National Clinical Audit of STIs and HIV: Feasibility Study Report

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Acknowledgements

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Acronyms

AMR	Antimicrobial resistance
BASHH	British Association for Sexual Health and HIV
BHA	Black Health Agency
BHIVA	British HIV Association
CASH	Contraception and sexual health
CPRD	Clinical Practice Research Data Link
CQC	Care Quality Commission
DH	Department of Health
EPR	Electronic patient record
FSRH	Faculty of Sexual and Reproductive Healthcare
GMFA	Gay men's health charity
GP	General practice
GPES	General Practice Extraction Service
GUM	Genitourinary medicine
GUMAMM	Genitourinary Medicine Access Monthly Monitoring tool
GUMCAD	Genitourinary Medicine Clinic Activity Dataset
HARS	HIV and AIDS reporting system
HCP	Healthcare professional
HCW	Healthcare worker
HES	Hospital Episode Statistics
HQIP	Healthcare Quality Improvement Partnership
LGBT	Lesbian, gay, bisexual and trans (community)
MEDFASH	Medical Foundation for HIV and Sexual Health
MSM	Men who have sex with men
NAT	National AIDS Trust
NAZ	The NAZ project London
NCA	National clinical audit
NCAPOP	National Clinical Audit and Patient Outcomes Programme
NCSP	National Chlamydia Screening Programme
NICE	National Institute of Health and Care Excellence
NIGB	National Information Governance Board for Health and Social Care
PHE	Public Health England
PHOF	Public Health Outcomes Framework
PHW	Public Health Wales
PN	Partner notification
PPE	Patient and public engagement
PPI	Patient and public involvement

PREM	Patient Reported Experience Measure
PROM	Patient Reported Outcome Measure
SCCI	Standardisation Committee for Care Information
SRH	Sexual and reproductive health
STI	Sexually transmitted infection
SWS	Sexual Health in Wales Surveillance Scheme
UNAIDS	Joint United Nations Programme on HIV/AIDS

Executive Summary

Introduction

The UK has a significant problem with sexual ill health, with half a million sexually transmitted infections (STIs) diagnosed in 2014, many more undiagnosed and a worsening profile. Conversely, we also have some of the best networks of sexual healthcare, which provide free, open access, confidential, specialist services for the diagnosis, treatment, and management of these infections. We also have one of the most comprehensive, high quality STI and HIV surveillance data and epidemic intelligence systems in the world. Clinical services are crucial in limiting the spread of STIs, control of which goes beyond treating patients themselves, and includes contacting sexual partners to prevent re-infection, persistence, and onward transmission, as well as health promotion.

STIs and HIV, although preventable, present an individual and a population health problem, with high clinical, psychosocial, and economic costs. There are marked inequalities in the distribution of these infections across the life-course and between different ethnic groups, sexual orientations, and geographic locations. There is also evidence of variation in the delivery and quality of care between clinical services, such as in the coverage of HIV testing and waiting times for access or treatment.

Background

In 2013, STIs and HIV were prioritised as a topic for inclusion in the National Clinical Audit and Patient Outcomes Programme (NCAPOP). In 2014, the Healthcare Quality Improvement Partnership (HQIP) commissioned MEDFASH (Medical Foundation for HIV and Sexual Health) to work in collaboration with Public Health England (PHE), the British Association for Sexual Health and HIV (BASHH) and the British HIV Association (BHIVA) to conduct a feasibility study. The purpose was to explore and evaluate the feasibility, and inform the design, of a future national clinical audit of STIs and HIV, specifically concerning the management of HIV[1], gonorrhoea, chlamydia, and syphilis. The study involved three key stages:

1. Identifying and prioritising suitable topics and measures for audit
2. Assessing the technical feasibility of data collection
3. Defining and recommending the scope of audit

Key concerns, suitable topics and measures for audit

To drive quality improvement in the clinical management of STIs and HIV, outcomes of national and local concern were identified and prioritised according to scale and severity. Patients, providers, commissioners, and a wider group of stakeholders took part in the process. Key concerns identified were the impact and onward transmission of STIs, the growing threat of antimicrobial resistance (AMR) in gonorrhoea, and continuing high rates of late HIV diagnosis.

<u>Impact of STIs and onward transmission</u>

HIV, gonorrhoea, chlamydia and syphilis can all have serious immediate and lifelong consequences, including chronic morbidity, psychosocial distress and, for HIV, premature death. These infections can be asymptomatic and can silently spread between sexual contacts and within sexual networks. STIs disproportionately affect men who have sex with men (MSM) and black ethnic groups who experience the highest diagnosis rates for each of these four infections.

[1] Excluding HIV care delivered in specialised HIV services (covered by the HIV dashboard)

Chlamydia remains the most common bacterial STI, with over 200,000 diagnoses in 2014, more than half of which were among young people aged 15 to 24 years. The long-term consequences of untreated chlamydia can continue to affect people later in life and include tubal infertility, ectopic pregnancy and pelvic inflammatory disease.

Although syphilis is much less common than chlamydia, diagnoses have risen more than tenfold, since the late 1990s, to over 4,000 in 2014. Among MSM, the rise has been even greater, increasing by 46% between 2013 and 2014 alone. The consequences of untreated syphilis can be serious and include cardiovascular and neurological disease, and death.

Concurrent infection is common and some STIs, such as gonorrhoea and syphilis, can biologically facilitate the acquisition and transmission of other STIs, including HIV. Poor quality clinical management at any stage of the patient care pathway fosters onward transmission of STIs and also HIV, which has a lifetime treatment cost of between £280,000 and £360,000 for every infection that is not prevented.

Rising rates of gonorrhoea and the threat of AMR

Gonorrhoea diagnoses have doubled in a decade, now reaching 35,000 a year, with an overall increase of 19%, and a much higher increase among MSM at 32%, between 2013 and 2014. Failure to prevent and manage gonorrhoea effectively can result in immediate and long-term clinical consequences for individuals and their sexual partners, including prostatitis, tubal infertility and ectopic pregnancy.

Increasing AMR is jeopardising the future treatability of gonorrhoea. Following an outbreak of high-level azithromycin resistant gonorrhoea in Leeds in 2015, the Chief Medical Officer highlighted AMR as “a growing clinical and public health issue of the greatest importance” and urged clinicians to “ensure that those diagnosed with gonorrhoea receive optimal and appropriate treatment in order to ensure effective care for that individual, protect public health and reduce the risk of AMR”. This is a strong driver for quality improvement.

Continuing high rates of late HIV diagnosis

There are over 100,000 people living with HIV in the UK and one in six remains undiagnosed. Late diagnosis (defined as a CD4 count of below 350 cells/mm^3), when the immune system is already severely compromised, limits the effectiveness of antiretroviral therapy and carries a tenfold greater risk of death within the first year. Late diagnosis also prolongs the risk of transmission. Forty percent of HIV infections are diagnosed late and rates are higher still among people of black African ethnicity, at 58%. Once diagnosed, however, patients are linked into a very high standard of care with highly effective antiretroviral therapy, near-normal life expectancies and an improved quality of life.

Reducing late diagnosis and onward transmission of HIV are national and international priorities. Late diagnosis is a key indicator within the Public Health Outcomes Framework (PHOF); and UNAIDS has set the 90-90-90 target, with 90% of all people living with HIV to know their HIV status, 90% of those to be on treatment, and 90% of those to have achieved viral suppression, by 2020. Meeting these targets is necessary for achieving the eventual end to the AIDS pandemic.

Technical feasibility of data collection

Within each main area of clinical concern identified, audit measures were chosen and aligned with a simplified patient pathway. These measures were selected on the basis that they had a clear role in the overall quality of patient care, were amenable to change and the audit process is likely to lead to improvement. The feasibility of collecting suitable data to answer the proposed audit questions was assessed in consultation with PHE and Public Health Wales' (PHW) STI and HIV surveillance experts.

In England, the majority of STI (including HIV testing) services are provided in approximately 225 specialist genitourinary medicine (GUM) or integrated sexual and reproductive health (SRH) clinics, while the National Chlamydia Screening Programme (NCSP) provides stand-alone chlamydia testing in a variety of settings. Some primary and community healthcare services also provide a more limited range of STI and HIV related care. In Wales, care is provided by 29 integrated SRH clinics.

Recommended scope of the audit

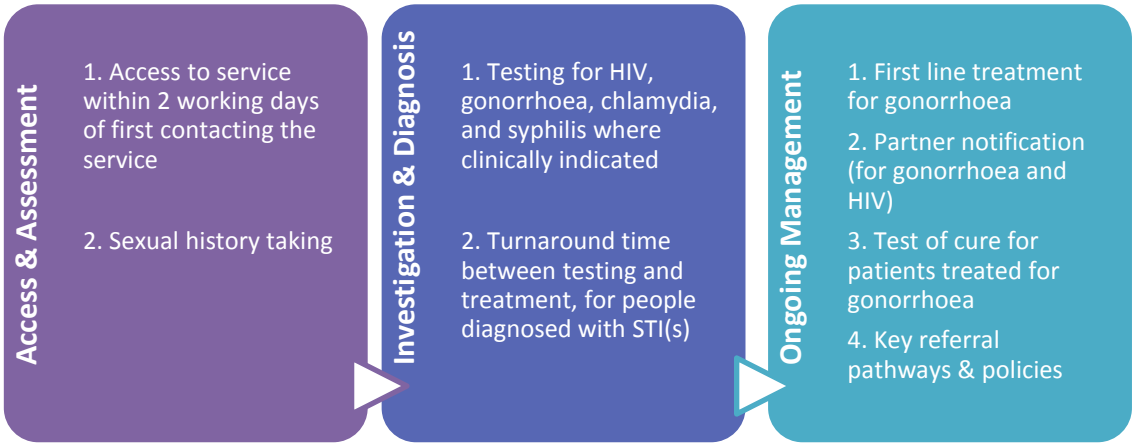
1. A national clinical audit of STIs and HIV is feasible and should be conducted in all services commissioned to provide specialist GUM or integrated SRH care in England and Wales.

2. The audit should aim to improve patient outcomes and reduce STI and HIV transmission and specifically to:
   - Limit the impact and transmission of STIs
   - Mitigate against the development of antimicrobial resistant gonorrhoea
   - Reduce late diagnosis of HIV

3. The objective of the audit should be to review existing quality of care against nationally agreed standards and use the findings to drive quality improvement.

4. The audit should drive quality improvement in clinic-level performance at the three key stages on the patient care pathway where clinical services have the biggest impact on STI transmission, shown in figure 1:

Figure 1 Recommended audit domains and topics



5. The audit should use existing nationally agreed standards and guidelines, and any associated recommended national audit measures already defined.

6. The audit should use a mixed-methods approach, by which most data is collected continuously and through established mandated surveillance systems held by PHE and PHW. Where data are not already available, supplementary data should be collected using simple electronic methods. The introduction of data collection should be phased according to priority of audit topic, and audit and re-audit data should be shared at clinic-level in a timely manner.

7. A clear structure for national, regional, and local ownership, participation, training, and support for quality improvement should be developed. This should build on existing mechanisms, such as the existing BASHH and BHIVA audit structures and PHE's regional Sexual Health Facilitators.

8. Audit and re-audit results should be published and include clinic-level, local authority, regional, and national comparative data. Results should be shared with clinical teams, patients, provider organisations, commissioners, and other key stakeholders, with clear recommendations for quality improvement for each audience, in a style accessible to the public.

Study conclusions

A national clinical audit of STIs and HIV is appropriate and feasible and presents a unique opportunity to improve access to high quality services, to limit the impact and transmission of STIs, to mitigate against the development of antimicrobial resistant gonorrhoea, and to reduce late diagnosis of HIV.

An audit would be launched from a strong platform of established and world-class data, with the support of committed clinicians, commissioners, and civil society stakeholders. The alignment of the audit measures recommended in this study with existing national priorities, and local key performance indicators, will maximise the impact of the audit results. Furthermore, an STI/HIV audit will catalyse the transformation of a strong data collection culture into one of measurable quality improvement, for the benefit of patients today and tomorrow, and the wider public health.

1. Overview of feasibility study

This report details the key findings of a one-year study, which explored the scope and feasibility of a national clinical audit (NCA) of sexually transmitted infections (STIs) and HIV to address the following overarching problem:

> *The number of STIs is rising, HIV prevalence is increasing, vulnerable and high risk groups bear a disproportionate burden of STIs and HIV and infections continue to spread*

1.1. Study overview and process

In 2014, MEDFASH (Medical Foundation for HIV and Sexual Health) was commissioned by the Healthcare Quality Improvement Partnership (HQIP) to undertake a one-year feasibility study to inform a NCA of services providing healthcare for people with STIs and/or HIV. This was to be carried out in collaboration with Public Health England (PHE), the British Association for Sexual Health and HIV (BASHH) and the British HIV Association (BHIVA). The remit was to define a scope for an achievable and impactful NCA, which would drive improvements in the quality of care provided to patients with HIV, gonorrhoea, chlamydia, and/or syphilis. A Steering Group, including a Clinical Lead experienced in clinical audit, a Study Manager from MEDFASH, representatives from PHE, BASHH and BHIVA, and patient and public representatives, guided study development and met on alternate months throughout the study. A Reference Group was set up to provide additional expert advice as required throughout the study and members represented a wide range of professional groups involved in STI and HIV care, surveillance, policy, and research. Specialist advice was sought from experts on audit methodology and patient and public involvement. Details of the Steering Group and Reference Group are included in Annex 1.

1.2. Study background

The commissioning of the current study follows previous work conducted between 2011 and 2013. In 2011, two separate topic proposals were submitted for inclusion in the National Clinical Audit and Patient Outcomes Programme (NCAPOP), one relating to STIs including HIV by BASHH and MEDFASH and one relating to HIV by BHIVA. Following consideration by the Department of Health (DH) and NCAPOP panel, HQIP, in 2012, commissioned a development project to produce a joint topic proposal for a NCA combining STIs and HIV. This project was conducted jointly by BHIVA and BASHH, with MEDFASH as a delivery partner. In September 2013, a specification development meeting for the funders and commissioners from the DH and the NCAPOP considered the key findings, strengths, and weaknesses of the combined HIV and STI audit topic proposal. A commissioners' meeting immediately afterwards reflected on the information provided by subject experts and concluded that the mechanism by which an audit could be achieved was unclear and that a feasibility study should be commissioned. The feasibility study would need to identify how best to achieve a combined audit, which would 1) stimulate quality improvement through the provision of high quality data comparing providers, 2) achieve and maintain close alignment with National Institute of Health and Care Excellence (NICE) guidance and quality standards, where appropriate and 3) consider and plan for effective change initiatives from the outset.

1.3. Study aims

The study aims as outlined in the specification from HQIP:

1. Determine the main issues regarding the quality of care and outcomes for each of the four patient groups (HIV, chlamydia, gonorrhoea and syphilis*) which are both of particular concern nationally and are most likely to be improved through stimulation by a NCA rather than by other quality improvement mechanisms.
2. Identify appropriate existing data sources and how they may be accessed, analysed and linked to other datasets within existing governance arrangements to report on these issues.
3. Outline any requirements for new additional data collection where there are no appropriate existing data sources.
4. Identify effective ways of stimulating quality improvement including the reporting of provider comparisons for relevant audiences and at the relevant level of granularity.**

Effective and integral patient/carer representation must be included in all stages of the design and execution of the feasibility study, just as it would be included in any future national audit.

*Individuals can be at risk of and diagnosed with HIV, gonorrhoea, chlamydia, and syphilis at the same time. As the care pathway for patients is broadly similar, this report refers to individuals at risk of or diagnosed with HIV and STI(s) rather than four distinct patient groups.

**Following guidance from HQIP project managers, objectives 1 to 3 were prioritised. The feasibility study team was advised that, if a NCA is commissioned, the audit development team would be responsible for exploring communication and dissemination plans (as in objective 4).

1.4. Key study objectives

The specific objectives for the feasibility study were to:

1. Explore the content and quality of existing datasets including GUMCAD[2] and HARS[3], and how they may be used to support the analysis and reporting of key process and outcome measures within existing information governance arrangements of the data custodians (PHE), and prioritise according to aim 1 (above);
2. Investigate the capacity to link meaningfully across data sets and to other data sources such as Hospital Episode Statistics (HES), including the use of NHS number and the potential use of HES linkage to enrich data regarding missed HIV diagnosis opportunities;
3. Identify where the audit will need to achieve synergy with existing national quality assessment initiatives such as the HIV Clinical Reference Group dashboard;
4. Investigate the feasibility of including all levels of sexual health services in the audit or whether the audit should be restricted to providers of level 2 and 3 services[4];
5. Detail any essential new data required and identify how such data could be collected;
6. Explore patient and service consent issues and propose solutions;
7. Propose the most effective types of feedback and reports, identifying specific outputs and target audiences, to support local quality improvement;
8. For the future methodology proposed, explore how Welsh participation could be achieved given that not all the relevant existing datasets are collected in Wales.

[2] GUMCAD - Genitourinary Medicine Clinic Activity Dataset
[3] HARS - HIV and AIDS reporting system
[4] Level 3 and level 2 refer to the types of services that are provided in different clinical settings. A list of specific services provided at level 3, 2 and 1 is provided in Annex 2.

The scope of the feasibility study, defined by HQIP, **excluded**:

1. An organisational audit;
2. Research, including health policy research;
3. Other STIs not specified above - as these four STIs had already been prioritised in the earlier development project;
4. HIV care delivered in specialised HIV services - as information about the quality of performance in services providing specialist ongoing HIV care is covered by an existing HIV clinical data dashboard – the *HIV Quality Dashboard* (1);
5. Patient Reported Outcome Measures (PROMs)/Patient Reported Experience Measures (PREMs) (at the feasibility stage).

1.5. Feasibility study methodology

The feasibility study comprised three main project phases:

1. Identifying and prioritising suitable topics and measures for audit
2. Assessing the technical feasibility of data collection
3. Defining and refining a scope for audit

Table 1 provides a project overview and a full breakdown of study deliverables, workstreams and activities can be found in Annex 1.

Table 1 Project overview

Project Phase	Q1	Q2	Q3	Q4
1. Identifying and prioritising suitable topics and measures for audit				
Identifying key concerns in sexual health				
Defining topics and measures for audit				
Consulting stakeholders on priority topics for audit				
2. Assessing the technical feasibility of data collection				
Assessing data requirements				
Exploring feasibility of data collection and linkage				
Investigating feasibility of expanding audit beyond providers of level 2 & 3 services				
Exploring patient and service consent issues for data processing				
Exploring how Welsh participation could be achieved				
3. Defining and refining a scope for audit				
Exploring examples of achievable and impactful audits				
Exploring levers for quality improvement				
Exploring audit feedback mechanisms and reports				
Preparing feasibility study report				

2. Introduction to sexual health, STIs and HIV in England and Wales

2.1. Context of sexual health services

Specialist sexual healthcare services diagnose, treat, and manage STIs. The impact of doing so reaches beyond the individual patient. By interrupting the chain of transmission, clinical services provide a key role in protecting the public from outbreaks and in reducing the onward spread of STIs and HIV. Overarching principles of STI management include:

- Detecting new cases of infection
- Tracing sexual partners and contacts to offer them testing and treatment
- Minimising the period of infectivity (through prompt, effective treatment)
- Reducing re-infection by identifying potential risk factors (e.g. alcohol, substance misuse) and offering behavioural interventions

Effective management of STIs needs to address a range of psychosocial factors and experiences, which often cluster with sexual health needs and can increase vulnerability to poor sexual health. For concerns such as sexual violence, safeguarding, alcohol and substance misuse and low self-esteem, STI and HIV services often refer patients onto appropriate services.

At each point of care, the STI clinician has a unique opportunity to promote healthy lifestyle choices and improve the outcome for their patient as well as indirectly for the people in connected sexual networks and the broader population.

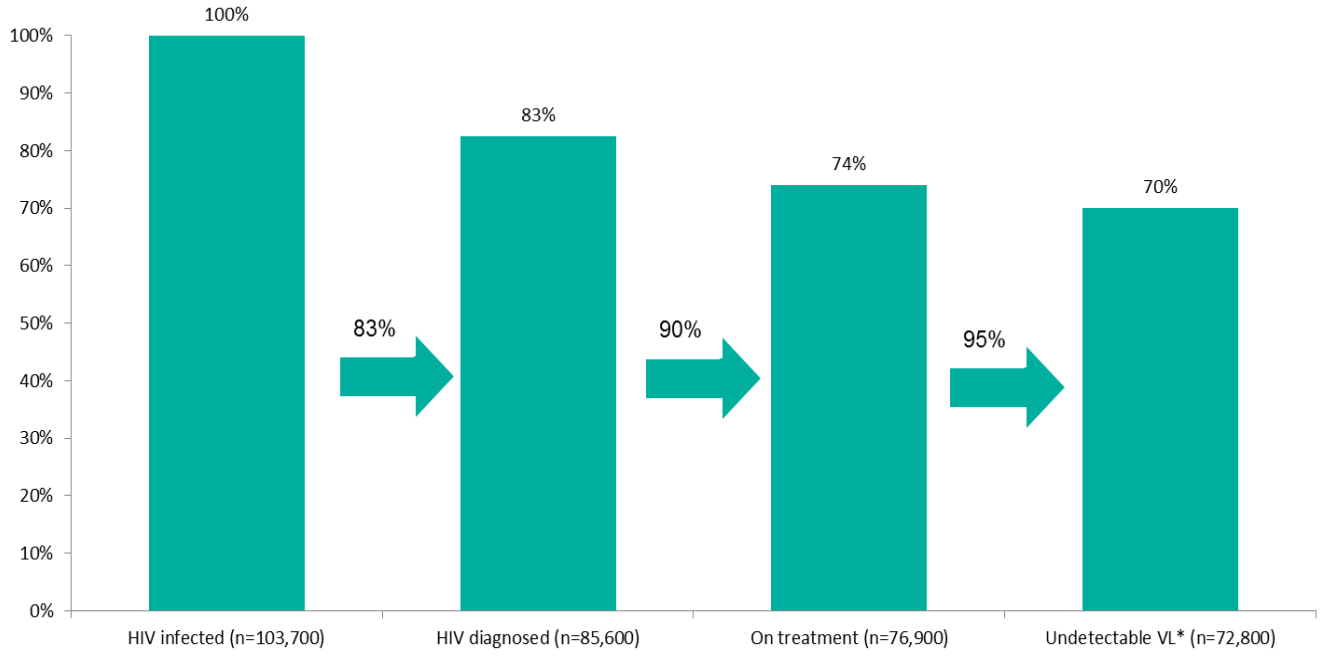
2.2. HIV

It is estimated that there are over 100,000 people living with HIV in the UK; 17%, one in six, are unaware of their infection (2;3). Over 600 people died from HIV in the UK in 2014, the majority of whom were diagnosed late[5]; 40% of all new HIV diagnoses that year were late presentations (2;3). The burden of late diagnosis falls disproportionately on black African and other black ethnicities (58% and 45% respectively of all new diagnoses in these groups) and people living in the North of England (48%) (4).

Prolonging the time between the acquisition of infection, diagnosis and treatment compromises individual clinical outcomes, threatens population health and places a preventable burden on the economy(4;5). HIV has a lifetime treatment cost of between £280,000 and £360,000 for every infection that is not prevented.

[5] Late diagnosis is defined as having a CD4 count below 350 cells/mm³ within three months of diagnosis. A normal CD4 cell count is usually above 500 cells/mm³

Figure 2 Treatment cascade of adults living with HIV: UK, 2014



* Viral load (VL)< 200 copies/ml

Late presentation with HIV in the UK has been described as a modern tragedy (6). Despite access to the most effective treatments available and excellent outcomes for people who are diagnosed early, late diagnosis remains the biggest barrier to achieving consistently high clinical outcomes for all. Reducing late diagnosis will have the greatest impact on patient outcomes, and will also reduce HIV transmission at a population level (7).

Internationally the United Nations advocates targets to ensure 90% of all people living with HIV know their HIV status, 90% of those are on treatment, and 90% of those have achieved viral suppression, by 2020. This 90-90-90 goal is to make HIV transmission rare and end the AIDS pandemic (1;8). Achieving these targets in the UK will require a concerted approach to detecting undiagnosed infection, which currently stands at over 15,000 people.

Specifically, late diagnosis:

- reduces the effectiveness of anti-retroviral therapy when it is finally initiated (9)
- leads to a tenfold increase in the risk of death within one year of diagnosis (4)
- increases the risk of HIV transmission to sexual contacts (10-12)

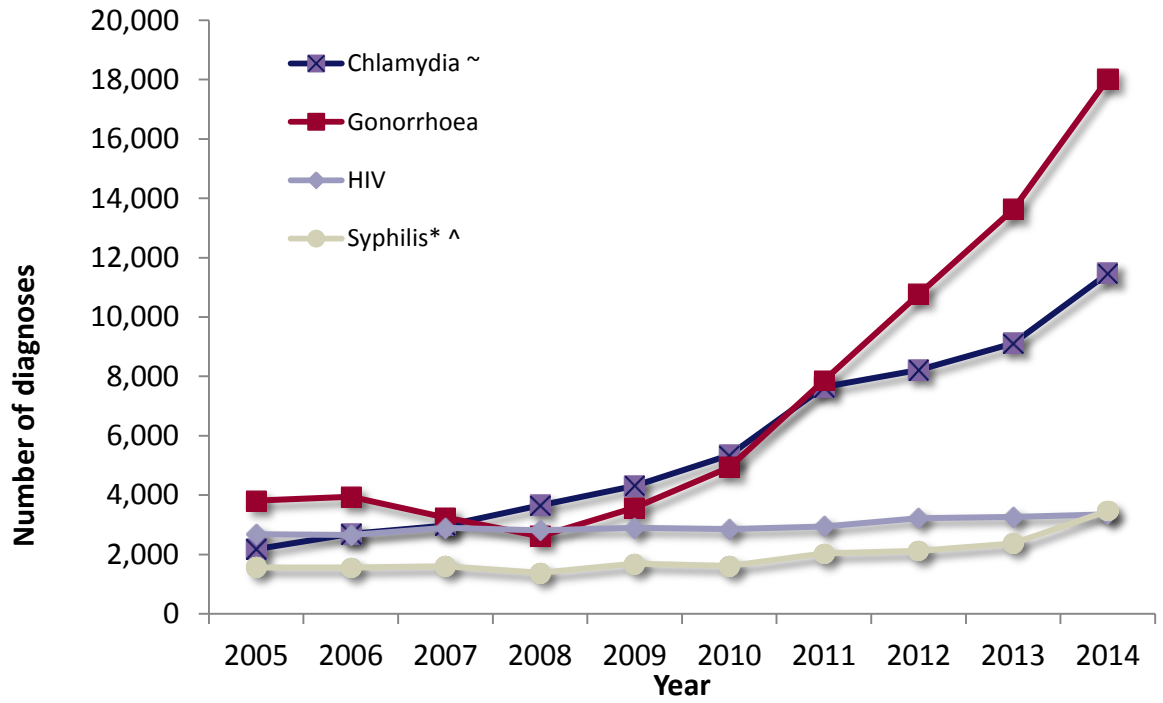
A clear mechanism therefore needs to be set up to ensure:

- nationwide implementation of the NICE guidance on increasing uptake of HIV testing among men who have sex with men (MSM) and black Africans in England, which, alone, would prevent 3,500 cases of HIV transmission within five years and save £18 million in treatment costs per year (13)
- HIV testing is included as an integral part of a comprehensive sexual health screen to all service users for whom a screen is clinically indicated, and in line with national standards for care in all settings
- widespread provision of high quality partner notification (PN) strategies to identify undiagnosed infection and quickly reduce onward HIV transmission

2.3. Gonorrhoea

Over the past decade, annual gonorrhoea diagnoses have doubled, with 35,000 new cases diagnosed in 2014 following a 19% increase between 2013 and 2014. The infection disproportionately affects MSM, amongst whom there was an alarmingly high increase of 32% between 2013 and 2014, as shown in Figure 3. At the same time, black ethnic groups continue to experience the highest rates of gonorrhoea diagnosis among heterosexuals, at four times those observed in the white ethnic population. These statistics evidence a major and sustained failure to address the sexual health needs of these two minority groups (14).

Figure 3 Number of STI diagnoses among MSM: England, 2005-2014



ǂ Data from routine GUM service returns; New HIV diagnoses sourced from HIV & AIDS New Diagnoses & Deaths Database
~ Chlamydia data from 2012 onwards are not comparable to data from previous years (please see Annex 2 for more details)
*First episode; ^ Includes diagnoses of primary, secondary & early latent syphilis

Undetected or inadequately treated gonorrhoea can lead to prostatitis, epididymo-orchitis, pelvic inflammatory disease , serious systemic infection, tubal infertility and ectopic pregnancy (15).

Antimicrobial resistance (AMR) is a key concern for gonorrhoea, with widespread resistance to many formerly used antibiotics such as the quinolones. The current BASHH recommended regimen is for dual therapy to decrease the risk of emerging resistance. In relation to these two drugs, ceftriaxone resistance is currently rare, but azithromycin resistance, at approximately 1% prevalence, is of growing concern (16). An outbreak of high-level azithromycin resistant gonorrhoea in Leeds in 2015(17) illustrates that AMR presents a real threat to the future treatment of this infection. With limited treatment options now available, full national implementation of the entire gonorrhoea care pathway, including compliance with recommended first line dual therapy, is essential, as highlighted by the Chief Medical Officer, who, in December 2015, urged clinicians to (18):

"ensure that those diagnosed with gonorrhoea receive optimal and appropriate treatment in order to ensure effective care for that individual, protect public health and reduce the risk of AMR"

Infection with gonorrhoea is also a sensitive marker for high-risk sexual behaviour and is linked to a high probability of co-infection with other STIs, including HIV. In 2014, a third of people diagnosed with gonorrhoea reported a previous gonorrhoea episode, 70% reported having two or more sexual partners in the preceding three months, and one in three had concurrent chlamydia, syphilis, and/or HIV. Good management of gonorrhoea therefore provides wider opportunities for preventing further STI and HIV acquisition and transmission (16).

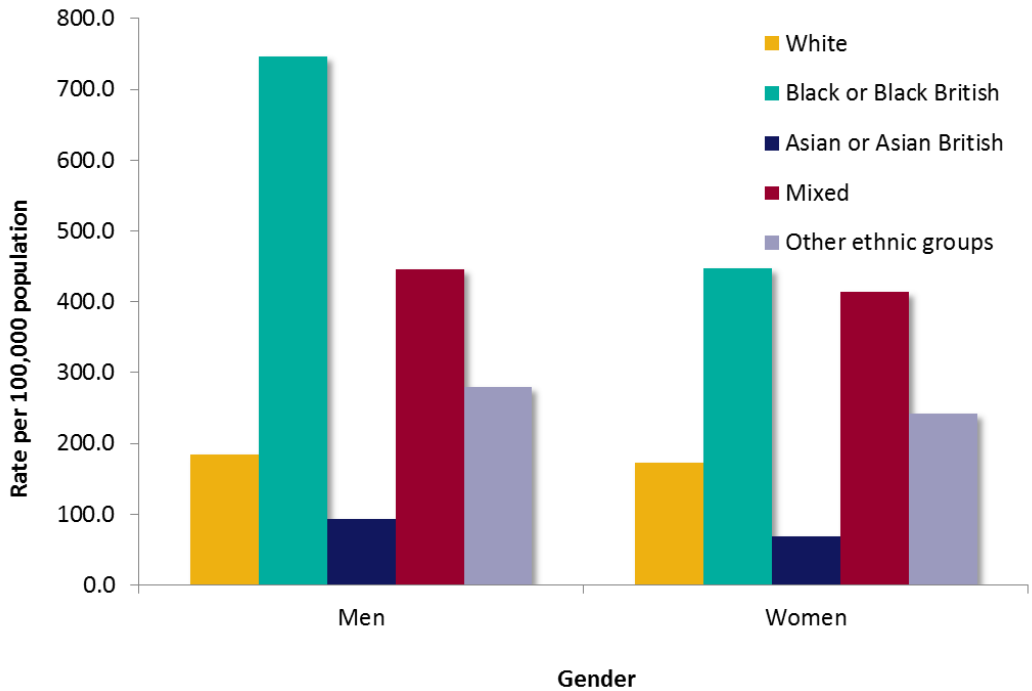
Pressing concerns related to gonorrhoea are:

- the clinical sequelae of untreated infection
- growing AMR
- the role of gonorrhoea in biologically facilitating HIV acquisition and transmission

2.4. Chlamydia

Chlamydia is the most commonly diagnosed bacterial STI in England and Wales, with over 200,000 diagnoses made in 2014 (14). The greatest impact is on young people aged 15-24, who account for half of all diagnoses, and black ethnic groups, who experience the highest rates of diagnosis, as shown in Figure 4 . There has been little change in the rate of chlamydia diagnosis over the last ten years and this is mainly driven by new infections and some re-infections (14;19;20).The individual harms of long-term untreated chlamydia and the related sequelae can be high. These include tubal infertility, ectopic pregnancy, and pelvic inflammatory disease. As chlamydia can be asymptomatic, opportunistic screening is an essential element of good quality sexual healthcare provision for young people. The National Chlamydia Screening Programme (NCSP) in England aims to detect and treat asymptomatic chlamydia in order to reduce onward transmission and the consequences of untreated infection. The NCSP has standards for the minimum quality of care expected from providers of chlamydia screening; this includes the offer of a retest to young people with a positive chlamydia test result at around three months following their diagnosis.

Figure 4 Rates of chlamydia diagnoses among men and women by ethnic group: England, 2014



*Data from routine GUM service returns.

2.5. Syphilis

While syphilis diagnoses are relatively low compared with chlamydia and gonorrhoea, they have risen from around 300 per year in the late 1990s to over 4,000 in 2014. In particular, the latest figures show a step change in the number of diagnoses in MSM, with a 46% increase in a single year between 2013 to 2014 (14) (see Figure 3).

The consequences of untreated syphilis include long-term cardiovascular and neurological complications, some of which can be fatal. The increase in syphilis infections in recent years highlights the need to ensure that syphilis testing is offered wherever it is appropriate and certainly alongside testing for HIV, chlamydia and gonorrhoea. Given the serious consequences of untreated syphilis, effective management (in particular follow-up) of existing cases is essential to avoid onward transmission.

2.6. Commissioning and delivery landscape

STI management in England, including HIV testing and PN, is provided by a combination of:

- 225 genitourinary medicine (GUM) or sexual health clinics
- 250 integrated sexual and reproductive health (SRH) clinics, offering contraception and varying levels of STI management (sometimes referred to as CASH (contraception and sexual health) services).
- 422 providers in other medical and community settings (including general practices and pharmacies specially commissioned to provide sexual health services, and community-based testing services).

A recent analysis of longitudinal electronic health records from the Clinical Practice Research Data Link (CPRD)[6] determined that general practice (GP) makes an important contribution to the diagnosis and treatment of bacterial STIs in England (21). Between 2000 and 2011, GPs diagnosed between 9% and 16% of chlamydia cases and between 6% and 9% of gonorrhoea cases in England. Surveillance data also indicate that approximately 80% of all new HIV diagnoses are made in GUM settings (100).

In Wales, STI management is delivered in 29 integrated SRH clinics and in some GP settings.

In England, since the implementation in 2013 of the Health and Social Care Act 2012, different aspects of sexual and reproductive healthcare are now commissioned by:

- local authorities
- clinical commissioning groups and
- NHS England (see Annex 2)

This new commissioning landscape means that a single individual's STI and/or HIV care may be both commissioned and provided by more than one organisation. Most STI testing and management, and most HIV testing, is commissioned by local authorities as part of public health. However, HIV treatment and care is a specialised service commissioned by NHS England. While the full implications and opportunities of the new commissioning and delivery arrangements are yet to be realised, BASHH, the Faculty of Sexual and Reproductive Healthcare (FSRH) and a number of other professional bodies, including the All Party Parliamentary Group on SRH (23), have queried whether a dispersed system of commissioning may lead to disruption in the quality of care (24;25).

[6] CPRD covers 9% of GP clinics in England.

2.7. Financial climate

Challenges to providing high quality sexual healthcare within the new commissioning landscape are accompanied by the experience of financial restrictions and the prospect of more to come. Regardless of whether they are delivered by NHS or independent sector providers, all GUM and integrated SRH services are commissioned by local authorities and thus fall outside the budget protection afforded to the NHS.

Current and planned financial restrictions include:

- Projected cuts in central funding to local authorities of 25-40% (26)
- Recurring 'in-year' cuts of £200m (6.2%) to the public health budget (announced in July 2015)
- Additional annual 'public health saving' of 3.9% announced in the Chancellor's 2015 Autumn Spending Review (27)

In this challenging financial climate, service redesign is underway or planned in many areas. As this is implemented, it is important to monitor any potential impact on outcomes and to ensure consistent high quality care is maintained. A national programme of audit would clarify the extent of variation between clinics and drive quality improvement so that different population and risk groups all benefit from the highest possible standards of care.

2.8. Established standards of care

The multi-professional sexual healthcare community, consisting of doctors, nurses, health advisers and other professionals, is well established and committed to providing quality care. This is evidenced by the collaborative development of *Standards of care for the management of STIs* by BASHH and MEDFASH (28), *Standards for care for people living with HIV 2013* by BHIVA (29) and the *HIV partner notification for adults: definitions, outcomes and standards* jointly developed by BASHH, BHIVA, the National AIDS Trust (NAT) and the Society of Sexual Health Advisers (SSHA) (30). The alignment of these standards with National Institute for Health and Care Excellence (NICE) guidance (31;32), and PHE recommendations (2;3;14;16) also shows that the community has complementary visions for care (see Annex 2).

2.9. Existing, high-quality national STI and HIV data flows

PHE and Public Health Wales (PHW) capture robust data on STI testing and diagnosis at the patient level from GUM, SRH and some GP services commissioned to provide sexual healthcare. These established and validated surveillance datasets are used primarily to monitor epidemiological trends, inform national policy and describe outcome data at regional and national level. The sexual healthcare community currently consistently reports clinic-level data to PHE and PHW in a timely manner. The challenge lies in utilising those data (in a timely way) to effect the changes required at the local level.

2.10. Huge potential impact of a future national clinical audit

While the commitment and enthusiasm of the GUM and integrated SRH community is evident, the lack of a clear mechanism focused on continual quality improvement limits clinics' ability to drive sustainable change at the local level. Establishing a NCA of STIs and HIV will provide a mechanism to maximise the utility of existing data, offer a nuanced understanding of the provision of care and its impact on patient outcomes, and catalyse the transformation of a strong data collection culture into one of quality improvement.

3. Identifying and prioritising suitable topics and measures for audit

3.1. Introduction

The process of identifying and prioritising suitable topics and measures for early inclusion in a NCA involved PHE, PHW, the Steering Group, and the Reference Group. The starting point was the extensive formative work already undertaken by the same stakeholders, in 2012 and 2013, to inform a new audit topic proposal).

This previous work identified the following key issues of concern:

- Missed HIV diagnoses outside of GUM and SRH healthcare services
- PN for STIs including HIV
- Co-infection (outcomes for people diagnosed with two or more STIs)

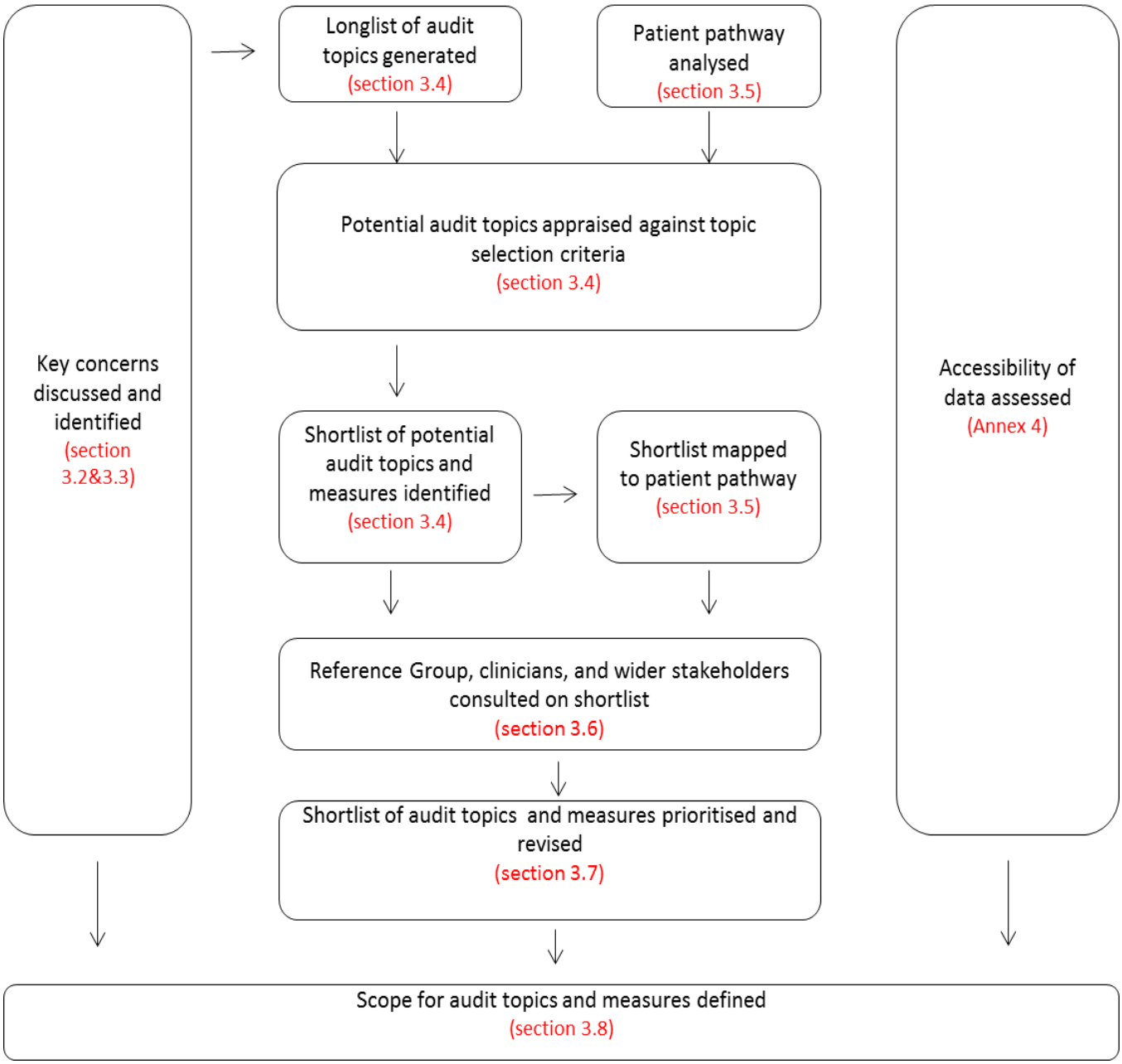
To build on these findings for the current study, the Study Manager conducted an epidemiological scoping of vulnerable populations (young people, black ethnic groups, and MSM) and reviewed published and grey literature on service policy, provision, and care pathways. Standards were identified and extracted from existing guidelines.

The Steering Group considered summary findings from the earlier work alongside this scoping exercise and defined the overarching problem as follows:

> *The number of STIs is rising, HIV prevalence is increasing, vulnerable and high risk groups bear a disproportionate burden of STIs and HIV and infections continue to spread*

An iterative process was then followed to reach the final list of recommended topics. The Steering Group pinpointed three main concerns and two underlying contextual challenges surrounding sexual healthcare in England and Wales and used these to generate a longlist of potential audit topics. The longlist was reviewed against pre-defined topic selection criteria (see Annex 3) and likely national data availability. The shortlist of auditable topics was shared with the Reference Group to gather their feedback and inform the refinement and prioritisation of the selected topics. The topic identification process is summarised in Figure 5.

Figure 5 Overview of topic identification and prioritisation process



3.2. Identifying key concerns in sexual health

Three key concerns relating to STIs and HIV were identified and used to guide the selection and prioritisation of audit topics and measures. These were:

Impact of STIs and onward transmission

All STIs are transmissible and many are asymptomatic. As such, STIs can silently spread between sexual contacts and within sexual networks. Young people, MSM and black ethnic groups experience the highest diagnosis rates for HIV, gonorrhoea, chlamydia and syphilis, and are therefore disproportionately affected by these STIs and at increased risk of acquiring and transmitting STIs. Concurrent infection is common and some STIs, including gonorrhoea, can biologically facilitate the acquisition and transmission of other STIs, including HIV.

Rising rates of gonorrhoea and the threat of AMR

With the number of gonorrhoea diagnoses now reaching 35,000 a year and a 19% increase between 2013 and 2014, rising rates of infection are a real cause for concern. This is because of the clinical impact on individuals, the increased likelihood of HIV transmission and AMR, which jeopardises the future treatability of this infection. All stakeholders consulted considered management of gonorrhoea at all stages of the care pathway to be a high priority.

Continuing high rates of late HIV diagnosis

Late diagnosis of HIV continues in the UK despite the availability of free and high quality treatment for those diagnosed. Late diagnosis has immediate and long-term clinical, public health and economic consequences and black African communities continue to experience the greatest impact of this. Reducing late diagnosis and onward transmission of HIV are national and international priorities, which need to be addressed consistently and promptly by all GUM and SRH providers.

3.3. Additional concerns

An underlying issue is the changing sexual health environment in which services have been delivered since April 2013. Provision of STI care and HIV testing is expanding beyond the traditional specialist GUM services (including to pharmacies, general practice and community settings) alongside a general move towards greater integration of GUM and SRH services (managing both STIs and contraceptive provision). Clinicians and wider stakeholders consulted during the feasibility study agreed that maintaining high quality care across all settings in which care is commissioned and delivered is a priority.

The holistic nature of sexual healthcare, and the relationship between sexual ill health and alcohol, substance misuse and psychological ill health, were highlighted within early Steering Group discussions. At the point of contact for sexual health needs, it is important that clinicians take the opportunity to assess service users for alcohol and substance use, or to refer to appropriate services.

3.4. Longlisting and shortlisting

A longlist of relevant topics for further assessment was defined using a combination of existing standards and guidelines and the previous scoping work of 2013 (see Annex 3). These topics concerned several aspects of care of primary importance to sexual health outcomes.

The longlisted topics were appraised against topic selection criteria (33) which were pre-defined and agreed among the Steering Group at the start of the feasibility study, including:

- Consequences of poor quality care
- Variation in and unacceptable care quality and patient outcomes
- Scale of the problem
- Alignment with national public health priorities
- Potential for measurement
- Amenability to change through audit at the clinic level
- Likely acceptability among clinicians and non-clinical stakeholders, patients and the public
- Alignment with previous, current, and planned audits and improvement initiatives.

A shortlist of topics and measures was agreed by the Steering Group. Topics and measures were excluded or deferred at this point if they were not feasible to audit in the near future. Where possible an alternative audit measure was recommended within the same audit domain. Further details of the full set of topics considered are in Annex 3.

3.5. Pathway analysis and mapping

Shortlisted auditable measures were mapped against a simplified care pathway to identify fracture points in the quality of clinical services, which could be amenable to change through audit.

Managing the risks of STIs and HIV transmission is complicated by the different clinical and epidemiological characteristics of each infection. Each stage of the pathway is important for reducing the impact and transmission of STIs. Additionally, each stage has a direct impact on subsequent stages of the pathway. For example, having an appropriate sexual history taken informs the offer of all necessary STI tests and experiencing a minimal gap between testing and notification of results impacts on time to treatment. Although all these aspects of care are defined and benchmarked in the *Standards for the management of STIs*, achievement of these standards is not consistently measured and reported nationally.

The open-access nature of sexual healthcare (patients can choose to attend any clinic without referral) means that, unless a person has been transferred from one clinic to another, there is no way to identify the same person attending more than one service (no unique patient identifier is available). This means that a longitudinal audit of continuous individual patient care over an extended period is not feasible. However, data that allow audit of individual episodes of care, including multiple attendances, are available through comprehensive and mandatory reporting of GUM and SRH clinical activity and this allows for a continuous audit of individual topics.

Key points at which clinical services can make the largest contribution to reducing STI transmission were identified as:

1. Before a patient with an infection is diagnosed (access and assessment)
2. Before a patient with an infection is treated (investigation and diagnosis)
3. After a patient with a diagnosed infection is offered treatment (ongoing management)

3.6. Stakeholder consultation

At an early stage, the study's Reference Group, clinicians working in specialist and integrated SRH settings, PHE and PHW's surveillance experts and a wider group of stakeholders in the field were consulted on the proposed topic selection and prioritisation. The following section describes the methods of consultation and the summary findings.

<u>Reference Group topic selection survey</u>

The Reference Group was consulted via an online survey. All Reference Group members were presented with the shortlisted audit topics and invited to provide feedback using a short, structured survey focusing on the following[7]:

- Current priorities in sexual healthcare
- Awareness of quality improvement initiatives in any of the areas shortlisted
- Perceived importance of each aspect of care for reducing transmission
- Top three aspects of care most likely to be improved through audit, and why

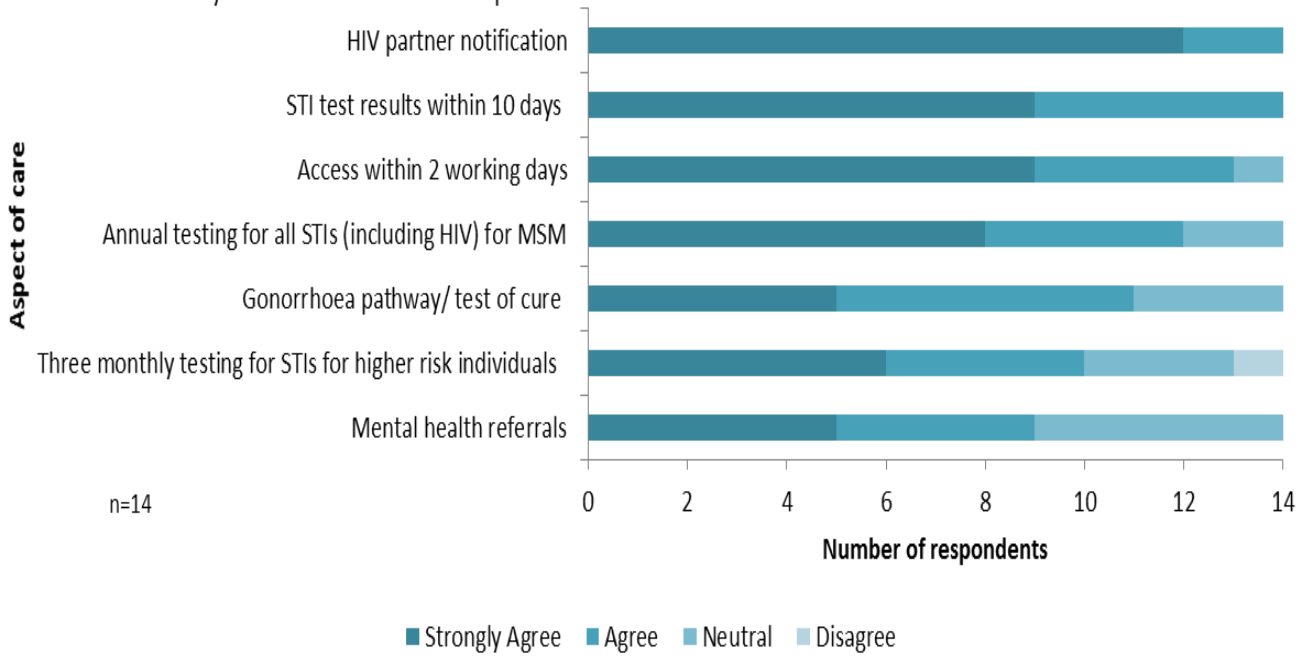
Sixteen out of nineteen invited Reference Group members responded to the survey. An overview of their responses is shown in Figure 6:

[7] Full details of the topic selection survey questions and responses and consultation meetings are provided in Annex 3 The Reference Group was presented with the initial shortlisted audit measures, however only the responses relevant to the audit measures recommended for early inclusion in an audit are presented in the main body of this report.

Figure 6 Reference Group survey responses

Aspects of care important for reducing STI and HIV transmission:

The Reference Group rated each aspect of care according to its importance for reducing STI and HIV transmission and was asked to prioritise aspects of care for audit. The Group collectively agreed that HIV partner notification and turnaround times between the STI test and the availability of results were the most important measures for audit:



Aspects of care most likely to be improved through NCA:

The Group was asked to select the three aspects of care which they felt were most likely to be improved through NCA. Collectively, clinicians reported that the following were most likely to be improved through a NCA. The four aspects of care which the group collectively selected as being most likely to be improved through NCA were:

1. HIV partner notification *(64% selected)*
2. Annual testing for all STIs (incl. HIV) among MSM *(50% selected)*
3. Access to services within 2 working days *(36% selected)*
4. STI tests results within 10 days *(36% selected)*

"there is an ever-increasing rise in the amount of cases of early syphilis, so we need to stay on top of the epidemic"
FSRH on syphilis

"Small improvements in annual testing, regular testing and obliterating the gap between results availability and timeliness of action will make huge impact and drive for improving the tertiary care pathway as well as further community/partner notification aspects."
Royal College of Physicians on pathways

"I have chosen the areas of service that are most likely to have high impact - prevention and wider population / partners. I think these areas often are lower priority than the direct clinical care..." **Local Government Association on HIV PN, chlamydia re-testing & information to patients**

Consultation with clinicians working in GUM and integrated SRH services

Clinicians working in GUM and integrated SRH services were also asked to feedback using the online survey. Participants were recruited via BASHH (members' newsletter, National Audit Group and Clinical Effectiveness Group), BHIVA (autumn conference and members newsletter) and an e-bulletin sent by the FSRH to its network of lead clinicians in GUM and/or SRH settings. Forty-five clinicians, most of whom were consultant GUM physicians, and just over half of whom had a defined local or regional role in audit took part. A summary of their feedback is given in Figure 7.

Figure 7 Consultation with clinicians working in GUM and integrated SRH services - survey responses

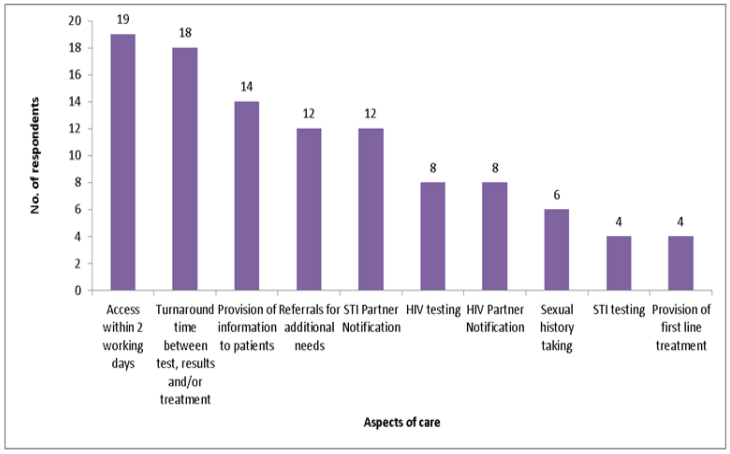
Overview of survey respondents

- 45 clinicians working in GUM and integrated SRH clinics took part in the online survey
- 64% worked in settings which provide specialist GUM care only
- 12% worked in settings which provide integrated SRH healthcare
- The overwhelming majority of respondents described their role as 'Consultant'
- 58% had a defined role in clinical audit

Aspects of care most likely to improved through NCA:

Clinicians were asked to select the three aspects of care which they felt were most likely to be improved through NCA. Collectively, clinicians reported that the following were most likely to be improved through a NCA:

1. Access within 2 working days (53% selected)
2. Turnaround time between test, results and/or treatment (50% selected)
3. Provision of information to patients (39%)



Experience of audits in local setting

Collectively, clinicians reported that their clinics had taken part in an audit of at least one of the shortlisted aspects of care. Additionally, nearly all clinicians reported that their clinical setting had undertaken one or more audits in topics other than those shortlisted.

These findings suggest that local settings are already familiar with collecting audit data. However, local audits' ability to drive quality improvement is hindered because:

- They are intermittent
- Samples sizes are small (usually 40 cases for each audit measure)
- A re-audit phase is not included

Barriers to quality improvement in local clinics

Clinicians were asked whether anything specific hinders quality improvement in their local setting. Responses were consistent and included:

- Limited protected time for quality improvement
- Limited human and financial resources to engage meaningfully in audit
- Lack of support from the Trust and/or board
- Focus on a large number of key performance indicators
- Emphasis on audit target rather than improvement
- Difficulty balancing clinical delivery and audit requirements
- Uncertainty caused by tendering and commissioning process and attitudes
- Poor quality data, including lab data

Facilitators of quality improvement in local clinics

The overwhelming response from clinicians consulted throughout this feasibility study suggests that a mandatory national clinical audit is desired, provided that the resources to implement it are also made available at clinic level. Clinicians were asked whether anything specific would help drive quality improvement in their local setting. Their responses were consistent and the main suggestions were:

- Benchmarked data against national standards
- Comparative data at local authority, regional and national level
- Sharing of best practice
- Training and support for all staff involved

Consultation with commissioners of STI and HIV care and PHE sexual health facilitators

The English HIV and Sexual Health Commissioners Group is the professional forum for those undertaking sexual health and HIV commissioning activities in England. The Study Manager presented the proposed audit measures at a scheduled meeting of the group and sought feedback. Meeting attendees suggested that it would be helpful to audit access to care and that safeguarding should be audited in some way (see section 3.10).

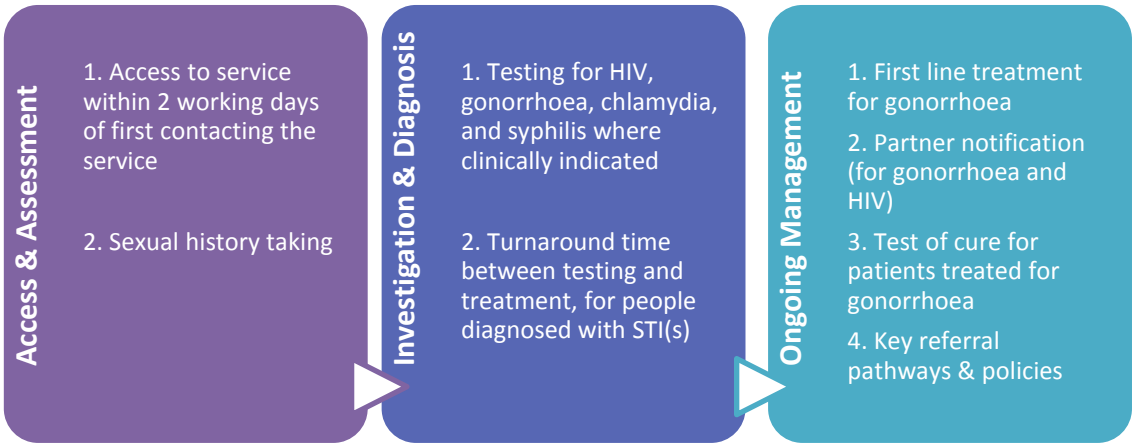
Feedback was also sought, using a similar approach, from PHE's regional Sexual Health Facilitators who are responsible for supporting the commissioning and delivery of sexual health, reproductive health, and HIV services across defined geographical areas. The consensus was that it would be feasible to audit the proposed measures in GUM and SRH settings where local specifications are based on the suggested service specification published by the DH (34) and require compliance with BASHH clinical guidelines. The Facilitators were asked to review a sample of local service specifications and share these with the Study Manager. Findings from this scoping exercise suggest that some services are already required to report relevant data to their local authority commissioner. It was suggested that at present, provider organisations and healthcare professionals prioritise performance indicators where suboptimal performance leads to a financial penalty, and alignment between these indicators and the recommended audit measures would be a strong local driver for quality improvement.

3.7. Prioritisation and revision of shortlisted audit measures

Following the scoping, pathway analysis, consultation and discussion of key concerns, the shortlist was reviewed again in order to prioritise audit measures for early inclusion in a NCA. Methods of data collection to capture each of the measures were assessed and the Steering Group agreed on a revised shortlist of audit topics and measures.

The audit domains, topics and measures are presented in this report as a collection, which, if audited together, could provide a comprehensive review of the quality of care across the entire pathway. Each audit domain comprises two or four audit topics (see Figure 8):

Figure 8 Recommended audit domains and topics



PHE and PHW's surveillance team representatives identified alignment of the shortlisted audit topics with existing national data flows. An early overview of data availability is shown in Table 2:

Table 2 Availability of data for shortlisted audit topics

	All data available nationally or locally (by 2017)	Some data available nationally or locally (by 2017)	No existing plans for data collation nationally or locally (by 2017)
DOMAIN A: Access & Assessment			
1. Access to service within 2 working days of first contacting the service	✓		
2. Sexual history taking	✓		
DOMAIN B: Investigation & Diagnosis			
1. Testing for HIV, gonorrhoea, chlamydia, and syphilis, where clinically indicated	✓		
2. Turnaround time between testing & treatment, for people diagnosed with STI(s)	✓		
DOMAIN C: Ongoing Management			
1. First line treatment for gonorrhoea			✓
2. Partner notification (for HIV and gonorrhoea)		✓	
3. Test of cure for patients treated for gonorrhoea	✓		
4. Key referral pathways & policies			✓

3.8. Domain A: Access & Assessment

Access and assessment comprises two audit topics, which are elements in reducing STI transmission in the period between infection and diagnosis.

Topic A1: Access within two working days of first contacting a service

Rationale

Access to services is a fundamental part of any STI or HIV care pathway. The public health reasons for improving access to sexual health services are well documented and the effective provision of rapid testing, diagnosis and treatment of STIs (including HIV), has been shown to have a large impact on reducing their onward transmission (35;36). A 48-hour GUM waiting time target was previously introduced as a priority target in the 2006/7 NHS Operating Framework for England (35) and then as a standard until 2011. The standard was initially monitored by the Health Protection Agency and BASHH, and then by the DH from 2009 to 2011 via a Genitourinary Medicine Access Monthly Monitoring tool (GUMAMM). Data were collected, from over 140 NHS providers and one in the private sector, to monitor the attainment of the target (37). During this period, waiting times improved to almost 100% by 2011. GUMAMM was suspended in 2011 and formally withdrawn by Information Standards Notice in April 2014 (8).

Recommended standard

Standard 1 in the *Standards for the management of STIs* (1.2.1 and 1.2.2) (28) states that people with needs relating to STIs should have rapid and open access to a range of local confidential services for STI testing and treatment[8].

Measures	Standard	Recommended audit question
The percentage of people with needs relating to STIs contacting a service who are offered to be seen or assessed with an appointment or as a 'walk-in' within 2 working days of first contacting the service.	98%	*What percentage of people with needs relating to STIs contacting a service are offered to be seen or assessed with an appointment or as a 'walk-in' within 2 working days of first contacting the service?*
The percentage of people with needs relating to STIs contacting a service who are seen or assessed by a healthcare professional within 2 working days of first contacting the service.	80%	*What percentage of people with needs relating to STIs contacting a service are seen or assessed by a healthcare professional within 2 working days of first contacting the service?*

Availability of data

Although national data collection through GUMAMM was discontinued in 2011, access to care within two working days is still included in the majority of local authorities ' service contracts as a key performance indicator[9], and so most providers will already have in place a mechanism for collecting these data. The burden of the bespoke data collection for this measure is therefore believed to be minimal.

8 This means that people with needs relating to STIs can go to any sexual health service, in or out of their local area, without needing to see their GP first and should be able to either 'walk in' or be offered an appointment within two working days of contacting a service commissioned to manage STIs. This includes the option to pre-book an appointment within their local authorities.

9 Based on consultation with PHE Sexual Health Facilitators who scoped a sample of their local service specifications in Dec 2015-Jan 2016.

Topic A2: Sexual history taking

Rationale

Taking an accurate sexual history underpins good clinical management and helps to assess risk and ascertain contributory risk behaviours, determine the potential source of infection and guide the clinician to offer appropriate testing (for example, specimen type and site), information and advice (38) .

A limited BASHH audit of sexual history taking in 2008 showed sub-optimal numbers of clinicians collected information about condom use at last sex, and only a marginal improvement (3%) was observed at re-audit two years later. There is clear room for improvement and initiatives include:

- Improving competency in sexual history taking
- Training for staff to enable them to capture all required information during consultations
- Improving and standardising proformas to improve documentation and decrease variability in sexual history taking

Standard 2.2.1 of the *Standards for the management of STIs* (28) states that people with needs relating to STIs should have a medical and sexual history taken, which includes questions about sexual behaviour and other risk factors. Two markers of sexual history have been chosen for their sensitivity as a measure of good risk assessment. As a future NCA develops over time, it may be possible to use sexual risk assessment algorithms instead of the proxy markers recommended at this early stage.

Recommended standard

Measure	Standard	Recommended audit question
Sexual history taking: The percentage of people accessing services …who have a relevant sexual history taken (as defined by BASHH national guidelines for differing symptoms) by the STI service provider.	97%	*What percentage of people receive a full sexual history assessment, as evidenced by a documented response to the following questions:*[10] How many sex partners did you have in the last 3 months? **AND** For heterosexuals: Did you/your partner use a condom the last time you had penetrative (vaginal or anal) sex? **OR** For MSM: Have you had any condomless anal intercourse in the last 3 months?

Availability of data

Data on sexual history taking are available in patient records; many of which (although not all) are electronic. These data are however difficult to extract, especially when entered as free-text, and an audit can currently only be performed by individual case-note review, thereby limiting the sample size. PHE's planned GUMCADv3 system (see section 4.6) has provision to record and report these data electronically to the national dataset and, dependent on data completeness, would enable the entire population accessing STI care to be included in a NCA and for all clinics reporting to this mandated dataset to be included.

10 PHW may use different marker questions.

3.9. Domain B: Investigation & Diagnosis

Domain B comprises two topics relating to process measures central to reducing STI transmission, before an individual with an STI infection receives a positive diagnosis of their infection(s) and any further treatment or care.

Measure B1: Offer of STI testing

Rationale

'Testing' is an overarching term that refers to diagnostic and opportunistic testing for STIs in both symptomatic and asymptomatic individuals, in any setting (39). STI testing is a core component of the STI patient care pathway and of STI prevention at the population level. The main benefits of STI testing arise from the diagnosis and prompt treatment and management of the patient to limit serious sequelae, prevent onward transmission and facilitate PN (39). With many infections being asymptomatic, testing is fundamental to clinical services' ability to reduce morbidity and, in the case of HIV, mortality.

HIV infection has a long asymptomatic latent phase and can remain undiagnosed for several years, during which it can be transmitted to others. At the individual level, undiagnosed HIV can lead to late presentation, progressive damage to the immune system and life-threatening, AIDS-defining illness such as tuberculosis, leading to increased healthcare costs.

The comprehensive offer of a diagnostic test for HIV, gonorrhoea, chlamydia, and syphilis, as part of an STI screen, is recommended to maximise the opportunities for prompt diagnosis.

Testing for HIV is a key national and international priority for the prevention and management of this chronic infection; however, there appears to be both an inequity in access to testing for certain groups and significantly variation in delivery across services. In 2014, 80% (179/223)of GUM clinics in England achieved the BASHH standard of 80% HIV testing coverage among eligible MSM attendees (40). However, HIV testing coverage was lower among heterosexual men and women, where only 15% of clinics achieved the 80% standard (40). There are marked variations in HIV test coverage between regions and between clinics in the same region (14). Studies have estimated that between 3% and 7% of MSM who did not have an HIV test at their clinic visit have undiagnosed HIV infection (41;42).

The case for early diagnosis of chlamydia is also compelling; with late diagnosis leading to significant increased risk of infertility (43). In 2014, there was notable variation in the chlamydia detection rate among 15 to 24 year-olds by geographic area, which largely reflects variable rates of testing around England. An audit would aim to reduce variability in testing and improve detection of chlamydia, thereby reducing transmission. The largest proportion of chlamydia tests took place in GUM clinics (35%), with a significant proportion also taking place in SRH (19%) and primary care (18%) venues (14). The establishment of the NCSP and the inclusion of chlamydia detection rates as a Public Health Outcomes Framework (PHOF) indicator indicate the national importance of chlamydia testing.

Standard 2.4.7 of the *Standards for the management of STIs* (28) states that people with needs relating to STIs should as a minimum be offered tests for gonorrhoea, chlamydia, syphilis and HIV.

Recommended standard

Measure	Standard	Recommended audit question
The minimum investigations, even if asymptomatic, are tests for chlamydia, gonorrhoea, syphilis, and HIV.	97%	*What percentage of patients with needs relating to STIs are offered a test for chlamydia, gonorrhoea, syphilis, **and** HIV at first attendance?*

Availability of data

STI testing data are already routinely collected and reported by all GUM and around half of SRH clinics in the GUMCAD dataset. Quarterly data submission means that benchmarked performance feedback can be provided to clinics on a regular basis but currently has a time lag. For the purpose of a NCA, improving the turnaround time for the availability of audit results would be most beneficial for observing the effects of quality improvement initiatives and encouraging clinician engagement.

Measure B2: Turnaround time between test and treatment

Rationale

There is suspected variation in the length of time it takes for patients to receive their STI results and re-attend for treatment between different clinics. Untreated infection is a cause of continued STI transmission. A cross-sectional survey of over 3000 consecutive new patients attending four GUM clinics found that, among symptomatic GUM clinic attendees, 45% of men and 58% of women continued to have sex while awaiting treatment, with 7% reporting sex with more than one partner (36). Reducing turnaround time will help ensure prompt and correct treatment and interrupt STI transmission.

Measuring the length of time between the offer of STI testing and uptake of treatment is a composite measure of several processes, namely:

1. time between specimen collection (patient testing) and laboratory receiving specimen(s)
2. time between laboratory receiving specimen(s) and providing results to the clinic
3. time between clinic receiving results and making these available to the patient
4. time between patient receiving results and attending for treatment

Recommended standard

Standard 4.4.10a in *Standards for the management of STIs* states that all providers of services commissioned to manage STIs should ensure that they have appropriate mechanisms in place to provide treatment to people diagnosed with an STI in as short a timescale as possible.

Measure	Standard	Recommended audit question
All patients should start treatment promptly	97%	*What is the turnaround time (in days) between STI testing date and STI treatment date?*

Availability of data

While the duration of each of the stages described above depends on clinic availability, laboratory turnaround times and patient ability and willingness to attend, there is scope for clinics to improve access for patients requiring treatment, for example, by using SMS reminders or fast-track appointment services, thereby reducing the length of time of untreated infection and transmission. By auditing the beginning and end-points, clinics whose patients are not routinely receiving treatment promptly after STI testing can be prompted to investigate their local clinical and laboratory processes, perform root-cause analyses, and pinpoint the stage of the pathway that is leading to delays. While the *Standards for the management of STIs* state that 97% of patients should receive their STI test results within 10 working days of the specimen being taken and should receive 'prompt' treatment, BASHH national clinical guidelines for the management of gonorrhoea chlamydia and syphilis do not specify an optimal time within which treatment should have commenced. A future audit therefore has the potential to set achievable and aspirational standards for turnaround times, which could become the basis for refining BASHH's national clinical guidelines and the *Standards for the management of STIs*.

3.10. Domain C: Ongoing Management

Ongoing management comprises four topics relating to aspect of care that are vital for reducing STI transmission after an individual with an STI infection receives a diagnosis of their infection(s).

Topic C1: First line treatment for gonorrhoea

Rationale

Gonorrhoea, caused by the bacterium *Neisseria gonorrhoeae*, is the second most common bacterial STI in England. Gonorrhoea has successively become resistant to different antimicrobials over time. Current first line treatment for gonorrhoea involves dual therapy with ceftriaxone (500mg) and azithromycin (1g). Prescribing according to these national treatment guidelines will help slow the spread of resistant gonorrhoea (15).

Sentinel surveillance in 25 GUM clinics, set up to monitor gonococcal resistance, has clearly demonstrated the development of resistance over time. The prevalence of azithromycin resistant gonorrhoea was 1% in 2014 and while infections resistant to ceftriaxone are still rare, 0.3% of isolates reported from diagnostic laboratories that year were resistant, supporting the dual therapy approach (16).

The sentinel surveillance further showed that 14.2% of patients were not prescribed the recommended treatment. It is likely that nationally the proportion is higher. Most of these patients were prescribed a different dual combination (ceftriaxone and doxycycline) possibly to manage a complicated gonococcal infection or co-infection with rectal chlamydia. However, it is now recommended in these cases to prescribe all three antibiotics. Since over 70% of gonococcal isolates are resistant to tetracycline/doxycycline, use of this drug in combination with ceftriaxone does not provide a good pharmacological barrier to the development of resistance (44).

Recommended standard

The BASHH *UK national guideline for the management of gonorrhoea in adults* (15) makes the following recommendation:

Measure	Standard	Recommended audit questions
All patients with gonorrhoea should receive first line treatment (ceftriaxone 500 mg intramuscularly immediately plus azithromycin 1 g orally immediately) or the reasons for not doing so should be documented	97%	a) *What percentage of patients with gonorrhoea receive appropriate first line treatment?* b) *For patients who did not receive appropriate first line treatment, for what percentage were the reasons for treatment choice documented?*

Availability of data

The treatment prescribed for gonorrhoea is likely to be recorded in patient notes and available from individual clinics. First line treatment is not one of the suggested Quality Outcome Indicators[11] in the suggested national service specification, which local authorities use when commissioning sexual health services, nor is it reported through GUMCAD. Supplementary data collected directly from clinics would be needed to answer this audit question.

[11] Quality Outcome Indicators are locally determined by local authorities commissioning the service.

Topic C2a: Partner notification for gonorrhoea

Rationale

PN, sometimes referred to as contact tracing, is the process of identifying, contacting, testing and, where indicated, offering treatment to exposed sexual partners of index patients who have been diagnosed with an STI. PN includes identifying a look-back period during which STI transmission may have occurred, agreeing and recording with the index patient which sexual partners to contact and how this should be done, and following up and recording the outcomes of attempted contact actions.

Reinfection with gonorrhoea, often occurring between sexual partners when both are infected but only one treated, is common (45). Therefore, informing and encouraging testing among sexual contacts is important for targeted detection and diagnosis among those at risk, with consequent benefits of reducing onward transmission, including that of drug-resistant strains, and reducing the complications of untreated infection among individual patients. Successful PN also presents an opportunity to meet other sexual health needs, such as managing risk behaviour (46), and providing prevention messages for other STIs and HIV. As PN has the potential to improve the outcomes of individual sexual contacts and wider sexual networks, the process can result in individual and population health gains (47-54).

PN is important for all STIs but gonorrhoea has been chosen initially as a marker for this process because infection suggests high-risk behaviour and the short symptomatic phase or, commonly, a lack of any obvious symptoms means that infection often spreads silently within sexual networks. A number of recommendations exist for effective PN based on studies conducted outside the UK. Several research studies are currently underway to identify the most effective way for PN to be delivered in the UK, which will, in time, inform quality improvement initiatives. Auditing this outcome measure will provide invaluable data that can be used to interpret the effectiveness of PN strategies over time for patients diagnosed with gonorrhoea

Recommended standard

Both a process and an outcome measure are recommended here, as this would provide clinics with useful baseline information from which to investigate their PN activities further and develop action plans to address any underperformance in this area.

The 2011 BASHH *UK national guideline for the management of gonorrhoea in adults* (15) states all patients identified with gonorrhoea should have PN carried out according to the published standards of the BASHH Clinical Standards Unit. The 2012 BASHH *Statement on Partner Notification for STIs* states that at least one discussion (which may be a face-to-face or telephone discussion) should be offered to people found to have the infections listed [which include chlamydia, gonorrhoea, syphilis and HIV] to begin the PN process. This discussion should be provided by a healthcare worker (HCW) with the appropriate documented competency. If the offer of discussion of PN is declined, the reason for this should be documented. Standard 4.5.11 in *Standards for the management of STIs (2014)* also states all services managing STIs should be expected to instigate PN as part of the management of STIs.

Based on these three sources, the following auditable process and outcome measures are recommended:

Measures	Standard	Recommended audit questions
The percentage of index cases documented as offered at least one discussion, which may be a telephone discussion, for the purpose of PN with a HCW with the appropriate documented competency.	97%	a) *What percentage of index patients are documented as having been offered at least one discussion, which may be a telephone discussion, for the purpose of PN with a HCW*
The number of all contacts whose attendance at a sexual health service was documented as reported by the index case, or by a HCW, within four weeks of the date of the first PN discussion.	At least 0.4 contacts per index case in London clinics, or at least 0.6 contacts in clinics outside London, and documented within four weeks of the date of the first PN discussion.	b) *How many contacts were documented as having attended a sexual health service, as reported by the index patient or by a HCW, within four weeks of the date of the first PN discussion?*

Further details of how to measure PN for gonorrhoea can be found in 2012 BASHH *Statement on Partner Notification for STIs*-see Annex 3.

Availability of data

PHE plans to collect data about contacts attending a service through PN; however these are not likely to be available until 2017 and only address the outcome measure (number of contacts attending through PN) recommended above. Process and outcome related data for gonorrhoea PN are likely to be recorded at the local clinic level but, due to the complexity of PN and varying definitions, are unlikely to be collected consistently between different clinics. Consultation with PHE's Sexual Health Facilitators suggests that supplementary audit data about PN for gonorrhoea can be collected directly from clinics using a bespoke data collection tool and with clear guidance for data definitions, coding, capture, and submission.

Topic C2b: Partner notification for HIV

Rationale

BASHH and BHIVA conducted a joint audit of HIV PN, by case-note review in 2011 (55)[12]. This exercise found that PN was very effective at case finding, with 21% of susceptible contacts tested through the PN process diagnosed with HIV infection as a consequence.

The diagnosis rate was highest, at 24.6%, among black Africans. The study estimated that a further 138 *potentially* contactable individuals were infected with HIV but remained undiagnosed. The audit found significant regional variation, ranging from 62% to 97% of patients for whom PN was done, and that this was unlikely to be accounted for by case mix alone. The audit recommendations included a call for all services to review their performance and seek to improve PN outcomes. The BASHH standards for HIV PN have since been developed and published.

Surveillance data, which record when a patient attends an STI clinic as a result of PN (2), suggest that the HIV PN ratio of contacts per index case attending an STI clinic was 0.54, which is notably lower than the minimum BASHH/BHIVA standard of 0.8 per index case. The same surveillance data also show that 5.6% of patients attending following PN, who had an HIV test, received a positive test result (2).

The positivity rate found through the BASHH and BHIVA audit is much higher than that calculated from surveillance data. This variance might be due to a combination of:

- different time periods for data collection (BASHH/BHIVA – 2011; PHE – 2014)
- different data collection methodologies (BASHH/BHIVA - case note review; PHE – estimated figures)
- different settings (BASHH/BHIVA – included infectious disease services; PHE – sexual health services only

In 2015, for the first time, national definitions, outcomes, and standards for HIV PN(49) were published that aim to support the improvement of HIV PN delivery. It is recommended that PN should be completed within three months following diagnosis but should continue for longer if applicable. Inclusion of HIV PN in a NCA will enable more reliable and continuous capture of data, to identify best performers and facilitate the sharing of good practice for sustainable quality improvement.

[12] Contact tracing also includes follow-up, and testing of children born to newly diagnosed mothers.

Recommended standard

BASHH and BHIVA recommend that HIV PN be audited against the following process and outcome measures:

Measures	Standard	Recommended audit questions
Proportion (%) of indexes for whom there is a documented PN plan in the case notes 4 weeks after index case diagnosis.	97%	a) *For what percentage of index patients is there a documented PN plan in the case notes 4 weeks after index patient diagnosis?*
Number of contacts[13] tested per index	0.6 HCP[14] verified	b) *How many contacts are tested per index patient as verified by the HCW at 3 months after diagnosis?*
	0.8 Index reported or HCP verified (i.e. those captured via either)	c) *How many contacts are tested per index patient as reported by the index patient or verified by the HCW at 3 months after index patient diagnosis?*

Availability of data

As for gonorrhoea PN, PHE plans to collect data about contacts attending a service through HIV PN; however these are not likely to be available until 2017 and only address the outcome measure (number of contacts tested) recommended above. Data for PN for HIV are likely to be recorded at the local clinic level but, due to the complexity of PN and varying definitions, they are unlikely to be collected consistently between different clinics. Consultation with PHE's Sexual Health Facilitators suggests that supplementary audit data about PN for HIV can be collected directly from clinics using a bespoke data collection tool and with clear guidance for data definitions, coding, capture and reporting.

[13] Definitions for contacts, partners, contactable partners and other terms associated with PN are included in Annex 2

[14] Healthcare professional and healthcare worker are used interchangeably.

Measure C3: Test of cure for gonorrhoea

Rationale

The increasing prevalence of infection, especially in groups who exhibit high-risk behaviours, the declining susceptibility to currently used antibiotic treatment and the growing risk of poor reproductive and sexual health outcomes, as well the risk of onward transmission, make gonorrhoea a major public health concern. Patients previously diagnosed with gonorrhoea are more likely to be infected with azithromycin resistant strains. The offer and uptake of a test of cure following treatment is deemed an important aspect of high quality management of gonorrhoea infection (15). Infections that appear to persist following the recommended course of treatment are tested for resistance to inform further management.

Auditing test of cure will support quality improvement by clinicians to:

- confirm adherence to abstinence advice
- ensure symptoms, if present, have been resolved
- identify treatment failure
- identify emerging resistance
- take a sexual history to explore the possibility of reinfection and promote low risk behaviours
- continue follow up and PN
- exclude re-infection

Recommended standard

The BASHH *UK national guideline for the management of gonorrhoea in adults* (15) recommends that all patients treated for gonorrhoea should be offered a test of cure.

Measure	Standard	Recommended audit questions
All patients treated for gonorrhoea should be recommended to have a test of cure.	97%	*What percentage of patients treated for gonorrhoea receive a test of cure within 2 weeks of completing treatment?** *To establish variability in the offer of test of cure, receipt of test of cure will be used as a surrogate marker.

Availability of data

Data about the receipt of a test of cure can be obtained indirectly from GUMCADv2. A defined coding algorithm should be used to identify a diagnostic visit followed within an agreed timeframe by a visit likely to be a test of cure visit, as indicated by the nature of the assigned coding. As an audit develops over time, it may be possible to collect spotlight direct data on the offer and/or uptake of a test of cure.

Measure 4: Documented evidence of referral pathways and safeguarding policies

Rationale

Alcohol and substance use, and mental health concerns, can be important underlying contributory factors for STI acquisition and reinfection (56-59). These broad health concerns require effective management at the patient level to address high-risk behaviours and prevent onward transmission and reinfection. Effective management includes initial recognition of the risk through effective sexual history taking, provision of information, advice and support by sexual health services and a broader range of health promotion and other interventions by services specialising in alcohol and substance misuse and mental health.

All healthcare professionals have a direct or indirect role in health promotion and supporting patients to make healthy lifestyle choices. The NHS England framework, *Making Every Contact Count* (60), and the NICE *Alcohol-use disorders* guidance (61) seek to promote a whole-systems approach to behaviour change. Utilising these frameworks would enable partners in different sectors to work together to achieve real and lasting changes in individual behaviour, which would reduce the risks of STIs at individual and population level. Specifically, standard 2.5.3 in the *Standards for the management of STIs* ((44) states that alcohol history taking is recommended as part of the risk assessment for STIs, and the use of recreational drugs, history of sexual coercion and intimate partner violence should also be considered for specific groups. Additionally, the standards (2.5.5) state that if specific needs are identified that the healthcare professional or service cannot manage, care pathways should be in place for onward referral of the individual.

Paragraph 2.5.6 in the *Standards for the management of STIs* states that staff providing care for under-18s should follow local and national guidance on safeguarding children and paragraph 2.4.2 states that all providers of services managing STIs should ensure that they have appropriate mechanisms in place for implementing safeguarding and vulnerable adults' policies and the training of staff to support these(28). Furthermore, to support the Care Quality Commission's (CQC) efforts in safeguarding children and adults (62) and to help sustain improvements resulting from the 2013-2015 CQC inspection on local health arrangements for safeguarding children, it is recommended that simple data be collected from all STI care providers in line with the S*tandards for the management of STIs*.

Recommended standard

Measures	Standard	Recommended audit questions
All clinics should have care pathways for patients with identified alcohol, drug and/or mental health needs	97%	*Does the clinic have documented care pathways for patients with identified:* ○ *Alcohol related needs?* ○ *Drug related needs?* ○ *Mental health needs?*
All providers should have documented good practice protocols and/or guidance for safeguarding of children and adults in their care.	97%	*Does the clinic have documented good practice protocols and/or guidance for safeguarding of children and adults in their care?*

Availability of data

The auditable standards of care (above) relating to alcohol, drugs, and mental health refer to patient level care. Although limited patient level audit data, concerning drug use and alcohol use, will be collected nationally through PHE's future GUMCADv3 dataset, these are currently 'optional' data fields. Consultation with surveillance experts at PHE suggests that the level of completion of these specific fields is likely to be low following the initial roll out of the dataset, and therefore an unsuitable source of patient level audit data. No data are collected nationally concerning the mental health needs of patients attending services for STI related care. Due to the limited availability of patient level data relating to alcohol, drugs, and mental health, it is recommended that these priority areas be explored initially through the collation of organisational data on existing care pathways and good practice protocols and/or guidance. These organisational data are likely to be available directly from individual clinics. Collecting these data would require simple dichotomous questions, which can be presented to clinics using a bespoke data collection tool.

4. Assessing the technical feasibility of data collection

4.1. Introduction

The audit topics recommended for early inclusion in a NCA each pertain to a specific aspect of the care pathway. The component audit measures within each topic have been selected to highlight variation in clinical performance. While each audit topic can be audited independently, the interdependency of multiple stages in the patient pathway means that auditing all aspects of care together would lead to quality improvements, which extend to other STIs and throughout wider sexual and reproductive healthcare.

The feasibility of obtaining audit data from all GUM and integrated SRH clinics nationally was reviewed with particular emphasis on providing feedback to clinicians and maximising early engagement in the audit, reducing the burden of data collection and making the best use of existing data available nationally. This process involved consultation with PHE and PHW's national STI and HIV surveillance experts and PHE's regional Sexual Health Facilitators, and reviewing existing datasets.

4.2. Recommended audit settings for early inclusion and availability of data

In England, it is recommended that all GUM and integrated SRH clinics that are commissioned to manage STIs at level 3 or level 2[15] be included in the audit. In Wales, all providers of STI and HIV care (integrated SRH clinics) should be included in a future NCA.

Data are collected from GUM and integrated SRH clinics in England and Wales through the surveillance systems, GUMCAD and SWS[16], respectively. For four of the eight topics proposed in this report, these systems can either already provide or are currently being developed to be able to provide some or all of the information needed. For two topics, national data are likely to be readily available for a future national clinical audit but will need to be collated from existing local sources. Supplementary data needed to audit the two remaining topics can be collected using a bespoke tool. Table 3 provides an overview of recommended data sources for each audit measure and the likely availability of this data. More detail about data fields required, exemptions, exclusions and considerations are available in section 4.6.

[15] Level 3 and level 2 refer to the types of services that are provided in different clinical settings. A list of specific services provided at levels 3, 2 and 1 is provided in Annex 2.

[16] Sexual Health in Wales Surveillance Scheme (SWS)

Table 3 Summary of data sources and availability

	Availability of data	Data source
DOMAIN A: Access & Assessment		
1. Access to service within 2 working days of first contacting the service (offer)	Locally collated	Bespoke reporting required
Access to service within 2 working days of first contacting the service (seen)	Locally collated	Bespoke reporting required
2. Sexual history taking	Nationally collated by 2017	Mandated data flow from GUMCAD3*, in England Bespoke reporting required, in Wales
DOMAIN B: Investigation & Diagnosis		
1. Testing for HIV, gonorrhoea, chlamydia and syphilis, where clinically indicated	Nationally collated	Mandated data flow from GUMCADv2 or 3*/SWS
2. Turnaround time between testing & treatment, for people diagnosed with STI(s)	Nationally collated	Mandated data flow from GUMCADv2 or 3*/SWS
DOMAIN C: Ongoing Management		
1. First line treatment for gonorrhoea	Captured at clinic level	Bespoke reporting required
2. Partner notification (for gonorrhoea) - documentation	Captured at clinic level	Bespoke reporting required
Index: contact ratio	Nationally collated by 2017	Mandated data flow from GUMCAD3*, in England Bespoke reporting required, in Wales
Partner notification (for HIV) - documentation	Captured at clinic level	Bespoke reporting required
Index: contact ratio	Nationally collated by 2017	Mandated data flow from GUMCAD3*, in England Bespoke reporting required, in Wales
3. Test of cure for patients treated for gonorrhoea	Nationally collated	Mandated data flow from GUMCADv2 or v3/SWS
4. Key referral pathways & policies	Captured at clinic level	Bespoke reporting required

* References to GUMCAD v2 or v3 are included to show that data are currently available in GUMCAD v2 and will be retained in GUMCAD v3. Data regarding sexual history taking are not currently collected in GUMCAD v2 and will therefore only be available once GUMCAD v3 is implemented nationally.

4.3. PHE Datasets

Sexual health services providing level 3 and 2 management of STIs are required to report to GUMCADv2. Details of the GUMCADv2 and v3 datasets are included in Annex 4.

Table 4 Overview of service levels provided in different healthcare settings reporting GUMCAD data

Service Type	Service levels provided	Mandatory reporting of GUMCADv2
GUM services	Level 3[17]	Yes
Integrated GUM and SRH services		
SRH services	Level 2[18]	Yes - but only if the service has been commissioned to provide STI management at Level 2 as recommended by the *Standards for the management of STIs* (28).
Young people's services e.g. Brook clinics		
Enhanced GP		
Other sexual health services e.g. outreach programmes, termination of pregnancy services, community testing services		

GUMCAD v2 and v3

GUMCADv2, the primary surveillance system for sexual health in England, links care episodes to individual GUM clinic attendees (patients) and produces pseudo-anonymised[19] longitudinal sexual health data by place of residence for patients who continue to attend the same clinic. GUMCADv2 data are collected and analysed to monitor trends in new diagnoses of STIs and other sexual health problems and to determine which specific groups are at particular risk.

GUMCAD data are used to:

- identify public health priorities to shape policy and the public health response
- improve the planning and management of services
- develop, adapt and refine interventions
- monitor the effectiveness of sexual health policies and interventions
- enable effective commissioning of sexual health services
- contribute to research of sexual health needs and service delivery

GUMCADv3 will build on GUMCADv2 and will collect information about the following:

- sexual behaviour
- alcohol and drug use behaviour
- previous STI clinic attendance
- PN
- enhanced monitoring of HIV pre-exposure prophylaxis

These additions are based on recommendations made in the 2013 *UK national guideline for consultations requiring sexual history taking* (63).

[17] Coverage is 100%
[18] Coverage is around 45% of all providers of level 2 services and is improving over time
[19] Pseudo-anonymised means that data contain the patient's clinic/hospital number but they do not contain patient-identifiable information such as name, date of birth, or postcode.

The aim is to accommodate them through modification of existing clinic electronic patient record (EPR) systems. Working with software suppliers and a subset of six sites, including providers of level 3 (GUM) and level 2 (integrated SRH) services, a GUMCADv3 'patch' to the existing EPR has been developed and piloted at five sites. By adapting clinic EPRs, good levels of completion of the additional sexual health data were ensured whilst minimising service disruption and workloads. Compliance with paper data collection was relatively low. Feedback from this first phase of piloting suggested that this enhancement was a feasible and welcome development, but that selected sections of the specification should be simplified. As a result, a second phase of GUMCADv3 piloting commenced in September 2015 and has an anticipated end date in the summer of 2016.

Information generated while piloting GUMCADv3 will inform an application for approval of the dataset to the Standardisation Committee for Care Information (SCCI). Once approval has been given, the GUMCADv3 patch will be adopted to enhance existing surveillance at all GUM clinics and providers of level 2 services in England. It is expected that the first data extracts from GUMCADv3 will be available from 2017.

Information Governance

GUMCADv2 is a SCCI (formerly known as the Information Standards Board; Information Standard 0139) and ROCR (ROCR/OR/0080/005MAND) approved dataset, which has been implemented in relevant services since 2008.

The collection of the GUMCADv2 dataset was approved by the National Information Governance Board for Health and Social Care (NIGB). NIGB functions transferred to the Confidentiality Advisory Group of the Health Research Authority in April 2013. All information is used in accordance with the Data Protection Act 1998, the Public Health (Control of Disease) Act 1984, the Public Health (Infectious Diseases) Regulations 1988, and the NHS Act 2006 (section 251). GUMCADv2 data and their storage and access are under strict control and are governed by the PHE HIV/STI Data Sharing Policy. All records are kept securely in compliance with the Caldicott Guidelines.

PHE is the custodian of GUMCADv2 and v3 datasets and therefore only individuals employed by PHE and directly involved in work relating to STI and HIV surveillance may access these datasets. Should an organisation other than PHE wish to access GUMCADv2 or v3 data for performing a NCA, nominated individuals from these organisations would need to do this under an honorary contract with PHE.

Data quality and conformance

Data quality is ensured by following NHS Data Dictionary formatting and definitions. Data for GUMCADv2 can only be submitted in the defined format as approved by SCCI (see GUMCADv2 *Technical Guidance and Extract Specification for Data Extract* in Annex 4). Data submitted that do not follow the specified format are rejected. In addition, PHE has a number of automated validation rules to ensure data compliance and quality. Data are then cleaned further to generate testing and diagnosis episodes.

GUMCADv2 data:

- are complete and submitted in the correct format
- do not have any blank fields in the data submission, with the exception of "episode_activity"
- are accurate (central validations will be undertaken on the data to test validity, with providers required to resubmit data if necessary)
- are timely (in line with data submission deadlines, 6 weeks from end of quarter)
- are submitted using the secure HIV/STI Web Portal
- are held securely at all points

4.4. PHW datasets

SWS is a disaggregate dataset which combines clinic diagnoses and laboratory reports on both positive and negative tests. This is a live system where data flow readily, as frequently as daily (from laboratories), weekly or monthly. Data are extracted quarterly and the dataset replicates the GUMCAD dataset collected at PHE. The quality of data submitted from laboratories has improved over time, as Lab Information Management Systems are now able to track the movement of samples from the initial collection site. PHW also have an enhanced syphilis surveillance system that records syphilis diagnoses and information about sexual networks and the use of Apps for establishing sexual contacts.

Of the 29 clinics (formerly GUM clinics) in Wales, 24 report directly to SWS and five in the South Hywel Dda area of Wales report data in aggregate, rather than disaggregate form. Since the integration of services, many smaller community clinics (formerly Family Planning and Community Contraceptive clinics) have started providing GUM services, fourteen of which report directly to SWS. There may be some community clinics which have not yet begun reporting to SWS; an evaluation is underway in Wales to explore this further.

SWS data are robust and cover 20 out of 22 local authorities in Wales (the remaining two are the local authorities in South Hywel Dda, mentioned above).

Access to the central SWS database is restricted to PHW employees; however, it may be possible for PHW to produce a data extract from this central database for the purpose of audit after obtaining permission from the laboratory, Datastore data custodian and/or clinic concerned.

Further information about SWS is available in Annex 4.

4.5. Inclusion of primary and hospital care in an audit

STI and HIV care provided in general practice is important for the control and management of STIs. Some GPs are commissioned to provide STI management and many GPs and hospitals in areas of high HIV prevalence are commissioned to offer and perform HIV tests to help identify people with undiagnosed HIV and reduce late HIV diagnosis.

GPs and hospitals also have an important role to play in the clinical diagnoses of undiagnosed HIV infection when patients present with HIV indicator conditions such as tuberculosis, hepatitis or pneumonia. There is evidence that a significant proportion of people who are diagnosed late with HIV have been seen by healthcare professionals in the year before their diagnosis with what were, in retrospect, HIV-associated symptoms but were not offered an HIV test (64).

Auditing these aspects of STI and HIV care relies on accessing the required data. Although GPs commissioned to provide STI management are required to report to PHE's GUMCAD system, coverage is currently very low and therefore GUMCAD is unsuitable for use as a source of audit data from GP settings. Audit data for GP and hospital settings would need to be accessed from other sources, such as HES, General Practice Extraction Service (GPES), or CPRD).

This study initially aimed to investigate the capacity to link meaningfully between GUMCAD and HES, explore the use of NHS number and the potential use of data linkage to enrich data regarding missed HIV diagnosis opportunities in hospital and GP settings. Early in this study, the feasibility study team were advised by HQIP that there was a hold on commissioning any NCAPOP audits that rely on collecting new data from primary care. These restrictions from NCAPOP are in response to several challenges facing audit teams and projects that are already committed to establishing new data flows and that, in July 2015, had not gained access to primary care data nor did they have a definite commitment to a future timeline. The advice from HQIP was that once these audits have established primary care data flows, this would provide one or more models with predictable costs and timescales and would enable HQIP to explore the further inclusion of primary care data in the Programme.

Advice from our HQIP Project Manager was to restrict consideration of primary care during the feasibility study to in principle issues rather than data availability and flow.

Given the importance of offering HIV testing beyond traditional GUM and SRH services, and of reducing rates of missed HIV diagnosis in non-HIV specialist healthcare settings, it is recommended that a future audit development team monitor the availability of GP and hospital data and explore how these settings can be included in an audit as it evolves over time. The audit domains recommended have been selected to address the most pressing aspects of STI and HIV care, and the phased and mixed methods approach recommended allows for primary care and/or hospital data to be included in the future in Domain B, if this is still deemed appropriate at the time.

To support and inform the use of audit data from GP and hospital settings, a consultation meeting with HIV patient representatives was held (further details can be found in section 5.3).

4.6. Recommended audit questions and required variables

The following data sources, fields, exclusions and exemptions are recommended for early inclusion in a NCA of STIs and HIV:

Topic A: Access & Assessment

Audit topics (Question(s))	**Data source**	**Data fields required for every patient in sample**	**Exclusions, exemptions and notes**
Access to service within 2 working days of first contacting the service a) *What percentage of people with needs relating to STIs contacting a service are offered to be seen or assessed with an appointment or as a 'walk-in' within 2 working days of first contacting the service.* b) *What percentage of people with needs relating to STIs contacting a service are seen or assessed by a HCP within 2 working days of first contacting the service?*	Bespoke from providers (EPR review)	**Numerator a:** The total number of people offered to be seen/assessed with an appointment or as a 'walk-in' within 2 working days. **Numerator b:** The total number of people seen/assessed with an appointment or as a 'walk-in' within 2 working days. **Denominator:** The total number of people contacting a service during the same interval, with an STI need.* **Fields:** A. Date first contacting service B. Time first contacting service C. Date appointment offered D. Time appointment offered E. Attendance date F. Attendance time	Individuals for whom an appointment within 2 working days would be clinically inappropriate should be excluded from the audit population. *The audit development team should identify a suitable marker for STI need and use this to select cases to be included in the denominator.

Audit topics (Question(s))	Data source	Data fields required for every patient in sample	Exclusions, exemptions and notes
Sexual history taking *What percentage of people receive a full sexual history assessment?*	Mandated data flow (GUMCADv3) and bespoke data collection from Welsh clinics	**Numerator**: The total number of people with a documented response to the following questions: How many sex partners did you have in the last 3 months? AND *For MSM:* Have you had any condomless anal intercourse in the last 3 months? OR *For people reporting heterosexual sex:* Did you/your partner use a condom the last time you had penetrative (vaginal or anal) sex? **Denominator**: The total number of new attendances in the service within the same interval. **Fields**: A. GUMCADv3 question 13 or 16 B. GUMCADv3 question 15 or 18	Individuals who report no history of sexual intercourse should be excluded from the audit population. These data should be analysed separately (each question) and as a composite measure (both questions). *

Topic B: Investigation & Diagnosis

Audit topic (Question(s))	**Data source**	**Data fields required for every patient in sample**	**Exclusions, exemptions and notes**
Testing for chlamydia, gonorrhoea, syphilis, and **HIV, where clinically indicated** *What percentage of patients with needs* relating to STIs are offered a test for chlamydia, gonorrhoea, syphilis, and HIV at first attendance?*	Mandated data flow (GUMCADv2) or SWS	**Numerator:** the total number of patients with GUMCAD code T4, T3+P1C or T3 +P1B, within a defined timeframe. **Denominator:** the total number of new patients and new episodes in the service, for whom a test for the above 3 STIs and HIV is clinically indicated**, within the defined timeframe. **Fields:** A. T3 chlamydia, gonorrhoea and syphilis tests B. T4 Full sexual health screen (chlamydia, gonorrhoea, syphilis and HIV tests) C. P1C codes – HIV test not appropriate D. P1B codes – HIV test offered and refused E. H codes – HIV positive (exclude from HIV testing cohort)	People for whom an HIV test is inappropriate, who refused the offer of an HIV test, or who are known to be HIV positive should be excluded from the audit population. These are indicated by P1C, P1B and H codes. People not attending for a sexual health screen, but for chlamydia screening only or HIV outreach testing only should be excluded from the audit population. ** The audit development team should clearly define 'needs relating to STIs', for the purpose of the audit.* *** The audit development team would need to provide guidance to PHE and PHW on how to ascertain this.*

Audit topic (Question(s))	Data source	Data fields required for every patient in sample	Exclusions, exemptions and notes
Turnaround time between test and treatment *What is the turnaround time (in days) between STI testing date and STI treatment date?*	Mandated data flow (GUMCADv2) or SWS or bespoke data in Wales	**Numerator:** The total number of patients with diagnosed gonorrhoea, chlamydia, and/or syphilis who are treated within a defined timeframe. **Denominator:** The total number of patients with a new diagnosis of gonorrhoea, chlamydia and/or syphilis, within the defined timeframe. **Fields:** A. Date of test/sample taken (first attendance in episode) B. Test code C. Diagnosis code D. Date of re-attendance (proxy for treatment)	BASHH's Clinical Standards Unit states that patients should be offered 'prompt' treatment for STIs, however this is not defined. A future NCA can be used to identify current practice, to inform BASHH Clinical Standards Unit decision-making and to refine the published guidelines. Care needs to be taken in interpreting date of re-attendance as this could indicate the patient has returned for a test of cure rather than treatment. Data need to be retrieved from the pre-analysis data extracts submitted to GUMCAD and STI surveillance experts from PHE and PHW should be consulted to interpret re-attendance data. Additionally, immediate treatment, which may be either presumptive treatment or based on positive microscopy for gonorrhoea (in men), should be considered by the audit development team.

Topic C: Ongoing Management

Audit topic (Question(s))	**Data source**	**Data fields required for every patient in sample**	**Exclusions, exemptions and notes**
Recommended first line treatment for gonorrhoea *a) What percentage of patients with gonorrhoea received recommended first line treatment?* *b) For patients who did not receive recommended first line treatment, for what percentage were the reasons for not doing so documented?*	Bespoke from providers (New case note/ EPR review)	**Numerator a:** The total number of index cases prescribed recommended first line treatment for gonorrhoea, within a defined timeframe. **Denominator a:** the total number of index cases who received treatment for gonorrhoea, within the defined timeframe. **Numerator b:** The total number of index cases for whom a reason for not receiving first line treatment was documented, within a defined timeframe. **Denominator b:** The total number of index cases who did not receive first line treatment for gonorrhoea, within the defined timeframe. **Fields:** A: Treatment code B: Reason for not giving first line treatment	None

Audit topic (Question(s))	Data source	Data fields required for every patient in sample	Exclusions, exemptions and notes
Partner notification for gonorrhoea a) *What percentage of index cases are documented as been offered at least one discussion, which may be a telephone discussion, for the purpose of PN with a HCW with the appropriate documented competency.* b) *How many contacts were documented as having attended a sexual health service, as reported by the index patient or by a HCW, within four weeks of the date of the first PN discussion?*	Bespoke from providers (New case note/ EPR review) and GUMCADv3 (for measure b)	**Numerator a:** The number of index cases, who have a documented offer of at least one discussion, which may be a telephone discussion, for the purpose of PN with a HCW with the appropriate documented competency. **Numerator b:** The number of all contacts whose attendance at a sexual health service was documented as reported by a HCW, within four weeks of the date of the first PN discussion. **Numerator c:** The number of all contacts whose attendance at a sexual health service offering services at Level 2 or 3 was documented as reported by either the index case or by a HCW, within four weeks of the date of the first PN discussion. **Denominator:** The total number of index cases newly diagnosed with gonorrhoea, during a defined timeframe. **Fields:** A. Date of gonorrhoea diagnosis B. Date of PN discussion C. Outcome of PN discussion D. Number of contacts referred through PN as reported by the index case or by a HCW	None

Audit topic (Question(s))	**Data source**	**Data fields required for every patient in sample**	**Exclusions, exemptions and notes**
Partner notification for HIV a) *For what percentage of indexes is there a documented PN plan in the case notes 4 weeks after index case diagnosis?* b) *How many contacts are tested per index case as verified by the HCW at 3 months after diagnosis?* c) *How many contacts are tested per index case as verified by the HCW or index case at 3 months after diagnosis?*	Bespoke from providers (New case note/ EPR review) and GUMCADv3 (for measures b and c)	**Numerator a:** The number of indexes for whom there is a documented PN plan in the case notes 4 weeks after index case diagnosis. **Numerator b:** The number of contacts tested as verified by the HCW at 3 months after index diagnosis. **Numerator c**: The number of contacts tested as reported by the index, at 3 months after index diagnosis. **Denominator:** The total number of patients newly diagnosed with HIV, during a defined timeframe. **Fields:** A. Index patient identifier B. Date of HIV diagnosis C. Date of first PN discussion D. Total number of contacts in look back period	None

Audit topic (Question(s))	Data source	Data fields required for every patient in sample	Exclusions, exemptions and notes
Test of cure for gonorrhoea *What percentage of patients treated for gonorrhoea receive a test of cure within 2 weeks of completing treatment?*	Mandated data flow (from GUMCADv2 and GUMCADv3) and proxy data from GUMCADv2&3 or SWS	**Numerator:** Total number of people receiving a test of cure for gonorrhoea within 2 weeks of completing treatment. **Denominator:** Total number of people treated for gonorrhoea within the defined timeframe. **Fields:** A. B1 code – gonorrhoea diagnosis B. T2/T3 or T4 code* – test for gonorrhoea after/within defined time period	Care needs to be taken in interpreting date of re-attendance as a proxy for test of cure. STI surveillance experts from PHE and PHW should be consulted for advice. . *T2 - chlamydia and gonorrhoea test only; T3 - chlamydia, gonorrhoea and syphilis tests; T4 Full sexual health screen (chlamydia, gonorrhoea, syphilis and HIV tests)

Audit topic (Question(s))	Data source	Data fields required for every patient in sample	Exclusions, exemptions and notes
Documented evidence of referral pathways and safeguarding policies a) *Does the clinic have a documented care pathway for patients with identified:* ○ *Alcohol related needs?* ○ *Drug related needs?* ○ *Mental health needs?* b) *Does the clinic have documented good practice protocols and/or guidance for safeguarding of children and adults in their care?*	Bespoke from providers (New case note/ EPR review)	**Numerator:** Total number of clinics with referral pathway or policy for: ○ Alcohol related needs. ○ Drug related needs. ○ Mental health needs. ○ Safeguarding of children and adults in their care. **Denominator:** Total number of clinics **Fields:** A. Alcohol misuse referral pathway B. Substance misuse referral pathway C. Mental health concerns referral pathway D. Safeguarding policy	

4.7. Metadata

To enable the interpretation of audit data and adjustment for case-mix effects, a small amount of information is needed about each clinic taking part in the audit.[20] These data collected by GUMCAD and SWS include:

- Clinic name
- Clinic identifier
- Clinic address
- Number of clinic attendees (by ethnic group, gender, sexual orientation, and age)
- Number of staff
- Type of services provided (according to the *Standards for the management of STIs* – see Annex 2
- ONS local government geography code (local authorities district)

4.8. Analysis and presentation of audit and re-audit results

Simple analysis supports simple presentation of audit data, which is preferable to clinicians as well as lay audiences and encourages open discussion among all relevant stakeholders. Analysis of audit data should, therefore, mostly involve calculating simple percentages of performance, based on the numerators and denominators recommended in Section 4.6 for each audit measure.

For some audit measures, for example those using data from mandated national data flows, the entire population of service attenders is captured and when presenting the data, confidence intervals are superfluous and should not be used. Where samples of larger populations are taken, it is appropriate to generate confidence intervals to provide a level of certainty about the audit results. Outliers should be explored with the lead clinician at the relevant clinical setting to determine whether a data handling or sampling error could explain the unexpected results.

For some topics (see Table 5), it will be useful to calculate and present the arithmetic mean at clinic level. If there are true outliers that distort the mean values, the median should be used instead which gives a more accurate reflection of the results.

At a minimum, clinic-level performance for each audit measure should be visually presented alongside the nationally agreed standards against which performance is being measured. All audit results should include the relevant sample sizes, percentages, and be supported by confidence intervals and mean values, where applicable. Bar charts may be used and these should be accompanied by supporting data tables for ease of cross-referencing. When re-audit results become available, these should be presented in the same way and enable comparison with the standard, as well as with previous performance as identified in the initial audit. Where possible, a suggested interpretation of each audit result and evidence-based recommendations for improvement should be provided alongside audit results. Data should include clinic level comparisons and benchmarking against the published standards and be reported at regional and national level to enable meaningful comparisons.

- [20] GUMCADv2 and v3 and SWS collect these data. Two named contacts for audit should also be identified for each clinic participating in the audit.

Section 5.4 provides recommendations for disseminating audit and re-audit data

Table 5 Recommended data analyses

	Percentages	Confidence intervals	Mean at clinic level
DOMAIN A: Access & Assessment			
1. Access to service within 2 working days of first contacting the service	✓		✓
2. Sexual history taking	✓		
DOMAIN B: Investigation & Diagnosis			
3. Testing for chlamydia, gonorrhoea, syphilis and HIV, where indicated	✓	✓	
4. Time between testing & treatment	✓		✓
DOMAIN C: Ongoing Management			
1. First line treatment for gonorrhoea	✓	✓	
2. Partner notification (for HIV and gonorrhoea)	✓	✓	
3. Test of cure for patients treated for gonorrhoea	✓		
4. Key referral pathways & policies	✓		

4.9. Mixed-methods data collection

Consultation with stakeholders revealed that a balance between early clinical engagement, early feedback and minimising the burden of data collection were important to the success of a future NCA. A mixed-methods approach is recommended using data from established mandated surveillance systems held by PHE and PHW, where available. Where data are not already available, supplementary data should be collected using simple electronic methods. Data collection should be phased according to priority of audit topic and measures (see Table 6). Continuous data collection refers to constant flows of data from clinic to audit team (whether via PHE, PHW or directly). Snapshot data collection involves collecting a specific piece of information once at an early stage in the audit and a second time at the re-audit stage, to review improvement. Spotlight data collection involves gathering specific information on selected topics, in this case PN and recommended first line treatment. While GUMCADv3 aims to collect data for some aspects of PN, bespoke spotlight data collection is needed to supplement this and to examine documented offers of PN as well as PN outcomes.

Table 6 Recommended data collection approach

	Continuous	Snapshot	Spotlight
DOMAIN A: Access & Assessment			
1. Access to service within 2 working days of first contacting the service	✓		
2. Sexual history taking	✓		
DOMAIN B: Investigation & Diagnosis			
3. Testing for chlamydia, gonorrhoea, syphilis and HIV, where clinically indicated	✓		
4. Time between testing & treatment, for patients diagnosed with STI(s)	✓		
DOMAIN C: Ongoing Management			
1. First line treatment for gonorrhoea			✓
2. Partner notification (for HIV and gonorrhoea)			✓
3. Test of cure for patients treated for gonorrhoea	✓		
4. Key referral pathways & policies		✓	

5. Defining and refining a scope for audit and quality improvement

5.1. Introduction

This feasibility study found that a NCA of STIs and HIV is both appropriate and feasible in all services commissioned to provide specialist GUM or integrated SRH care in England and Wales. The audit should aim to drive quality improvement in processes directly related to STI and HIV outcomes, thereby improving individual patient outcomes and reducing STI and HIV transmission.

Specifically, the quality improvement driven by the NCA should relate to its objectives:

- To limit the impact and transmission of STIs
- To mitigate against the development of antimicrobial resistant gonorrhoea
- To reduce late diagnosis of HIV

An STI/HIV audit should address three key domains of care on the STI and HIV patient care pathway[21]. Data collection is feasible, using a mixed methods approach described in section 4.9. Extensive consultation with the Steering Group, Reference Group and leads of other NCAs (including the stroke and lung cancer audits), emphasised that the engagement of audit stakeholders is of central importance to the successful design and implementation of a NCA and to driving sustainable quality improvement.

This section outlines how BASHH and BHIVA's existing audit structures and the current (high) level of integration between, and engagement among, STI and HIV clinicians, commissioners, and policymakers can be harnessed to improve the audit. The proposed scope also seeks to employ NCA as a mechanism for transforming the strong data collection culture within the field into a quality improvement culture by:

1. Boosting clinical engagement and participation in all stages of the audit cycle
2. Involving patient and public representatives, as well as carefully developing communication and results dissemination strategies, to enhance the impact of quality improvement and of the audit
3. Disseminating audit and re-audit data using appropriate channels to all stakeholders
4. Facilitating the sharing of best practice and supporting quality improvement, for example by capitalising on the existing BASHH, BHIVA and FSRH event infrastructure (such as national and regional meetings).

[21] This excludes care delivered in specialised HIV services for people diagnosed with HIV, as clinic-level data is provided in the HIV dashboard.

5.2. Clinical engagement and participation in audit

It is anticipated that high levels of participation in a NCA can be achieved because:

- Through consultation with STI and HIV clinicians and wider stakeholders, firm support for the priority areas of care recommended for inclusion in a NCA has been confirmed. This is strengthened by the alignment of these priorities with the PHOF, which informs sexual health service commissioning, as well as with the Chief Medical Officer for England's prioritisation of effective gonorrhoea management.
- Among STI and HIV clinicians, there is an established respect for the importance of maintaining high quality services, as indicated by their engagement through BASHH and BHIVA in the development of clinical guidelines and standards.
- There is also an established culture of data collection and submission among providers of STI and HIV care, which is facilitated by PHE's National Surveillance Scientists, PHE's Regional Sexual Health Facilitators, and BASHH's existing Regional Audit Leads. These roles can be used to support the work of a NCA coordinator.

The following considerations are also recommended to maximise participation in a NCA:

- **Appointing and supporting Regional and Local Audit Champions**: Appointing senior clinicians as Audit Champions (where these do not already exist) at the local clinic level is key to driving quality improvement through NCA. Certificated training and workshops should be arranged to ensure Local Audit Champions are equipped with the necessary knowledge, skills and enthusiasm to support their staff and to communicate with their Trust Board as necessary. BASHH's Regional Audit Chairs may be able to recruit those with existing audit responsibilities and interests and support Local Audit Champions in their role. Inviting third sector staff and/or volunteers to offer their support to local clinical teams may help improve participation by local clinics in the audit, quality improvement and the sharing of best practice.

- **Opportunities for professional development**: The opportunity to demonstrate involvement in audit is likely to be attractive for clinicians who need to do so as part of their General Medical Council clinical revalidation. Regional (e.g. BASHH) and Local Audit Champions should participate in the preparation of audit tools and timescales and in training in the full cycle of audit (as local audits and the BASHH national audits rarely involve re-audit or a quality improvement phase). Local teams should also be given the opportunity to review local audit results and receive support in how to interpret these, before they are disseminated more widely. Local and regional clinical teams should also be encouraged to perform smaller re-audits for their continued professional development. These steps are important to maintain ownership and responsibility for the success of the audit at the local level and the positive impacts will filter through their clinical team and also to maintain the improvements made. Regular web-based conferencing, webinars, and/or set-up of an online audit champions' forum would help maintain support between Regional and Local Audit Champions.

- **Establishing support at trust and commissioner Level**: Time and resources should be spent during the initial audit development stage to communicate the importance of full audit participation to provider board members and commissioners. The focus on sustained quality improvement over time rather than the audit result per se should also be explained. This higher level of understanding and engagement will encourage provider organisations and commissioners to allocate appropriate financial and human resources to clinical teams so that they can effectively implement required changes.

- **Enabling clinical sites to allocate time for audit**: Communicating the timescales for a NCA well ahead of time will allow clinical settings to allocate their staff and time appropriately and participate fully in all phases of the audit cycle.

- **Providing clear guidance and instructions for submitting data**: Consultation with clinicians revealed that while some teams prefer electronic forms, others describe the electronic form used in previous audits as "complex". To ensure clinical teams are able to complete the data collection tools efficiently, it is important to explain which data should and should not be submitted, in what format and by which date(s). The NCA team should consider providing explanations or tutorials in text-based, audio, and visual formats to suit different people. As needs will change over time with the development of electronic infrastructure, this should be reviewed annually

- **Supporting clinical sites throughout the audit cycle**: Leaders of existing audit programmes advised that having a dedicated helpline/helpdesk for clinical sites has been invaluable in establishing rapport with reporters and supporting them through the entire audit process, from data collection to re-audit.

5.3. Patient and public involvement

The views of patient and public representatives and their constituencies have been shared, reviewed and incorporated into the recommended audit topics. These were gathered at Steering Group meetings and during a patient consultation held to discuss the use of HIV patient data for a NCA. A patient and public involvement (PPI) adviser was appointed to provide advice on the best approach to PPI in the current feasibility study and in a future NCA.

As gonorrhoea, chlamydia, and syphilis are episodic rather than chronic infections, there is no recognised support group for people diagnosed with these infections. In addition, STIs are stigmatised and people affected rarely wish to speak publicly about their personal experience of them. This presents a challenge for recruiting people diagnosed with these STIs or sharing information about these STIs as part of a PPI strategy. There are however three key population groups who are most affected – young people, black ethnic groups and MSM. Engaging with charities and organisations who work specifically with and for people from these groups may be a useful way of contacting people who might be at increased risk of STIs and or who may have been diagnosed with an STI in the past. Examples of key organisations to include are the National Union of Students, Brook, Sexpression: UK[22], GMFA[23], the LGBT Foundation[24] the Black Health Agency (BHA)[25] and NAZ[26] as well as local community and social groups serving the needs of young black ethnic communities.

[22] Sexpression: UK is a student organisation that empowers young people to make decisions about sex and relationships by running informal and comprehensive sex and relationship sessions in the community.
[23] GMFA - the gay men's health charity, which was established to provide accurate, relevant information to gay men to support them in making appropriate choices to live healthy lives – physically, emotionally and sexually.
[24] The LGBT Foundation delivers a wide range of services to lesbian, gay, bisexual and trans (LGBT) communities
[25] The BHA is a health and social care charity, which supports individuals, families and communities to improve their health and wellbeing, focussing on black and minority ethnic, disadvantaged and other marginalised communities.
[26] NAZ is a charity providing sexual health services and programmes, specifically for men and women from Black Asian and Minority Ethnic communities.

While there is some overlap between the groups affected by STIs and HIV, the use of HIV patient data for non-clinical purposes is a different and complex issue from those to be raised in relation to STIs. It is recommended that a core group of HIV patient representatives be appointed for a future NCA. The patient representatives who attended the consultation meeting about use of HIV patient data for audit are all affiliated personally and/or professionally with key organisations providing essential support and care of people living with HIV. The consultation meeting group was, in principle, supportive of participating in the development of a future NCA. Its members felt that a future audit committee should gain support from the third sector, which can endorse the audit and inspire trust among people living with HIV who are likely to appreciate being approached about the use of their data for audit.

Implied consent was considered the preferred model for using data for purposes other than clinical care or national surveillance. However, the acceptance of this was predicated upon people living with HIV having been informed about current data protection regulations, how data are collected, and how they will be used. As a result, the group recommended that a minimum level of information should be developed nationally, with culturally appropriate variants, and made available to people living with HIV. Access to more detailed information should then be made available as needed for each individual.

People living with HIV should be represented on a future Steering Group and/or Reference Group and consulted on how to engage and involve patients and the public, and how to disseminate information about both the process and the results to patients and the public in a culturally relevant way. They should have an opportunity to contribute to decision-making, where appropriate. They could also be involved at local level to support staff in tailoring national information to suit particular local needs, such as resources for recent migrants.

It is recommended that PPI within a NCA programme be monitored and evaluated in line with HQIP guidelines concerning:

- Which elements of PPI or patient and public engagement (PPE) are having the desired effect (process)
- Whether engagement in PPI or PPE activities has changed over time (flow)
- Whether the intended outcomes of PPI and PPE were achieved (quality)
- Whether PPI made a difference at different stages in the programme (impact)

5.4. Disseminating audit and re-audit results

Key to driving quality improvement is ensuring that the right data are disseminated to the right audience, via the right channels, with the right message and at the right time. Audit data should be shared with all stakeholders, including patients and the public, clinicians and commissioners.

Where possible, a future audit development team should work with the existing BASHH audit network and BHIVA audit leads to explore the variations in and sub-standard quality of care to which that previous smaller BASHH and BHIVA audits have pointed out. These BASHH and BHIVA audits have aimed to scope performance on a small number of topics. A NCA of STIs and HIV commissioned within the NCAPOP would be on a much larger scale, have an emphasis on quality improvement and importantly provide measures of that improvement through a re-audit process. Findings from synergistic BASHH and BHIVA audits could provide additive spotlight and snapshot data to support the continuous national audit programme. The timing of dissemination should be coordinated with BASHH and BHIVA and where audit findings are related, joint recommendations for quality improvement could be made, for maximum impact.

The *Reporting for Impact* report, produced by HQIP for NCAPOP providers, offers a useful guide for a future NCA team. Such a team should also seek guidance from HQIP's Communications department for the details of other audit teams who may be able to share learning gained from their own audit's development. Some further considerations generated through consultation with audit leads[27] and clinicians[28] are summarised in Table 7:

27 Meetings were held with the national lung cancer, stroke and chlamydia screening programme audit leads and an interview was conducted with the head of quality assurance and standards for the NCSP.
28 Clinicians were consulted through online survey and 1-1 meetings throughout the course of the study.

Table 7 Report audience/information matrix

Audience	Key features to be included in a report	Additional considerations
Patients and representative organisations[29]	- The question(s) and overarching purpose of the audit - Key findings from the audit - Report recommendations and their intended target audience(s) - How their local clinic compares to others in terms of quality of care - Assurance on how patient confidentiality was maintained	- Content to be presented in a format clear to someone without a clinical background - Infographics with key message about quality of care at different stages in patient pathway - Lay report - Use of traditional, social media and networking channels, especially those most used by the distinct groups – young people, black Africans and Caribbean and MSM communities
Clinicians and HCPs involved in STI and HIV care Commissioners Wider stakeholders[30]	- The question(s) and overarching purpose of the audit - Key findings from the audit - Local bespoke report illustrating the performance of their clinic, against their regional and national performance as well as benchmarked against the published standard for each audit measure audited - Recommendations for quality improvement - Links to tools/guidance/support available to assist local quality improvement action planning e.g. Regional and Local Audit Champions	- Different stakeholders should receive the same information but in different levels of granularity appropriate to their needs - Coordination of communications with BASHH, BHIVA, FSRH, and PHE communications and publications teams - Use of traditional, professional and social media and networking channels[31] with high-frequency use to showcase examples of best practice or data submission deadlines - The level of interactivity required from a dashboard. Should it be possible to view data according to user preference and selection e.g. showing results by stage of the patient pathway, region, or clinical setting?

29 This will include charities and support agencies that work directly with patients.
30 Wider stakeholders might include policymakers, service directors/medical directors, regulators, PHE Sexual Health Facilitators, Royal Colleges and societies.
31 For example YouTube, LinkedIn, or Twitter.

5.5. Sharing best practice

Sharing of best practice was consistently cited as an enabler of quality improvement by clinicians, who provided feedback through the course of this feasibility study.

As funding for a future NCA is not expected to cover the costs of implementing change at the local provider level, the recommendations for an achievable and impactful audit include effective and innovative mechanisms for sharing evidence of best practice to inform commissioners' and local providers' decision-making and for maximising the utility of audit data, as outlined below. Existing BASHH National Audit Group structures could be used to facilitate national sharing among Regional Audit Champions who could then share the key messages with local audit leads, who in turn could share information and examples of best practice at their local meetings.

BASHH has a long established history of organising and hosting a number of events, including a three-day annual conference, which features lectures and plenary sessions on topical issues in STI care, research and audit as well as a range of symposia, exhibitions and poster viewing sessions where local providers showcase their work. BASHH also organises quarterly scientific meetings focusing on different topics and there is the potential to dedicate one (or more) of these to the STI/HIV audit.

Similarly, for the last 22 years, BHIVA and its affiliated organisations have organised a number of events and conferences each year, notably the spring and autumn conferences, the former of which is held at different locations each year, maximising opportunities for members across the UK to attend. These events are well attended by clinicians providing care for every stage of the HIV patient pathway.

As some clinicians are unable to attend BASHH and BHIVA events, the audit development team should endeavour to make a podcast available of relevant conference sessions so that non-attendees can also learn from the best practice and developments shared. The audit development team may wish to explore the possibility of funding from pharmaceutical companies to support this. Additionally, to ensure the universal opportunity to learn and share best practice, all regional audit champions should be invited to attend, at the least, a free annual conference, workshop or other event designed and hosted by the audit development team.

These existing and new events present a real opportunity to 1) inform clinicians about audit results 2) review national recommendations for quality improvement, 3) facilitate the sharing of best practice, 4) celebrate success and innovation and 5) communicate next steps for future audit topics. It is recommended that a future NCA group consult with BASHH and BHIVA to ensure that programmes and events are supportive rather than duplicative.

Additional activities recommended for consideration are:

- **National and regional awards for innovation and improvement**: Recognition of participation in audits and improvements in the quality of care audited is important for achieving full participation in the audit programme and maintaining collective momentum.

- **Interactive polls of clinicians during the conferences**: Clinicians can provide live feedback on audit results and comments can be used to stimulate discussion. A suitable software for this would be Pigeon Hole, which includes features such as:
  - running up to eight question and answer sessions
  - conducting a live survey to gather insight from clinicians
  - exporting data to Excel for analysis which can be shared among NCA stakeholders who were unable to attend the event

- **NCA workshop or breakout groups**: Conference delegates can share, learn, and encourage one another during guided or facilitated workshops. Clinicians can be allocated to specific workshops to maximise their opportunities for development, for example, based on their clinic's audit results or case-mix. Third sector organisations could provide input about patient and public perceptions of the audit process.

- **Training sessions**: Conference delegates could be invited to a training session, which could be jointly hosted by PHE and PHW surveillance team representative(s) and the audit contract holder. Depending on the stage in the audit cycle, these sessions could aim to:

  - provide support to Regional and Local Audit Champions in how to introduce the audit to their local teams
  - alleviate concerns about the clinical audit process
  - clarify timescales for the implementation of the audit
  - answer specific technical questions about data collection and reporting
  - obtain feedback on the implementation of the audit to help refine the audit process nationally

5.6. Risks and mitigation

Several risk factors have been identified and ways to mitigate these risk factors have been incorporated into the design and scope of the recommended NCA (see Table 8 below). In addition to the risk factors highlighted here, it is possible that others will present during the audit. It is recommended that the project team create, maintain, and regularly review a risk log to flag such risk factors, their probability of occurring and their potential impact on the audit. Action as appropriate would be recommended to reduce the probability of these risk factors materialising.

Table 8 Risk and mitigation grid

Risk factor	Probability[32]	Impact[33]	Risk rating[34]	Mitigation steps	Revised risk rating[35]
METHODOLOGICAL RISKS					
Limited internal validity of audit measures As some of the audit questions recommended are based on complex measures, there is a risk that measurements may not provide a valid or consistent measurement of local performance. This could be due, for example, to issues such as 'gaming', or performance data concerning access to care within 2 working days may overestimate the proportion of clients who are truly able to access a service and be seen by a clinician within the specified time period.	2	4	8	a. It is recommended that all audit measures, and related data collection fields, sources and time-periods should be clearly defined in a consistent way across all NCA documentation and with due consideration and reference to the context in which data are collected. b. It is recommended that the wording used in the audit guidance documentation mirror that used in the relevant standards and in GUMCAD and/or SWS so that there is consistency between tools. c. Where possible, automated validation rules should be included in the data collection tool to highlight inconsistencies, which may indicate invalid results.	4

[32] The probabilities of risks occurring were classified as 1 – low, 2 – medium, 3 – high or 4 – very high.

33 Potential risk impacts on an audit were classified as: 1 – no impact, 2 – little impact (requiring extra efforts or activities), 3 – moderate impact (could cause schedule delays), 4 – significant impact (could threaten audit continuation or audit quality) or 5 – major impact (could lead to audit suspension or termination).

34 Risk rating is produced by multiplying the probability and impact of each risk factor occurring.

35 Follow the mitigation plan outlined, it is anticipated that the probability of each risk factor will be reduced by 1. The revised rating is a multiplication of the revised probability and the impact of each risk factor occurring. Revised risk ratings are classified as low risk (1-6), medium risk) 8-12) or high risk (15-20).

Risk factor	Probability[32]	Impact[33]	Risk rating[34]	Mitigation steps	Revised risk rating[35]
Systematic bias toward providers of GUM and level 3 services compared with services providing integrated SRH or level services The scope of the recommended audit focuses on aspects of the STI/HIV patient pathway, but the settings in which care is provided, and would be audited, extend beyond level 3 STI service providers, whose primary function is to provide specialist STI care, to providers of sexual and reproductive healthcare. Additionally, as the set-up, case-mix and context of all clinics vary, it is possible that audit results will not be directly comparable between clinics.	3	3	9	a. The main process/outcome audit should be supplemented with the collection of simple meta-data relating to a few key features of service delivery. b. During collation and analysis of audit data, these key features can be used to define or distinguish between service types for the specific purpose of interpreting audit data. c. When audit data are presented, there should be a clear and unambiguous reference made to the differences in service types such that there is a fair balance between transparency and the presentation of truly comparative data. d. Differences between the structure of STI and HIV care in England and Wales should be stated clearly alongside each audit result – to avoid misinterpretation.	6
PARTICIPATION RISKS					
Audit fatigue It is possible that clinicians and those involved in providing audit data will experience/have experienced audit fatigue as some clinics take part in BASHH, BHIVA, and NCSP audits, as well as reporting regularly to GUMCAD or SWS. Audit fatigue can affect participation rates.	2	4	8	a. Existing and planned mandated data flows are recommended for four of the eight recommended audit topics. Supplementary data collection for two topics is likely to have a minimal burden for clinics as they already capture and report these data locally. For two topics, a bespoke tool is recommended, and, in England, this is only until some aspects of PN data become available in GUMCADv3. Data collection should only be repeated for re-audit purposes. b. The audit development team should support Champions, clinicians and administrative staff in securing adequate time and capacity to engage meaningfully in the full audit cycle. c. It is recommended that the audit contract holder work in partnership with BASHH, BHIVA, PHE, and PHW to ensure alignment of audit data collection and routine surveillance timetables and topics.	4

Risk factor	Probability[32]	Impact[33]	Risk rating[34]	Mitigation steps	Revised risk rating[35]
IMPLEMENTATION RISKS					
Delay in accessing GUMCADv3 data GUMCADv3 is currently in its second pilot phase and full national implementation is not expected until 2017. Delays to the GUMCAD rollout will limit timely access to GUMCADv3 data fields.	2	3	6	a. Audit can begin with the other data collection items and use other data collection approaches to collate audit data, such as snapshot methods. b. Project development team to work closely with PHE's GUMCAD team so that the audit can progress independently of the GUMCADv3 timelines.	3
Increased demand on high performing services Sharing information in the public domain may increase demand for services at high-performing clinics. This may have budgetary implications if, for example, clinics see surges in numbers of people accessing care with the expectation of being offered a prompt appointment.	2	3	6	a. Clinical teams should be encouraged to review their audit data and consider and plan for the possible impact on their service delivery – from the clinical view and from the service user view. b. Commissioners should be engaged in the audit in its early stages, ensuring that they understand the potential change in demand to the services that they procure. c. High performing clinics should be encouraged to assist lower performing neighbouring clinics with quality improvement so that over time improved performance will lead to more a more evenly redistributed demand across different clinics.	3
Unintended consequences on reproductive healthcare and outcomes A NCA will bring a focus and resources to STI care. In integrated SRH settings, this may lead to the diversion of resources (staff and budgetary) away from reproductive health. Audit publicity which generates increased or reduced demand for some STI services may increase or reduce demand for associated reproductive health services. If any of these situations arise, they may present challenges for retaining the engagement of SRH clinicians and services in the STI/HIV audit.	2	3	6	a. Consultation with clinicians, some of whom provide integrated SRH care suggested that improvements in STI care are likely to lead to positive changes to reproductive health outcomes. b. Sufficient time and resources should be allocated to ensuring that key stakeholders at local clinic level understand that improvements in STI and HIV care should not be at the expense of reproductive healthcare services. c. Significant time needs to be dedicated to engaging SRH clinicians and fostering joint working between SRH and GUM clinicians in relation to audit. This might include, for example, joint meetings.	3

6. Opportunities for further development

Late HIV diagnosis

Reducing late HIV diagnosis by increasing the range and uptake of HIV testing is a national and international priority. This includes a universal offer of testing in general practice and hospital general medical settings in areas where the prevalence of HIV is greater than 2 per 1000 population (36% of upper tier local authorities) and the routine offer of testing to all patients with HIV indicator conditions. At the time of this feasibility study, access to GP data and Hospital Episode Statistics (HES) was limited, nationally, and so measuring care in these settings was not deemed to be feasible in the early stages of a NCA. It is recommended that a prospective NCA team periodically check the availability of GP and HES data and reassess the feasibility of auditing GP and hospital compliance to HIV testing guidelines, including the NICE guidance currently in development - *Increasing the uptake of HIV testing among people at higher risk of exposure* (65).

As part of this feasibility study, a consultation meeting with HIV patient representatives explored the use of HIV patient data, trust, and confidentiality. A full report of this meeting is included Annex 5. Key points discussed included:

- Trust and confidentiality
- Concerns and benefits of sharing data for audit
- 'Opt out' consent for audit
- Information for patients
- Collaboration with third sector organisations

The findings from this consultation should be used to inform how third sector organisations which provide support to people living with HIV are involved in a NCA and in particular how they can help communicate the importance of data sharing for audit purposes to people living with HIV.

Reproductive healthcare

Contraception and related aspects of reproductive health are closely linked with sexual health and several stakeholders highlighted the need to maintain high quality reproductive healthcare alongside STI care.

While it is anticipated that improvements in sexual healthcare generally will improve outcomes for people using integrated services that provide both STI and reproductive healthcare, it is important for any unintended consequences of the audit on reproductive healthcare delivery to be logged and shared as appropriate. Additionally, the allocation of sufficient time and resources for audit at the local level should avoid the diversion of resources away from reproductive health to STI services (this is also explored in Section 5.6).

PREMs and PROMs

The Steering Group and Reference Group felt that an important measure of quality of care is whether people accessing specialist and integrated services are receiving clear information about their diagnosis, STI transmission and prevention. The topic 'providing information to patients' was considered for inclusion in a future NCA and was ranked as third most important topic for audit by clinicians working in GUM and integrated SRH settings . The feasibility study team decided that because of the different and changing ways in which information is given (verbal, leaflets, website links, apps) the best way to capture services' performance against this standard would be to gather data from patients. As PREMs and PROMs were excluded in HQIP's specification for the scope of this study, the topic was not considered further. The Steering Group and wider stakeholders do however believe this is an important area of care, which potentially has a significant impact on risk behaviour. A future NCA team should therefore consider whether and how PREMS and/or PROMs should be incorporated into a NCA.

6.1. Triangulation between expenditure, outcomes and quality data

Since 2013, local authority expenditure on public health services, including sexual health, has been published by the Department for Communities and Local Government. It has always been difficult to compare unit increases in spending with sexual health outcomes. For example, in areas with a high burden of HIV and STIs an increased investment in testing, a key prevention measure, will lead, at least initially, to an increase in diagnoses; an outcome that could be interpreted as a worsening of the problem, rather than an improvement in delivery. With the prospect of a suite of measures that look specifically and nationally at service quality indicators, the ability to readily compare these against both local spend and outcomes data could be very powerful.

7. Study recommendations and conclusions

This study explored the feasibility of a NCA of STIs and HIV. The main findings of this study suggest that an STI/HIV audit is needed to address the variation in clinical outcomes for people diagnosed with and at risk of HIV, gonorrhoea, chlamydia, and syphilis. High quality sexual healthcare needs to be maintained in all the settings in which it is delivered, regardless of how it is commissioned or where it is delivered. While it is not currently feasible to audit all care settings, focusing on the quality of care in the services providing the majority of STI management (specialist GUM and integrated SRH services) will provide a solid baseline audit on which to build over time.

7.1. Study recommendations

This study recommends that:

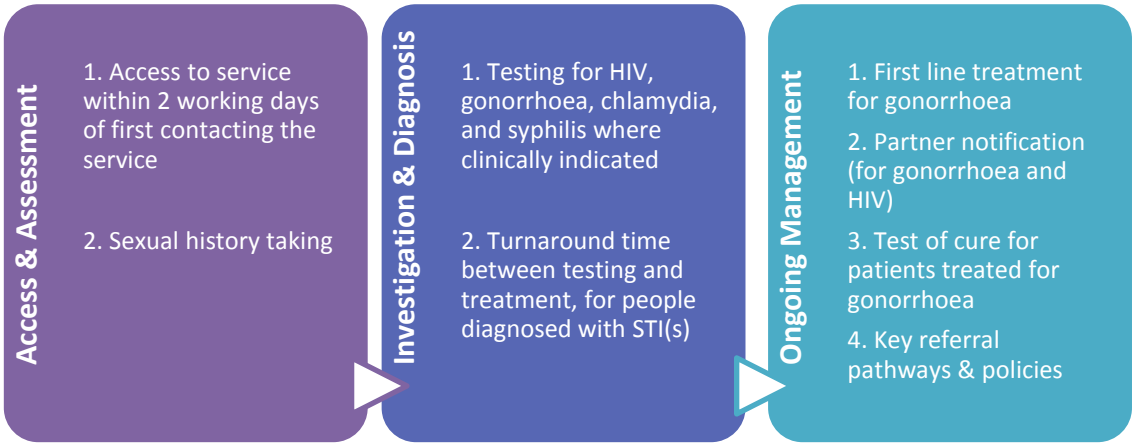
1. A national clinical audit of STIs and HIV is feasible and should be conducted in all services commissioned to provide specialist GUM or integrated SRH care in England and Wales.

2. The audit should aim to improve patient outcomes and reduce STI and HIV transmission, and specifically to:
   - Limit the impact and transmission of STIs
   - Mitigate against the development of antimicrobial resistant gonorrhoea
   - Reduce late diagnosis of HIV

3. The objective of the audit should be to review existing quality of care against nationally agreed standards and use the findings to drive quality improvement.

4. The audit should drive quality improvement in clinic-level performance at the three key stages on the patient care pathway where clinical services have the biggest impact on STI transmission, shown in Figure 9.

Figure 9 Recommended audit domains and topics



5. The audit should use existing nationally agreed standards and guidelines, and any associated recommended national audit measures already defined.

6. The audit should use a mixed-methods approach, by which most data is collected continuously and through established mandated surveillance systems held by PHE and PHW. Where data are not already available, supplementary data should be collected using simple electronic methods. The introduction of data collection should be phased according to priority of audit topic, and audit and re-audit data should be shared at clinic-level in a timely manner.

7. A clear structure for national, regional, and local ownership, participation, training, and support for quality improvement should be developed. This should build on existing mechanisms, such as the existing BASHH and BHIVA audit structures and PHE's regional Sexual Health Facilitators.

8. Audit and re-audit results should be published and include clinic-level, local authority, regional, and national comparative data. Results should be shared with clinical teams, patients, provider organisations, commissioners, and other key stakeholders, with clear recommendations for quality improvement for each audience, in a style accessible to the public.

7.2. Study conclusions

To conclude, a NCA of STIs and HIV is both appropriate and feasible. An STI/HIV audit presents a unique opportunity to improve access to high quality services, regardless of area of residence, to limit the impact and transmission of STIs, to mitigate against the development of antimicrobial resistant gonorrhoea, and to reduce late diagnosis of HIV.

An audit would be launched from a strong platform of established and world-class data, with the support of committed clinicians, commissioners, and civil society stakeholders. The alignment of the audit measures recommended in this study with existing national priorities, and local key performance indicators, will maximise the impact of the audit results. Furthermore, an STI/HIV audit will catalyse the transformation of a strong data collection culture into one of measurable quality improvement, for the benefit of patients today and tomorrow, and the wider public health.

8. Appendices

Annex 1 - Contract and project management

I. Feasibility study team members and consultees
II. Feasibility Study - Reference Group
III. Feasibility study deliverables
IV. Summary of the formative work

Annex 2- STIs, HIV, and sexual health in context

I. England STI slideset, 2014
II. Explanatory notes regarding PHE's STI surveillance data
III. Public Health England Reports, guidance and recommendations
IV. Summary of responsibilities for commissioning sexual health services
V. Other useful data sources
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Annex 3- Identifying and prioritising suitable topics and measures for audit

I. Topic selection criteria
II. Prioritisation of audit topics
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V. Survey of BASHH members

Annex 4 - Assessing technical feasibility of data collection

I. GUMCADv2 dataset
II. GUMCADv2 SHHAPT codes and notes
III. GUMCADv3 dataset
IV. Public Health Wales – SWS – dataset

Annex 5- Defining and refining a scope for audit

I. Patient and Public Involvement consultation meeting on HIV patient data, trust, and confidentiality

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