

Gilead Sciences Ltd.

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December 2022

Relationships with Healthcare Professionals, Other Relevant Decision Makers, Healthcare Organisations and other Organisations and Joint and Collaborative Working in the United Kingdom

(1) TRANSFERS OF VALUE MADE TO HCPS/ORDMS AND HCOS

Healthcare professionals, other relevant decision makers and healthcare organisations with whom we work provide valuable, independent, and expert knowledge derived from their clinical and management experience. This expertise makes an important contribution to our efforts to improve the quality of patient care, with benefits for individuals and society at large. We believe healthcare professionals, other relevant decision makers and healthcare organisations should be fairly compensated for the legitimate expertise and services they provide.

Transfers of Value made to HCPs/ORDM/HCOs from 2015

Each of Gilead Sciences Ltd, Gilead Sciences International and Gilead Sciences Europe Limited (collectively “Gilead”) is required, by the ABPI (Association of the British Pharmaceutical Industry) Code of Practice for the Pharmaceutical Industry (“the ABPI Code”), to document and publicly disclose certain transfers of value made to healthcare professionals and healthcare organisations (“Disclosures”). Methodological notes help with understanding how the Transfers of Value from Gilead to healthcare professionals, other relevant decision makers and healthcare organisations in the UK have been collated and reported, and can be found, alongside disclosures, [here](#).

Yearly disclosures remain in the public domain for at least three years from the time of first disclosure. Gilead retain the records for at least five years after the end of the calendar year to which they relate.

(2) GILEAD SCIENCES LIMITED JOINT AND COLLABORATIVE WORKING PROJECTS

Gilead Sciences Limited works in collaboration with other Organisations to deliver initiatives that enhance patient care, are for the benefit of patients or benefit the NHS (and maintain patient care) to pool skills, experience and/or resources for the joint development and implementation of these projects and where there is a shared commitment to successful delivery.

CURRENT JOINT AND COLLABORATIVE WORKING PROJECTS

Executive Summary of Collaborative Working Agreement

Project name: HIV Lens

Organisations involved: NAM Publications, Watipa and Gilead Sciences

Project Overview:

HIV Lens is an interactive mapping resource that visualises the impact of HIV on communities across England. It presents data from the UK Health Security Agency (UKHSA) including regional variation, health inequalities and available services. NAM and Watipa have full editorial control over the resource and source the required data with Gilead providing funding and strategic advice on priority areas for the tool to cover.

Project Objectives:

HIV Lens aims to visually present data in an easy-to-understand way. A challenge of this project was taking complicated datasets and transforming them into clear and concise graphical and visual representations. The next phase of HIV Lens will explore extending the geographical remit of the site, as well as providing more granular data and new data sets.

Expected project outcomes:

Accurate and accessible data will support a wide range of stakeholders and audiences to engage with local and national patterns of HIV prevalence, HIV testing and treatment uptake. Accurate data will help to inform and improve HIV service delivery and planning.

Expected project benefits include:

To patients/people living with HIV:

- Access to information about local HIV services
- Informed service planning and delivery
- More accurate reporting on HIV prevalence and incidence

To NAM and Watipa

- Comprehensive, accurate and accessible data about HIV prevalence and incidence, aiding reporting and sharing of data
- Collaborative working to inform and uplift the HIV sector

To Gilead Sciences:

- Opportunity to use the data from the project for policy advocacy

Duration of the project: We are aiming to end this new phase of the project in December 2022.

Contact:

- Gilead Sciences: Frances Luff Frances.luff@gilead.com
- NAM: Matthew Hodson, Matthew@nam.org.uk
- Watipa: Valerie Delpech, Valerie@watipa.org

Executive Summary of Collaboration Agreement: Positive Voices 2022

Project name: Positive Voices 2022

Organisations involved: Gilead Sciences Limited and UK Health Security Agency

UK Health Security Agency and Gilead Sciences Limited are undertaking this collaborative working with the aim of gaining insights and experiences of ~ 5000 people living with HIV of care in the non HIV setting.

The findings of the 2017 Positive Voices Survey highlighted the need for new models of HIV care to reduce dependency on HIV specialist services, free up NHS resources and time and provide holistic patient centre care. However, little is known about people living with HIV's current use and attendance patterns of non-HIV specialist healthcare, primary care and social care services.

In Positive Voices 2021, a specific subproject involving UKHSA and Gilead will aim to capture current levels of NHS and social care service use by people with HIV outside of the HIV specialist service.

Additionally, it will aim to better understand the prevalence of HIV stigma and discrimination within the NHS and social care system .

This Project will consist of one specific subproject of additional survey questions examining care and patient experience in the non HIV setting. This will be completed by ~5000 people living with HIV. Additionally, this collaboration supports 2 Sub analyses of responses to these additional questions and publications as detailed below:

- 1.- Use of non-HIV NHS and care services and
2. - Patient experience outside HIV settings

This Collaboration Project will benefit the NHS and could benefit patients in several different ways, including those set out in detail above and by:

- Providing valuable knowledge and insights into the experiences of care provision for people living with HIV outside of the HIV service.
- Providing people living with HIV (~5000) the opportunity to share their patient experience outside of the HIV setting which could ultimately lead to an improved experience in the non-HIV setting
- Once published these data and recommendations could lead to:
 - Increasing an equitable, and person-centred care

- Improve the access, engagement to and retention in care in the non-HIV setting
- Facilitating a better health outcome

Overall project delivery will be overseen by a Manager from the Gilead HIV Standards Support Team and on behalf of UK Health Security Agency by Adamma Aghaizu. The project will run from December 2021 through until June 2023 (end date is dependent upon availability of UKHSA Teams due to Covid-19 priorities).

Recruitment is well underway, at a similar rate to the 2017 survey. However, due to the higher recruitment target in this survey, both in terms of numbers of clinics and people with HIV. In order to meet this target, we anticipate extending the recruitment period.

Contact: Claire Hutton (Claire.Hutton@gilead.com)

Executive Summary of Joint Working Agreement

Project Name: Exploration of The Effective Management of Complex HIV Clinical Care (ageing and co-morbidities) with Digital Technology

The Parties: Chelsea and Westminster Hospital and Gilead Sciences

The Term: Commenced December 2020 and ongoing due to Covid-19 related delays

The Project:

This project's objective is to identify digital offerings that may measurably improve the care of people living with HIV (PLWHIV) in early frailty and/or with co-morbidities and assess the potential impact that implementation of digital technologies could have on several domains, including impact on patient outcomes and the impact on staff and patient time, assessing PLWHIV ability to self-care and improvement in clinician knowledge in the management of PLWHIV with complex needs.

This objective shall be achieved by:

- Capturing patient voice in patient and Chelsea and Westminster staff questionnaires by identifying knowledge of existing technology, potential technology options and existing patient pathway challenges, bottlenecks and digital improvement opportunities
- Mapping and analysis of Chelsea and Westminster's current care and treatment pathways (both clinical and patient), including generating a baseline of current patient experience for PLHIV in early frailty and/or living with co-morbidities
- Delivery of workshops to further identify, explore and examine proposed digital solutions
- Identification, modelling and prioritisation of digital solutions that may measurably enhance patient experience and care for PLHIV in early frailty and/or living with co-morbidities and associated impact of such solutions on improving current care pathway
- Completion of report collating and prioritising results and insights into proposed digital

Benefits:

For the Patient:

- Capturing the patient voice and experience in the mapping of the HIV care pathway for PLWHIV who are aging and/or with more complex needs at Chelsea and Westminster
- Identifying and prioritising digital offerings that may measurably improve the care and experience of people living with HIV (PLWHIV) in early frailty and/or with co-morbidities

For the NHS:

- Providing Chelsea and Westminster hospital with clear insights to consider how to improve the experience and care of PLWHIV with digital technology in several domains, including impact on patient outcomes and impact on staff and patient time, assessing PLWHIV ability to self-care and improvement in clinical knowledge of the management of PLWHIV with complex needs
- Analysis of the current HIV care pathway for PLWHIV who are aging and/or with more complex needs and the opportunities for improvement via digital offerings
- Understanding of current trends in digital health and healthcare improvement provision and assessment of applicability at Chelsea and Westminster Hospital

For Gilead:

- Gilead has a goal to become the chosen partner to lead improvements in health and healthcare for patients in the UK and Ireland in disease/therapy areas in which Gilead operate.
- Involvement in this project is anticipated to further Gilead Sciences Ltd's understanding of current and future HIV treatment/prevention care and services.
- In order to better understand patient pathways and how patients can receive care efficiently, Gilead would like to explore how existing practices and physical access to medicines and services may change if digital technology is further incorporated in hospitals.

For more information please contact:

Marta Boffito, Chelsea and Westminster Foundation Trust, Marta.boffito@nhs.net

Adrian Coleman Gilead Sciences Limited (Adrian.Coleman@Gilead.com)

Executive Summary of Joint Working Agreement

NHS Substance Misuse Alliance – Hepatitis C Patient Identification Collaboration
Executive Summary

Joint Working Project Extension

NHS Addictions Provider Alliance (NHSAPA) (formally known as the NHS Substance Misuse Provider Alliance (NHSMPA)) – Hepatitis C Patient Identification Collaboration

(1) The Midlands Partnership NHS Foundation Trust (MPFT) and (2) Gilead Sciences Limited are engaged in a Joint Working Project to identify, test and treat people at risk of having Hepatitis C with the goal of eliminating Hepatitis C in advance of the WHO target of 2030.

All parties have committed resources to support this project, which commenced in August 2019 for an initial period until March 2022.

In discussion the Parties have agreed to a 2-year extension to that agreement in accordance with the principles and guidance relating to joint working between the NHS and the pharmaceutical industry, in line with the ABPI Code of Practice for the Pharmaceutical Industry until March 2024.

Aims

- To increase the number of at-risk people per month who are tested for Hepatitis C within the NHS Addiction Provider Alliance territories;
- To increase the number of people appropriately referred into the care of a treater, either those who are newly diagnosed Hepatitis C positive or those previously diagnosed with Hepatitis C but not treated;
- To improve the efficiency with which Hepatitis C positive patients are diagnosed and ultimately treated as measured, e.g. through data reported by Operational Delivery Networks.

Benefits

- Patients will benefit from reduced time from viral infection to diagnosis and improved access to specialist care and treatment to prevent disease progression and complications with the ultimate objective of elimination of Hepatitis C within this patient population.
- Patients and the NHS will benefit as earlier diagnosis and care interventions may also prevent onwards transmission of Hepatitis C.
- Patients and the NHS will benefit from the development of innovative hepatitis C care pathways.

- Gilead and the NHS will benefit from a better understanding of the effectiveness and value of early testing and the creation of innovative hepatitis C care pathways particularly in high prevalence areas.
- All Joint Project Group members will have the option of co-authoring presentations and publications from this work.
- The project will direct public health protection interventions through patient engagement in harm reduction programs and treatment of at-risk individuals.

For further information please contact:

Medical Affairs, Gilead Sciences Ltd:

08000 113 700

UHS DigiPROM

Project Name: The co-design of a digital health pathway of care for the delivery of the POSITIVE OUTCOMES PROM

The Parties:

1. University Hospitals Sussex NHS Foundation Trust (UHS), having its principal place of business at Sussex House, Kemp town, Brighton BN1 9RH
2. Gilead Sciences Ltd, a company registered in England (registration number: 02543818), having a principal place of business at 280 High Holborn, London WC1V 7EE ("Gilead")

The Term: 12 Months

The Project:

This Joint Working Project aims to co-design a digital health pathway of care for the delivery of a PROM ensuring it is person-centred and acceptable from a patient and clinical perspective with regard to user experience (UX) and flow.

Objectives and outcomes:

- Co-design a person-centred digital PROM pathway for people living with HIV;
- Digitalise the PROM ensuring that people living with HIV and their clinicians are able to utilise it effectively;
- Implement the PROM within a digital platform that is integrated with the Trust's IT systems;
- Ensure that the pathway, digital PROM and digital platform will be developed based on user and clinician opinion and feedback throughout the project.

Benefits:

People living with HIV

- It is intended that the Joint Working Project will benefit people living with HIV in a number of different ways, including by:
- creating a co-designed digital pathway for the delivery of the POSITIVE OUTCOMES Patient Reported Outcome Measure that will enable people living with HIV to be able to report the outcomes that are important to them digitally.
- ensuring that the digital PROM tool and pathway are accessible, usable and acceptable in a

real world situation

- ensuring that people living with HIV are involved in the co-design of their person-centred services (particularly important as services re-set post-Covid given that many changes during this time have been implemented rapidly during the pandemic).
- In the context of digital inequalities this project will ensure that “no-one is left behind” as the PROM is introduced digitally and that appropriate adjustments are available for those who may not be as digitally literate or engaged.

University Hospitals Sussex NHS Foundation Trust

- Facilitating the provision of person-centred services via a digital PROM pathway will help the Trust to achieve their goals in line with the NHS long-term plan
- Potentially reducing the time taken for a clinician to identify the reported needs of individuals living with HIV and improving the time to refer for an intervention via a robust methodology/technology.
- Providing framework to assess the impact of the PROM on referrals to other services and on appointment types
- Ensuring that the digital provision of a PROM is usable and acceptable for clinicians which could be applied to other services locally and other Trusts nationally.
- Providing insights into digital literacy within the cohort – starting the journey towards understanding and improving digital literacy ensuring that no-one is left behind.

Gilead Sciences Ltd

- Gilead has a goal to become the chosen partner to lead improvements in health and healthcare for patients in the UK and Ireland disease/therapy areas in which Gilead operate. Involvement in this project is anticipated to further Gilead Sciences Ltd understanding of current and future HIV treatment/prevention care and services.
- This project will allow Gilead a greater insight into what is important to patients with respect to their treatment journey, how they wish to be communicated with and how they may wish to be managed in the future.
- Gilead would like to understand how existing practices and physical access to care may change via the digitalisation of PROMs tool.

Contact: Adrian.coleman@gilead.com

Project Name: Peer based Hepatitis C patient finding (Assigned Project name TBC)

The Parties: The Hepatitis C Trust, [charity number 1104279, 27 Crosby Road, London, SE1 3YD] (the “Hepatitis C Trust”); and Gilead Sciences Ltd, a company registered in England (registration number: 02543818), having a principal place of business at 280 High Holborn, London WC1V 7EE (“Gilead”)

The Term: 9 Months

The Project:

The core focus of this project is on the empowerment of people with lived experience of addiction, and possibly Hepatitis C, who are already based and established within the communities where drug use is known to be prevalent; untapping this lived experience to deliver more informed and enriched services and to create a network of peers who have the shared aim of elimination of hepatitis C as a public health threat.

Objectives:

- The creation of a network of peers to support Hepatitis C patient finding and linkage to care enhancing access to treatment for individuals that may find it hard to access services through more traditional routes and who otherwise may not benefit from existing engagement pathways
- Support clients through treatment and to access the core support already available
- Seek service user and peer feedback on potential improvements to engagement and treatment pathways for feedback to wider stakeholders and Managed Care Networks (MCNs)
- Collate feedback and outcomes for publication to inform future activity.

Core project outcomes of the delivery model:

- To test up to 2000 high risk clients and support between 150-200 PCR+ clients into care (subject to prevalence) – records will be kept of numbers of client engagement, tests delivered, and numbers of clients subsequently engaged into treatment pathways
- Participants will improve the treatment and testing experience for themselves and/or their peers in the local area through involvement, volunteering, campaigning, advocacy, and the provision of peer support as measured through questionnaires, peer engagement records and workshop reports
- Participants will have increased access to the testing and treatment of Hep C
- Participants and the community will have increased skills, confidence, and knowledge on the subject and to effect change

Benefits

Benefits for individuals at high risk of being to be infected with Hepatitis C:

- Increased access to testing and treatment
- Increased access to peer support
- Improved choice and control
- Improved health outcomes through access to treatment for Hepatitis C and improved engagement with the healthcare system
- Improved future pathways to care for individuals unable to access current pathways measured through data provided by the Managed Care Networks.

Benefits for the Hepatitis Trust:

- Increased access to high-risk individuals through enhanced relationships with stakeholder groups
- Increased understanding of the needs of high-risk individuals within Scotland
- Improved partnership relationships across Scottish networks
- Better understanding of existing test and treatment pathways and opportunities to improve and enhance them
- An increased evidence base for the role of peers in engaging individuals into treatment and testing pathways
- An improved understanding of the particular cultural issues affecting Scottish drug users likely to be at high risk of Hepatitis C
- Access to materials, questionnaires and reports developed through the project

Benefits for Peer Champions:

- Reduced isolation and loneliness
- Increase in meaningful activity/daily structure
- Increased skills and confidence
- Personal development and employability
- Reduced stigma

Benefits for Gilead:

- Better informed and enriched services
- Increased user voice in service delivery and campaigns and influencing work
- Increased local profile
- Increased and improved local partnerships
- A better understanding of the effectiveness and value of innovative care pathways in areas of potential high prevalence

Contact: matt.milner@gilead.com

Project Name: The digitalisation of patient pre appointment assessment and annual health review

The Parties: Royal Free Hospital NHS Foundation Trust, Central & North West London NHS Foundation Trust and North Middlesex Hospital Trust

The Term: 2 years

The Project:

The proposed project will involve the North Central London (NCL) HIV Network[#] and Gilead Sciences Ltd jointly working together to develop a digital solution to facilitate patient-reported health outcomes and clinician guided health data collection to assist clinicians to deliver more holistic care to people living with HIV. The tool will support self-management allowing the patient to undertake a pre-appointment health review, which can then be referred to by clinicians during consultations to assist the development of a personalised care plan which is relevant, appropriate, and accessible. Through ensuring a person-centred care approach the project is expected to improve adherence to BHIVA Standards¹ and Monitoring Guidelines² as well as delivering equitable HIV care and empowering people living with HIV to experience an innovative and up-to-date service care provision.

Aims:

- Develop a digital solution that enables and empowers people living with HIV to optimise self-management of their condition and their care, supporting clinicians in the delivery of person-centred holistic care, promoting adherence to the BHIVA Standards of care, and monitoring guidelines

Objectives:

- To improve service provision for PLHIV when measured against national standards¹
- To standardise a network-wide health review proforma in line with BHIVA Standards of care¹
- To assist self-management by using a digital solution that enables patient-reported health outcomes which are accessible to the clinician
- To promote self-management for PLHIV through a patient-reported health review, utilising a person-centric approach

- To ensure a person-centred care approach is maintained, improving adherence to BHIVA standards of care¹, and monitoring guidelines²

[#]Royal Free Royal Free London NHS Foundation Trust (RF), Mortimer Market Centre, Central & North West London Sexual Health (MMC), North Middlesex University Hospital (NMU)

1.- BHIVA Standards of Care for People Living with HIV 2018. Available at: <https://www.bhiva.org/standards-of-care-2018>. Accessed October, 2020.

2.- BHIVA guidelines for the routine investigation and monitoring of adult HIV-1-positive individuals 2016 (2019 interim update). <https://www.bhiva.org/HIV-1-treatment-guidelines> . Accessed October, 2020.

Outcomes:

- A digital solution that results in improved patient engagement in own health
- Increase in uptake of annual health reviews
- Improvement in comorbidity assessment and increased adherence to BHIVA Standards¹ and monitoring guidelines²
 - Significant measurable improvement in patient outcomes versus the BHIVA standards

Benefits to Patients

This Joint Working Project will benefit patients in several different ways, including those set out in detail above and by:

- Providing people living with HIV within NCL HIV Network[#] a standardised assessment which meets the BHIVA Standards of care¹ and monitoring guidelines²
- Providing to people living with HIV within NCL HIV Network[#] an improved experience in the HIV service provision, virtual or face-to-face consultation
- Facilitating the opportunity for patients to develop self-management skills through this digital solution
- Increasing an equitable, and person-centred care
- Improve the access, engagement to and retention in care
- Value-added outcomes in patients with complex HIV care needs
- Facilitate a better sexual and reproductive health outcome
- Enhanced psychological care and wellbeing outcomes

The benefit to the NHS within NCL HIV Network

- Analysis of the current performance versus BHIVA Standards of Care¹ and Monitoring Guidelines²
- A Network-wide[#] approach of a patient-reported health review, assisting clinicians in the delivery of a holistic HIV care consultation, in a virtual or face-to-face environment
- Funding and support to develop a digital solution that enables the adherence BHIVA Standards of Care¹ and Monitoring Guidelines² resulting in higher quality care
- A platform that supports audit and continuous improvement in HIV service care delivery and services configured around patient needs

The benefit to Gilead Sciences

- Involvement in this project anticipates bringing further understanding of the BHIVA Standards of care¹ and monitoring guidelines². This insight shall allow the HIV Standards Support team to better support other NHS Trusts
- Gilead's HIV Standards Support team shall utilise insights from this project to disseminate best practice, and support other NHS Trusts to develop similar digital solutions

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Project Name: STEP-C Free (Support to Treatment by Engagement with Peers = Hep C Free

The Parties: NHS Forth Valley Health Board & Gilead Sciences Ltd

The Term: 12 Months

The Project:

Aims and Objectives

The primary aim of this project is to micro-eliminate HCV in Forth Valley Health Board by optimizing the current testing, diagnosis and treatment pathway; facilitate more rapid and equitable access to treatment for hard-to-reach patients by:

1. Reducing the time from screening to commencing treatment from over 10 weeks to less than one week
2. Improving patient attrition by reducing the number of steps required from screening to Treatment
3. Moving from DBS testing to point of care screening and testing using Ab Oral screening tests and Cepheid GeneXpert POC HCV RNA tests
4. Expanding a peer support network and increasing capacity of CNS
5. Expanding reach to patients beyond traditional clinical settings

Benefits:

Outcomes for Patients:

- Easier access to testing, significantly reduced waiting time, compared to 8-week DBS result delay
- Immediately placed into shortened pathway once Cepheid result known
- Treatment starts within few days as opposed to 10 weeks
- The new pathway will allow access to test, treat and support for client groups who don't currently engage with standard pathways
- Peer worker will significantly increase support and harm reduction messages to hard to engage groups
- Easier and seamless testing will positively encourage those testing negative to undergo regularly repeat process if further risk activity is identified.

Outcomes for NHS

- Improve access to testing and treatment for hard to reach and marginalised groups, improving health inequalities and reducing burden of long-term chronic disease in disadvantaged populations
- Significantly increase the use of "Treatment for Prevention" strategy in those groups with highest prevalence of Hepatitis C, thus reducing risk of secondary transmission and reinfection
- Will enable NHS Scotland target of Hepatitis C elimination to be reached by 2024-5 within Forth Valley

Outcomes for the Gilead:

- Explore the use of alternative strategies for treatment delivery in a Scottish Health Board setting.
- Involvement in this project is anticipated to further Gilead Sciences Ltd understanding of current and future HCV treatment pathways, including testing modalities, prevention/harm

reduction, linkage to care and services – especially for difficult to reach patient.

- This project will allow Gilead a greater insight into where and how to engage with people living with HCV outside of the regular NHS touchpoints. To help Gilead understand what is important to patients with respect to their treatment journey, how they wish to be communicated with and how they may wish to be managed in the future.
- As geographies across the UK and Ireland get close to micro-elimination, the insights and learnings from this pilot can support micro-elimination by means of sharing best practice

For more information please contact:

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Project name: Gay Men's Sexual Health Survey 2022

Organisations involved: University College London (who is engaging Department of Health and Social Care, UK Health Security Agency, Healthy London Partnership) and Gilead Sciences

Project Overview:

Since 1996, the Gay Men's Sexual Health Survey has captured the sexual behaviour of Men Who Have Sex With Men (MSM) using self-completion questionnaires. Since 2011 the survey included an anonymous salivary testing for HIV in association with the behavioural questionnaires. Saliva testing has the advantage that it can be collected by the participants themselves without discomfort and is safe to use in non-clinical settings. PHE (now UKHSA) has used saliva testing successfully in previous surveys conducted since 1999 (Wayal et al., 2008). Participants are provided an information sheet which has a step-by-step pictorial guide on how to collect a saliva specimen. Since 2005 the survey has been conducted in London.

Project Objectives:

To measure the HIV prevalence amongst a community based sample of MSM in London and explore the association between HIV status and HIV testing and prevention behaviours, and awareness, uptake and source of HIV pre-exposure prophylaxis (PrEP). The study will also assess the accuracy of self-reported HIV status.

Expected project outcomes:

- To measure the prevalence of HIV (diagnosed and undiagnosed) amongst MSM attending community social venues;
- To compare the rates of HIV infection in men who report that they attend sexual health clinics and non-sexual health clinic attenders who may utilise other services (e.g. internet, self-testing or self-sampling services);
- To examine the association between HIV status and key sexual behaviour data;
- To examine the association between HIV and STI testing, sexual behaviour and use of PrEP;
- To measure the accuracy of self-assumed HIV status;
- To examine HIV testing and STI testing behaviours;
- To examine self-reported sexual health service use and use of STI/HIV prevention measures;
- To assess the proportion of participants reporting a monkeypox diagnosis/vaccination offer and uptake;
- Examination of self-reported PrEP use (longitudinal comparison of 2016, 2019, 2022).

Expected project benefits include:

Benefits for the population

- To support estimations of undiagnosed HIV cases
- To support HIV pathway redesign (if needed)
- To update data on key population not being captured by other epidemiological surveillance systems
- To inform dedicated sexual health services tailored to the community.

Benefits for UCL

- To lead the main sexual health attitude survey on HIV and key populations.
- To provide academic HIV data to researchers, policy makers and the public.
- To examine and publish evidence on HIV & STI prevention behaviours & attitudes.

Benefits for public health systems (DHSC, UKHSA, Health London Partnership)

- To measure the prevalence of HIV (diagnosed and undiagnosed) amongst MSM
- To examine the association between HIV testing, sexual behaviour and use of PrEP;
- To compare the rates of HIV infection in attenders of sexual health clinics vs non-sexual health clinic

Benefits for Gilead Sciences

- To explore knowledge and attitudes towards new technologies for treatment and prevention
- This project will allow Gilead a greater insight in to what is important to patients with respect to their treatment journey and how they may wish to be managed in the future.

Duration of the project

Project is aiming to be completed by Spring 2023

For more information please contact:

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Project Name: ATTC Bridging – CAR-T Patient Referrals Pathway Gap Analysis

Organisations Involved

- Autolus Limited
- Cell and Gene Therapy Catapult
- Gilead Sciences Limited
- Janssen Cilag Limited
- NHS Blood and Transplant
- The Christie NHS Foundation Trust

Project Overview

Currently, demand for CAR-T referrals is relatively low within the NHS and relies on national structures such as the National CAR-T Clinical Panel (NCCP) or regional clinical trial networks to identify patients appropriate for CAR-T treatments. As the spread and scale of CAR-T widens, and with the potential loss of the NCCP, effective processes for referring patients are needed to maintain patient access to standard of care CAR-T as well as investigational CAR-Ts.

A group of institutions including, the Cell and Gene Therapy (CGT) Catapult, Advanced

TherapyTreatment Centre (ATTC) Network Autolus Limited (Autolus), Gilead Sciences Ltd (Gilead), Janssen-Cilag Limited (Janssen), NHS Blood Transplant (NHSBT) and The Christie NHS Foundation Trust (The Christie) ("the Parties") have agreed to participate in a Collaborative Working Agreement in line with the ABPI Code of Practice to identify and analyse CAR-T patient referral pathways in the UK to recommend future best practice.

The project will be delivered by The Christie and NHSBT for the CGT Catapult in collaboration with the Parties. The project will capture the consolidated view of surveys, interviews and mappings at CAR-T treatment centres and convey the critical analysis of pathways with service improvement suggestions and the outline business case for change at the two sites of focus (The Christie and NHSBT).

This project involves a balance of contributions from all parties with the pooling of skills, experience and resources.

Project Plan

- Survey a broad range of adult CAR-T treatment centres, secondary referrals centres, patient advocacy groups and governing structures.
- Interview key opinion leaders from survey responses to further explore their opinions.
- Map the patient referrals processes from secondary referrals centres into CAR-T treatment centres, critically analyse referral practices, highlighting best practice and evaluating root causes for ineffective practices.
- Define patient and healthcare professional requirements for a high-quality referrals process.
- Explore how equity of access is affected by referral practices and how current processes can account for anticipated changes in CAR-T environment.

Expected Project Outcomes

The project outputs will be a white paper with a set of justified recommendations for improved, standardised future CAR-T patient referral practice and an outline business case for The Christie and NHSBT.

It is expected that this project will enable:

- The creation of powerful collaborations which overcome the challenges in CAR-T patient referrals pathways / processes and transform these barriers into industrial advantages that develop new perspectives on CAR-T patient referrals
- Support of clinical adoption and delivery of CAR-T therapies in the UK
- Better understanding of the challenges faced by NHS organisations providing CAR-T
- Informing of a best practice referral and care coordination process from referring centres to CAR-T centres which is patient-centric and fully supported by documentation.
- Creation of greater synergy between CAR-T treatment centres and referring centres.

Expected Project Benefits

To patients:

- More effective patient referrals and thus improved access to care.
- Equity of access to CAR-T around the country.

To the NHS:

- Better understanding of the challenges faced by NHS organisations providing CAR-T.
- Information on requirements to deliver better service for patients.
- Shared learning across the NHS through the white paper.

**To the Cell and Gene Therapy Catapult:**

- Better understanding of the challenges faced by NHS organisations providing CAR-T.
- Creation of powerful collaborations which overcome the challenges in CAR-T patient referrals and transform these barriers into industrial advantages that develop new perspectives on CAR-T patient referrals.

To the Pharmaceutical Company Partners:

- Better understanding of the challenges faced by NHS organisations providing CAR-T.
- Improved NHS processes to ensure increased access to CAR-T products for all eligible patients.

Duration of Project

6 months (Dec 2022 – Jun 2023)

Contacts

- Fiona Thistlethwaite, ATTC Project Lead / Director iMATCH
- James Griffin, NHSBT Lead / Medical Director Cell, Apheresis & Gene Therapies
- Justin Hayde-West, Janssen Cell Therapy Coordination Manager
- Luis Calleja Calatrava, Janssen Cell Therapy Account Lead
- Anita Ralli, Gilead UK Associate Director Government Affairs
- Sarah Waluda, Autolus Senior Director Clinical Programme Lead

HISTORIC COMPLETED JOINT AND COLLABORATIVE WORKING PROJECTS

EMERGENCY DEPARTMENT UNLINKED ANONYMOUS BBV SEROPREVALENCE - 'ENABLE'

A number of NHS Trusts*, Public Health England and Gilead Sciences Limited are engaged in a Joint Working Project to estimate local prevalence of certain blood-borne viruses (BBVs). All parties committed resources to support this project, which commenced in November 2016 and was originally expected to complete within 7 months.

Aims

The aim of this joint working project is to estimate local prevalence of BBVs (HIV, HBV, HCV) by performing an unlinked anonymous seroprevalence survey using residual blood samples (taken for other purposes) from patients attending the Accident and Emergency Department (A&E) at the NHS Trusts*. The samples will be anonymised, with solely the patient's sex, age and ethnicity remaining associated with the sample for epidemiological analysis.

Benefits

Using anonymised samples is a simple but well established public health strategy providing valuable data to inform local BBV epidemiology and health protection decisions. This will enable the NHS Trusts* and Public Health England to determine whether there is a need for the implementation of any testing initiatives in A&E, with an associated clinical care pathway, to identify BBV patients that are undiagnosed or diagnosed but not in care and ensure that they receive the appropriate management for their BBV.

*1.1 Royal Liverpool University Hospital

*1.2 Blackpool Teaching Hospitals

*1.3 Imperial Healthcare Foundation NHS Trust

Outcome: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6972612/>

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Joint Working Project

VirA+EmiC – Accident and Emergency Department HBV and HCV opt-out testing combined with an enhanced rapid care pathway

(1) Guy's and St Thomas NHS Foundation Trust, (2) Lambeth Clinical Commissioning Group, (3) Public Health England and Gilead Sciences Limited are engaged in a Joint Working Project to evaluate the feasibility, effectiveness and acceptability of a combination of innovative viral hepatitis (HBV and HCV) opt-out testing for patients.

All parties have committed resources to support this project, which was commenced in October 2016 and originally expected to complete within 12 months.

Aims

The aim of the VirA+EmiC Joint Working Project is to evaluate the feasibility, effectiveness and acceptability of a combination of innovative viral hepatitis (HBV and HCV) opt-out testing for patients over 16 years having bloods taken in St Thomas' Hospital A&E department combined with an enhanced rapid hepatitis care pathway for patients testing positive for either infection.

Benefits

The expected benefits of the VirA+EmiC Joint Working Project to patients are that all Parties will have a better understanding of the effectiveness and value of routine opt-out viral hepatitis testing as part of A&E attendance in high prevalence areas, in combination with an innovative hepatitis care pathway. Patients will benefit from reduced time from viral hepatitis infection to diagnosis and improved access to specialist care and treatment to prevent disease progression and complications. Earlier diagnosis and care interventions may also prevent onwards hepatitis transmission. The project will direct public health protection interventions through patient engagement in harm reduction programs and vaccination of at risk individuals.

Outcome: <https://onlinelibrary.wiley.com/doi/full/10.1111/jvh.13676>

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Joint Working Project

'Get tested LeEDs' – Accident and Emergency Department blood borne virus (HBV, HCV,HIV) opt-out testing combined with an enhanced rapid care pathway

Leeds Teaching Hospital Trust (LTHT), and Gilead Sciences Limited are engaged in a Joint Working Project to evaluate the feasibility, effectiveness and acceptability of innovative blood borne virus (HIV, HBV and HCV) opt out testing for patients combined with enhanced linkage to care. All parties have committed resources to support this project, which commenced in May 2018 and originally expected to complete 18 months.

Aims

The aim of *Get tested LeEDs Joint Working Project* is to evaluate the feasibility, effectiveness and acceptability of innovative blood borne virus opt-out testing for patients over 16 to 65 years of age having bloods taken at LTHT's A&E Departments combined with an enhanced rapid hepatitis care pathway for patients testing positive for either infection.

Benefits

The expected benefits of the *Get tested LeEDs Joint Working Project* to patients are that all Parties will have a better understanding of the effectiveness and value of routine opt-out blood borne virus testing as part of A&E attendance in high prevalence areas, in combination with an innovative hepatitis care pathway. Patients will benefit from reduced time from viral blood borne virus infection to diagnosis and improved access to specialist care and treatment to prevent disease progression and complications. Earlier diagnosis and care interventions may also prevent onwards transmission. The project will direct public health protection interventions through patient engagement in harm reduction programs and vaccination of at risk individuals.

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Joint Working Project

London Initiative for Glandular fever HIV Testing (LIGHT)

(2) Guy's and St Thomas' NHS Foundation Trust, (2) King's College Hospital NHS Foundation Trust, (3) Stockwell Group Practice, (4) Southwark Council Department of Public Health, (5) Lambeth Council Integrated Commissioning Team, (6) GSTS Pathology LLP and Gilead Sciences Ltd are engaged in a joint working project to configure existing electronic laboratory ordering software (TQuest®) used by Guy's and St Thomas' NHS Foundation Trust and King's College Hospital NHS Foundation Trust hospital laboratories to include an HIV test (on an opt-out basis) as part of the electronically requested routine glandular-fever screens in primary care.

All parties have committed resources to support this project, which was commenced in 2014 and originally expected to complete within 2 years.

The purpose of the joint working project is to implement and monitor the impact of opt-out HIV testing in electronically requested glandular fever screens in primary care practices across Lambeth and Southwark.

This project is designed to provide benefits to patients, the NHS and Gilead and, in particular, to support:

- testing for HIV in a primary care setting to encourage:

- earlier HIV diagnosis and linkage to care
- de-stigmatisation of HIV testing through incorporation into routine medical investigations
- implementation of recommendations in clinical guidelines and alignment with the NHS commissioning QIPP agenda
- deliver and monitor care within a setting convenient for patients

Outcome: <https://onlinelibrary.wiley.com/doi/full/10.1111/hiv.12914>

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Executive Summary of Collaborative Agreement on: Development of a high-level best practice process map to optimise services and care across the HIV care continuum in Liverpool

Sahir House, Liverpool and Gilead Sciences Limited are undertaking this collaborative working with the aim of optimising HIV services and care in Liverpool. Development of a best practice and linkage to care process map which will entail mapping of the current access to care by HIV populations and identification of gaps in the current care provision. These could include increase HIV testing and linkage to care, retention in care, and viral suppression, detailing aspects such as how to refer people living with HIV, how often to see such individuals in line with guidelines and how to engage and retain the individuals in care.

This Project will consist of development of (i) high-level Best Practice Linkage to care service process map and (ii) a detailed exemplar of one section of the Linkage to care service process map. Initial discussions indicate that the detailed exemplar will likely focus on the management of a person living with HIV and co-morbidities. The Best Practice Linkage to Care Service Process Map will not discuss HIV treatments.

The collaboration involves a balance of contributions with the pooling of skills, experience and resources from both Gilead and Sahir House.



Intended Benefit of the Project is to:

- To improve quality of service for people living with HIV through enabling better referral, care and follow up.
- To measure the improvement in quality of service for people living with HIV through clearly defined outcomes and indicators.
- To support improved commissioning in HIV services across the full pathway of care focus on quality, outcomes and value.
- To support the achievement of national standards of care (BHIVA)
- Improve health inequalities through reducing unwarranted variation in treatment and services.

Overall project delivery will be overseen by a Manager for the Gilead Outcomes and Services Support Team (now known as Gilead HIV Standards Support team) and on behalf of Sahir House by an external Project Manager from EQE Health.

The project was anticipated to run from February 2021 through until November 2021, unfortunately due to the impact of Covid -19 and staff relocation the project was terminated following the development of the draft process map.

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