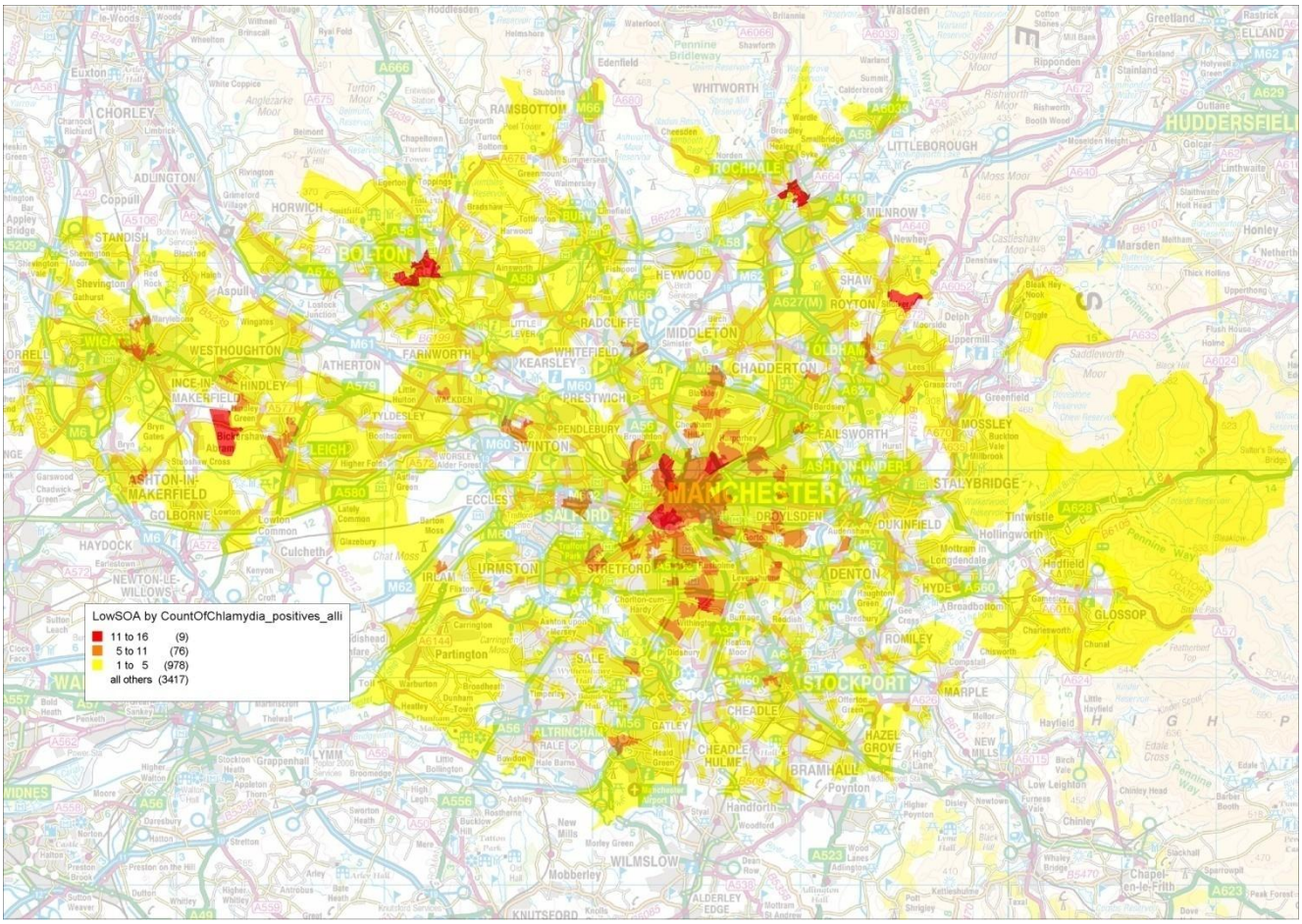
Variables table for GC positive cases:

Variable	**Cases variable occurs in**
Treatment centre of test	All
Sexuality	Where available in notes
Ethnicity	Where available in notes
Number of times appointment DNAd	All
Symptoms prior to confirmatory test	All
Pharynx sample taken (y/n)	Clients offered and consenting to the sample.
Pharynx sample result	Clients offered and consenting to the sample.
Rectal sample taken	Clients offered and consenting to the sample.
Rectal sample result	Clients offered and consenting to the sample.
Cervical sample taken	Females offered and consenting to the sample.
Cervical sample result	Females offered and consenting to the sample.
Urethral sample taken	Clients offered and consenting to the sample.
Urethral sample result	Clients offered and consenting to the sample.
GC retest results	All offered and consenting to further tests.
GC confirmed on microscopy	All tested using microscopy
GC confirmed on culture	All tested using culture
Retested on TMA	All
Positive on TMA retest	All
Sexual health screen tests	All consenting to a full sexual health screen
Sexual health screen results	All tested for a full sexual health screen
Previously treated for CT	All
GC treatment prescribed	All
Resistance testing	For all those consenting to testing
Partner tracing information	All wherever available

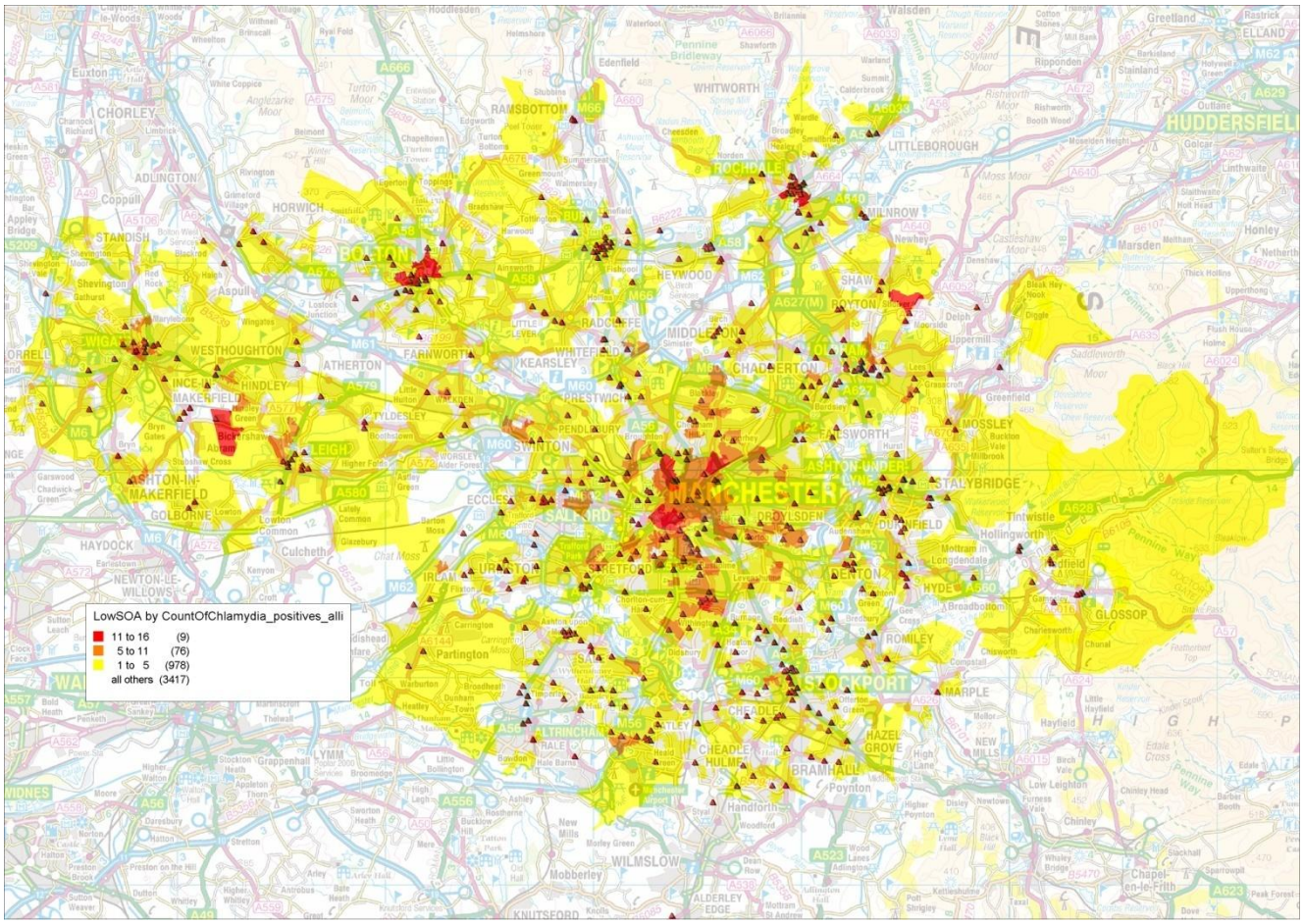
Appendix 5

MAPS

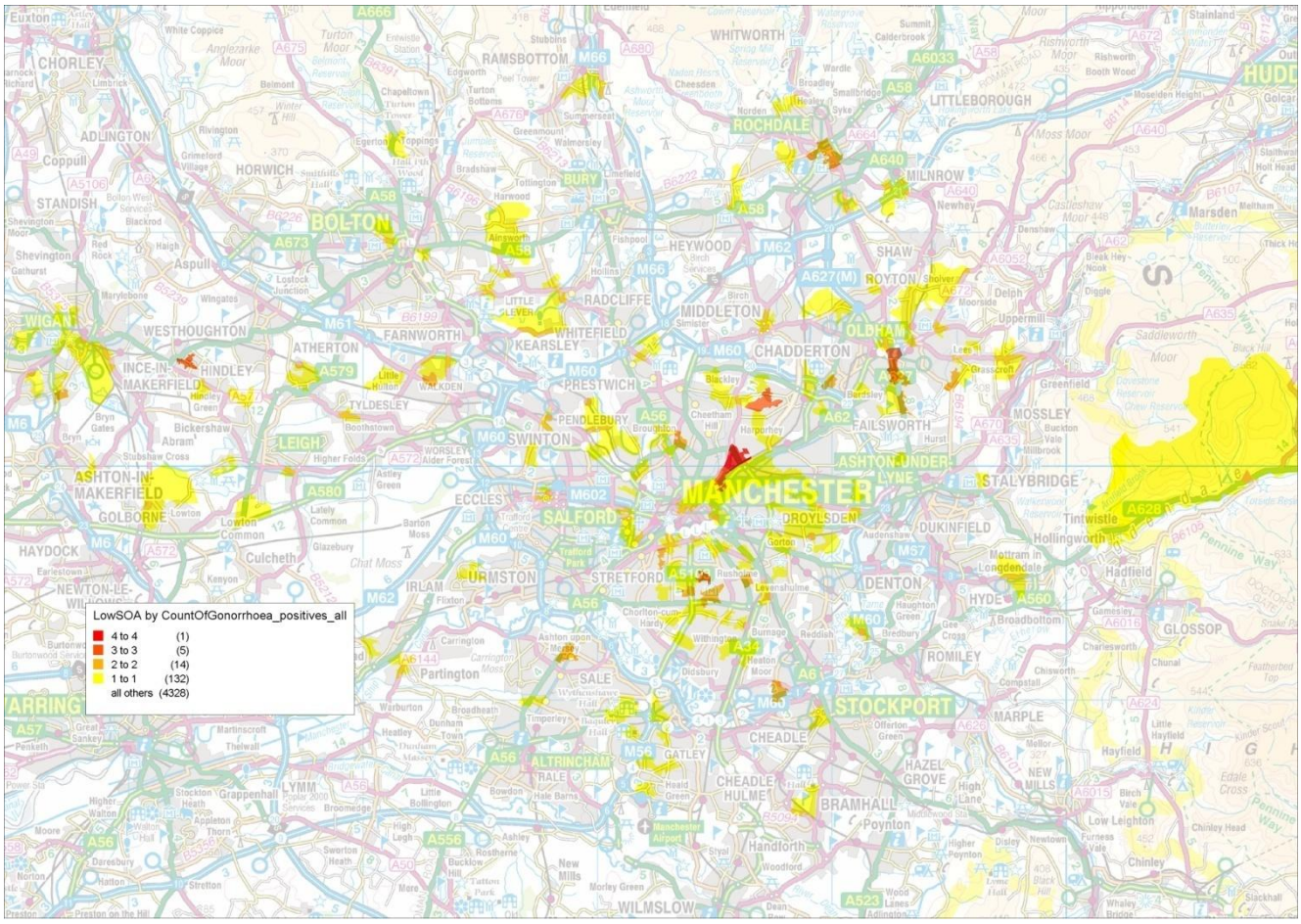
MAP 1: CT diagnoses by LSOA in Greater Manchester



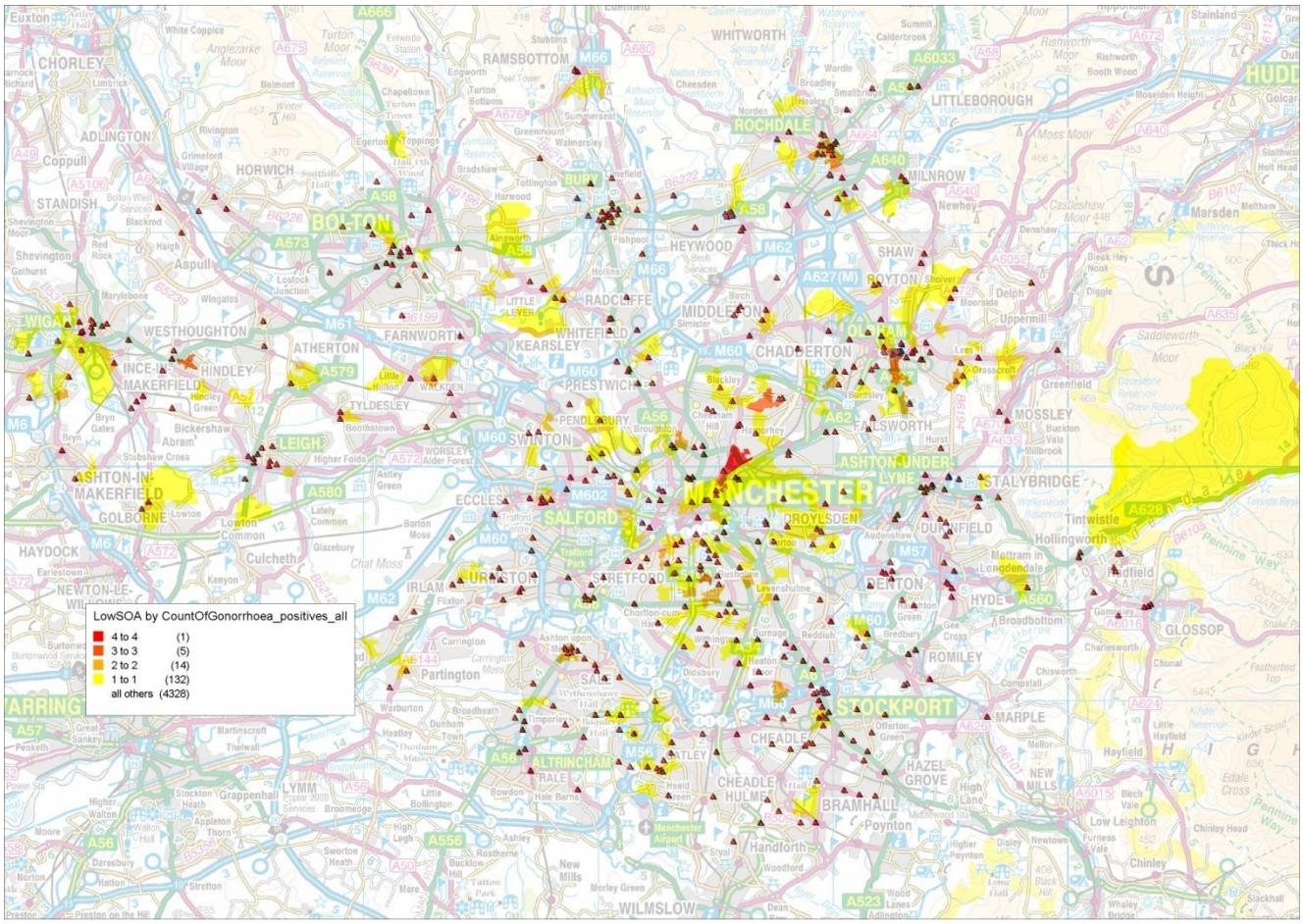
MAP 2: CT diagnoses by LSOA in Greater Manchester with clinics



MAP 3: GC diagnoses by LSOA in Greater Manchester



MAP 4: GC diagnoses by LSOA in Greater Manchester with clinics



Appendix 6

RU Clear? **Programme – roll out time line**

Date	**Action**	Notes
October – November 2006	First Wave Screening sites established (Family Planning & Brooks)	**Ashton, Leigh & Wigan, Bury, Heywood, Middleton & Rochdale, Manchester, Oldham, Tameside, Trafford**
December 2006	1st wave Screening established	**Bolton**
January 2007	1st wave Screening established in all areas 2nd wave screening sites established (ongoing)	**Salford**
February 2007	Official Launch Key 103 Campaign Press release	
March 2007 – April 2008	Spot advertising small scale across Greater Manchester	Not **Ashton, Leigh & Wigan.**
March 2007 – April 2008	GP pilot established	Not **Bolton, Heywood, Middleton & Rochdale or Stockport**
July 2007	1st wave screening established **STOCKPORT**	
Sept 2007 – January 2008	XFM adverts	
January 2008 – March 2008	Salford based letters/ adverts and road shows Health Bytes in selected Colleges ADVANCE	

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