Walter, S. R., Macleod, J. A. A., Horner, P. J., Hollingworth, W., Redaniel, M. T., Jackson, J., Lorenc, A., Kesten, J., Brangan, E., Mohiuddin, S. G., Crofts, M., Muir, P., Steer, J., Turner, J., Phillips, D., Wheeler, H., Clarke, M., Hartman, C., & Holly, J. (2020, Jan 17). Unity Sexual Health rapid testing, diagnostic and treatment service evaluation: study protocol. Unpublished. NHS National Institute for Health Research.

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**NIHR CLAHRC West**
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# Full title: Unity Sexual Health rapid STI testing, diagnostic and treatment service evaluation

## Short title: Unity Rapid Results Service Study

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| **Protocol version number** | v1.1 |
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| | will co-ordinate the development and implementation of new service model.<br><br>Professor John Macleod, Professor of Clinical Epidemiology, University of Bristol. John will advise on data linkage and use of administrative data in service evaluation.<br><br>Dr Peter Muir, Consultant Virologist, Public Health England. Peter will support with implementation and accreditation of Point of Care (POC) testing.<br><br>Jonathan Steer, Infection Sciences Service Manager, Public Health England. Jon will support with implementation and accreditation of POC testing<br><br>Jonathan Turner, South West Regional Head of Laboratory Operations, Public Health England. Jon will support with implementation and accreditation of POC testing<br><br>Lorraine Warr, Specialty Manager for Sexual Health, USH, University Hospitals Bristol NHS Trust. Lorraine will co-ordinate the implementation of the new service model.<br><br>Professor William Hollingworth, Professor of Health Economics, University of Bristol. William will manage the efficiency team, advise on the quantitative aspects of the study and contribute to research papers.<br><br>Dr Syed Mohiuddin, Research Fellow, CLAHRC West Efficiency Team. Syed will provide methodological expertise, develop and analyse the simulation modelling work and contribute to research papers.<br><br>Dr Emer Brangan, Senior Research Associate, CLAHRC West Ethnography Team. Emer will carry out qualitative data collection, analysis and dissemination under the supervision of JH.<br><br>Dr Joanna Kesten, Senior Research Associate, CLAHRC West Ethnography Team. Jo will carry out qualitative data collection, analysis and dissemination under the supervision of JH.<br><br>Dr Ava Lorenc, Senior Research Associate, CLAHRC West Ethnography Team. Ava will carry out qualitative data collection, analysis and dissemination under the supervision of JH. |

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| | Dr Theresa Redaniel, Research Fellow, CLAHRC West Effectiveness Team Lead. Theresa will manage the effectiveness team, advise on the quantitative aspects of the study and contribute to research papers.<br><br>Joni Jackson, Research Associate, Epidemiology Team. Joni will carry out the management and analysis of quantitative data for the evaluation of the sexual health clinic.<br><br>Dr David Phillips, Consultant Physician, Croydon Health Services NHS Trust |

## I. LIST OF ABBREVIATIONS

| | |
|---|---|
| **DES** | Discrete event simulation |
| **EPR** | Electronic patient record |
| **GUMCAD** | Genitourinary Medicine Clinical Activity Dataset |
| **ITS** | Interrupted time series |
| **MSM** | Men-who-have-sex-with-men |
| **NAAT** | Nucleic acid amplification testing |
| **PHE** | Public Health England |
| **POC** | Point of care |
| **SFTP** | Secure File Transfer Protocol |
| **STI** | Sexually Transmitted Infection |
| **USH** | Unity Sexual Health |

## II.STUDY SUMMARY

| | |
|---|---|
| Study Title | Unity Sexual Health rapid STI testing, diagnostic and treatment service evaluation |
| Internal ref. no. (or short title) | P315: Unity Rapid Results Service Study |
| Study Design | Mixed methods evaluation using quantitative and qualitative data. |
| Study Participants | A range of patients attending the sexual health service, clinic and laboratory staff and commissioners involved in the rapid results sexual health service and online testing. |
| Planned Size of Sample | Qualitative interviews will be conducted with up to 30 patients and 20 clinic staff members and commissioners |
| Planned Study Period | This project will take 22 months from initial set up (October 2017) to completion of the study (July 2019). |
| Research Question/Aim(s) | 1. To investigate patients' who attend the clinic, clinic staff and commissioners' views and experiences of the rapid results sexual health service.<br><br>2. To evaluate the impact of the new sexual health service on the service delivery and resource needs of the sexual health clinic |

## III.STUDY MANAGEMENT

**Sponsor and Host**

University Hospitals Bristol NHS Trust will be the host organisation for this research. The Trust will oversee the implementation of all aspects of the study and will ensure the Study meets its contractual, legal and financial obligations. The Sponsor will be the University of Bristol who will ensure the Trial has adequate insurance and meets all regulatory obligations.

**Funder**

This research is funded by the National Institute for Health Research Collaborations for Leadership in Applied Health Research and Care West (NIHR CLAHRC West) at University Hospitals Bristol NHS Trust. Funder reference no: P315

**Project Management Group (PMG)**

The study will be supervised by a PMG and will consist of Paddy Horner, Jeremy Horwood, Suneeta Soni, Emer Brangan, Jo Kesten, William Hollingworth, Corry Hartman, Joni Jackson, Jon Kerslake, Syed Mohiuddin, Peter Muir, Theresa Redaniel, Jonathan Steer and Lorraine Warr. The PMG will meet monthly either face to face or via conference call.

**Project Advisory Group (PAG)**

The role of the PAG is to monitor and supervise the progress of the project. The PAG will include members of the PMG and Helen Wheeler, Megan Crofts, Jenny Holly, John Macleod, Jonathan Turner. The PAG will meet quarterly.

**Patient and Public Involvement (PPI)**

Two members of the public who have experience of the Unity sexual health service will be recruited to join the project team. PPI contributors will fulfil a number of roles:

- Review patient-facing materials, ensuring that these materials, as well as recruitment and data collection approaches, are patient friendly with minimal burden
- During recruitment, PPI meetings will focus on: troubleshooting to inform the PMG
- At the end of the study, PPI meetings will focus on: interpreting results and dissemination methods.

## IV SERVICE FLOW CHART

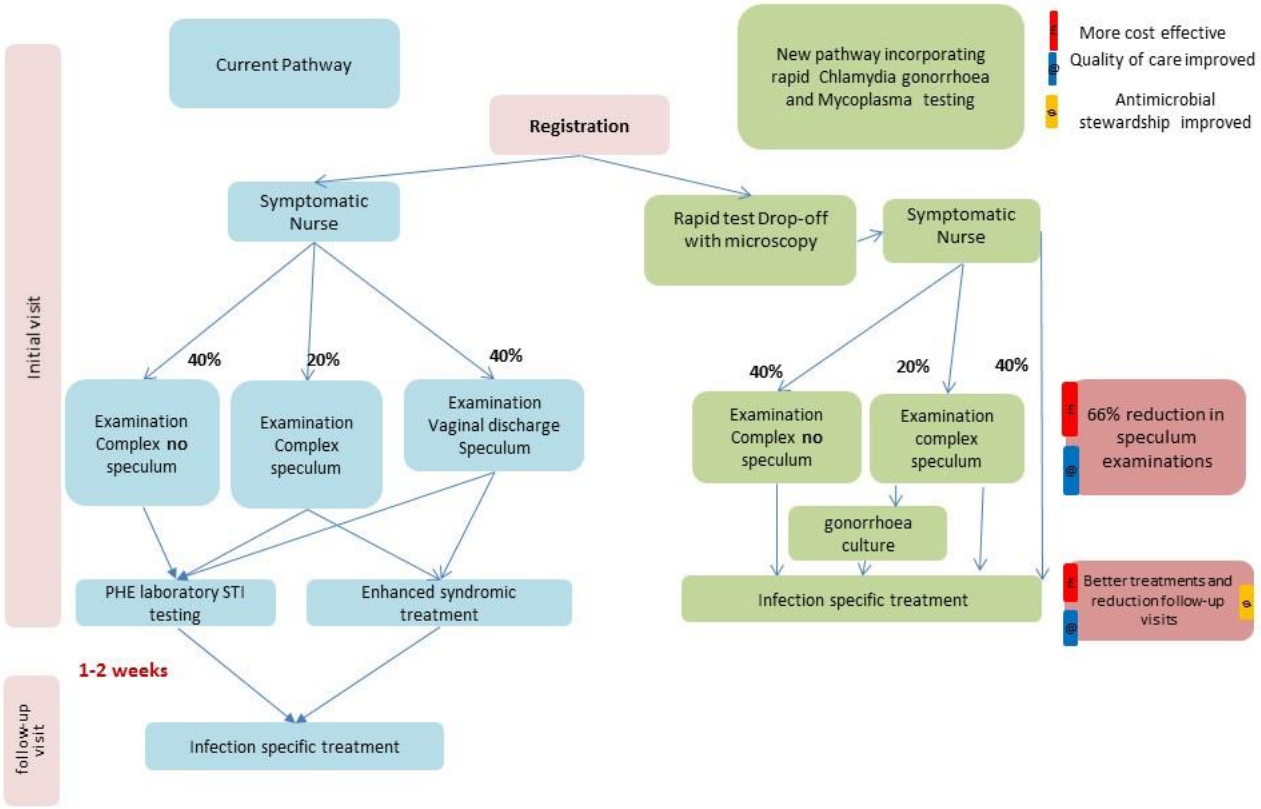



Figure 1 Flow chart demonstrating current flow path of female patients (left) and new pathway following the introduction of rapid testing service using the Panther. “Complex” refers to patients requiring a genital examination in whom the presenting problem is not a genital discharge or vaginal irritation. This may either be visual inspection in order to diagnose vulval problem such as gential warts or an internal per vaginal digitial examination in women with pelvic pain. Enahanced syndromic treatment refers to the use of microscopy on Gram-stained vaginal and cervical smears and a vaginal wet mount for Trichomonas.

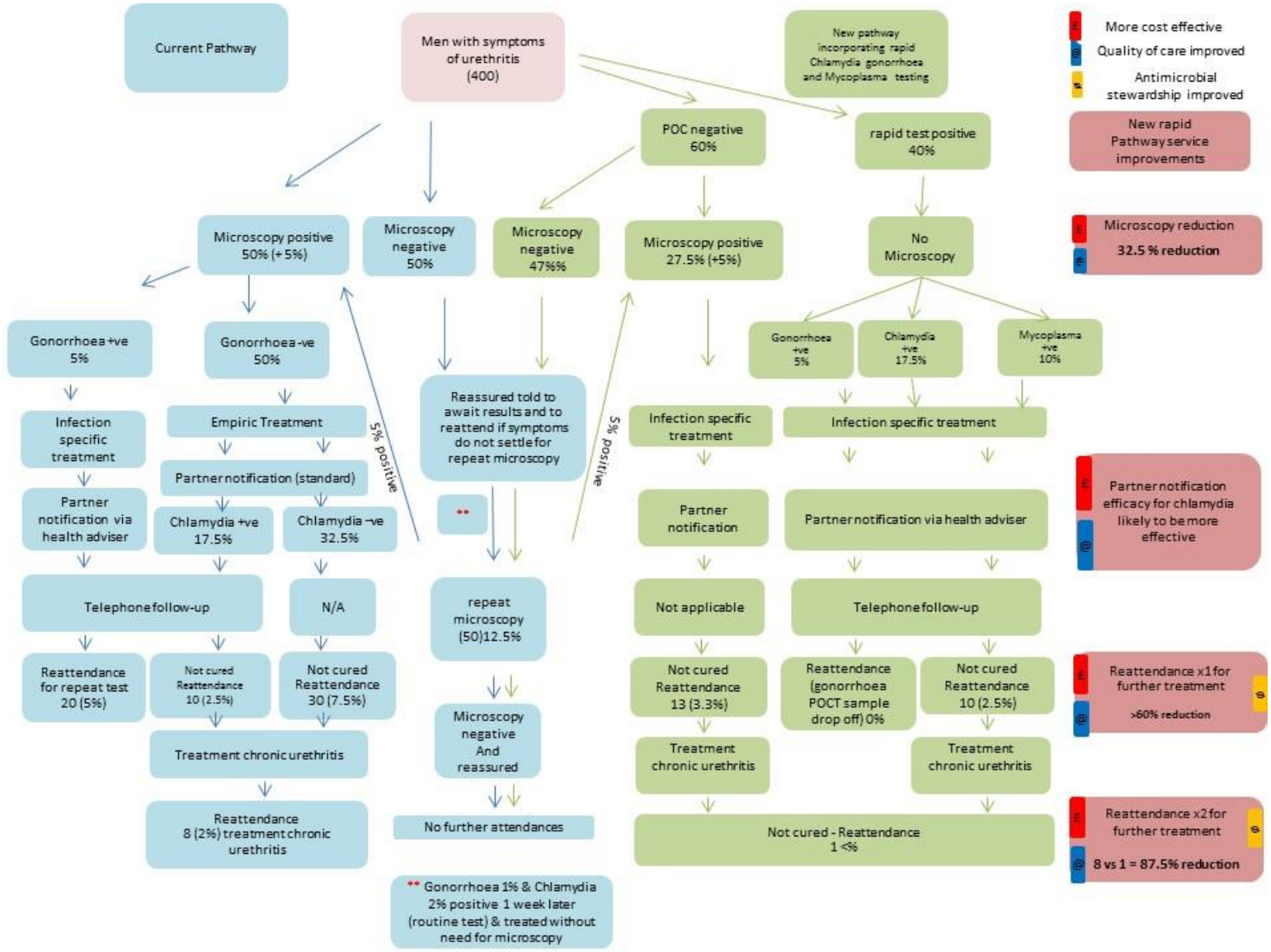



Figure 2 Comparison of new and old pathways for men presenting with urethral symptoms.

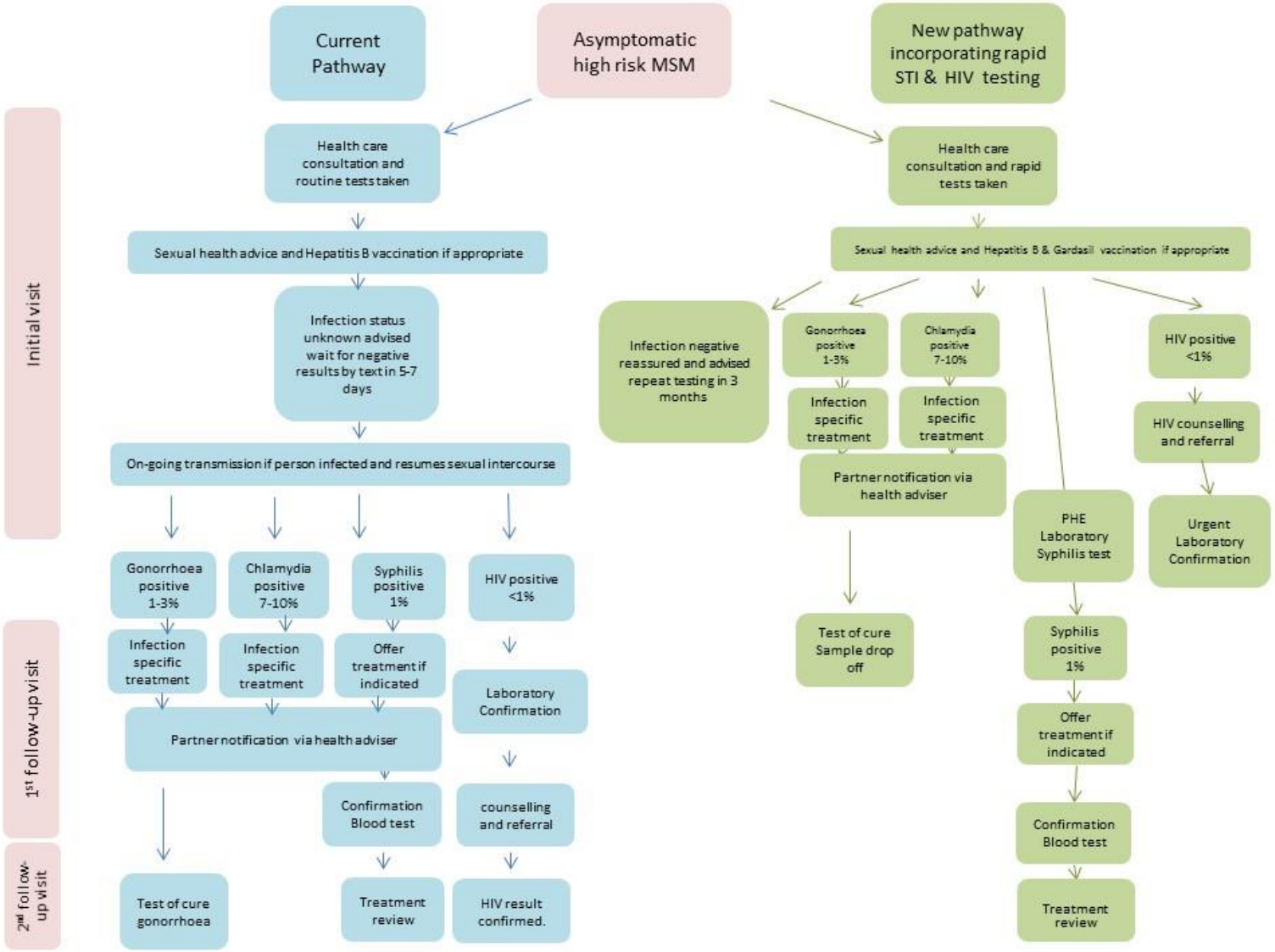



Figure 3 Comparison of new and old pathways for high risk men who have sex with men (MSM)

## 1. PLAIN ENGLISH SUMMARY

**Project description**

Sexual health services are facing financial constraints due to reduced local authority budgets. At the same time, there is increased demand for HIV and sexually transmitted infection (STI) testing. In April 2017, Unity Sexual Health successfully bid to provide sexual health services for Bristol, North Somerset and South Gloucestershire. Unity re-designed its service to improve access and delivery of care. This includes use of new rapid STI tests, which are as good as Unity's current laboratory tests, so patients can get results of their tests within 4 hours i.e. on the same day or next day. Currently patients and clinicians may have to wait over a week for results of tests for chlamydia and gonorrhoea.

The Unity website will direct patients to the service which best meets their needs. Asymptomatic, low risk patients will be encouraged to self-manage using the online services, including postal testing kits.

Symptomatic patients will be encouraged to attend the new rapid sexual health service at Unity Central Health Clinic. Rapid STI testing will be offered to patients who attend the clinic. This means patients will be asked to drop-off their self-taken samples (e.g. urine sample, vaginal or rectal swab) and 4 hours later (or in some cases next working day) will be asked to return for their test results and treatment, often without the need for the clinicians to examine the patients. Bloods for HIV and syphilis testing will still be sent to the laboratory for testing. For asymptomatic high risk patients such as men who have sex with men (MSM) and commercial sex workers, Unity will offer an appointment based service during which rapid HIV testing in addition to rapid STI testing will be undertaken, and vaccinations including Hepatitis B offered at the time of specimen drop off. Individuals testing positive for STIs and/or HIV will receive appropriate treatment, advice on the need for repeat testing, safer sexual practices and support in hours (previously patients had to wait over a week for their test results) reducing the need to re-attend. As most infections do not cause any symptoms, early detection and treatment can help stop onward transmission and serious disease developing such as infertility and death.

**What is the aim of the project?**

CLAHRC West will evaluate changes to the Unity Central Health Clinic service.

**What are we doing?**

We are using quantitative and qualitative methods to understand the impact of the new service on service delivery, costs and resources and to examine patients' and clinic staff views and acceptability of the service.

## 2. BACKGROUND

Rates of STIs continue to increase worldwide despite STI control efforts. Most STIs do not cause any symptoms, therefore early detection and treatment are necessary to prevent their

spread and serious disease developing such as death and infertility. In 2016, Bristol had the highest new STI diagnosis rate of those aged 15 to 64 in the South West of England (3,199 per 100,000 excluding chlamydia in < 25 year olds) (Public Health England, 2016).

High quality sexual health services are important to local authorities. While local authority budgets, which fund sexual health services, are being reduced (White, 2017), Public Health England recommends a significant increase in HIV and STI testing frequency (every 3 months) in high risk groups such as men who have sex with men (MSM) (Public Health England, 2014a, Brown et al., 2013, White, 2017). Therefore, local authorities and sexual health services need to identify strategies to optimise service delivery efficiency while maintaining high quality care provision (White, 2017).

In April 2017, Unity Sexual Health successfully bid to provide sexual health services for Bristol, North Somerset and South Gloucestershire in a competitive retendering process. Unity at University Hospitals Bristol NHS Foundation Trust and PHE Bristol are introducing rapid (Point of care (POC)) tests with test results being delivered in hours rather than days, with the aim of improving the delivery of care, while reducing costs. To ensure results are available prior to the clinical consultation patients will be asked to provide self-taken specimens (e.g. self-taken urine sample, vaginal or rectal swab) for analysis four hours in advance. Evaluation of the new service is essential to facilitating both achievement of the desired improved outcomes, and dissemination of successful innovation (Public Health England, 2014b).

Point of care tests provide an accurate test result at the time of the patient visit enabling the clinician to make better and timelier management decisions. When introduced, along with self-swabbing so that the result is available prior to the clinical consultation, modelling indicates it will reduce: 1) the need for invasive diagnostic testing in both men and women – speculum examinations will decrease by 50-80%, 2) the prescribing of unnecessary antibiotics and 3) the need for follow-up appointments. In addition a negative POC test result reduces the anxiety patients experience while waiting for the result (which is currently over a week) (Turner et al., 2013). HIV POC testing has been available for a number of years and is preferred by high risk MSM (Read et al., 2013, Public Health England, 2014a). Recently an accurate and affordable POC test for detecting *Neisseria gonorrhoeae* (Gonorrhoea) and *Chlamydia trachomatis* (Chlamydia) has been developed by Cepheid using its GeneXpert system (Gaydos et al., 2013). This is a nucleic acid amplification test (NAAT) which provides a result in 90 minutes. The system which will be implemented in Unity is the Panther (Hologic Inc) which includes tests for gonorrhoea, chlamydia, *Trichomonas vaginalis* (Trichomonas) and *Mycoplasma genitalium* (Mycoplasma). Currently NAAT testing for *M. genitalium* is not routinely available in Bristol. Targeted NAAT testing is recommended in Europe for men with urethritis and women with pelvic inflammatory disease and post coital bleeding (Jensen et al., 2016). This will also be the recommendation in the forthcoming UK guideline (P Horner personal communication). The Panther provides a result in 3.5 hours. The Panther is widely used as a laboratory-based system; this is the first initiative anywhere in the world to implement and evaluate the Panther as a near patient rapid or POC test. As more bacterial STI POC assays become available through different commercial providers, the cost of these assays and the time to result will decrease.

Although POC bacterial STI testing is more expensive than current tests it could be cost effective as it would result in fewer gonorrhoea and trichomonas cultures, follow-up visits and a reduction in unnecessary antimicrobial therapy of patients found not to be infected (Adams et al., 2014) and quicker more targeted treatment of those found to be infected. However this needs to be demonstrated in clinical practice (Miners, 2014). The use of sensitive molecular diagnostic tests also enables testing using less invasive samples than those required for traditional culture and microscopy-based tests, and modelling work at Bristol has demonstrated that the introduction of such technology would potentially result in the reduction of painful urethral smears by a third (Apoola et al., 2011, Carter et al., 2015) in symptomatic men and a 66% reduction in speculum examination in symptomatic women. However, following a pilot study in symptomatic men it was evident these advantages are only likely to be realisable if the result of POC testing is known prior to the initial consultation. This will require redesign of the current patient care pathway, extensive revision of management protocols and development and introduction of the requisite training packages for staff. In the long term this redesign may also contribute to lower costs by reducing the duration of consultations and the number of consultations required per patient episode.

The Dean Street Express service in London, currently provides rapid Chlamydia and Gonorrhoea testing for asymptomatic infections (Whitlock et al., 2017). Results from a service evaluation found this service improved sexual health outcomes including quicker treatment, lower infectious periods and fewer transmissions. In addition, partner clinic attendance and costs were lower. Research suggests that reduced waiting times for STI test results may enhance patient acceptability (Natoli et al., 2015, Rompalo et al., 2013) and increase uptake of testing (Horwood et al., 2016, Lorenc et al., 2011). Patients have expressed preferences for earlier provision of results (Llewellyn et al., 2013) due to the stress of waiting (Llewellyn et al., 2012). However, it has been highlighted that the introduction of immediate results needs to be carefully implemented to avoid increasing patient anxiety (if patients feel unready to receive them), clinician unpreparedness (to deliver results within short turnaround times) and interruptions to clinic work-flow (keeping other patients waiting while delivering results to patients tested earlier) (Hsieh et al., 2010).

Preferences for rapid, accurate and private result provision have been identified in previous research to support the design of online sexual healthcare using smartphone result provision (Aicken et al., 2016). Some participants in this qualitative study expressed concerns about *"electronic evidence of sexual healthcare use or STI diagnosis visible on their phone"* (p7), emphasising the importance of confidentiality and privacy. It will be important to understand how these issues are experienced in the current service redesign. In support of the current changes, participants have previously highlighted favourable views of reduced clinical contact for negative results as this removes the embarrassment of face-to-face sexual history taking and enables sexual health service use to be kept hidden from others (family, friends) (Aicken et al., 2016). Conversely face-to-face contact from clinicians for positive results may be appreciated due to the provision of reassurance (Aicken et al., 2016).

A recent systemic review and meta-analysis concluded that self-collected swabs had comparably high sensitivity and specificity compared to swabs collected by clinicians and recommends their use (Lunny et al., 2015). Soni and White (2011) found that all MSM and

most women experienced self-swabbing as acceptable and would like this form of testing in the future (Soni and White, 2011). The evidence suggests that women and MSM like self-testing for sexually transmitted infections and that these specimens are just as accurate as clinician taken (Paudyal et al., 2015, Soni and White, 2011). Self-taken vaginal swabs are the method of choice for testing for Chlamydia and gonorrhoea in asymptomatic women (Nwokolo et al., 2016, Stewart et al., 2012). We recently demonstrated that self-taken swabs were just as accurate for detecting Trichomonas vaginalis using a NAAT (Nicholls et al., 2017). Self-taken swabs to prepare a Gram stained smear are also of similar accuracy to clinician taken swabs and can be used to diagnose bacterial vaginosis at home (Schwebke et al., 1997, Nelson et al., 2003, Oakeshott et al., 2004, Schwebke et al., 2016).

With the introduction of POC testing and self-swabbing at Unity Sexual Health it is important to understand how patients and clinic staff experience changes to service design and to understand the impact of the new service on service delivery, costs and resources.

## 3. RATIONALE

While the current economic climate points to the need for cost saving strategies in sexual health care services, it is important to optimise the introduction of these changes for clinic staff and patients. It is therefore necessary to explore the acceptability, barriers and facilitators to uptake and any unintended consequences of the new service model among clinic staff and patients. Although modelling indicates that this new model of care is likely to be cost effective, this remains to be demonstrated in clinical practice. Understanding experiences and impacts of the new service will allow it to be refined and improved and will support the integration of the service into the health system.

## 4. NEW SERVICE DESCRIPTION

Patients will access the new service via a redesigned website which will direct them to the service which best meets their needs.

1. Asymptomatic/low risk patients will be encouraged to self-manage using on-line services, including postal testing kits.
2. Symptomatic/high risk patients will be encouraged to attend the rapid sexual health clinic at Unity Sexual Health Centre

STI testing at Unity Sexual Health Centre will be switched to rapid NAAT testing for detecting Gonorrhoea and Chlamydia initially (subsequently Trichomonas and Mycoplasma as well), and HIV POC testing will be offered to high risk patients.

Symptomatic patients will be asked to drop off self-taken specimens prior to their appointment and approximately 4 hours later they will be seen by the clinician with the test results. This will result in an estimated reduction in two thirds of speculum examinations in women and one third of urethral smears in men. Currently patients and clinicians wait a week for the results of laboratory based Chlamydia and Gonorrhoea NAAT testing, and initial management uses an enhanced syndromic approach based on the findings from microscopy. *M. genitalium* NAAT testing is not currently available but targeted testing will shortly be recommended nationally (personal communication PH). Trichomonas NAAT testing although

more sensitive than current approach of wet prep microscopy and culture is also not available (Nicholls 2017). Individuals testing positive for STIs and HIV within the new service will therefore all receive appropriate treatment, advice on the need for repeat testing (as indicated), safer sexual practices and support, on the day (or next day) of attendance.

The Unity website will explain why waiting four hours would reduce the need for invasive testing and lead to more successful treatment outcomes (currently the average wait in clinic is 2 hours). High risk asymptomatic individuals including Men-who-have-sex-with-men (MSM) and commercial sex workers would be reviewed by health advisers and brief interventions will be used to reduce their level of risk.

Asymptomatic low risk patients, including contacts of chlamydia and gonorrhoea will no longer be routinely reviewed by doctors/senior nurses and instead will be reviewed by Band 3 nursing assistants. Only contacts testing positive for these infections will be treated (currently all contacts are treated)(Department of Health, 2013) and seen by health advisors, therefore reducing unnecessary antibiotic use.

## 5. RESEARCH AIMS

1. To investigate patients' who attend the clinic, clinic staff and commissioners' views and experiences of the rapid results sexual health service.

2. To evaluate the impact of the new rapid results sexual health service on the service delivery and resource needs of the sexual health clinic

### 5.1 QUALITATIVE OBJECTIVES

The objectives of the qualitative component of this evaluation are:

1. To examine patients' and clinic staff views and acceptability of the rapid results sexual health service.

2. To understand patients' and clinic staff perceptions and experiences of rapid results sexual health service.

3. To consider the opinions of patients, clinic staff and commissioners regarding the effectiveness and perceived impact of rapid results sexual health service.

4. To observe the day-to-day processes of the rapid results sexual health service.

5. To examine the main factors or mechanisms that explain the success or failure of the rapid results sexual health service.

6. To explore the learning, education and support needs of patients and clinic staff regarding rapid results sexual health services.

7. To identify potential barriers and facilitators for the implementation of rapid results sexual health services.

### 5.2 QUANTITATIVE OBJECTIVES

The objectives of the quantitative component are:

1. To determine the impact of the same /next day testing on health service delivery outcomes for STIs:
    a. Primary outcomes:
        i. Number of clinical consultations per staff member per day
        ii. Time to notification of results
        iii. Number of people who have examinations
    b. Secondary outcomes:
        i. Consultations
            1. Length of consultation time with clinicians
            2. Number of asymptomatic patient consultations for STI and HIV testing only (per staff member per day, weekly average)
        ii. Episodes of care
            1. Number of patient episodes of care initiated
            2. Number of follow-up visits per episode of patient care
        iii. Testing
            1. Number of MSM having STI and HIV testing per month
            2. Number of high risk MSM having repeat STI and HIV testing per month
            3. Numbers of samples submitted for gonorrhoea culture.
            4. Proportion of men having a urethral smear when presenting with symptoms of urethritis
            5. Proportion of women having a speculum examination when presenting with symptoms of a vaginal discharge.
        iv. Treatment
            1. Median and mean time to treatment of chlamydia and gonorrhoea
            2. Proportion of patients treated syndromically for chlamydia or gonorrhoea (i.e. without POC result, or without a positive test result )
        v. Partner notification and treatment
            1. Mean and median time to partner notification

2. Proportion of partners / contacts tested and treated per chlamydia and gonorrhoea diagnosis

2. The total cost per care episode, stratified by patient subgroup (e.g. high risk asymptomatic MSM, etc.)

## 6. STUDY DESIGN

This is a mixed methods study using qualitative and quantitative data.

1. Qualitative: face-to-face or telephone interviews will be conducted with patients that attend the clinic, clinic staff and commissioners, along with observations of the clinic.

2. Quantitative: observational study using routinely collected patient data. Using electronic patient data records, we will conduct a controlled Interrupted Time Series (ITS) Study to determine the effect of the rapid testing on service outcome measures.

### 6.1 QUALITATIVE RESEARCH METHODS

A focused ethnographic approach to data collection and analysis (Higginbottom et al., 2013) will include observations and interviews. We will use Weiss' 'theory based evaluation approach' (Weiss, 1997). Weiss distinguishes between 'program theory' which specifies the mechanism of change and 'implementation theory', which describes how the intervention is carried out. To develop the 'program theory' we used a realist approach (Pawson, 1997) to understand provision of the new rapid results service in terms of context, how and why the new service might lead to benefits and challenges (mechanism) and what matters to patients and practitioners (outcomes). To contribute to an 'implementation theory' we will examine staff and patient experiences, including the perceived impact and effectiveness of the rapid results service. Using a realist evaluation approach (Pawson, 1997) we will aim to understand if the rapid results service works, for whom it works and the sets of circumstances within which it works.

#### 6.1.1 Observations

In order to understand how the new service is operationalised in day-to-day practice a series of non-participant observations will be conducted. Up to 45 hours of observations will be conducted across different times of the day and days of the week. Researchers will be located in the reception and laboratory and waiting areas of the clinic. Observations will focus on how clinic staff integrate the new service into their day-to-day working practice and examine whether particular factors promote or inhibit successful incorporation. This ethnographic approach provides insights into peoples' views and actions by observing the contexts and locations they inhabit (Reeves et al., 2008). The researcher will write accounts of observations based on brief field notes taken at the time of those observations (Emerson et al., 1995). These notes may include both direct observations and reflection on what has been observed. Observations will record activities, events, their time and location and will describe interactions, communication patterns, workflows and tasks in the Unity clinic environment. Field notes will also include anonymous reflections of informal conversations with staff.

### 6.1.2 Interviews

Clinic staff will be invited to take part in two in-depth semi-structured qualitative interviews after service introduction. Initial interviews will explore experiences, acceptability and feasibility of the new service. Issues identified from the first round of interviews will be fed back to inform service refinement. The second round of interviews will consider (i) views and experiences of the clinic, (ii) impact on workload, (iv) impact on clinical practice, (v) information and support needs, (vi) sustainability of the service and (vii) attitudes to the future implementation of the service in other locations. The study design will allow for the iterative development and evaluation of the rapid results sexual health service and allow for adaptation, refinement and system integration. Comparisons will be drawn between the findings of the two data collection points.

Interviews with clinic and lab staff will be structured in relation to Normalization Process Theory (NPT) (May et al., 2009). NPT is a sociological theory that has been widely promoted as a means to understand implementation, embedding and integration of innovation in healthcare settings (Murray et al., 2010). NPT proposes that implementation of interventions is dependent on the ability of participants to fulfil four criteria which can be understood using four constructs:

*1. Coherence*: the process and work of sense-making and understanding that individuals and organisations have to go through in order to promote or inhibit the routine embedding of an intervention.
*2. Cognitive Participation*: commitment and engagement by participants - the process and work that individuals and organisations have to go through in order to enrol individuals to engage with the intervention.
*3. Collective Action*: the work that individuals and organisations have to do to make the intervention function.
*4. Reflexive Monitoring*: participants reflect on or appraise the intervention - the work inherent in the informal and formal appraisal of a new practice once it is in use, in order to assess its advantages and disadvantages, and which develops users' comprehension of the effects of an intervention

Patients will be interviewed once to investigate (i) views and acceptability of the service, (ii) interaction and experience of the service and (iii) perceived impact of the service. Patients who take part in interviews will be offered a £10 High Street shopping voucher.

Commissioners involved in the service will also be invited to take part in interviews towards the end of the study.

A flexible topic guide will be used to assist questioning during interviews. The topic guide will be devised to ensure that the primary issues are covered across all interviews, but will not dictate data collection. The topic guide will incorporate considerable flexibility to enable participants to introduce new issues unanticipated by the researchers. Topic guides will be modified as necessary throughout the course of the study to reflect findings as they emerge. The researcher will use open-ended questioning techniques to elicit participants' own experiences and views of key events and participants will be asked to provide examples. Should participants become upset or distressed during the interview the researchers will follow a distress protocol (see Appendix 2). Interviews are expected to last around 30 minutes.

When conducting observations face-to-face interviews the qualitative researchers will make themselves aware of the University of Bristol, Bristol Medical School, Conducting Research with Members of the Public Safety Policy (dated June 2017), and will adhere to the field work visit precautions, a designated person being appointed and a fieldwork visit record form given to the designated person before each fieldwork visit. This will involve informing a designated person from the study team prior to the interview, the details of the interview and calling in when the interview has been completed at an agreed time.

## 6.2 QUANTITATIVE RESEARCH METHODS

Using electronic patient data records, we will conduct a controlled Interrupted Time Series (ITS) Study (Craig et al., 2017) to determine the effect of the rapid testing on service outcome measures. We will use anonymised electronic patient records (EPR) to determine the effect of the introduction of the rapid testing on service delivery targets.

MillCare, provided by Mill Systems (http://www.millsystems.com/millcare/), is the patient electronic patient record (EPR) system used at Unity Sexual Health. All information during the clinical consultation is entered onto predefined proformas. The information recorded includes, demographics, sexual behaviour, mode of presentation, diagnostic testing and treatment. These data can be used to categorise case complexity. It is used to generate the mandatory Genitourinary Medicine Clinical Activity Dataset (GUMCAD) reports for Public Health England (https://www.gov.uk/guidance/genitourinary-medicine-clinic-activity-dataset-gumcadv2) and commissioners. The database can be searched using business objects software. An excel spread sheet containing an anonymised extract of the data will be generated and used for the analysis.

For partner notification and treatment, we will be using the Unity Sexual Health Partner Notification database which is stored securely on the Unity server. Patients are identified using their unique clinic number. The information recorded includes the time of giving patients their result and time to treatment, number of partners, time taken to inform partners and time between initial diagnosis and contact being informed.

For postal testing we will be using the data from Unity Sexual Health on-line testing service stored by Cyber Media on their secure server. Patients' demographic data and risk behaviour are recorded for each requested test and stored under a unique test reference ID. The unique specimen ID with the test result is securely held on a Unity Sexual Health database manged by Chlamydia Screening programme.

Service delivery outcomes will be measured weekly, covering the period of 12 months prior to the introduction of the rapid testing service in the centre and 9 months after the introduction of the service. This allows us to assess the effect of the introduction of the online postal testing service and separate it from the effects of the introduction of the rapid testing service. We have mapped out how the activities affect key service outputs and outcomes (Figure 1) and this logic model will inform the statistical analysis.

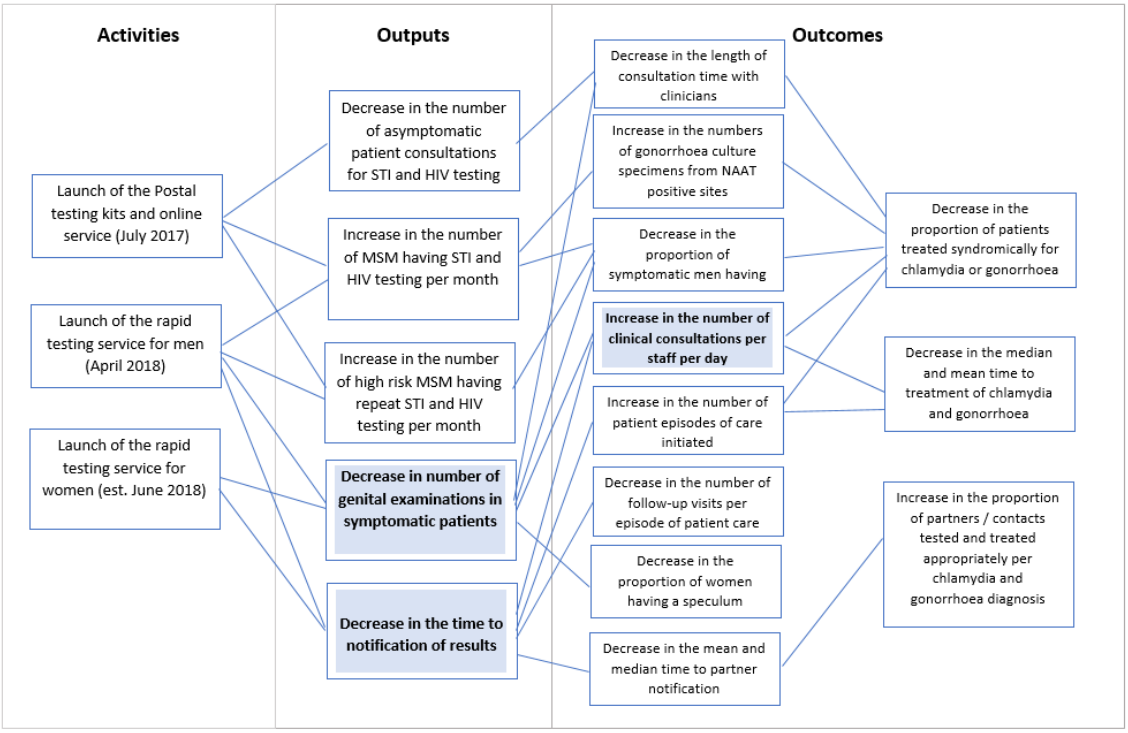



***Figure 1. Logic model for activities, outputs and outcomes***

Outcome trends from the Unity Central Health Clinic service will be compared to those in the Croydon Sexual Health Centre service. The comparison is to take into account temporal changes in trends. Croydon Sexual Health Centre was chosen because they cover a similar sized city and have a similar clinic set-up and are comparable in terms of patient characteristics. Like Unity Central Health Clinic, Croydon Sexual Health Centre is also based in a University Teaching Hospital (Croydon University Hospital) and use the same EPR system (MillCare).

The outcomes will be measured as weekly averages or totals and are defined as:

1. Primary outcomes:
    a. Number of clinical consultations per staff member per day
    b. Time to notification of results – time from first consultation for an episode until the results are communicated to the patient
    c. Number of people who have examinations - number of people who were tested for STI or HIV
2. Secondary outcomes:
    a. Consultations
        i. Length of consultation time with clinicians - length of time of the consultation with a clinician in minutes
        ii. Number of asymptomatic patient consultations for STI and HIV testing only - number of consultations by patients who presented without

symptoms, measured per staff member per day, and summarised as the monthly average

b. Episodes of care

   i. Number of patient episodes of care initiated

   ii. Number of follow-up visits per episode of patient care - number of times the patient went back for follow-up consultations with a clinician for the same episode of care

c. Testing

   i. Number of MSM having STI and HIV testing per month - number of MSM who were tested for STIs or HIV in clinic and on-line

   ii. Number of high risk MSM having repeat STI and HIV testing per month - number of high risk (an episode of unprotected anal intercourse in previous 3 months) MSM who were tested at least every 3 months for STIs or HIV in clinic and on-line

   iii. Numbers and proportion of swabs submitted for gonorrhoea culture from gonorrhoea NAAT-positive urogenital tract, throat or rectum.

   iv. Proportion of men having a urethral smear and/or genital examination when a) presenting with symptoms of urethritis (discharge and/or dysuria) b) presenting with symptoms and diagnosed with Chlamydia, Gonorrhoea and *M. genitalium*

   v. Proportion of women having a speculum and/or genital examination when a) presenting with symptoms of vaginal discharge b) diagnosed with bacterial vaginosis, vaginal candidiasis, non-specific vaginitis

d. Treatment

   i. Median and mean time to treatment of chlamydia and gonorrhoea

   ii. Numbers of patients treated syndromically for chlamydia or gonorrhoea (i.e. without POC result, or without a positive test result)

e. Partner notification and treatment

   i. Mean and median time to partner notification – mean or median time from time patient was informed of the diagnosis to the time the partner was notified of the diagnosis in days

   ii. Number of partners / contacts tested and treated per chlamydia and gonorrhoea diagnosis – number of partners and contacts treated for each patient diagnosed with chlamydia and gonorrhoea

Data measuring these outcomes will be extracted as text files using Microsoft Business objects. These will be anonymised, encrypted (using 7-zip encryption) and sent to the research team in CLAHRC West using a secure file transfer protocol (SFTP).

### 6.4 STUDY DURATION

This project will take 22 months from initial set up (October 2017) to completion of the study, analysis and write up (peer-reviewed papers and future grant application) in July 2019 (see Appendix 1: study project plan). Major milestones are:

- Ethics and HRA approvals - Feb 2018 - April 2018
- One-stop sexual health service delivery starts - April 2018
- Qualitative Study
    - Recruitment of interview participants - May 2018 – September 2018
    - Service provider qualitative interviews - May 2018 – August 2018
    - Patient qualitative interviews - May 2018 – September 2018
    - Data analysis – June 2018 – November 2018
    - Write up of results – November 2018 – January 2019
    - Dissemination – February 2019 – March 2019
- Quantitative Study
    - Data specification and preparation - February 2018 – December 2018
    - Data analysis – December 2018 – July 2019
    - Write up of results – May – July 2019
    - Dissemination – June – July 2019

## 7. SAMPLE AND RECRUITMENT

Multi-centre study. The study will take place within University Hospitals Bristol NHS Trust's Unity Sexual Health Centre which is based in Bristol. The quantitative component will include a second site, The Croydon Sexual Health Centre service administered by the Croydon Health Services NHS Trust.

### 7.1 STUDY POPULATION

A range of patients attending the service, and clinic staff and commissioners involved in the rapid results sexual health service and online testing.

### 7.2 ELIGIBILITY CRITERIA

All patients using the new sexual health services provided by Unity Sexual Health.

#### 7.2.1 Qualitative Inclusion Criteria

Patients attending the new sexual health service provided by Unity Sexual Health for STI testing.
Older than 16+ years old.
Staff involved in commissioning, designing and delivering the new rapid results sexual health service, or whose work at the Unity clinic is affected by the introduction of the new service.

### 7.2.2 Qualitative Exclusion Criteria

Under 16 + old

### 7.2.3 Quantitative Inclusion Criteria

Patients accessing the Unity Sexual Health services or the Croydon Sexual Health Centre services (either face-to-face or online).

### 7.2.4 Quantitative Exclusion Criteria

None

## 7.3 QUALITATIVE SAMPLING

Purposive sampling will select interview participants to attempt to capture maximum variation in views and experiences in order that they adequately reflect those of a range of patients and staff involved in the rapid results sexual health service.

A purposive sample will be drawn in relation to (i) socio-demographic variables such as gender, age, ethnicity, sexuality and socio-economic status and (ii) health status (i.e. those testing either positive or negative during the one stop sexual health service).

A purposive sample of staff, representing all grades involved with patient contact will be interviewed to understand the views and attitudes towards the new service and perceived obstacles to its implementation and potential solutions. Staff participants will include consultants, Doctors, nurses, health care assistants, health advisors, laboratory staff and receptionists.

## 7.4 QUALITATIVE SAMPLE SIZE

The qualitative sample size will be determined by the need to achieve data saturation, such that no new themes are emerging from the data by the end of data collection (Sandelowski, 1995). Interviews will be analysed in batches, and sampling will continue until no new themes are emerging from the interviews. The sample size of up to 30 patients and 20 clinic staff members and commissioners is expected to be sufficient to achieve this aim (Guest et al., 2006).

## 7.5 QUALITATIVE PARTICIPANT RECRUITMENT

A sample of patients attending the service will be given study information by clinic staff either when they drop off self-taken specimens or at the end of their clinic visit and invited to contact the researcher. Participants will be given the option to be interviewed in situ or later at a mutually convenient time and location, or via the telephone.

In addition a purposeful sample of patients, after they have received their results in the usual manner (text message or consultation with staff), will be given study information by clinic staff or directed via a text message to an electronic version of the study information on the Unity website, and invited to contact the researcher. Participants will be interviewed at a mutually convenient time and location or via the telephone.

We will also use Unity Sexual Health social media channels to advertise to clinic patients the opportunity to take part in an interview. Potential participants will be directed to an electronic version of the study information on the Unity website, and invited to contact the researcher. Participants will be interviewed at a mutually convenient time and location or via the telephone.

Staff involved in the new service, or whose work is affected by it, will be sent information about the study by email, forwarded by the Unity sexual health clinical lead, and invited to contact the researcher if they wish to participate.

## 7.6 QUALITATIVE PARTICIPANT CONSENT

All potential interview participants will be provided with a study information and further questions invited. The voluntary nature of participation in the study will be made clear in information given to participants. Interview participants will be asked to provide written consent for face-to-face interviews and audio recorded verbal consent before taking part in telephone interviews

The researchers will convey to participants via the information sheet that their participation in the research study is voluntary and that they can withdraw for up to one month after they complete their interview. This will also be verbally conveyed at the point of obtaining consent. The reason for communicating a time limit on withdrawal is that once anonymised interview data has been incorporated in the thematic analysis, it is not possible to remove an individual's data. As the interviews with staff are longitudinal, involving two data collection points, the researcher will remind participants at each time point of their right to withdraw from the interview study. To withdraw, participants contact the study researcher. As there is only one data collection point for patient participants, if they wish to withdraw their data will be destroyed. Staff participants will be asked for their permission to retain any data already collected. If permission is not given, their data will be destroyed.

All participants will be assured of the confidentiality of the data collected, and will be asked for permission to publish anonymised quotations from the qualitative interviews. The data will be stored in accordance with MRC guidance on good research practice (Medical Research Council, 2012).

A similar undertaking will be made with staff who participate in the non-participant observation part of the data collection. Researchers will make sure that staff have the opportunity not to take part and that researchers will withdraw from observation if the member of staff has not consented or indicates that they no longer wish to participate. There will be a full information sheet for the observational research and staff will give verbal consent prior to observations being undertaken. We will not rely on staff management to inform the staff about the research, the researcher will ensure that all staff understand what is involved in the research, what data will be collected, how it will be stored and anonymised. Researchers will withdraw from situations which feature particularly sensitive issues and where patients and/or staff become distressed e.g. if a patient gets upset in reception.

Patients will be present during the period of non-participant observation and we will seek informal consent for our presence by giving a brief description of the research and our role. We will not record any patient details and as such full informed consent from the patient should not be necessary.

# 8. DATA ANALYSIS

## 8.1 QUALITATIVE ANALYSIS

For the observations, the researcher will write detailed fieldnotes, which will be transcribed for analysis. Interview audio files will be fully transcribed, anonymised and checked for accuracy. The observation and interview transcripts will be imported into NVivo (version 10) qualitative data analysis software to aid data management and indexing of qualitative data, and enable comparisons/build relationships between the different parts of the data (e.g. field notes, observation data and interviews with staff and patients). Analysis will begin shortly after data collection starts, and will be ongoing and iterative. Analysis will inform further data collection: for instance, analytic insights from data gathered in earlier interviews will help identify any changes that need to be made to the topic guide during later interviews.

Thematic analysis (e.g. (Braun and Clarke, 2006)), utilising a data-driven inductive approach (Boyatzis, 1998), will be used to scrutinise the data in order to identify and analyse patterns and themes of particular salience for participants and across the dataset using constant comparison techniques (Glaser and Strauss, 1967, Charmay, 2006). Firstly, the transcripts will be read several times, to gain familiarisation with the data and initial ideas noted. The transcripts will then be examined on a line-by-line basis with inductive codes being assigned to the segments of the data that provide insight into the participants' views and understanding of their experiences. An initial coding frame will be developed and new data will be compared initially to previous data, and then to the properties of emerging categories that contain the main themes. A subset of transcripts will be independently double-coded by other members of the research team and compared; any discrepancies will be discussed within the research team and resolved in order to achieve a coding consensus and to maximise rigour. The process of constant comparison will allow for the generation of new themes, re-classification of themes and incorporation of themes within other themes (Glaser and Strauss, 1967, Charmay, 2006) and the coding frame will be modified, if needed, as analysis develops. The data will be scrutinised for negative cases and reasons for the deviance will be explored by comparison with the whole dataset. Initially this will enable the production of a descriptive account. In the context of relevant literature this account will be analysed further to arrive at theoretical findings that should also be applicable to other settings (Glaser and Strauss, 1967, Charmay, 2006).

## 8.2 STATISTICAL ANALYSIS

The ITS will make use of a segmented regression model, which will provide an estimate of the changes in the outcome measures using Poisson regression. For each outcome measure, we will fit a Poisson model for the trend before the intervention, a dummy variable for the period (before or after intervention), and a variable for the trend after the intervention (Lopez Bernal et al., 2016, Bhaskaran et al., 2013). The ITS will control the level and trends of the outcome measures prior to the introduction of the intervention, and possible confounding variables (Craig et al., 2017, Lopez Bernal et al., 2016, Bhaskaran et al., 2013).

In our analysis, we will control for the effect of possible confounders:

1. Type of clinical session – whether the patient was walk-in or booked

2. Type of patient – whether the patient was asymptomatic, symptomatic or a complex case. Complex cases are defined as

    a. Patients under 18 years of age

    b. Have been / are currently exposed to child sexual exploitation, domestic violence, sexual assault

    c. Has a current record of substance misuse

    d. Has a current diagnosis of syphilis

    e. Has current multiple diagnoses clinical diagnoses (GUMCAD coding B &/or C)

    f. Has a history of / current diagnosis of genital herpes or had a swab taken for genital herpes

    g. Has had post exposure prophylaxis after sexual exposure to HIV (PEPSE)

    h. Needed an interpreter / use of translation service

    i. Has current diagnosis of D2B on GUMCAD

    j. Females who:

        i. Receive contraceptive care

        ii. experienced pelvic pain, dyspareunia or post coital bleeding

        iii. are pregnant

        iv. experienced female genital mutilation.

    k. Males who:

        i. are bisexual

        ii. has sex with men

        iii. Experienced testicular pain

        iv. has a history / current record of chronic pelvic syndrome (C5C)

3. The number of people accessing the online service – the number of people who use the online services

4. Case mix of the patients by age (mean age), sex (male: female ratio), ethnicity (proportion of patients from ethnic minority groups) and if male, whether the patient was MSM or heterosexual

5. Type of consultation – whether the clinical session was conducted in clinic, by telephone or online

6. NAAT result – whether the test result was positive or negative

We will also take into consideration regular placement changes in the trainee doctors that occur every March, August and December. These will be captured by using either Fourier terms or flexible spline functions in the model (Bhaskaran et al., 2013, Lopez Bernal et al., 2016). The impact models (Lopez Bernal et al., 2016) for each outcome will illustrate if the same/next day service is effective.

We will use these data (i.e. consultation number and duration, tests, and treatments) combined with standard NHS unit costs to estimate the NHS cost of care per episode, stratified by patient subgroup, before and after the introduction of same/next day service.

## 9. DATA MANAGEMENT

Storage of all data will comply with the Data Protection Act 1998 and subsequent data protection laws that supersedes the DPA, and the University of Bristol's data protection policies.

Qualitative and quantitative electronic data will be stored on a secure password protected University network filestore space where access is controlled by use of user accounts and file access control lists. Servers providing the system hosting are located in secure data centres within the University of Bristol estate. These buildings are protected by secure automatic locking doors, requiring appropriate University Card (MiFare2) and biometric second factor controlled access to enter (for limited authorised personnel only) and are monitored by CCTV by University security services. Locations of routers and switches are physically restricted to IT Services staff.

Data from routinely collected electronic patient records will be provided to the CLAHRC West data analysis team, in a fully anonymised form, for quantitative analysis. The files will be encrypted and sent to the research team in CLAHRC West secure file transfer protocol (SFTP). Datasets will be stored on a secure password protected University network filestore space where access is controlled by use of user accounts and file access control lists. Access to the data is managed, auditable and restricted to individuals of the analysis team who will process the data for the purposes of the study.

All quantitative anonymised study data will be securely archived at the end of the study with the University of Bristol Research Data Storage Facility (RDSF) and retained for a minimum of ten years, with the Principal Investigator as data custodian.

Qualitative interviews will be digitally audio recorded using University approved encrypted digital audio recorders. Digital audio recordings will be transcribed by Bristol Transcription Services, a Bristol university approved transcription company and a confidentiality agreement will be signed prior to this work commencing. Data will be encrypted in accordance with the University of Bristol Information Security Policies whenever it is transmitted electronically or otherwise conveyed.

Data in written form, such as written consent forms, will be stored in locked filing cabinets in secure University of Bristol offices. Interview transcripts will be edited to remove identifying

details, and participants will be allocated codes in order to prevent linkage of data to participant details except by the lead researcher and the two researchers carrying out the interviews.

The electronic audio recordings from interviews, once analysed will be deleted. In accordance with the University of Bristol's 'Guidance on the Retention of Research Records and Data For studies involving human participants, their tissue and/or human data' (Research Governance Team, Research Data Service, dated: 25th March 2015, Anonymised interview transcriptions, anonymised analysed data e.g. NVIVO database and summaries of data and consent forms will be held for 10 years after the study is finished. After this period consent forms will be disposed of using the University of Bristol's confidential waste service.

The risk of re-identification from the anonymised interview data is low. We are therefore proposing that the data in the form of anonymised transcribed interviews be made available to bona fida researchers on request via the University's Research Data Repository, data.bris. A section on the interview consent form to be signed by the participants will seek agreement for participant's data (anonymised transcripts) to be made avaliable to other researchers on request. If participants decline this aspect during the consenting process we will still include them in the research as long as they sign up to the other parts, but their data will not be made available on data.bris for secondary analysis.
Only authorised users can access controlled data stored within the data.bris. The University Research Data Service (data.bris.ac.uk) is responsible for the repository and is committed to maintaining published datasets over the long-term and for a minimum of twenty years.. Access to controlled data by an outside researcher would need ethical approval and then need to submit an application to University of Bristol Data Access Committee (DAC) to discuss and decide whether to release the data if they agree to preserve the confidentiality of the information. For more information on data.bris access levels see https://goo.gl/ui2VRt.

## 10. ETHICAL AND REGULATORY CONSIDERATIONS

### 10.1 ETHICAL APPROVAL

Before the start of the study, a favourable opinion will be sought from the HRA and NHS REC for the study protocol, informed consent forms and other relevant documents.

Any subsequent protocol amendments will be submitted to the REC, on the agreement of the Sponsor and with the prior approval of the funder, and we will make NHS organisations aware.

Annual progress reports will be submitted to the main REC. The first report will be submitted 12 months after the date on which the favourable opinion was given, and thereafter until the end of the study. Copies of these reports will be sent to the Sponsor prior to submission.

An end of study declaration will be submitted to the REC within 90 days of the end of the study. A final report at conclusion of the study will be submitted to the Sponsor, the REC within one year of the end of the study.

### 10.2 PUBLIC AND PATIENT INVOLVEMENT

During study design, PPI meetings were held with three members of the public with recent experience of using existing Unity sexual health services. These meetings focused on reviewing patient-facing materials such as the study information sheet and consent form, text message invite and potential social media posts; acceptability of proposed recruitment and data collection methods; and views of the proposed quantitative outcomes to be measured. Feedback from these meetings was used to inform the study design. During recruitment, PPI meetings will focus on troubleshooting and advising on recruitment. At the end of the study, PPI meetings will focus on interpreting results and dissemination methods - PPI members will help identify non-academic dissemination avenues, and will advise on materials for press releases, print media, social media and patients facing materials, including presentation of results. Our PPI participants will be supported by our PPI coordinator and offered research training via FutureLearn online and People in Health, West of England (see http://www.phwe.org.uk/). The PMG will use plain language and provide a glossary of terms and acronyms.

## 10.3 INVESTIGATORS RESPONSIBILITY

Investigators will be required to ensure that local research approvals have been obtained and that any contractual agreements required have been signed off by all parties before recruiting any participant. Investigators will be required to ensure compliance to the protocol. Investigators will be required to allow access to study documentation or source data on request for monitoring visits and audits performed by the Sponsor or any regulatory authorities.

Investigators will be required to read, acknowledge and inform the study team of any amendments to the study documents approved the REC that they receive and ensure that the changes are complied with.

## 10.4 CONFIDENTIALITY

The Principal Investigators and the research team will preserve the confidentiality of participants in accordance with the Data Protection Act 1998 and subsequent data protection laws that supersedes the DPA. All research data will be handled according to the principles of the Data Protection Act and University of Bristol data protection policies, especially for sensitive, personal data. Data will be anonymised and stored on a password protected computer located in the University of Bristol and appropriately backed up.

Disclosures suggesting any significant or serious threat to the well-being of the interview participant or others, including dependants, will be dealt with through appropriate organisations after discussion with the participant, explaining the need to breach confidentiality. Disclosures will be reported to the PI in the first instance.

The presentation and reporting of data will remove any information that may lead, directly or deductively, to the identification of individuals. Confidentiality of qualitative data will be maintained by anonymising the interview transcript, providing participants with pseudonyms and ensuring that any identifiable individuals or institutions discussed during interviews are anonymised sufficiently to ensure they cannot be readily identifiable. The pseudonyms will be linked to the participants in a ‘code breaker’ database, which will be password−protected and stored on a University of Bristol computer.

### 10.5 INDEMNITY

The University of Bristol has arranged Public Liability insurance to cover the legal liability of the University as Research Sponsor in the eventuality of harm to a research participant arising from management of the research by the University. Also standard NHS insurance and indemnity arrangements apply.

### 10.6 STUDY SPONSORSHIP

The University of Bristol will act as Sponsor for the study. Delegated responsibilities will be assigned to the University. CLAHRC West will be responsible for, and administer the financial aspects of the study.

## 11. DISSEMINATION POLICY

Once analyses are complete, but prior to publication, we will discuss results with as many of our stakeholders as possible, in order to include all perspectives regarding the implications of our results.

All publications and presentations will be in accordance with NIHR CLAHRC West Dissemination Policy (version 8 20/12/2017) the publication policies of the NIHR and acknowledge their financial support.

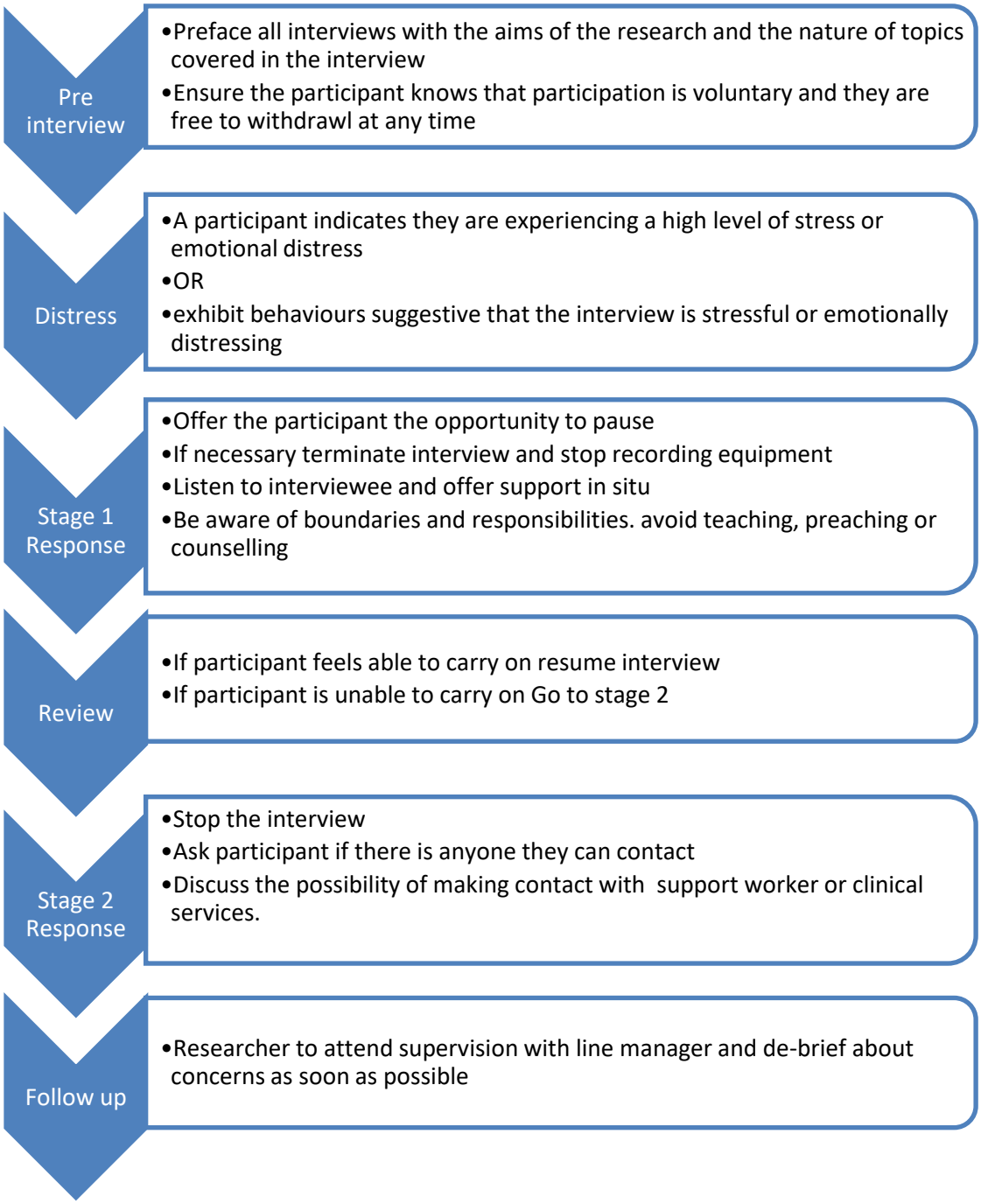
The study findings will be disseminated through publication in peer-reviewed open access journals as well as presentation at local and national conferences. We will make commissioners aware of our findings through meetings and circulation of appropriate materials highlighting the results. We will also ensure study participants, and members of the research population more widely, are aware of the findings through flyers, presentations and the Unity website. We will involve service users and our PPI group in all stages of dissemination and encourage them to co-present and contribute if they feel that is appropriate.

All interview participants will be offered a lay summary of the main findings of the study.

## APPENDIX 1: STUDY PROJECT PLAN, TIMETABLE AND MILESTONES

| Year | 2017 | | | 2018 | | | | | | | | | | | | 2019 | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Month | Oct | Nov | Dec | Jan | Feb | Mar | Apr | May | Jun | Jul | Aug | Sep | Oct | Nov | Dec | Jan | Feb | Mar | Apr | May | Jun | July |
| Month number | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 | 18 | 19 | 20 | 21 | 22 |
| Protocol development | | | | | | | | | | | | | | | | | | | | | | |
| Research governance approvals | | | | | | | | | | | | | | | | | | | | | | |
| Qualitative evaluation | | | | | | | | | | | | | | | | | | | | | | |
| Clinic staff interviews (1) | | | | | | | | | | | | | | | | | | | | | | |
| Patient interview | | | | | | | | | | | | | | | | | | | | | | |
| Observation | | | | | | | | | | | | | | | | | | | | | | |
| Clinic staff interviews (2) | | | | | | | | | | | | | | | | | | | | | | |
| Commissioners interviews | | | | | | | | | | | | | | | | | | | | | | |
| Transcription | | | | | | | | | | | | | | | | | | | | | | |
| Analysis | | | | | | | | | | | | | | | | | | | | | | |
| Report/paper writing | | | | | | | | | | | | | | | | | | | | | | |
| Dissemination | | | | | | | | | | | | | | | | | | | | | | |
| Quantitative Evaluation | | | | | | | | | | | | | | | | | | | | | | |
| Data specification and preparation | | | | | | | | | | | | | | | | | | | | | | |
| Data extraction | | | | | | | | | | | | | | | | | | | | | | |
| Analysis | | | | | | | | | | | | | | | | | | | | | | |
| Report/paper writing | | | | | | | | | | | | | | | | | | | | | | |
| Dissemination | | | | | | | | | | | | | | | | | | | | | | |

## APPENDIX 2. INTERVIEW DISTRESS PROTOCOL



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