

Testing behind bars: A mixed-methods realist
evaluation of opt-out blood-borne virus
testing and associated pathways of care
within London prisons

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Declaration of authorship

I, Seth Francis-Graham, confirm that the work presented in this thesis is my own. Where information has been derived from other sources, I confirm that this has been indicated in the thesis.

Signature:

Date: ____/____/____

Abstract

Background: The elimination of viral hepatitis C by 2025, hepatitis B by 2030, and the control of the human immunodeficiency virus is predicated on the diagnosis and treatment of these infections in high prevalence settings. In response to historic low testing rates, opt-out blood-borne virus testing has been implemented and linked with treatment pathways throughout the English prison estate. The aim of my PhD was to evaluate this initiative in London.

Methods: Guided by realist methodology, a mixed-methods evaluation was performed. I began by conducting a pilot assessment of a hepatitis C care pathway implemented within one London prison. From this, I decided to focus on the testing stage of the implemented pathways. I analysed routine data to assess outcomes from opt-out testing across the London estate. I then conducted a rapid-realist review to begin developing an explanatory framework for the outcomes reported. Theories developed during the review were used to guide a qualitative comparative case-study, which explored the variation in performance between a higher and low performing local London prison.

Results: The pilot evaluation highlighted significant attrition throughout every stage of the hepatitis C care pathway. Analysis of test outcomes revealed that healthcare teams operating within local prisons struggled to test people, whilst also reporting the highest test positivity for hepatitis C exposure. The review flagged a range of potential drivers of poor performance, including access issues and incentives for prisoners to refuse testing. Results from the qualitative comparative case study suggested that differences in the numbers of new prisoners tested, between two local London prisons, primarily stemmed from access issues, rather than test acceptability.

Conclusion: The implementation of opt-out blood-borne virus testing has occurred at a difficult time for the prison service. The ability of healthcare staff to deliver testing and treatment pathways for blood-borne viruses is dependent on prison staff providing access to prisoners. Although small-scale pathway adaptation may help improve programme performance, better resourcing of prisons and systemic change that places healthcare at the centre of the rehabilitative mandate of the English prison service should be considered.

Impact statement

Throughout the conduct of this evaluative research I have made both methodological contributions and encouraged practical policy change. My interest in analysing the interaction between a healthcare programme and its wider context led to the development of a novel realist evaluation framework. This combined concepts from critical realism with realist evaluation methodology. It is my intention that this framework will continue to be applied and further refined in future research projects, facilitating a more comprehensive assessment of a programme's performance.

As this research was funded by the National Institute for Health Research, emphasis was placed on translating findings into policy recommendations, or small-scale interventions, designed to improve the quality of care prisoners received during the diagnosis and treatment of blood-borne virus infections. As these recommendations and interventions were a central part of the research process, and were evaluated in subsequent stages of the project, they are discussed in the main body of text.

However, to summarise contributions made during this project:

- In Chapter 4 I discuss an information card and interactive website, developed to facilitate continuity of care for prisoners diagnosed with chronic viral hepatitis C infection. This intervention was shared with NHS England partners and is currently undergoing costing before national implementation.
- In Chapter 5 I discuss a novel data system that I developed with NHS England, Public Health England, and prison healthcare providers, which was designed to improve the quality of monitoring data available in London. Although not currently implemented, this helped inform national efforts to improve the quality of data used to monitor services for blood-borne viruses within English prisons.
- In Chapter 6 I discuss a script, developed to guide the delivery of an opt-out test offer, and a "switching cost form". The script was disseminated nationally by NHS England and Public Health and Justice. It was crucial in raising awareness about the importance of wording when delivering an opt-out test offer. The "switching cost form" was implemented across London prisons.
- In Chapter 8 I summarise the "TO-BE-FIT" proposals, designed to improve the diagnosis of blood-borne virus infections within English prisons. These proposals were shared with national Public Health and Justice partners and helped inform the industry re-development strategy.

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Publications and conferences

In the course of completing this PhD I have published in a peer-reviewed scientific journal, contributed to a book chapter, and presented findings at national and international conferences.

Publications:

- Francis-Graham S, Ekeke NA, Nelson CA, Lee TY, Haj S El, Rhodes T, Vindrola C, Colbourn T, Rosenberg W. Understanding how, why, for whom, and under what circumstances opt-out blood-borne virus testing programmes work to increase test engagement and uptake within prison: a rapid-realist review. *BMC Health Services Research*. 2019; 19(1):1-18.
- Francis-Graham S, Rosenberg W. Treating prisoners with hepatitis C: should we do it and how? In Foster G and Reddy R (eds.) *Clinical dilemmas in viral liver disease (2nd edition)*, Wiley-Blackwell, New Jersey, United States, 2020.

Conferences (oral presentations):

- A realist evaluation of a viral hepatitis C pathway within a local London prison. Francis-Graham S, Ekeke NA, Rosenberg W. Pivot meeting: Diagnosing and treating hepatitis C in high transmission settings across London, UK, 2017 (invited speaker).
- Active case detection in prison: increasing testing through opt-out screening. Francis-Graham S and Rosenberg W. 7th Annual London Joint Working Group on Substance Use and Hepatitis C, UK, 2017 (invited speaker).
- Testing behind bars: Screening prisoners for hepatitis C within English prisons. Francis-Graham S and Rosenberg W. 7th Conference of the Central European Hepatologic Collaboration, Warsaw, Poland, 2018 (invited speaker).

Conferences (poster presentations):

- Improving the detection and management of hepatitis C infection in prisons. Ekeke NA, Francis-Graham S, King T, Demma S, Macdonald D, Rosenberg W. EASL: The International Conference, Paris, France, 2018.
- Fragile success: A realist process evaluation of opt-out blood-borne virus testing within London prisons. Francis-Graham S, Vindrola C, Rhodes T, Rosenberg W. 4th Qualitative Health Research Network Conference, London, UK, 2019.

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Abbreviations

AIDS	Acquired immunodeficiency syndrome
Anti-HCV	Hepatitis C antibodies
Anti-HIV	Human immunodeficiency virus antibodies
BBV	Blood-borne virus
CI	Confidence intervals
CMO	Context-mechanism-outcome (CMOc = context-mechanism-outcome configuration)
CNS	Clinical nurse specialist
CR	Critical Realism
CRC	Community Rehabilitation Company
DAA	Direct acting antiviral
DBS	Dried blood spot (DBST = dried blood spot test)
DNA	Deoxyribonucleic acid
ELF	Enhanced Liver Fibrosis test
FNC	First night centre
HCW	Healthcare worker
HBV	Hepatitis B virus (cHBV = chronic hepatitis B)
HBsAg	Hepatitis B surface antigen
HCV	Hepatitis C virus (cHCV = chronic hepatitis C)
HJIPs	Health and Justice Indicators of Performance
HMPPS	Her Majesty's Prison and Probation Service
HIV	Human immunodeficiency virus
IDU	Injecting drug use
LBCSG	The London Blood-Borne Virus Core Steering Group
Ma-Mi	Macro-to-micro mechanism
MDT	Multi-disciplinary team meeting
Mi-Ma	Micro-to-macro mechanism
Mi-Mi	Micro-to-micro mechanism
NHSE	The National Health Service England
NICE	National Institute for Health and Care Excellence
ODN	Operational Delivery Network
PC	Primary care
PCR	Polymerase chain reaction
PHE	Public Health England
PWID	People (person) who inject drugs
RAMESES	Realist and Meta-narrative Evidence Syntheses: Evolving Standards
RE	Realist Evaluation
RNA	Ribonucleic acid
RRR	Rapid-realist review
SM	Substance misuse
SVR	Sustained viral response
WHO	World Health Organisation

Glossary

Agency	The capacity of individuals to act independently and make their own free choices
Abduction	A form of logical inference, which starts with an observation and then seeks to find the most plausible explanation for that observation
Ancillary resource	A property pre-existing the implementation of a social programme, which is involved in the realisation of a programme resource (see the definition for “programme resource” in this table)
Community rehabilitation company	Privatised probation services, managing low and medium risk offenders. The National Probation Service is focused on managing those offenders considered “high risk”
Context-mechanism-outcome configuration	An explanatory statement that outlines how a programme (or component of a programme) may bring about a change within a given context
Custodial manager	An officer responsible for developing and managing the regime for a certain area of the prison, whilst line managing supervising officers and prison officers
Default Effect	Describes the propensity of most people to stick with the default option during decision making
First night screening	Also called “first reception” and “first night in custody”, first night screening is a clinic hosted on the evening a person arrives at a prison. It is designed to identify and manage urgent physical and mental health needs
Governing Governor	The highest-ranking manager of a prison
Health and Justice Indicators of Performance	Monitoring metrics used by NHS England to assess the delivery of healthcare services within prison. These cover services related to the diagnosis and treatment of blood-borne viral infections
Healthcare officer	A prison officer assigned by the Governing Governor to enable the delivery of healthcare services
Macro-to-micro mechanism	An emergent effect, generated through the interaction of several social structures (see definition for this term), that conditions or incentivises certain actions in a manner relevant to consider during programme implementation or evaluation
Micro-to-macro mechanism	A change in social or physical structures, brought about through the interaction of people responding to a social programme
Micro-to-micro mechanism	The reasoning and/or behaviour change of individuals in response to the resources implemented by a social programme
Middle-range theory	A theory that is specific enough to generate testable hypotheses, but is abstracted enough to be applied across different programmes or contexts
Mixed methods sequential explanatory design (case-selection)	A mixed methods research study design, where quantitative data is analysed first and then used to target in-depth qualitative work, which aims to explain quantitative results
Nudge Theory	A branch of behavioural science and behavioural economics concerned with the role of indirect suggestions and environmental change in shaping peoples’ behaviour and decisions

Opt-in	Opt-in and active choice can, and have, been distinguished as separate ways of framing a decision. However, in this thesis opt-in refers to a situation where an individual has to make an active decision to accept a test
Opt-out	A decision where the recommended action is the default option (i.e. a person is tested unless they actively refuse)
Pilot evaluation	A small-scale evaluative study, designed to trial methodology and generate data that can help target more in-depth evaluative work
Primary care department	A nursing team within prison, responsible for the physical health of prisoners that do not have a history of substance misuse
Prison regime	The daily timetable that a certain area of the prison must adhere to and that prison officers are required to facilitate and deliver
Realist action research	Action research using a realist lens of enquiry. The cyclical and participatory process of planning a solution, trialling it, evaluating it, and reformulating it is used to develop and refine realist programme theory alongside the intervention or programme
Remand	The process of detaining someone who has been arrested and charged with an offense, pending trial
Resource	A property that is associated with an implemented component of a programme or intervention
Retroduction	A method of moving between deductive (testing theory against empirical evidence) and inductive (using evidence to generate theory) enquiry to generate and test theories about underpinning causal processes
Secondary screening	Also called “second reception”, “wellman”, and “second day screening”; secondary screening is a clinic, usually held within 72 hours of a person entering a prison, designed to identify physical and mental health needs
Structure	Those factors, generated by the interaction of humans, which influence, limit, incentivise, or direct an individual’s decisions (e.g. social class, religion, gender, ethnicity, and customs). Physical structures, (i.e. locations, objects, the environment) may also shape an individual’s decision making
Supervising officer	An officer that acts as a supervisor for a particular area of the prison and is responsible for a team of prison officers
Substance misuse department	A nursing team within prison, responsible for the physical health of prisoners with a history of substance abuse
SystmOne	A clinical IT system in use throughout the English prison estate
Violent bureaucracy	A term used in this thesis to describe how complex and ineffective bureaucratic prison processes may incentivise prisoners to by-pass protocol by committing strategic acts of self-harm

Chapter 1: Blood-borne viruses and the English prison estate

1.0 Introduction

For many years national and international public health authorities paid little attention to the healthcare needs of people within prison (1). Issues surrounding the delivery of care within carceral settings were understudied and rarely featured in academic training programmes or within the published literature (1,2).

Prisons were considered a “world apart” until the 1980s, where these institutions began to receive attention from health authorities for the first time as a result of the acquired immunodeficiency syndrome (AIDS) pandemic (1). Now, with new global targets and the availability of highly effective treatments for viral hepatitis C (HCV), carceral settings are experiencing a renaissance of Public Health and medical interest, internationally and within the UK (3).

This thesis forms part of this Public Health renaissance, focusing on testing for blood-borne viruses (BBVs) within the English prison estate. It is composed of eight chapters, with the first three providing information on the topic, the BBV test programme, and the research design (figure 1). Taken together, they should provide a grounding from which to interpret the four empirical chapters, where research methods and results are discussed (figure 1). The final chapter concludes this thesis, by summarising key findings and considering future areas of research.

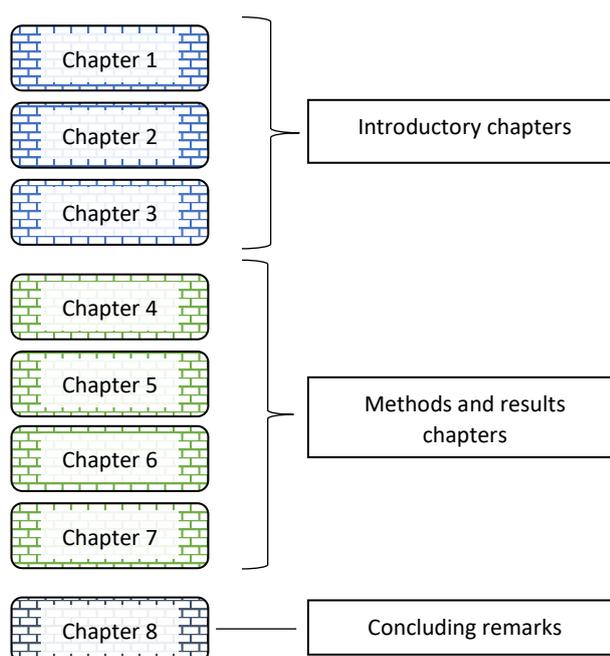


Figure 1. Outline of the thesis structure. Block colour signifies the aim of the chapter (blue = introductory; green = methods and results; dark blue = concluding remarks).

In this chapter, I introduce the research by briefly providing background information on three BBVs commonly diagnosed within prisons: HCV, hepatitis B (HBV), and the human immunodeficiency virus (HIV). Although all three are discussed throughout this thesis, my primary focus is HCV. Consequently, more detail is provided about this viral infection.

I then describe features of the English HCV elimination strategy and consider the role that prisons may have in facilitating elimination objectives. Finally, I end the chapter by describing the current condition of the English prison estate; highlighting the challenges it is facing and the changes it is undergoing.

1.1 Blood-borne viruses

BBVs are viruses that can be transmitted by an infected individuals' blood (3,4). HCV is a ribonucleic acid (RNA) *Flavivirus* (5), with six different genotypes and >50 subtypes (6). HBV is a deoxyribonucleic acid (DNA) virus of the *Hepadnaviridae* family (7). Both are aetiological agents that cause hepatitis (inflammation of the liver) (8).

Exposure to either virus is preceded by an "acute" phase of infection, which is frequently asymptomatic and rarely associated with the formation of life threatening disease (i.e. fulminant hepatitis) (5,6,8). It is estimated that 15-20% of HCV-infected individuals will naturally clear the virus during acute infection (8). The remaining 75-80% develop chronic HCV (cHCV) infection, with most patients remaining asymptomatic or displaying only mild, non-specific, symptoms (8,9).

In contrast, progression to chronic HBV (cHBV) infection is primarily determined by the individual's age at acquisition (8). In adult-acquired infection the chronicity rate is ≤5%, whereas approximately 90% of perinatally acquired infections evolve to become chronic (8). Like cHCV, cHBV infection is usually clinically asymptomatic, but if symptoms do manifest they tend to be nonspecific (8).

Nevertheless, chronic hepatic inflammation caused by infection from either virus generates fibrosis (liver scarring) (8). Over time this damage can progress to cirrhosis (advanced fibrosis), liver failure, and/or hepatocellular carcinoma, a cancer with a high malignancy-related mortality status (6,8).

The human immunodeficiency virus

HIV, an RNA virus belonging to the *Retroviridae* family, similarly generates disease over an extended period. However, unlike hepatic viruses HIV attacks the human immune system (10,11). Following initial exposure, rapid viral replication in infected cells produces high levels

of circulating virus and leads to both viral and immune-mediated destruction of CD4 lymphocytes (a key component of the human immune system) (12,13). During this period of “primary” infection, ~50% of individuals display flu-like symptoms (12). However, following the development of a specific antibody, viral levels decline whilst CD4 levels increase, and infection generally becomes asymptomatic (12).

Over a period of 6-8 years viral replication can steadily increase again, inhibiting immune function and enhancing the risk of acquiring an opportunistic infection (such as tuberculosis, pneumonia, and certain types of cancers) (12,13). As the disease progresses, some individuals may be diagnosed with AIDS, referring to a state of extreme immunosuppression characterised by certain indicator infections and/or a CD4 count <350 per mm^3 (14). Mortality occurs from HIV infection indirectly, via one or multiple opportunistic infections.

Although these three viruses differ biologically, they therefore share commonalities in terms of modes of transmission, the asymptomatic nature of infection, and the severity of disease they can generate. They also inflict a heavy burden on societies across the globe, with 71 million people estimated to be infected with cHCV, 257 million with cHBV, and 37.9 million with HIV (6,15,16).

As each virus causes a high amount of mortality globally (399,000 deaths from cHCV in 2016, 887,000 from cHBV in 2015, and 770,00 from HIV-related causes in 2018), management of these infections has become a key focus for both international and national health authorities (6,15,16).

1.2 Management of blood-borne viruses in England

The management of BBV infections is dictated by a combination of international and national targets, as well as the availability of preventative and curative measures (3,4). In England, HIV has long been a primary focus for health authorities, thanks to a strong advocacy base for the disease. Effective antiretroviral treatments and intense case-detection efforts have meant that both England, and the wider UK, have been able to meet the Joint United Nations Programme on HIV/AIDS 90:90:90 targets (17,18).

In 2017, Public Health England (PHE) estimated that 92% of people living with HIV infection had been diagnosed, 98% of these people were receiving treatment, and that 97% of those on treatment achieved viral suppression; meaning they can no longer transmit the infection (18). This represents a huge achievement for health authorities from across the UK.

In contrast, steps to reduce the burden of infection from hepatic viruses is only just getting underway. In 2013 viral hepatitis was the leading cause of mortality worldwide (1.46 million) (19). In 2010 and 2014 two World Health Assembly resolutions were passed (WHA63.18 and WHA67.6) and a specific action to “combat viral hepatitis” was included within the resolution of the 2030 “Agenda for Sustainable Development” (19,20).

However, it was only on the 28th May 2016 that the World Health Assembly adopted a “Global Health Sector Strategy on Viral Hepatitis”, introducing the first-ever global targets for these infections (table 1) (20,21). These targets were designed to encourage nation states to eliminate hepatic viruses, as a major public health threat, by 2030 (3,21).

Table 1. World Health Organisation: Global Health Sector targets for viral hepatitis elimination as a major public health threat by 2030 (HBV = hepatitis B; HCV= hepatitis C; PWID = person who injects drugs).

Target area	2020 targets	2030 targets
<u>Impact targets</u>		
Incidence	30% reduction	90% reduction
Mortality from HBV and HCV	10% reduction	65% reduction
<u>Service coverage targets</u>		
HBV childhood vaccine coverage	90%	90%
Prevention of HBV mother-to-child transmission	50%	90%
Safe injections (% of injections administered with safety-engineered devices)	50%	90%
Harm reduction (number of sterile needles and syringes provided to PWID per year)	200	300
HBV and HCV diagnosis	30%	90%
HBV and HCV treatment	-	80%

For HBV, the availability of a highly-effective and inexpensive vaccine, but absence of curative treatment for chronic infection (22,23), has meant that elimination efforts have primarily centred on preventative measures. A high vaccine coverage in at-risk populations is essential (19,24). This, in combination with routine antenatal screening, therapies to prevent mother-to-child transmission, and managing chronic infection via available treatments, form a potential framework for elimination (3,19,22,23).

However, the elimination of HCV infection posed a number of challenges. The absence of an effective vaccine against infection was a major limitation for a prevention-based approach (25). In addition, efforts to treat HCV infection have historically been challenging, as interferon and ribavirin regimens were poorly tolerated (side effects included anaemia, depression, and flu-like symptoms), long-course (24-48 weeks), and their effectiveness at

achieving a sustained viral response (SVR) (i.e. viral eradication) was genotype dependent (genotype 2 and 3 = 75-80%; genotype 1 = 40%) (26,27).

In response, pharmaceutical companies began developing drugs that directly targeted the biological mechanisms of the HCV virus. In 2011 the first generation of direct acting antiviral (DAAs) medications became available and were used alongside interferon and ribavirin as a triple therapy (9). This improved SVR outcomes for individuals with genotype 1 infection, but side effects remained (9).

However, it was the development of second generation oral DAA's which re-defined the HCV treatment landscape (20). These new treatments were short-course (8-12 weeks), induced few side effects, and had an SVR efficacy of >95% for genotype 1 infection (28). Since then innovation has continued, opening up second generation DAA treatments for different viral genotypes; with the recent development of pan-genotypic DAA combinations closing final gaps in the treatment portfolio (29).

An approach to elimination has therefore begun to crystallise around these new treatments. Large scale case-detection and DAA-based treatment, in combination with preventative measures to reduce new infections, is encouraged by the World Health Organisation (WHO) targets (table 1) (3,19). As treatment does not confer immunity, a "treatment as prevention" approach; whereby case-detection and DAA-based treatment efforts are concentrated on those individuals transmitting the virus (30), has also been discussed as a potentially cost-effective model (31–33).

The components necessary for HCV elimination are therefore coming together. However, for this Public Health objective to be realised, health authorities in England need to encourage political momentum in support of the WHO targets and successfully operationalise DAA-based therapies for a large-scale treatment effort (19,23,32).

1.2.1 The English approach to eliminating hepatitis C

The National Health Service England (NHSE) has announced plans to eliminate HCV by 2025, 5 years earlier than the WHO targets (34). To achieve this goal it needs to diagnose 90% of the 160,000 people that were estimated to be cHCV infected prior to the elimination effort and treat 80% of those diagnosed (35). It also needs to develop a strategy to significantly reduce new infections, primarily through harm reduction initiatives (36).

However, the approach to elimination that health authorities could take was shaped by NHSE's initial licensing of expensive (£35,000 per course) DAA treatments (37). Following the

National Institute for Health and Care Excellence (NICE) approval of second generation oral DAA's as "cost-effective" in 2015 (28), NHS operational delivery networks (ODNs) were established by NHSE for the purpose of coordinating the assessment and treatment of viral hepatitis (38). These delivery networks utilised a "hub and spokes" model, where community clinics fed patient details to regional centres, which then hosted multi-disciplinary team meetings (MDTs) to manage treatment decisions and prescribing (39). 22 of these networks were formed, with four covering different areas of London (figure 2).

However, ODNs were not free to treat patients indiscriminately. Instead, networks were assigned minimum and maximum treatment targets by NHSE, which were enforced by financial penalties (termed "run-rates") (39). These were widely criticised for creating waiting lists, for initially disincentivising case-detection, and for being poorly aligned to the varying regional prevalence of HCV infection (38,39). ODNs were also required by NHSE to prioritise access to treatment for those at greatest risk of harm, mainly those with the most advanced disease (39).

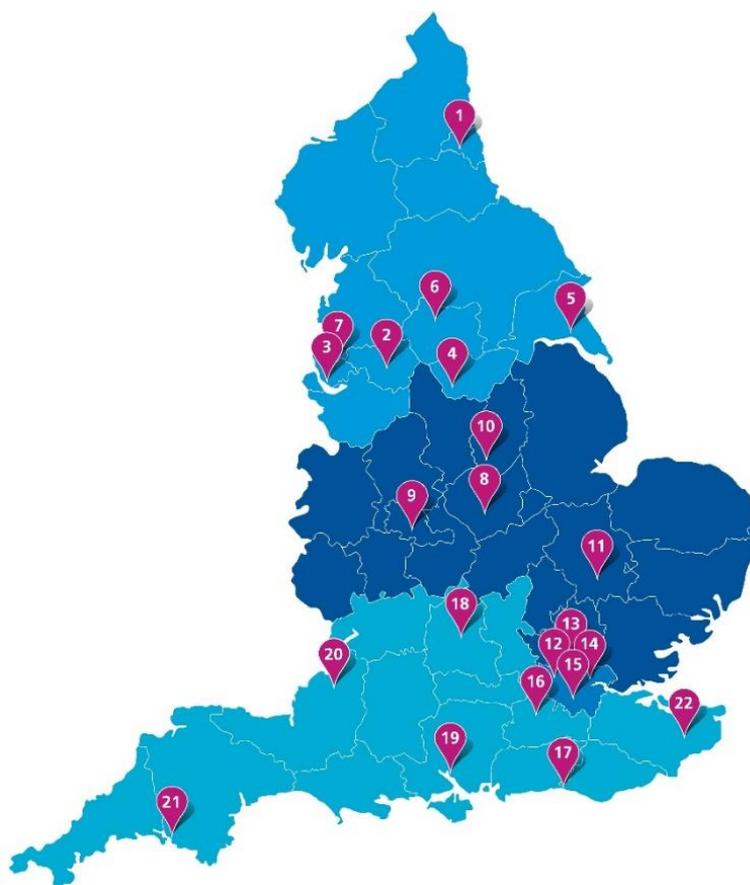


Figure 2. Map of England, highlighting the location of 22 NHS "Operational Delivery Networks", tasked with assessing and overseeing treatment for viral hepatitis. Map produced by NHS England.

As a result, the NHS initially focused on treating the ~23,500 patients that were already diagnosed with cHCV, that were in contact with healthcare services, and that had moderate to severe liver damage (figure 3) (36). NHSE estimated that 10,000 people were treated in 2016/17, 12,500 in 2017/18, and 13,000 in 2018/19 (40). This would indicate that significant progress has already been made in addressing infection in the cohort with advanced disease (figure 3). In addition, the WHO 2020 target of a 10% reduction in HCV-related mortality has already been achieved (36).

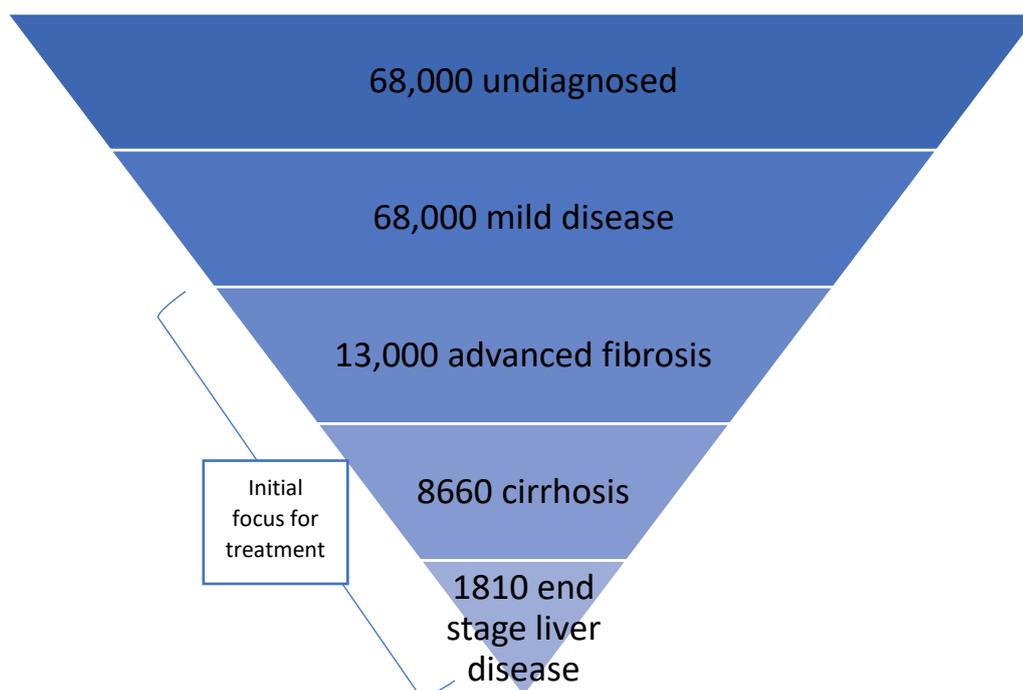


Figure 3. Distribution of chronic hepatitis C infection in England prior to the elimination effort. Currently most people with end stage liver disease, cirrhosis, and advanced fibrosis have either died or been treated for infection. Progress has also been made in treating those with mild disease. Health authorities throughout England increasingly need to concentrate on reducing the pool of undiagnosed infection.

Now in 2019, PHE estimates suggest that ~113,000 people remain chronically infected, with >50% having already been diagnosed (36). A new procurement deal has reduced drug costs to roughly £5,000 per treatment course and given ODNs greater flexibility in terms of prescribing DAA treatments for HCV (41). Life Science companies have also provided health authorities with additional funding for case-detection initiatives (42,43).

What is therefore required to drive forward elimination, and to keep pace with planned NHSE treatment targets, are innovative educational, testing, and referral programmes, targeted at high-risk populations; in combination with outreach initiatives to encourage those historically diagnosed, but not yet treated, to engage with services (36).

1.2.1.1 High-prevalence settings

In England, injecting drug use (IDU) is recognised as the most important risk factor for HCV infection, cited in 92% of laboratory reports where risk factors have been disclosed (36). Other methods of transmission include intranasal cocaine use, crack smoking, tattooing, sharing razors, and certain sexual practices where exposure to blood is more common (5,6).

As a result, the epidemiology of infection is closely linked with intravenous drug use. In 2017 52% of people who inject drugs (PWID) surveyed were found to be positive for HCV antibodies (anti-HCV), indicating exposure to the virus, whilst 49% had evidence of chronic infection (36). Other “high-risk” groups include those injecting performance enhancing drugs (anti-HCV positivity = 5%), those that received infected blood products before 1991 (44), and communities with links to high prevalence regions (e.g. South Asia) (36).

Healthcare services that current injectors, or those with a history of IDU, commonly engage with therefore tend to report a high anti-HCV prevalence. BBV testing completed within English drug treatment services, for example, highlighted an anti-HCV positivity of 9.2% (45), making these locations a key target for case-detection and referral initiatives (36).

However, prison populations also over-represent people from a confluence of underserved and minority backgrounds (32,46,47). Sentinel Surveillance (covering ~25% of the English prison estate) reported an anti-HCV positivity of 8.0%, a hepatitis B surface antigen (HBsAg) (indicative of active infection) positivity of 1.3%, and an HIV antibody (anti-HIV) positivity of 0.5% during testing carried out in 2017 (45,48–51) (table 2). These data may be an underestimation, with HCV prevalence estimates for Western European prisons as high as 15.5% (52).

Table 2. Numbers tested, numbers positive, and positivity for BBV infection from prisons reporting testing data to Public Health England Sentinel Surveillance between 2013-2017 (anti-HCV = hepatitis C antibody; HBsAg = hepatitis B surface antigen). Data excluded dried blood spot and oral fluid testing.

Date	Numbers tested for anti-HCV	Numbers positive	Prevalence estimate (%)	Numbers tested for HIV	Numbers positive	Prevalence estimate (%)	Numbers tested for HBsAg	Numbers positive	Prevalence estimate (%)
2013	4,242	400	9.4	3,627	19	0.5	3,477	51	1.5
2014	4,089	327	8.0	2,834	16	0.6	3,301	49	1.5
2015	3,265	220	6.7	2,481	15	0.6	2,318	30	1.3
2016	3,664	199	5.4	3,218	13	0.4	3,107	44	1.4
2017	8,171	655	8.0	7,759	37	0.5	8,575	115	1.3

Nevertheless, with a community primary care anti-HCV positivity of 1.3% (HBsAg = 1.0%; HIV = 0.5%) (45), the prevalence of HCV infection is noticeably elevated within English prisons. Arguably it is the criminalisation of drugs and the relationship between dependency and crime that works to concentrate PWID, and therefore HCV infection, within the English prison estate (53,54).

Moral and criminological questions regarding the mass incarceration of PWID aside, this mechanism makes prisons a key setting for HCV case-detection interventions (31,32,55). Not only do they represent an opportunity to engage a sub-set of PWID, not necessarily involved with community primary care or drug treatment services (56), but the controlled environment of a prison may be beneficial in terms of the delivery of treatment (57,58).

However, prisons are institutions designed for incarceration and punishment, not the delivery of healthcare (59). The extent to which their public health potential for HCV elimination can be realised, will therefore depend on the condition of the wider English prison estate and the ability of health authorities to mesh their priorities with those of Her Majesty's Prison and Probation Service (HMPPS).

1.3 The prison environment

Prisons are “total institutions”; closed settings cut-off from wider society and characterised by hierarchic structures, repressive bureaucratic regimes, a discipline orientated culture, and population surveillance (1,2,60). Prisoners are deprived of their social ties and autonomy, concentrated in enclosed and frequently squalid conditions, and subjected to corrective punishments (1,52,61).

These features mean prisons commonly stand in stark opposition to what the WHO regards as a “health promoting environment” (1,52). Indeed, incarceration has been shown to concentrate individuals with a higher burden of infectious disease (including BBVs), into a confined area often fertile for transmission (52). Prisons can therefore act as reservoirs for infection, posing a threat to those incarcerated and working within them, as well as to the wider community when a prisoner is released (52,54).

However, the structured daily life and proximity of social and healthcare services within prisons paradoxically may also provide an opportunity for improving prisoner health (1,2,47). For this potential to be realised, the delivery of healthcare needs to be conceptualised as a core part of a prison's function (2).

1.3.1 The English and Welsh prison estate

Whitehead (2006) highlighted England and Wales as being two of the most active world regions for affecting healthcare reform within prisons (2). In particular, the transfer of responsibility for prison healthcare services from under the jurisdiction of the Home Office to the Department of Health and NHSE in 2006, represented a crucial step towards addressing their historic isolation from the wider healthcare system (2,62,63). The commitment of the NHS to principles of equivalency of care for those incarcerated, in line with those of the community, has also been an important symbolic step (1,64).

However, despite positive healthcare reform, the prison service itself is in crisis. The estate is currently composed of 118 prisons, 116 of which were operational as of May 2018 (46). Around a quarter of these prisons were built before 1900 and many are structurally uncondusive for fostering a culture of safety and reformative justice (65). The estate has also been put under additional strain by a dramatic increase in prison population (a 69% increase in the last 30 years), which has left two thirds of prisons designated as “overcrowded” in 2017/18 (65,66).

This population is currently categorised by “risk”, ranging from Category A for the highest risk offenders, to D for those posing the lowest risk to society (65). It is also separated into male, female (5% of the population), and youth offenders (aged 15-18) (67). Prisoners are then housed within a range of institutions that have a “predominant function”: including local prisons (serving courts), training prisons (delivering longer-term rehabilitative programmes), resettlement prisons (helping prisoners prepare for release), and high-security institutions (holding those considered an extremely high-risk to the public) (65–67).

However, because of a mismatch between estate capacity and the volume of different classifications of prisoners, many prisons actually incarcerate a complex mix of different people (68). The male estate, for example, had 10,500 excess places within local prisons and a deficit of 14,400 places in training and resettlement prisons in 2016 (65). Large numbers of male prisoners were therefore inappropriately housed within local prisons for extended periods of time, with little access to educational and rehabilitative programmes (65).

In addition, prisons are a revolving door. Out of those incarcerated in 2018, 69% were for non-violent crimes and 49% were for a sentence <6 months (66). Although rehabilitation has been a stated objective of the prison service for many years, in practice this has rarely governed administrative culture (59); evidenced by 48% of adult offenders being reconvicted within one year of release (66).

The increase in the English and Welsh prison population has also coincided with a period of budget cuts. Between 2010-11 and 2014-15 HMPPS delivered cumulative savings of £900m (20% of their budget) (66,69). Frontline operational staff numbers fell by over a quarter between 2010 and 2017, with experienced prison officers disproportionately represented in this decline (69).

The result of this austerity has been an anaemic workforce, the rapid decline of safety standards, and a drop in the wellbeing of incarcerated people (66,70). Self-inflicted deaths have spiked and are currently 6.2 times higher in prison, when compared with the wider population (66). Assaults on staff have also tripled and all forms of assault are at the highest levels ever recorded by the Prison Reform Trust (66).

Drug use is also increasing, with 47% of men and 31% of women reporting that it is easy to obtain drugs in prisons (71), as well as 7% of adults reporting IDU whilst incarcerated (72). Therefore, despite prisons housing a population with a high prevalence of HCV, theoretically available for engagement by healthcare services, socially they may pose significant challenges to testing and treatment initiatives.

The scale of the problem has been recognised by the UK government and £1.3 billion invested in order to reform and modernise the prison estate (65,66). Plans outlined in the “Prison Estate Transformation Programme” involve the simplification of the male estate into three types of prison: “reception”, “training”, and “resettlement” (figure 4) (68,73,74). Prisoners, in turn, will be assigned to specific cohorts, including: a “reception cohort”, “training cohort”, “resettlement cohort”, and a “specialist needs (training) cohort” (65).

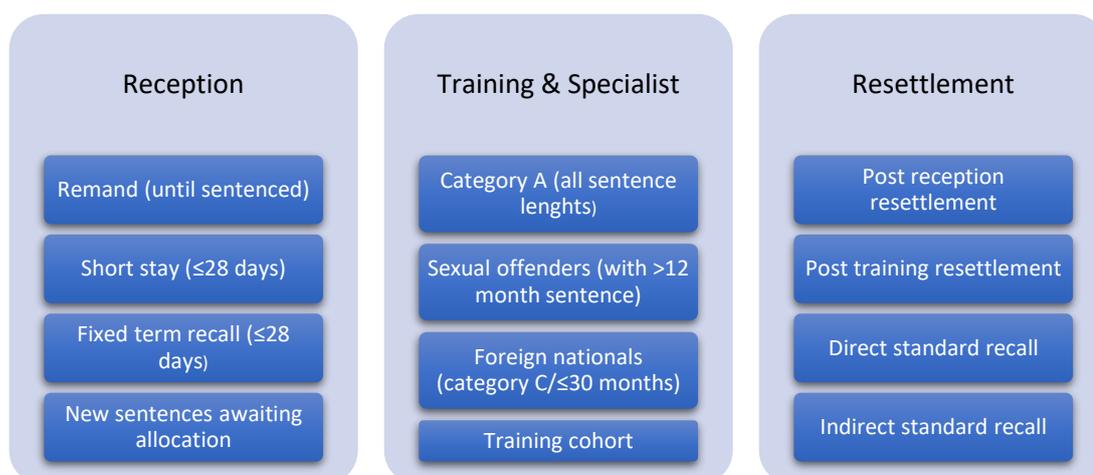


Figure 4. “Cohorts” of prisoners assigned under three types of prison. Direct standard recall refers to those individuals who were re-incarcerated for breach of probation, processed in a reception prison, and then sent directly to resettlement. Indirect standard recall refers to a similar situation, but that the prisoner spent time in a training prison, before being transferred for resettlement.

This restructuring is intended to simplify prisoner movement through the estate and ensure individuals are incarcerated within an institution appropriately resourced for their security grade, length of incarceration, and service requirements (65).

In addition, HMPPS committed £100 million to recruit 2,500 more prison officers by December 2018 (66). However, this has not directly translated into improved conditions, partly because of the level of inexperience amongst the current workforce (35% of officers across the estate have been in post <2 years) (66). The extreme conditions that new staff are facing at work has also meant that retention has become a problem, with 54% of officers leaving the service having been in post <2 years (66).

This staff attrition has helped to perpetuate the system of institutional inexperience and, in turn, violence (66). Indeed, the current social conditions created by the combination of budget cuts and mass incarceration appear to have become entrenched and self-reinforcing. Consequently, it may take considerable time, and further resources, before HMPPS is able to nudge prisons into a more conducive social equilibrium, amenable to the delivery of rehabilitative and healthcare services.

The goal of HCV elimination and revitalised public health interest in prisons has therefore occurred at a time of drastic change, as the UK government tries to resuscitate the prison system. Despite movement within health authorities towards an ambition of a “health promoting” prison, the prison service within England and Wales is currently unlikely to be in a position to prioritise or facilitate these ambitions (75).

Regardless, English health authorities have decided to try and capitalise on the potential that prisons pose for HCV elimination, via the implementation of a testing strategy for BBVs: “opt-out BBV testing”. Alongside this, the development of innovative pathways of care to manage identified infection has been encouraged. Amongst a backdrop of public health enthusiasm for HCV elimination and carceral crisis, this programme represents a challenging, but potentially valuable, public health initiative.

Chapter 2: Opt-out blood-borne virus testing and associated pathways of care

2.0 Introduction

In this chapter I provide background information on the opt-out BBV test programme and associated pathways of care. I begin by discussing programme implementation from a national perspective. I then present details of the roll-out of opt-out BBV testing and treatment pathways within the London region. I end the chapter by explaining the rationale for conducting an evaluation of this programme and by outlining the research questions that guided data generation.

2.1 The national strategy

The majority of prisons in England provided some form of BBV testing service prior to 2014 (76). These services historically only covered a small proportion of the prison population, with an estimated 2.4% of prisoners tested for HCV between 2005-2008 (77). Testing amongst newly incarcerated individuals was similarly low, with 5.3% tested for HCV in 2010/11, 6.1% in 2011/12, and 8.6% in 2013/14 (35,77).

In order to improve test coverage within secure settings, interest in an opt-out test programme for BBVs began to be championed by PHE, the Hepatitis C Trust, the British Liver Trust, and the National Aids Trust (78). This solution to the problem of under testing amongst the prison population was chosen, based on reported increases in HIV testing within antenatal settings following the transition to an opt-out system in the 1990s (79,80).

On the 9th of July 2013 a multi-agency meeting composed of representative from PHE, NHSE, and HMPPS formally agreed that an opt-out model of testing would be introduced across the prison estate, becoming priority number 12 of the 2013-14 'National Partnership Agreement' (and renewed in subsequent agreements) (81):

"NHS England, NOMS [now HMPPS], and PHE will work together to design and deliver an appropriate 'opt out' model of testing for BBVs by April 2014"

Under this new agreement PHE were positioned to provide expert advice on programme design and evaluation, whilst NHSE were responsible for commissioning of healthcare services, as per Section 15 of the Health and Social Care Act (2012), and therefore programme implementation (82). HMPPS support was also vital for programme enablement, as safety and security protocols require that prison officers monitor clinics, as well as the movement of prisoners to and from locations where healthcare services are delivered.

2.1.1 Opt-out testing and BBV treatment guidance

In their role as expert advisers, PHE developed and disseminated guidance for the opt-out test strategy in 2014. This deliberately afforded NHSE commissioners and healthcare providers a degree of flexibility, so that they could tailor programme delivery to the specific context in which they were working (83–85). In this way it was hoped that local and regional innovation would help incrementally refine programme design in the years following implementation, culminating in an evidence-based model of best practice (83–85).

2.1.1.1 Guidance: opt-out BBV testing

PHE guidance recommended that a BBV test offer be made within 72 hours of a person entering a prison (figure 5) (83). Within English prisons a mandatory Prison Service Order stipulates that all new arrivals should undergo “*first reception*” (a health screen on the first night to triage immediate health needs) and “*second reception*” (a more in-depth health assessment to be conducted during the first week). These two clinics were therefore opportune times for engagement and BBV testing of newly incarcerated individuals (86).

Guidance also recommended that those incarcerated prior to programme implementation, as well as those that were offered a BBV test during reception, should be (re-)offered at multiple points during their period of incarceration (figure 5) (79).

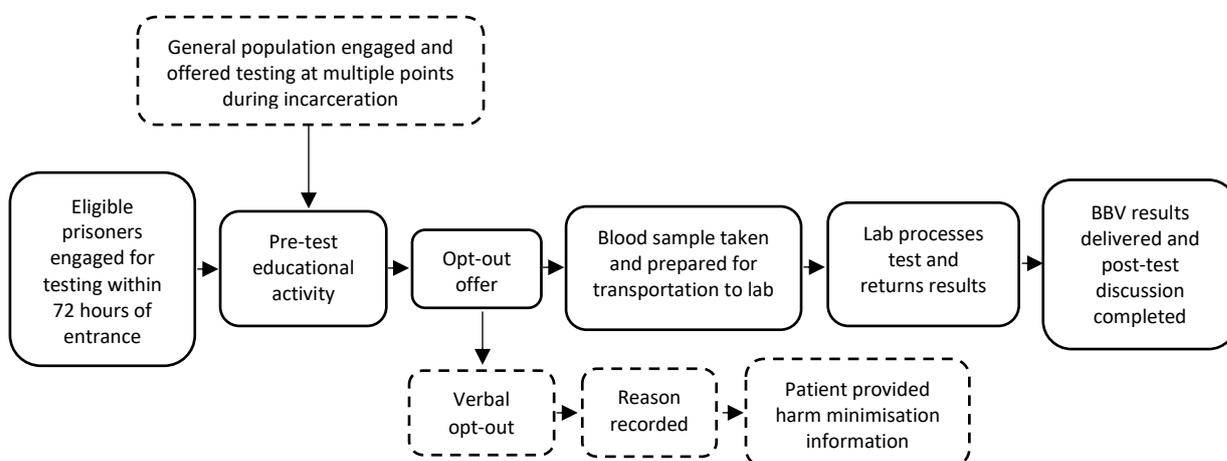


Figure 5. Opt-out BBV testing algorithm, as recommended by Public Health England in collaboration with NHS England and Her Majesty’s Prison and Probation Service.

Prisoners engaged for testing were then to be provided a pre-test discussion covering: what the test was for, what it involves, benefits of testing and risks if the person does not test, and when and how they could expect to receive results (83). During this discussion, healthcare workers (HCWs) were expected to check the individual’s capacity to consent and their eligibility for BBV testing. Recommended exclusion criteria for the programme included:

- The individual has been tested in the last 12 months and has not subsequently put themselves at risk of infection;
- They have a documented test and are confirmed positive for a BBV;
- HBV: the individual has documented evidence of a negative serostatus and has been fully vaccinated.

Eligible prisoners should have been offered a test for HCV, HBV, and HIV in an “opt-out” format (83). No explicit information was provided on what constituted an opt-out offer and how delivery would differ from other ways of framing testing, such as providing an active choice to “opt-in” (79,83,87,88). Initial guidance also suggested that blood acquisition could be completed using a dried blood spot test (DBST) or a venous sample (83). However, later guidance recommended DBST as advantageous, on the grounds that it improved uptake in IDU and people who are needle-phobic (89).

Blood samples were then to be sent to a lab to undergo serological testing. PHE recommended that samples be tested for the presence of anti-HIV and “P24” antigen simultaneously, reducing the time between infection and an individual testing positive for HIV (i.e. the “window period”) to roughly a month (90). For HBV, samples were tested for the presence of HBsAg, which is indicative of either acute or chronic infection (8).

For HCV, healthcare providers were instructed to request an anti-HCV test using an enzyme-linked immunosorbent assay (window period roughly three months), where a positive result indicated exposure to the virus (DBST pooled sensitivity and 95% confidence interval = 97.3%, 94.3-98.8%; specificity = 99.6%, 98.5-99.9%) (8,91,92). Positive anti-HCV samples should have automatically undergone a reflex polymerase chain reaction (PCR) test, to identify active infection (DBST sensitivity range = 93.8-100%; specificity = 94.0-100%) (8,93).

Once lab results were received and processed by healthcare teams, positive results were to be delivered face-to-face, by the same person that conducted the test and ideally within 48-hours of receiving the result (83). People with a negative result were supposed to be engaged, informed of their result, provided information on harm minimisation, and encouraged to undertake further testing in the event of subsequent exposure (83).

In this way, the programme was designed to engage all new prisoners soon after entrance, offer and test a sizeable number of them for BBV infection, whilst encouraging safer behaviour and continued engagement with services for those individuals that were found to be negative (79,83).

2.1.1.2 Guidance: referral and treatment

PHE guidance specified that those prisoners identified with HIV infection should be referred and seen by a specialist within two weeks of diagnosis. Those identified with HBV or HCV infection should be referred and seen within 18 weeks (figure 6) (83). Treatment options were to be discussed with the patient during this consultation.

With patient consent, treatment was recommended to be delivered via in-reach, either directly by specialist care providers or by prison healthcare staff with specialist support (79). Guidance also highlighted that short sentences, release, or transfer, should not be a barrier to treatment and that care pathways should incorporate sign-posting to other relevant support services (e.g. mental health and drug & alcohol treatment) (79).

In the event of patient transfer, the healthcare team were instructed to update medical records and inform the recipient team that the individual was undergoing treatment for BBV infection (figure 6) (79,83). In the event of release, guidance specified that the prison healthcare team liaise with community specialists to discuss continuity plans, alert the patient's GP, and enlist the support of community rehabilitation companies (CRC's) and the National Probation Service, to help maintain patient engagement after release (79,83).

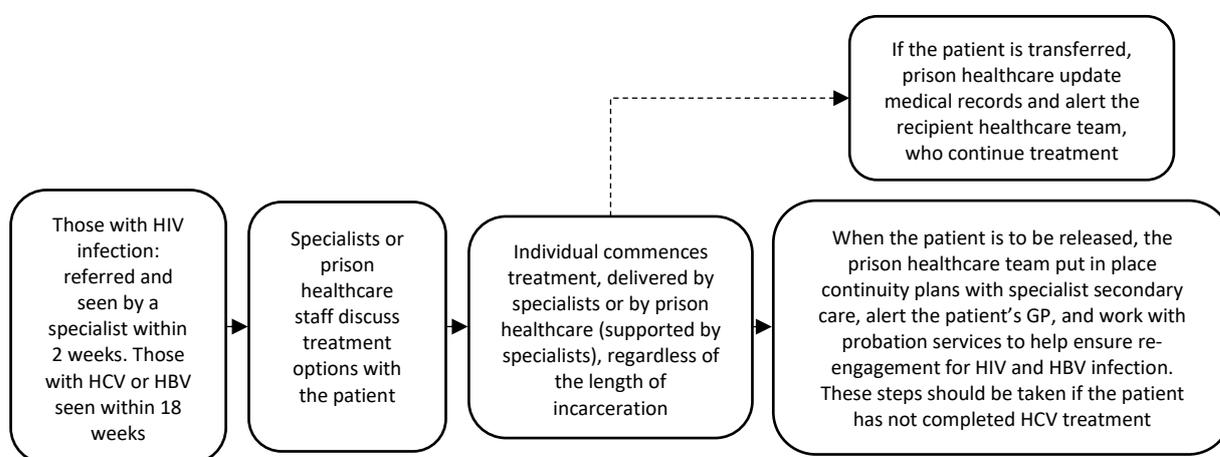


Figure 6. Referral and treatment algorithm, as recommended by Public Health England in collaboration with NHS England and the Her Majesty's Prison and Probation Service.

Guidance was therefore designed to ensure that all patients began treatment quickly, whilst implementing protocols to ensure continuity of care (79,83). Factors that might affect the referral and treatment of HIV and HBV remained relatively stable, following the development of this guidance. However, initial restrictions imposed on ODNs in terms of the delivery of HCV treatment (i.e. treatment caps and requirements to prioritise those at most risk), complicated the treatment process for this viral infection (94).

2.1.2 Outcome targets

Alongside PHE guidance, NHSE began developing the Health and Justice Indicators of Performance (HJIPs), to act as the primary monitoring system for assessing the delivery of clinical care within prisons (95). These were designed for data extraction from “SystmOne” (the clinical IT service in use throughout the English prison estate) and included specific indicators for BBVs, which helped NHSE commissioners monitor test programme performance (table 3).

Table 3. Details of the Health and Justice Indicators of Performance related to blood-borne virus testing and treatment within English prisons (HBsAg = hepatitis B surface antigen; anti-HCV = hepatitis C antibody; PCR = polymerase chain reaction).

HJIP indicator	Details of indicator
HBV: offered	The percentage of new prisoners offered HBV testing within 72 hours of reception (excluding those already vaccinated)
HBV: HBsAg	The percentage of new arrivals that underwent HBsAg testing within four weeks of arrival, of the total eligible during the reporting period (excluding those already vaccinated)
HBV: referral	The percentage of those positive for chronic HBV, referred to a specialist service
HCV: offered	The percentage of new prisoners offered HCV testing within 72 hours of reception (excluding those already diagnosed with, or treated for, HCV)
HCV: Ab	The percentage of prisoners who have undertaken an anti-HCV test (excluding those already diagnosed with, or treated for, HCV)
HCV: PCR	The percentage of prisoners anti-HCV positive, who underwent PCR testing
HCV: referral	The percentage of prisoners testing HCV PCR positive, referred to a specialist service
HIV: offered	The percentage of new prisoners offered HIV testing within 72 hours of reception (excluding those already confirmed positive for HIV)
HIV: uptake	The percentage of eligible prisoners who have undertaken an HIV test (excluding those already confirmed positive for HIV)
HIV: two weeks	The percentage of HIV positive prisoners seen by a specialist service within two weeks of diagnosis

As part of this monitoring process, NHSE also announced targets for the opt-out programme based on PHE recommendations. These included that 100% of eligible prisoners should be offered a test within 72 hours of entrance to a prison, with either $\geq 50\%$ (lower threshold) or $\geq 75\%$ (desired performance threshold) of eligible prisoners tested for HCV, HBV, and HIV (78).

These targets were not insignificant and demonstrated the ambitions that NHSE had for the opt-out programme. They were also conservative, as the HJIP offer and test metrics did not exclude individuals who had already been tested within a 12-month period prior to incarceration, despite original PHE guidance regarding exclusion criteria (table 3). This meant healthcare teams would need to offer BBV testing to recidivists and transfers multiple times, over relatively short periods of time (96).

2.1.3 National implementation and evaluation

With guidance developed and a new monitoring system in place, implementation could commence. This was initially led by PHE, who adopted a three-phased approach of piloting and evaluation (95). The first phase began in 2014, when 11 “phase 1 pathfinder prisons” implemented the opt-out programme (table 4) (79). PHE then conducted a questionnaire-based evaluation, with key findings including (79):

- Healthcare teams within three prisons delivered BBV testing during both the first night and secondary screening clinic. The remaining eight (50/50 split) offered testing once at either clinic. The healthcare provider for HMP Hull switched from first to second reception, as willingness to accept BBV testing was reportedly higher.
- Healthcare teams reported a near doubling of newly incarcerated people tested for BBV infection following opt-out implementation. Testing for HIV and HCV increased from 11% between January and December 2013, to 21% between April and September 2014, and from 12 to 22% respectively for HBV. Eight healthcare teams also reported recommending testing to existing prisoners on an ongoing basis.
- Only seven healthcare teams reported using DBST for sample acquisition. The remaining four acquired blood samples intravenously. In addition, <50% of teams requested serological testing in line with national PHE guidance.

PHE attributed the increase in testing to the introduction of the opt-out programme and so implementation moved to the second phase (79). An additional 10 prisons became “pathfinders”, with a focus on developing methods to ensure linkage into secondary care. PHE conducted another questionnaire-based evaluation, with findings including (97):

- Healthcare teams within all responding prisons indicated that pathways were in place to ensure patients were linked into specialist care.
- The average waiting time from referral to assessment by specialist services was four weeks. This was below the period recommended for viral hepatitis (maximum of 18 weeks) but exceeded the two-week limit recommended for HIV.
- Despite all healthcare teams reporting established referral pathways for viral hepatitis, six were unsure whether cHCV cases were discussed at an ODN MDT. In addition, no teams were aware of ODN treatment targets, suggesting that strong links between the prisons and these networks had not yet been developed.

Finally, eight prisons implemented the programme as a tertiary wave between 2015 and 2017 (table 4). Their focus was on the treatment stage of the programme. Following

implementation, PHE published their final questionnaire-based evaluation in December 2017, with findings including (89):

- BBV medicines were supplied almost exclusively to prisons by hospitals. Two prisons indicated problems accessing medicines for patients, citing insufficient supply of DAAs upon reception or transfer out of prison. Only 3 prisons reported providing DAAs “in-possession”, with high costs provided as the justification.
- Nearly all phase 3 prisons provided existing patients with a 7-day supply of BBV medicine when they were transferred to another prison or released. One prison reported that treatment was usually not commenced for those on a short sentence, with these individuals instead initiating treatment following release.
- Fewer than half of the healthcare teams reported implementing peer support programmes to help patients adjust to their diagnosis and adhere to treatment.

Table 4. Phase 1, 2, and 3 pathfinder prisons (HMP = Her Majesty’s Prison; YOI = Youth Offender Institution). The name for one of the phase 3 pathfinder prisons within London was replaced with “Prison 2”, to ensure a level of institutional anonymity was preserved throughout the thesis.

Phase 1 - Area team	Phase 1 - Prison
Derbyshire & Nottinghamshire	HMP Nottingham
	HMP Stocken
Lancashire	HMP Kirkham
	HMP Manchester
	HMP Buckley Hall
	HMP & YOI Forest Bank
West Yorkshire	HMP Hull
	HMP Leeds
Bristol, North Somerset, Somerset and South Gloucestershire	HMP Dartmoor
	HMP Channings Wood
	HMP Exeter
Phase 2 - Area team	Phase 2 - Prison
East Anglia	HMP Bedford
	HMP & YOI Hollesley Bay
Derbyshire & Nottinghamshire	HMP Glen Parva
	HMP Foston Hall
	HMP Sudbury
	HMP Whatton
	HMP Lincoln
	HMP North Sea Camp
	HMP Leicester
West Yorkshire	New Hall
Phase 3 - Area team	Phase 3 - Prison
Bristol, North Somerset, Somerset and South Gloucestershire	HMP Bristol
Shropshire & Staffordshire	HMP Dovegate
	HMP Stoke Heath
London	Prison 2
	HMP The Mount
East Anglia	HMP Highpoint
	HMP Warren Hill
Durham, Darlington and Tees	HMP Durham

During phase 2 and 3, PHE began to report that the lack of standardisation of programme delivery may have been inhibiting performance, rather than encouraging innovation (89,97). Concern centred on the fact that few healthcare teams were reporting adherence to established BBV pathway algorithms and that increases in testing remained below NHSE targets (97).

However, their evaluation relied on healthcare team self-report and did not generate the in-depth information required to help refine programme delivery (79,89,97). Instead, because the transition to opt-out had appeared to increase testing marginally, responsibility for implementation was transferred to NHSE and wider roll-out of the programme was pushed forward, unguided by an evidence-based model of best practice.

The London region was one of the final areas to implement opt-out BBV testing and new treatment pathways, as it was believed to pose unique challenges owing to the large size of many of its prisons, the transient nature of the London prison population, and the high proportion of foreign nationals it incarcerates. Nevertheless, on the 1st of April 2017 it formally adopted an opt-out BBV test model, with English estate-wide implementation completed by March 2018 (95).

2.2 The London Prisons Project

In London, the uncertainty that surrounded programme design, combined with concerns about the challenges posed by the prison estate, fuelled questions about the feasibility of successful programme implementation. As a result, NHSE sponsored the creation of a regional steering group in 2016: “The London Blood-borne Virus Core Steering Group” (LBCSG) (see table 5 for a summary of the different stakeholders involved), to oversee the implementation of opt-out testing across the estate (78).

The group’s initial objectives were to facilitate shared learning and offer guidance to the London prison healthcare providers prior to programme implementation (78). To do this, it approached a UCL research team to lead on the development and evaluation of opt-out BBV testing and a novel HCV pathway, implemented within the phase 3 pathfinder: “Prison 2”.

The group then drew on the experience of staff from Prison 2, as well as other pathfinder sites from across England, who presented their approaches to BBV testing and treatment during a “BBV development day”. This development day was hosted for London prison healthcare management in September 2016 (78).

Table 5. Responsibilities of different organisations involved in the implementation of the “London Prisons Project” (BBV=blood-borne virus).

Organisation	Responsibility	Description
Public Health England	Guidance on programme format and implementation	Develop and disseminate guidance notes on how opt-out BBV testing should be delivered
	Evaluation of outcome data	Analyse routine data collected from opt-out BBV testing
NHS England	Commissioning	Responsible for commissioning the opt-out BBV test programme
	Collection of routine data	Responsible for collating routine monitoring data from the London prisons
Her Majesty’s Prison and Probation Service	Prison guidance	Responsible for enabling the BBV opt-out programme, via the implementation of security supervision and facilitation of prisoners’ attendance at healthcare appointments
Prison healthcare providers	Implementation of testing strategy	Responsible for reviewing guidance and implementing the programme within their prison
	Appointment of a dedicated BBV nurse	Responsible for recruiting a dedicated BBV nurse using additional funding from NHS England
Hepatitis C Trust	BBV opt-out training	Provided on-going training to prison healthcare teams on how to conduct opt-out BBV testing
	Guidance on programme format and implementation	Developed and disseminated guidance notes on how opt-out BBV testing should be delivered
GILEAD Sciences Ltd.	BBV opt-out training	Hosted training days across London and provided guidance on opt-out programme design
North East London Commissioning Support Unit	Developing opt-out templates on SystemOne	Responsible for developing digital templates and “READ codes” to record data on opt-out testing and BBV treatment within prisons
University College London	Development and evaluation of pilot programme	Responsible for piloting the opt-out BBV programme and a novel hepatitis C care pathway within the London region

Through this process, the LBCSG developed a “London approach” to opt-out BBV testing and treatment, which made the following additions to the programme guidance outlined by PHE (see section 2.1.1.1) (78):

1. DBST was to be used universally across the London prisons;
2. All eligibility criteria for BBV testing of new arrivals were removed;
3. The cost of DBST kits used within London prisons was covered by NHSE, to remove perverse incentives to not increase testing due to the increased financial costs;
4. Funding for a dedicated “BBV lead nurse” was provided by NHSE. This nurse was responsible for overseeing implementation and championing the programme within each London prison;
5. Prison healthcare teams focused on testing new arrivals to the prison, whilst the Hepatitis C Trust spearheaded repeat testing of the general population via awareness days and “World Hepatitis Day” events (98);
6. The Hepatitis C Trust was involved in challenging stigma and raising awareness of BBV infection, by providing literature to prisons, hosting “Hep Awareness Days” for prisoners and staff, and via their “Peer Training Programme”.

To support their approach, the LBCSG contracted GILEAD Sciences Ltd. and the Hepatitis C Trust to develop training packages. Seven sessions were completed for London staff (four by GILEAD and three by the Hepatitis C Trust) prior to programme implementation (reaching ~200 staff), whilst financial provisions were put in place by the LBCSG so that additional sessions could be delivered periodically following implementation (78).

Finally, the LBCSG implemented a monitoring system whereby data were sent by London prisons to the group on a monthly basis, so that programme performance could be compared against national targets and discussed at regular meetings. In this way, the combination of regional oversight, additional resource inputs for BBV testing, and rigorous training, was intended to maximise the volume of people tested, referred, and treated for BBV infection within London; although an explanation for how these resources would work in combination to do so had not been articulated by the group (see logic model that I developed to summarise programme inputs and intended outcomes - figure 7) (99,100).

Indeed, the model set-up by the LBCSG across the eight Greater London prisons, all of which incarcerated male offenders (organisational details summarised in table 6 (101–108)), was widely considered by other NHSE commissioning regions to represent current best practice. However, outside of outcome monitoring the LBCSG had not implemented formal plans to evaluate the London Prisons Project to inform programme refinement.

Table 6. Organisational details of eight central London prisons included in this evaluation (YOI = Youth Offenders Institution). Data available from Gov.UK, Public Health England opt-out bulletins, and Her Majesty's Chief Inspector of Prison reports. Proportions of sentenced and remand prisoners vary monthly and will begin to change considerably following the "Prison Estate Transformation Programme".

Prison	Category	Prison status	Operational capacity	Average receptions per month (Apr-Sep 2017)	Sentenced/Remand mix (approx.) (%)	Healthcare	Date of opt-out implementation
Prison 1	B local (secondary cat-C resettlement function)	Public	1,658	539	70/30 (2017)	NHS Trust	1 st April 2017
Prison 2	B local	Public	1,250	436	75/25 (Jan 2017)	Private	December 1 st 2015
Prison 3	C/D resettlement	Public	810	90	Sentenced only	Private	1 st April 2017
Prison 4	B local	Public	1279	444	75/25 (Aug 2017)	Private	1 st April 2017
Prison 5	A high security and B local	Public	938	186	73/27 (Feb 2015)	Private	1 st April 2017
Prison 6	B local	Private (Serco)	1,232	497	67/33 (May 2017)	NHS Trust	1 st April 2017
Prison 7	C training + YOI	Public	628	83	Sentenced only	NHS Trust	1 st April 2017
Prison 8	YOI	Public	370	82	Sentenced only	Private	1 st April 2017

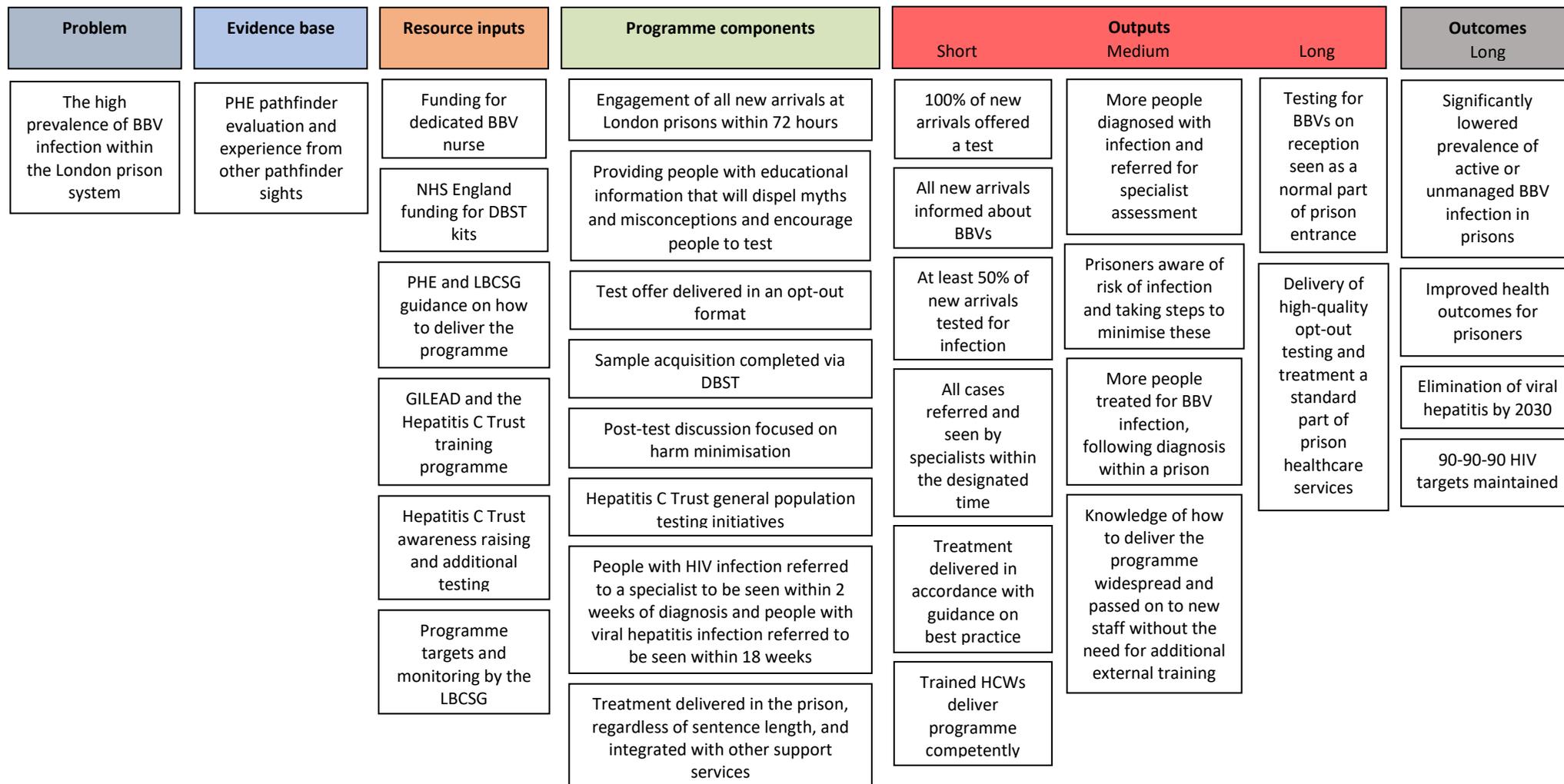


Figure 7. Logic model outlining the evidence base, resource inputs, programme components, programme outputs, and outcomes for the London Prison Project. Key outcomes of interest include the elimination of viral hepatitis by 2030 and the maintenance of 90-90-90 HIV targets (BBV = blood-borne virus; DBST = dried blood spot test; LBCSG = London Blood-Borne Virus Core Steering Group; PHE = Public Health England; HCWs = healthcare workers). Programme theory, connecting programme components to outcomes, was not developed by the LBCSG (i.e. intervention a “black-box”).

2.3 Thesis rationale, aims, and research questions

Opt-out BBV testing and treatment pathways are complex interventions that were given flexibility in terms of design, to allow for gradual refinement of delivery. However, national piloting of the programme by PHE resulted in muted success, with little information available to help formulate models of best practice for different prison settings (109,110).

The London Prisons Project represented an ambitious extension to the original programme, but commissioners needed robust information on how the programme had been implemented and how it was performing. I therefore joined the LBCSG and conducted a realist evaluation, rooted in sociological concepts derived from critical realism (111–113), to begin developing an evidence-base for the policy.

Findings from the evaluation were intended to contribute to the refinement of the London Prisons Project and, in turn, ongoing efforts to address the burden of BBV infection in prison, culminating in the elimination of HCV by 2025 (114,115). This thesis therefore attempts to marry public health objectives with a sociological understanding of complex health programmes and social change.

To start, I wanted to familiarise myself with the design and operation of a newly implemented BBV pathway within a single London prison. I reasoned that conducting a micro-evaluation of a whole pathway would help me identify key challenge points, which could then be analysed in greater detail during subsequent sections of the project. From this piloting work I decided to focus on the first stage of BBV care pathways: opt-out testing.

2.3.1 Research questions

Data generation for this thesis was guided by the following research questions:

1. What proportion of newly incarcerated people are offered a BBV test, what proportion offered are tested, and what proportion of new arrivals are tested for BBV infection within London prisons (Chapter 5)?
2. How is routine opt-out testing on reception to a prison thought to increase test offer and uptake and why might variation in performance occur (Chapter 6)?
3. Given the variation in numbers offered a test and tested across London prisons, how is opt-out BBV testing actually working, why, and in what circumstances (Chapter 7)?
4. What can be done to improve the proportion of receptions offered a test and the proportion offered who are tested within London prisons (Chapters 5, 6, and 7)?

Other chapters in this thesis cover the evaluative framework developed for the project (Chapter 3) and the results of the piloting work (Chapter 4).

Chapter 3: Evaluative framework and research design

3.0 Introduction

This chapter completes the introductory section of the thesis. I begin by discussing different approaches to programme evaluation. I then situate my approach amongst a tradition of critical realism (CR) and realist evaluation (RE). Key concepts from CR, important for understanding RE, are discussed and then the process of conducting a RE is outlined. Finally, I present my elaboration of RE methodology, followed by a summary of the research design that I developed to structure my evaluation of the London Prisons Project.

3.1 Evaluative research

The field of evaluation has historically been mired by mixed outcomes when attempting to implement a programme across a variety of contexts (111). This issue stems from the way in which social programmes have commonly been conceptualised. Evaluators often treat a programme as a “black box” (110). Black box evaluations restrict data generation and analysis to understanding what has been implemented and assessing whether a certain outcome has been achieved. No attention is given to how, why, and when the programme produced this outcome (109,110).

However, it is increasingly recognised that programme outcomes are context sensitive and therefore confirming whether a programme brings about a change is not sufficient to either improve performance or scale-up a programme (111,116). Evaluators need to grapple with the complex task of explaining how different components of the programme, interacted with features of the context to produce outcomes (opening the black box), in order to aid in programme refinement and reproduction across contexts (111,117).

To this end, various “theory-driven” evaluative approaches have been proposed (100,111,116,117). These develop “programme theory”, explanations for how a programme brings about a change within a context. Given that NHSE and PHE commissioners wanted this evaluative research to help guide the refinement of the opt-out testing and treatment programme, a theory-based approach to the evaluation seemed appropriate.

However, despite the emphasis that these approaches place on analysing the role of context in shaping programme performance, I frequently found that when operationalised, their assessment and characterisation of context was limited and uni-directional (i.e. only focused on how context shapes the programme) (118,119).

Social programmes are embedded in, and constitute, social reality (110,111,118). They are events in a wider system that are both shaped by that system and capable of leaving a “lasting footprint” (120). Their implementation can therefore have wider implications for the social environment over an extended period, falling outside of the narrow objectives for which they were originally designed (118–120).

Considering the current condition of the English prison service (i.e. a struggling social system requiring reform), I wanted to both assess programme performance and critically analyse the London prison context (118,120). I wanted this analysis to consider whether the programme worked by utilising and/or perpetuating negative aspects of the prison context (e.g. because of a power imbalance, HCWs present testing as mandatory) and whether the programme could be used as a catalyst for stimulating wider structural change (i.e. could interest in BBV testing for HCV elimination act as a stimulus for wider moves towards a “health promoting” prison).

To achieve this ambition, I developed a novel evaluative framework. However, to understand this framework a brief description of the scientific paradigm (i.e. CR) and evaluative methodology (i.e. RE) underpinning it is required.

3.2 Critical realist philosophy

A realist philosophy of science asserts that the world, physical and social, exists and is independent from human experience or conceptions of it. CR is one form of realist philosophy, which takes the world as objectively given, but views theories about it as socially constructed (121). However, despite its relativistic stance not all beliefs are considered equally “valid”. Ideas about the world are considered “theories”, capable of being rationally tested for their ability to accurately characterise reality (122).

3.2.1 A stratified reality

To develop theories about physical and social reality, the nature of that “reality” first needs to be considered. A key idea from CR is that reality is stratified into three levels (113,121,123,124):

- **The Real:** The stratum of mechanisms, powers, and tendencies (121). It is these mechanisms that science tries to uncover.
- **The Actual:** The stratum where sequences of events occur (121). The interaction of mechanisms in the “Real” stratum, produces events in the “Actual”.
- **The Empirical:** The level of observable and experienced events, which comprise a small subset of the “Actual” stratum (121).

Through this lens, events are considered to be the actualisation of causal mechanisms (125):

“The world consists of mechanisms, not events. Such mechanisms combine to generate the flux of phenomena that constitute the actual states and happenings of the world. They may be said to be real, though it is rarely that they are actually manifest and rarer still that they are empirically identified [...] This is the arduous task of science: the production of the knowledge of those enduring and continually active mechanisms of nature that produce the phenomena of our world.”(126)

This perspective has important implications for how an evaluator analyses a social programme. By distinguishing mechanisms from patterns of events, they are encouraged to develop explanatory hypotheses (theories) for why and how patterns of events, sampled from the “actual” and recorded at the “empirical” level, occur (121). Consequently, the aim of realist evaluative enquiry is to conduct an accurate assessment of the sequence of events of interest (e.g. test offer and uptake), whilst developing an understanding of the causal processes (mechanisms) that produce them (111,115).

3.2.2 Causality in social programmes

This ontological view also has important implications for how causality is then analysed. CR holds that events have a real cause in the form of a mechanism (121). These mechanisms are constitutive of events and are consequently described as “generative” (121,125). They are also “potentialities”, which may or may not be realised, because they interact. Therefore, CR rejects a successionist view of causality, where one or a combination of elements (e.g. $X_1, X_2 \dots$) influences another (e.g. Y), in favour of a “generative model” (121,127).

Under generative causality, simple predetermination, where manipulation of one factor leads to a change in another, can only be achieved in a “closed system” (125). This refers to a situation where a mechanism of interest is completely isolated from other causal processes (121). Experimentation in the natural sciences often attempts to engineer a closed environment, by controlling context, with the aim of isolating and stimulating one mechanism, allowing for an independent assessment of that causal link (figure 8) (121,127).

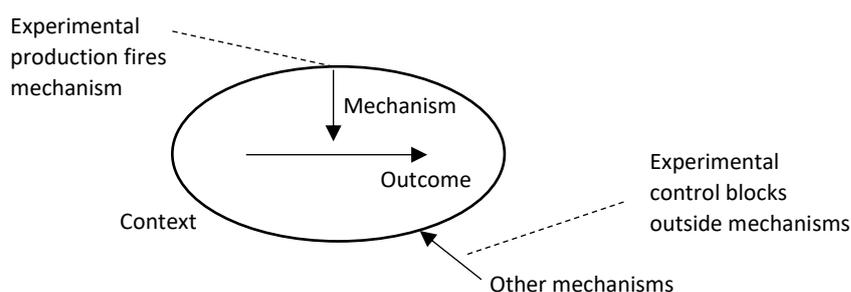


Figure 8. Experimental model of generative causality for closed systems (112).

However, with social phenomena it is difficult to determine how the various causal mechanisms could be isolated experimentally (111). This is because humans cannot be divorced from their culture, experiences, and environment. Social systems are therefore considered “open”, with mechanisms interacting in complex causal webs (figure 9) (121).

When exploring causality within an open system, like a complex health programme, evaluators need to identify a causal process and theorise how the context (or rather the wider milieu of mechanisms that exist in this context) shapes or blocks this process to produce a recorded outcome (111,128). Patterns of outcomes in open systems become “demi-regularities”, with the influence of context making them only semi-predictable (129).

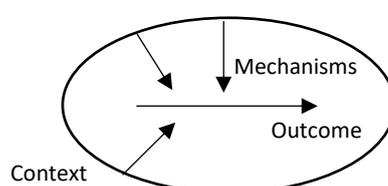


Figure 9. Generative model of causality in an open system (112).

3.2.3 Society and social programmes

To better understand how a social programme brings about change, and how context shapes that change, consideration needs to be given to how social programmes “work”. Unlike in physical experiments, where mechanisms can be sub-atomic processes, social programmes work by generating a change in the collective decision making and/or the behaviour of target stakeholders (113,130).

However, these stakeholders are participants in wider social systems. Any change that may be engendered in their reasoning and/or behaviour will therefore be influenced by the cultural (norms, beliefs, habits), social (class, job status, law, relations), and physical (environmental aspects) structures that surround them (figure 10). Social interaction in this wider system also leads to the reproduction, modification, or transformation of different social structures over time (figure 10) (113,118,121).

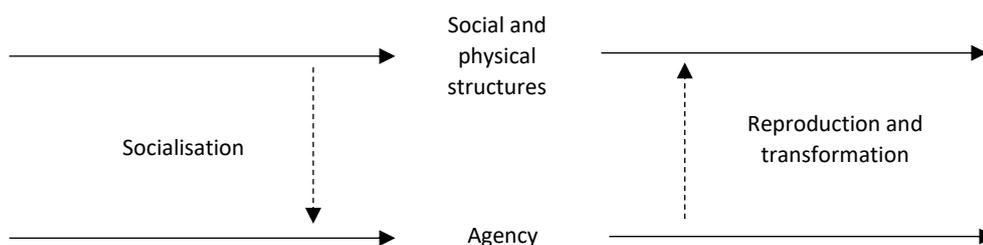


Figure 10. Bhaskar's transformational model of social activity, outlining the interplay between structure and agency within social systems (121). It is into these complex and potentially evolving systems that social programmes are embedded.

Accordingly, CR argues that a symbiotic relationship exists between people (human agency) and society (social structures) in which each enables and depends on the other (121,125). This interplay between structure and agency results in the flux (if human agency leads to modification of social structures) or stagnation (if social structures strongly encourage or enforce socialisation of the individual) of social systems, into which a social programme is implemented (130).

As a result, the ability of a social programme to generate change may vary as the wider system evolves, potentially enabling or constraining its operation (111). It is also possible that a social programme may bring about a large enough change to stimulate the evolution of a stagnated system, or “change the course of change” for one that is in flux. (113,122).

Nevertheless, analysing the interplay between a social programme and the surrounding social system is a complex task, and CR offers no practical guidance on how this could be done. Thankfully, RE emerged as an approach to help structure evaluations of complex programmes and the dynamic social processes that they might engender (111,131).

3.3 Realist evaluation

RE was formally described in the 1990’s by Pawson and Tilley (1997). A form of theory-driven evaluation (132), sitting within the paradigm of Scientific Realism, RE focuses on asking, “why a programme works, for whom, and in what circumstances” (111).

To answer these questions, RE recommends that the evaluator starts by constructing “initial programme theories”, which are hypothesised explanations for how a programme brings about changes to a social phenomenon within a given context (116). These theories can be developed in various ways (e.g. by reviewing the literature or via stakeholder interviews/focus groups).

RE uses a generative model of causality to guide the format of these theories. Accepting that the change stimulated by a new programme will be influenced by its context, RE develops hypotheses for how a programme works using a “context-mechanism-outcome” (CMO) heuristic, which provides a framework for evaluators to then build evidence around (112,132–134).

The constituents of these CMO statements can be interpreted in different ways, although increasing use of the methodology has helped to provide consensus (table 7). Dalkin's et al. (2015) definition for a programme mechanism is now widely accepted, as well as taught to budding RE neophytes. This conceptualises the primary mechanism of interest during the

evaluation of a social programme to be both the resource that a programme inserts into a context and the reasoning and behaviour change of people in response to it (figure 11) (135).

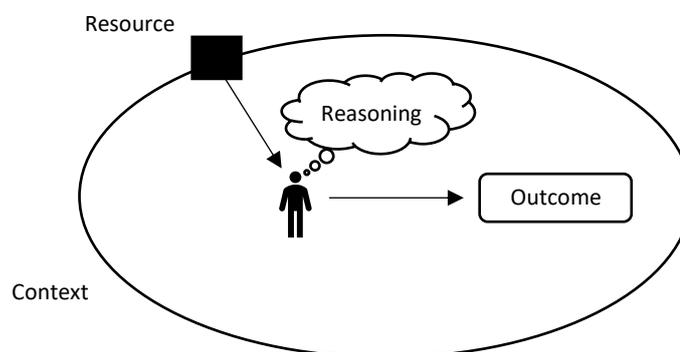


Figure 11. Conceptualisation of context, mechanism, and outcome, as described by Dalkin et al. (2015).

Table 7. Common definitions for the different components of realist programme theory.

Programme theory component	Definition
Outcome	Both the intended and unintended consequences arising from the implementation of a social programme. Outcomes can be proximal, intermediate, or final
Mechanism	An individual's reasoning and preference construction, which occurred in response to resources implemented by the social programme
Context	Covers the programme context and the broader contextual backdrop that the programme is situated in, which modify the expression of mechanisms

Initial programme theories, developed in a CMO format, are then used to guide data generation (111). RE advocates for methodological pluralism (or mixed-methods approaches) (125), with the choice of method led by the type of theory to be tested (111). Both quantitative and qualitative data may therefore be used within RE (111).

The collected data should then be analysed with the purpose of confirming, falsifying, adapting, or refining the original programme theory (111). This usually involves reconfiguring or developing new CMO configurations (CMOc) from sections of the data, and then grouping them around stages of a social programme to form an explanatory model.

Groups of "refined" CMOs, pertaining to a particular outcome, can then be compared across contexts, to develop a general statement about how a programme functions (136). These "abstracted" statements are commonly described as "middle-range theories", being suitably close to original data to remain operational for applied research, whilst also providing cross-cutting lessons (137–139).

Finally, “refined” CMO statements (or middle-range theory) become the “initial programme theory” for future evaluative activities (111). In this way, RE encourages evaluators to proceed in an iterative and cyclical manner (figure 12) (111), with the process of theory elicitation, testing, and refinement contributing to a better understanding of the programme under evaluation (111).

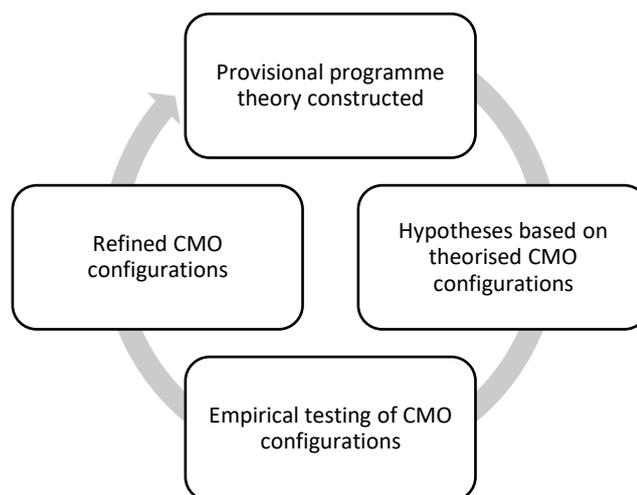


Figure 12. The realist research cycle, used to structure the assessment and evaluation of an intervention or social programme (CMO = context-mechanism-outcome) (111).

3.4 An elaboration of context-mechanism-outcome

This thesis draws on RE methodology as the basis for structuring the evaluation. However, RE’s CMO heuristic for assessing change processes facilitate detailed programme evaluation, but provide little guidance on how to assess the relationship between the intervention and its wider context (118).

To do this, I drew inspiration from various “relational approaches” developed within the discipline of CR, which look at the interplay between structure and agency; such as Archer’s “Morphogenetic” approach to understanding social change (130), Bhaskar’s “Transformational Model of Social Activity” (mentioned in section 3.2.3), and Jessop’s “Strategic-relational” approach (122).

To understand system-level change, these approaches start by looking at the a-priori structural conditions that provide the context within which the beliefs and behaviour of individuals can be understood (i.e. exploring how wider society shapes individual behaviour) (130). Once this has been characterised, the social interaction taking place is then assessed and theories developed for how this interaction may, in turn, reproduce or modify social structures, leading to the stagnation or gradual transformation of society (130).

However, social structures do not impact all individuals equally and instead are often strategically selective (122). Indeed, the resources that a social programme implements can be viewed as strategically selective structures, being commonly targeted at certain groups and designed to intentionally privilege certain stakeholder actions over others.

With that in mind, I began developing a realist model that could help me conceptualise a social programme as an embedded event within a wider system (120). This was done by combining a system-level assessment of context with the CMO methodology of RE and by separating the programme and its wider context into two strata (see figure 13 on page 49).

Using this model, the undesirable features that currently exist, and for which a programme or intervention had been designed to address, were conceptualised as a product of the interaction between social, cultural, and physical structures and human agency (130). A key task in evaluation is therefore to unpick, with the aid of empirical evidence, how the context into which a programme is implemented conditions the plans or intentions of individuals in a manner that is directional but not deterministic (130). I term these processes, “macro-to-micro” (Ma-Mi) level (or conditioning) mechanisms (figure 13) (110,111).

A programme then attempts to redirect change by introducing programme structures (or resources) into the context (111,118,135). These resources should modify, cancel, or replace one (or a combination) of undesirable macro-to-micro level mechanisms, in turn encouraging a change in reasoning and behaviour (111,118,135). However, resources interact with the wider social and physical context, whilst people reflect and respond in different ways, meaning changes in behaviour are unpredictable and context dependent (111,130,140). The changes in behaviour or belief, which occur in response to the resources that a programme introduces within a particular context (RE programme mechanisms), are considered “micro-to-micro” (Mi-Mi) level mechanisms using this model (figure 13) (110,135).

Finally, human agency and social interaction during programme delivery will reproduce or modify programme resources (i.e. change how the programme is carried out). Changes to programme resources and the outcomes of that programme, in turn, may help contribute to the reproduction or modification of wider social, cultural, or physical structures via “micro-to-macro” (Mi-Ma) level mechanisms. These describe the transformative, or reproductive, effects that collectivised reasoning and behaviour change, engendered by a social programme, can have on the wider social context (figure 13) (110). In this way, the model proposes a dynamic feedback process, whereby context shapes programme function, but programme function can also shape context.

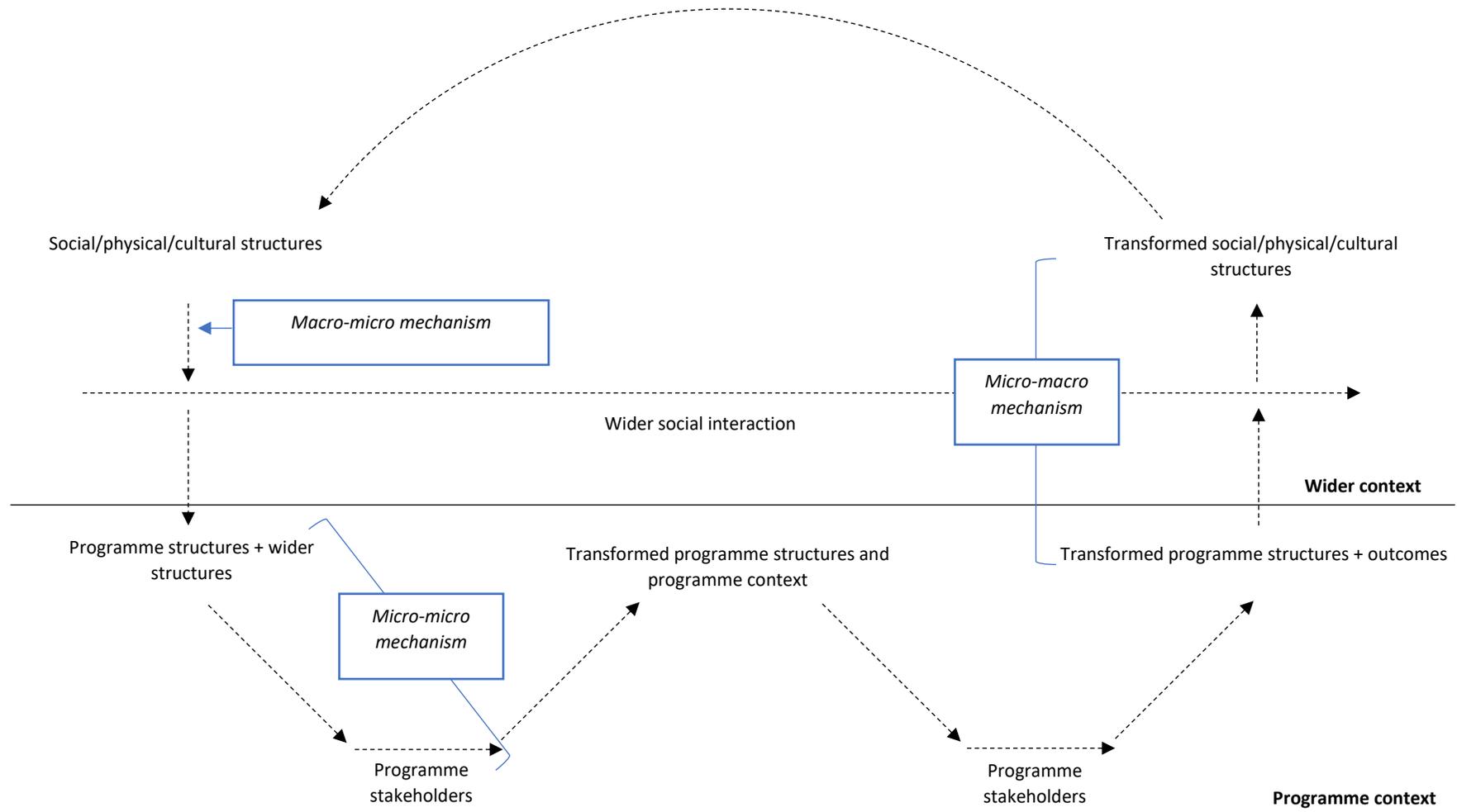


Figure 13. Three classifications of a generative mechanism, operating within social reality, that may have utility when attempting to understand both how a social programme works, and its role in shaping the surrounding social and physical context. The looping arrow at the top of the diagram signifies that the wider changes stimulated by a programme may, in turn, shape how it works.

3.5 Evaluative research design

I developed the theoretical framework outlined in figure 13 to facilitate a more detailed evaluation of the London Prison Project. My intention was that this would involve both an assessment of programme implementation and performance, alongside a critical appraisal of the London prison context. However, despite the Medical Research Council recommending that a programme theory should be developed prior to the implementation of a complex health programme, the LBCSG had not done so, leaving the London Prison Project as a “black box” (100,141).

For this evaluation, I therefore needed to both develop a programme theory, and then refine it iteratively throughout the various stages of the project using the data generated (100,111). To do this, my first step was to conduct a mixed-methods pilot evaluation of a whole BBV pathway, focused on developing a broad realist programme theory (composed of Mi-Mi theories) (figure 14) (142). This was designed to help me select a particular stage of the pathways of care to focus on during follow-up evaluative activities.

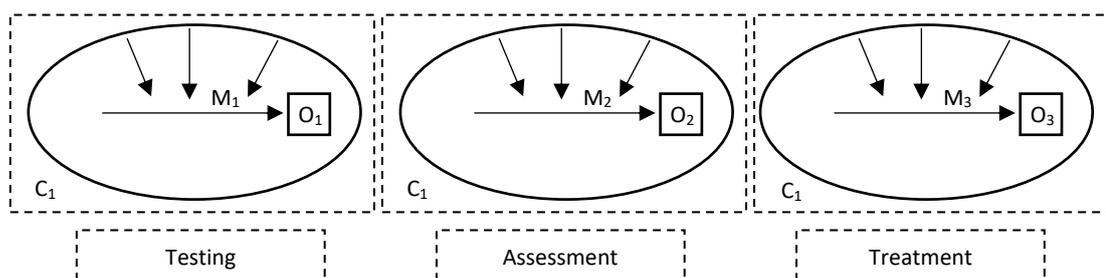


Figure 14. Outline of the pilot evaluation using realist theory. The pilot evaluation aimed to broadly assess the testing, assessment, and treatment stages of a hepatitis C care pathway implemented within a single London prison. Context (C), mechanism (M), and outcome (O) were summarised for each stage of the pathway.

As outlined in Chapter 2, from this pilot work I decided to focus on the first stage of the implemented pathways: opt-out BBV testing (justifications for this decision can be found in the summary for Chapter 4). The research questions that were developed (also outlined in Chapter 2) were designed to structure the assessment of this stage of the programme.

To answer the questions posed, I adopted a mixed-method sequential explanatory design (case-selection variant) (142,143). I started by analysing routine data collected by the LBCSG, which facilitated an assessment of programme outcomes and a critique of data practices (figure 15). I reasoned that starting with an assessment of outcome patterns would allow subsequent evaluative activities to focus on developing explanations for any variation in performance observed.

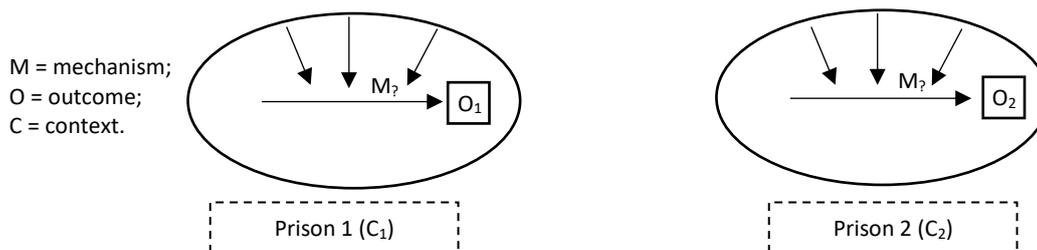


Figure 15. Outline of the outcome evaluation using realist theory. Routine quantitative data were analysed to assess outcomes from the opt-out programme in different London prisons (O). However, this assessment provided limited evidence to help uncover the mechanisms that produced these outcomes (M_?).

A rapid-realist review of the literature was then employed to begin developing explanatory theory for how components (specifically: programme resources) of the opt-out programme, may have facilitated different outcomes under different prison conditions (figure 16). This assessment primarily centred on exploring Mi-Mi realist mechanisms of change, associated with framing testing as “opt-out”, and was used to develop an explanatory model that could be applied to understand the variation in test performance between the London prisons.

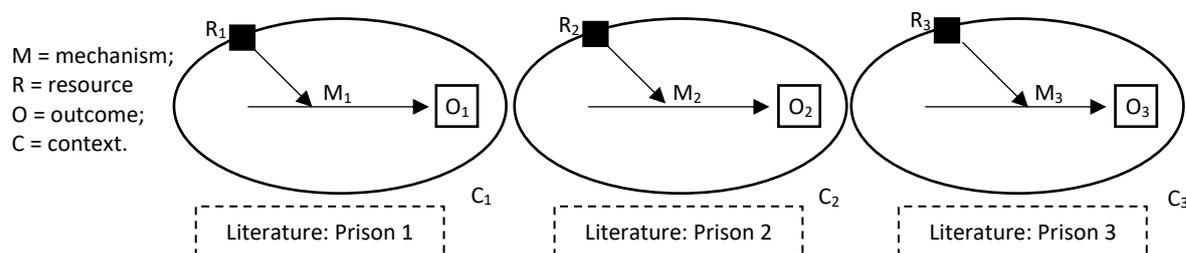


Figure 16. Outline of the rapid-realist review using realist theory. A review of the literature was completed to uncover potential context (C), mechanism (R/M), and outcome (O) configurations, which proposed partial explanations for variation in outcomes during opt-out blood-borne virus testing within prisons. These theories were also used to help understand some of the variation in performance within the London prisons.

Finally, qualitative data generation involving observation, document analysis, and realist interviews was completed within two London prisons reporting divergent programme outcomes, to further develop and refine theories for how, why, and under what conditions, opt-out BBV testing can elicit a high-test coverage (figure 17).

It was at this point that I hoped to employ the novel realist evaluative framework that I had developed to full effect (figure 13, page 49). However, time constraints meant I was unable to conduct the longitudinal data generation required to explore the wider contextual changes that the implementation of the programme may have stimulated (although the direction of certain changes were observable).

Instead, I focused on exploring programme implementation, explaining inhibiting contextual properties (unchallenged and undesirable Ma-Mi mechanisms), and outlining programme operation (Mi-Mi mechanisms) within the two prisons.

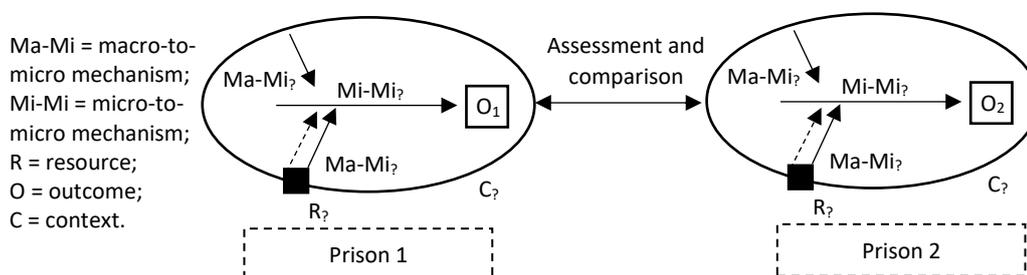


Figure 17. Outline of the qualitative comparative case-study using realist theory. Two prisons, one with desirable outcomes under opt-out (O_1) and the other with undesirable outcomes (O_2), were selected. Context (C), mechanisms (R/M), and outcomes (O) were assessed and cross-compared, with the aim of identifying conditions for success (C, R/M, and O).

By completing these three complementary evaluative projects, I aimed to assess the implementation and performance of the opt-out stage of the London Prisons Project, whilst developing theories to explain any variation observed. If barriers to effective programme function were identified, my intention was to develop policy recommendations and sub-interventions, designed to enhance case-detection (figure 18).

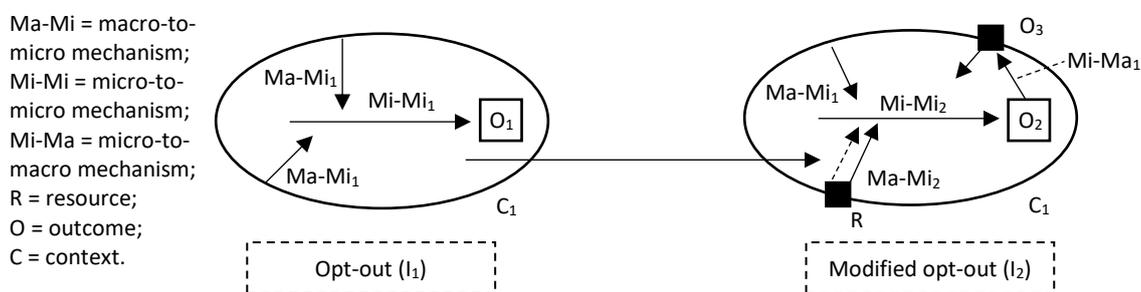


Figure 18. Outline of hypothesised change processes using realist theory. Change from undesired outcome (O_1) to desired outcome (O_2) by the introduction of a resource (R) associated with a complimentary sub-intervention (I_2), which blocked one macro-to-micro mechanism and stimulated a new one (MA-Mi₂), in turn allowing the expression of a new micro-to-micro level mechanism (Mi-Mi₂). Over time the outcome (O_2) stimulated a micro-to-macro mechanism (Mi-Ma₁), which generated a wider contextual change (O_3).

Overall, it was my intention that the work would help to place London prisons in a better position to facilitate English HCV elimination objectives. Figure 19 (page 53), summarises all the research activities discussed in this thesis and their impact on the London Prisons Project. This diagram can therefore be used as a point-of-reference for understanding the relationship between each empirical chapter.

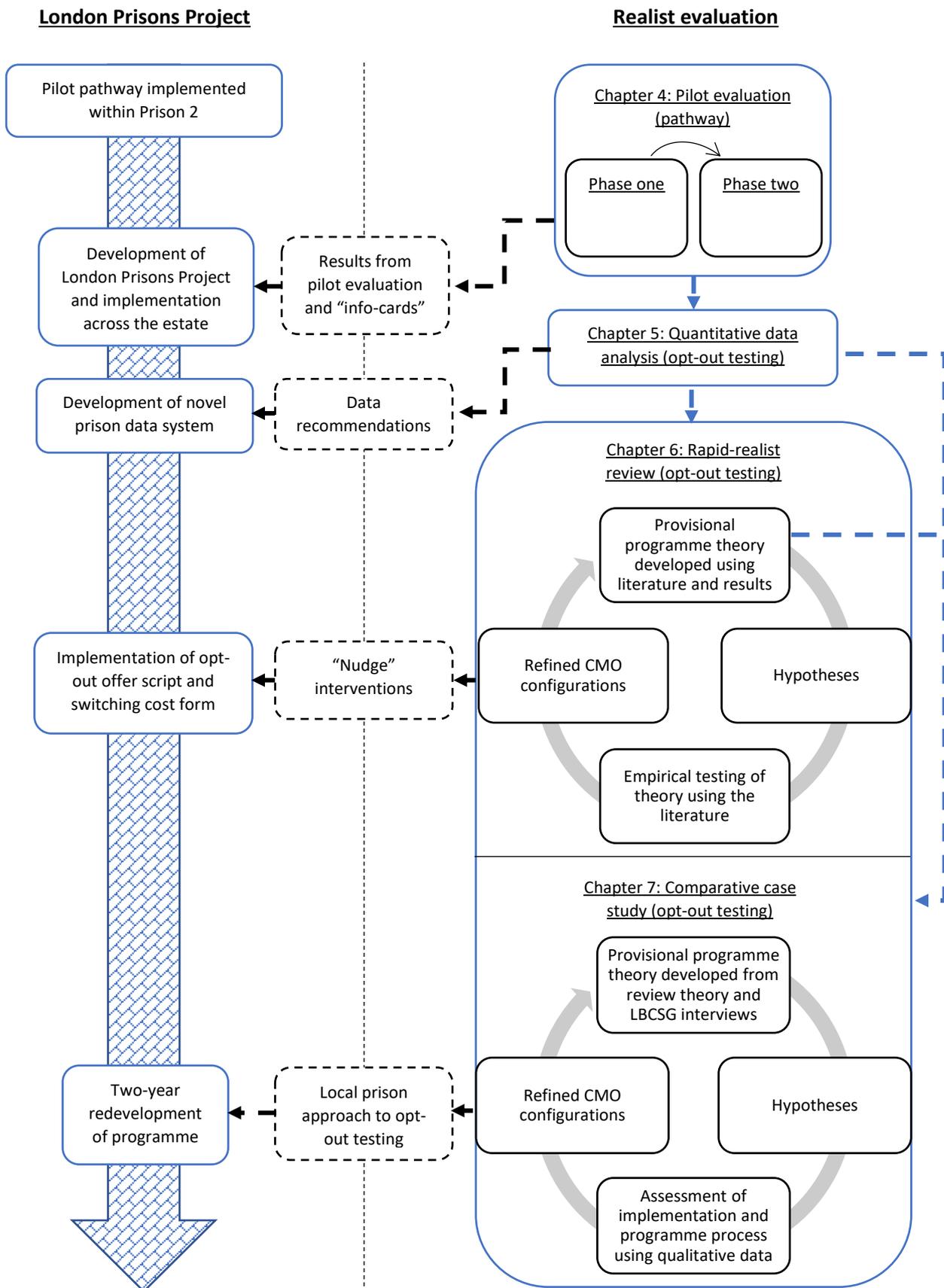


Figure 19. Schematic of the evaluative research design (CMO = context-mechanism-outcome; LBCSG = London Blood-Borne Virus Core Steering Group). Black arrows represent outputs from each piece of evaluative research and their influence on the London Prisons Project. Blue arrows represent a work stream informing another piece of work.

Chapter 4: Service re-design case study (pilot realist evaluation)

4.0 Introduction

Having outlined the background information that contextualises this research, I now focus on presenting the methods used, and results of, each stage of the evaluation sequentially (figure 20). Empirical chapters begin with a description of the methods employed, before results are presented and discussed. Interventions or policy recommendations, developed in response to evaluative results, are highlighted at the end of relevant chapters.

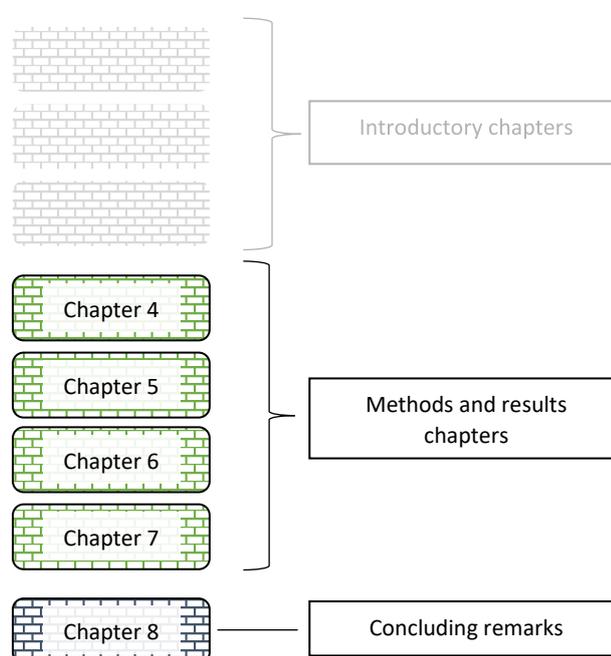


Figure 20. Outline of the thesis structure. Block colour signifies the aim of the chapter (blue = introductory; green = methods and results; dark blue = concluding remarks). Introductory chapters are in grey to signify that they have already been presented.

In this chapter I discuss the pilot stage of this evaluative research. As mentioned in Chapter 2, responsibility for the design and evaluation of a novel HCV pathway was awarded to a UCL research team based at the Royal Free hospital and working closely with the local ODN (also based at the Royal Free).

The team decided to trial this pathway within Prison 2, which had implemented opt-out BBV testing as part of the phase 3 pathfinder programme. Seeing this as an opportunity to familiarise myself with an entire pathway of care, implemented within a London prison, I decided to work with the Royal Free team to help evaluate and refine the programme.

4.1 Method

The Royal Free team drew on Action Research as a methodology for designing the HCV care pathway within Prison 2 (144). Action Research is a participatory approach that involves researchers and stakeholders co-developing a solution to a problem, trialling it within a context, assessing it, and then reformulating the solution iteratively (145). As a result, evaluative methods play a key role in the “assessment” stage of this process (146).

The Royal Free team planned for two phases of pathway implementation, assessment, and reconfiguration (144). I completed a pilot realist evaluation, using a synthesis of qualitative and quantitative data, to inform the re-design of the pathway between each phase (111,142). I hesitate to term this “realist action research”, as the evaluation was not explicitly participatory (145,147,148).

My objectives included:

1. To develop a provisional realist programme theory for the pathway of care;
2. To analyse pathway outcomes;
3. To explore options that may improve pathway performance;
4. To identify a stage of the pathway to be the focus of further evaluative research.

4.1.1 Phase one: December 2015 – February 2017

Developing a programme theory: The pathway was implemented in December 2015 and my evaluative activities began in December 2016. Upon my request, 17 documents were provided by PHE, the Royal Free team, and the healthcare provider for Prison 2.

Combined, these documents provided detailed information on how each stage of the pathway should have been carried out. However, documents frequently lacked an explanation for why certain actions were recommended and how these actions were intended to maximise the numbers of prisoners with HCV infection being diagnosed, assessed, and cured.

To explore stakeholder decision making, I first used information from the documents to develop a model outlining the pathway process. This model was then shared with stakeholders from the Royal Free team and Prison 2’s healthcare provider during meetings in December 2016. Stakeholders were asked to explain pathway design and describe how each stage of the pathway was intended to work. By synthesising verbal explanations for programme implementation, with the model detailing pathway process, I constructed a provisional programme theory (see figure 21 – page 57 for a summary of the different data streams used in phase one of this pilot evaluation) (111).

Assessing implementation: Assuming that additions and omissions were likely to have been made to the pathway following implementation, I decided to retrospectively explore pathway evolution during phase one (111). To do this, I developed two “pathway logs” using Word (Microsoft Office, 2016): one for recording modifications to the pathway and the other for recording barriers to programme delivery.

PHE and NHSE commissioners had arranged a monthly stakeholder meeting to discuss the implementation and evaluation of the pathway. These meetings were attended by representatives from PHE, NHSE, the Royal Free Team, and Prison 2’s healthcare provider. During meetings hosted between December 2016 and March 2017, I asked stakeholders to report modifications and barriers to programme delivery during phase one.

Information came primarily from a clinical nurse specialist (CNS), responsible for overseeing treatment delivery, and a senior nurse from Prison 2, who managed stages of the pathway within the prison. Barriers and modifications were recorded in the relevant pathway logs and used to develop a timeline, which outlined pathway evolution.

To confirm pathway format at the end of phase one, I also completed two site visits (one to Prison 2 and the other to the Royal Free Hospital) in March 2017. During visits I observed the testing, assessment, and treatment process, and discussed contemporary challenges to pathway delivery with the CNS and prison healthcare staff. Relevant data were recorded in field notes and then added to the pathway logs (149). Using this information, I developed a model for how the pathway had been implemented in practice during phase one.

Phase one outcomes: The Royal Free research team collected baseline outcome data between December 2015 and February 2017. Data for stages of the pathway conducted inside the prison were recorded using SystmOne templates. The treatment stage was covered by the Royal Free Hospital’s ODN Microsoft Access database: “Priority-C”.

The absence of a centralised electronic patient record system, linking prison and community healthcare (a legacy of their historic separation), meant that the prison’s data analyst had to extract information from SystmOne and then send this information to the Royal Free team periodically. However, data format varied considerably as a result of staffing changes within the prison, with individualised data provided at times, and at others only an aggregate value.

Information on treatment was extracted from Priority-C by the Royal Free team, with ODN approval. Data were then manually cleaned, synthesised, and entered into a central Excel (Microsoft Office, 2016) database. I was involved in overseeing this process but did not clean

or process the data. I then assisted the Royal Free team analyse pathway outcomes for phase one using descriptive statistics.

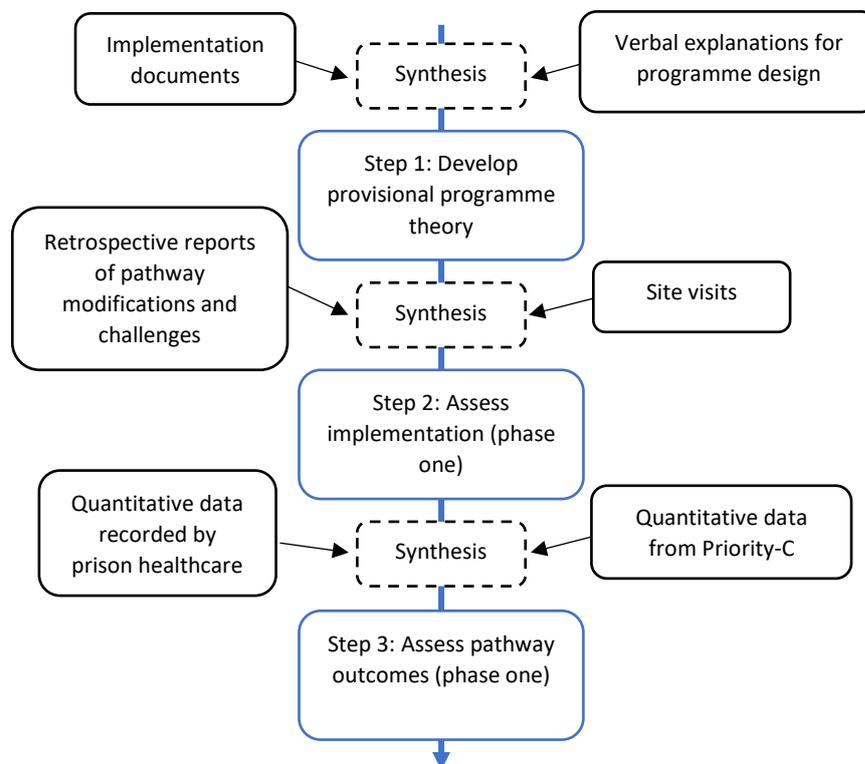


Figure 21. Diagram detailing the different data streams (black boxes) and how they were combined to inform each step (blue boxes) of the first phase of the evaluation of a pilot hepatitis C care pathway, implemented within a local London prison.

4.1.2 Phase two: March 2017 – May 2018

Reconfiguring the programme theory: Phase one outcomes were cross-compared with information recorded in the pathway logs (142). Key points of attrition were linked with challenges (either reported retrospectively or observed during site visits) and then summarised as a list of barriers to programme function (see figure 22 – page 58).

To explore ways of addressing these barriers, I scoped the literature to appraise the design of different testing and treatment programmes for HCV within prison (150,151). This review was performed on MEDLINE, EMBASE, CINHAL Plus, ASSIA, PsycINFO, and Scopus, using a simple search algorithm that was amended as required for each database (see appendix A).

The titles and abstracts of search results were exported into Word (Microsoft Office, 2016) and reviewed using pre-specified eligibility criteria (see appendix A). Those citations that met the inclusion criteria were downloaded in PDF format and subjected to a full-text review, to acquire a final sample of relevant articles. Information about HCV testing and treatment was then extracted from this sample and summarised in a data matrix, developed on Excel (Microsoft Office 2016).

Programme resources that could mitigate listed challenges were identified in the matrix. These were then used to develop Mi-Mi realist programme theories, explaining how the inclusion of the programme resource into Prison 2's HCV pathway could help improve performance (145). During a stakeholder meeting in March 2017, a series of modifications to the original pathway design (informed by these theories) were agreed and then implemented, with follow-up site visits in May, July, and December 2017 to ensure realisation of planned changes.

Phase two outcomes: Second phase data were collected between March 2017 and May 2018 in the same way as phase one. Data were used to conduct a comparative analysis of outcomes between the two phases (142). As a result of data limitations (discussed at the end of this chapter), the analysis was restricted to descriptive statistics on Excel (Microsoft Office, 2016). Confidence intervals (CI) were calculated using Stata 15 (StataCorp, 2017). Finally, by comparing results between phases one and two, I refined the programme theory for the novel HCV pathway of care, implemented within Prison 2.

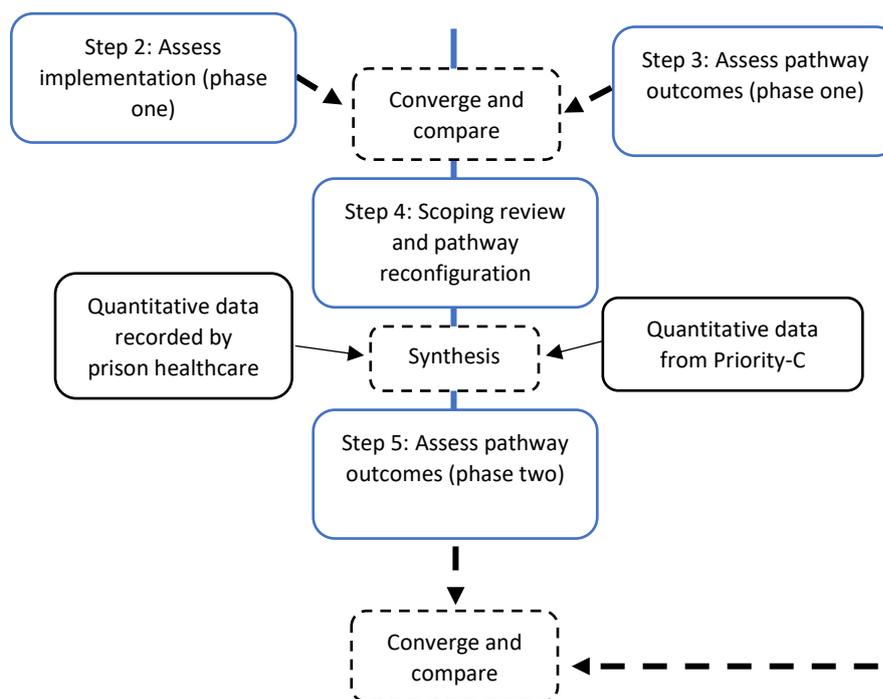


Figure 22. Diagram detailing the second phase of the evaluation of a pilot hepatitis C care pathway. Black arrows show different data streams. Thick black dotted arrows show where results from different stages of the evaluation were converged and compared: data from phase one (step 2 and 3) were compared to create a list of challenges to programme delivery. Phase two outcomes were compared with those from phase one.

4.1.3 Ethics

This project was judged to be service evaluation using the Medical Research Council's guidance and was registered as such. Ethical approval was therefore not considered necessary.

4.2 Results

For phase one I begin by discussing the pathway process (alongside the provisional programme theory underpinning it), go on to outline how the programme had been implemented, and then describe programme outcomes. For phase two I present the theories developed from the scoping review, discuss the re-design of the pathway, and highlight programme outcomes following the reconfiguration effort.

4.2.1 Phase one: provisional programme theory

Table 8 (pages 62 and 63) outlines the 11 provisional programme theories developed during phase one. Three pathway objectives were distilled, in line with NHSE's policy and funding strategy for HCV treatment via ODNs:

- Identify cirrhotic patients in order to rapidly assess and treat;
- Identify those on a disease trajectory that puts them at risk of developing cirrhosis in the future, with the aim of monitoring disease progression, addressing lifestyle factors, and treating those that meet NHSE eligibility criteria;
- Gather information about those not at a high-risk of developing cirrhosis, and that do not meet NHSE's eligibility criteria for immediate treatment, whilst providing education on how to manage the disease and information about engaging with healthcare services on release.

The pathway developed to do this was divided into seven stages. The design and implementation of stages one and two were informed by the wider PHE opt-out test strategy, with little input from the Royal Free team.

4.2.1.1 Stage one and two: BBV testing

All new arrivals were supposed to be engaged by prison healthcare staff during their first night screening assessment and provided information verbally about BBV infection. The next day, all individuals were to be re-engaged for secondary screening and provided pre-test information. Testing should have been offered in an opt-out format and DBST used for sample acquisition.

Completed samples should have been sent to the PHE central laboratory in Birmingham daily for serological testing, in line with PHE recommendations (see Chapter 2). It was agreed with the laboratory that this process would take approximately one week to be completed.

Results should have then been received digitally from the lab, imported into SystemOne, and manually filed by a member of the prison healthcare team. Prisoners receiving negative results were to be informed and post-test information/harm minimisation provided, either

via private post or in a clinic with a member of the healthcare team. Those patients that received a positive HCV RNA test (indicating active infection), should have been immediately booked into the next available sexual health clinic.

4.2.1.2 Stage three: assessment

Patients attending the sexual health clinic should have been informed of the positive HCV result and had a blood sample taken for laboratory assessment. This sample was to undergo testing for genotype, viral load, full blood count, urea and electrolytes, liver function, clotting factors, and for the degree of liver fibrosis. The assessment of fibrosis was completed using the Enhanced Liver Fibrosis test (ELF).

The vernacular for these, in the context of the pathway, was “stratification” tests. These were used by the Royal Free ODN to both prioritise patient access to treatment, in line with NHSE requirements, and for informing the use of specific drug regimens (viral load, genotype, and the presence of cirrhosis determined duration and suitability of certain treatments).

In addition, the inclusion of the ELF test to assess fibrosis was intended to streamline the pathway, reducing the time from diagnosis to cure, as the prison healthcare team would no longer need to carry out phlebotomy and a separate assessment of fibrosis (i.e. transient elastography or biopsy) (see programme theory in table 8).

4.2.1.3 Stage four: advice and counselling

It was agreed that stratification tests would take roughly one week to be processed by the laboratory. Once results were received, they were to be collated by a prison HCW and then referred to a CNS working with the Royal Free ODN, via email, using a standardised referral template. At this point responsibility for pathway progression was transferred to the CNS, who visited the prison weekly to conduct a liver clinic.

At the clinic, patients were supposed to be informed of their results and provided with information covering harm minimisation, prognosis, and treatment options. This interaction was also an important opportunity for the CNS to check previous HCV treatment history and enquire about other co-morbidities that may have affected the suitability of different drug regimens (e.g. HIV/HBV co-infection or kidney disease).

4.2.1.4 Stage five: logging patients on Priority-C

The CNS was also responsible for logging patients on the Royal Free ODN Priority-C database. Information input into the database (such as fibrosis stage, virology, and co-morbidities) was used to generate a priority score, which dictated the patient’s position in a waiting list and therefore their access to rationed treatment (in line with NHSE guidance for ODNs).

Those inputting this information were also able to provide an additional soft score, alongside a justification (adjusted for frequency of use by clinician). Through this process, logged patients became stratified based on a standardised assessment of disease severity.

4.2.1.5 Stage six: multi-disciplinary team assessment

A weekly MDT meeting was hosted by the Royal Free ODN. This was led by a specialist viral hepatology consultant and attended by pharmacists, virologists, and hepatitis specialist nurses. Prioritisation of cases for discussion was based on their priority score, meaning those determined to be at a lower risk had to wait for a longer period before being discussed.

In addition, despite PHE guidance that treatment should commence regardless of length of incarceration (see Chapter 2), the ODN was concerned about ensuring continuity of care. Facing financial penalties in the event of failing to complete clinical follow-up, as well as restrictions on retreatment, the ODN decided to only commence treatment when an individual could complete the regime whilst incarcerated. The following decisions were therefore typically made as a result of MDT discussion:

1. If the patient could complete the appropriate drug regimen whilst incarcerated at Prison 2, treatment was authorised to commence in line with NHSE guidance.
2. If the patient was due to be transferred before the appropriate drug regimen could be completed, a capsule summary was developed. The CNS was to continue seeing the patient up until the date of transfer, where the capsule summary was to be sent to the recipient ODN and prison healthcare team.
3. If the patient was due for release within 3 months, a capsule summary was developed. The CNS was to continue seeing the patient up until the date of release, where the capsule summary was to be sent to the recipient ODN and the patient's GP (if identified), so that treatment could be initiated in the community. Probation services were not engaged, due to complications related to information governance.

4.2.1.6 Stage seven: treatment management

For those patients starting treatment at Prison 2, this was supposed to commence within 7 days of the MDT outcome. Treatment delivery was overseen by the CNS, with an assessment at 2, 4, and 8 weeks after initiation.

Following completion (roughly 8-24 weeks depending on the drug regimen), the CNS was required to carry out a 12-week post treatment follow-up to ensure SVR. They were also required to do a 24 and 48-week HCV test, in line with NHSE requirements, to ensure that the ODN was reimbursed for treatment.

Table 8. Provisional realist programme theory for different stages of opt-out blood-borne virus testing and a novel hepatitis C pathway of care, implemented within Prison 2 (HCV = hepatitis C; ELF = Enhance Liver Fibrosis Test; BBV = blood-borne virus; ODN = operational delivery network; DAA = direct acting antivirals; NHSE = NHS England).

Theory	Aims	Context	Mechanism ----->		= Outcome
			+ Resource	Response	
Awareness raising (stage 1)	Encourage engagement with the HCV pathway	Knowledge of HCV transmission risk, symptoms, severity, and treatment options frequently poor amongst prisoners	Information about HCV covering transmission risk, symptoms, and improved prognosis (thanks to new treatment) provided on the first night	New arrivals re-evaluate their need for testing	Prisoners more likely to see the value in, and engage with, the HCV pathway
Pre-test information (stage 2)	Encourage people to test for BBVs	Testing for a blood-borne virus can be a stressful experience, particularly within a prison environment where individuals may experience stigma	Information about how the test is done (i.e. a small finger prick) and reassurance about medical confidentiality	Individual feels reassured about testing	Some individuals with reservations about testing feel reassured and are therefore more likely to accept the test
Sample acquisition (stage 2)	Encourage people to test for BBVs	A proportion of people will be averse to needles when testing involves venepuncture	Blood samples collected via dried blood spot, which requires a finger prick rather than venepuncture	Discomfort caused by the finger prick does not outweigh the benefit of knowing serostatus	Individuals who usually refuse a test because of a fear of needles are more likely to accept
Opt-out (stage 2)	Steer people into testing for BBVs	A large proportion of newly incarcerated people may lack a strong preference about testing for blood-borne virus infection	If the individual does nothing they are tested (default option)	Those with no clear preference “go with the flow”	Those without a strong preference are tested alongside those that actively want to test
Post-test information (stage 2)	Prevent reinfection	Individuals engaged in risky activities may feel reassured by a negative result, but not alter subsequent behaviour to avoid infection	Negative result presented negatively and information about harm minimisation provided	The individual is encouraged to reassess their risk behaviour	Those testing negative take steps to minimise their risk of infection
Use of ELF for assessment (stage 3)	Rapidly obtain all information required for treatment decision	Local prisons have a rapid population turnover. The requirement to conduct blood tests and transient elastography or biopsy delays patient progression to treatment	Use of the ELF test allows all diagnostic information required for a treatment decision to be obtained in a single blood draw	Healthcare worker only needs to see a person once during the assessment stage	Takes less time for the patient to progress from diagnosis to treatment, in turn reducing attrition through release or transfer
Encourage continued engagement (stage 4)	To maintain continued engagement with pathway	The receipt of a positive result can be stressful for patients in prison	Information about patient’s disease, prognosis, and treatment options provided by a specialist nurse	Patient feels supported by a perceived expert and feels prepared to face their diagnosis	Patient continues to engage with the pathway and feels informed and supported

Table 8. Continued.

Theory	Aims	Context	Mechanism ----->		= Outcome
			+ Resource	Response	
Managing health condition (stage 4)	Mitigate avoidable damage and risk of transmission	Knowledge on how to manage HCV infection is poor amongst prisoners and also frequently amongst prison healthcare staff	Information about the patient's infection and how to manage it responsibly provided by a specialist nurse	Patient motivated to take actions that will reduce the risk of transmission and additional damage to the liver	Patient motivated to make lifestyle changes that can help them better manage their infection whilst awaiting treatment
Stratification (stage 5)	Ensure treatment prioritised for those at greatest risk of mortality	NHSE policy necessitates ODNs prioritise treatment for those at greatest risk of mortality	Priority-C provides a standardised way of assigning a "priority score" for patients based on biomedical markers of disease severity	Healthcare worker able to calculate a priority score, simply, quickly, and in a standardised manner	Treatment prioritised for those at greatest clinical risk of harm in a transparent and fair manner
MDT assessment (stage 6)	Inter-disciplinary specialist decision on patient treatment	New DAAs are expensive and the decision of what drug regimen to use requires expert clinical insight	Expert forum negotiates whether to treat or refer the patient and what treatment regimen should be used	Experts negotiate treatment options, a care plan, and decide an appropriate treatment regimen to use, based on a considered appraisal of clinical factors	The most clinically appropriate treatment decision is made by a specialist group of clinicians. In the event of referral, a comprehensive capsule summary is developed containing all relevant clinical and social information, which is then sent to the recipient ODN
Treatment (stage 7)	Monitor treatment to ensure patient achieves a sustained viral response	Complications can occur during treatment	A clinical nurse specialist monitors treatment to ensure viral response, adherence, and addresses patient concerns	Patient feels supported by a trusted specialist, who can address their concerns and give them person-centred care during the treatment process	Patient adheres to treatment, is monitored closely to ensure safety, completes the therapy, and progresses to achieve a sustained viral response

4.2.2 Phase one: implementation challenges

A variety of challenges to pathway implementation were reported by stakeholders or were observed during site visits. Prison HCWs reported that there was no time to provide educational information during first night screening. The prison healthcare team also reported struggling to engage new arrivals on the second day, either because prisoners refused to attend the secondary screening clinic or because officers were unable (or unwilling) to facilitate the clinic due to staffing constraints.

Confusion around what opt-out meant was also noted and, because of a lack of time to provide people with details of a negative result via prison post, frontline HCWs implemented a “no news is good news” policy. This meant prisoners were not being informed of a negative result or provided post-test information focused on harm minimisation.

Issues also occurred during the assessment stage of the pathway. Between January and July 2016 there was a delay in establishing the ELF test, making identification of individuals without obvious cirrhosis difficult. Once this delay was addressed, HCWs still did not request ELF testing until training was provided in October 2016. Key HCWs involved in conducting the assessment also left between November and December 2016, which led to a breakdown in the pathway that continued until redevelopment in March 2017 and meant that the Royal Free ODN received no referrals from the prison during that time.

When referral forms were received, they often had vital clinical information missing, meaning the CNS had to request additional blood tests during the consultation with the patient. In addition, the CNS faced access issues, both to patients (who frequently did not turn-up to clinics) and to the prison itself (because of recurrent incidents where movement in and out of the prison was suspended).

Finally, keeping track of patients was challenging, with rapid transfers and releases taking place across large geographic areas and frequently without prison healthcare or the CNS being provided with warning. This meant measures to ensure continuity of care could not be put in place and the CNS quickly became overwhelmed trying to track and reengage patients retrospectively. As patients were not routinely provided with ODN contact information, they also lacked a clear method of reengaging with care themselves.

Consequently, the pathway experienced a range of informal modifications during the implementation process, which meant operation differed to what had originally been conceived (figure 23). Those delivering the pathway also faced a range of barriers, which

inhibited the effective diagnosis, assessment, and treatment of prisoners with HCV infection within the prison.

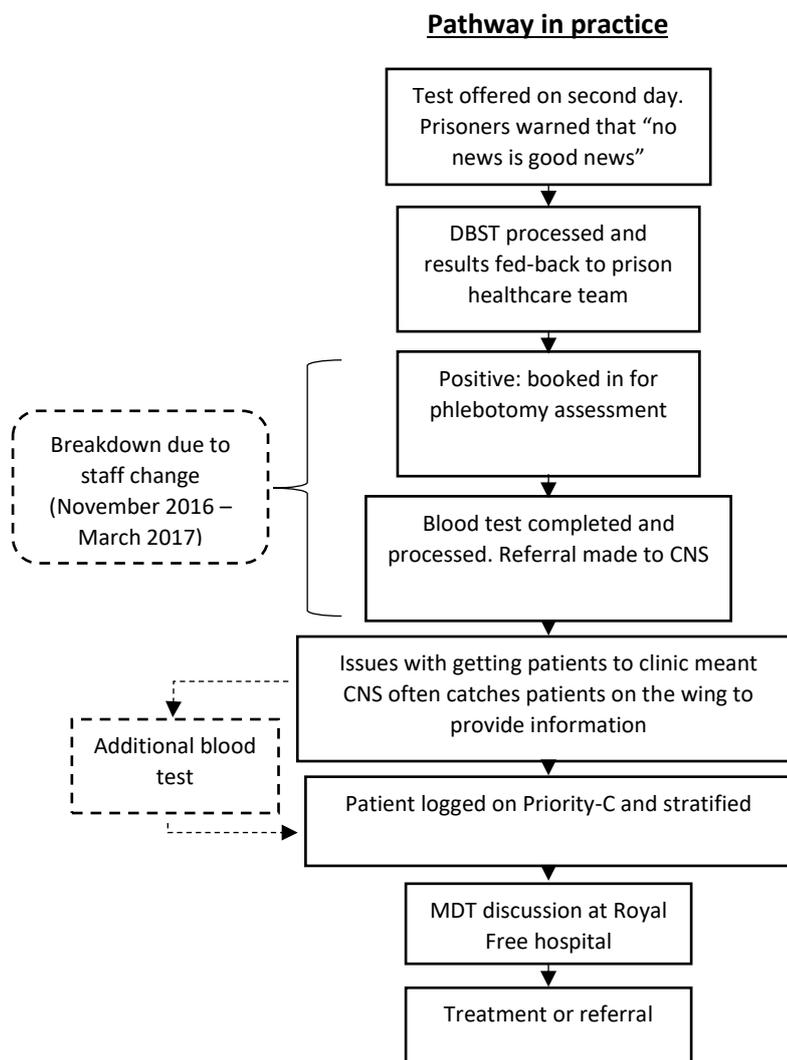


Figure 23. Phase one hepatitis C pathway in practice. Pathway developed using information from site visits and stakeholder meetings (DBST = dried blood spot test; CNS = clinical nurse specialist; MDT = multi-disciplinary team).

4.2.3 Phase one: outcomes

Between December 2015 and February 2017 6767 individuals entered Prison 2, with 2795 recorded BBV test offers (41.3%). There were only 1324 recorded BBV tests completed, 47.4% of the total number of offers.

Of those tested, 96 were identified as HCV RNA positive (positivity of 7.3%, 95% CI: 5.9-8.8%) and all were booked for a phlebotomy assessment. However, only 79 (82.3%) were recorded as completing all stratification tests, with the other 17 failing to complete HCV genotype testing, a viral load measurement, basic biochemical/haematological tests, and/or the fibrosis assessment necessary for treatment allocation.

Records from the Royal Free ODN indicated that the CNS received complete referrals for 22 HCV RNA positive patients (22.9% of all positive samples and 27.8% of those that had a stratification test). Where a referral was received, just 11 (50%) went on to be reviewed by the CNS in prison.

Following CNS review, 10 (90.9%) HCV RNA positive cases were referred to the ODN MDT. 3 of these patients were treated, (30%), 5 were referred (50%), and 2 had contraindications to treatment (20%). Only 10.4% of prisoners identified with cHCV infection were managed appropriately by the pathway, whilst the majority (89.6%) were lost to follow-up throughout various stages:

- Between reception and a test offer, 3972 new arrivals were lost ($3972/6767 = 58.7\%$);
- Between a test offer and the test being completed, 1471 people were lost ($1471/2795 = 52.6\%$);
- Between a reactive DBST and stratification, 17 patients were lost ($17/96 = 17.7\%$);
- Between stratification and referral, 57 patents were lost ($57/79 = 72.2\%$);
- Between referral and CNS review, 11 patients were lost ($11/22 = 50\%$);
- Between CNS review and ODN MDT, 1 patient was lost ($1/11 = 9.1\%$).

4.2.4 Phase two: pathway re-development

Outcomes from phase one indicated that there was significant scope for re-development of the pathway to improve performance. By comparing phase one outcomes with challenges to programme implementation, barriers to delivery were identified. The scoping review carried out to explore solutions to these barriers identified 1334 potentially relevant citations related to the diagnosis, referral, and/or treatment of HCV within prisons (figure 24).

After duplicates were removed, 793 citations remained to be screened. In the first round of screening, 729 records were excluded based on a title and abstract assessment. A further 36 articles were excluded during the second round. 20 articles and 8 abstracts were included in the final sample.

The Mi-Mi realist theories that were produced are presented in text as italics, with components highlighted: C=context, MR=mechanism resource, MRE=mechanism reasoning response and O=outcome. A description of the barrier, which the proposed programme resource was anticipated to address, is provided alongside.

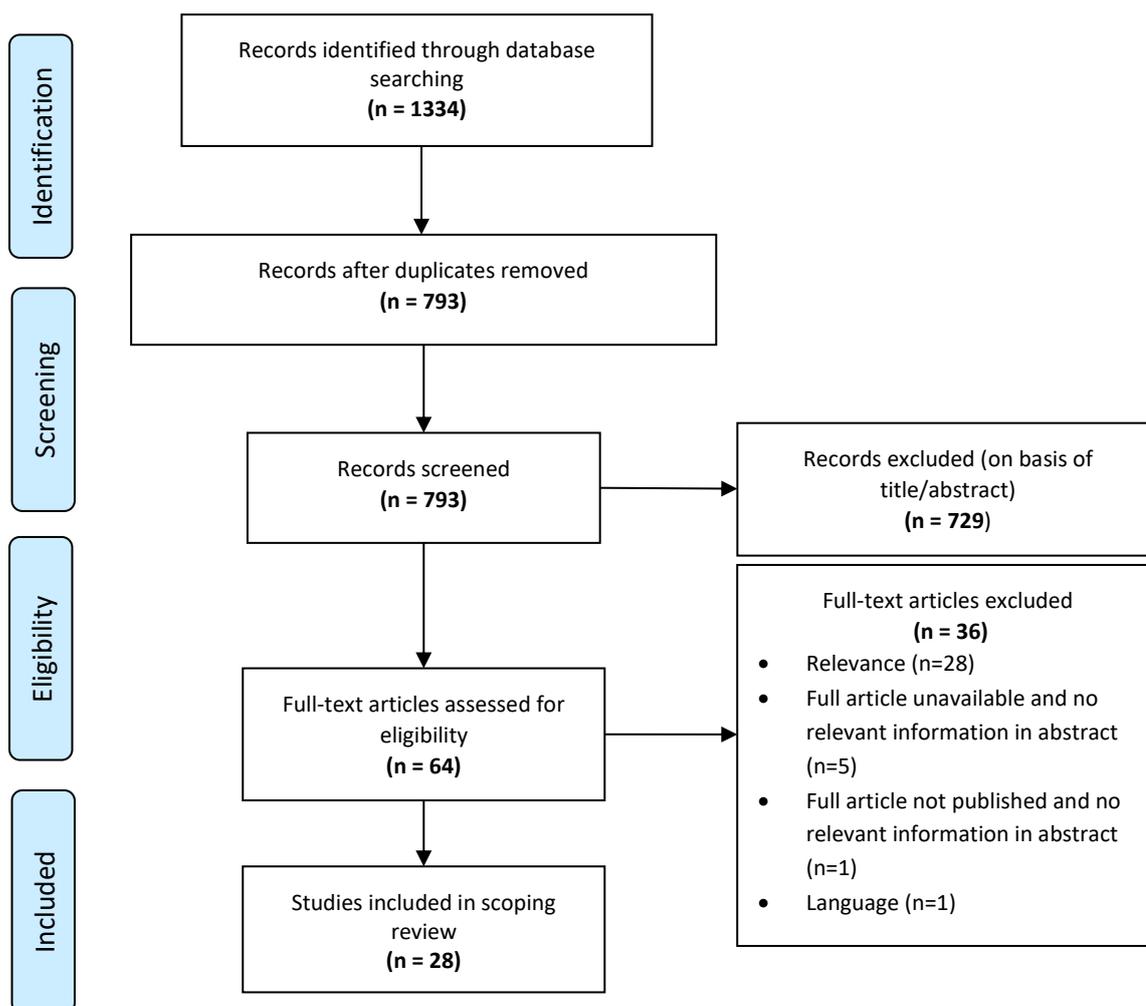


Figure 24. Flow diagram detailing the screening process utilised in the scoping review. The diagram was designed following recommendations made by the PRISMA Group (2009).

4.2.4.1 Stages one and two: education and testing

A lack of time during first night screening was identified as a barrier to the delivery of educational information on BBV infection during phase one. However, educational interventions in the literature were frequently delivered as seminars, where details of HCV could be given to a group (96,152–155). This allowed prison HCWs to engage a large number of people in a relatively short period of time.

CMOc - Awareness raising: *The first night screening clinic is time pressured (C). By providing educational information to a group, rather than during individual consultations (MR), prison healthcare teams were able engage more people in a shorter period (MRE), helping to compensate for time constraints during reception (O).*

Issues with engaging newly incarcerated people for testing were also mentioned in the literature (56,153,154,156). These included competing prisoner priorities during the first few days of incarceration (i.e. educational classes, gym, socialising, court appearances) and

logistical barriers related to security (56). Diversification of a programme's engagement strategy, by employing a combination of testing approaches, was a potential option to mitigate the impact of these barriers.

CMOc – Diversifying engagement methods: *Healthcare teams may face access issues when attempting to engage and test newly incarcerated people (C). Testing upon intake can be married to other engagement strategies (such as testing on wings or during recreational activities) (MR), to help compensate for these issues (MRE) and enhance the numbers of people offered a test (O).*

4.2.4.2 Stage three: patient assessment

To guide the allocation of treatment for those identified with cHCV infection, a range of tests needed to be completed on a blood sample acquired from the patient (157–161). However, an assessment of liver fibrosis, which was also required for treatment allocation, has historically required additional intervention.

Methods of assessing fibrosis reported in the literature included transient elastography and biopsy (56,96,161–165). This meant patients had to undergo one of these procedures, in addition to a blood test, in order to complete the pre-treatment assessment. The two approaches also commonly required prisoners to visit a community hospital, which was costly, logistically difficult for the prison, and a potentially humiliating experience for the incarcerated individual (57,158,166).

Although issues with implementing the ELF test during phase one delayed the pre-treatment assessment, literature suggested that the introduction of a test that could measure fibrosis through serum biomarkers in the blood was appropriate, in order to streamline the assessment process. However, the beneficial impact of this intervention relied on the ELF test being securely embedded into routine practice.

CMOc – ELF test for assessment: *ELF is a relatively new and specialist test that may be unfamiliar to many HCWs (C). Using the test to streamline the assessment process is appropriate, provided it is embedded into routine practice (MR). If this is achieved, all the diagnostic information required for treatment should be available from a single blood draw (MRE), speeding up the assessment stage of the pathway and removing the need for patients to leave the prison (O).*

4.2.4.3 Stages four – seven: patient management

Dependency on a visiting CNS to meet patients, host a liver clinic, and then refer to the ODN, resulted in delays that risked attrition from the pathway. In contrast, many programmes in the literature had devolved responsibility for overseeing treatment to registered nurses within the prison (even those utilising old interferon-based regimens), who were able to solicit specialist support via telemedicine (167–169).

Having prison nurses provide advice, deliver, and monitor treatment could be beneficial, as these staff have greater flexibility to engage patients (169).

CMOc – Internalise the pathway: *Reliance on outside staff visiting once a week to provide specialist care introduces delays due to access issues (to both the prison and the patient) and fails to enfranchise the prison staff (C). Internal staff have the flexibility and knowledge to work around the prison regime and with the increasing simplicity of DAA regimen delivery, HCV treatment could be prison-nurse led, with specialists taking on a support role (MR). This would free prison nurses to refer directly to the ODN MDT (MRE), saving time and therefore reducing the risk of attrition from the pathway (O).*

Finally, unannounced release from the prison and local courts, as well as transfers to other institutions, resulted in attrition throughout all stages of the pathway. In addition, there was no simple method for patients, released into the community without a referral, to re-engage with their local ODN. Similar issues were highlighted in a number of programmes identified in the literature (57,158,170,171).

In the Centre Penitentiaire de Luxembourg, all patients were provided with a copy of their medical records, as well as training on how to engage with care in the community (166). This enhanced prisoner agency to navigate accessing care but was completed as part of the preparations for release and was therefore still reliant on collaboration between custodial and healthcare services.

The New York State “Hepatitis C Continuity Program” reported one of the best examples of institutional collaboration, with prison healthcare teams, community care providers, probation, and prison services all co-operating to complete pre-release preparations (172). In addition, strong partnership between these organisations meant institutional support for reengagement with care could be extended into the community. By encouraging prisoners to sign consent forms, where they agreed to share “limited and specific” information with probation services, personal probation workers were able to assist healthcare services with tracking newly released patients in the community (172).

A combination of enhancing patient agency to follow-up with their own care, in combination with building better partnership between custodial and community organisations, therefore represented a potential solution to the problem of patient attrition.

CMOc- Maintaining engagement with care: *Transfer or release can be a disorientating experience for patients, inhibiting re-engagement with care (C). To increase the likelihood of re-engagement, patients should be provided with clear instructions on how to do this, as soon as possible following initial*

diagnosis, and the process should be made as simple as possible (MR). Institutional support should also be extended to the community, via collaboration between prison and community services (MR). In this way, a two-pronged approach (MRE) can help maximise the chances of re-engagement (O).

4.2.5 Phase two: implementation

The programme theories developed from the scoping review were translated into recommendations to improve performance. At the time of the pathway re-design, the Royal Free ODN had reduced its treatment waiting list. Pathway objectives had therefore shifted from managing patients with mild disease and treating cirrhotic patients, to diagnosing and treating everyone as quickly as possible.

Informed by the realist theories, and in line with the changing objectives, the pathway was reconfigured by the Royal Free team and the prison healthcare provider, in consultation with PHE and NHSE, ready for phase two (figure 25).

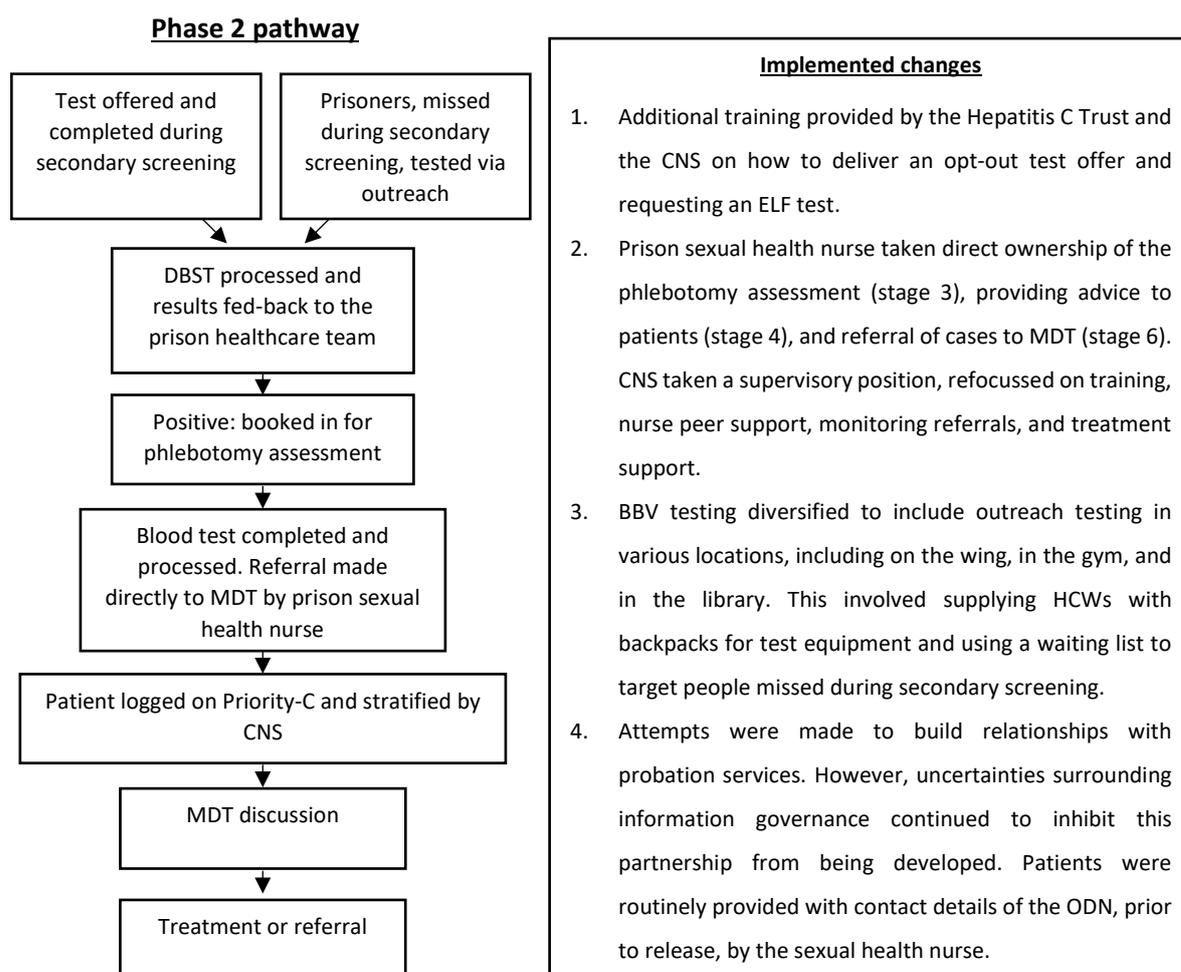


Figure 25. Phase two hepatitis C pathway (DBST = dried blood spot test; CNS= clinical nurse specialist; MDT = multi-disciplinary team; HCV= healthcare worker; ODN = operational delivery network; BBV = blood-borne virus; ELF = Enhance Liver Fibrosis). Changes focused primarily on simplifying the pathway. Site visits and information provided in meetings helped confirm that this process was in place.

4.2.6 Phase two: outcomes

Following pathway re-design, a higher proportion of test offers were made when compared with phase one (figure 26). In addition, a higher proportion of tests were completed relative to new arrivals (29.9%) and offers (51.2%). However, only 72 DBSTs were identified as HCV RNA positive during the second phase, a test positivity of 3.9% (95% CI: 3.1-4.9%).

Of the 72 positive samples, 46 (64.9%) patients went on to have a blood draw to complete stratification tests. 43 patients were directly referred by prison healthcare to the ODN (93.5% of those stratified) and discussed at MDT. At the time of the evaluation, 13 had commenced treatment, 15 had been referred to another ODN, 5 were awaiting treatment, and 10 were lost to follow-up (figure 26). During phase two, 45.8% of patients were managed appropriately by the pilot pathway.

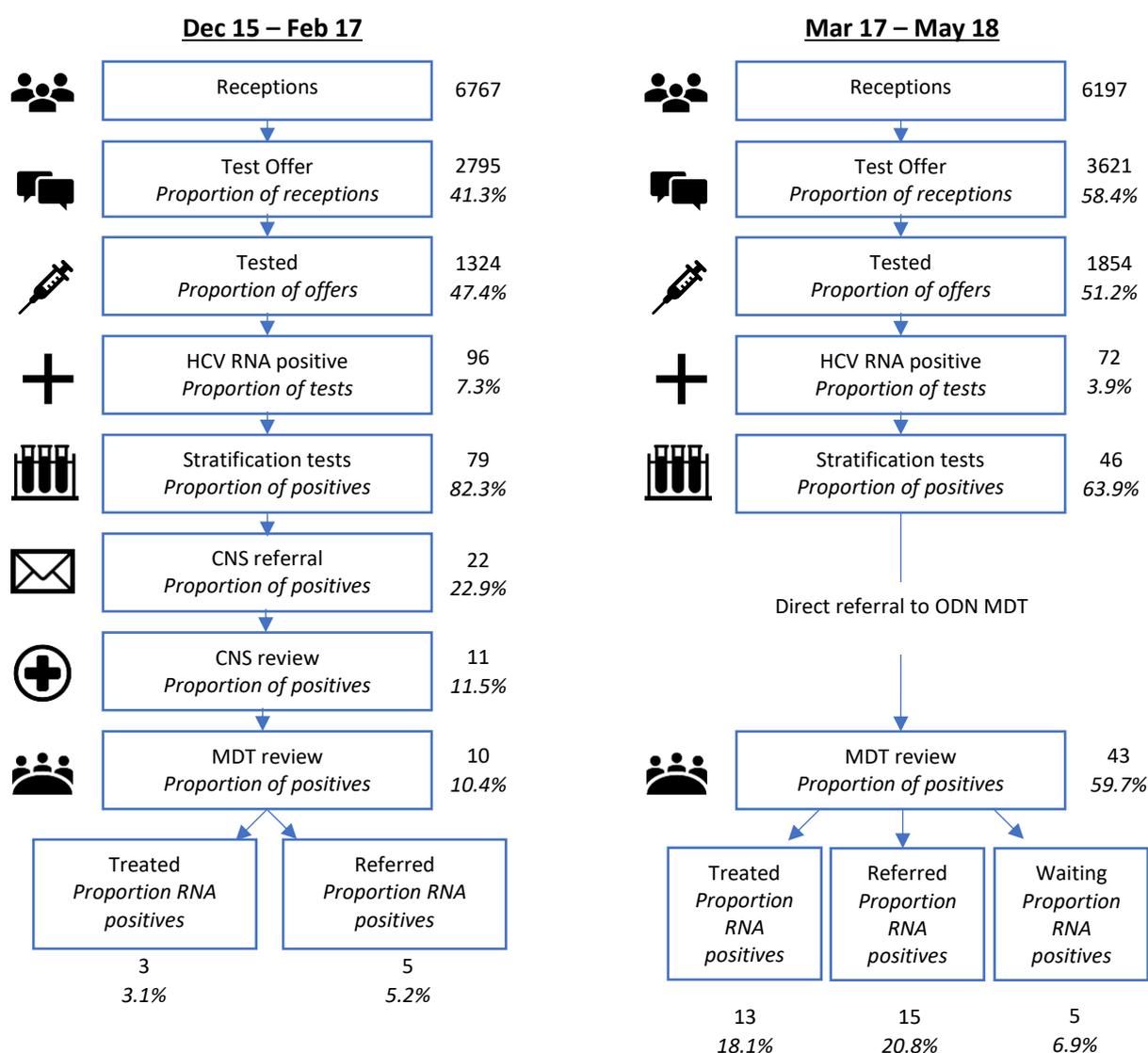


Figure 26. The proportion of prisoners completing each step of the hepatitis C pathway of care within Prison 2 and between phases 1 and 2 of pathway implementation (HCV = hepatitis C; RNA = ribonucleic acid; CNS = clinical nurse specialist; ODN = operational delivery network; MDT = multidisciplinary team meeting).

4.3 Discussion

A pilot realist evaluation was completed, to guide the redesign of a novel HCV pathway implemented within a local London prison (111). Evolution of the pathway channelled resources into progressing those diagnosed with HCV into treatment rapidly. Aspects of the intervention designed to raise awareness of BBVs or encourage further engagement with testing for those found to be negative were quickly discarded, so that resources could be prioritised for managing those with identified infection (see figure 27 – page 77 for the refined programme theory of the phase two pathway).

Nevertheless, offering all newly incarcerated people a test for BBV infection remains the first and essential step for a pathway to be effective (3,38). Results indicate that any delay to engaging new arrivals for testing within a local prison results in attrition. However, the inclusion of outreach test activities during phase two may have helped to improve the proportion of new prisoners engaged and offered a test (56,153,154,156).

A comparison of outcomes between phase one and two also suggested that an unnecessary dependence on secondary care caused attrition. The experience at Prison 2 suggests that referral and treatment is best conducted by trained prison staff, not in-reach staff from the ODN, and that DAA-based treatment can be safely delivered by HCWs within the prison, with minimal supervision from specialist services (167,169).

However, not all changes led to improved performance. The difference in HCV RNA test positivity between phase one (7.3%, 95% CI: 5.9-8.8%) and phase two (3.9%, 95% CI: 3.1-4.9%) was concerning, as it was unlikely that the prevalence of active infection would have declined over such a short period. Instead, depreciation of the metric could have occurred if there was targeted testing taking place during phase one, the prison experienced a change in sentencing and incarceration patterns, or if there was systematic underrepresentation of high-risk prisoners because of pathway reconfiguration or a change in other contextual factors during the second phase (e.g. security considerations in the prison) (173).

Although site visits during phase two confirmed that pathway reconfiguration had occurred, data that could explain the drop in HCV RNA positivity were not generated (100). Nevertheless, it was noteworthy that those staff who had been responsible for programme delivery, and that left the prison during phase one (see section 4.2.2), had been assigned to work specifically with those prisoners that had a history of substance misuse. In contrast, the Sexual Health nurse that led the pathway during phase two was assigned to work with primary care prisoners. Further evaluative research is therefore required to explore whether

(and how) this departmental switch may have affected the representation of high-risk prisoners during testing.

Increased attrition of individuals identified with active HCV infection, before the completion of stratification tests, was also unexpected during the second phase. One explanation was that the sexual health clinic (where phlebotomy took place) was located away from the main prison complex. This presented numerous logistical barriers to patient attendance (54,174). In addition, the Sexual Health nurse worked part-time and was only able to host three assessment clinics per week.

In contrast, responsibility for stratification testing was shared amongst different nurses during phase one, who were able to engage patients at various times and locations throughout the week. The loss of patients prior to disease stratification during phase two, may therefore indicate that ownership needed to be balanced with the capacity of those responsible for completing the phlebotomy assessment to run regular clinics.

The requirement to complete stratification tests also created delays to progressing patients from diagnosis to cure. These tests were completed to establish whether an individual met ODN specific treatment eligibility criteria and to identify aspects of a patient's infection that were relevant for making a treatment decision (38,175). However, as the English elimination strategy has progressed, ODNs have increasingly worked through their waiting lists, with less need to prioritise patients for rationed treatment. In addition, the availability of pan-genotypic DAA's removes the need for genotyping (29,175).

If pan-genotypic treatments could be freely prescribed, a new assessment process, designed to acquire the minimum clinical dataset required to make a treatment decision (i.e. liver function tests, viral load, and ELF to rule out cirrhosis), could be considered (176,177). Indeed, these assessment tests could be completed as part of a general health check during reception, allowing for rapid referral to ODN MDT, whilst potentially identifying non-HCV related liver disorders, such as non-alcoholic fatty liver disease and alcoholic liver disease, amenable to lifestyle modifications during incarceration (178,179).

Finally, difficulties with managing referrals from the prison disrupted continuity of care. In local prisons like Prison 2, many patients cycle in and out of custody or are rapidly transferred after sentencing (180–182). However, despite healthcare handover protocols being in place, HCWs were not always informed when an individual was leaving their establishment. This disrupted engagement with care for those being transferred and commonly resulted in

attrition for those released into the community; as navigating health services likely became a secondary priority to reintegrating with society (183,184).

It is therefore essential that prison staff work with healthcare teams to ensure adequate notice is provided for referral preparations. Patients also require a simple mechanism to allow direct self-referral into ODN care and should be motivated to do so, through positive relationships with healthcare staff and through the use of incentives (36,185,186). With everyone who spends \geq two days in custody required to serve a minimum of 12 months under community supervision (66), probation services also represent a currently unutilised resource for re-engagement into treatment (79,172).

However, until robust release protocols are established, patients are provided with (and motivated to use) a simple means of self-referral, and concerns around information sharing between probation and health services are addressed, seamless HCV care during release remains an unrealised ambition. This discourages ODNs from treating short-stay prisoners, hindering both the public health impact and cost-effectiveness of HCV care pathways within English prisons (32).

4.3.1 Limitations

This pilot evaluation employed a combination of quantitative and qualitative data, in order to evaluate opt-out BBV testing and a novel HCV pathway implemented within a local London prison (142). By combining information from documents outlining the intended pathway process, with verbal explanations for implementation decisions, a robust provisional programme theory was developed.

However, relying on retrospective reports and infrequent site visits (made towards the end of phase one) to identify modifications and challenges to pathway delivery, introduced uncertainty. In particular, some pathway modifications may not have been reported or observed. Challenges to delivery were also unlikely to be comprehensive, having primarily come from the Royal Free CNS and a senior nurse from Prison 2, or from observations made during a single visit to the prison and hospital.

In addition, inconsistencies with the quantitative data acquired from the prison healthcare team were identified (187–189). During phase one, prison HCWs were recording information on Excel spreadsheets (Microsoft Office, 2016), rather than using SystmOne. This reportedly occurred because staff felt uncertain about how to use the software and were unable to extract the information required to guide their day-to-day work. These data spreadsheets

were highly susceptible to human error and significant time was required to patch them together. As a result, the accuracy of quantified outcomes during phase one was uncertain.

These data limitations meant that barriers to programme delivery, identified by triangulating phase one outcome and process data, were unlikely to be comprehensive. In addition, hypothesised barriers may have been linked with attrition caused by data recording errors, as opposed to a genuine loss to follow-up stemming from pathway function. Limitations with constituent quantitative and qualitative data therefore inhibited the scope and potential positive impact of pathway reconfiguration efforts (142).

There were also several limitations with evaluative activities completed during the second phase. Referral protocols were rarely mentioned in the literature sampled during the scoping review, which was likely a product of the search strategy employed (appendix A). I was also the only person involved in screening the literature and extracting data, risking systematic bias that could have resulted in pertinent research (and in turn programme resources) being missed (190,191). These limitations were justified based on the need to prioritise speed over comprehensiveness (150).

In addition, SystemOne was unable to automatically track an individual patient's engagement with services. Instead, "data dumps" were provided during the assessment of phase two outcomes, covering different stages of the pathway. This meant that the Royal Free team had to triangulate various sources of information in order to track individuals, which was a time-consuming process. For a number of months, offer and testing data were also provided as an aggregate value. It was unclear exactly how this information had been extracted from SystemOne and how it should be interpreted. These factors may have influenced the accuracy of quantified changes in pathway performance, summarised during the second phase.

Crucially, the design of the pilot evaluation also restricted the explanatory potential of the data (100). Despite modifications to the pathway coinciding with certain improvements in performance, it was not possible to differentiate the impact of these changes from variations in the wider context, or from unaccounted for implementation changes (e.g. improved performance may have occurred as staff were becoming more familiar with the programme). This was because time and resource constraints meant detailed qualitative data could not be generated during phase two. Caution should therefore be exercised when ascribing changes in performance to pathway redevelopment (100).

Finally, this piloting work highlighted a tension between the depth of realist theory building and evaluative scope. Although focus on a whole pathway facilitated a macro assessment of performance, the realist programme theories developed were broad and often insufficient to characterise the many important, and complex, generative processes taking place (figure 27). Although a broad assessment can be useful as a piloting stage, it is therefore important that follow-up evaluative activities focus on key points of attrition, to provide more detailed explanations for why this is taking place.

4.3.2 Conclusion

Testing 30% of newly incarcerated people for BBV infection and treating 18% of patients identified with cHCV is not sufficient to facilitate English elimination objectives. Results from this service re-design highlight the importance of offering newly incarcerated people BBV testing as soon as possible after they enter a prison. In addition, results indicated that referral and treatment is best conducted by trained prison staff, supported by specialists, because they have more time for patient engagement, greater flexibility, and the experience to work around the prison regime.

Despite improvements in performance during phase two, outcomes remained below expectation, suggesting that there were numerous additional barriers that were either missed, or not completely characterised and addressed during pathway redevelopment. Consequently, there remains significant scope for further innovation to improve the performance of programmes designed to diagnose and treat HCV within prisons.

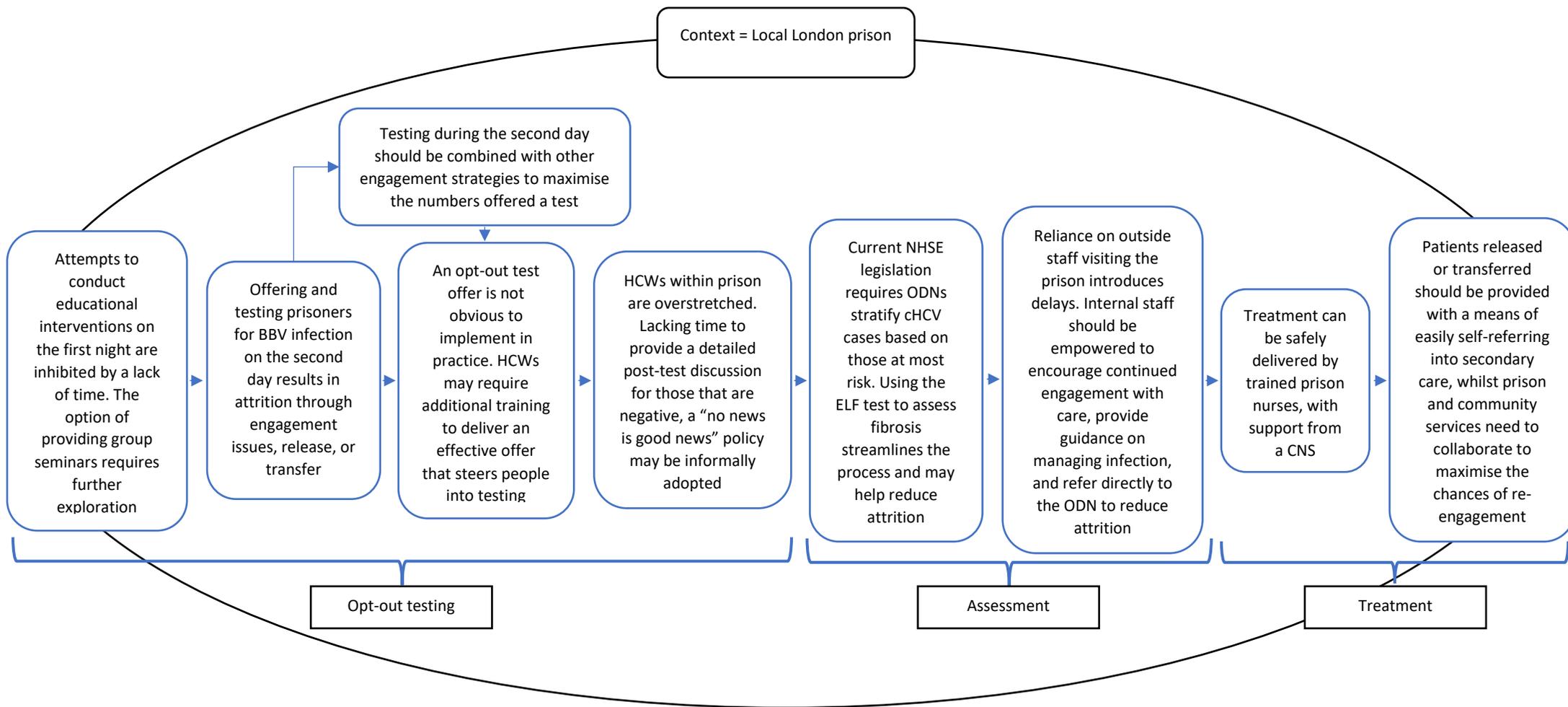


Figure 27. Refined programme theory for opt-out BBV testing and a novel hepatitis C care pathway implemented within a local London prison (CNS = clinical nurse specialist; ODN = operational delivery network; NHSE = NHS England; BBV = blood-borne virus; cHCV = chronic hepatitis C; HCW = healthcare worker; ELF test = Enhance Liver Fibrosis test).

4.4 Referral intervention: “HepC InformOut”

Results from the pilot evaluation at Prison 2 highlighted the need to better co-ordinate care as individuals, identified with cHCV infection, transition between different prisons and the community (1). However, prison and community services are currently fragmented and information governance concerns inhibit partnership. In order to move towards a more robust referral process, the following resource requirements were identified:

1. Greater efforts from custodial services and courts to ensure prison healthcare teams are made aware of an impending release or transfer, so that referral preparations can be put in place.
2. An intervention that can help prisoners, diagnosed with HCV infection, easily self-refer into secondary care after release or prison transfer. As prison and community healthcare IT systems are currently separated, patients should carry details about their infection, to speed-up reengagement and minimise medical resources being wasted through unnecessary re-test and assessment (186).
3. A platform that can help prison healthcare teams, ODNs, drug services, courts, prison services, and probation services collaborate and triangulate institutional support for continuity of care.
4. Clear guidance on information governance considerations, alongside ways in which prison and community services can collaborate to ensure continuity of care, whilst respecting data protection regulations.

Work is currently underway between the Department of Health and Ministry of Justice to develop guidance on information governance. This should help facilitate institutional collaboration within and between prison and community services. For the second and third requirement, myself and the Royal Free team developed an HCV health card (85.6 x 54.0 mm), containing key clinical information about a patient’s disease status and contact information so that they can directly self-refer to an ODN (figure 28).



Figure 28. Front and back profile of a sample viral hepatitis information card, which can be given to patients in prison. Card remains “in development”.

These cards were designed to make it easier for patients to re-engage with secondary care following release or transfer, as well as minimise instances of medical resources being wasted through unnecessary re-test and assessment (172,186). A website was also developed to be used in conjunction with the card (figure 29). This was designed to act as an information sharing platform, so that ODNs could coordinate referrals more effectively between themselves, as well as other relevant service providers (e.g. probation and drug services) (96).

The idea was presented at the British Viral Hepatitis Group meeting on “Best Practice for ODN Stakeholders” (11/01/2018) by Professor Rosenberg, where there was strong support for the intervention. The concept was then shared with the LBCSG, where concerns regarding the patient identifiable and clinical information on the card were raised (figure 29). It was decided that clinical information should be recorded using acronyms (e.g. “G” rather than “genotype”) and a General Data Protect Protection specialist within NHSE would need to be consulted about card content.

Discussions are currently underway with NHSE for national implementation, following further piloting and evaluation. Provided concerns around information governance and card content can be addressed, it is anticipated that this intervention will simultaneously empower prisoners and help co-ordinate the extension of re-engagement support into the community; the ambition being to continue integrating prisons so that they become part of, rather than separate from, the wider care community (1).

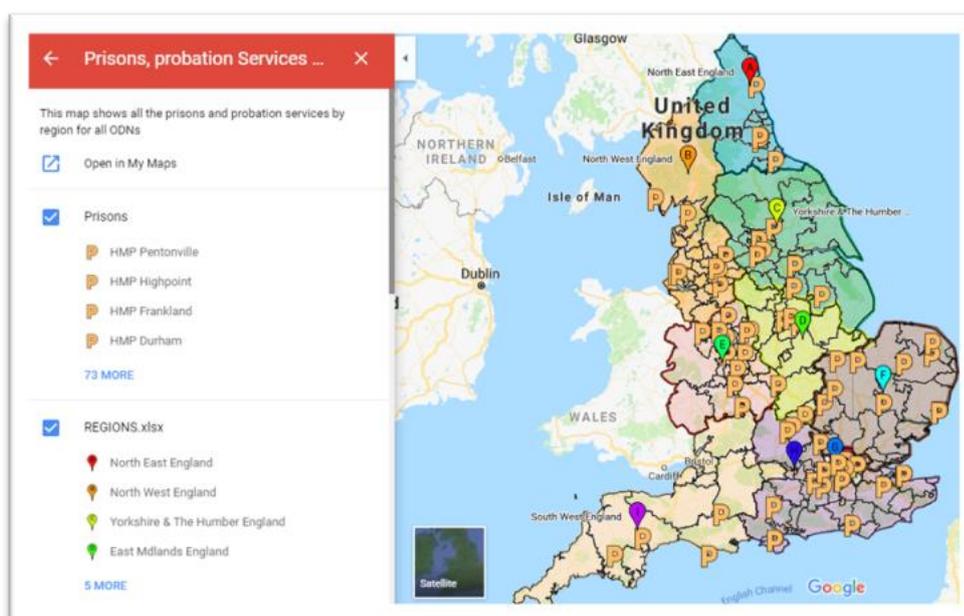


Figure 29. Interactive google-based map, detailing prisons, operational delivery networks, drug treatment services, and probation services across the different regions of England.

4.5 Chapter summary

In this chapter I have demonstrated how a realist approach to understanding social programmes, aided in the redesign of opt-out BBV testing and a novel HCV pathway, implemented within a local London prison. In doing this I was able to:

- Develop a provisional programme theory;
- Assess pathway outcomes;
- Refine the programme theory and inform the redevelopment of the pathway of care;
- Gather information to help guide future evaluative activities;
- Co-develop an intervention to support continuity of care during release or transfer for incarcerated people diagnosed with HCV infection.

As outlined in Chapters 2 and 3, I concentrated subsequent evaluative activities on opt-out BBV testing. This was a pragmatic decision, based on three considerations:

1. Performance of opt-out testing had been found to be poor, both at the national level and within Prison 2. The lower HCV RNA sample positivity, reported during the second phase of the pilot pathway in Prison 2, also required further exploration.
2. Opt-out testing is the first stage of the implemented pathways of care. The success of the assessment and treatment stages, hinges on the rapid identification of viral infection.
3. For elimination of HCV to be achieved by 2025, a dramatic increase in case detection is required (36).

Chapter 5: Opt-out blood-borne virus testing outcomes for the London prison cluster

5.0 Introduction

With a rough idea of how BBV testing and a pathway of care for HCV were working within a single London prison, I decided to simultaneously broaden and narrow my lens of enquiry, by focusing on opt-out testing across the London prison estate. As summarised in Chapter 3, my first objective was to quantitatively assess outcome patterns from the opt-out BBV test programme.

In this chapter, I describe how quantitative data were acquired and then analysed. Results from this analysis are then presented and discussed. The chapter ends with an assessment of data limitations and a summary of the steps taken to re-develop the BBV testing and treatment database, used to manage the London Prisons Project.

5.1 Method

BBV testing within English prisons is primarily measured at the institutional level by NHSE using HJIP data (36). However, these metrics were not made widely available during the implementation of the London Prisons Project, due to data limitations and a high volume of missing information. As a result, the LBCSG developed its own data system to monitor programme performance.

BBV test data were recorded within the London prisons using SystmOne templates (available for review in appendix B). HCWs inputting information into these templates generated a “READ code”. Aggregate data were then extracted by each prison’s data analyst by running SystmOne algorithms (i.e. “READ code reports”), which summarised the number of times a specific code had been recorded within a defined time frame.

Aggregate monthly data were then recorded on a reporting form developed by the LBCSG (appendix B) and sent to NHSE commissioners for discussion at the next steering group meeting. In this way the LBCSG periodically received data sheets from each of the eight London prisons, containing outcome data for BBV testing of prisoners. In addition, data sheets had a section for healthcare teams to record qualitative explanations for any variation in programme performance reported (see exemplar data sheet in appendix B).

Seeing this as an opportunity to assess programme outcomes, I adopted the role of “data analyst” for the steering group. I began transposing test outcomes from the data sheets into

a centralised spreadsheet, developed using Excel (Microsoft Office, 2016). Information provided by prison healthcare teams, to explain any variation in reported outcomes, was also extracted from data sheets and input into this spreadsheet.

As I was unaware of how opt-out BBV testing had been implemented within the London prisons (other than Prison 2), NHSE commissioners agreed to share eight implementation documents. These outlined the testing process within each prison and allowed me to analyse performance, with consideration to variations in programme set-up across the estate.

5.1.1 Analysis

My assessment of the LBCSG data took place over two years, from April 2017 to March 2019, and was divided into three phases (36). After each phase I produced a data report that was shared with the LBCSG, helping to inform policy decisions related to the diagnosis of BBVs within the London prison cluster (example report available in appendix B):

- Phase 1: a preliminary assessment, using data from April – September 2017, and focused on data comprehensiveness, as well as programme performance.
- Phase 2: a yearly assessment of data (April 2017 – March 2018), with an in-depth assessment of data limitations.
- Phase 3: a final analysis, using all available data, from April 2017 – March 2019.

I had hoped to summarise test data using descriptive statistics, whilst looking at the relationship between the percentages of people offered a test and tested using binomial logistic regression (189). Key outcomes of interest included: the proportion of new receptions offered a test (to assess engagement), test uptake (to assess the effectiveness of the opt-out offer), and the proportion of new arrivals tested (to assess public health impact). This was in line with question one of my evaluative research (see Chapter 2).

However, extensive limitations with the LBCSG data were identified (see section 5.3.1 for a detailed discussion). These issues meant that an accurate assessment of test uptake was not possible. I also faced barriers to using logistic regression, as there were a limited number of explanatory variables, data points were not necessarily independent (the same person could appear in the data of multiple prisons within the same month) and, because the data were aggregate, identification of repeated measures (from repeat testing, recidivism, or transfer between the prisons) to account for correlation could not be ascertained or approximated without access to additional information that was not readily available (192).

Given the extensive uncertainties surrounding data accuracy, and issues associated with its format, I decided to focus on characterising data limitations and helping the LBCSG re-develop its data process, with the aim of creating a system that could produce outcome data more suitable for in-depth statistical analysis (see section 5.4) (192,193).

In turn, I limited my final assessment of the LBCSG data to descriptive statistics on Excel (Microsoft Office, 2016), which characterised programme performance against NHSE targets (i.e. 100% of new prisoners offered a test, with a lower performance threshold of $\geq 50\%$ and upper threshold of $\geq 75\%$ tested). Confidence intervals were calculated using Stata 15 (StataCorp, 2017). This analysis also allowed me to target a sample of prisons for follow-up qualitative data generation (see Chapter 7) (142).

5.1.1.1 Exploring data limitations

Exploring inconsistencies in the LBCSG data became a core part of the quantitative outcome assessment. Although inconsistencies could be identified (e.g. when data suggested that 100 people were offered a test and 108 people were tested), I did not have access to SystemOne to explore the underlying cause. Instead, I discussed identified issues with HCWs (tasked with recording data in SystemOne), prison data analysts (tasked with extracting the data), a SystemOne expert from North East London NHS Commissioning Support Unit, and a NHSE commissioner. I also visited four London prisons, where data recording and extraction processes were observed.

With a clearer idea of why inconsistencies in the data were occurring, I developed a report for the LBCSG, which summarised the cause and potential impact of these limitations. With support from NHSE, I then co-hosted a preliminary LBCSG “data meeting” on the 16/02/2018. Data limitations were presented and discussed, with prison healthcare representatives agreeing to explore issues within their respective establishments. On the 30/07/2018 I then co-hosted a larger follow-up meeting, where limitations were again discussed, and it was agreed that a new data system would be required (see section 5.4 for a discussion of steps taken to develop this system).

5.1.2 Permission & Ethics

Permission to use LBCSG data was given by the NHSE Interim Commissioner for Greenwich Cluster & Wandsworth Prisons and Project Manager (London Region) on the 20/10/2017. The UCL Research Ethics Committee were approached and asked whether analysis of the data would require approval. Ethical approval was not deemed necessary as I was dealing with aggregate information, which could not be linked to specific individuals.

5.2 Results

Between April 2017 and March 2019 there were 50,006 registered receptions across the eight Greater London prisons, 36,790 recorded BBV test offers, and 23,740 recorded BBV tests. This corresponded to a regional offer proportion (% of test offers, relative to the number of receptions) of 73.6% and a test coverage (% of tests completed, relative to the number of receptions) of 47.5%. Prison specific data are presented in table 9.

Table 9. The number of receptions, blood-borne virus test offers, tests completed, offer rate, and coverage from April 2017 to March 2019 for seven Greater London prisons. Data for Prison 8 was reported between April 2017 and September 2018. Mean and standard deviation was calculated at a monthly level. *Prison 3 reported offering more tests than the number of individuals entering the prison.

Prison	Function	Receptions (mean; standard deviation)	Offers (mean; standard deviation)	Tests completed (mean; standard deviation)	Offer proportion (%)	Coverage (%)
Prison 1	Local prison	11909 (M=496; SD=48)	9739 (M=406; SD=48)	7803 (M=325; SD=61)	81.8	65.5
Prison 2	Local prison	8986 (M=374; SD=72)	5239 (M=218; SD=71)	3048 (M=133; SD=58)	58.3	33.9
Prison 3	Resettlement prison	2410 (M=100; SD=22)	2433 (M=101; SD=29)	1802 (M=75; SD=41)	101*	74.8
Prison 4	Local prison	8869 (M=370; SD=88)	6510 (M=271; SD=144)	3620 (M=151; SD=93)	73.4	40.8
Prison 5	Local and high security prison	3918 (M=163; SD=22)	3088 (M=129; SD=10)	2246 (M=94; SD=22)	78.8	57.3
Prison 6	Local prison	11048 (M=460; SD=49)	7533 (M=314; SD=80)	3546 (M=148; SD=57)	68.2	32.1
Prison 7	Adult training and young offenders (age: 18-21)	1996 (M=83; SD=10)	1483 (M=62; SD=22)	1151 (M=48; SD=19)	74.3	57.7
Prison 8	Youth and young offenders (age: 15-21)	870 (M=58; SD=26)	765 (M=43; SD=21)	524 (M=29; SD=8)	87.9	60.2

Outcomes varied between the different types of prison. Prison 3, which incarcerated sentenced adults as they prepared for release, was the only institution that reported data meeting both the NHSE offer and upper test coverage targets for the two-year period (table 9). Offer proportions in the other prisons ranged from 58.3-87.9%.

In addition, a mixture of prisons (1, 5, 7, and 8) reported data suggesting that they had achieved the lower NHSE coverage threshold (i.e. $\geq 50\%$). Prison 7 and 8 both held sentenced populations and were small institutions, receiving an average of 83 and 58 new arrivals per month respectively (table 9). Prison 5 was a dual function local and high security prison, with a medium number of monthly receptions (mean = 163).

However, Prison 1 was the only large local prison in London to achieve the lower NHSE test coverage target (table 9). The other three (Prison 2, 4, and 6) failed to achieve either the

offer or coverage target. Being solely designated to serve nearby London courts, these prisons incarcerated high numbers of short stay sentenced and remanded prisoners (average monthly new receptions ranged from: 370-496).

5.2.1 Quarterly offer proportions

Implementation documents revealed two models of opt-out BBV test delivery within the London prisons. The first involved engaging and offering new arrivals a BBV test on their first night, with a follow-up clinic taking place between 1-3 days after to complete sample acquisition. This was necessary, as healthcare teams reportedly lacked the time to complete sample acquisition during the first night screening clinic. The other approach involved healthcare teams offering new arrivals a BBV test simultaneously with sample acquisition, which took place during secondary screening, 1-3 days after reception.

The prisons where teams engaged new arrivals on the first night (Prison 3 and 4), both reported quarterly offer proportions of 100% during the two-year period (figure 30). However, a large and sustained drop was observed within Prison 4 following Oct-Dec 2017, with performance only rallying slightly in the final quarter (figure 30). This drop coincided with a change in practice, from offering testing on the first night, to offering during the secondary screening clinic.

The remaining prisons in London offered at the point of testing for BBV infection. Healthcare teams in these prisons initially reported lower offer proportions when compared to Prison 3 and 4. However, the smaller institutions (i.e. Prison 5, 7, and 8) increased their offer proportions over the two-year period, ranging from 97.9-100% in their final reporting quarters (figure 30). The pronounced dip in performance within Prison 7, between Jul-Sep 2017 and Jan-Mar 2018, reportedly coincided with a period of staffing change (figure 30).

Out of the large local prisons (i.e. Prison 1, 2, 4, and 6), only Prison 1 reported a consistently high offer proportion, which ranged from 75.5-94.5% (figure 30). In Prison 6, there were periods of high performance (quarterly range: 41.3-91.2%), but variability meant that a 68.2% offer proportion was reported overall for the two-year period.

Prison 2 similarly reported variable offer proportions (range: 40.1-80.6%), but at a lower level than Prison 6 (figure 30). Indeed, the healthcare team at the prison reported an offer proportion of <50% for three quarters, suggesting that HCWs were failing to engage and offer BBV testing to a sizeable number of newly incarcerated people within the prison.

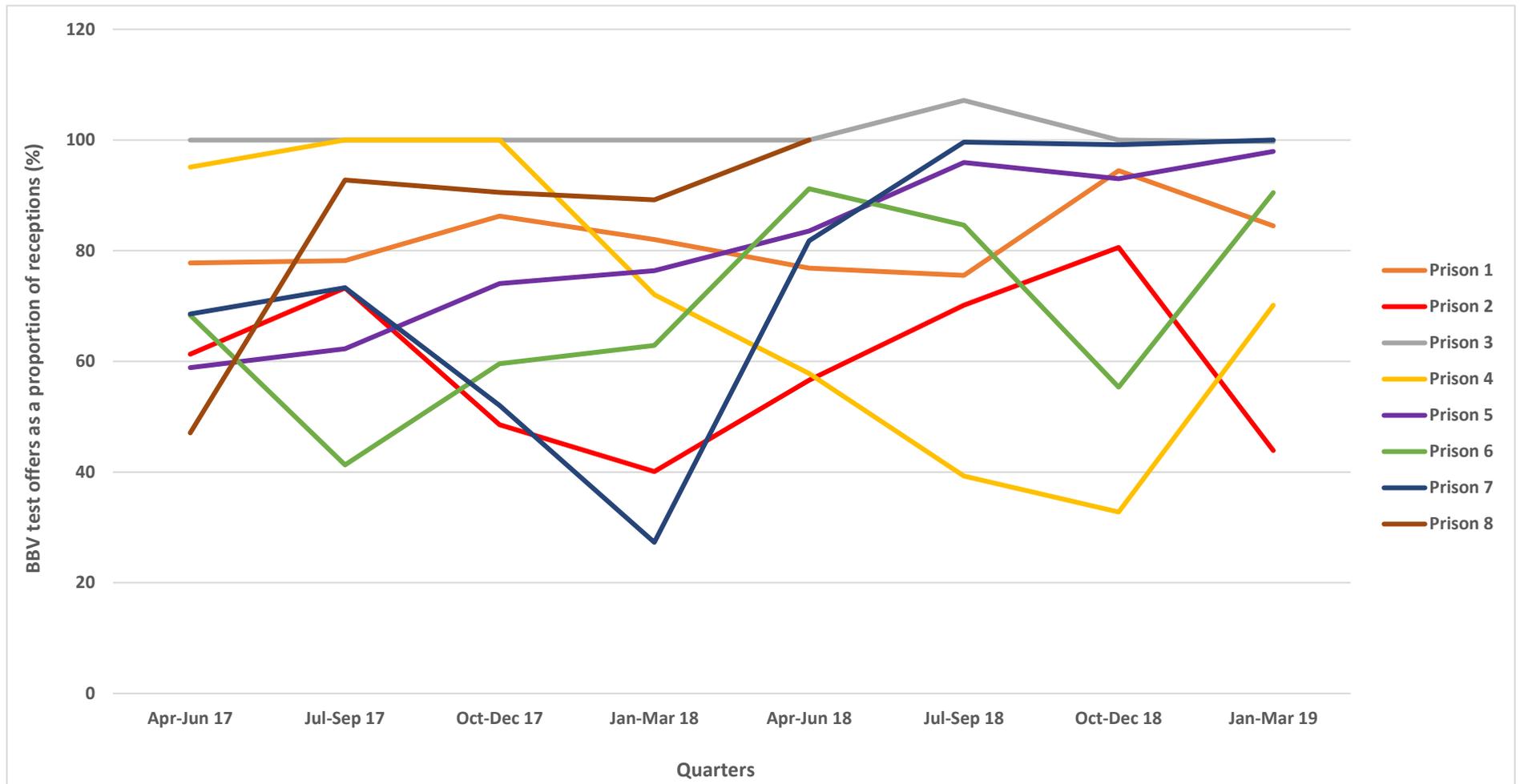


Figure 30. Proportion of blood-borne virus test offers, relative to quarterly receptions, between April 2017 and March 2019. Prison 8 reported data between April 2017 and June 2018 (BBV = blood-borne virus).

5.2.2 Quarterly BBV test coverage

Quarterly programme coverage (i.e. tests completed as a proportion of new receptions) ranged from 10.2-140.5% (figure 31). This was divided into three performance bands, based on NHSE targets: $\geq 75\%$ = high BBV test coverage; $\geq 50\%$ = medium coverage; $< 50\%$ = low coverage.

Prison 3 reported the highest coverage amongst the London estate (74.8% for the two-year period). However, this was not consistent, with a medium coverage (range: 53.4-64%) reported in six of the eight quarters. A large peak in Apr-Jun 2017 (coinciding with an initiative to test prisoners that had been incarcerated before the implementation of the programme) and again in Jul-Sep 2018 (coinciding with efforts from HCWs to test people who had previously been missed when entering the prison) served to push overall performance into the higher bracket (figure 31).

Prisons 1, 5, 7, and 8 formed a middle performance bracket. Coverage in Prison 1 was consistent over the two-year period, ranging from 46.1-80.9% (figure 31). The only quarter where the lower NHSE performance threshold was not exceeded by the healthcare team, occurred directly following implementation in Apr-Jun 2017. Prisons 5 and 6 also consistently reported either medium or high coverages, except during a dip in performance between Jan-Jun 2018. However, like Prison 3, Prison 8 registered low coverages for three out of five of its reporting quarters, which was then compensated for by a large peak of 82.8% in Apr-Jun 2018 (figure 31).

Finally, Prisons 2, 4, and 6 represented the lower bracket of performance. Prison 2 began the reporting period with the lowest proportion of tests completed, with a coverage of just 10.2%. Performance then steadily improved, with a peak in Oct-Dec 2018 of 64.5% (figure 31). Prison 6 similarly reported poor test coverages, before peaking at 58.0% in Jan-Mar 2019 (the only time the health team achieved a medium coverage).

Prison 4's performance displayed a high degree of fluctuation, with certain dips in test coverage reportedly coinciding with periods of key staff absence (i.e. the "BBV lead") (figure 31). The large peak of 113.6% in the final reporting quarter occurred at a time where the number of people being processed through reception was significantly reduced (553 between Jan-Mar 2019, compared to a quarterly average of 1109). It is unclear whether this was a reporting error or reflected a real change in population dynamics within Prison 4.

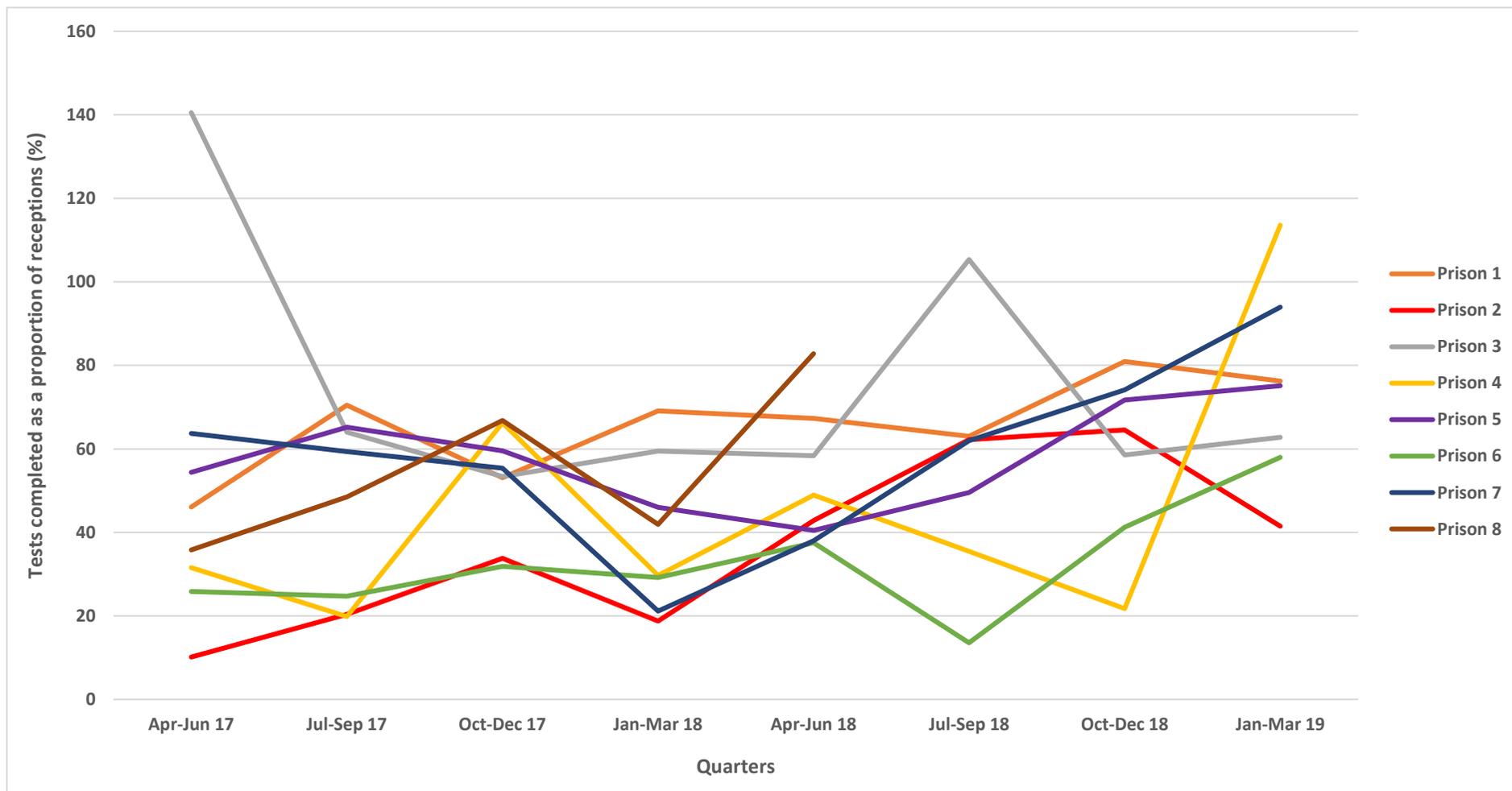


Figure 31. Proportion of tests for blood-borne virus infection completed, relative to quarterly receptions, between April 2017 and March 2019. Prison 8 reported data between April 2017 and June 2018.

5.2.3 Additional testing

During my exploration of data limitations, I identified that additional BBV testing of the prison population was being conducted, which was not being distinguished from opt-out testing upon reception. On my request, healthcare providers began differentiating between testing of new entrants and testing offered to the established population, either as a re-test or a new test, between January 2018 and March 2019. Details of the number of additional tests completed, and the method by which this testing occurred, are presented in table 10.

Healthcare providers reported some form of additional testing taking place within all of the London prisons. Prisons 1, 3, 5, and 7 reported activities in every quarter after Jan-Mar 2018. Prison 2 only reported additional testing taking place during Jan-Mar 2019. As outlined in table 10, this initiative focused on prisoners with a history of substance misuse and occurred in response to a latter part of this evaluative research (see Chapter 7).

The number of additional tests completed ranged from 37-799. Prison 1 reported testing the largest number of prisoners via additional programmes, with a monthly mean of 53 (table 10). Additional testing activities therefore represented a significant source of BBV tests for the prison. Both Prison 2 and Prison 8 reported the lowest monthly means, of 5 and 4 additional tests per month.

Common methods of completing additional BBV tests included during genitourinary medicine clinics, through Hepatitis C Trust awareness raising projects, and via outreach testing conducted on the wings. Prisons 5 and 7 also reported additional testing during a World Hepatitis event and Prison 4 reported testing via an “OraSure” pilot programme, implemented by a London NHS Hospital Trust.

Table 10. Additional blood-borne virus testing carried out between January 2018 and March 2019 (GUM = genitourinary medicine; BBV = blood-borne virus). Prison 8 reported data between April 2017 and September 2018. Mean (M) and standard deviation (SD) calculated at a monthly level.

Prison	Number tested (mean; standard deviation)	Reported method of testing
Prison 1	799 (M=53.3; SD=29.1)	Testing of general population via catch-up testing in cells and extra BBV clinics
Prison 2	56 (M=4.7; SD=11.1)	Targeted testing of prisoners with a history of substance misuse
Prison 3	205 (M=13.7; SD=17.5)	Testing elicited via men’s health clinic, self-referral, awareness events, offering testing on the wings, and testing of existing waiting list
Prison 4	151 (M=12.6; SD=17.1)	OraSure pilot programme
Prison 5	204 (M=13.6; SD=21.1)	GUM clinic, BBV catch-up testing on wing, World Hepatitis event
Prison 6	112 (M=9.3; SD=10.2)	GUM clinic, BBV catch-up testing on wing
Prison 7	397 (M=26.5; SD=36.1)	GUM clinic, BBV catch-up testing on wing, World Hepatitis event
Prison 8	37 (M=4.1; SD=6.5)	No information provided

5.2.4 Sample positivity

Out of 25,701 recorded BBV tests (including additional tests), 1067 anti-HCV (4.2%, 95% CI: 3.9-4.4%), 542 HCV RNA (2.1%, 95% CI: 1.9-2.3%), 327 HBsAg (1.3%, 95% CI: 1.1-1.4%), and 166 anti-HIV (0.7%, 95% CI: 0.6-0.8%) positive samples were detected (table 11). There was no means of distinguishing between new and previously diagnosed infection, using the aggregate LBCSG data. Furthermore, Prisons 4, 5, 6, and 7 were unable to report HCV RNA positive results for a large portion of the evaluative period, because of commissioning complications that prevented reflex testing.

Nevertheless, the proportion of anti-HCV positive samples varied across the London prison estate. Those prisons serving courts (i.e. local prisons) reported higher positivity rates, compared to prisons that only incarcerated sentenced populations (table 11). Prisons 1, 4, 5, and 6 also reported a noticeably higher HBsAg sample positivity and Prison 6 reported a particularly high HIV positivity (table 11).

There was also a pronounced difference in the volume of positive BBV samples, reported by prisons in the Greater London region. The four large local prisons (i.e. Prison 1, 2, 4, and 6) accounted for 90% of all anti-HCV, 95% of HCV RNA, 84% of HBsAg, and 89% of HIV positive samples detected during the two-year period.

Indeed, Prison 1 alone accounted for 60% of anti-HCV, 79% of HCV RNA, 37% of HBsAg, and 38% of HIV positive samples. Outcomes from this prison therefore comprised a significant portion of the positive samples detected by the Greater London region. In contrast Prison 8, which only incarcerated youth and young offenders (ages 15-21), reported no positive samples for any BBV infection between April 2017 and September 2018 (table 11).

Table 11. Prison specific diagnostic data between April 2017 and March 2018 (anti-HCV+ = hepatitis C antibody positive; HCV RNA+ = hepatitis C ribonucleic acid positive; HBsAg+ = hepatitis B surface antigen positive; HIV Ab/AgP24+ = HIV antibody and P24 antigen positive, CI = confidence interval). Several prisons had issues implementing a reflex polymerase chain reaction test on hepatitis C antibody positive samples, which lowered their ribonucleic acid test positivity.

Prison	Anti-HCV+	Anti-HCV positivity (%) and 95% CI	HCV RNA +	HCV RNA positivity (%)	HBsAg+	HBsAg positivity (%) and 95% CI	HIV Ab/AgP24+	HIV positivity (%) and 95% CI
Prison 1	629	7.3 (6.8-7.9)	428	5.0	121	1.4 (1.2-1.7)	63	0.7 (0.6-0.9)
Prison 2	100	3.2 (2.6-3.9)	50	1.6	26	0.8 (0.5-1.2)	12	0.4 (0.2-0.7)
Prison 3	21	1.0 (0.6-1.6)	21	1.1	11	0.5 (0.3-1.0)	8	0.4 (0.2-0.8)
Prison 4	100	2.7 (2.2-3.2)	25	0.7	65	1.7 (1.3-2.2)	24	0.6 (0.4-0.9)
Prison 5	76	3.1 (2.5-3.9)	5	0.2	31	1.3 (0.9-1.8)	6	0.2 (0.1-0.5)
Prison 6	131	3.6 (3.0-4.2)	13	0.4	62	1.7 (1.3-2.2)	49	1.3 (1.0-1.8)
Prison 7	10	0.6 (0.3-1.2)	N/A	N/A	11	0.7 (0.4-1.3)	4	0.3 (0.1-0.7)
Prison 8	0	0	0	0	0	0	0	0

5.3 Discussion

The London region did not meet the NHSE offer target, nor the lower coverage target, during a two-year period following implementation of opt-out BBV testing (36). At the institutional level, analysis of LBCSG data identified several local prisons (Prisons 2, 4, and 6) that were struggling to test $\geq 50\%$ of newly incarcerated people for BBV infection. As these institutions combined received the majority of new arrivals to the London estate, this poor performance likely inhibited the region as a whole from meeting targets (77).

Poor performance of opt-out BBV testing within local prisons has similarly been highlighted in the West Midlands (189). These institutions serve courts and consequently incarcerate large numbers of people for short periods of time (65). This means that delays to engagement risk greater volumes of attrition through release and transfer, when compared to prisons that incarcerate longer sentenced populations (77,189).

However, local prisons also reported a high volume of positive BBV tests and a higher anti-HCV sample positivity (77). The volume of HIV and HBV positive samples detected reflects the size of these prisons' populations (65). The higher anti-HCV positivity would seemingly reflect the epidemiology of IDU, as PWID tend to commit repeat petty crimes to feed their habit (32). Consequently, PWID are often given shorter sentences (average of 4 months in the UK), likely to be served within a local prison, rather than progressing on to training and resettlement prisons (figure 32) (32,36,77).

Until implementation of the Prison Estate Transformation Programme has been completed, local prisons should therefore be a focus for quality improvement initiatives, in order to help facilitate national HCV elimination objectives (3,34,189). To guide this process, lessons could be learnt from the design of opt-out BBV testing within Prison 1, the only large local prison in London where outcomes suggested that the programme was working effectively (100).

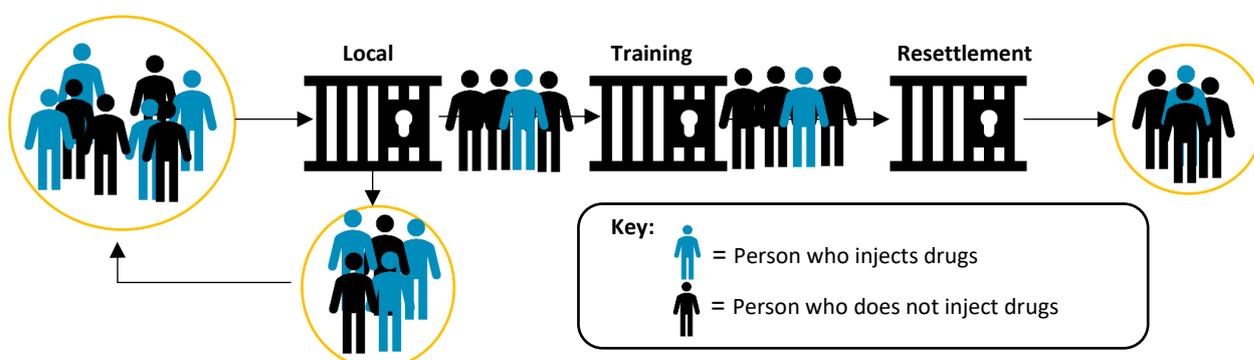


Figure 32. Visual representation of the hypothesised movement of people with a history of injecting drug use through the prison estate. As these individuals are likely to receive short sentences, it is proposed that they will usually cycle in and out of local prisons, rather than progressing to training and resettlement prisons.

Healthcare providers in most prisons also failed to offer every individual entering their prison a BBV test. Results support findings from Chapter 4, which suggest that offering testing during first reception could increase the proportion of new arrivals offered a test, because fewer individuals are lost to follow-up between reception and engagement (194,195).

Benefits of offering more people a test could include awareness raising and test normalisation (196). However, because none of the healthcare teams that offered BBV testing at first reception had the capacity to complete sample acquisition at that time, loss to follow-up still occurred between the offer and completion of the test. Whether offering a BBV test independently of sample acquisition represents a meaningful clinical interaction or is simply a convenient way for healthcare providers to meet NHSE offer targets, requires further consideration.

It was also noteworthy that healthcare teams within all prisons reported some form of additional testing taking place. Far from being a singular intervention upon entrance, data confirms (in line with PHE recommendations) that opt-out BBV testing has become multifaceted in most prisons, with healthcare teams and the Hepatitis C Trust working together to implement complementary micro-testing programmes for the general population (111,189). These methods of testing deserve evaluation in their own right, to help determine what configuration of activities facilitate the highest BBV test coverage within different types of prison (111).

Finally, data from London revealed a surprisingly low anti-HCV sample positivity (4.2%, 95% CI: 3.9-4.4%). This was lower than a recent study looking at opt-out BBV testing across West Midland prisons (anti-HCV = 9.3%) (189), as well as national sentinel surveillance estimates spanning 2013 (9.4%) to 2017 (8.0%) (45,48–50,197). It was also significantly lower than prevalence estimates reported in the Scottish (19%) (180,198), Australian (8-52%) (199), and US (16-41%) (200) penal systems, but was similar to a cross-sectional study carried out in the French prison estate (4.8%); although this was obtained from reviewing medical records rather than active testing (180,201).

Mirroring concerns expressed in Chapter 4, it remains unclear whether this value approximates the actual prevalence of anti-HCV amongst the London prison population, partially stems from data reporting errors, or is evidence of systematic omission of high-risk prisoners taking place under routine opt-out testing (78,202). Exploration of programme implementation and delivery, with the intention of explaining this lower than anticipated anti-HCV positivity, remains a critical objective of this evaluative research.

5.3.1 Data limitations

My assessment of the LBCSG data system highlighted several omissions in protocol that may have inhibited data comparability. In particular, there were no definitions provided by the LBCSG to the London healthcare teams for the requested data. There was also no standardised SystemOne algorithm, developed to extract data from across estate. This risked each healthcare team interpreting data fields differently and using different parameters to extract information.

In addition, the LBCSG anticipated that the data it was collecting would characterise the journey of a monthly cohort of newly incarcerated people along the pathway of care (see figure 33 for an illustration of the different testing variables). However, early into this analysis inconsistent values for the numerator and denominator were identified, resulting in monthly test offer and coverage proportions >100%.

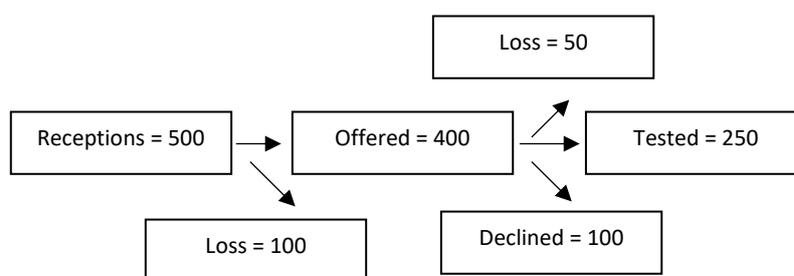


Figure 33. Example of monthly variables required to calculate offer rate, uptake, and programme coverage. Using these example figures, an offer rate of 80%, an uptake rate of 71%, and a programme coverage of 50% would be calculated. However, because there was no means of distinguishing between loss to follow-up and someone declining a test between the offer and sample completion using the London Steering Group data, uptake would be calculated at 63%.

These inconsistencies occurred for two reasons. First the LBCSG assumed that the SystemOne template for recording BBV testing would only be used when someone was tested whilst entering a prison. However, within the London prisons the template had actually become a method of recording any form of BBV testing, which occurred at any point during incarceration.

This meant that the same READ codes were being used for both opt-out testing upon entrance and repeat testing, with individuals able to appear as multiple “test offered” and “test completed” events, whilst only being recorded as a single reception (figure 34). Despite attempts to get healthcare providers to distinguish between reception-based and general population testing, this was difficult to do using SystemOne, and consequently not done consistently in the data reported to the LBCSG.

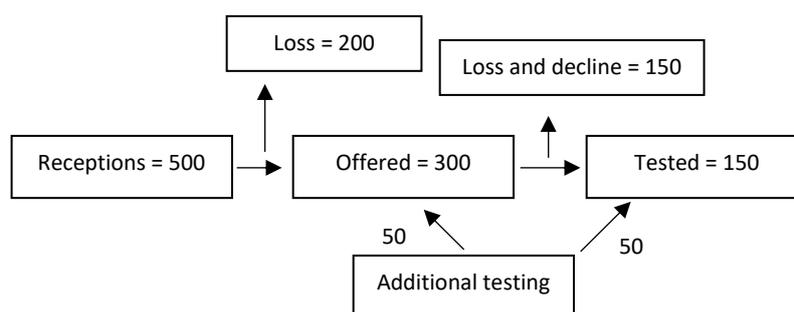


Figure 34. Example of additional testing and its impact on data interpretation. Without additional testing, offer rate = 60%, uptake = 50%, and coverage = 30%. With additional testing, offer rate = 70%, uptake = 57%, and coverage = 40%.

The second cause related to the way data were extracted. Healthcare providers extracted data based on the “event date”. This logged when a member of staff had recorded a READ code for an individual but did not link back to that individual’s date of incarceration. Because of this practice, and because healthcare teams in most London prisons engaged in periods of more intense testing activity, aggregate data became distorted as a result of roll-over between months (figure 35).

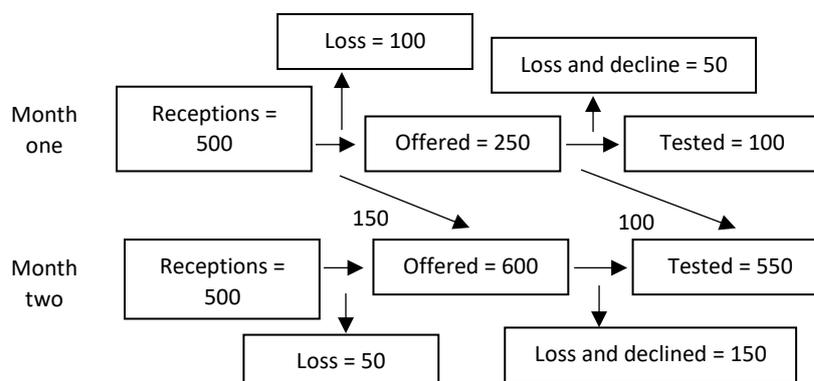


Figure 35. Example of roll-over between variables used to calculate offer rate, uptake, and programme coverage. Under this scenario, month one would record an offer rate of 50%, a test uptake rate of 40%, and a test coverage of 20%. For month two an offer rate of 120%, a test uptake rate of 91.7%, and a test coverage of 110% would be calculated.

When assessing test offer and coverage, the impact of these limitations was moderated by the reliable denominator (the number of new prison entrants was extracted by the prison service) and quarterly analysis. However, for test uptake, where both the numerator and denominator were affected by these limitations, data interpretation became even more challenging.

In addition, interpretation of test acceptability was further complicated by the practice of offering testing independent of sample acquisition, which occurred formally within Prison 3

and 4 where testing was offered on the first night. Representatives from other prisons also reported separating these two interactions when time was limited or staff ran-out of test equipment. Consequently, attrition through release or transfer could occur between the offer and test, meaning that the difference between these two metrics did not necessarily reflect the acceptability of BBV testing.

Finally, the assessment of BBV positivity was based on the number of positive samples, not positive individuals. In addition, there was no means of distinguishing between new and previously diagnosed infection, meaning the same individuals could appear multiple times within the same prison's metrics. The LBCSG was therefore unable to determine with any certainty, whether the London Prisons Project was identifying new cases of infection, or if positive samples came from repeat testing of transfers and recidivists, who were already aware of their diagnosis.

There is therefore an evident need for individualised data on BBV testing within prisons, to facilitate in-depth quantitative analyses of programme performance (189). With access to such data, evaluators would be able to more accurately monitor testing outcomes and case-detection, as well as assess whether certain social and demographic groups engage or avoid testing. Without data that allows for accurate monitoring and evaluation, commissioners in London risk prioritising supportive resources, designed to improve testing, based on a misguided interpretation of programme performance.

5.3.2 Conclusion

The London region did not achieve the $\geq 50\%$ NHSE BBV test coverage target during a two-year period following programme implementation. Results suggest that local prisons may particularly struggle to achieve a high test coverage. However, the volume of tests identified as positive for a BBV infection by Prison 1, emphasises the importance of enhancing performance in these settings (see figure 36 for a refined programme theory, produced using results from this chapter).

This analysis also highlighted issues with the way data were both recorded and extracted. Addressing data limitations should be a critical objective for both the LBCSG and the wider national NHSE team. If HCV elimination is to be achieved by 2025, commissioners, clinicians, and public health professionals require access to accurate and individualised patient data, from services operating within high-risk settings like prisons.

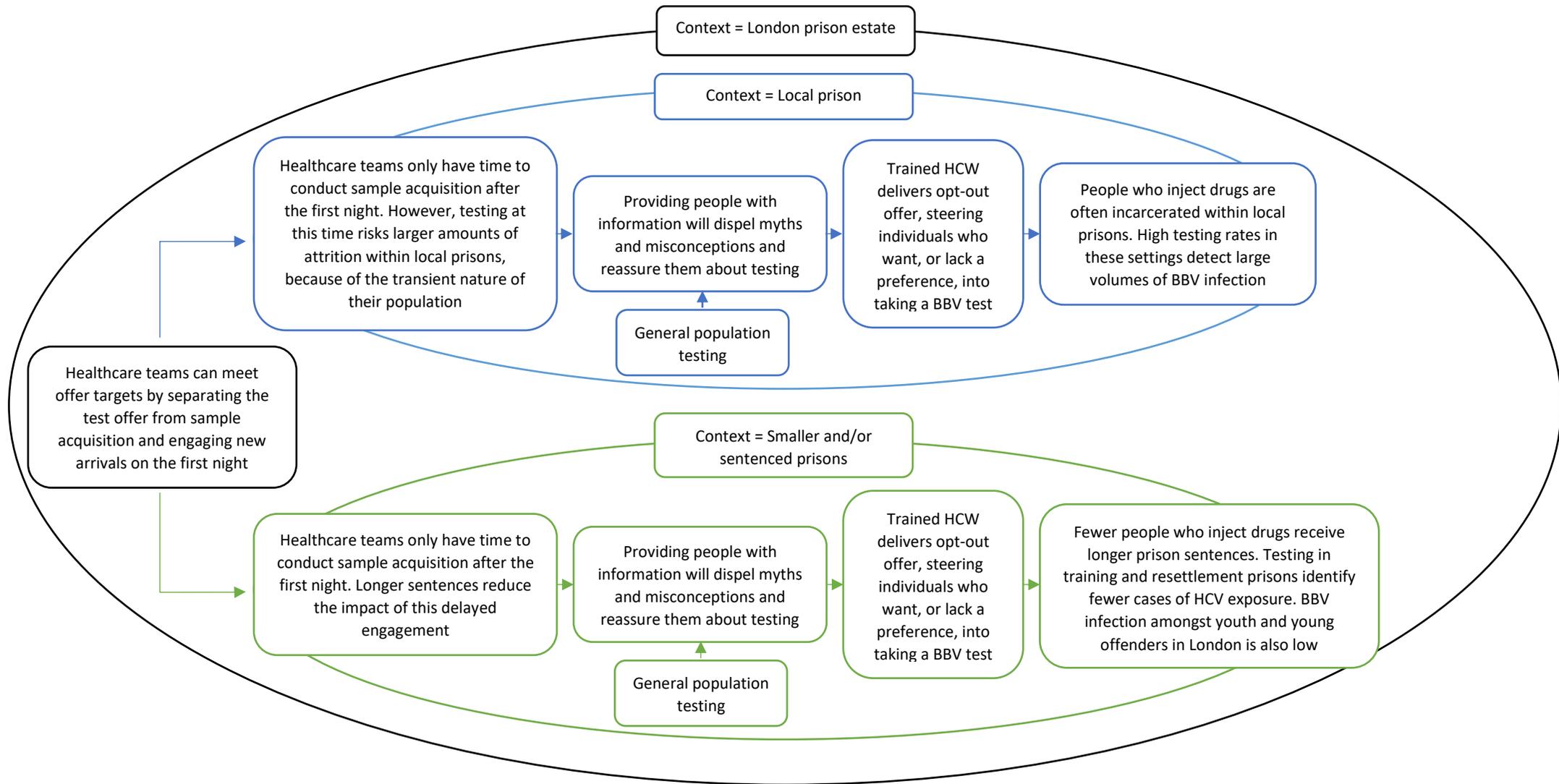


Figure 36. Refined programme theory for the opt-out blood-borne virus test programme, following analysis of testing outcomes from eight Greater London prisons (HCW = healthcare worker; BBV = blood-borne virus; HCV = hepatitis C).

5.4 Data quality improvements: “The London prisons pathway project”

Outcome orientated evaluative activities were inhibited by the nature and quality of the quantitative data available. In both Chapters 4 and 5, limitations with the data extracted from London prisons meant that I was restricted to using descriptive statistics to roughly characterise programme performance. These limitations stemmed from three issues: variable data entry practices, difficulties in extracting accurate and individualised information from SystemOne, and the lack of standardised extraction algorithms or reporting definitions used.

In addition, there were limited options for accessing other forms of data to assess programme performance. Data on BBV infection, diagnosis, and treatment within prisons can come from a variety of sources: including HJIPs (although these are also aggregate and suffer from data quality issues), PHE Sentinel Surveillance, the Genitourinary Medicine Clinic Activity Dataset, the Survey of Prevalent HIV Infections Diagnosed, the Hepatitis C patient registry, and ODN databases (203). However, some databases only cover one BBV infection, others are designed for surveillance (not monitoring and evaluation), and none cover the entirety of prison BBV care pathways (figure 37).

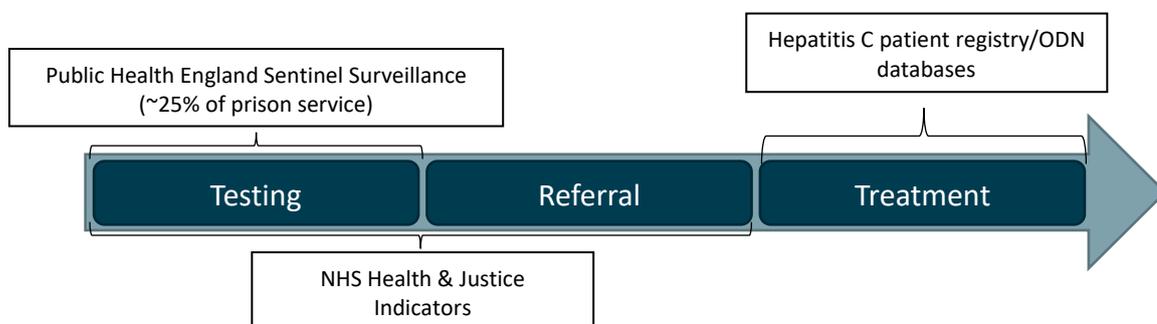


Figure 37. Data sources for viral hepatitis C testing and treatment services within English prisons.

Results from the evaluation strongly suggest that a database, spanning the entirety of prison pathways and containing individualised patient data, is required to progress the objectives of viral management and elimination (3,4,17). Without the ability to accurately analyse the engagement of individuals with healthcare services for BBV infection within prison, evaluative and commissioning activities are stunted. Furthermore, the dearth of reliable data for service improvement may risk contradicting principles of care equivalency (1).

With that in mind, I began working with NHSE to develop a system for extracting individualised patient data from all eight Greater London prisons. To begin, I developed a

database on Excel (Microsoft Office 2016) that could host information from different stages of the testing and treatment pathways. This database was then refined by NHSE, ready for piloting (see appendix B for details of this database).

Representatives from North East London Commissioning Support worked with data analysts from Prison 1 to develop a series of SystmOne algorithms, which could be used to extract data suitable for tracking an individual's engagement with services. The intention was that data on testing, assessment, and referral would be acquired directly from prison healthcare teams using these algorithms. Data on treatment delivery and outcomes were initially intended to come from local ODNs. However, with the development of the Hepatitis C Patient Registry, it was subsequently decided that linking this with our prison testing and referral database should also be attempted (203).

With a data extraction system agreed and in place, the process was then trialled by Prison 1's healthcare administrative team. During three "co-development and problem-solving" meetings between myself, Prison 1 staff, NHSE commissioners, and PHE advisers, the following resource requirements were identified:

- The creation of additional READ codes so that all requested data could be recorded in an easily extractable format on SystmOne;
- A data analyst within each prison, with the time to extract information and then input it into the database;
- A written guide, containing definitions for the requested data and details of the standardised method of data extraction from SystmOne.

Because these proposals had costing implications outside of the LBCSG budget, the database was shared with a national team within NHSE for consideration. It is anticipated that some version of this data system will be implemented within London in the coming years, helping to guide the management of the London Prisons Project and progress the ambition of HCV elimination within the region (203). It is also hoped that if a cost-effective model can be developed in London, that this will be used to help inform the development of a similar national database, containing a representative sample of different types of prison from across the different regions of England.

5.5 Chapter summary

In this chapter I focused on addressing question one of the evaluative research project. To do this, I amalgamated and analysed data collected by the LBCSG, providing regular reports to the group in the process. Key findings from this analysis included:

- The London region did not achieve NHSE targets for the opt-out programme. Large local prisons struggled to offer and test a high proportion of new prisoners. However, local prisons also contained the highest concentration of HCV infected individuals, making successful BBV testing in these settings crucial for viral elimination.
- Data limitations inhibited an accurate or detailed assessment of programme performance. It is critically important that data improvements are made, to facilitate appropriate commissioning as well as future research. The lower than anticipated anti-HCV positivity across the London prison cluster also requires further exploration, using other forms and sources of data.
- I co-developed a novel data system; whereby individualised patient data could be extracted and input into a London wide database. Currently under consideration by NHSE, such a database would be a valuable resource for informing the elimination of HCV, the management of HBV infection, and the continued viral control of HIV across London.

Chapter 6: Rapid-realist review

6.0 Introduction

Analysing BBV test outcomes from the London Prisons Project revealed low performance within several local prisons and fluctuating performance across the estate (see Chapter 5). However, given limitations with the available quantitative data, I needed to find an alternative means of developing explanations for the variation in outcomes observed (100).

Use of qualitative data to explore programme implementation and function was a logical next step, but faced delays as a result of the ethical review processes associated with primary prison research (204). I therefore began the development of an explanatory framework to understand the outcomes seen in London, by conducting a review of the literature.

6.1 Method

By appraising research projects that utilised published and unpublished literature to develop a realist explanatory framework, two suitable methods were identified: realist synthesis and rapid-realist review (RRR) (205,206). Both approaches provide guidance on developing realist theory, to explain how a programme works across different contexts (205,206). However, realist synthesis is an expansive, and consequently resource intensive, method. RRRs therefore emerged as an alternative approach, suited to small bodies of literature or as a single step in a multi-phase project (206–208).

Given that this review formed one component of my research, and acted a pre-cursor to the qualitative data generation (see Chapter 7), I considered a RRR to be the more appropriate option (206). This approach was first outlined by Saul *et al.* (2013), and places emphasis on the use of stakeholders in review conduct, to help streamline the process and ensure outputs are useable for policy (206). Key stages include (206):

1. Clarifying project scope (usually with knowledge users);
2. Development of specific research questions (usually with stakeholder input);
3. Development of a purpose statement;
4. Development of search terms;
5. Identification of articles (often by getting stakeholders to send key articles first);
6. Quality review (usually based on contributing evidence) (205);
7. Data extraction;
8. Validation of findings with content experts;
9. Synthesis in a final report and dissemination of results.

Although these components are similar to a traditional systematic review, the process of searching, quality review, and data extraction is iterative (206). I broadly followed the steps outlined by Saul *et al.* (2013), whilst also using guidance from the “Realist and Meta-narrative Evidence Syntheses: Evolving Standards” (RAMESES) group to inform aspects of the study design (139,209,210). In addition, I registered the review on PROSPERO, to ensure methodological transparency (ref: CRD42017068342).

6.1.1 Review process

I began the review by securing support from the LBCSG (206). In consultation with LBCSG stakeholders, I decided to focus on reception-based opt-out BBV testing (not additional testing activities) and specifically on two outcomes of public health interest relevant for HCV elimination: the proportion of new arrivals offered a test and the proportion of people that accept a test for BBV infection (78,79,95).

To do this, I needed to develop a provisional programme theory focused on these two outcomes (111,206). Although I had developed and refined a programme theory for opt-out testing during the pilot evaluation (Chapter 4) and outcome assessment (Chapter 5), this was broad and not grounded in formal behaviour change theory (100,211,212). I therefore wanted to take advantage of the potential behaviour change theories available in the literature, to reunite opt-out testing with its theoretical underpinnings during provisional programme theory development (211).

Using empirical evidence from the literature, I then intended to challenge assumptions inherent within the LBCSG’s design and by doing so, develop recommendations that could help prison healthcare teams improve performance (113). Through collaboration with the LBCSG, a series of review questions were developed to guide this process (206):

1. How is opt-out BBV testing thought to work to increase test offer and uptake?
2. How might the physical and social context of different prisons influence programme outcomes?
3. What could be done to improve the performance of an opt-out test programme?

To answer these questions, a three phased literature search was carried out to construct (phase one), refine (phase two), and reinforce (phase three) a programme theory for opt-out BBV testing (205,206). As the search and analysis process varied between each phase, it is described sequentially. All search results were handled using MENDEL (Elsevier, 2019) bibliographic software.

6.1.1.1 Phase one

In phase one I developed a provisional programme theory for opt-out testing upon prison entrance (205,206). To do this, the LBCSG supplied me with documents used in the development of the English opt-out test programme and the London Prisons Project (206). Because this guidance lacked information on what “opt-out” meant, or how it worked, documents sent by the LBCSG were supplemented with literature identified via a series of unstructured searches, carried out on Google Scholar and MEDLINE, for previous programmes that used opt-out to enhance uptake.

By synthesising this literature, along with findings from the pilot (Chapter 4) and quantitative analysis (Chapter 5), I constructed a provisional explanatory model for the numbers of people offered a test and tested for a BBV infection upon reception at a prison. Phase one articles did not undergo a formal process of eligibility review or quality appraisal, as they were only used to develop the framework that structured subsequent review iterations (205).

6.1.1.2 Phase two

With the provisional programme theory developed, I then conducted a systematic search for empirical data to refine that theory. A structured search algorithm was developed for bibliographic databases and piloted in MEDLINE, in consultation with a database expert based at the Royal Free London NHS Foundation Trust’s Medical Library.

Search terms focused on opt-out testing within a prison context and were informed by Rumble's *et al.* (2015) search strategy for a systematic review of routine test methods for BBVs in prison (table 12) (54). However, the search did not specify testing for HCV, HBV, or HIV, meaning articles discussing cousin interventions, which nonetheless could be useful for theory refinement, were identified (205).

Table 12. Population, location, exposure table, summarising search terms used during the systematic search of online databases. Word root searching (denoted using the symbol “*”) was used to find variant forms of a single word.

Population	Location	Exposure
<ul style="list-style-type: none"> • Prisoner* • Offender* • Convict* • Detainee* • Inmate* • Incarcerated 	<ul style="list-style-type: none"> • Prison* • Gaol* • Jail* • Penal institution* • Correction* or penal or remand* or detention or custody) adj2 (centre or department or facility* or system*) • Penitent* 	<ul style="list-style-type: none"> • Mass screen* • (Mandatory or systematic or routine or compulsory or obligatory) adj (test* or screen* or diagnos* or identif* or assess) • Opt-out • Opt* out

MEDLINE, PsycInfo, EMBASE, Scopus, CINAHL+, and ASSIA were all searched using the systematic algorithm, amended as required for each database, in June 2017 (see appendix C for example search strategy). A search of five grey literature databases (ProQuest Dissertations and Theses Global, DART-Europe-E-Theses Portal, Open Grey, Google/scholar and “.GOV”) was also completed in June 2017 (139).

Assessment

Search results from phase two underwent a formal process of eligibility assessment and quality appraisal, assisted by four members of the Royal Free research team that had been involved in evaluating the pilot HCV pathway within Prison 2 (Chapter 4). Each stage was completed by me and one of these researchers independently. Disagreements were resolved in consultation with the other researcher.

To begin, citations had titles and abstracts reviewed against the following criteria: “Does the citation indicate a prison context?”, “Does the citation indicate testing for a physical disease?”, and “Does the citation discuss physical disease in a population not an individual?” Any citations that failed to answer “yes” to these questions were excluded. The full-text was then downloaded and assessed against three dimensions of relevance: “Provides information related to mechanisms stimulated by opt-out testing”, “Provides information on outcomes of opt-out testing”, “Provides contextual information related to opt-out testing within prisons”.

Articles that did not provide information on one of these dimensions were excluded. A traffic light system was then used to highlight how many dimensions were covered by each article (red articles covered one dimension, orange two, and green three). Each reviewer also assigned articles a score from 1-10, to indicate how useful they believed it would be in the analysis. An average of the two reviewers’ scores was taken and assigned alongside the colour, allowing for some prioritisation of articles.

To assess quality, the Mixed Methods Quality Appraisal Tool (213) was used for primary research and the Critical Appraisal Skills Programme: Systematic Review Checklist for systematic reviews (214). The unit of analysis was the contributing evidence, although an overall quality score was assigned to each included study (205). If a piece of information within an article was deemed low quality, it was excluded, but other pieces of data of acceptable quality were retained from the article (131,205).

As grey literature and narrative literature review articles did not undergo quality assessment, data on context and mechanism were included if it was supported by, or consistent with, data from other empirical articles, but quantitative outcomes were not used.

Programme theory development

Data from articles were annotated and coded as either context, mechanism, or outcome and extracted using a standardised template (appendix C). This evidence was then grouped into a realist matrix, allowing for theming across the matrix (215). Data were synthesised with the provisional programme theory developed during phase one, via a process of adjudication and amalgamation, producing a refined list of programme theories (205). These were discussed in data meetings and validated in consultation with the LBCSG (206). I also observed staff training and opt-out testing conducted within two London prisons, further helping validate CMOcs.

6.1.1.3 Phase three

Following phase two, a refined programme theory had begun to take shape. However, to further reinforce some of the CMOcs developed, I undertook a series of purposive unstructured searches on MEDLINE and Google Scholar (139,216).

Searches focused on acquiring qualitative and theoretical articles, discussing testing for BBVs within prison and non-prison settings. This was not an exhaustive process, but aimed to purposefully draw together a diverse range of literature, which was then used to reinforce the theoretical “backbone” of the refined programme theory (216).

In addition, phase three articles did not undergo a formal process of eligibility assessment, but were assessed for quality using the Mixed Methods Quality Appraisal Tool (213). They did not contribute evidence to outcomes, but were included as they reinforced aspects of context and mechanism (216).

6.2 Results

The LBCSG supplied me with 26 documents and 18 articles were identified via unstructured searching (figure 38). A further 3435 citations were identified via database searching and 663 through grey literature searching. After duplicates were removed, 3381 titles and abstracts were screened, and 457 articles remained for full-text review.

11 documents from the LBCSG and 9 articles from the unstructured search were used in programme theory development (appendix C). 29 empirical articles were used in programme theory refinement (table 13). These were supplemented with a further 11 articles identified through purposive unstructured searching (appendix C).

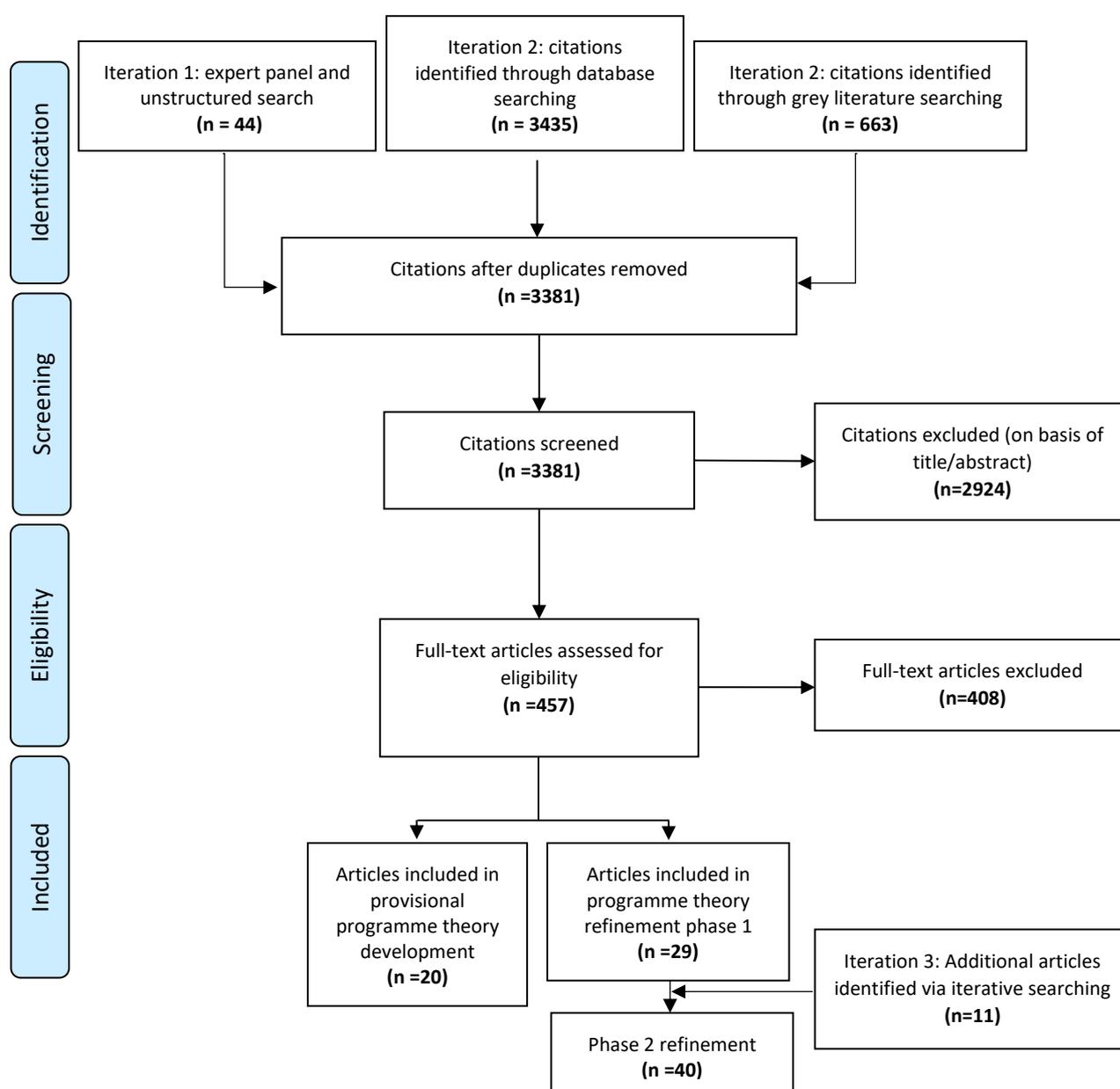


Figure 38. Flow diagram detailing the search results from the rapid-realist review. Diagram design guided by recommendations made by the PRISMA Group (2009).

Table 13. Characteristics of phase two studies, summarising first author/year, country, prison, disease, study design, method of data collection, aims of the research, relevance, and quality assessment score (unacceptable: *, acceptable: **, good: ***, excellent: ****). HIV = human immunodeficiency virus; HCV = hepatitis C; HBV = hepatitis B; STI = sexually transmitted infection.

<i>First author, year</i>	<i>Country</i>	<i>Prison</i>	<i>Disease</i>	<i>Study design</i>	<i>Data collection</i>	<i>Aims</i>	<i>Dimensions of relevance</i>	<i>Strength of relevance</i>	<i>Quality score</i>
<i>Kavasery, 2009 (195)</i>	U.S.	Urban men’s jail – New Haven Connecticut	HIV	Non-randomised control trial	Quantitative data capture	Determine the optimal timing of opt-out HIV testing for newly incarcerated jail detainees	Red Orange Green	9	****
<i>Beckwith, 2011 (229)</i>	U.S.	Rhode Island Jail	HIV	Mixed methods: sequential explanatory	Routine data and interviews/FGD	Implement and evaluate rapid opt-out HIV testing within Rhode Island Jail	Red Orange Green	8	****
<i>Public Health England, 2015 (79)</i>	U.K.	Mixture of phase 1 “pathfinder” prisons	HIV, HCV, and HBV	Project evaluation	Questionnaire	Evaluate opt-out testing for blood borne viruses, implemented throughout pilot English prisons	Red Orange	4	N/A
<i>Elkington, 2016 (245)</i>	U.S.	Mixed	HIV	Literature review	Systematic search	To review the effectiveness of HIV testing and linkage programmes and review barriers and facilitators to these programmes in the correctional setting	Red Orange	4	N/A
<i>Rosen, 2016 (239)</i>	U.S.	North Carolina	HIV	Before and after study	Routine data	Assess the impact of routine opt-out testing in terms of case detection	Red	5	****
<i>Rice, 2011 (230)</i>	U.S.	Wayne County Jail	HIV	Thesis	Multiple	Design, implement, and evaluate a jail-based HIV testing programme	Red Orange Green	10	N/A
<i>Spaulding, 2015 (226)</i>	U.S.	Fulton County Jail	HIV	Mixed methods: sequential explanatory	Routine data and questionnaire	To establish and evaluate a rapid opt-out HIV testing programme, led by the jail-based nursing team	Red Orange Green	6	***
<i>Lucas, 2016 (227)</i>	U.S.	Eight prison reception centres (California)	HIV	Quantitative descriptive evaluation	Routine data	Conduct an evaluation of routine HIV services, implemented throughout California	Red	4	***
<i>Rosen, 2007 (249)</i>	U.S.	8 intake prisons in North Carolina	HIV	Thesis	Routine data	Evaluation of a large southern state opt-out HIV testing programme	Red Orange Green	5	N/A
<i>Schoenbachler, 2016 (242)</i>	U.S.	Durham County Jail, Florence Detention, Orangeburg Jail, Marion Jail and Darlington Jail	HCV	Quantitative descriptive evaluation	Routine data	Evaluate an HCV testing and linkage-to-care post release programme among detainees of small-to-medium sized jails	Red Orange	5	**
<i>Grinstead, 2003 (250)</i>	U.S.	Mixed	HIV, HCV, HBV, and other STIs	Qualitative exploration	Interviews	Explore providers’ experiences regarding HIV, hepatitis, and other sexually transmitted infection testing services within prison	Red Orange	7	***

Table 13. Continued.

<i>Centres for Disease Control, 2011 (269)</i>	U.S.	Washington State Department of Corrections (12 male facilities)	HIV	Quantitative descriptive evaluation	Routine data	To assess the rate of testing under three different strategies: on-request, routine opt-in, and routine opt-out	Red Orange Green	5	***
<i>Centres for Disease Control, 2009 (196)</i>	U.S.	N/A	HIV	Opt-out testing programme guidance	N/A	To guide the implementation of opt-out HIV testing in the correctional setting, by highlighting suggested components and tenants of such an approach	Red Orange	6	N/A
<i>Peter, 2009 (231)</i>	U.S.	Orleans Parish Prison, Jefferson Parish Correctional Centre	HIV	Thesis	Routine data	Look at the effectiveness of opt-out and opt-in approaches to HIV testing in jail populations	Red Orange	7	N/A
<i>Muessig, 2016 (243)</i>	U.S.	North Carolina State Prison System	HIV	Qualitative	Interviews – 76 men and women	Exploring issues of HIV stigma within an opt-out programme	Red Orange Green	10	***
<i>Walker, 2005 (241)</i>	U.S.	N/A	HIV	Letter(s)	N/A	Discuss the ethical concerns surrounding routine opt-out HIV testing within the prison setting	Red	4	N/A
<i>Beckwith, 2010 (253)</i>	U.S.	N/A	HIV	Literature review	Search	Provide a review of the current state of delivering HIV testing, prevention, treatment and transition services to incarcerated populations	Red Orange	4	N/A
<i>Rosen, 2015 (235)</i>	U.S.	North Carolina State Prison System	HIV	Quantitative cross-sectional survey	Quantitative survey and routine data	To explore prisoners understanding of the voluntary nature of routine opt-out testing	Red Orange	8	***
<i>Grodensky, 2016 (234)</i>	U.S.	North Carolina Prison System	HIV	Quantitative cross-sectional survey	Quantitative survey and routine data	Estimate the proportion of people unaware of being tested and the proportion of people tested who did not want a test under an opt-out system	Red Orange Green	9	***
<i>Cole, 2014 (232)</i>	U.S.	Cook County Jail	<i>Chlamydia trachomatis</i> & <i>Neisseria gonorrhoeae</i>	Retrospective analysis	Routine data	Evaluate the impact of opt-out testing on rates of testing and diagnosis of infection among incarcerated women, assess the proportion of infections successfully treated, and evaluate factors associated with receipt of treatment	Red Orange Green	8	***
<i>Public Health England, 2016 (254)</i>	U.K.	Local London prison	HIV, HBV, and HCV	Pilot evaluation	Routine data	Report results from provisional data analysis for the pilot blood-borne virus care pathway trialled within a local London prison	Red Orange	5	N/A
<i>Jack, 2016 (238)</i>	U.K.	East Midlands Category B male prison	HCV	Qualitative phenomenology	Interviews (prison officers)	To explore the views of prison officers about prisoners being tested and treated for HCV	Red Orange	6	****

Table 13. Continued.

<i>Beckwith, 2012</i> (240)	U.S.	Baltimore Department of Corrections, Philadelphia Prison System, District of Columbia Department of Corrections	HIV	Quantitative descriptive evaluation	Routine data	To assess the feasibility of implementing large scale rapid and routine opt-out testing programmes for HIV in large urban jails	Red Orange Green	6	****
<i>Centres for Disease Control, 2013</i> (225)	U.S.	Fulton County Jail	HIV	Quantitative descriptive evaluation	Routine Data	Evaluate a routine opt-out testing programme in a large county jail	Red Orange Green	5	***
<i>Centre for Disease Control, 2010</i> (268)	U.S.	Rhode Island Jail	HIV	Quantitative descriptive evaluation	Routine Data	Review of Rhode Island Jail's testing records	Red Orange	4	***
<i>Kavasery, 2009</i> (194)	U.S.	York Correctional Institution, Connecticut	HIV	Non-randomised control trial	Quantitative data capture	Evaluate the optimal time to conduct routine opt-out HIV testing of newly incarcerated jail inmates in a manner that maximises the number of individuals capable of consenting and willing to be tested	Red Orange Green	9	****
<i>Newlan, 2016</i> (228)	Indonesia	Banceuy Prison	HIV, HBV, and HCV	Natural experiment	Routine data	To compare the efficacy of two different testing strategies (routine or targeted)	Red Orange Green	5	**
<i>Rumble, 2015</i> (54)	Mixed	Mixed	HIV, HBV, and HCV	Systematic review	Systematic literature search	Describe components of routine HIV, HBV, and HCV testing policies in prisons and quantify testing acceptance, coverage, result notification, and diagnosis	Red Orange Green	7	****
<i>Gagnon, 2012</i> (247)	N/A	N/A	HIV	Literature review	Search	Provide a sociological critique of mandatory testing in light of other testing approaches, including opt-out	Red Orange	7	N/A

6.2.1 Provisional programme theory – how was opt-out testing thought to work?

Using data from the phase one search, a provisional programme theory was developed (figure 39 – page 111). This explained how components of opt-out testing upon reception were thought to work, to maximise the number of newly incarcerated individuals offered a test and tested for BBV infection.

PHE and LBCSG guidance primarily focused on the timing of the test offer, as a means of increasing the proportion of new arrivals offered a test (86,94,97). The instruction that healthcare teams should engage new arrivals within 72 hours, therefore formed the primary resource through which the programme was intended to maximise engagement (figure 39) (79).

For test uptake, guidance on the pre-test discussion differed between sources. PHE recommended an interactive conversation, where capacity to consent was checked, and that covered transmission risk, advantages of testing, how results would be relayed, what happens in the event of a positive result, what support services were available, and harm reduction options (84). In contrast, training provided by GILEAD in London conceptualised the pre-test discussion as a short priming activity, designed to check capacity to consent and briefly explain advantages of testing (217).

Nevertheless, both approaches were designed to ensure new arrivals were aware of the severity of infection, were able to reflect on their personal susceptibility, and that they perceived testing to be an advantageous action (79,84,217). In this way, the pre-test discussion was designed to motivate new arrivals to test (218). In addition, the use of DBST was anticipated to be more acceptable than venepuncture, as it involved less physical discomfort and was potentially less stigmatising for those that had collapsed veins through injecting drugs (figure 39) (219).

However, it was the way testing was framed that represented the central innovation of the programme. The unstructured searches carried out during phase one, identified literature that suggested the “Default Effect”, a component of behavioural economic “Nudge Theory”, underpinned opt-out (139,215). The Default Effect suggests that for any choice or action, there is a tendency for individuals to stick with the default option (220). By aligning the default option of a testing programme with the public health objective (i.e. newly incarcerated people are tested), opt-out was hypothesised to encourage test uptake in a variety of ways (220–222):

1. **Switching cost:** Individuals incur a cost (e.g. having to justify decision or fill out a form) when opting-out of testing. If this cost exceeds the benefit of opting out, then it is irrational for the individual to do so (223).
2. **Loss aversion:** Individuals tend to weight losses more heavily against equivalent gains. By making testing the default option, loss of benefits provided by testing are weighted more heavily against potential gains of not testing (88).
3. **Cognitive effort:** Making an active decision requires cognitive effort. By making testing the default option, opt-out testing exploits an individual's bias not to expend this effort, encouraging those who do not exhibit a strong preference to test through passive decision making (223).
4. **Recommendation:** Making testing the default option can act as an implicit or inferred recommendation to test (88,220).

In this way, the programme was designed to engage people early, motivate them to want to test for BBV infection, and exploit quirks of human behaviour to steer those not exhibiting a strong preference into testing anyway (figure 39) (79,223). However, offering testing in an opt-out manner is not the norm for HCWs. The success of the "opt-out" aspect of the programme therefore hinged on the fact that HCWs were trained and able to deliver an opt-out test offer in practice (224).

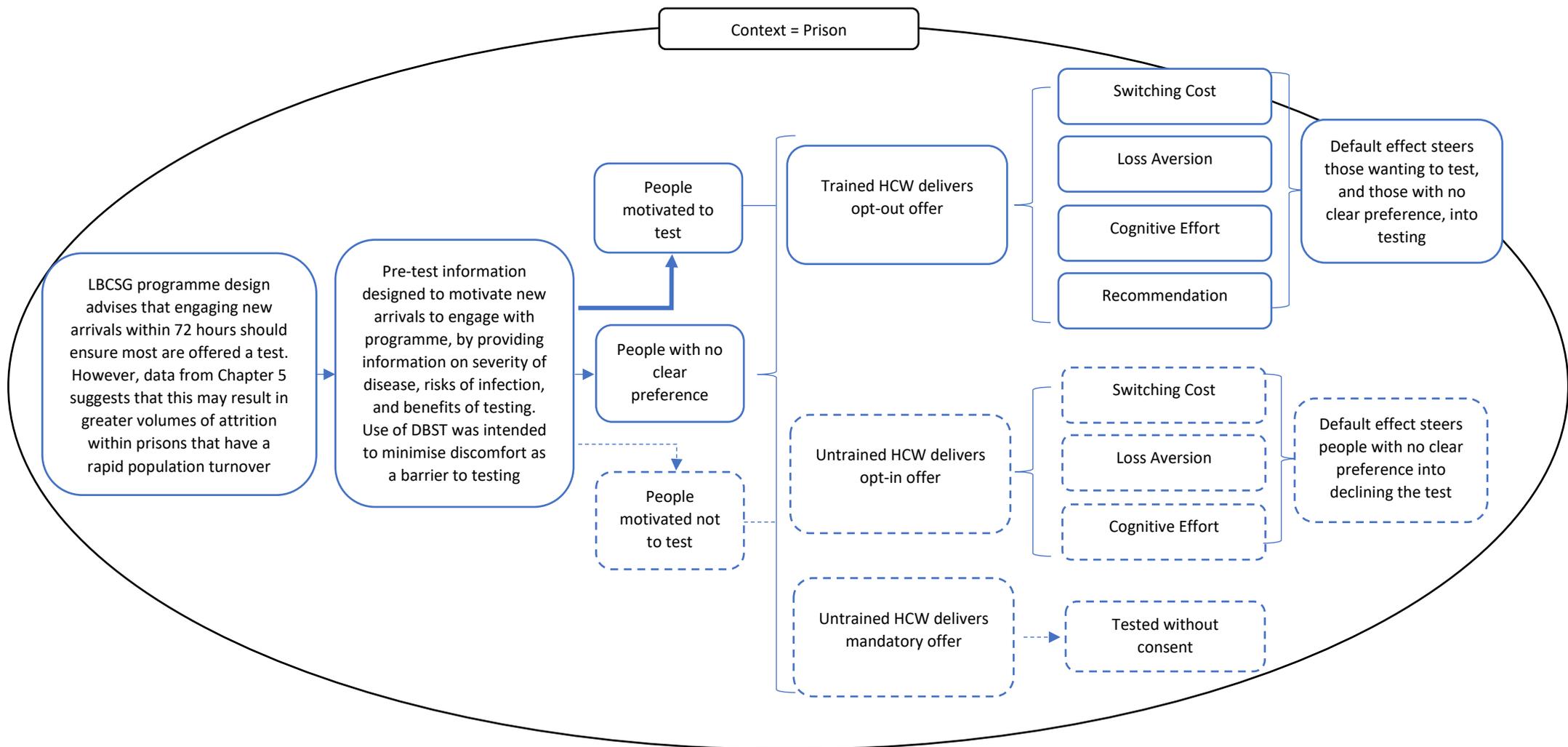


Figure 39. Provisional programme theory for opt-out testing on reception, developed using articles acquired during phase one and considering results from earlier evaluative activities (LBCSG = London Blood-Borne Virus Core Steering Group; HCW = healthcare worker; DBST = dried blood spot test). The thick arrow signifies the intended programme process, whilst the dotted arrows and boxes signify undesirable processes.

6.2.2 Refined programme theory – how might opt-out testing work in practice?

6 Mi-Mi CMOcs for the proportion offered testing and 7 for test uptake are presented in text. Other realist theories developed during the RRR are tabulated at the end of this chapter (see tables 14-20 on pages 126-131). Under each CMOc background information is provided. The configuration is then presented in italics with components highlighted: C=context, MR=mechanism resource, MRE=mechanism reasoning response, and O=outcome.

Exemplifying data is also presented, providing access to empirical evidence that contributed to theory development and refinement. As reported in other realist reviews, this empirical evidence rarely presented a clear description of all three theoretical constituents, making abductive reasoning critical to ensure complete CMOc articulation.

6.2.2.1 Proportion offered testing

There was significant variation in the proportion offered BBV testing between different prison-based opt-out programmes, ranging from 13-100% (54,194,195,225–229). Failure to offer testing was an implementation issue, stemming from a combination of generative processes.

CMOc 1: delayed test offer

Mirroring results from Chapter 5, the timing of the test offer was a salient programme resource affecting the proportion of new arrivals offered a test (54,79,194–196,227,230–233). Seven studies reported offering opt-out testing during a first night health check (225,226,231,232,234,235). Seven others reported testing taking place anywhere between 3-14 days after first reception, often during a secondary health check (227,228,230,236–239). Delays often occurred because of a lack of time during the first night, or because the first night health check was reserved for dealing with urgent healthcare problems, which required immediate intervention (227,228,230,236–239).

CMOc: *In a prison that has a rapid population turn-over (C), a programme mandated delay in engaging intake with an opt-out test offer (MR) reduces the proportion of intake offered a test (O), as some individuals have already been released or transferred (MRE).*

This was exemplified during Beckwith's *et al.* (2012) evaluation of rapid-HIV testing within three urban jails. A 3-4 day delay in the Baltimore Department of Corrections resulted in a 13% test offer proportion, compared to 100% and 89% respectively in the Philadelphia Prison System and District of Columbia Department of Corrections, which offered testing during a first night health check (240).

CMOc 2: early testing and capacity to consent

The desirability of first night testing was tempered by the need to acquire informed consent. This was primarily a consideration for those prisons receiving newly incarcerated people from the community (194–196,225,233,241).

CMOc: *Newly incarcerated people may lack the capacity to consent to medical intervention on the first night (e.g. because they are undergoing withdrawal from a substance). As opt-out testing requires informed consent (C), healthcare workers that identify this lack of capacity (MR) and view it as important (MRE) will not offer testing (O).*

This issue was highlighted in two prospective control trials conducted in US jails, which found 10-11% of new intake were not medically competent to be tested immediately upon entrance, limiting the utility of first night testing (194,195). This dropped to 0-4% when testing took place 1-7 days after first reception (194,195).

CMOc 3: prioritisation of security and prison processes

One consideration, not covered by the provisional programme theory, was the role of prison officers in enabling healthcare services within prison. Prison officers were often required to unlock and escort prisoners to a location within the prison, in order for opt-out testing to take place (230–232,238,242). However, enabling the delivery of healthcare was not the priority of these staff.

CMOc: *Prison officers have a challenging role, particularly when budget cuts have strained the workforce (C). Opt-out testing often requires officers to collect prisoners, bring them to clinic, and supervise them (MR). Officers prioritise security and prison processes, over escorting and monitoring people at clinic (MRE), meaning prisoners frequently do not arrive, or are not allowed to be at the clinic, to be offered a test (O).*

This process of prioritisation was demonstrated in quotes from qualitative work with prison officers: “the issue with the health should be considered, if its’ not life threatening ... then security should be the priority” (238). This was also highlighted by HCWs: “I think you can’t get away from the fact that we’re entirely dependent on prison officers to deliver healthcare services ... We’ve lost, since I’ve been here, twenty five percent of prison officers ... Who would have thought that ‘do not attends’ are a massive problem in prison?” (94).

CMOc 4: provider capacity to run clinics

Strained working conditions meant healthcare teams occasionally lacked the capacity to deliver all services (79,196,217,233). HCWs naturally prioritised medical emergencies and managing other urgent conditions, rather than delivering opt-out testing.

CMOc: *Prisons are a demanding place to work (high burden of mental illness, physical morbidity, and regular medical emergencies) and budget deficits result in healthcare staff cuts (C). These working conditions reduce the capacity of staff (MR), forcing them to prioritise certain activities (MRE), such as dealing with urgent conditions or emergencies, resulting in testing clinics being delayed or cancelled and prisoners not offered a test (O).*

Insufficient staffing was the most frequently reported response to the question “*what other barriers did you encounter when trying to complete an HIV test ... at intake?*”, delivered to providers in a New York City Jail (233).

CMOc 5: refusal to attend clinic

Prisoner agency can act as a barrier to offering testing (54,230,231). However, the provisional programme theory developed during phase one (figure 39) did not consider the agency of prisoners to decide whether to engage with healthcare services and did not include resources designed to encourage them to attend the clinics where testing took place. This was similar to many programmes in the literature and, as a result, individuals refused to attend clinics, particularly when it clashed with another desirable activity.

CMOc: *When testing is conducted concurrently with other prison activities (C), attendance at clinic becomes an opportunity cost for prisoners (MR). If attending the clinic is a lower priority, relative to this other activity (MRE), the person will refuse to attend (O).*

Programme stakeholders in the literature reported prisoners refusing to come to clinics where testing was offered because they were sleeping, watching TV, playing sport, or attending the gym (54,230,231).

CMOc 6: rebooking prisoners

When prisoners failed to attend a clinic or when clinics were cancelled, HCWs were required to rapidly rebook them for testing, in order to minimise the chance of attrition through release or prison transfer (79,196,217,233). However, under the strained working conditions of many prisons, rebooking prisoners became delayed.

CMOc: *Budget deficits have led to healthcare staff cuts (C). Stretched staff that are required to re-book prisoners (MR), prioritise medical emergencies and other tasks that require immediate attention (MRE), delaying the test offer further (O). Overworked healthcare staff (C) may also forget to rebook people that have been missed (MRE).*

In high-turnover prison settings (C), a failure to rapidly rebook missed people (MR), reduces the proportion of new arrivals offered testing (O), as individuals may be released or transferred by the time they are rebooked (C).

6.2.2.2 Test uptake

The proportion of prisoners that accepted a test under an opt-out system varied from 22-98% (54,194,195,225–229). There was a notable lack of switching costs implemented by programmes in the literature, with most simply requiring people to verbally opt-out (229,234,235,240). Several costs and gains associated with opt-out BBV testing within a prison context were also identified. These were activated and modified depending on the presence of certain programme resources.

CMOc 1: confidentiality and stigma

Confidentiality was a key resource for opt-out BBV testing, as the enclosed environment of a prison amplifies fears about infectious diseases amongst prisoners and staff (238,243,244).

CMOc: *People known, or suspected to have, a BBV infection are often stigmatised within the prison environment (C). Maintenance of confidentiality (MR) is therefore crucial, so that people feel safe (MRE) to share personal information (O). If somebody distrusts prison healthcare's ability to maintain confidentiality (MR), they may fear stigma as a result of engaging with testing, or in the event of a positive result (MRE), encouraging opt-out (O).*

Officers often view prisoners with an infection as a personal risk and may attempt to elicit confidential information from healthcare staff (238,244). The close contact between staff and prisoners also means information can be spread, both within and between staff and prisoner groups: “Would I tell somebody else, a close friend, if I knew they were in contact? Possibly yeah?” (prison officer) (238). Breaches in auditory and visual confidentiality can also occur due to the confined environment, security requirements, and the use of prisoner “workers” for the maintenance of the prison environment (227,233,238,243–247).

CMOc 2: coping with a positive diagnosis

Incarceration is stressful and the potential diagnosis of an infectious disease, often perceived as terminal, can be daunting (54,195,226,241,245,246,248–250).

CMOc: *Infection with a BBV can be a daunting prospect for many prisoners, who may hold misconceptions about prognosis (C). The provision of supportive information (e.g. treatment options, dispelling myths around prognosis, and details of available psychosocial support) (MR), reassures people about coping if they test positive for an infection (MRE), encouraging test uptake (O).*

However, failure to provide supportive information (MR) can leave prisoners feeling unable to cope with the perceived burden associated with a positive diagnosis (treatment, stigma, psychological distress, lifestyle changes) (MRE), encouraging opt-out (O).

This was highlighted in quotes from healthcare staff: “Some clients will refuse to take the test out of fear of a positive result” (226) and prisoners: “Er, I don’t know really, [pause] er, I don’t really know, I mean, I think like I say, I think people are just frightened ye na. People are frightened to get the test ye na, thinking that it could be a killer not knowing what, not knowing what it actually is, what it actually does to you, I mean?” (246).

CMOc 3: fear of an invasive procedure

Sample acquisition can involve a degree of physical discomfort. In the literature, a fear of needles was frequently highlighted as a justification for people deciding to opt-out of testing when sample acquisition involved venepuncture (54,187,194,228,229,243,250–252).

CMOc: *A proportion of prisoner’s fear needles (C). When testing is conducted using a venous sample method (MR), people that are uncomfortable with the method of blood acquisition (MRE) may decide to opt-out (O) in order to avoid the anticipated discomfort.*

This was detailed in quotes from HCWs: “... I would say nine out of ten people say ‘I hate needles’ and tense up and freak out, and some people are really upset by it” and “They were definitely more compliant with it [oral testing]; they’re more willing to get it done as opposed to getting their blood drawn”(229). In line with the provisional programme theory, less invasive sample measures, such as DBST or oral testing, may therefore help to minimise physical discomfort as a barrier to testing.

CMOc 4: institutional recommendations and trust

Making testing the default option acts as an implicit recommendation to test. Positive encouragement from staff can also reinforce this message (230,231). However, success at encouraging testing hinges on trust having been established between the prisoner and the healthcare team.

CMOc: *Recommendations to test, in circumstances of trust (C), provide an institutional social pressure (MR) that encourages an individual to comply with the perceived positive action (MRE), encouraging test uptake (O). However, institutional distrust is also prevalent in prison (C). Institutional social pressure (MR) can be perceived as a coercive process of surveillance, triggering resistance from the individual (MRE) and encouraging opt-out (O) (245,250,253).*

CMOc 5: personal interpretation of risk

Educational information on BBVs was an important resource for opt-out programmes, as it helped individuals more accurately determine their risk of infection (54,173,228,233,234,243,246,249). Perceived susceptibility, in turn, provided the main

incentive to test, but could also interact with, and magnify, other costs associated with testing.

CMOc: *Misconceptions around BBVs are common amongst prisoners (C). Individuals that have been informed about modes of transmission and symptoms of the disease (MR) are empowered (MRE) to accurately interpret their risk of infection (O).*

For those that self-identify as “at risk” (C), testing can be an opportunity to confirm serostatus (MR), allowing the individual to either confront infection (MRE) or be reassured by a negative result (MRE), encouraging test uptake (O).

In the absence of supportive programme resources, prisoners that see themselves as “at risk”, or that fear stigmatisation, may feel unable to cope and instead opt-out (see CMOc 1 and 2 in this section) (54,226,246).

CMOc: *People that interpret themselves as low risk (C), but that face no other barriers to testing (MR), may still value reassurance (MRE), encouraging test uptake (O). However, those that face other barriers to test uptake (e.g. fears around confidentiality or discomfort with the test method) (MR), may view testing as an unnecessary burden (MRE) and opt-out (O).*

A range of articles reported issues with the delivery of pre-test information, with this stage often being truncated (54,194,195,231–233,241,246). In the absence of educational information, prisoners often interpreted themselves as low risk, due to a lack of symptoms, or because they had tested previously and were found to be negative (54,194,195,225,226,228,230,232,237).

CMOc 6: defaults and capacity to consent

Newly incarcerated people often suffer from substance withdrawal, have untreated mental health conditions, are physically exhausted, and emotionally overwhelmed (194–196). By making testing the default option and offering it soon after prison entrance, there was a risk that individuals may be tested without understanding what it is they are testing for (235,241).

CMOc: *Newly incarcerated people frequently lack capacity to provide informed consent (C). If the healthcare worker fails to identify this, or does not think it is important, and proceeds with an opt-out test offer (MR), these individuals may misunderstand what is taking place (MRE) or be unable to make an active decision to opt-out (MRE), instead appearing to comply with testing (O).*

Grodensky et al. (2015) found that out of 871 patients undergoing an opt-out HIV test, 103 were not aware of being tested, 94 did not want to be tested, and 30 were not aware they were tested and did not want a test.

CMOc 7: opt-out fidelity

The distinction between eliciting consent in an opt-in, opt-out, or mandatory manner is nuanced and difficult to operationalise in practice (79,234,235,254). The review highlighted variation in the delivery of an opt-out test, which may partially account for variation in test uptake.

CMOc (implementation): *If programme implementers misinterpret how to deliver an opt-out test (C), training and offer scripts provided to healthcare workers (MR) will encourage them to comply (MRE) with the delivery of either an opt-in (O) or mandatory (O) test offer.*

An opt-out test offer is not the norm (C). When healthcare workers have little training, and no standard script (MR), the meaning of an opt-out test may be misinterpreted (MRE) resulting in either opt-in (O) or mandatory (O) test offers. The way testing is offered when there is no standard script (MR), can also morph with each encounter, with rapport (C), situational distractions (C) and fatigue (C) all potentially influencing test delivery (O).

Literature suggested that framing testing as opt-in would steer those individuals that did not have a strong preference (usually those who do not consider themselves to be at risk and that face no strong disincentives to test), into declining rather than accepting a test (via the “Default Effect”). In contrast, framing testing as a mandatory action (intentionally or unintentionally) increases uptake, but contradicts principles of informed consent.

CMOc: *Prisoners that are motivated to either decline or accept a test are likely to do so, regardless of whether testing is framed as “opt-in” or “opt-out”. However, a proportion of prisoners may develop no strong preference about testing, despite attempts from healthcare staff to promote this action (C). When testing is framed as “opt-out” (MR), these individuals are steered by the “Default Effect” (MRE) into testing (O). When testing is framed as “opt-in” (MR), they are steered by the “Default Effect” (MRE) into declining the test (O).*

When testing is framed as mandatory (MR), individuals who want to test (C) or that have no strong preference (C) will comply with the instruction (MRE). Those that do not want to test (C) will have to decide whether to fight against a perceived compulsory protocol (MRE), or comply with the instruction (MRE), increasing test uptake overall (O).

A survey conducted by Rosen et al. (2015), as part of an opt-out testing programme that had a 95% test uptake (234,235), found that less than 40% of prisoners identified testing as voluntary (235). This was partly attributed to an ambiguous consent process and widespread failure of nurses to mention a person’s right to decline the test (235).

6.3 Discussion

I synthesised 60 implementation documents and research articles to develop realist theories, which can help to explain the variance in test offer and test uptake during opt-out testing within prison settings.

The unstructured search conducted during phase one identified a number of articles highlighting that the Default Effect underpins “opt-out” (220,223). It was notable that no documents supplied by the LBCSG during phase one, and none of the articles from phase two, mentioned Nudge Theory or the Default Effect as a consideration in the development, or subsequent evaluation, of opt-out BBV testing within carceral settings (223). It appears that these concepts, which underpin the intervention, have been widely forgotten, as “opt-out” is reproduced by stakeholders in different contexts (113).

However, several articles suggested that “normalisation” was behind increases in test uptake under an opt-out system (196). Far from being a primary opt-out mechanism (like, for example, switching costs), normalisation of either being offered or accepting a test is contingent on how testing is presented and/or programme outcomes (255). Normalisation was therefore considered a resource that could be implemented by individuals (e.g. if an HCW tells new arrivals that everyone normally accepts a test), or a contextual feature generated via a transformative (Mi-Ma) mechanism (e.g. a culture of accepting a BBV test upon prison entrance develops), using the realist model developed for this PhD (see tables 19 and 20 at end of this chapter for these theories) (110).

Nevertheless, the response of prisoners to the normalisation of BBV testing remains unclear. Norms can be descriptive (a visual or social cue to what is commonly done) or injunctive (what is considered the correct thing to do) (211,256), with literature suggesting that either (or both) may effect peoples’ decision to test. Further work is therefore required to unpick how norms become operationalised during opt-out BBV testing within prisons (196,218,256).

6.3.1 Numbers of new arrivals offered a test

Implementation factors were found to significantly limit the proportion of prison intake offered testing (225,226,231,232,234,235). Consistent with results from other aspects of this research, programmes that implement testing early were found to increase the proportion of people offered a test, but those prisons serving courts may be inhibited by greater volumes of newly incarcerated individuals unable to provide informed consent (194,195).

There was also limited data available to explore the implications of offering testing early on acceptability. The review identified two prospective control trials in US jails, designed to

address this question (194,195). Results from both suggested that HIV testing was less acceptable on the first night, compared to 24 hours after entrance. Authors explained this by suggesting that more people were distraught and tired upon entrance (194,195).

However, it was noteworthy that test results were provided within 20 minutes, meaning new arrivals faced the prospect of receiving an HIV diagnosis the night of their incarceration (194). In addition, despite being termed “opt-out testing”, the exemplar test offer actually gave new arrivals an active choice to opt-in (194). It is therefore possible that these two programme resources (receiving results on the first night and having to accept, rather than decline, the test), encouraged tired new arrivals to refuse testing.

By extension, had a method of testing been employed with delayed results, in combination with a true opt-out offer (where testing requires less effort than not testing) (220,223), acceptability may have been higher. Consequently, further evaluative work is required to explore context-resource interactions that make testing more or less acceptable at different times (194,195). In the interim, healthcare providers operating within prisons that have a short average incarceration length should consider conducting testing on the first night, during second reception, and at any appropriate subsequent clinics, in order to balance risk of release, capacity to consent, and the influence of timing on acceptability (194,195,217).

Healthcare teams also faced a range of barriers, which limited their access to new arrivals. These further delayed the realisation of the test offer and operated in causal chains (138), with several intermediate outcomes leading to the final outcome of a failed test offer (figure 40). Even when programmes specify an appropriate period within which the test offer should occur, given the average incarceration length of their population, it is therefore likely that a proportion of people will be engaged much later, all the time risking release.

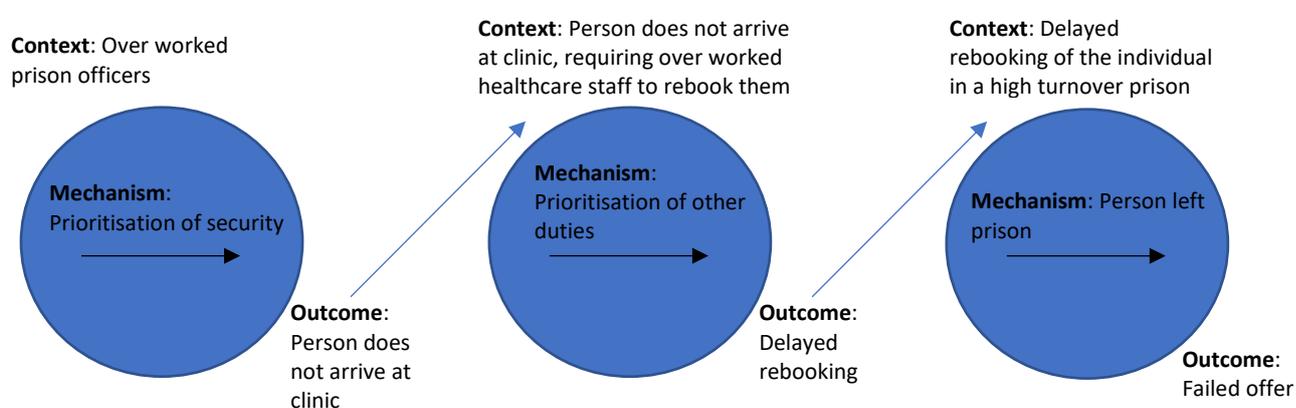


Figure 40. Example causal chain, with various intermediary outcomes that lead to the final outcome of public health interest. Each intermediary outcome forms the context of a subsequent programme theory.

The operational capacity of prison officers and HCWs were reoccurring contextual features within these causal chains (79,196,217,233). Historic de-valuation of prisoner well-being is often enacted through budget cuts to the prison estate, reducing the capacity of the staff working within them (181). Greater emphasis should therefore be placed on prisoner well-being via appropriate funding of the prison estate, both out of public health and ethical necessity (53).

More immediate options for opt-out programmes struggling with engagement could include: complimentary sub-interventions to foster collaboration between HCWs and prison officers, educational events in prison to encourage prioritisation of the programme, and incentivising clinic attendance for prisoners (e.g. by making it a compulsory pre-cursor in order to be medically approved for gym attendance or access to work) (230–232,238,242).

6.3.2 Test uptake

Varying numbers of people offered a test were found to opt-out (54,194,195,225–229). The lack of compelling switching costs, implemented by many opt-out programmes reviewed, may be explained by the absence of Nudge Theory in programme conception (79,196).

Much of the power of opt-out strategies, when used in sectors like marketing, comes from “sleight of hand” tactics (e.g. using miniature font) (220,222,223). Those implementing healthcare programmes do not have the luxury of such tactics and therefore need to optimise their use of defaults, whilst working within the ethical paradigm of informed consent (220,222). Minor switching costs could therefore be piloted as part of the London Prisons Project, and their impact on test uptake assessed (257).

The review also highlighted ethical considerations related to the exploitation of individual bias not to expend cognitive effort under opt-out (220,223,257). As the default action involves accepting a medical intervention, healthcare providers need to be vigilant of capacity to consent, ensuring those that do not make an active decision do so from a lack of preference, as opposed to inability (e.g. because of substance withdrawal) (194,195,223).

The decision of people to accept testing or opt-out was however found to be influenced by a range of incentives and disincentives related to testing for BBV infection within prison (figure 41). Results suggest that educational information is crucial, in order to help prisoners better interpret their risk of infection (218).

Individuals that perceive themselves to be at risk of infection are likely to place greater focus on testing (258–260). Some may be motivated to test, in order to confront and resolve the

expected infection, or be reassured by a negative result. However, perceived susceptibility to infection can also act as a strong motivation to avoid testing if, for example, the person does not feel able to cope with a positive diagnosis or is concerned about confidentiality and stigmatisation (238). It should therefore be an imperative that test programmes in prison encourage those concerned about BBV infection to test, by ensuring prisoners are provided with a confidential and supportive healthcare environment (258).

In contrast, individuals that perceive themselves to be at a low risk of infection are less likely to focus on BBV testing. It is these individuals that the nudging effect of an opt-out offer primarily targets (255,261,262). However, the invasive nature of testing presents a scalable disincentive (depending on method and how adverse the individual is to different procedures), whilst a lack of trust can manifest in resistance to perceived institutional recommendations (263–265). The ability of a programme to achieve high test uptake rates amongst this sub-group is therefore dependent on ensuring that the steering effect of an opt-out offer is not counterbalanced by disincentives to test (figure 41) (222,223).

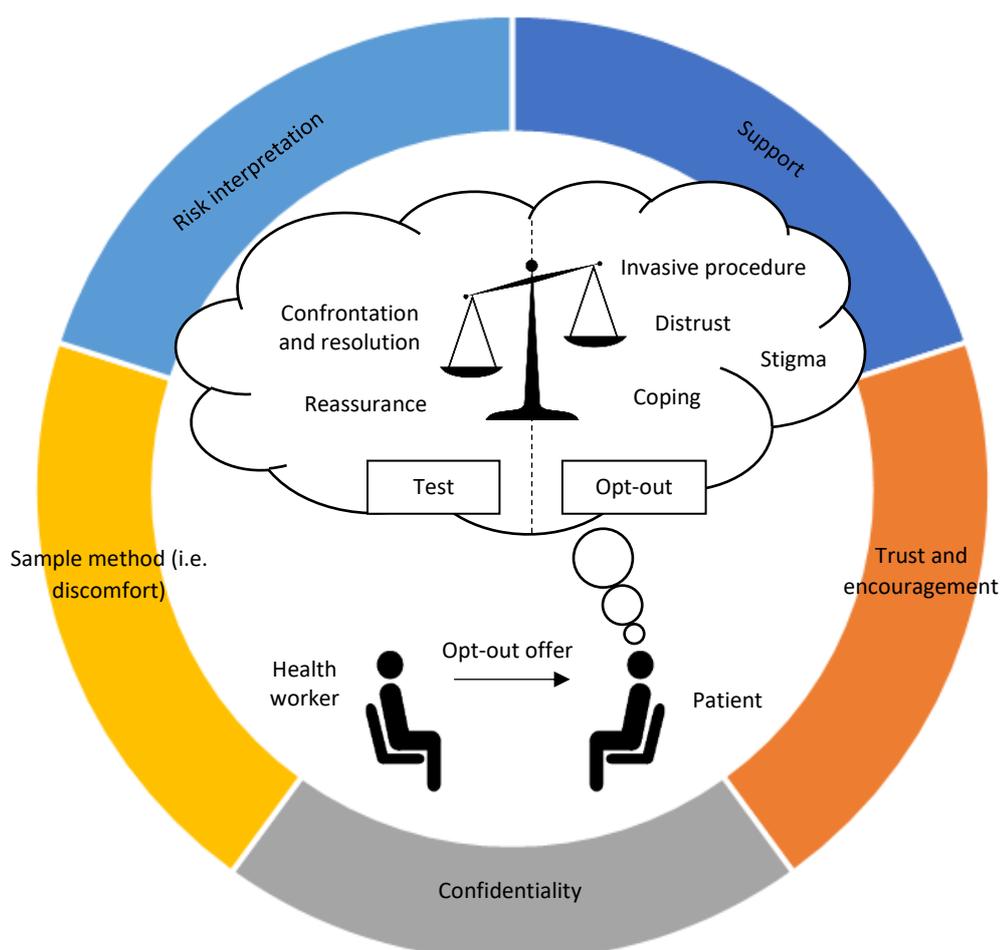


Figure 41. Incentives and disincentives related to blood-borne virus testing within a prison context. Salient resources, which influence the realisation of these costs and benefits, are depicted surrounding the person's decision making. Loss aversion suggests that the scales should be initially balanced in favour of testing under an opt-out system.

Resources that mitigate disincentives, such as confidentiality, trust, psychosocial support, and less invasive sample methods were therefore found to be crucial for effective programme function (figure 41). These were frequently built into the opt-out programmes identified in the literature, and were included within the design of the London Prisons Project (79,83,196). For programmes that experienced issues with the implementation of one, or several of these resources, further research is required to unpick why these resources were unsuccessfully realised within different prison contexts.

Finally, refined theory highlighted challenges to the fidelity of opt-out, which stemmed from the conceptualisation of the offer by programme implementers, misinterpretation by those delivering the test offer, and/or due to contextual pressures (79,234,235,254). The need to acquire consent can naturally lead to asking a person if they would “like to test” (194,195), failing to adhere with the principles of an opt-out approach and potentially limiting uptake (54,87).

However, not informing prisoners that they have the right to decline, given the punitive context, borders on a mandatory approach (266,267) and raises ethical questions if people interpret it as such (234,235). Further work is therefore required to determine what constitutes an opt-out offer and how adherence to opt-out can be ensured in practice.

Nevertheless, through an iterative review process I was able to elucidate the implicit programme theory underpinning the London Prison Project and then interrogate it using empirical evidence from the literature. This allowed me to construct an explanatory framework (see figures 42 and 43 and tables 14-20), which can be applied and refined to help understand variations in opt-out BBV test programme performance in London and across other prison contexts (111,131).

6.3.3 Limitations

Much of the empirical data came from opt-out HIV testing conducted within US prisons, potentially limiting the applicability of refined theories for the English prison context, where HIV, HCV, and HBV are tested for together. However, validation with LBCSG stakeholders and observation of opt-out training and testing within two London prisons, was undertaken in an attempt to ensure relevance (206).

Several articles did not include information about the wording of the offer, meaning I was forced to assume that testing really was, for the most part, offered as an opt-out (225,226,269,227–229,232,240,242,253,268). It is important that details, preferably a standard quote for the process of gaining consent to test, are presented, providing

transparency and allowing for an assessment of the true nature of the offer process (87,194,195,234,235).

I was also heavily reliant on author justifications for the failure to offer testing and prisoner opt-out. Qualitative insights into the reasoning processes of different programme stakeholders were scarce and therefore often inferred. In all reviews that utilise realist methodology, there will be some judgement involved when making inferences between the data found in included studies (139,270). However, further qualitative research is required to provide greater insight into the decision-making process of relevant stakeholders.

The framework that I have sketched out in this review is therefore intended to provide a starting point on which to build our understanding of opt-out BBV programmes in prison (113). The CMOcs presented are falsifiable and require further refinement using primary data (113). To help enable this process, and in line with best practice, I attempted to maximise the transparency of the review process (270).

6.3.4 Conclusion

Evaluation of opt-out BBV testing has revealed variability in performance. Through an iterative theory development and refinement process, using stakeholder documents and the wider published literature, this review constructed and then interrogated the London Prison Project's approach to opt-out BBV testing.

The synthesis highlighted important implementation considerations, which influence the effectiveness of these programmes. Sampled literature also suggested that the fidelity of opt-out may be challenged, as a result of misunderstanding surrounding the concept.

Those implementing opt-out programmes within prison are recommended to utilise Nudge Theory within their design, to take full advantage of the Default Effect for public health benefit. They are also encouraged to think carefully about the timing of the test offer, work with prison authorities to overcome logistical barriers to accessing prisoners, explore ways of enhancing the fidelity of an opt-out offer, and ensure the realisation of key programme resources that can mitigate disincentives to test.

6.3.4.1 Dissemination

Results were disseminated during a presentation at the London Joint Working Group Conference (2017) and during LBCSG meetings. The review was later published in BMC Health Services Research (271).

6.4 Refined programme theory: test offered

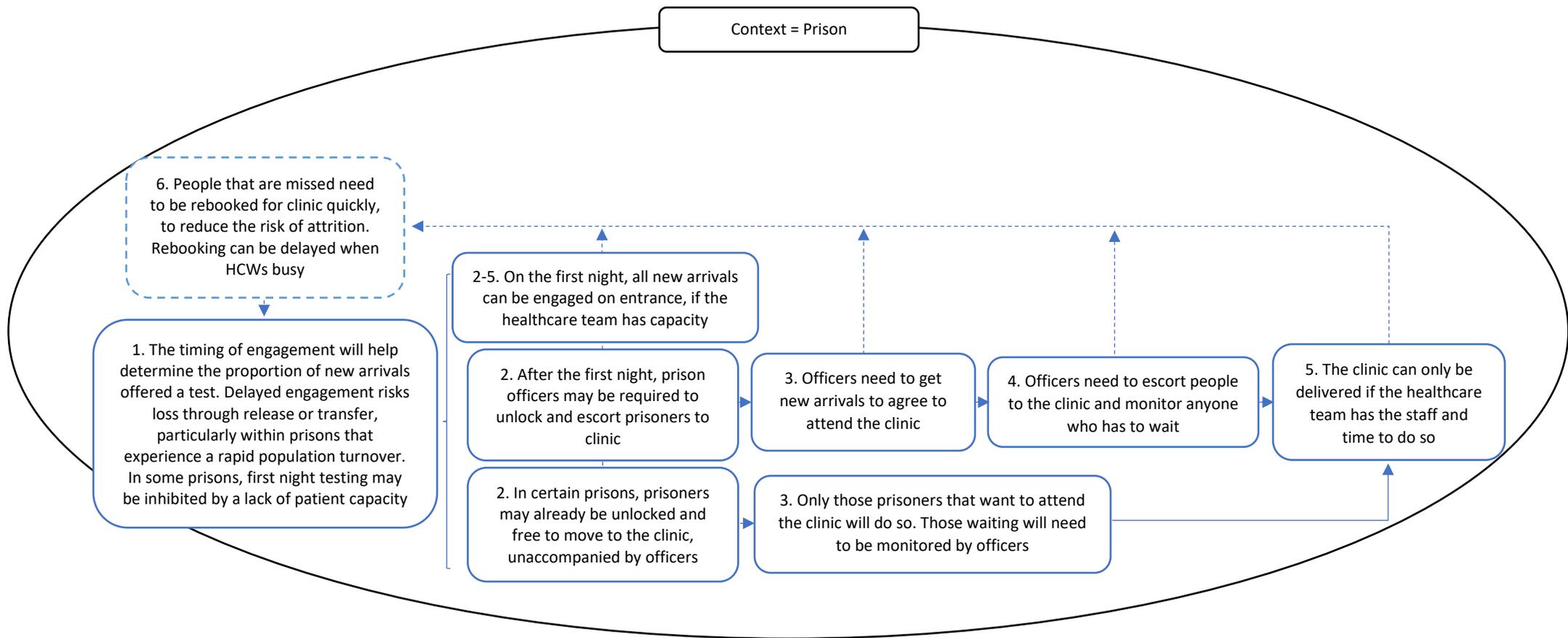


Figure 42. Refined programme theory for the steps involved in engaging newly incarcerated people, in order to deliver a blood-borne virus test offer (BBV = blood-borne virus; HCW = healthcare worker).

Table 14. Refined programme theories that explain potential sources of variability in the proportion of new arrivals to a prison that are offered a test.

Theory	Context	Mechanism ----->		= Outcome	Supporting references
		+ Resource	Response		
1. Delayed test offer	<i>Prison with a high population turnover</i>	<i>Programme mandated delay in test offer</i>	<i>Short stay individuals leave or are transferred</i>	<i>Proportion of new arrivals already left before being engaged</i>	(54,79,239,252,267,313,193,194,226,227,229–232).
2. Institutional scramble	<i>Access to a prisoner is often easier during the first few days of incarceration and a requirement for some organisations. This encourages an institutional scramble with charities, chaplaincy, immigration services, courts and healthcare all vying to engage new arrivals</i>	<i>Requirement to engage new arrivals for testing early</i>	<i>Some people engaged by other services</i>	<i>Proportion of people not accessible, as being seen by another organisation, and therefore not offered a test (see re-booking theory)</i>	(230–232,242).
3. Refusal to attend clinic	<i>Testing conducted concurrently with other prison activities</i>	<i>Attendance at clinic becomes an opportunity cost</i>	<i>Person prioritises healthcare over other activity</i>	<i>Person more likely to agree to attend the clinic (if officer facilitation required) or attend themselves (if officers are not required)</i>	(54,230,231).
			<i>Person prioritises other activity over healthcare</i>	<i>Person likely to refuse to attend the clinic (see re-booking theory)</i>	
4. Prisoner movement to clinic	<i>Prison officers have a challenging role and budget cuts have left them short staffed</i>	<i>Requirement of officers to bring prisoners to clinic</i>	<i>Prioritisation of security processes over transportation</i>	<i>Proportion of people do not arrive at clinic to be offered a test (see re-booking theory)</i>	(230–233,238,242).
		<i>Prisoners free to move to clinic unaccompanied</i>	<i>Prisoners that wish to attend the clinic are not reliant on anyone else to supervise them</i>	<i>Those people that wish to attend the clinic, arrive to be offered a test</i>	
5. Provider capacity to run clinics	<i>Prisons are a demanding place to work and budget cuts result in less healthcare staff. In the event of staff absence, this can result in restricted service provision</i>	<i>Capacity of healthcare staff stretched</i>	<i>Prioritisation of urgent conditions and emergencies</i>	<i>Testing clinic delayed or cancelled, and prisoners require re-booking (see rebooking prisoners' theory)</i>	(79,228,230–233,250).
5. Language barriers	<i>Certain prisons, either in metropolitan areas or designated as immigration centres, have a high proportion of foreign nationals</i>	<i>Translation service available</i>	<i>Healthcare worker able to offer testing</i>	<i>Person offered a test</i>	(54,233).
		<i>Translation service not available</i>	<i>Healthcare worker unable to offer testing</i>	<i>Person not offered a test (see re-booking theory)</i>	
5. Early testing and capacity to consent	<i>A proportion of newly incarcerated people may lack capacity to consent to medical intervention on the first night</i>	<i>Healthcare worker recognises inability to consent</i>	<i>Views inability to consent as important</i>	<i>Person not offered a test (see re-booking theory)</i>	(194–196,225,233,241).
6. Rebooking prisoners	<i>Prisons are a demanding place to work and budget deficits result in healthcare staff cuts</i>	<i>Missed people need to be re-booked by a healthcare worker</i>	<i>Healthcare worker prioritises medical emergencies and conducting other tasks that require immediate attention</i>	<i>Test offer delayed (see delayed test offer theory)</i>	(79,228,230–233,250).

6.5 Refined programme theory: test uptake

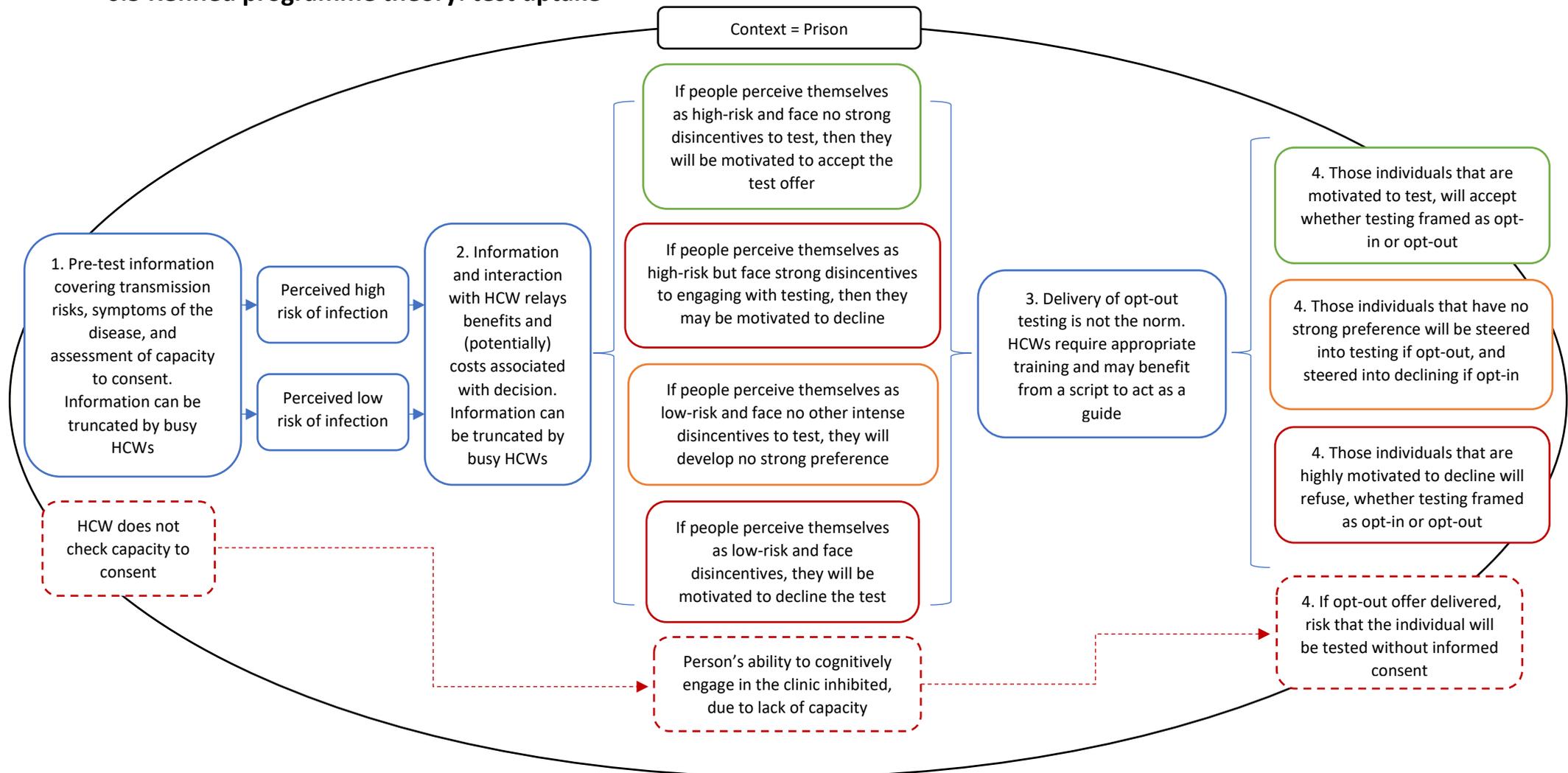


Figure 43. Refined programme theory for the steps involved in delivering an opt-out test and newly incarcerated peoples' response to the opt-out offer (HCW = healthcare worker).

Table 15. Refined programme theory for pre-test information (BBV = blood-borne virus, HCV = hepatitis C; HBV = hepatitis B; HIV = the human immunodeficiency virus).

Theory	Context	Mechanism ----->		= Outcome	Supporting references
		+ Resource	Response		
1. Pre-test information on risk	<i>Misconceptions about BBVs are common amongst incarcerated people</i>	<i>Educational information about modes of transmission and symptoms of disease</i>	<i>Individual listens to the information provided and then applies it to themselves and their experiences</i>	<i>Individual develops a perception that they may be at risk of infection</i>	(54,228,233,234,243,246,249). (54,194,195,225,226,228,230,232,237).
			<i>Individual doesn't listen to the information provided, either out of lack of interest, capacity, or distraction</i>	<i>Individual maintains latent perception of risk</i>	
		<i>Information truncated by busy healthcare staff</i>	<i>Prisoner not provided with information that allows them to interpret their risk of infection</i>	<i>Individual maintains latent perception of risk</i>	

Table 16. Incentives and disincentives to test (HCW = healthcare worker BBV = blood-borne virus).

Theory	Context	Mechanism ----->		= Outcome	Supporting references
		+ Resource	Response		
2. Presenting testing as the norm (descriptive norm)	<i>Testing carried out in a confidential setting, where the individual has not witnessed other people being offered a BBV test</i>	<i>HCW informs the person that testing is routine and that everyone normally accepts</i>	<i>Descriptive norm frames testing as potentially beneficial, as this is the action that everyone else is taking as well</i>	<i>Test uptake encouraged</i>	(173,195,243,245,306).
2. Coping with a positive diagnosis	<i>The potential diagnosis of a BBV within prison can be a stressful experience for prisoners. The person believes they are susceptible to infection</i>	<i>Supportive information (e.g. treatment options, dispelling myths around prognosis, and details of available psycho-social support) provided</i>	<i>Person more likely to be reassured about their ability to cope if they test positive</i>	<i>Test uptake encouraged</i>	(54,228,233,234,243,246,249). (54,194,195,225,226,228,230,232,237).
		<i>Supportive information not provided</i>	<i>Person may feel unable to cope with the perceived burden associated with a positive result</i>	<i>Test uptake discouraged</i>	
2. Confidentiality and stigma	<i>Infection with a BBV is stigmatised within a prison context. The person believes they are susceptible to infection</i>	<i>Confidentiality maintained inside and outside of clinic</i>	<i>Person more likely to feel safe to engage with testing and share personal information</i>	<i>Test uptake encouraged</i>	(194,195,245,246,250,253,315,226,227,233,238,240,241,243,244).
		<i>Confidentiality not maintained inside and outside of clinic</i>	<i>Person may distrust prison healthcare's ability to maintain confidentiality and may fear stigma as a result of engagement</i>	<i>Test uptake discouraged</i>	

Table 16. Continued.

2. Previous experience of poor quality of care	<i>Person has had previous experience (directly/indirectly) of poor-quality healthcare within a prison environment</i>	<i>No attempt to build rapport and put the person at ease and/or clinic perceived as an unprofessional environment</i>	<i>Testing may be viewed as an unpleasant or dangerous experience</i>	<i>Test uptake discouraged</i>	(241,245).
		<i>Professional approach attempts to build rapport, and provide opportunities for person to verbalise concerns related to engaging with healthcare</i>	<i>Person may feel reassured about engaging with healthcare</i>	<i>Test uptake encouraged</i>	
2. Fearing consequences of opt-out	<i>Prisons are inherently coercive environments where incarcerated people have little self-determination</i>	<i>The separation between healthcare and the prison service is not made clear</i>	<i>Individual may fear declining the test because they believe this could result in punitive action from the prison service</i>	<i>Person may comply with testing, even if they do not wish to test</i>	(194,196,234,235,316).
2. Institutional recommendations and trust	<i>Person trusts the prison staff and healthcare providers</i>	<i>An opt-out offer can be interpreted as an implicit recommendation to test and/or HCW makes explicit recommendation to test</i>	<i>Person may want to act in line with the recommendation from a trusted authority</i>	<i>Test uptake encouraged</i>	(230,231,245,250).
	<i>Person distrusts prison staff and healthcare providers</i>		<i>Test offer may be viewed as a coercive means of surveillance or control</i>	<i>Test uptake discouraged</i>	
2. Refusal to engage in protest	<i>Newly incarcerated people often have grievances with police from the arrest and are angry at the court's decision to incarcerate them</i>	<i>Testing requires collaboration between prisoners and healthcare staff</i>	<i>Frustration and anger can manifest in a refusal to engage with authorities as a form of protest</i>	<i>Test offer declined</i>	(54,233,238).
2. Defaults and capacity to consent	<i>A proportion of newly incarcerated people may lack capacity to consent to medical intervention on the first night</i>	<i>Healthcare worker fails to recognise inability to consent</i>	<i>Healthcare worker believes it is okay to proceed</i>	<i>Person offered a test, risking test uptake without informed consent</i>	(194–196,225,233,241).
2. Invasive procedure	<i>Testing for BBV infection is an invasive procedure that may cause discomfort. Most people will not agree to additional discomfort, unless there is a perceived benefit to this action. Venous sampling is frequently perceived as generating greater discomfort than a finger prick or oral swab</i>	<i>Testing conducted using a venous sample method</i>	<i>People with serious needle phobia, or those who perceive the discomfort caused as greater than the benefit of knowing serostatus</i>	<i>Strong disincentive to test</i>	(54,187,194,228,229,243,250,251).
		<i>Testing conducted using dried blood spot</i>	<i>Most people perceive the method of sample acquisition as less intrusive/painful than a venous sample</i>	<i>Lesser disincentive to test</i>	
		<i>Testing conducted using an oral swab</i>	<i>Method of sample acquisition unlikely to be perceived as painful but may be considered invasive</i>	<i>Lesser disincentive to test</i>	

Table 17. Refined programme theory for opt-out test offer delivery.

Theory	Context	Mechanism ----->		= Outcome	Supporting references
		+ Resource	Response		
3. Opt-out fidelity	<i>Programme implementers misinterpret how to deliver an opt-out test</i>	<i>Training provided to healthcare workers encourage opt-in or mandatory test offer</i>	<i>Healthcare workers encouraged to deliver a poor opt-out message</i>	<i>Opt-in or mandatory test offer</i>	(79,234,235,237,316).
	<i>Opt-out testing not the norm</i>	<i>Little training and no standard script</i>	<i>Healthcare worker misinterprets how to deliver test offer</i>	<i>Opt-in or mandatory test offer</i>	
		<i>Training and/or script provided</i>	<i>Healthcare worker understands how to deliver the test offer</i>	<i>Opt-out test offer</i>	
	<i>Healthcare worker fatigued, distracted, or has a high level of rapport with a prisoner</i>	<i>No standard script</i>	<i>Healthcare worker defaults to old way of offering a test</i>	<i>Opt-in test offer</i>	
3. Language barriers	<i>Language barrier between prisoner and healthcare worker, but translation service present</i>	<i>Failure to highlight the need for testing to be opt-out to translation provider</i>	<i>Misinterpretation of how to offer testing by translation provider</i>	<i>Opt-in test offer</i>	(54,233).

Table 18. Refined programme theory for test uptake (HCW = healthcare worker; BBV = blood-borne virus).

Theory	Context	Mechanism ----->		= Outcome	Supporting references
		+ Resource	Response		
4. Active decision to test	<i>An individual who feels comfortable engaging with the health service, who perceives themselves to be at risk, feels capable of dealing with potential consequences of a positive result, and faces no other strong disincentives</i>	<i>Opt-out or opt-in test offer</i>	<i>Test offer seen as an opportunity to confront infection or be reassured by a negative result</i>	<i>Test uptake</i>	(54,228,233,234,243,246,249) (193,194,224,225,227,229,231,236).
4. Passive decision to test or not test	<i>An individual who has no strong preference to either test or not test and is not wanting to engage effort in the clinic encounter</i>	<i>Testing provided in opt-out format</i>	<i>Individual likely to comply with the default option</i>	<i>Test uptake</i>	
		<i>Testing provided in opt-in format</i>		<i>Declines the test</i>	
4. Active decision to decline	<i>An individual who faces strong disincentives to test</i>	<i>Opt-in or opt-out test offer</i>	<i>Test offer viewed as an unnecessary burden and/or potentially a (directly/indirectly) threatening act</i>	<i>Declines the test</i>	
4. Cognitive engagement	<i>A proportion of new arrivals will not cognitively engage due to a lack of capacity (e.g. undergoing substance withdrawal)</i>	<i>Opt-out test offer</i>	<i>Unable to cognitively assess test offer</i>	<i>Test uptake if healthcare worker fails to act on inability to consent. Failed offer if healthcare worker notices and acts on inability to consent</i>	
4. Mandatory test offer	<i>Prisons are inherently coercive places and delivering an opt-out test offer is open to misinterpretation by healthcare staff</i>	<i>Mandatory offer or opt-out offer that blurs the line</i>	<i>Most people will comply with the perceived mandated protocol. A small proportion of people, facing strong disincentives, may try to refuse</i>	<i>High test uptake – not necessarily with informed consent</i>	

6.6 Conditioning (Ma-Mi) and transformative (Mi-Ma) mechanisms

Table 19. Conditioning theories developed during the rapid-realist review.

Theory	Interaction between contextual features	Mechanism ----->	= Conditioning of prisoner decision making	Supporting references
Counter-normative behaviour (injunctive)	<i>In a high-test uptake but stigmatised setting, where confidentiality is poorly maintained</i>	<i>Activities that are counter-normative may signal that a person has something to hide and could be a health threat</i>	<i>Person encouraged to comply with norm and take a test (even if they do not wish to)</i>	(173,195,243,245,306).
	<i>In a low-test uptake but stigmatised setting, where confidentiality is poorly maintained</i>		<i>Person encouraged to comply with norm and opt-out (even if they do not wish to)</i>	
Counter-normative behaviour (descriptive)	<i>In a high test-uptake setting, where confidentiality is poorly maintained</i>	<i>The fact that everyone else is testing encourages others to perceive testing as an advantageous action to take</i>	<i>Person encouraged to comply with norm and take a test</i>	(173,195,243,245,306).
	<i>In a low test-uptake setting, where confidentiality is poorly maintained</i>	<i>The fact that nobody is testing encourages others to perceive not testing to be the sensible or advantageous option</i>	<i>Person encouraged to comply with norm and opt-out</i>	
Situational group pressure	<i>Testing procedures conducted sequentially on a group that are able to communicate and become supportive of testing</i>	<i>Autonomy of individual eroded by situational group pressures</i>	<i>Peer pressure encourages test uptake</i>	(234,247).
	<i>Testing procedures conducted sequentially on a group that are able to communicate and become oppositional to testing</i>		<i>Peer pressure encourages opt-out</i>	

Table 20. Transformative theories developed during the rapid-realist review (BBV = blood-borne virus).

Theory	Programme outcome	Mechanism ----->	= Contextual transformation	Supporting references
Routine offer leads to offer normalisation	<i>Opt-out programme successfully offers most new arrivals a test</i>	<i>Being offered a BBV test becomes normalised</i>	<i>Being offered a BBV test on entrance to a prison becomes the expectation of prisoners</i>	(79,195,229,239,241,269).
Routine testing leads to taking the test becoming the norm	<i>Opt-out programme successfully tests most new arrivals</i>	<i>Being tested for BBVs within prison becomes normalised</i>	<i>That people get tested for BBV infection on entrance to a prison becomes the expectation of prisoners</i>	

6.7 Nudge interventions

As part of the RRR, realist theories developed using the literature were validated by observing opt-out testing within two London prisons. This exercise revealed poor opt-out fidelity, with most HCWs delivering opt-in testing. Much like programmes in the literature, this issue appeared to stem from a widespread misunderstanding of what “opt-out” meant.

With a call from the “All-Party Parliamentary Group on Liver Health” for a “clear national protocol” regarding wording of an opt-out test offer, I developed a written script to act as a guide (38,189,272). To do this, the LBCSG sent an exemplar quote, which I then refined using the “MINDSPACE” framework (developed by the UK Government’s Behavioural Insights Team) and with input from my supervisory team (figure 44) (255,273). A specialist in behavioural economics (Professor Ivo Vlaev) was also consulted about wording (261).

Opt-out offer script

“We screen everybody entering this prison for hepatitis B, hepatitis C, and HIV. Screening is free, confidential, and the sample will not be used for anything other than this test. You can be infected and still feel healthy, so it is important to test even if you feel fit and well. If you have hepatitis C, we can treat you with new medication that works in almost all cases, usually with no side effects. Are you happy to proceed?”

Key:

- Establish norm.
- Provide key information to avoid negative automatic responses.
- Priming words.
- Provide opportunity to opt-out whilst default remains testing.

Figure 44. Opt-out offer script, developed using guidance from the MINDSPACE Framework and based on findings from the rapid-realist review.

My intention was that the script would:

1. Provide a uniform message for different organisations, commissioned by NHSE, to deliver during training;
2. Act as a guide for trained and experienced HCWs to construct their opt-out message around;
3. Act as a script for untrained and agency staff to follow.

This script was disseminated during a national BBV engagement event, run by PHE in London (2017) (95). NHSE has also disseminated the intervention to regional commissioners and upper CareUK management for implementation. The script is currently in use nationally and forms part of NHSE sponsored training, delivered by GILEAD and the Hepatitis C Trust.

6.7.1 Switching cost form

During analysis of LBCSG quantitative data (Chapter 5), I noticed that healthcare providers were not reporting justifications provided by prisoners for refusing a test (despite this information being requested). Provision had been made for this information to be recorded using a free-text box on one of the SystemOne templates. However, this required HCWs to go back and manually enter information, something that was commonly not done. In addition, the LBCSG received reports that some HCWs were discouraging people from taking a test, to shorten the consultation.

Viewing these two challenges as a potential opportunity, I developed a confidential opt-out switching cost form, based on findings from the RRR and using guidance from the MINDSPACE framework (255,261). An example of the form is presented in appendix C. My intention was that the form would be given to prisoners to complete, in the event that they expressed a desire to decline the test. The form could then be sealed in an envelope and at the end of the month, all envelopes could be opened and anonymous justifications for prisoners' decision to opt-out sent to the LBCSG, alongside the other data routinely reported.

However, in addition to collecting routine data, the form also aimed to:

- Check that prisoners had received appropriate information about the test from HCWs. It was hoped that this would, in turn, incentivise HCWs to provide appropriate information about the test, before someone decided to decline.
- Increase the time it takes for someone to decline testing, mitigating perverse incentives for HCWs to discourage testing in order to speed-up the clinic consultation.
- Act as a switching cost to encourage testing (223,255,261).

Development and piloting of the form was approved during a LBCSG meeting (15/12/2017). I produced a first draft and "SMOG" (stands for: Simplified Measure of Gobbledygook) tested it for a reading age of 11-12 years old (66). This was then piloted by the Hepatitis C Trust during peer and educational programmes that they were running within the London prisons. Feedback from this process is summarised in appendix C.

Following piloting, the form was further refined (based on received feedback) and finally implemented across the London prison estate on the 20/02/2017. It was also disseminated to other NHSE commissioners for implementation across other regions.

6.8 Chapter summary

In answering the questions posed at the start of this chapter, I have searched the literature, analysed the results, and continued developing a realist explanatory framework for the variation in numbers of new arrivals to a prison offered a test and tested under an opt-out approach to BBV testing. In summary:

- The concept of making testing “opt-out” was found to be underpinned by behavioural economic theory (i.e. the Default Effect). However, neither those that implemented programmes in the literature, nor those who evaluated these programmes, mentioned it as a consideration. Consequently, the review highlighted issues with fidelity, stemming from confusion around opt-out as a concept.
- Engaging all new arrivals to a prison for testing is not straightforward. Delays to engagement, capacity to consent, reliance on prison officers for facilitation of clinics, people’s refusal to attend clinics, and healthcare providers’ lack of capacity to deliver testing, all reduce the proportion of new receptions offered a test.
- Prisoners should be motivated to test, by providing educational information that helps them to determine their risk of infection. However, strong disincentives to test for those that perceive themselves as at risk (e.g. poor confidentiality) need to be addressed. Those who perceive themselves as low risk should be steered into testing, by minimising common disincentives (e.g. discomfort or distrust) associated with testing.
- Issues with opt-out fidelity were identified in London prisons. In an attempt to remedy this, and address perverse incentives during the clinic encounter, I developed an opt-out offer script (implemented nationally) and an opt-out disclaimer form (implemented within London prisons).

Chapter 7: Qualitative comparative case study

7.0 Introduction

At this point in the evaluative research, I had developed an explanatory framework for opt-out BBV testing by analysing routine data from the London Prisons Project and by synthesising the relevant literature. However, the reality of what was actually taking place within London prisons remained unclear (274).

Results from Chapters 5 and 6 both suggested that I needed to generate qualitative data, to better understand how opt-out testing was actually working within London (addressing question three of this evaluative research – Chapter 2). To do this, I needed to select a sample of prisons to target for field work (100). I used quantitative performance data from Chapter 5 to guide this selection, settling on a higher and low performing local London prison. I focused on local prisons, as data suggested that these institutions may have faced additional barriers to testing, whilst also reporting the highest anti-HCV sample positivity (274).

This stage of the evaluative research aimed to use qualitative data to develop theories that explained the variance observed in quantitative outcomes between these two prisons. Informed by explanatory theory on what made opt-out BBV testing effective, I then intended to make recommendations to improve performance within local prisons. To do this, two separate analyses of the generated data were conducted: one focused on assessing programme implementation and the other on explaining how variation in implemented resources produced different outcomes (274).

I begin the chapter by discussing the methods used. Results section one then outlines the implementation of the opt-out BBV test programme within each prison (274). Section two assesses how stakeholders within each prison reacted to programme resources to generate outcomes (i.e. programme function) (111). The chapter ends with policy recommendations, concluding remarks, and a refined programme theory for an effective approach to opt-out testing within local prisons.

7.1 Method

Results from the quantitative assessment (Chapter 5) were used to identify two local prisons that were similar structurally, but reported divergent outcomes in terms of test programme performance (i.e. numbers offered a test, tested, and found to be positive for a BBV infection) (275). Prison 1 was selected as outcome data suggested that the programme was working effectively. Prison 2 was chosen as a comparator because LBCSG data suggested it

was struggling with test coverage and because the prison healthcare team were reporting a surprisingly low anti-HCV sample positivity (275).

In line with the RE framework I outlined in Chapter 3, I wanted to assess the interaction between the programme and the wider prison context. Qualitative data generation was therefore guided by the following questions (274):

- How does the prison context influence programme design and function?
- How was opt-out BBV testing implemented within Prison 1 and 2 and why was it implemented that way?
- How was opt-out BBV testing delivered in practice within each prison?
- What is recommended for an effective approach to opt-out BBV testing within local prisons?

7.1.1 Data generation

My research design was influenced by prison ethnographies, such as Kuester (2016), which have proven effective at generating detailed contextual data (276–278). Mirroring an ethnographic approach, I aimed to employ a combination of qualitative methods, which could then be triangulated to provide a robust assessment of each prisons' context, programme implementation, and the way the programme functioned (274).

A data generation process consisting of realist interviews, participant observation, and document analysis was therefore employed (276,279). Field work was completed in four segments, spanning 21/05/2018 to 07/02/2019 (274):

1. Before the main body of field work commenced, inductive observations were carried out within each prison for one week to allow for research question refinement and topic guide modification (280,281). This “sensitisation” period was completed between 21/05/2018 and 08/06/2018.
2. Data generation within Prison 1 commenced on the 18/06/2018 and ended on the 12/10/2018. This occurred when quantitative outcomes suggested that programme performance was improving within the prison (Chapter 5, figures 30 and 31).
3. Data generation within Prison 2 commenced on the 15/10/2018 and ended on the 07/02/2019. This occurred when quantitative outcomes suggested that programme performance had peaked and then begun to decline (Chapter 5, figures 30 and 31).
4. LBCSG interviews were carried out between the 21/05/2018 and the 07/02/2019.

7.1.1.1 Sensitisation

Initial field visits were spent introducing myself and the research and building relationships with key “gatekeepers” (282). Observations during this period were centred on the provision of BBV testing and were conducted from a position of moderate participation. They were jotted in notebooks and later processed, using Word (Microsoft Office 2016), to form field notes (282,283). Processing took place each evening and the following day (283).

A week was spent “cleaning” field notes and familiarising myself with the data after the sensitisation period. Data were then used to modify research questions and highlight important features of context and programme set-up, worth exploring in more detail during the main period of data generation.

7.1.1.2 Observation

The main period of data generation took place sequentially, starting in Prison 1. Unstructured observations, involving a medium level of participation (282), were carried out throughout the fieldwork within each prison, focused on characterising each prisons social and physical context (282,284). As part of these observations I had “informal discussions” with staff and prisoners, which centred on working and living in the prison environment. Verbal consent to record these discussions was always secured, before notes were taken (see appendix D for further information on acquiring consent during observation).

Semi-structured observations focused specifically on the processes involved in new arrivals moving to and from clinics, the sequence of events that constituted opt-out testing, and any additional BBV testing that took place within the prison (281,285). These observations began from a medium level of participation, but I steadily became more involved in the activities I was observing, helping with the logistics of running clinics and occasionally taking blood samples myself (282).

Notes from observations and informal discussions were recorded in field notebooks. At the end of each day, and during the following day, these were translated into field notes using Word (Microsoft Office 2016). During translation I tried to consider how my background and position as a “prison researcher” shaped the data generation process, facilitating reflexivity throughout the fieldwork (281,282,285).

7.1.1.3 Realist interviews

Realist interviews were conducted with four respondent groups: healthcare staff (implementers), prison staff (facilitators), prisoners (recipients), and LBCSG stakeholders (programme developers) (286). Inclusion and exclusion criteria can be found in appendix D.

I aimed to recruit 5-7 officers per prison (looking to include supervising officers and those responsible for facilitating clinics where BBV testing took place), 5-9 HCWs per prison (looking to include supervising healthcare staff and those delivering testing, whilst seeking diversity in their approach to opt-out test delivery), 5-12 prisoners per prison (seeking diversity in decision to test, age, and ethnicity), and 5-8 LBCSG stakeholders (seeking diversity in organisation representation). Sample sizes were predicted to achieve adequate data saturation, whilst working within HMPPS requirements that the research would have minimal operational impacts (286).

Prison-based recruitment took place roughly a month after observations commenced, providing time for respondents to familiarise themselves with myself and the aims of the evaluation (287). Consent was recorded manually on consent forms for all respondent groups (see appendix D for an example consent form).

Recruitment of officers and healthcare staff

Staff within the prison were approached during observational data generation. Those that were interested in participating were emailed information about the research (see information sheet in appendix D) and a date for interview was arranged.

Prison officers were often hesitant to take part in an interview (287). This usually stemmed from a fear of “snitching” and seemed to be more pronounced amongst experienced staff. However, in Prison 1 I was able to establish relationships with those officers that were facilitating the clinics I was observing, by providing educational information, reassurance about BBV infection, and by advocating on their behalf for access to the HBV vaccine.

In Prison 2, officers facilitating testing clinics were also responsible for managing a prison wing and therefore lacked the time to engage with me. Although some older officers were happy for me to record discussions during observation, they were resistant to conducting a formal interview, particularly as this involved signing a consent form (287). Furthermore, any officer that agreed to interview had to sacrifice their lunch break. Under these conditions, younger graduate prison officers were the only prison staff who agreed to participate.

Recruitment of prisoners

Recruitment of prisoners was similarly difficult (204). I had planned to recruit individuals during clinics. Prisoners that expressed an interest then needed to be cleared by the prison’s security department. Once the individual had been approved, I intended to arrange a follow-up meeting for the interview, but re-gaining access to interested prisoners proved impossible because of restricted regimes, short sentences, and a lack of prison officers for facilitation.

To address these barriers, I developed a new recruitment system following recommendations made by each prisons' security department. This involved recruiting and interviewing prisoners directly after they had attended a clinic where they were offered a test (rather than attempting to regain access). A member of the healthcare team made the initial approach, in line with recommendations on ethical best practice (287).

If the individual agreed to be interviewed, I then got officers and HCWs to clear them for participation by checking SystmOne and the prison IT system for medical conditions and/or security considerations that might preclude involvement. With staff approval, the person was then taken to a private room, given time to read the participant information sheet, and provided information about the evaluative research verbally by myself. However, because interviews were completed during busy clinics, duration was short (lasting 12 - 32 minutes).

Recruitment of LBCSG stakeholders

Potential participants were approached after LBCSG meetings and asked to participate. Those that agreed were sent additional information via email and a time to interview was arranged. Interviews were conducted in various locations across London, including stakeholder offices and public libraries.

Interview format

Interview format roughly followed the "teacher-learner" approach recommended by Pawson and Tilly (1997) (see example topic guide in appendix D) (111,279). Interviews commenced with opening questions, designed to get the respondent to clarify their involvement in the programme (279,288). Participants were then asked a series of open-ended questions, providing an inductive element to the encounter (279).

More specific questions, grounded in programme theory were then delivered, based on the respondent's position and involvement in opt-out BBV testing (279,288). These were often developed specifically for each interview (based on observational data), making pre-interview preparation intensive (279). Finally, question format reverted back to open questions, aimed at eliciting important considerations that may have been missed (288).

There is ongoing debate about the validity of realist interviews (289). The approach has been criticised on the grounds that its theory proposition process risks leading the respondent and is subject to confirmation bias (289). I decided to take the following precautions to help minimise this risk (289):

- I wore casual clothing during interviews, where possible and appropriate (287).

- I tried to emphasise the position of the respondent as “prison experts” and all respondents were encouraged to disagree with any propositions I made.
- Interviews had a period of inductive discussion, allowing other topics to arise.
- The theory testing stage of the interview with prisoners used indirect questions (implicit testing) and, where possible, I asked for examples during the participants response (289). More direct propositions were made to staff and LBCSG stakeholders, who were in a better position to feel confident about “teaching” me how they saw the programme working.
- Provisional interview topic guides were checked and validated by two sociologists.

Recording interviews in prison

It was my intention to audio record all interviews, despite audio recording devices being classified as a “List B controlled item” under the Prison Act: “PSI 10/2012” (290). In Prison 1, permission to use an audio recording device was granted by the security department, so all interviews were recorded using an encrypted device and supported with interpretive field notes made after the encounter (149,291,292).

In Prison 2, I was unable to secure permission from the security department to use an audio recording device. Although I was able to complete several audio recorded interviews outside of the prison, most were conducted inside and recorded by hand in field notebooks (149).

During these interviews I focused on recording direct quotations, in an attempt to avoid underrepresenting the participant’s perspective (149). However, this interrupted the flow of the interview as I often had to ask interviewees to slow down or repeat sections of the discussion. Following interview completion, I left the prison and audio recorded as much information as possible, before developing a transcript on Word (Microsoft Office 2016) using both the recording and notes. However, the depth of data I was able to generate through this process remained limited (149,291).

7.1.1.4 Documents

In Prison 1, documents related to the development, planning, and implementation of opt-out testing within the prison were obtained by consulting healthcare management (293). Additional documents were obtained during interviews (e.g. sketches made by respondents), and during my time observing clinics where testing took place (healthcare booklets for patients, posters on HCV etc.).

In Prison 2, some documents were obtained from the Royal Free research team before commencing the fieldwork. These related to the development, implementation, and

evaluation of opt-out BBV testing and the novel HCV pathway of care (see Chapter 2). Additional documents were acquired after, or during, interviews and throughout my time generating data within the prison.

7.1.2 Characteristics of the data

A total of 45 interviews were completed (32 were audio recorded and 13 hand recorded) and 60 field note entries were made (consisting of 565 typed pages). Within these field notes, 30 informal discussions were recorded (with 40 people). A total of 29 documents related to programme implementation were also collected. Further details of the data are summarised in tables 21-23. Table 24 compares the sampling frame for interviews, with those completed (both formal and informal).

Table 21. Summary of interview respondents from the LBCSG (BBV = blood-borne virus; NHSE = National Health Service England; PHE = Public Health England). Interviews came to a total of 462 audio recorded minutes and 296 pages of typed transcript.

Organisation	N=7
BBV lead	1
NHSE commissioner	1
PHE commissioner	1
Hepatitis C Trust	2
GILEAD	1
CareUK commissioner	1

Table 22. Summary of qualitative data for Prison 1 (HCW = healthcare worker; BBV = blood-borne virus). 12 documents constituted 34 pages; 29 field note entries constituted 284 pages; 21 audio recorded interviews constituted 1082 recorded minutes and 931 typed pages of transcript.

Documents	N=12
Healthcare documentation	2
Prison documentation	2
Details of the management structure and BBV pathway	4
Notes made during interviews and talks	4
Observation	Number of times observed
Locating and bringing patients to opt-out BBV clinic	6
Secondary screening	24
Catch-up BBV testing	6
Catch-up secondary screening	6
BBV test offers	169 – 10 different HCWs
Informal discussions	N=16 discussions with 24 people
HCWs	12
Prisoners	3
Governing Governor	1
Prison officers	8
Realist interviews	N=21
Prisoners	5
Prison officers	7
HCWs (including management)	9

Table 23. Summary of qualitative data for Prison 2 (HCW = healthcare worker; BBV = blood-borne virus). 31 field note entries constituted 281 pages; 4 audio recorded interviews constituted 230 recorded minutes and 155 typed pages of transcript; 13 hand recorded interviews constituted 108 pages.

Documents	N=17
Healthcare documentation	6
Prison documentation	1
Details of management/BBV pathway	9
Notes made during interviews and talks	1
Observation	Number of times observed
Primary care secondary screening	16 (twice the clinic was cancelled)
Officers facilitating primary care secondary screening	4
Primary care sexual health clinic	3 (twice the clinic was cancelled)
Primary care catch-up secondary screening	5 (twice the clinic was cancelled)
Primary care wing testing	2
Primary care phlebotomy	7
Primary care “declining”	2
Substance misuse secondary screening	8
BBV test offers	119 – 8 different HCWs
Informal discussions	N=14 with 16 people
HCWs	2
Prisoners	7
Prison officers	7
Realist interviews	Audio recorded (N=4); hand recorded (N=13)
Prisoners	4
Prison officers	4 (one interview with two officers)
HCWs (including management)	10

Table 24. Interview sampling frame and the verbal data acquired from both interviews and informal discussions (HCW = healthcare worker; BBV = blood-borne virus; PC = primary care; SM = substance misuse; HCA = healthcare assistant; CM = custodial manager; SO = supervising officer). Where someone participated in an informal discussion and interview, they were counted once (i.e. duplicates excluded).

LBCSG interview sampling frame	Interview sample
5-8 respondents from: NHS England, Public Health England, Prison Healthcare Providers, Her Majesty’s Prison and Probation Service, GILEAD Sciences Ltd., and the Hepatitis C Trust	All organisations were represented in interviews, except Her Majesty’s Prison and Probation Service
Prison 1 interview sampling frame	Interview sample (excluding duplicates)
Prisoners = 5-12 seeking diversity in decision to test, age, and ethnicity	8 prisoners: Age range: 20-50s. Ethnicity: Middle East, Black, White. 5 accepted a test, 1 refused, 2 did not say whether they tested
HCW = 5-9 seeking diversity in terms of job role and delivery of opt-out testing	15 HCWs: Including head of healthcare, matron, BBV lead, PC nurses, SM nurses, HCAs
Officers = 5-7 seeking diversity in approach to facilitating opt-out testing and job role	12 prison staff: Including Governing Governor, senior healthcare officers, and healthcare officers
Prison 2 interview sampling frame	Interview sample (excluding duplicates)
Prisoners = 5-12 seeking diversity in decision to test, age, and ethnicity	10 prisoners: Age range: 18-60s. Ethnicity: Black, White, mixed. 7 had accepted a test, 1 declined, 2 had not been offered, and 1 did not say whether he tested
HCW = 5-9 seeking diversity in terms of job role and delivery of opt-out testing	10 HCWs: Including head of healthcare, head of SM, BBV leads, PC nurses, SM nurses, and a GP
Officers = 5-7 seeking diversity in approach to facilitating opt-out testing and job role	11 officers: 2 CM’s (responsible for the first night centre), 1 SO, 3 officers detailed to the SM wing, 4 officers detailed to the PC wing, 1 healthcare officer

7.1.3 Data analysis – concurrent analysis and preparing the data

During the field work, analytical ideas about the prison context, programme implementation, and how the opt-out test programme functioned were recorded in interpretive sections of field notes (279). These ideas were then incorporated into future interviews and directed observational work (274,279).

After completing the field work, a number of months were spent cleaning and transcribing the generated data. A professional transcription service was used for all interview audio recordings (276). Using NVIVO 12 pro (developer: QSR International), three separate case files were then created for Prison 1, Prison 2, and the LBCSG stakeholders. Corresponding data (interviews, field notes, and documents) were uploaded into NVIVO as internal sources under each file.

A coding framework based on thematic areas, rather than “context”, “mechanism”, and “outcome”, was developed. This framework initially divided data into “programme activities” and “wider context”. Under each of these, relevant sub-codes were developed (e.g. programme activities: “implementation”, “facilitation”, and “testing”; and for the wider context: “healthcare context”, “prison context”, and “prisoner context”).

I then commenced line-by-line thematic coding (similar to thematic analysis (294)), modifying coding trees with fresh codes inductively generated from the data (295). Once coding of field notes was completed, code hierarchies were re-organised (276). In this way, qualitative data were prepared for the two separate analyses.

7.1.4 Ethics & approvals

Attention was given to ensure the ethical collection and secure storage of data (see details in appendix D) (204). Exemption from the UCL Research Ethics Committee was obtained on the 19th September 2017. Sponsorship for NHS ethical review was sought from the UCL and UCLH Joint Research Office on the 27/11/2017. The Joint Research Office reviewed all project documentation and determined it to be service evaluation on the 13/12/2017 (email confirmation in appendix D). Permission from the Health Research Authority was therefore not considered necessary.

An application was sent to HMPPS’s “National Research Committee” for ethical review, which was approved after minor amendments on the 26/02/2018 (see appendix D). Heads of healthcare from Prison 1 and Prison 2 both provided written and verbal approval for the evaluation to be undertaken. The Governing Governor for Prison 1 and for Prison 2 approved the evaluation on the 09/10/2017 and 18/09/2017 respectively.

Programme implementation (section one)

7.2 Section one: Introduction

In this section I outline how interview, document, and observational data were used to assess each prisons' context and programme implementation. By doing this, I aimed to identify contextual challenges to programme delivery, highlight key programme features (i.e. "resources") that may address these challenges, and explain why these had been implemented, or not, within each prison. I end the implementation section by considering the advantages and disadvantages of each prisons' programme set-up.

7.3 Section one: Method

Coded qualitative data from the comparative case study were used to assess the implementation of opt-out BBV testing upon reception within each prison. Because NHSE and PHE had been flexible about how healthcare providers implemented certain aspects of the programme (78,79), I set-out with the explorative goal of situating opt-out BBV testing within the wider London prison context (296) and explaining programme set-up, rather than quantitatively measuring its characteristics (i.e. dose, fidelity) (274,284).

To begin this process I developed a provisional programme theory using results from Chapter 6, combined with data generated through realist interviews with LBCSG stakeholders (111,113,134). This model outlined how I anticipated an effective opt-out BBV programme to have been implemented, within the context of a local London prison, and was used to guide the analysis.

Information related to different contextual features were then extracted from NVIVO case files, exported into memo documents for Prison 1 and 2, and amalgamated under themes for each prison. For some of these themes I began linking contextual properties to the observed actions of individuals within the prisons and reasons respondents gave for these actions. By doing this, several emergent contextual properties (structures) and their conditioning effects were identified (118).

Finally, data from documents were triangulated with observations and verbal accounts of testing procedures provided during interviews, to develop a model for how the programme was carried out in practice (293). I identified resources within each prisons' opt-out BBV testing set-up, which provided advantages or disadvantages to programme operation in relation to features of the context (284). I then explained how these programme resources had been realised, through the development of realist implementation theories (297).

7.4 Section one: Results

The provisional programme theory (figure 45) included additional interventions that I had produced, and that London prisons were supposed to have implemented, following the RRR (i.e. the opt-out offer script/switching cost form). The model made the following hypotheses:

1. To maximise the proportion of new arrivals offered a test, those that can consent should be offered and tested on the first night, with a phased follow-up for those that cannot. In this way, the programme minimises the chance of attrition through release or prison transfer, whilst ensuring people can consent to testing.
2. Testing clinics should not occur at the same time as activities preferred by prisoners. This will help to ensure that clinics are not missed by people, because they are prioritising their time for this other activity.
3. HCWs should provide pre-test information, designed to help new arrivals assess their risk of infection. The clinic interaction should incorporate resources designed to encourage those concerned that they are at a high-risk of infection to accept testing (e.g. developing rapport and providing supportive information), whilst not presenting major obstacles for those who perceive themselves as low-risk to comply with the opt-out offer.
4. Delivery of opt-out testing is not the norm for HCWs. However, if HCWs are trained and provided with a standard script to offer an opt-out test, variation in the form of the offer can be minimised and a genuine opt-out offer is more likely to be made.
5. If HCWs deliver an opt-out test, prisoners that have a preference to accept, and those that have no clear preference, are likely to agree to be tested for BBV infection.
6. Certain prisoners will have reasons for not wanting to be tested. If HCWs explore these reasons, they may be able to provide information that can subsequently be used to encourage test uptake.
7. Use of an opt-out disclaimer should minimise perverse incentives for HCWs to discourage testing in order to speed-up the clinic consultation. It should also increase the effort required to refuse testing, increasing the switching cost incurred by declining the test (see Chapter 6 for details of the switching cost form).
8. People are strongly influenced by what others do. If an opt-out programme is able to maintain high testing rates, and HCWs present testing as the norm, not testing becomes counter normative. Individuals presented with a culture of testing may focus on the desirable aspects of knowing their serostatus, consider testing to be the “right” thing to do, or not actively consider declining as an option.

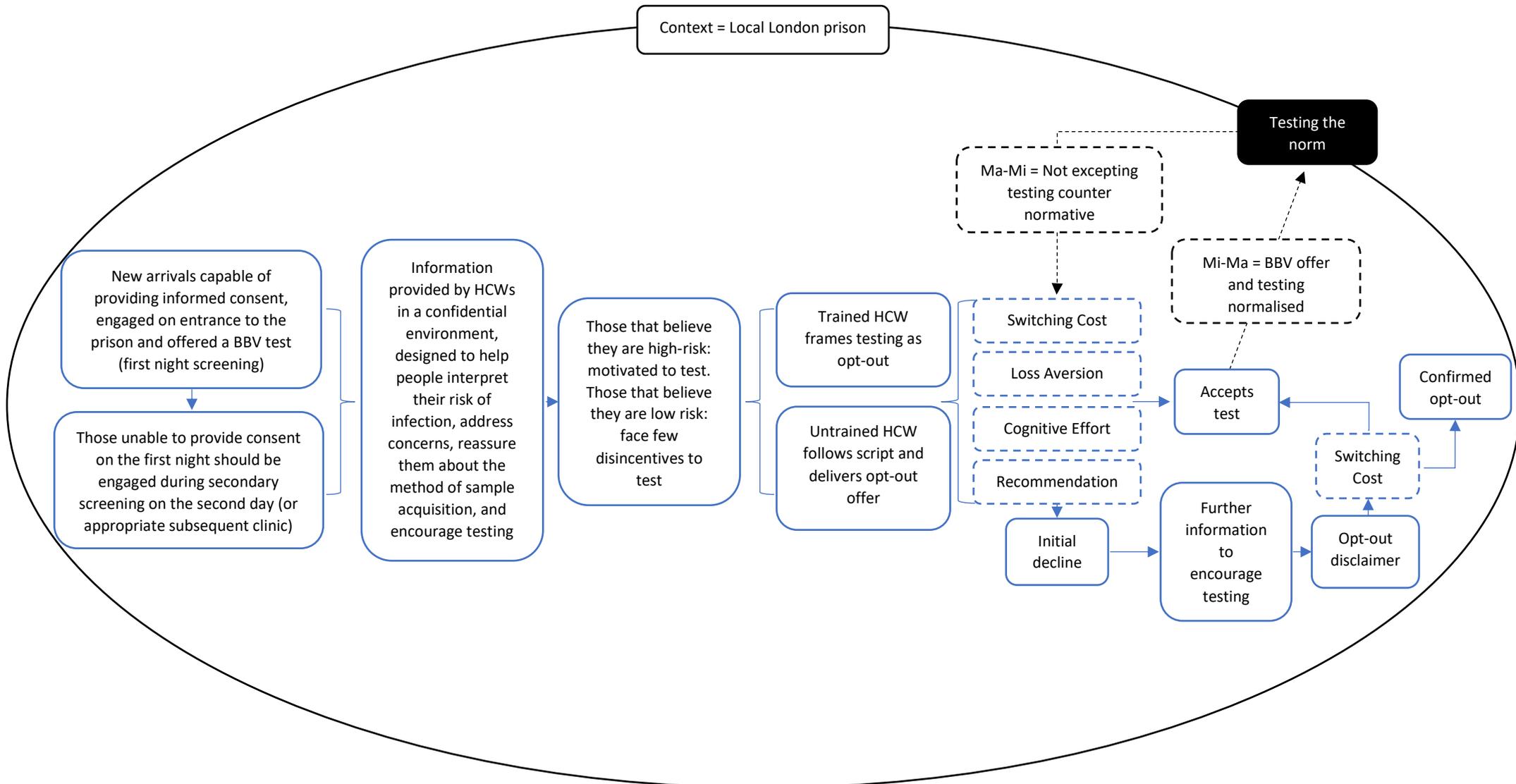


Figure 45. Provisional programme theory for an effective opt-out blood-borne virus test programme within a local prison context, in terms of maximising the number of new prisoners offered a test and tested (HCW = healthcare worker; Ma-Mi = Macro-to-micro mechanism; Mi-Ma = Micro-to-macro mechanism). Model developed using realist programme theory from the rapid-realist review (Chapter 6) and from stakeholder interviews with the LBCSG.

7.4.1 Refined theory: implementation

To understand the geography of a prison, see figure 46. The steps comprising opt-out BBV testing within each prison are summarised in figures 47 and 48 (see pages 149 and 150). Programme implementation in both prisons differed to the hypothesised “effective” process outlined in the provisional programme theory. There were also key differences in programme resources available for opt-out BBV testing within each prison.

A total of 14 realist implementation theories (Mi-Mi), explaining how programme resources had been realised, were developed. In addition, evaluation of the context of both prisons led to the development of a range of conditioning theories (Ma-Mi), which were found to produce an adverse setting for the opt-out programme. Due to space constraints, not all theories could be discussed in the results.

Key implementation theories are presented alongside supporting qualitative extracts (others are available in appendix E). For these configurations: C=context, MaR=ancillary resource (i.e. a property involved in the realisation of a programme resource), MRE=reasoning response, and O=outcome (i.e. realisation of a programme resource). Conditioning theories are also alluded to in the results, but all Ma-Mi theories developed during the analysis are available at the end of the results section (see table 25 – pages 159 and 160).

7.4.1.1 Timing of engagement

Because both prisons incarcerated short stay prisoners, healthcare teams needed to engage new arrivals quickly. However, healthcare providers within both prisons offered BBV testing during secondary screening (the morning after people arrived), rather than during the first night clinic. This occurred because of a perceived lack of time during the first night, because offering testing as people arrived was considered inappropriate, and because testing was not seen to be in line with the objectives of the healthcare team at that time.

CMOc – Timing of engagement: *The first night health check is time-pressured, new arrivals are often distraught or intoxicated, and clinic time is reserved for activities that ensure immediate prisoner safety (C). Opt-out BBV testing addresses non-immediate threats (MaR), so healthcare teams view its inclusion in first night screening as inappropriate (MRE), encouraging the integration of testing into secondary screening and introducing a slight delay to engagement (O).*

Seth: *“Why is it that secondary screening is the place to do it [BBV testing]?”*

Healthcare management (Prison 1): *“Well, firstly you can’t do it [on the first night] because it is time pressured. The guys might have been at court all day. They might have spent an hour or so in the sweat box ... and the focus must be about risk assessment of the most immediate physical and mental health issues that you have to deal with ...”*

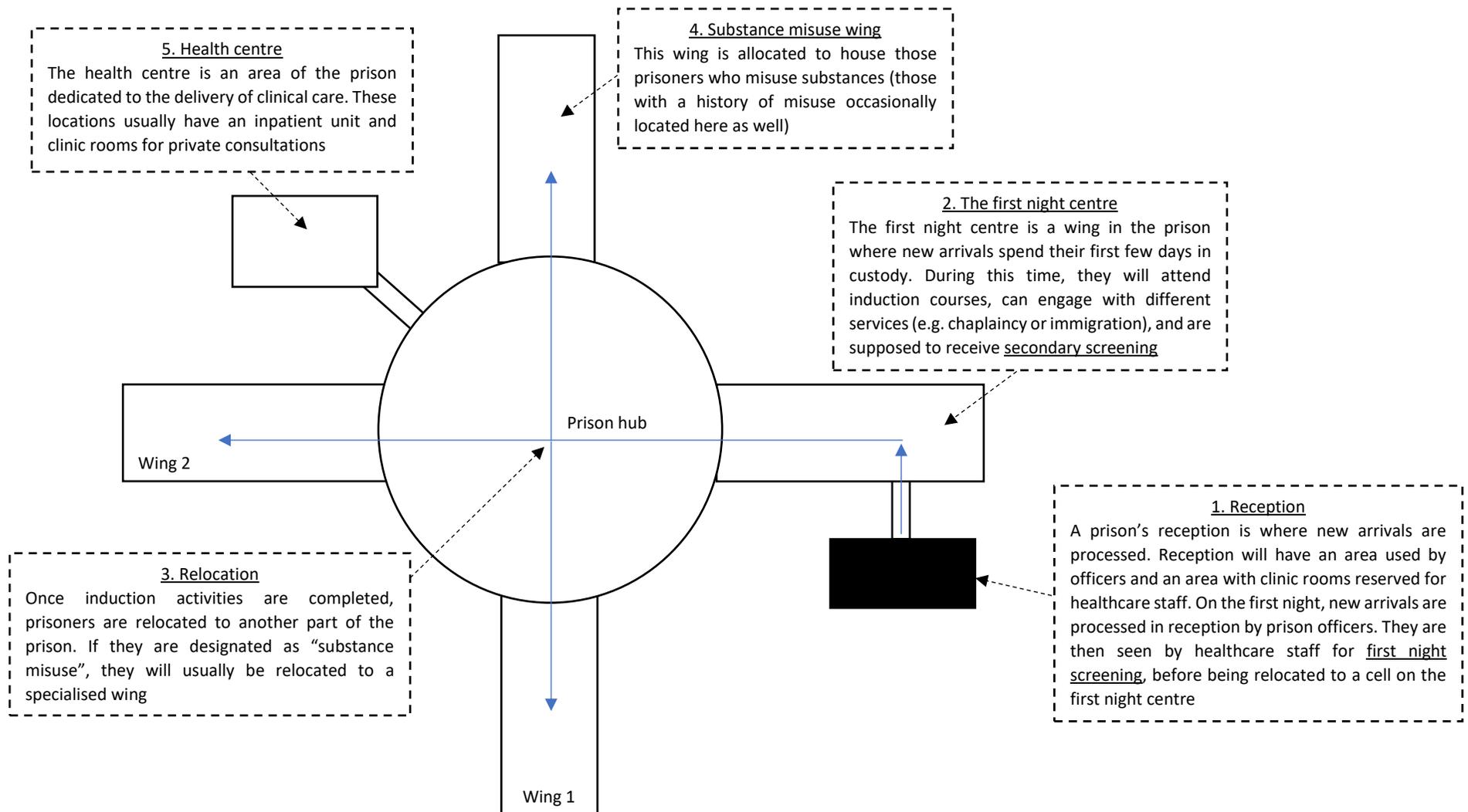


Figure 46. Simplified depiction of a prison. Blue arrows signify the movement of new arrivals through reception, onto the first night centre, and then to another part of the prison. Descriptions of the different areas of a prison have been provided. Note: this is not a reproduction of the geography of either Prison 1 or 2, out of consideration for prison security.

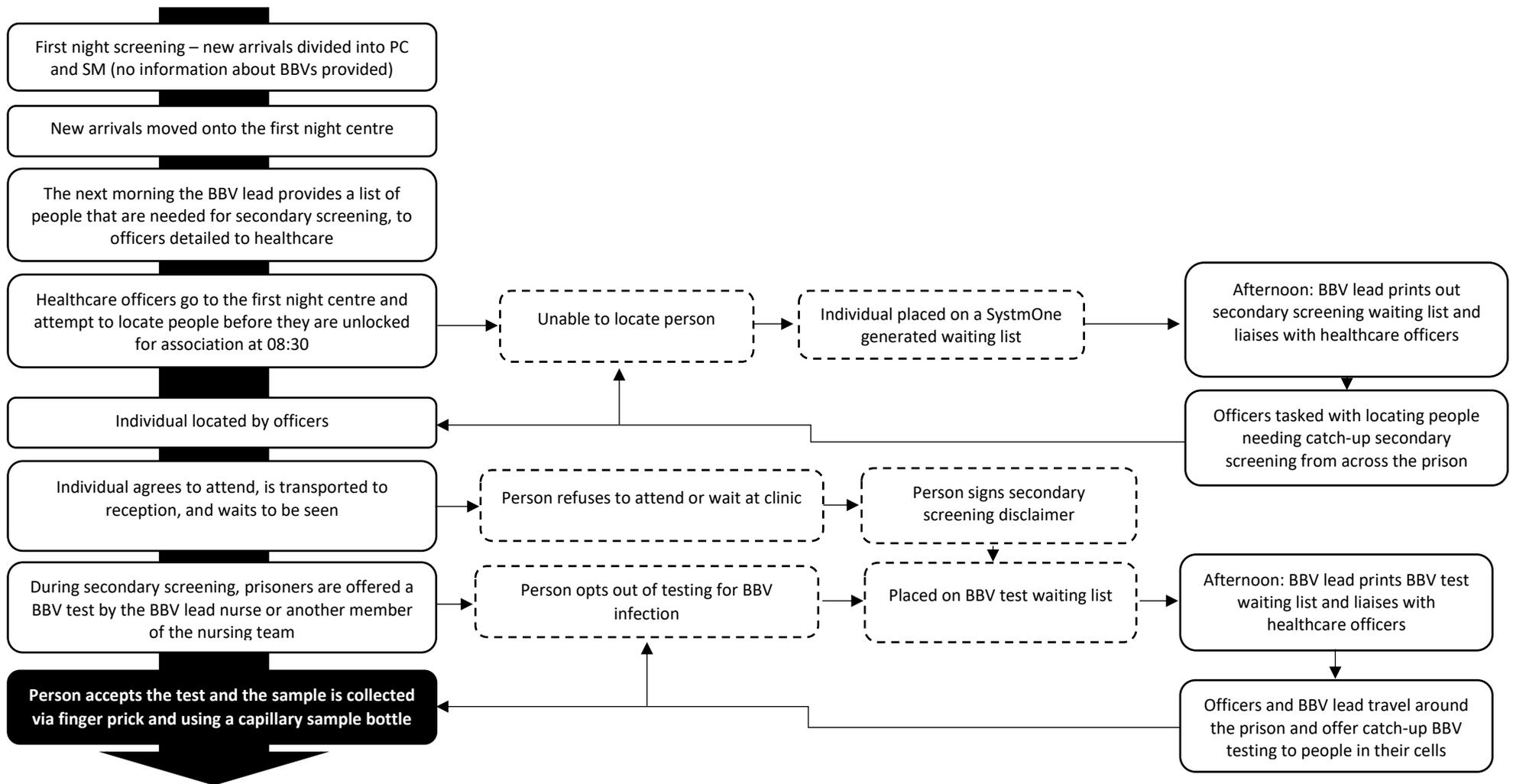


Figure 47. Steps composing the opt-out blood-borne virus test programme within Prison 1 (BBV = blood-borne virus; PC = primary care; SM = substance misuse). Diagram developed by triangulating observational and interview data with prison healthcare documents.

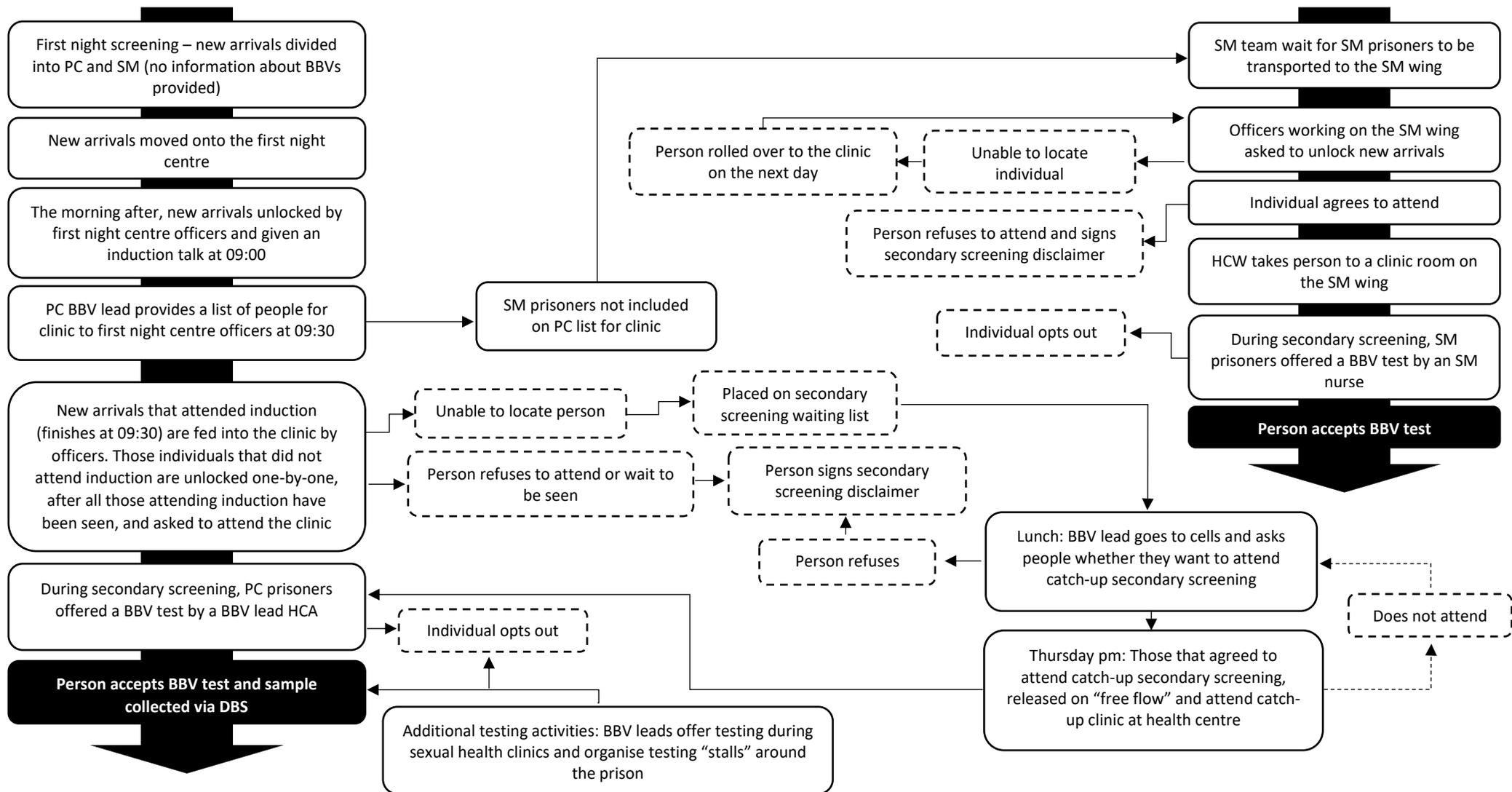


Figure 48. Steps composing the opt-out blood-borne virus test programme within Prison 2 (BBV = blood-borne virus; PC = primary care; SM = substance misuse; HCA = healthcare assistant; DBS = dried blood spot). Diagram developed by triangulating observational and interview data with prison healthcare documents.

7.4.1.2 Clinic facilitation

On the second day new arrivals were locked in cells in the first night centre (FNC) (see figure 46), which meant prison officers were required to unlock them and bring them to the secondary screening clinic. Healthcare providers had two options for this process: rely on officers working on a wing to unlock people or assign healthcare officers (staff allocated by the Governing Governor to support healthcare delivery) to facilitate the clinic.

However, the prison service in both prisons was under pressure from overcrowding and understaffing. Officers assigned to a wing were therefore too busy trying to run the prison regime, meet their own performance targets, and maintain the security and safety of the prison population, to prioritise facilitating healthcare (see conditioning theories in table 25).

Officer: "In the prison the NHS say we've got to keep them healthy. Ultimately, you're in prison, our rules come first because we're prison officers ... And our number one priority is to keep these people in custody, that's it ... Second priority is to keep them safe and that's from fire, self-harm, gang violence, disease, we have to keep them safe ... But there's a big difference between safe and healthy."

Because of this, healthcare management needed to prioritise the small number of available healthcare officers for enabling key clinics. In Prison 1, secondary screening was considered a core part of clinical care, so two healthcare officers were assigned to it. In Prison 2, secondary screening was not prioritised over the delivery of other clinics (such as GP and optician appointments), and so HCWs were reliant on officers, assigned to the wing where secondary screening was being hosted, to unlock prisoners.

CMOc – Dedicated facilitation: *Officers working a wing are overstretched and do not prioritise healthcare. In contrast, healthcare officers are dedicated to enabling the delivery of clinical care (C). If providers have access to healthcare officers and prioritise secondary screening (MaR), they will assign these staff (MRE) to facilitate the clinic (O). If providers do not prioritise secondary screening (MaR), they are more likely to assign healthcare officers (MRE) to facilitate other clinics (O).*

Supervising healthcare officer (Prison 1): *"... having dedicated staff increases the attendance massively, erm and like you said it increases the relationships between the clinical and the operational. My staff who repeatedly come up to [secondary screening] because they're cross deployed here build rapport and have these working relationships ... it just helps you out."*

However, healthcare officers also had increased access to health-related information, because of their time spent in clinics and via their relationships with HCWs. This was problematic because most officers were aware of the high prevalence of infectious disease amongst the prison population and were regularly exposed to body fluids in the course of

their duties; incentivising them to seek out health-related information for personal protection (see theory: “living and working in an infectious environment” – table 25).

Officer: *“If you’re working in an environment where there is a risk of catching AIDS, hepatitis B, or hepatitis C, I think we should know who has it, so you can take precautions. After all, getting one of these things would change your life.”*

People incarcerated within the prisons also expressed concerns about coming into contact with an infectious disease and attempted to acquire information through various means, including during interviews.

Prisoner: *“Yeah, like on G-wing at the moment, there is word trickling that TB is spreading. . . You know anything about TB?”*

Seth: *“Yeah, I know a bit about TB, although it isn’t the focus of this research ...”*

Prisoner: *“Do you know what is going on with G-wing? Is there TB getting spread about?”*

Seth: *“I’m not too sure, I haven’t heard anything ...”*

Prisoner: *“Yeah, well the word is getting about. Apparently, some guys have been walking around wearing those mask things, you know the ones Chinese people are always wearing. People are saying it’s because of the TB ...”*

This paranoia around infection meant disease detection programmes, like opt-out BBV testing, were supported by officers and prisoners alike, as a proxy form of self-protection. However, healthcare providers needed to ensure that rigorous confidentiality standards were maintained, so that testing worked for the benefit of the individual prisoners and not as a means of facilitating a witch-hunt for “infectious” people within the prison.

Seth: *“And do you think it’s important to do opt-out blood borne virus testing in the prison?”*

Officer: *“What? Oh, this is where they haven’t got to give their blood, I think that’s bullshit. Sorry, no everyone should have their blood tested.”*

Seth: *“Everyone, mandatory?”*

Officer: *“Mandatory, yeah.”*

Seth: *“How come?”*

Officer: *“Because I want to know if anyone’s carrying anything, right? Again, I’m thinking of safety here.”*

7.4.1.3 Physical location

In both prisons the nursing team was split into Primary Care (PC) and Substance Misuse (SM) departments and prisoners were similarly divided along these lines. In Prison 1, healthcare management had arranged for secondary screening to take place in the health centre (see description in figure 46), but this was under renovation at the time of the fieldwork.

Instead, new arrivals were taken back to the reception area by healthcare officers, which was appropriately resourced for the provision of clinical care and had the space (i.e. clinic rooms)

for PC and SM staff to run the clinic together. The management team also enforced a professional culture where PC and SM staff were expected to work together to see all new arrivals. However, the decision to conduct secondary screening in reception meant prisoners had to wait to be seen in an uncomfortable “holding cell”. In addition, the clinic took place at the same time as association (free time out of the cell where people could wash, make phone calls, and socialise), meaning those attending risked missing this activity (see implementation theory “opportunity cost” in appendix E).

In Prison 2, officers assigned to facilitate secondary screening were also responsible for running the FNC’s regime and maintaining the security of that location. This meant that they were tied to the FNC and were unable to transport new arrivals to another area of the prison for secondary screening (e.g. reception or the health centre).

Instead, secondary screening took place in a renovated cell located on the FNC. At the time the clinic was run, prisoners were locked in cells or finishing induction activities (hosted next door), meaning officers could slowly feed them into the clinic. However, the renovated cell was not large enough for PC and SM staff to deliver the screening together. Use of the room had informally become PCs, frequently forcing SM staff to wait for their patients to be transferred to the SM wing, where they could then be seen in a converted cell (figure 48).

CMOc - Integrated working: *Nursing services are often split into PC and SM (C). When healthcare management have an ethos of integrating these two groups (MaR) and provide the physical space so that staff can conduct secondary screening together (MaR), HCWs share the responsibility (MRE) and work as one team to see new arrivals (O). When PC and SM work separately (MaR), staff are positioned to compete (MRE) in order to access their specific patients (O).*

Seth: *“Why did you want to work in both substance misuse and primary care?”*
HCW (Prison 2): *“Well as you know there is a big entrenched divide between primary care and substance misuse. They live in a world of their own and we work in our world completely separate. So, I wanted to try and create a link between these two departments and facilitate dialogue as it is you know ... it’s good to know both sides of the work, rather than just throwing patients at each other ...”*

In addition, because HCWs in Prison 2 used clinic rooms on the wing, they spent more time around prisoners and commonly witnessed violent incidents. For inexperienced staff (particularly amongst the PC team), this helped entrench perceptions that the prison was dangerous, and encouraged some staff to avoid certain locations and minimise engaging with prisoners (see theory: “a dangerous environment” – table 25).

Field note (Prison 2): *Outside I hear one prisoner shouting, “I’m not fucking going back in that cell. It’s filthy bruv you can’t fucking make me. See what I’ll do if you*

come near me, you cunt” ... I head back into the clinic room where the HCW is on her own again. She shakes her head, saying she has never felt so vulnerable in all her time working at [Prison 2]. She berates the officers for unlocking so many people and tells me, “I was in such a panic that I forgot to offer anyone a test. I think I tested the first person, but I was just declining everyone after that as more guys started to come down ...”

7.4.1.4 BBV leads

Opt-out BBV testing was an additional burden on already over-stretched healthcare teams. In response, the LBCSG provided financial resources for a “BBV lead” to be recruited within each prison. In Prison 1, the healthcare provider recruited a Band 6 nurse who worked across PC and SM departments. This lead was supported in delivering secondary screening each day by an HCA, another nurse (from either PC or SM), a pharmacist, and a GP.

In Prison 2, healthcare management recruited two HCAs assigned to work with PC but struggled to recruit an HCA to work with the SM team. BBV lead HCAs delivered secondary screening each day (unsupported by any other staff) for PC prisoners. However, they refused to see SM patients as they were not considered to be their responsibility. This meant secondary screening for SM prisoners was left to be run by different nurses from the SM team, almost all of whom were agency staff (see figure 48).

Recruitment of BBV leads provided ownership and encouraged individuals occupying the post to maximise testing. However, the lack of a BBV lead amongst the SM team within Prison 2 meant nobody was championing testing amongst this high-risk sub-population (see conditioning theory: “Defining their role” - table 25).

CMOc – BBV champion: *Healthcare teams within prisons are overstretched and the inclusion of BBV testing into routine practice represents an additional task for staff (C). By appointing someone to act as a “BBV lead”, responsibility for championing the programme is vested in that individual (MaR), incentivising them (MRE) to maximise testing (O). When interdepartmental working does not take place and a department lacks a BBV lead (MaR), existing staff from that department take-on the additional burden of testing (MRE) but do not champion the programme (O).*

BBV lead (Prison 1): *“So, this screening is available to them and we need to sell it as best as we can because I actually think it's a wonderful opportunity. I actually believe in it. Do you understand? And I think that's where the crux is, is that I've bought into this screening programme, I believe in it ...”*

7.4.1.5 Emergencies

Healthcare teams within both prisons faced an overwhelming number of daily medical emergencies. These occurred in part because the under resourced organisations that

comprised the prison system were unable to provide the large number of incarcerated people with the support they required. Prisoners were often bounced between multiple agencies or made to follow convoluted protocols, seemingly designed to limit the number of requests staff received, rather than effectively fulfilling their needs.

HCW (Prison 2): *“You ask any prisoner; they’ll feel like they’ve been passed around.”*

Seth: *“Yeah, why is that?”*

HCW (Prison 2): *“Because there’s so many areas of work. So, there’s just so many areas. Like in terms of like even today the guy asked for a phone here, that’s not my area so I have to pass him to someone else, you know. You can never just get information out of one person for everything, you know? So, it’s constant passing people around. You know I’m not a nurse, so I’ll pass you to the nurse and then they don’t know how to deal with it, so you’re passed onto the doctor. You know it’s just ... It’s not easy for the boys in jail.”*

Out of desperation, some prisoners were incentivised to manipulate the system by inflicting violence on themselves. This challenged the prison’s priority of “safety” and in so doing, forced staff to provide them with the attention they desired (see “Patronage” and “Degradation” theories – table 25).

Field note extract (Prison 2): *The “code red” [emergency] that we responded to was in relation to an individual who had been repeatedly cutting his throat. This individual was known to have been engaging in self-harm, but the staff appeared to be more resentful than distressed. One nurse I spoke to told me that the individual knew that there were “algorithms” that the system had to go through if he hurt himself and so knew it was a way of “gaming” the system.*

In Prison 1, a dedicated emergency team was formed from senior HCWs that responded to events around the prison, freeing other HCWs to deliver secondary screening (and other clinics) uninterrupted. In Prison 2, staff shortages meant that healthcare management were required to assign junior HCWs to the emergency team. Concerned that these staff would not be able to handle certain clinical situations, management requested that all HCWs in the prison respond to emergencies, including those delivering secondary screening.

CMOc - Ring fenced test delivery: *Medical emergencies are common within prison and often require experienced clinicians (C). If healthcare management are able to create a dedicated emergency team, composed of experienced HCWs (MaR), other staff are freed (MRE) to focus on delivering clinics like secondary screening (O). If management rely on a more junior emergency team (MaR), they may take the conservative approach (MRE) of instructing all HCWs to respond, placing clinic delivery in a state of uncertainty (O).*

Field note extract (Prison 2): *The PC BBV lead tells me that it used to be that only “hotel 7” (the emergency team) would respond, but that occasionally other*

people were needed. Therefore, it was decided that all staff “should just go”. She comments saying “it’s annoying because it just delays everything even more”.

7.4.1.6 Training and dissemination of LBCSG information

As part of the implementation of the London Prisons Project the LBCSG arranged training events, hosted by either GILEAD or the Hepatitis C Trust, for staff working in the London prisons (see Chapter 2). However, neither organisation initially covered what opt-out meant in-depth or provided specific information on how to deliver an opt-out offer.

Following the RRR, the BBV opt-out offer script was adopted by both organisations for training, meaning new staff that attended one of their sessions should have been informed (see Chapter 6). However, the LBCSG relied on those attending steering group meetings to disseminate information to established staff. Healthcare management from both prisons decided to attend meetings (so BBV leads could concentrate on testing), but their attendance was intermittent, and information was not always relayed back to BBV leads or other staff.

Consequently, confusion around the concept of an opt-out offer persisted and no staff in either prison routinely used the offer script or switching cost form; although there was diffusion of knowledge that opt-out required a change in the way consent was elicited.

CMOc - Information dissemination: *Baseline training did not cover what opt-out meant and how it should be offered (C). The LBCSG incorporated this information into future training sessions and relied on staff attending steering group meetings to disseminate information via word of mouth (MaR). Healthcare management from the prisons failed to properly disseminate information to members of staff (MRE), meaning confusion around opt-out persisted (O).*

Seth: *“... the Steering Group towards the end became a place of innovation ... Do you think [this was] actually filtering down to the front line?”*

Healthcare provider (LBCSG member): *“No so that’s it, I don’t think they filter down. Meetings happened on a Friday, so then the weekend happens, um, Heads of Healthcare didn’t attend consistently ... perhaps there should have been more actions taken in terms of feeding back.”*

7.4.1.7 Catch-up secondary screening

Within both prisons, provisions had been made to engage people who missed the secondary screening clinic (and consequently BBV testing). However, once new arrivals had completed induction activities on the FNC, they were quickly relocated to another part of the prison.

In Prison 1, individuals that were still resident on the FNC were rolled to the following day’s secondary screening clinic. For those people that had been relocated, a “catch-up secondary screening” clinic was hosted in the afternoons by the BBV lead (frequency based on the volume of people missed). Healthcare management prioritised the assignment of two

healthcare officers to collect relocated individuals in the afternoon, allowing the BBV lead to engage people regardless of their location. However, communication issues occasionally meant that these officers were not aware that the afternoon clinic was taking place, resulting in process breakdown (see “balancing integration and autonomy” theory – table 25).

Prison 1 (field note): *I ask where the officers are and the BBV lead tells me that they probably waited for us but have now been sucked into another job. She tells me that the healthcare officers we are waiting for are “brilliant”, so it is probably management’s fault because they arranged staff training, which delayed the commencement of the clinic, but did not inform the officers ...*

Within Prison 2, PC and SM teams similarly rolled missed prisoners, located on the FNC or substance misuse wing (respectively), to the following day’s secondary screening clinic. However, healthcare management did not provide either nursing team with healthcare officers to facilitate catch-up secondary screening, meaning they lacked the capacity to actively engage people moved to different locations.

Instead, SM HCWs had to try and convince officers, working on the wing where an individual was located, to transport that person to the SM wing for clinic. However, these officers were tied to their wing by safety protocols and facilitating a clinic was not included in their job profile. If SM staff were unable to “pull a favour” and get someone brought to the clinic, they had to wait in the hope that the person would eventually be relocated to the SM wing.

For PC prisoners on other wings, PC HCWs were expected to travel around the prison during lunch (when prisoners were locked in cells) and ask them, through their doors, whether they wanted to attend a catch-up appointment. These were held on Thursday afternoons at the health centre. Those who agreed were unlocked during Thursday afternoon “free flow”, a period of time after lunch where prisoners could move without officer escort to various locations across the prison for work, recreational activities, or medical attention.

CMOc – Outreach: *New prisoners are relocated to another part of the prison once induction activities are completed (C). When management prioritise healthcare officers for facilitation of secondary screening (MaR), HCWs can use these officers to source prisoners regardless of their location (MRE), which means access to BBV testing is not constrained by a person’s location (O). When no officers are supplied (MaR), HCWs lack the capacity to outreach (MRE) and have to find alternative means of getting people that missed secondary screening, moved to an area where they can be engaged (O).*

Healthcare officer (Prison 1): *“... you know if I do it [facilitating catch-up secondary screening] it’s like right I’m going to go get E wing twos and threes.*

Bring them over, go get E wing ones and fours, bring them over, go get a couple from D wing, bring them over and then push all the people from E wing back ...”

7.4.1.8 Catch-up BBV testing

Within both prisons, those individuals that declined to attend secondary screening were not offered a BBV test. As a result, healthcare teams within both prisons had developed “catch-up BBV test activities” to try and engage these people.

Within Prison 1, the BBV lead employed a targeted approach using a waiting list generated on SystemOne. On afternoons when catch-up secondary screening was not required, the lead would print this waiting list and travel around the prison, escorted by the two healthcare officers assigned to the clinic. Officers provided access to peoples’ cells, where the BBV lead would then offer a test for BBV infection and complete sample acquisition. Process breakdown resulting from miscommunication between officers and HCWs, which similarly affected catch-up secondary screening (see section 7.4.1.7), also impacted these activities.

In Prison 2, healthcare management had developed a waiting list, but this was not used by PC BBV leads as they were concerned management would use it to “monitor” their activity. Instead they set-up a stall in the gym, library, or on a wing periodically, and offered testing to anyone they could access. They also offered testing during self-referral sexual health clinics. However, PC BBV leads did not conduct these additional activities on the SM wing.

In addition, no SM staff carried out catch-up testing activities for their defined population, because they lacked a BBV lead to champion this activity and staff did not believe BBV testing was something that needed to be done outside of the secondary screening encounter. As a result, there was no provision for those SM patients who declined secondary screening to be actively engaged for testing.

CMOc – Targeted catch-up testing: *People that have declined secondary screening need to be followed-up and offered a test but may be scattered across the prison (C). If HCWs know who has been missed (i.e. by developing a waiting list), have the capability to access them, and the motivation to do so (MaR), they are able to focus their efforts (MRE) on providing targeted outreach (O). When HCWs avoid using a waiting list and do not have officer support (MaR), they are limited to offering testing semi-randomly (MRE) to those people that are out of their cells (O). When staff are not motivated to maximise testing (MaR), they do not take the time (MRE) to implement catch-up test activities (O).*

Field note extract (Prison 2): *As we walk, I probe to see how the PC BBV lead knows who has been tested and who hasn’t. I had noted that there didn’t seem to be any kind of list that staff were working from. She tells me it is just “in her head” or people ask for a test ...*

Table 25. Conditioning theories constructed during in-depth context evaluation of two local London prisons (HCW = healthcare worker).

Theory	Interaction between contextual features	Conditioning mechanism ----->	= Conditioning of decision making (outcome)
Hierarchies of priority	<i>Lack of prison staff to run the regime, large numbers of prisoners, and legislation that necessitates people receive certain services as a human right</i>	<i>Unable to provide a full complement of services for all, prison staff are incentivised to ensure that most prisoners receive the services required to meet their basic human rights</i>	<i>Prison staff are required to cancel the facilitation of services that fall outside of what is considered “basic human rights” (i.e. gym, library, certain forms of healthcare) when short of staff</i>
Officers as bureaucrats	<i>Large numbers of prisoners, combined with low operational staffing levels</i>	<i>Officers focus on meeting targets that ensure people have the bare minimum that they are entitled to and that officers can protect their role in the event of inquiries</i>	<i>Officers encouraged to engage in a form of care delivery more preoccupied with demonstrating all required bureaucratic actions have been taken, rather than ensuring people receive the physical and psychological support they actually need</i>
Strained working and dependence	<i>Large numbers of prisoners, low staffing levels, and reliance on officers to provide access to people. Officers are not held directly responsible for the performance of services commissioned by other organisations</i>	<i>Prison officers lack the time to complete all their tasks and so are incentivised to complete core duties associated with their role</i>	<i>Prison officers incentivised to prioritise prison tasks, for which they are held directly responsible, rather than helping facilitate the work of other organisations (including healthcare services that do not ensure a prisoner’s immediate safety)</i>
Security everyone’s priority	<i>By virtue of differing roles, HCWs and prison officer priorities do not align. However, the common conceptualisation of what a prison is (i.e. a secure institution to safely hold people), fits with officer priorities. This is reinforced by the physical layout of these institutions and the “regime”, which dictates the structure of each prison day</i>	<i>Dominant culture entrenches officer priorities</i>	<i>Prison officers encouraged to believe that their work should take priority. The cancellation of healthcare clinics so that resources can be prioritised for maintaining prison priorities (i.e. security and safety), seen as a natural response by prison officers</i>
		<i>Dominant culture conflicts with HCW priorities</i>	<i>HCWs encouraged to believe prison officers’ work should take priority and may acculturate, taking on social aspects of the dominant prison culture. The cancellation of clinics for prison purposes seen as a natural part of prison healthcare</i>
Balancing integration and autonomy	<i>Prison cultural attitudes are dominant and healthcare management are concerned about staff taking on inappropriate aspects of this culture. They also need to maintain patient confidentiality, but are reliant on prison officers to provide access to patients</i>	<i>Healthcare management incentivised to deliver services in a manner that ensures the autonomy of healthcare maintained</i>	<i>Healthcare management encouraged to perpetuate an institutional divide between their department and the prison service, by keeping communication channels, IT systems, and meetings separate, risking logistical confusion</i>
Living and working in an infectious environment	<i>Officers and prisoners are aware of the high prevalence of infectious disease. Violence in prison is commonplace and the physical environment is cramped, dirty, and decaying</i>	<i>Individuals are incentivised to seek out information related to infectious diseases for self-protection</i>	<i>Officers interacting with healthcare staff are encouraged to seek out confidential information related to infectious diseases for self-protection or the protection of other friends in the prison</i>
			<i>Prisoners interacting with healthcare are incentivised to seek out confidential information for self-protection or the protection of other friends in the prison</i>

Table 25. Continued.

Theory	Interaction between contextual features	Conditioning mechanism ----->	= Conditioning of decision making (outcome)
Care exhaustion	<i>Large numbers of patients, complex patient needs, risk of manipulation, dehumanisation of “prisoners”, rule-based system, and a lack of time to provide in-depth care</i>	<i>HCWs, aware that they cannot meet all patient needs, are incentivised to provide a basic level of care sufficient to defend themselves in the event of an inquiry</i>	<i>HCWs encouraged to engage in a form of care delivery more preoccupied with demonstrating that the appropriate actions have been taken, rather than ensuring that the patient has received the person-centred care that they require. Rigid adherence to healthcare protocol becomes a method of controlling the work burden</i>
Defining their role	<i>Large numbers of patients, complex patient needs, risk of manipulation, and a lack of time to provide in-depth care</i>	<i>HCWs, aware that they cannot meet all patient needs, are incentivised to provide a basic level of care sufficient to defend themselves in the event of an inquiry</i>	<i>HCWs encouraged to prioritise tasks that are conceptualised as a core part of their role and for which they may be held accountable for. HCWs incentivised to ignore tasks that are not seen as integral to their role and for which they will not be held directly responsible</i>
Patronage	<i>Ineffective and confusing service protocols, combined with an urgent need to access certain resources</i>	<i>Prisoners are incentivised to try bypassing formal protocol</i>	<i>Prisoners incentivised to attempt to access resources via the cultivation of social relationships with members of staff. Through these relationships, prisoners may be able to by-pass formal protocol and acquire information or other resources more rapidly</i>
Degradation	<i>Ineffective and confusing protocols combined with an urgent need to access certain resources, but inability to obtain patronage</i>	<i>Prisoners are incentivised to try to manipulate the system</i>	<i>Prisoners incentivised to engage in behaviour that threatens a core priority of the prison. In this case, acts of self-degradation are enacted in order to threaten their “safety” and, in turn, the mandate on the prison service to keep all prisoners safe during their period of incarceration</i>
A dangerous environment	<i>High numbers of violent incidents (witnessed by staff), staff spend more time working on the wing, fewer officers, officers perceived as unable to enforce discipline or protect healthcare staff</i>	<i>Healthcare staff perceive their place of work as an unsafe environment, incentivising them to take precautionary action</i>	<i>Healthcare management encouraged to enforce restrictive rules about how HCWs engage patients, at what times, and in what locations; even at the expense of ensuring prisoners can access non-urgent clinical care HCWs encouraged to reconsider how and where they engage prisoners and may impose self-determined restrictions on how they carry-out their work within the prison environment</i>

7.5 Section one: Discussion

Interview, document, and observational data from two local London prisons delivering opt-out BBV testing (one higher and one low performing) were analysed. This was done with the objectives of outlining programme implementation and assessing the wider contextual conditions present within the two prisons. By assessing both features, the suitability of implemented programme resources could be considered, in terms of their ability to mitigate the effect of challenging contextual pressures (110,118).

A range of contextual features were identified that could frustrate the delivery of opt-out BBV testing (table 25). However, two stood out: a culture amongst prison officers of not prioritising the delivery of clinical care and an informal incentive structure placed on prisoners that encouraged acts of self-inflicted violence, in order to leverage attention from overstretched services (276). Both conditions have been noted in previous qualitative work within Irish, UK, and US prison settings (238,276,298).

Despite the partnership agreement between healthcare, social care, and the prison service (81), data suggested that a cultural imbalance persists within English prisons (189,298). Although security and safety are undoubtedly important aspects of incarceration, it is similarly crucial that healthcare services are prioritised by prison officers and other operational staff (1). Not only is this important for ensuring compliance with principles of care equivalency, but could bring social, penal, and economic benefits, by reducing health inequalities and recidivism (61,299,300).

It is also vital that further research be carried-out to explore the social impact of limited service access in prisons (276). Confusing prison, health, and social service protocols meant that the two prisons took on properties of a “violent bureaucracy” (301); where for some people, committing acts of “degradation” (commonly self-inflicted violence) appeared to be the only passport for accessing the support they needed (276). Strategies designed to reduce “illegitimate” prisoner requests may instead fuel self-harm, burdening healthcare teams and forcing them to prioritise reactive rather than proactive care.

Both of these contextual conditions are likely exacerbated by the austerity enforced on the English prison service and the current judicial approach of mass incarceration (69,75). It is therefore crucial that current efforts to bring about structural and social reform to the prison estate (65), include policies designed to move these institutions towards becoming health promoting environments, both for the benefit of BBV programmes and the delivery of wider clinical care (2,62,75).

7.5.1 Programme implementation

When assessing programme implementation, I wanted to go further than simply describing the BBV testing process and identifying beneficial or inhibiting programme resources. I also wanted to explain how these resources were realised within each prison, by developing realist implementation theories. In this way, I hoped to better understand why healthcare providers had made certain decisions about the implementation of opt-out BBV testing within their prison (79,83,85).

Data highlighted some similarities in programme design between the two prisons, with BBV testing performed at second reception (i.e. secondary screening) and catch-up activities implemented for those people that missed or declined to attend the clinic. Healthcare teams in both prisons were also strongly opposed to the idea of testing during a prisoner's first night in custody, both for logistical reasons and because testing for BBV infection was not seen to "fit" with the priorities of staff or patients at that time.

However, by including testing within secondary screening, staff introduced a slight delay to engagement. Officers were also required to facilitate the secondary screening clinic in both prisons, meaning that the success of BBV testing was linked to the priority that these staff placed on healthcare delivery and their ability to locate and move prisoners to the required location (table 26) (238).

The assessment of programme implementation also revealed pertinent resource differences between the two prisons (table 26). The willingness of healthcare management in Prison 1 to assign healthcare officers to facilitate secondary screening brought several benefits. First, these officers were dedicated to facilitating healthcare, whereas officers assigned to a wing had to split their time between enabling clinics (for which they were not held directly responsible) and running the regime (for which they were held directly responsible). Healthcare officers were also not tied to a particular location, allowing secondary screening to take place in reception (so SM and PC jointly deliver the clinic) and providing HCWs with the capability to access new arrivals regardless of their location (189,298).

However, use of healthcare officers to facilitate clinics may present greater challenges to medical confidentiality, because officers are incentivised to acquire information about "infectious prisoners" for self-protection, and through the increased time these officers spend in clinics and the relationships that they develop with HCWs. A failure by healthcare management to avoid a timetable clash between secondary screening and association also introduced competing incentives for prisoners to attend the clinic within Prison 1 (table 26).

Table 26. Summary of key programme features and associated resources (in italics) between Prison 1 and Prison 2 (PC = primary care; SM = substance misuse; BBV = blood-borne virus; LBCSG = London blood-borne virus core steering group).

	Programme feature	Prison 1 (resources)	Prison 2 (resources)
	PC and SM integrated working	Yes <i>(staff share responsibility to see all prisoners, relationships build between the two nursing departments)</i>	No <i>(staff are only responsible for seeing their designated patients, development of relationships between the two groups stifled, staff positioned to compete for access to their prisoners and healthcare facilities)</i>

Secondary screening

	Programme feature	PC & SM (resources)	PC (resources)	SM (resources)
	Timing	Second day <i>(delayed engagement)</i>	Second day <i>(delayed engagement)</i>	First week <i>(extended delay to engagement)</i>
	Clinic reliant on officer facilitation	Yes – healthcare officers <i>(performance dependent on prison staff, officers are dedicated to facilitation, officers not tied to a location, officers and healthcare staff build relationships, potentially greater risk of confidentiality breaches)</i>	Yes – wing officers <i>(performance dependent on prison staff, wing officers not dedicated, officers tied to a location, limited capacity for officers and healthcare staff to build relationships)</i>	Yes – wing officers <i>(performance dependent on prison staff, wing officers not dedicated, officers tied to a location, limited capacity for officers and healthcare staff to build relationships)</i>
	Clinic clashes with desirable activity	Yes <i>(strong competing priorities for attendance)</i>	No <i>(weaker competing priorities for attendance)</i>	No <i>(weaker competing priorities for attendance)</i>
	Location of clinic	Reception <i>(perceived safe environment, allows integrated working, requires prisoner transport, uncomfortable waiting area)</i>	Wing <i>(perceived unsafe environment, does not require officer transport, no waiting area, inhibits integrated working)</i>	Wing <i>(perceived unsafe environment, does not require officer transport, no waiting area, inhibits integrated working)</i>
	BBV lead	Yes <i>(testing led by staff incentivised to maximise testing)</i>	Yes (x2) <i>(testing led by staff incentivised to maximise testing)</i>	No <i>(nobody championing testing amongst the department)</i>
	Staff follow LBCSG guidance	No <i>(confusion around what opt-out is and how it should be delivered)</i>	No <i>(confusion around what opt-out is and how it should be delivered)</i>	No <i>(confusion around what opt-out is and how it should be delivered)</i>
	Ring-fenced delivery	Yes <i>(delivery of testing not dependent on medical emergencies occurring around the prison)</i>	No <i>(testing dependent on medical emergencies occurring around the prison)</i>	No <i>(testing dependent on medical emergencies occurring around the prison)</i>

Table 26. Continued.

Catch-up secondary screening

Programme feature		PC & SM (resources)	PC (resources)	SM (resources)
	Engaging missed prisoners still on the first night centre (or substance misuse wing in Prison 2)	Rolled to the following day's secondary screening clinic <i>(minimal delay to engagement)</i>	Rolled to the following day's secondary screening clinic <i>(minimal delay to engagement)</i>	Rolled to the following day's secondary screening clinic <i>(minimal delay to engagement)</i>
	Engaging missed prisoners relocated to another area of the prison	Dedicated healthcare officers <i>(staff dedicated to the task of collecting prisoners, staff able to transport people from across the prison to the clinic, delivery reliant on officers, officers available every day)</i>	Free flow <i>(attendance at clinic dependent on motivation of prisoners and officers correctly unlocking the prisoner for free flow)</i>	No set protocol – favour-based request to wing officers <i>(escorting prisoners to clinic not part of the officer's job, prisoners require transportation, favour-based process, delivery reliant on officers)</i>
	Regularity of clinic for relocated prisoners	Whenever necessary <i>(minimal delay to engagement)</i>	Weekly + waiting list <i>(extended delay to engagement)</i>	Dependent on whether an officer agrees <i>(extended delay to engagement)</i>

Catch-up BBV testing

	Catch-up testing has dedicated officer support	Yes <i>(healthcare staff can access cells, healthcare staff can move around the prison under officer escort (safety), prisoners can be transported to a location by officers, testing reliant on officers)</i>	No <i>(healthcare staff limited in where they go in the prison by personal and mandated safety considerations, healthcare staff cannot access cells, healthcare staff cannot get prisoners escorted to a location, testing not reliant on officers)</i>	No process implemented <i>(no provision to test those declining secondary screening)</i>
	Format of testing	Cell-based testing <i>(semi-private environment, moderately safe – with officer escort, active engagement)</i>	Wing-based testing <i>(open environment, potentially dangerous, mostly passive engagement)</i>	N/a
	Targeted testing	Yes – waiting list used <i>(healthcare worker able to focus on those that have not been tested)</i>	No – waiting list not used <i>(healthcare worker reliant on memory or prisoner self-report to identify those who have not been tested)</i>	N/a

Within Prison 2, healthcare management did not prioritise healthcare officers to support secondary screening (and by extension BBV testing), meaning programme delivery either relied on busy officers tied to a particular wing to provide access to prisoners, or was geared around engaging people at times when they had already been unlocked (298). In addition, because healthcare management could not implement an experienced emergency response team, those delivering secondary screening were also required to respond to medical emergencies, risking disruption to the screening process (table 26) (238,298).

The fragmentation of programme delivery across autonomous PC and SM departments within Prison 2, also appeared to complicate the process of BBV testing. Staff in the two groups were positioned to compete for access to clinic rooms and officers to access patients, whilst the lack of BBV lead within the SM team meant that there was nobody championing the programme within the SM department (table 26).

Facing large numbers of patients with complex needs, SM staff were focused on aspects of their job for which they were held directly responsible. As no single individual was responsible for BBV testing, it had been side-lined by busy staff and no provisions were made to implement catch-up testing activities. Consequently, programme implementation within Prison 2 actually appeared to concentrate vital programme resources (i.e. staff incentivised and enthusiastic to maximise testing and catch-up test protocols) away from this prisoner sub-group who were at a higher risk of HCV infection (72,76,302).

Finally, results highlighted a break-down in the information dissemination protocols used by the LBCSG. This meant that interventions, such as the opt-out offer script and switching cost form, had not filtered down to front-line staff working within Prison 1 and 2 (223,271). As a result, there was a risk that variability and poor practice in test delivery would be perpetuated and that perverse incentives for HCWs to encourage people not to test (see “switching cost form” in Chapter 6) would remain (38,271).

The LBCSGs formation by NHSE has arguably had a positive impact in terms of performance monitoring, provision of finances for a BBV lead, and for acting as a multi-agency forum to help guide the implementation of the London Prisons Project (78). However, if the groups necessary evolution from programme implementation to project management, research, and refinement is to be achieved, stakeholders need to ensure that the interventions and guidance discussed at meetings are implemented in practice throughout the various London prisons (274).

Programme function (section two)

7.6 Section two: Introduction

In this section I analyse how prisoners, HCWs, and prison officers responded to implemented programme resources in semi-predictable ways to produce programme outcomes (111). Focus is placed on two outcomes of interest: the proportion of new arrivals offered a test and the proportion that accepted a test for BBV infection.

7.7 Section two: Method

Interview and observational data from code trees were extracted and input into a memo document for Prisons 1 and 2 (135,279). Data were grouped around different stages of the testing process, identified during the assessment of programme implementation (see section one of this chapter). A rough framework was then developed using this information, which detailed the relationship between each stage and their associated outcomes.

Programme outcomes were usually defined qualitatively. However, for the secondary screening encounter I developed a quantitative spreadsheet on Excel 2016, using data generated via semi-structured observation. This data provided information on when a test offer was observed, which HCW had made the offer, how consent had been elicited, and the person's decision in response to an offer. Consent elicitation was categorised as:

- “Opt-in” – person asked whether they would like to test;
- “Opt-out” - person told they will be tested, with some form of consent check;
- “Hard opt-out” - person told they will undergo a test, with no form of consent check;
- “Coercive/mandatory” - person told they have to test, or not told anything about what is taking place.

Using this spreadsheet, I was able to conduct a quantitative assessment of test offer and acceptability. Confidence intervals were calculated using Stata 15 (StataCorp, 2017). This partially compensated for the fact that I had been unable to assess test acceptability during the quantitative analysis of programme outcomes (see Chapter 5).

Data were then configured and iteratively developed into CMO configurations, which explained how programme resources were drawn on in specific contexts to produce outcomes (111). Constellations of CMO configurations, relating to a particular programme outcome, were finally amalgamated and abstracted to produce a middle-range programme theory for each stage of the opt-out BBV test programme (111,295).

7.8 Section two: Results

Outcome frameworks developed during the analysis are presented in figures 49 and 50 (see pages 168 and 169). These divided the operation of opt-out BBV testing into four stages: initial engagement, secondary screening, catch-up secondary screening, and catch-up BBV testing. Each stage is discussed, supported by data extracts, and concluded with a middle-range programme theory. Lower-level programme theories, detailing granular aspects of programme function, can be found in appendix F. Additional supportive qualitative data can also be found in appendix F.

7.8.1.1 Stage 1: Initial engagement

The success of opt-out BBV testing hinged on the ability of the programme to minimise the numbers of new arrivals that declined to attend secondary screening, those that were missed, and attrition through release or transfer (figure 49 and 50). In terms of mitigating attrition, rapid engagement was vital. However, because healthcare providers embedded testing into secondary screening, a minority of very short stay individuals left before being engaged; making some loss inevitable within both of the prisons.

This was exacerbated by the disunity between PC and SM within Prison 2, which meant HCWs from the two departments competed for access to the FNC clinic room. Despite attempts from SM staff to “work around” PC, they were routinely made to wait for their designated patients to transfer to the SM wing, adding additional delays to engagement that enhanced the risk of attrition amongst this high-risk sub-population.

Seth: ... these people located on different wings; do they ever miss [secondary screening]?

SM HCW (Prison 2): Yes yes, sometimes we do lose some as bearing in mind this is a remand prison so many of our clients are only here for a short period of time. By the time you realise that you have someone located on a different wing, he has been transferred or moved to a different court ...

Missing people during secondary screening was also inevitable for both programmes, as some individuals were engaged in legal procedures on the second day, were held in segregation (i.e. solitary confinement as a form of punishment) or were attending personal visits. However, the resources available for clinic facilitation were crucial in determining what proportion of the physically available pool of new arrivals could be successfully engaged by the healthcare team.

Staff, for example, had limited windows of time to engage prisoners around the regime (morning: 08:00-11:30; afternoon: 13:00-16:30) and had to continually adapt the delivery of services to the shifting circumstances of the prison.

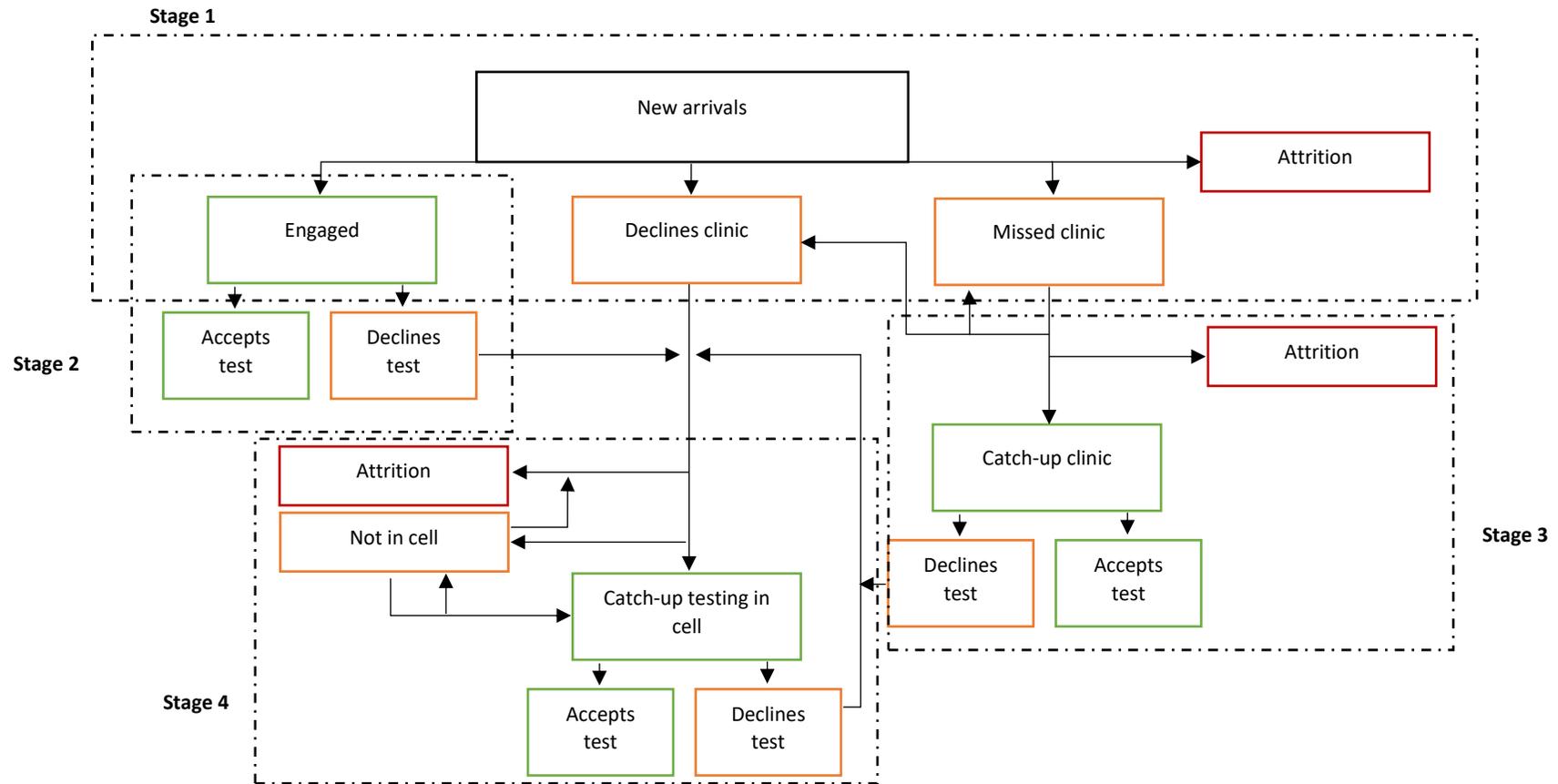


Figure 49. Prison 1 outcome framework. Colours represent whether a stage is part of an intended programme process/outcome (green), a planned for intermediate stage/outcome (orange), or an unintended/unwanted outcome (red). Programme processes are also divided into four conceptual stages (stage 1 = initial engagement; stage 2 = secondary screening; stage 3 = catch-up secondary screening; stage 4 = catch-up blood-borne virus testing). In Prison 1, these processes worked in synergy to ensure that most new prisoners were engaged and offered a test.

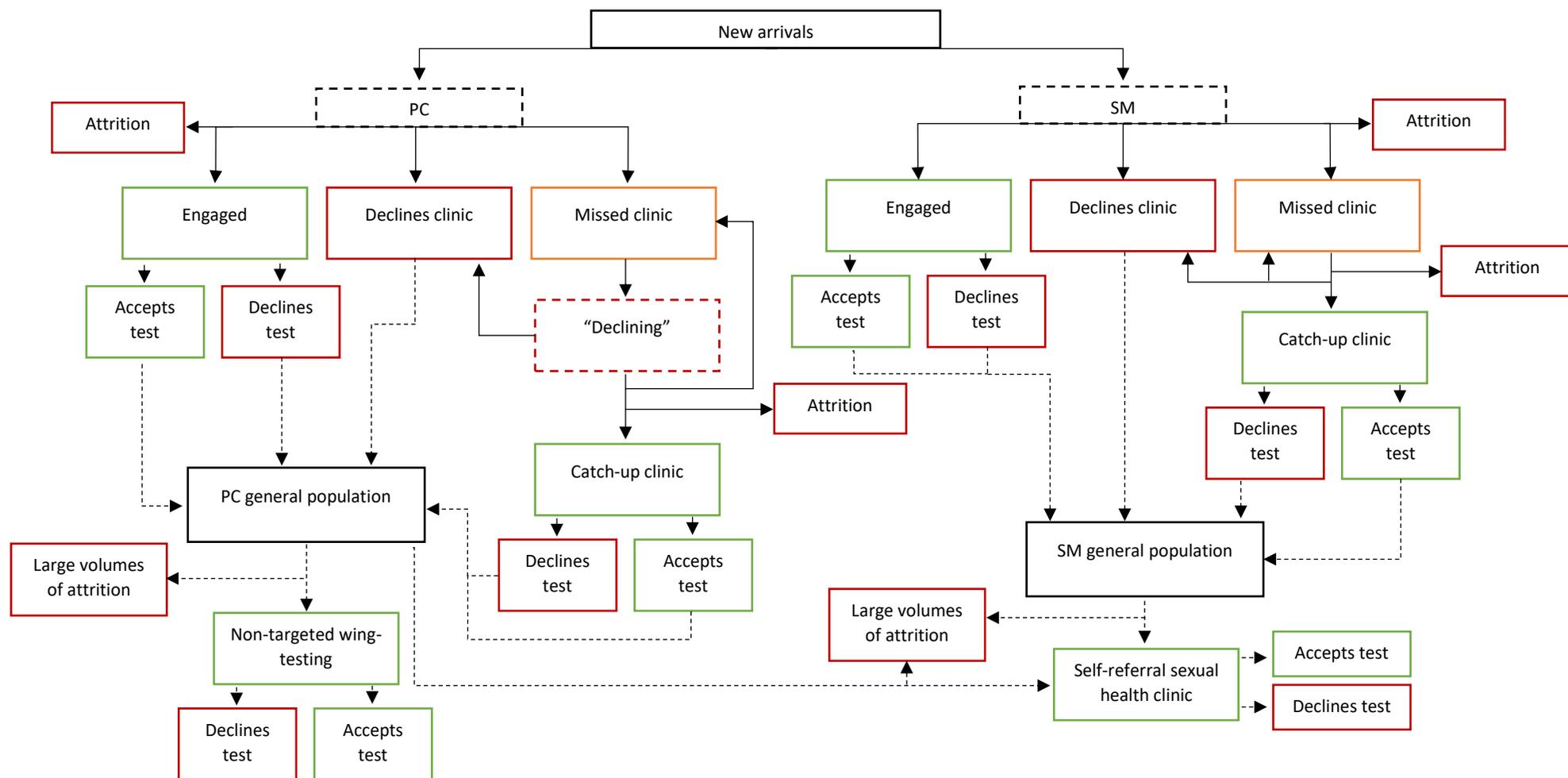


Figure 50. Prison 2 outcome framework. Colours represent whether a stage is part of intended programme process/outcome (green), a planned for intermediate stage/outcome (orange), or an unintended/unwanted outcome (red). Dotted arrows signify how new prisoners who either accept, decline, or miss a test, can be engaged in a self-referral sexual health clinic and via primary care wing-testing. In Prison 2, the various components of the test strategy did not work in synergy, meaning the programme experienced a large amount of attrition. In addition, primary care prisoners had greater opportunity to be tested, thanks to additional wing-based testing activities.

Within Prison 1, strong working relationships between healthcare officers and HCWs meant that the two teams collaborated to work around incidents. In contrast, within Prison 2 each team adapted work practices independently, in response to changing circumstances. This disrupted agreed protocols, creating delays that risked staff not being able to see all available new arrivals within the windows of time afforded by the regime.

FNC officer (Prison 2): *“...the only issue comes about if healthcare is late [note: they started arriving late as the BBV leads felt unsafe and didn’t want to deliver the clinic on their own]. You know they are meant to be here at half nine but sometimes they are turning up at ten or eleven and then running around getting upset that we have locked the guys back up. Turn up on fucking time then.”*

The capabilities vested in the differing officer roles also shaped access. Despite an agreement between healthcare and prison management that all new arrivals would be located on the FNC for a few days before relocation, in reality varying numbers of new prisoners were scattered across different wings of both prisons upon arrival because of space limitations. In Prison 1, healthcare officers had the flexibility to locate people from across the prison. In contrast, officers assigned to a particular wing were tied to it by work and safety protocols, meaning HCWs (both PC and SM) within Prison 2 could not access, and therefore missed, these scattered individuals.

Healthcare management (Prison 2): *“The prisoners come here, they are processed and then they come [to the FNC], and in theory, they have to spend their first five days in this area. The problem that we have in [Prison 2], [is] that actually maybe 40% of prisoners were not located here ... Um, they could end up scattered all over, and that’s why we are missing them ...”*

Clinics were also regularly cancelled or delayed within Prison 2, by wing officers when they were short staffed (and therefore focused on running the regime), and by the PC and SM team in order to respond to emergencies around the prison. The way programme resources were operationalised within Prison 2, therefore meant a sizeable proportion of new people were being missed during initial engagement.

Field note extract (Prison 2): *... a senior officer enters the FNC and marches over to us snapping, “your friend has been complaining about the setup here. You have got two officers, what’s the problem?” A little taken aback, the BBV lead defends herself, “we are trying to run [secondary screening] and the officers are just not bringing us the people”.*

As she is saying this, one of the officers is coming down the stairs behind the senior officer, who shouts over to him “hey [X], the nurses are saying you are not getting the patients for them, what’s going on?” Angrily he shouts back “the list

is with [another officer], she is not doing fucking anything, and I am trying to run this whole wing, what do you want me to do?"

Finally, healthcare providers needed to encourage people to agree to attend the clinic, but within the design of both programmes, “prisoners” were conceptualised as passive entities, with no incentives to encourage attendance incorporated as part of programme implementation. However, inherent within the process of attending a clinic were two commodities: companionship and the opportunity to be out of the cell, both of which were highly valued by some prisoners.

Prisoner (Prison 2): *“... some people are just thinking ‘I can’t be in the cell’ and so they think ‘if I cut myself the officer will have to come and talk to me’, so you get some company, and then they will usually have to take you to see a nurse as well. All of this time is time out of your cell. It sounds stupid, but just walking down that landing is a little taste of freedom and you forget for a second that you’re in jail because you’re not behind that door [points at door].”*

Healthcare teams in both prisons were aware of this, but the clinic needed to fit with the wider prison regime and therefore the timing had to be negotiated with the prison service. Within Prison 2, the screening took place when prisoners had finished induction and faced being locked back in cells, meaning most were eager to capitalise on the relative freedom afforded by clinic attendance. In Prison 1, the clinic occurred simultaneously with association, which meant numerous new prisoners prioritised this free-time and declined to attend, particularly as attendance meant waiting in a cramped holding cell.

Healthcare officer (Prison 1): *“Erm, a lot of them refuse because they ... they're honestly ... the issue ... they don't want to miss association. Because in association they get to chat to their friends, they can have their showers, things like that and they just don't want to miss it. Basically, it's where they're doing their deals. It's how you get your drugs and your tobacco and everything, that's what they don't want to miss.”*

Successful engagement for secondary screening was therefore found to hinge on a range of programme resources. These allowed staff to work as a team and dedicate their time to engaging new prisoners, whilst incentivising prisoners to attend the clinic.

Initial engagement middle-range theory: *The reception process of local London prisons is chaotic, officers working on a wing are overstretched, and new arrivals may be incarnated for short periods of time, as well as being scattered across the prison (C). Under these conditions, the capacity to engage all new arrivals quickly – regardless of their location (MR), partnership working between officers and HCWs (MR), the ability to incentivise prisoner attendance (MR), and having ring-fenced staff (MR), ensures all three stakeholder groups prioritise the clinic (MRE), maximising the number of new prisoners initially engaged (O).*

7.8.1.2 Stage 2: Secondary screening

For those new arrivals successfully engaged, HCWs needed to ensure that they maximised the numbers consenting to test. However, BBV testing was just one aspect of the secondary screening encounter, which involved numerous other physical and mental health assessments. The clinic was also chronically time pressured, as HCWs struggled to see large numbers of new arrivals before they needed to be locked-up for lunchtime “count”.

***Field note extract (Prison 2):** One BBV lead checks her watch ... She tells her colleague that they are going to have to get the men in and out as quickly as possible that morning. She tells me, “There’s just no love and no care. You have to just spit ‘em out because there’s no time”.*

Under these conditions, the motivation of BBV leads to maximise testing became a critical resource. For these staff, testing for BBV infection was conceptualised as the key component of the screening encounter. For other HCWs, BBV testing was afforded the same priority as other aspects of the clinic. This manifested in different approaches to clinic delivery, which influenced patient receptivity prior to the test offer, the way testing was framed, and whether staff spent time encouraging hesitant people to test.

In terms of maintaining receptivity, HCWs needed to assess prisoners quickly and tailor their interaction to fit with the person’s needs. Although a minority of people were unreceptive to healthcare intervention upon entrance (often because they were angry or distrusted the service), others became unreceptive as the clinic progressed. This occurred within both prisons because some prisoners made requests for medical intervention that HCWs were unwilling or unable to meet. Within Prison 1, people also disengaged with the clinic in an attempt to speed-up the encounter so that they could get back to the wing for association.

Without the time to develop relationships with all new arrivals, it made sense for HCWs (particularly within Prison 1) to deliver the clinic quickly and offer testing early to most people while they were still receptive, whilst taking the time to establish trust and placate those individuals who were unreceptive upon entrance. However, many HCWs did not tailor their interaction, instead following template questions on SystemOne designed to structure the encounter. This was often done formulaically, with some staff spending little time trying to get to know their patient or establish rapport.

***BBV lead ([prison removed]):** “...BBV screening is way down the line. So, here’s a man ... he’s on the [first night centre], there’s association yeah. And bang on in the time that we’ve got to get them to clinic, right ... and you’ve got nurses going word for word by the template, yeah and not looking at the man ... So, by the time they get to do the BBV thing, the man is exasperated. There’s a nurse*

just typing away, she hasn't looked at him for one second, yeah ... and it's like 'oh erm we need to do a BBV test, do you want it done?' 'No fuck off, I don't need this test, no I don't want it done' ... So for me when they come in here I'm like 'mate, the first thing we're doing is BBV'."

BBV leads from both prisons were notable exceptions. Because maximising testing was a core part of their professional role, they were more willing to tailor their interaction around the test offer. This involved offering testing to most people as soon as they entered the clinic, whilst spending time building rapport or providing emotional support to those prisoners that were perceived to require it.

The format of the test offer was the next crucial component. Contrary to the provisional programme theory (figure 45 – page 146), no HCWs employed a pre-test discussion designed to motivate prisoners to test, arguing that an in-depth discussion about the viruses put people off (in Prison 1 this delayed people returning to the wing for association and in Prison 2 HCWs felt it made testing seem abnormal). Instead, the information provided by HCWs usually only covered what the test was for, although some staff employed norms ("everyone is being tested") and included information on the method of sample acquisition ("it's just a finger prick").

Consent elicitation was embedded within this, and in the absence of an offer script to help guide delivery, showed inter and intra HCW variability (table 27). BBV leads and some HCWs were aware that new arrivals shouldn't be asked whether they "wanted a test" under an opt-out system. These individuals tended to elicit consent by framing testing as an "opt-out" or "hard opt-out" offer. Other HCWs were unaware of what opt-out meant and so defaulted to presenting testing as opt-in.

BBV lead (hard opt-out): *"Good morning, come in, come in, I need you to wash your hands for me. I just need to do a quick blood test for you to check for hepatitis C, hepatitis B, and HIV"*.

HCW (opt-in): *"... would you like to have a blood test? It is just a small one from the finger and it will test for hepatitis C, hepatitis B, and HIV?"*

However, in the absence of a defined rule for what constituted consent, some staff (notably certain BBV leads) seemed to stretch principles. One BBV lead was observed straying into coercive test offers, where people were not told what was happening unless they asked (table 27). Hard opt-out offers were also delivered as instructions, blurring the lines between an optional intervention and a mandated command; with some HCWs admitting that they framed testing in this way in the hope that prisoners would believe it was compulsory.

Table 27. Form of consent elicitation observed being delivered by healthcare workers during secondary screening (BBV = blood-borne virus; SM = substance misuse; PC = primary care). Variation occurred as a result of different conceptions of what “opt-out” meant and because delivery was influenced by the social dynamic between staff and prisoners.

Healthcare worker	Opt-in	Opt-out	Hard opt-out	Coercive/mandatory
Prison 1				
BBV lead	0	8	70	0
Nurse 1 (SM)	1	2	0	0
Nurse 2 (PC)	0	1	0	0
Nurse 3 (PC)	8	1	0	0
Nurse 4 (SM)	9	0	0	0
Nurse 5 (SM)	1	0	0	0
Nurse 6 (PC) – trained by BBV lead	0	1	3	0
Nurse 7 (PC) – trained by BBV lead	0	2	1	0
Nurse 8 (SM)	0	1	6	0
Nurse 9 (PC)	5	0	0	0
Prison 2				
BBV lead (PC)	5	6	9	0
BBV lead (PC – left)	0	4	1	0
BBV lead (PC – replacement)	0	7	19	3
Nurse 1 (SM)	2	0	1	0
Nurse 2 (SM)	4	1	0	0
Nurse 3 (SM)	1	0	0	0
Nurse 4 (SM)	1	0	0	0

To compound concerns, test offers were often made without the use of a translation service. In Prison 1, HCWs had access to “LanguageLine” (a phone-based translation service), but some staff would only use it when there was no other means of communication, as waiting for a translator extended the consultation. Within Prison 2, staff did not have access to LanguageLine and so relied on other prisoners, officers, or Google Translate to communicate, risking both a poor translation and breaching the confidentiality of medical information.

Field note extract (Prison 2): *The HCW motions for the person to sit down. She then loads Google Translate and types: “we are going to test you today for hep C and HIV is that okay?” I try and explain that the translation software may not know what “hep C” is, as she turns the screen so that the person can see the output. However, to my surprise he nods and says “okay”.*

The test offer was also commonly made in an environment that wasn’t confidential, as many HCWs left their clinic room doors open in both prisons out of fear of being assaulted. Officers and prisoners, who often waited outside and observed that most people were getting tested, mentioned that those people refusing to test may have something to hide. Consequently, open testing may have placed social pressures on prisoners to avoid counter normative behaviour, in order to demonstrate to those observing that they were not infected (note: this works both ways: if everybody refuses, those that don’t become counter normative).

Healthcare management (Prison 1): *“One thing I find about secondary screening, as eggs are eggs, if your first couple of patients for the day take the test, the rest of them follow.”*

Under these conditions, framing testing as opt-out or hard opt-out seemed to steer most people into taking a test (acceptance under opt-out offer: Prison 1 = 88% and Prison 2 = 94%; hard opt-out acceptance: Prison 1 = 84% and Prison 2 = 73%). In line with expectation, fewer people accepted a test in response to an opt-in offer (acceptance under opt-in: Prison 1 = 54% and Prison 2 = 62%). Justifications for not wanting to test included religious or spiritual beliefs, having HCV already, paranoia related to how the blood sample would be used, aversion to invasive procedures, having tested recently, and not considering themselves to be at risk.

Prisoner (Prison 1): *“Cos in a prison nobody trusts nobody, so how would you expect me to go and listen to a nurse ... you see them as the ‘other side of the door’. So, how’re you gonna trust them, you don’t know what’s in that needle ...”*

Once again, motivation to maximise testing became a critical component in shaping HCWs’ responses to this hesitancy. A minority of HCWs accepted patient hesitancy on face value. These individuals often expressed little motivation to test people and seemed to prefer prisoners declining as this sped-up the consultation. Had the switching cost form been appropriately implemented, this perverse incentive may have been negated.

HCW (Prison 1): *“Erm it takes longer to test ... so I think nurses are turned off er persuading patients to have it. So, if they say no straight away, I feel like some people will just go okay.”*

Other HCWs did attempt to encourage hesitant people to test, often by providing information on transmission risk or by reassuring the individual that the finger prick would not hurt. However, it was uncommon that someone changed their mind (proportion deciding to test after expressing hesitancy or refusal: Prison 1 = 33% and Prison 2 = 44%).

BBV leads were the most successful at encouraging testing (proportion of people encouraged to test by BBV leads: Prison 1 = 80%; Prison 2 = 100%). Leads tended to be more persistent, often framing opting out as something that required justification and reinforcing that everyone in the prison was getting tested. In Prison 1, the BBV lead also informed prisoners that testing had been sanctioned by religious leaders, that it was a duty to protect others, and framed healthcare as a way of subverting the prison system (“don’t imprison your health”). However, at times encouragement strayed into pressuring behaviours, potentially invalidating the voluntary aspect of consent.

Field note entry: ... [as the] patient nervously enters, the nurse says, “wash your hands for me, I need to do a quick blood test.” He stops short behind her chair and asks “what?” [Eastern European accent]. The nurse responds, “don’t worry it is just a finger prick test”, but the patient says “no, no” and begins to back out of the clinic room. At this point the nurse is sitting at her desk, trying to contort around without moving her chair back and running him over. She calls, “come in, come in, I can’t see you!”

As he reluctantly moves towards the chair, she continues, “we have to screen everybody ...” but the patient interrupts “I no want”. She continues speaking, “because hepatitis is a problem in the jail, and we have a duty of care to check. If you are negative, we will vaccinate and if you are positive, we treat.” He responds, “But I no have it”. The nurse continues, “It isn’t a matter of whether you have it, it is about protecting other people. Because of the violence in the prison, one drop can lead to infection. We have a duty of care to make sure people do not have it. Are you scared of the needle?” The patient tries to avoid responding, so she continues, “you need to give me a very good reason why you do not want to do this test”. He eventually concedes, “I no like the prick”. Smiling, the nurse responds, “it is a tiny prick, I will hold your hand ... come my friend, I won’t cause you harm” and so he gives her his hand.

In this way, BBV leads were found to achieve a high acceptance rate (table 28). The two prisons also had the same test acceptance rates overall during observation (Prison 1 = 86%; Prison 2 = 86%). However, in Prison 2 there was a noticeable difference in test acceptance between the two nursing departments (PC tested 91% of those offered; SM tested 62%).

Table 28. Number of blood-borne virus test offers observed, accepted, declined, and acceptance rate per healthcare worker within two local London prisons (BBV = blood-borne virus; CI = confidence intervals; PC = primary care; SM = substance misuse).

Healthcare worker	Number of offers observed	Accepted	Declined	Acceptance (%) and 95% CI
Prison 1				
BBV lead	79	75	4	95 (87.5-98.6)
Nurse 1 (SM)	4	1	3	25 (0.63-80.6)
Nurse 2 (PC)	1	1	0	100 (2.5-100)
Nurse 3 (PC)	9	6	3	67 (29.9-92.5)
Nurse 4 (SM)	9	6	3	67 (29.9-92.5)
Nurse 5 (SM)	1	1	0	100 (2.5-100)
Nurse 6 (PC)	4	4	0	100 (39.8-100)
Nurse 7 (PC)	4	3	1	75 (19.4-99.4)
Nurse 8 (SM)	7	6	1	86 (42.1-99.6)
Nurse 9 (PC)	5	3	2	60 (14.7-94.7)
Prison 2				
BBV lead (PC)	21	18	2	86 (63.7-97.0)
BBV lead (PC – left)	6	5	1	83 (35.9-99.6)
BBV lead (PC - replacement)	30	29	1	97 (82.8-99.9)
Nurse 1 (SM)	3	2	1	67 (9.4-99.2)
Nurse 2 (SM)	7	5	2	71 (29.0-96.3)
Nurse 3 (SM)	2	1	1	50 (1.3-98.7)
Nurse 4 (SM)	1	0	1	0 (0-97.5)

Motivation to test prisoners for BBV infection was therefore found to be a critical resource for maximising patient receptivity and encouraging testing during secondary screening. However, without clear guidance on informed consent and with consideration to the vulnerability of prisoners to coercion, practices were observed that blurred the line between an informed and voluntary intervention and a mandatory procedure.

Secondary screening middle-range theory: *Secondary screening is a time pressured environment within local prisons and HCWs will need to interact with a range of newly incarcerated people, some of whom will be resistant to engaging with healthcare or testing for BBV infection (C). Staff motivation to maximise test acceptance (MR) can manifest in beneficial behaviours, such as tailoring the interaction (to maximise prisoner receptivity), framing the choice as opt-out, and being more persistent at encouraging testing (MRE). However, it is critical that this motivation is combined with clear and enforced guidelines on how testing should be delivered and what constitutes informed consent (MR), in order to ensure that prisoners are provided with an offer that consensually steers them into accepting a BBV test (O).*

7.8.1.3 Stage 3: Catch-up secondary screening

New arrivals who missed secondary screening needed to be rapidly engaged to reduce their risk of attrition (see figures 49 and 50). Within Prison 1, the combination of engaging missed people during subsequent secondary screening clinics (for those still located on the FNC) and catch-up secondary screening clinics (for those that had been relocated), hosted in the afternoons and facilitated by healthcare officers, ensured that the team was able to see missed people quickly.

Within Prison 2, rolling missed prisoners (either located on the FNC or substance misuse wing) to the following day's secondary screening clinic was also effective at ensuring they were caught-up quickly. However, problems occurred when people were moved to, or already located in, different areas of the prison.

The SM team encountered issues getting busy officers, assigned to manage one of the prison wings, to agree to transport patients to and from the SM wing for the catch-up clinic. As a result, healthcare staff usually had to wait in the hope that the patient would eventually be transferred to a cell within the SM wing, where they could be more easily engaged. This introduced large delays to engagement, which commonly resulted in attrition.

Field note extract (Prison 2): *The SM nurse tells me that a key problem they face is that they have patients on other wings, but primary care staff refuse to see them. Accessing these people involves finding a landing officer and "begging" them to escort the patient to the SM wing.*

She tells me that it is “very difficult” to get officers to do this because officers forget, are short staffed, or have other priorities. She tells me that even when they do bring a patient, officers pressure nurses to see the person within a couple of minutes, so they can go back to their landing and continue with their own job.

For the PC team, the weekly catch-up clinic hosted on Thursday afternoons was not regular enough (only 5-6 appointment slots). Prisoners also used the opportunity to be unlocked during “free flow” to deal drugs or socialise, rather than attend the clinic. This meant PC BBV leads struggled to keep the waiting list down and expressed concerns that they would be disciplined by management because of this. Under pressure, HCWs began discouraging people from attending the catch-up clinic, a process that became known as “declining”.

Field note extract (Prison 2): *I ask how many new arrivals have been relocated to other wings and the HCW informs me fourteen! I ask what will happen to these people and she tells me that they will have to “decline them” ...*

We head to the wings, approach a door, and the HCW knocks on it. She shouts through a crack in the side, “is your name [X]? You feeling fit and healthy?” I hear the occupant respond “yeah” and so she continues, “so instead of booking you in for a clinic where all we will do is check your blood pressure, which is a bit pointless, can I get you to sign this?”

The occupant is hesitant and begins asking questions about what he is being asked to sign. The HCW reassures him by saying, “well you had a blood pressure check when you came in yeah? So, this is another one that we do but you don’t really need it”. The person eventually agrees to sign ... She thanks him, and I offer to hold the secondary screening disclaimer form. We move to the next cell ...

Indeed, this process became semi-formal policy within Prison 2 and was outsourced to “prisoner healthcare reps” for a few weeks, before they were caught dealing drugs. Nevertheless, because of this informal “declining” process, large numbers of missed PC prisoners were convinced by staff to sign forms stating that they refused to attend secondary screening within Prison 2. The lack of reliable access to people located outside of the SM wing or FNC, was therefore a major limiting factor for this component of Prison 2’s BBV test programme.

Catch-up secondary screening middle-range theory: *New arrivals that miss secondary screening may be incarcerated for short periods of time and located on different wings across the prison (C). HCWs require a means of rapidly accessing those that are missed – regardless of location (MR), which is reliable (i.e. not favour-based) (MR), regular (MR), and can ensure that most prisoners attend (MR). This gives HCWs the capacity to follow-up missed people quickly (MRE), minimising attrition and maximising the numbers offered a test and tested for BBV infection (O).*

7.8.1.4 Stage 4: Catch-up BBV testing

Prisoners that declined to attend secondary screening missed the BBV test offer. This was a problem within Prison 1, because attendance at the clinic meant people risked missing association. However, the use of a waiting list containing details of all the people that refused to attend the clinic, in combination with cell-based testing facilitated by healthcare officers, allowed the team to rapidly re-engage most individuals.

Field note extract (Prison 1): *We make our way onto the wing and the BBV lead asks the accompanying healthcare officers to locate the first person. Once the cell is located, the officers check through the glass, bang on the door, and then unlock it. They shout to the occupant inside, informing him that “healthcare” is here and then stand back on the wing.*

Unfazed, the BBV lead bustles into the cell saying “the reason I am here is I’m doing BBV tests. These tests are for hepatitis C, hepatitis B, and HIV. It is only a small finger prick and I’m testing everyone in the prison. Can I come into your home?” The occupant says yes, although she is already in the cell at this point. She lays out the kit on his bunk, takes his hand and makes an incision. His “celly” is sitting on the bed watching and a strong smell of marijuana hangs in the air.

In addition, the BBV lead was able to naturally frame catch-up testing as a routine opt-out process, because the method of engagement was active. Perhaps as a result, this cell-based approach was found to be highly effective at getting prisoners to agree to test (table 29). However, much like the circumstances surrounding secondary screening, an individual’s decision in response to the test offer was observable by both the officers standing outside the cell and anyone sharing it, whilst staff had no access to translation services and therefore tested people under circumstances of dubious consent (occasionally other prisoners or officers assisted with translating).

Table 29. Number of catch-up blood-borne virus test offers observed, accepted, declined, and acceptance rate per healthcare worker within Prison 1 (BBV = blood-borne virus; PC = primary care).

Healthcare worker	Catch-up test offers	Accepted	Declined	Acceptance rate (%)
BBV lead	32	30	2	94
Nurse 6 (PC)	1	1	0	100

In contrast, within Prison 2 no catch-up BBV waiting list was used. People that declined secondary screening were therefore not actively targeted for follow-up by the healthcare team. Instead, wing-based testing was carried out by PC BBV leads, but without officer support they were only allowed in certain areas (due to safety considerations) and could not access prisoners locked in cells. As a result, BBV leads frequently appeared to be retesting

the same available people (i.e. cleaners or other workers who spent more time unlocked on the wing).

Field note extract (prison 2): ... the BBV lead is testing another guy that is waiting. The group nearby begin getting rowdy and calls over to this individual asking, “you gettin another one, you’ve had about ten of them already?” He responds, “I’m just helping out” and begins laughing ...

In addition, whereas the nature of cell-based testing allowed HCWs in Prison 1 to naturally frame testing as opt-out, the more passive “market stall” approach of testing on the wing in Prison 2 meant that the offer was naturally framed as opt-in. Consequently, this approach appeared to rely primarily on normative action and peer pressure, with testing becoming increasingly popular once a few individuals had agreed to test.

Field note extract (Prison 2): We make our way to C-wing and spot a group of men gathered around a pool table. The BBV lead approaches them and begins to ask whether they want to do a “finger prick test”. The two men closest to us refuse and when I ask why, they tell me that they tested a few days ago.

However, one person from the group agrees to do a test. The BBV lead makes an incision and begins collecting the man’s blood, chatting a little nervously with him as she does so. Other prisoners see what is taking place and begin approaching, asking what is going on ...

However, partway through the field work these wing-based testing activities were cancelled by healthcare management, because they were no longer considered safe to deliver (I was informed of this in October 2019, which coincided with a decline in quantitative outcomes – Chapter 5). With no form of catch-up testing taking place amongst either the PC and SM population (the SM team had no catch-up process in place – see section 7.4.1.8), and in combination with PC’s “declining” process, a large number of new arrivals were neither seen at secondary screening, nor offered a test for BBV infection within Prison 2.

Catch-up BBV testing middle-range theory: People that decline to attend secondary screening miss the opportunity to be offered a BBV test and can be located in cells across the prison (C). Reception-based opt-out test programmes require resources that allow HCWs to identify these missed individuals (MR) and then rapidly (MR), as well as safely (MR), access them for testing regardless of their location (MR). With these capabilities in place, HCWs can provide a targeted catch-up test service (MRE) that minimises attrition and ensures equal access to BBV testing for all new arrivals (O).

7.9 Section two: Discussion

Data generated via observation and realist interviews were drawn on, to understand the mechanisms by which opt-out testing, implemented within a higher and low performing local London prison, worked to test new arrivals for BBV infection (36,79). Programme processes were divided into four stages: initial engagement, secondary screening, catch-up secondary screening, and catch-up BBV testing.

By developing outcome frameworks, these four components were found to work in synergy within Prison 1, ensuring that most people who declined secondary screening and those that were missed, were re-engaged at a later date (see figure 49, page 168). In contrast, different stages of the test programme within Prison 2 were fragmented, stemming from the separation of responsibility for testing across autonomous, and frequently competing, SM and PC departments (see figure 50, page 169).

Results suggest that where delivery of BBV testing is split across different teams, it is crucial that healthcare providers consider how each departments' activities work together, in pursuit of the overarching goal of maximising case-detection within prison (36).

7.9.1 Initial engagement

Both prisons suffered from attrition, because of their decision to include BBV testing during secondary, as opposed to first night, screening (240). This was worse for the SM department within Prison 2, because staff usually had to wait a few extra days for their new arrivals to be transferred to the SM wing, before being able to engage them (194,195,240).

In addition, healthcare teams within both prisons faced access barriers, which inhibited them from engaging all available people (54). In Prison 1 secondary screening clashed with association. This meant latent incentives that encouraged people to attend healthcare clinics were not effectively realised (54,211). Although prisoners are a "captive-population" (53), they remain active agents (not passive objects) and their motivations therefore need be accounted for during programme design and implementation (54).

Within Prison 2, challenges arose because the healthcare team were reliant on busy officers, attempting to run either the FNC or SM wing regime, to facilitate the clinic, whilst much of their target population was actually spread across the prison (figure 51). Clinics were also cancelled by officers, when short-staffed, and by HCWs, when responding to emergencies (79,196,217,233,298). Under the chaotic and violent conditions that currently characterise English prisons, results emphasise the importance of BBV test programmes having the

capacity to take place regardless of the location of new arrivals and independently of emergencies occurring across the prison (figure 51) (66).

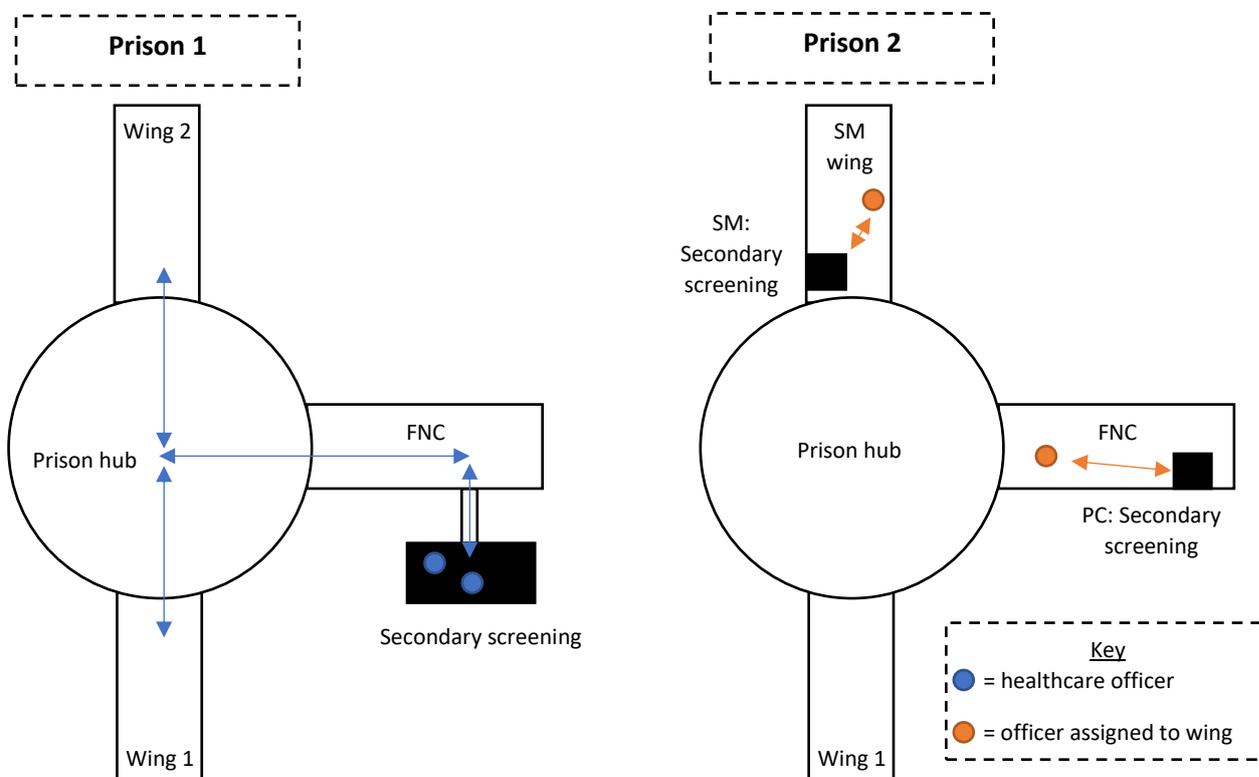


Figure 51. Demonstration of the outreach capabilities of healthcare officers in Prison 1, compared to reliance on officers assigned to wings in Prison 2 (SM = substance misuse; PC = primary care; FNC = first night centre). Within Prison 2, people requiring secondary screening on Wing 1 would have had to be engaged during catch-up activities, creating delays that risked attrition. The layout of each prison has not been accurately replicated, due to security considerations.

7.9.2 Secondary screening

Semi-structured observation of secondary screening provided data for a quantitative assessment of test uptake. Overall, BBV test acceptance was found to be the same during observation. Although what was observed may not have been representative of all test offers, taking place within each prison, this result suggested that differences in the ability to initially engage and catch-up missed people, rather than the way testing was being offered, may primarily lay behind the variation in programme performance identified in Chapter 5.

However, individual HCWs were found to have differing rates of success at getting people to agree to test, with those designated as “BBV leads” often found to be more effective. Indeed, because BBV leads contributed large volumes of successful test offers, the lack of lead amongst the SM team within Prison 2 may have helped to generate a departmental

difference in test acceptance (PC tested 91% of those offered; SM tested 62%), potentially contributing to the lower HCV sample positivity reported by the prison (see Chapter 5) (72,76,302).

It was hypothesised that the success of the BBV leads observed, stemmed from the way in which they delivered testing. Tailoring the interaction prior to the test offer (to maximise receptivity), combined with an opt-out or hard opt-out offer, and a more persistent approach to encouraging those that were hesitant about testing, was found to be consistently effective at steering people entering local prisons into testing (figure 52). This method was hypothesised to have been driven by a combination of experience (BBV leads made the majority of test offers) and professional responsibility for ensuring high testing rates.

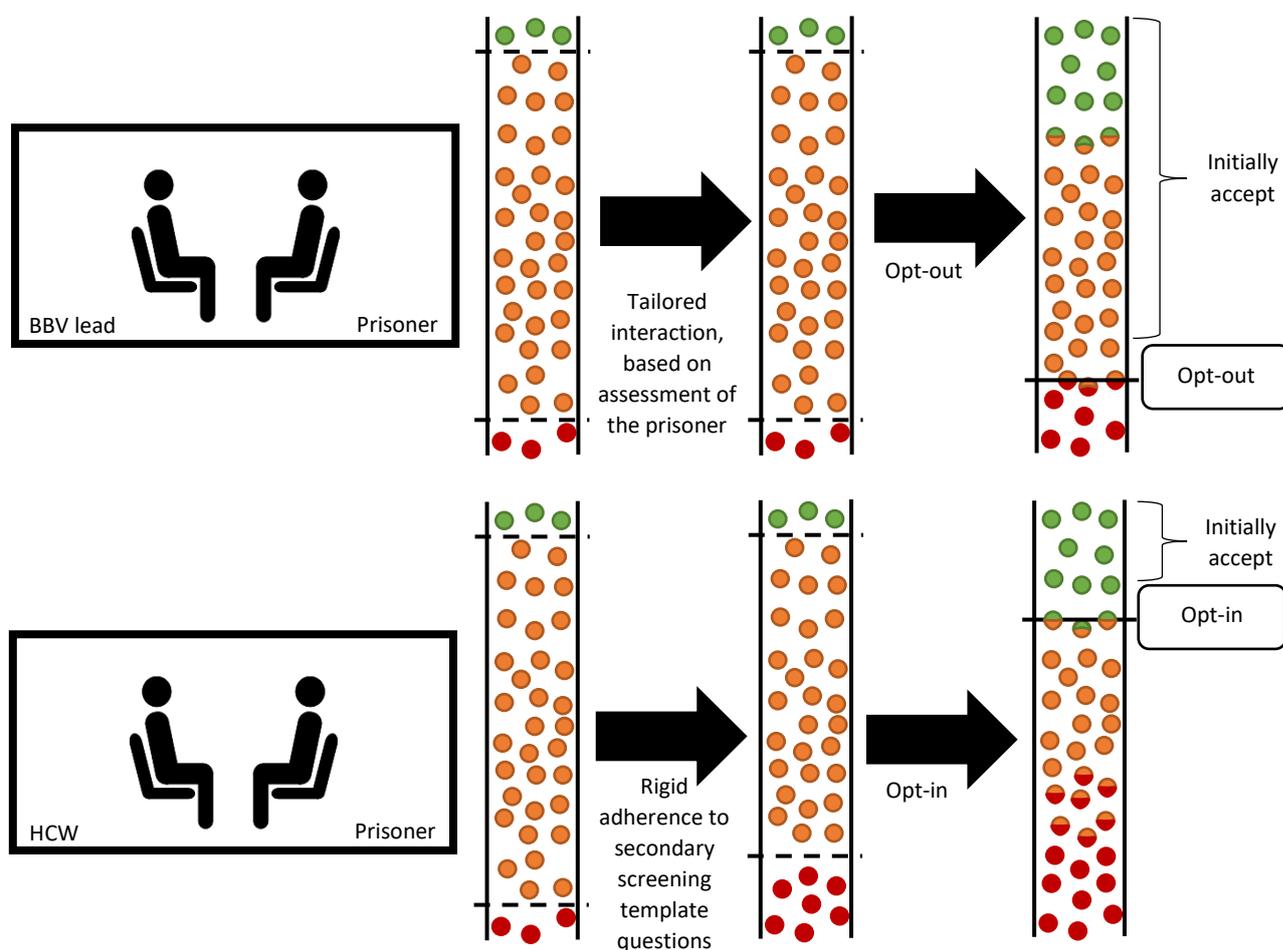


Figure 52. Visual representation of the impact of two healthcare worker interaction styles on prisoners' decision to test during the time pressured environment of secondary screening within a local prison. In the diagram, red = unreceptive/preference not to test; orange = receptive/no strong preference about testing; green = receptive with preference to test. By offering testing in an opt-in format, HCWs test those that are receptive and that have a preference to test. By offering testing in an opt-out format, HCWs test those that are receptive and that have a preference, and no clear preference, to test.

However, before a “BBV lead” approach is recommended as gold-standard, concerns around consent under opt-out require further exploration (235,298). In particular, framing testing as a “hard opt-out” could be interpreted as mandatory by prisoners, which may have been the intention of a minority of HCWs who delivered testing in this way (235). Some of the techniques used by HCWs to encourage testing also bordered on pressure and at times may have infringed on the “voluntary” nature of informed consent (303).

Although the majority of people interviewed reported that testing was a choice, not all respondents received a hard opt-out offer, nobody interviewed had experienced “persistent encouragement”, and for ethical reasons interviews were only carried out with English speakers and those without a diagnosed mental health condition (see ethical considerations in appendix D). It is therefore recommended that HCWs include some form of check for consent (example in opt-out offer script - Chapter 6), particularly as initial acceptance was higher under opt-out than hard opt-out (271,272). HCWs should also moderate how persistent they are when encouraging people to test and need to ensure that prisoners are aware that testing is voluntary (303).

The lack of access, as well as HCW reluctance to use translation services, was also concerning and opens up further questions around consent. It is crucial that healthcare providers supply staff with access to a confidential and accurate means of translation and that HCWs use these services during clinic delivery; ensuring the appropriate and respectful treatment of incarcerated individuals whose first language is not English (1,304).

Generated data also raised questions around the necessity of confidentiality during testing. This was poorly maintained during secondary screening because of a common safety practice amongst HCWs of leaving clinic room doors open. However, paranoia around infection with a BBV was rife within both prisons, despite interventions (such as the Hepatitis C Trust educational and peer programme) designed to challenge stigmatisation (98).

Data suggested that in a stigmatised environment, where confidentiality is poorly maintained, prisoners may face social pressures to avoid counter normative behaviour, as a demonstration of “cleanliness” (305,306). In the case of BBV testing, normative behaviour was presented as testing, meaning people may feel pressured into accepting a test. Indeed, not testing seemed to carry moral judgements from some prisoners and prison staff, and assumptions that the person must have something to hide. This suggested that testing was evolving to become an injunctive norm within both prisons (256).

Although constructing and operationalising an injunctive norm of BBV testing within prison (i.e. it is everybody's responsibility to test for the safety of fellow prisoners and staff), could have beneficial implications in terms of test acceptance (261,305,306), the pursuit of high-testing rates arguably should not supersede the right of incarcerated individuals to confidentiality, if their behaviour in response to a test offer could result in negative social consequences (305,306). Further sociological research is therefore required, to assess the strength and impact of this proposed phenomenon in greater detail.

7.9.2.1 Catch-up activities

Catch-up activities were vital within both prisons, as they allowed HCWs to compensate for access issues during initial engagement (either people declining to attend secondary screening or being missed). Within Prison 1, the use of healthcare officers to facilitate both catch-up secondary screening and catch-up BBV testing, provided HCWs with the flexibility to source people for clinic regardless of their location, or safely travel around the prison themselves, in order to engage prisoners confined to cells. Because a SystemOne generated waiting list was used, the BBV lead was also able to target these activities and so was able to ensure that new arrivals had equitable access to testing (95).

In contrast, the programme within Prison 2 lacked dedicated officer support, which meant HCWs struggled to access people located outside of defined areas (i.e. the SM wing or FNC). Methods to compensate for this (i.e. using free flow or petitioning wing officers to transport people as a favour) also proved unreliable and the PC team had no means of targeting people who declined secondary screening as no waiting list was used. This meant that they were unable to provide equitable access to testing for new arrivals. Indeed, a lack of any form of catch-up test activities amongst the SM population, may have meant higher risk prisoners were being systematically underrepresented during BBV testing, potentially contributing to the lower HCV sample positivity reported by Prison 2 (Chapter 5).

Finally, healthcare teams from both prisons relied on testing in non-confidential settings (i.e. wing-based and cell-based testing) in order to engage individuals initially missed. Mirroring concerns about open testing during secondary screening, this may infringe on informed consent (305,306). If additional research supports the theory that prisoners feel pressured to follow normative behaviour during open testing for BBV infection within prison, further innovation may be required to ensure catch-up activities take place in confidential settings, whilst remaining effective at engaging people rapidly (36).

Synthesis of qualitative results

7.10 Improving the design of opt-out testing for local prisons

Qualitative data were generated within a higher and low performing local London prison, to develop explanations for the variation in numbers offered a test and tested for BBV infection (100,274). Results have been presented and discussed in two discrete sections. My final task was to synthesise these results, in order to refine and consolidate the programme theory that has been incrementally developed throughout conduct of this thesis.

My intention was to produce a framework that programme stakeholders could use to guide their delivery of opt-out BBV testing within local prison settings (111). Different aspects of this framework are discussed, before a model depicting the refined programme theory is presented (figure 53, page 190) (111,113). This section ends the qualitative case-study chapter, by reflecting on the potential limitations associated with the data and, in turn, the proposals that have been made.

7.10.1 Pursuing systemic change

During this qualitative case-study, the effects of austerity on the delivery of opt-out BBV testing, as well as wider clinical care, could be analysed in-depth for the first time (65,66). Generated data revealed a symbiotic relationship between prison and healthcare services, where each relied on certain aspects of the other in order to function (1,238,298). However, this partnership was not equal, with prison staff having the power to dictate how, where, and when healthcare services could be delivered (238,298).

Under the current prison conditions created by mass incarceration and budget cuts (see details in Chapter 1), the English prison service has been forced to focus resources on maintaining its core-priorities of security and safety (298). This has precipitated an inhibiting at best, and hostile at worst, environment for the delivery of high quality healthcare; although emergency care remains a priority for prison staff as this supports safety objectives (238,276,298).

The prison service has also delegated a range of responsibilities to different organisations. This has evolved into a complex bureaucratic system, similarly placed under strain by England's "carceral crisis" (1,66). Poor communication between organisations, confusing protocols, and long waiting times meant that the two prisons took on properties of a "violent bureaucracy", where prisoners were incentivised to employ strategic acts of "degradation", in an attempt to leverage access to services (1,60,247).

Stakeholders pursuing viral control and elimination objectives through the use of prison populations should consider the wider conditions in which care is being delivered (3,38). It is recommended that those involved in developing and implementing interventions use their platforms, funding, and other resources to simultaneously pursue systemic change. These efforts should include both advocating for greater financial support for the prison service (as an effective prison workforce is a prerequisite for delivering high quality healthcare), whilst attempting to place an integrated, as well as accessible, clinical, social, and psychological service at the centre of the rehabilitative mandate of English prisons (2,75).

Policies to do this, (e.g. specific training/performance indicators related to healthcare for prison staff, greater operational resources reserved for healthcare facilitation, more time within the regime for the delivery of care, and better clinical resources) should be embedded within inter-organisational agreements, such as the National Partnership Agreement (65,75,81). The radical restructuring that the English prison service is currently undergoing, also represents an opportunity to advocate for the inclusion of accessible, safe, and confidential spaces for the delivery of healthcare (65).

By situating ideas of systemic change amongst the objectives of BBV interventions, this framework attempts to use enthusiasm for viral hepatitis elimination as a catalyst for driving wider healthcare reform within prisons. If achieved, these changes could have wide-ranging implications for both the management of disease (including BBV infection) and criminal behaviour (i.e. improved mental and physical health may reduce recidivism) (299,300).

7.10.2 An effective model for engagement

Although systemic change could have wide-reaching implications, those implementing opt-out programmes have to work with the conditions that they currently face (118). Engagement for BBV testing is the point in programme delivery where tensions between prison and healthcare services primarily manifest. Results from the qualitative case-study also suggested that access issues (either initially or during catch-up activities), represented the primary barrier to delivering BBV testing.

However, neither the London Prisons Project, nor the wider opt-out test strategy, provided resources to support engagement (i.e. funding for supporting officers or guidance on how facilitation of testing should be carried out) (78,79,83). Instead, BBV testing facilitation was left to be negotiated at the local level, by healthcare providers operating within each prison.

Results from this case-study suggest that NHSE, PHE, and HMPPS stakeholders should concentrate on developing an endorsed approach to engagement, which fosters partnership

between prison and healthcare services, whilst ensuring the confidentiality of medical information is respected. This approach should have a number of capabilities:

- The capability to reliably, safely, and rapidly engage new arrivals, regardless of their location within the prison;
- The capability to operate semi-independently from emergencies and other events occurring around the prison;
- The capability to incentivise prisoners to attend the clinic.

To this end, it is recommended that stakeholders consider recruiting a “BBV lead officer” within each prison to champion clinic facilitation, supported by other healthcare officers. This officer should have access to NHS training, focused on confidentiality and infectious diseases, and be responsible for delivering internal training, designed to promote the maintenance of medical confidentiality and challenge stigmatising views about infectious diseases amongst the wider prison officer workforce.

In addition, healthcare providers should ensure that the delivery of BBV testing is ring-fenced from emergencies and will need to work with prison authorities, to schedule testing clinics at a time where latent incentives to attend can be realised (or encourage attendance through the use of implemented incentives) (54).

Unfortunately, qualitative results could not provide a judgement on whether testing during the first night or secondary screening would be more effective within local prisons (194,195). In the absence of refined RE theories to better inform this decision, the recommendation for a phased engagement across the first night and second day continues to stand, although additional work may be required to explore the cultural opposition amongst HCWs to first night testing (194,195). If resource constraints only permit engagement at one point, providers should decide by weighing the feasibility of implementation, ease of prisoner engagement at different times, and time-related incentives or disincentives to test (111).

7.10.3 Ensuring consensual steering

The final consideration is the implementation of an appropriate opt-out BBV test offer. Within both Prison 1 and 2, many HCWs were effective at getting people to agree to test, but practices were identified that raised concerns about consent (306,307). Indeed, with enthusiasm for HCV elimination building across the UK, there is a risk that this fundamental clinical principle may get side-lined by some staff within prison, in the pursuit of high testing rates (36).

Data from the two London prisons also highlighted that interventions designed to guide the delivery of an appropriate test offer (i.e. the offer script) had not been effectively implemented (271,272). These findings emphasise the importance of supporting an evidence-based model of opt-out testing (223), with a management structure that can ensure adherence to the approach (38).

In terms of delivering an opt-out offer within local prisons, testing during the first night or secondary screening is likely to be time pressured. With little time to build relationships or provide a detailed pre-test discussion for all new prisoners, it is recommended that HCWs tailor their interaction to maximise patient receptivity prior to the test offer. This offer should include a verbal check for consent (271), alongside basic information about the test (so that people are aware of what it is they are consenting to), and translation services should be used for those that require them.

In the absence of robust information on the impact of open-testing on informed consent within prison settings, it is provisionally recommended that, as far as possible, healthcare providers deliver testing in confidential settings (cell-based testing could be made confidential by asking other occupants to step outside) (306). This approach should help steer those that actively want to test, and those that have no clear preference into testing (211,271). Time permitting, staff can then focus on addressing concerns and attempting to encourage engagement with healthcare, for those individuals that are initially hesitant (figure 53).

To support the implementation of these principles, NHSE and PHE are encouraged to develop regional oversight bodies (like the LBCSG) (78). BBV leads should be recruited (where needed) and encouraged to adopt a supervisory position within their prison, spanning both PC and SM departments. In this role, they should be required to attend all stakeholder meetings, be empowered to deliver training for other HCWs, and hold responsibility for ensuring best practice is adhered to during opt-out test delivery.

Other HCWs should also be incentivised to maximise testing (within the confines of acquiring informed consent) through positive incentives (e.g. reward schemes for those HCWs adhering to best practice) or negative incentives (e.g. “dash boarding” performance of the healthcare team). In this way, NHSE and PHE commissioners should support the implementation of an effective opt-out offer, which consensually steers most people into accepting a test for BBV infection (223).

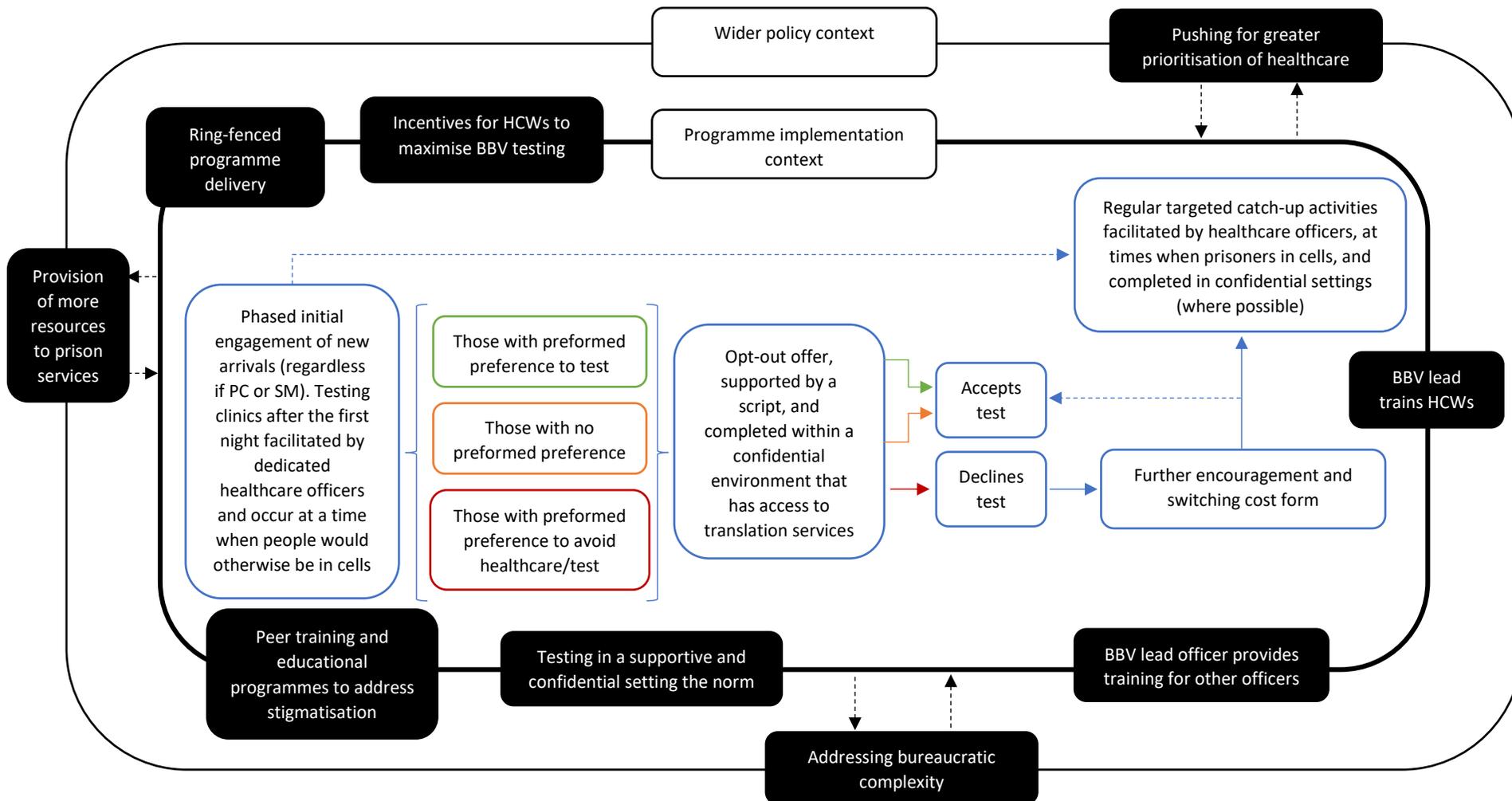


Figure 53. Refined programme theory for an effective opt-out blood-borne virus test programme, in terms of maximising the number of new prison entrants offered a test and tested within local prison settings (BBV = blood-borne virus; HCW = healthcare worker; SM = substance misuse; PC = primary care). Model developed using results from a qualitative comparative case-study. Black boxes, embedded within contextual layers, represent important resources (or activities) that should impact services designed to diagnose and treat blood-borne virus infections within prisons.

7.10.4 Qualitative data limitations

When interpreting the results of this comparative case-study, and the recommendations produced for opt-out testing within local prisons, several data limitations should be considered. These limitations broadly fall into two categories: limitations with the generated data and limitations associated with the evaluation's scopes.

When considering limitations associated with scope, this qualitative project only analysed a select number of programme outcomes (i.e. numbers offered and tested). However, healthcare providers also face an ethical obligation to inform people of results (particularly if positive) and link them into pathways of care (79). These aspects need to be assessed during future evaluative activities, to ensure progression of patients from diagnosis to cure.

There is also uncertainty regarding the applicability of results for other prison contexts (i.e. different types of male prison, prisons in different geographic areas, and for the female estate) (246). Prisons differ dramatically based on location and carceral function (65). Realist programme theory therefore needs to be developed and tested between different types of prison and across different regions of England (111,274).

In terms of data limitations, achieving a "representative" sample of officers and prisoners for interview was challenging (287). Officers had little time and were often sceptical about how the evaluative research data would be used. Because of difficulties in building relationships with this stakeholder group within Prison 2, only younger graduate officers agreed to do a formal interview. I was also restricted (due to safety/ethical reasons) to interviewing certain types of prisoners, meaning that the verbal responses recorded may not have been representative of the opinions of this stakeholder group overall.

In addition, I faced issues with the depth in which topics could be discussed during interviews. Time pressures caused by the regime within both prisons meant that I had to rush interviews with the different stakeholder groups (particularly prisoners). The prohibition of audio recording interviews within Prison 2, also meant that large amounts of information were lost (149,291). As a result, it was essential that verbal information acquired during formal interviews was triangulated with data from informal discussions, observations, and documents, to create a "confluence of evidence" that could reinforce developed programme theories (293,308,309).

Finally, limitations with data representation were not exclusive to interviews. Although I was able to conduct a rough quantitative assessment of test uptake using semi-structured observation of the secondary screening encounter, what was observed did not necessarily

reflect a representative sample of test offers within each prison, may have been influenced by the Hawthorne effect (310), and relied on a small number of observations. Caution should therefore be exercised when considering overall differences in acceptability between the two prisons, staff, and methods of consent elicitation.

Primary data generated as part of this comparative case study therefore represents an important next step in developing our understanding of opt-out BBV testing within prisons. However, findings need to be built on using different forms of data and information from other types of prison, stages of testing, and from different locations across England (189).

7.10.5 Conclusion

Qualitative data were generated within a higher and low performing local London prison, with the aim of exploring differences in the way opt-out BBV testing had been implemented and functioned. By assessing the interplay between each prisons' context, the resources implemented, and how these were responded to by different stakeholders to produce outcomes, an in-depth analysis was achieved.

Results indicated that access issues were the primary barrier faced by healthcare providers, although these manifested in different ways within each prison. When new arrivals were engaged by HCWs and offered a test, acceptance overall was found to be high and observed differences between the two prisons were minimal. However, practices that infringed on consent and confidentiality were identified during the field work.

Findings from both sections were synthesised to produce a refined programme theory for opt-out BBV testing within local prison settings. Healthcare providers were recommended to take a three-pronged approach, by pushing for systemic change, working with prison service partners to develop an effective model for prisoner engagement, and by implementing resources to help ensure opt-out testing consensually steers people into accepting a test.

Impact

- Provisional results were shared with LBCSG members and used to inform a two-year refinement of the London Prisons Project.
- The LBCSG ensured that SM HCWs were receiving training and championing testing within London prisons. Prison 2 engaged in additional testing of the SM population after results were shared (see Chapter 5).
- Final results from this case study informed industry preparation measures for the "ODN Plan 2019-2022".

7.11 Chapter summary

In answering the questions posed at the start of this chapter, this qualitative comparative case study has demonstrated the importance of analysing context when assessing programme implementation and function. Key results were outlined across three sections:

- In section one, contextual conditions and programme implementation were assessed. Data revealed a strained context, where the delivery of proactive healthcare was not prioritised by prison staff. Analysis of programme implementation suggested that BBV testing within Prison 1 had resource advantages, due to the support of healthcare officers and integrated working between PC and SM departments. In Prison 2, resources anticipated to help maximise testing were concentrated away from those individuals likely to be at the greatest risk of HCV infection.
- In section two, stakeholder responses to implemented resources were assessed. Both prisons struggled during initial engagement: Prison 1 struggled to get people to agree to attend clinics, whilst Prison 2 missed new arrivals. However, Prison 1's catch-up activities proved to be more effective, allowing the programme to reliably engage most new prisoners. When people were successfully engaged, overall test acceptance was similar between the two prisons during observation.
- In section three, results were synthesised to produce a refined programme theory for an effective approach to opt-out testing within local prisons. This suggested that stakeholders should look to enact systemic change, whilst implementing additional resources to ensure effective engagement and consent acquisition during opt-out testing for BBV infection.

Chapter 8: Concluding remarks

8.0 Introduction

In this final chapter, I briefly revisit the background and rationale for the PhD and summarise the key results from each chapter (figure 54). At the end of this summary, I move away from the particularities of London and apply some of the learning from this evaluative research to the national context.

Next, I present my reflections on the research process, focusing specifically on my experience of conducting research in prisons and using RE methodology. I end the chapter by proposing future areas of research, before concluding the thesis with a final statement.

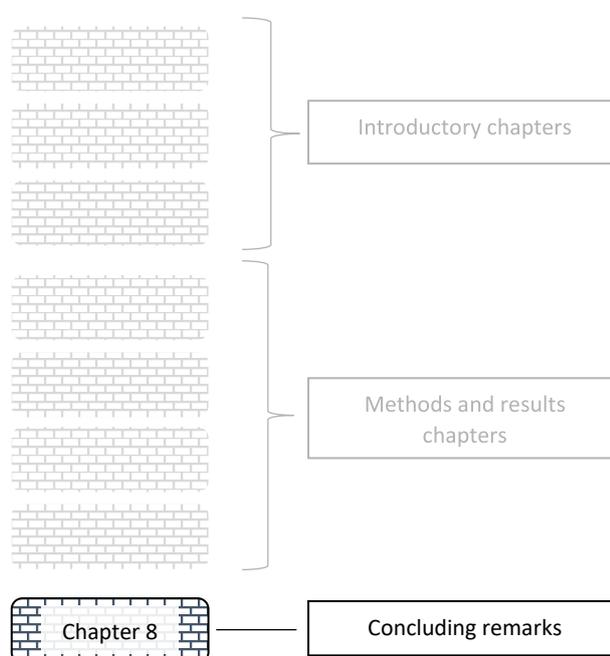


Figure 54. Outline of the thesis structure. Block colour signifies the aim of the chapter (blue = introductory; green = methods and results; dark blue = concluding remarks). Introductory and results chapters are greyed out, to signify that they have already been presented.

8.1 Summary of thesis chapter findings

The purpose of this thesis was to conduct a realist evaluation of the London Prisons Project. My intention was to explore programme design and function, with the aim of generating data to inform models of best practice (100,111,274). I hoped that findings would contribute to the evidence-base being constructed around viral hepatitis elimination and the control of HIV (3,17,36). To do this, I began by developing a novel evaluative framework, which then guided the conduct of four discrete, but complimentary, pieces of research.

Chapter 3- Developing an evaluative framework

I began the project by developing a framework that could help me better envisage a programme as an event within a wider social system. To do this I extended the interpretation of causality, usually used during realist evaluation, to include “conditioning mechanisms”, which explain how social structures influence behaviour, and “transformative mechanisms”, which outline the processes a social programme may catalyse to generate wider contextual change. This framework underpinned my evaluative approach, data collection, and analysis, but could not be fully operationalised as a result of time and resource constraints.

Chapter 4 – “Where is attrition taking place (pilot evaluation)?”

To begin empirical work, I helped evaluate and reconfigure a novel HCV pathway of care, implemented within a local London prison. My aim was to begin developing a programme theory for different aspects of the London Prisons Project, whilst identifying points of patient attrition that could be a focus for subsequent evaluative activities. Key findings from this pilot evaluation included:

1. The initial pathway that was implemented successfully managed 10% of those diagnosed with HCV infection. Following reconfiguration, this increased to 46%.
2. Barriers to successful delivery included attrition before and during (i.e. people declining) the opt-out BBV test offer, loss of patients awaiting disease assessment, and issues with ensuring continuity of care following release or prison transfer.
3. Changes that may have improved performance included: training on an opt-out offer, diversifying the method of engaging new arrivals for testing, and the empowerment of prison healthcare staff to assess patients’ disease and deliver new DAA-based treatments for HCV, with minimal supervision from community specialists.
4. The “Hepatitis C InformOut” project, created in response to identified challenges during the evaluation, culminated in the development of an information card and website to help coordinate care as prisoners’ transition to different institutions or back to the community.

Chapter 5 – “How does BBV testing vary across London (outcome assessment)?”

In this chapter I presented results from a descriptive analysis of opt-out BBV test outcomes from across the London prison estate. Data highlighted that the region, overall, did not meet NHSE offer or test coverage targets. Poor performance within a number of large local prisons was forwarded as a justification.

However, data also highlighted that these prisons identified larger volumes of positive HBV and HIV samples, whilst also reporting the highest anti-HCV sample positivity. The high anti-HCV positivity was theorised to relate to how PWID move through the prison estate. Results suggested that local prisons should be a target for quality improvement, in order to maximise the public health benefit from opt-out testing.

Unfortunately, the extent to which programme outcomes could be both assessed and explained was limited by the quality and nature of quantitative data available. Limitations with the data were outlined and the steps I took with NHSE to develop a novel database, which could host individualised patient data for BBV pathways of care within the London prisons (i.e. “The Prison Pathway Project”), was discussed.

Chapter 6 – “Why might this variation be taking place (rapid-realist review)?”

Following the assessment of programme performance, I focused on developing explanations for the variation in outcomes observed. To begin this process, a review was completed that sampled both English policy documents and relevant published/unpublished literature. This review aimed to explore both how opt-out testing was thought to work and develop explanations for variation in performance. Key findings from this process included:

1. Behavioural economic “Default Theory” was found to underpin the concept of making a recommended action “opt-out”. However, the review identified no consideration for this theory in the guidance developed for the national English programme or the London Prisons Project.
2. Delays to engagement result in attrition. These can be programme mandated (i.e. testing a few days after arrival) or result from access barriers. Barriers to accessing new arrivals were found to stem from staffing issues, the prioritisation of prison processes, and from prisoner refusal to engage with healthcare.
3. Literature suggested that healthcare teams should include resources that encourage those concerned that they may have an infection to test (e.g. a confidential, supportive, and trusted service), whilst minimising the barriers for those that believe themselves at low risk to comply with the opt-out offer (e.g. by minimising the discomfort caused by sample acquisition).
4. Poor fidelity to an opt-out message was observed in both the literature and within prisons in London. A script was developed to guide the delivery of an opt-out offer, which was implemented within London prisons and disseminated nationally. A “switching cost form” was also developed, which was designed to address perverse incentives and encourage test uptake.

Chapter 7 – “Why was there variation in performance between two similar London prisons (qualitative comparative case-study)?”

A qualitative comparative case-study was completed, exploring differences in programme implementation and function between a higher and low performing local London prison. A total of 45 interviews, 60 field note entries, and 29 documents comprised the qualitative data. Key findings from two analyses included:

1. Despite similarities in programme design, resources introduced as part of programme implementation within Prison 1 (higher performing) provided it with greater capacity to access new arrivals. Within Prison 2 (low performing), vital programme resources were found to have been concentrated away from those at greatest risk of infection (i.e. those with a history of substance misuse).
2. Contextual conditions within both prisons provided a challenging environment for the delivery of high-quality healthcare. In particular, a prison culture of security and safety prioritisation over proactive healthcare, frustrated attempts to promote prisoner health.
3. Differences in programme performance appeared to stem primarily from access issues. Healthcare teams within both prisons were able to achieve high test acceptance rates during observation. However, data raised questions about the appropriateness of open BBV testing within a stigmatising environment, as well as other practices that may have infringed on informed consent.

Combined, this work represents an important step towards understanding how opt-out BBV test programmes work, and how barriers to effective performance can be addressed, with the aim of advancing the role of prisons in HCV elimination. However, despite presenting policy recommendations and interventions throughout this thesis, my primary focus (and the source of most presented empirical data) was the London prison estate.

Towards the end of the evaluative research I therefore wanted to abstract results from the particularities of London, to produce summary proposals for the national BBV test and treatment strategy. To this end, I developed the “TO-BE-FIT” proposals for the delivery of BBV services within English prisons.

8.1.1 “TO-BE-FIT” proposals

To apply results from this thesis to the national context, I developed the “TO-BE-FIT” framework. This was developed for, and shared with, national Public Health & Justice partners and made the following recommendations:

T – Results from this project revealed a dearth of behaviour change and behavioural economic theory in both the development and implementation of opt-out testing and treatment pathways across English prisons. A theoretically informed, and universally endorsed, approach to delivering BBV testing and treatment in different prison settings should be developed, disseminated, and included within all training provided to healthcare staff working within English prisons.

O – Oversight should be promoted via the development of regional steering groups, to coordinate activities and develop, as well as disseminate, local innovation. Local HMPPS representatives and Prison Governors should be encouraged to attend these groups and attempts made to highlight the benefits that this initiative could bring to their own strategic priorities (e.g. rehabilitation and staff safety). Commissioners should foster ownership of the BBV opt-out programme via funding of BBV lead nurses within each prison. BBV leads should attend steering groups and be empowered to provide regular in-house training for nurses, patients, and officers.

B – Results suggest that better monitoring data (i.e. more accurate and comprehensive) is required to assess and improve BBV testing and treatment initiatives within English prisons. Mirroring the “The London Prisons Pathway Project” (discussed in Chapter 5), a national data system that allows for the assessment of a person’s journey from diagnosis to cure during incarceration is recommended. In addition, attention should be given to making prisons more accessible for researchers (see discussion in section 8.2.1), so that other forms of data can be generated and used to guide service delivery and reform.

E – Prisons should be enabling environments for the delivery of healthcare. It is of vital importance that the physical layout of a prison allows HCWs to access newly incarcerated people quickly and easily (something that is not always the case within Victorian-era buildings). Health authorities should also push for a standard of healthcare either equivalent or exceeding services in the community to be treated as a core part of the professional identity of all staff working within prisons (including prison staff).

F – Successful facilitation of a healthcare programme is reliant on some integration between healthcare and prison services. However, prison staff involved in facilitating healthcare clinics currently receive no training on working within a clinical environment. HMPPS and NHSE should collaborate to develop additional training for officers involved in facilitating healthcare. The recommendation (outlined in Chapter 7) for a BBV lead officer, to work in conjunction with a BBV lead nurse, should also be considered.

I – Results suggest that further work is required to integrate prison healthcare services with the wider care community. This is essential for ensuring continuity of care and minimising the disruptive impact of the cycle of incarceration and release (184,311). The integration of SystmTwo (the new clinical system expected to be implemented across English prisons) with the NHS Spine (the digital central point, that allows information exchange across local and national NHS systems), will be an important step.

ODNs also represent a readily available network to lead coordination efforts for the care of viral hepatitis. However, these networks require collaboration from probation services, courts, drug services, and prison healthcare staff, in order to effectively manage continuity of care. Use of interventions developed by the “Hepatitis C InformOut” project (i.e. the information card and information sharing website), are recommended to help facilitate this collaboration.

T – The design of opt-out BBV testing and care pathways should be tailored to the differing types of prison. The current approach of testing and attempting to treat everyone entering each prison is conservative, but resource intensive and fails to work with the movement of prisoners through the prison estate (figure 55) (65).

BBV test resources (staff, equipment, dedicated healthcare officers) should be concentrated within newly formed reception prisons, for a “hard and fast” opt-out test approach, following recommendations made in the final section of Chapter 7 (65). This should be combined with a rapid assessment of disease, for those found to be positive for HCV infection.

A less resource intensive “targeted” opt-out test approach should be employed within training and resettlement prisons, for those that were missed or declined testing during prior incarceration at a reception prison. Healthcare teams within training prisons should specialise in the delivery of an integrated treatment package for HCV, where biomedical intervention is combined with mental health and drug treatment services (figure 55).

Those staff operating within resettlement prisons (note: all reception prisons will have a resettlement component) should specialise in ensuring continuity of care and be incentivised to build strong relationships with community healthcare services, probations services, and local courts (figure 55).

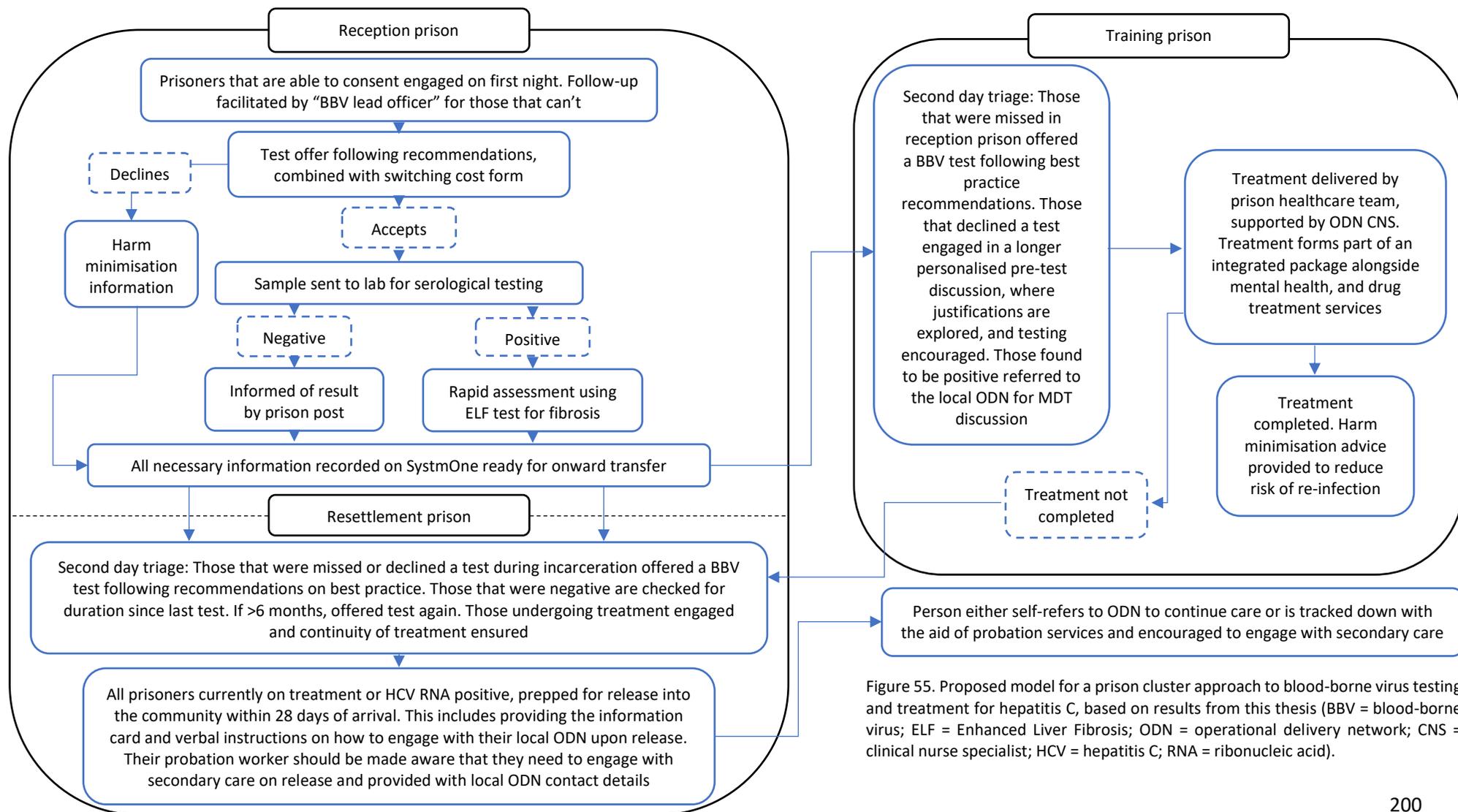


Figure 55. Proposed model for a prison cluster approach to blood-borne virus testing and treatment for hepatitis C, based on results from this thesis (BBV = blood-borne virus; ELF = Enhanced Liver Fibrosis; ODN = operational delivery network; CNS = clinical nurse specialist; HCV = hepatitis C; RNA = ribonucleic acid).

8.2 Reflections on the research process

Having summarised the empirical results presented in each chapter; I now briefly provide broader reflections on the research process. I focus this discussion on my experience of generating data within English prisons and the challenges I encountered when applying RE methodology to evaluate the London Prisons Project.

8.2.1 The challenges of prison research

The research setting (i.e. London prisons) introduced a range of unique challenges, with accessibility perhaps being the most disruptive. To access an English prison, researchers have two options:

1. Rely on internal staff to arrange “gate passes”, which need to be approved for every visit and require the individual to have a staff escort at all times.
2. Undergo security clearance that allows the researcher to apply for keys to different prisons, but that can take over nine months to complete.

Although I began the security clearance process early into the research (March 2017), I only received approval in December 2017 and had to wait for an additional two months in order to access keys to Prison 1 and 2. This meant that I was reliant on staff working within the London prisons to provide me with access to different sites, extract routine service data, and escort me when inside a prison for a significant portion of this evaluative research.

These physical limitations, in turn, shaped the form and quantity of data that could be generated (e.g. during the pilot evaluation I could not access the prison regularly and so I was unable to generate detailed qualitative data or extract quantitative service data myself). Researchers requiring regular access to a prison to generate data should therefore be prepared to set aside significant time in advance, to allow for security clearance and key approvals to be acquired.

I also found a lack of clarity on how to gain regulatory permission and undergo ethical review for research projects within prison (204). In the first instance, it was not clear exactly which ethical review boards needed to provide approval. This resulted in unnecessary delays to commencing primary data collection during the qualitative comparative case-study. Securing prison-specific approvals from the Governing Governor and Head of Healthcare was also a sensitive process, made easier thanks to commissioning contacts developed through my participation in the LBCSG.

Generating qualitative data within a prison also presented a host of logistical and ethical considerations, such as negotiating access to audio recording equipment when inside a prison, considering how informed consent could be ensured during recruitment, developing protocols for ensuring researcher safety, and implementing processes for dealing with notifiable information (204). These needed to be thoroughly accounted for during the application sent to the National Research Council, particularly as researchers are only permitted one resubmission for approval (312).

However, had it not been for the experience of my supervisory team, members of my expert panel, and the LBCSG, I would have struggled to address many of these issues with the information I found in previous research articles and through Google searches. Practical advice on managing different methodological challenges, associated with conducting research projects within prison settings, would be valuable for making prison research more accessible to early career researchers.

Finally, despite developing comprehensive safety and ethical protocols, in practice I still faced a range of unforeseen issues when generating qualitative data. These included violent incidents, receiving notifiable information, experiencing interruptions during interviews, having staff and prisoners trying to read confidential field notes, and experiencing staff coercively recruiting prisoners for the research. These issues required constant input from senior researchers, with experience of prison-based and qualitative research.

Nevertheless, despite prisons being dangerous and coercive environments, it is crucial that steps are taken to make them more accessible. Rather than prison research being treated as “exceptional”, high quality projects should be promoted in these environments, helping to ensure that these institutions are not cut-off from work that could bring benefits to the people living and working within them (204).

8.2.2 Limitations with realist evaluation

I used RE methodology to structure this evaluation, as it promised to help elucidate the inner workings of the London Prisons Project (i.e. open the black box), generate explanatory theories that could help refine delivery, and encouraged the analysis of context as a backdrop to the programme (125). On all of these promises, RE delivered.

Nevertheless, I encountered several limitations when using this approach. In particular, RE uses a range of terminology that can be difficult to navigate, particularly when there are conflicting definitions (133). The term theory for example is used interchangeably, covering both provisional hypotheses explaining how a programme generates change, to explanatory

CMOCs underpinned by empirical evidence (125). Defining context, mechanism, and outcome, is also a complex process, requiring a significant level of familiarity with realist philosophy and the published literature. This makes communicating results to researchers and stakeholders, unfamiliar with the approach, a challenging process.

In addition, multiple combinations of context and mechanism can bring about one or several outcomes and it is often difficult to delineate between resource and context. This makes the process of coding and constructing CMOCs time consuming and complicated. Crucially, because there is usually a large number of potential configurations, all of which can be articulated in various ways and refined further, there is no easily definable end-point for RE, other than that imposed by the researcher, time, and finances (133).

Finally, during the construction of CMOCs the researcher is forced to “fix” the various aspects of context that are theorised to be relevant for understanding the expression of a particular programme mechanism. Although this is conceptually useful, the focus placed on presenting theories during the results, reduces the space available to discuss the evolving nature of situated social practices and can give an artificial impression of a “stable” implementation context. When time and space permits, greater attention should be dedicated to providing a “thick” description of the evolving interactions that take place during the delivery of a programme and how the confluence of these practices compose the social context in which Ma-Mi mechanisms are experienced, Mi-Mi mechanisms are expressed, and Mi-Ma mechanisms are generated.

Despite RAMESES guidance making RE more accessible, the approach therefore remains complex (139,209). Researchers should be prepared to dedicate a significant amount of time to understanding the methodology, before being able to operationalise it effectively. They also need to consider how they present RE outputs, in a manner that balances explanatory processes with thick descriptions of an evolving context.

8.3 Future research

This PhD study has provided novel insights into the implementation and function of opt-out BBV testing within London prisons. However, additional research requirements were identified, which will be important for progressing the objectives of hepatitis elimination and HIV control:

1. Quantitative testing of realist programme theories

The work carried out in this thesis represents an important exploratory step. However, the realist explanatory model that I have incrementally developed in this thesis predominantly

relies on qualitative and secondary data. Consideration should be given to refining aspects of this model further using individualised quantitative data. This would be particularly valuable for specifying whether certain demographic groups are more or less likely to be offered a test and engage in BBV testing within different prison settings (111).

2. Experimental testing of sub-interventions

This evaluative research led to the development of various sub-interventions (i.e. the opt-out offer script, disclaimer form, and information card). Although attempts were made during the co-development process to pilot these, I was unable to collect data on their impact. Experimental testing of these sub-interventions should be considered, to more comprehensively explore their acceptability and effect (100,313).

In particular, attention should be given to the impact of including a check for consent during opt-out test offer delivery within a prison setting. Although results from this thesis indicated that a check should be included, further evidence would be desirable to better specify what form this should take in order to ensure informed consent is acquired, whilst exploring whether and how this influences test acceptance (271).

3. Determining whether timing of the test offer affects acceptability

The inability of this thesis to explore the interaction between timing of a BBV test offer and test acceptability means that an important policy question remains unanswered. Although two prospective control trials have been completed in the US exploring this question, US prisons differ from English prisons, the trials employed rapid HIV testing, and exemplar quotes for test delivery suggested that the offer was actually opt-in (194,195).

It is recommended that another prospective controlled trial be conducted, using both a realist lens of inquiry and the opt-out offer script developed during this research (140,141,271,313). Nested within this trial, qualitative data generation should evaluate programme implementation and peoples' justifications for refusing testing at different points in time, with the aim of developing explanatory theories for the moderating effect of timing of the test offer on incentives and disincentives to test (100).

4. Evaluation of industry elimination strategy and pathways of care

The new NHSE procurement deal for DAA treatments has meant Life Science companies are working with healthcare providers to develop case-detection initiatives for HCV (42,43). These initiatives will include case-detection within prison settings, meaning a new iteration of BBV test programmes will be soon be implemented across the English prison estate (hopefully building on learning from the original opt-out test strategy).

Similar evaluative activities should be conducted to explore the implementation and impact of these initiatives on case-detection, using theories developed in this project as a basis. Focus should also be placed on other stages of the pathways of care, in order to generate programme theories that can inform the evolution of strategies for patient assessment and treatment delivery, with the aim of ensuring the rapid and reliable progression of prisoners identified with a BBV infection from diagnosis to cure.

5. Longitudinal qualitative data generation to explore whether programme implementation catalysed wider contextual changes

The implementation of opt-out BBV testing represents an important “event” within the English prison system. However, I focused on conditioning (Ma-Mi) and programme theories (Mi-Mi) during the qualitative comparative case-study, rather than exploring whether programme implementation resulted in shifts in social interaction, norms, and culture. As a result, I was unable to explore whether, and how, the practices that composed the opt-out programme entrenched or challenged social and cultural prison structures (Mi-Ma) (see the evaluative framework in Chapter 3); limiting recommendations regarding systemic change to “top-down” policy change.

Research that explores whether and how the programme catalyses wider changes to the prison estate, via shifting social practices and interactions, should therefore be considered. This may help inform the development of additional interventions, designed to stimulate systemic change from the bottom-up, by targeting the interactions of key stakeholder groups.

Incremental refinement of strategies to diagnose, assess, and treat BBV infection in prison is therefore an ongoing process, beyond the scope of this thesis. Nevertheless, it was my intention that this work would provide a solid foundation, on which subsequent evaluative activities can then build.

8.4 Final statement

The innovation of DAA treatments for HCV has opened-up the exciting opportunity to eliminate this viral infection in England. Prisons and the BBV opt-out test programme should form a core part of the elimination strategy. However, outcomes from testing in London suggest that further work is required to meet NHSE performance targets, particularly within large local prisons.

An explanatory framework was developed using the literature, which highlighted a range of potential reasons for variance in the numbers of new prisoners offered a test and tested for

BBV infection. However, when this framework was applied to understand the difference in performance between two local London prisons (one higher and one low performing), the analysis suggested that variance primarily stemmed from access issues, as opposed to test acceptability. This result was in many ways unsurprising, considering the current challenges that the English prison estate is facing and the lack of attention given to prisoner engagement within the original opt-out BBV test design.

Results from this thesis suggest that those implementing opt-out BBV testing should focus on getting buy-in from the prison workforce and include additional resources to support the rapid and reliable engagement of new arrivals. Strategies to ensure acquisition of informed consent during opt-out testing should also be developed. Finally, health authorities should harness political enthusiasm for HCV elimination to pursue systemic change, advocating for better resourcing of the prison estate and highlighting the importance of physical and mental health services for the wider penal endeavour (i.e. rehabilitation and reform).

More work is therefore required to better understand and respond to the plethora of unique challenges presented by carceral settings. However, I remain hopeful that with further evaluative work and innovation, testing and treatment interventions can be developed that ensure London prisons, as well as the wider English prison estate, can rise to the challenge of HCV elimination as a major public health threat by 2025 (34).

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Appendix A: Scoping review

Search strategy

The search strategy for the scoping review was designed to be comprehensive. Search terms were developed from the review aims (i.e. to identify hepatitis C testing and treatment programmes within prison) and grouped around information displayed in the table. Both subject headings and key words were used in the search strategy, but search terms were kept simple and the use of “word root” searching was not employed.

Table. Person-location-exposure table, summarising search terms used during the scoping review.

Population	Location	Exposure
<ul style="list-style-type: none"> • Hepatitis C positive • Prisoner(s) 	<ul style="list-style-type: none"> • Prison • Gaol • Jail • Correctional institution 	<ul style="list-style-type: none"> • Testing • Treatment • Therapeutics

Example search strategy (MEDLINE)

Database: Ovid MEDLINE(R) Epub Ahead of Print, In-Process & Other Non-Indexed Citations, Ovid MEDLINE(R) Daily and Ovid MEDLINE(R) <2000 to Present>

Search Strategy:

- 1: exp Hepatitis C/ or hepatitis C.mp. (83859)
- 2: prison.mp. or exp Prisons/ (15173)
- 3: gaol.mp. (20)
- 4: jail.mp. (2076)
- 5: correctional institution.mp. (103)
- 6: 2 or 3 or 4 or 5 (16388)
- 7: treatment.mp. or exp Therapeutics/ (6894814)
- 8: testing.mp. (566288)
- 9: 7 or 8 (7301548)
- 10: 1 and 6 (651)
- 11: 9 and 10 (397)

Data extraction

Search results were first exported in word format with abstracts attached. Titles and abstracts were then reviewed and compared to the eligibility criteria outlined below. Abstracts that did not meet the inclusion criteria were excluded. Articles whose eligibility was hard to determine, were carried through into the second round.

Second round articles were downloaded in PDF format and subjected to a full-text review to ensure applicability. Conference abstracts were identified during the second round of screening and included if relevant information was presented within the abstract.

Inclusion criteria

- Articles were required to discuss programmes for screening or treatment of viral hepatitis C in prisons.
- Participants were required to be ≥ 18 years and stakeholders in either hepatitis C screening or treatment (e.g. patient, healthcare worker, or prison officer).

Exclusion criteria

- Articles published in any language, except English. However, articles published in other languages were included if relevant information was presented within an English language abstract.
- Research focused on the role of substitution therapy.
- Articles that only discussed or assessed the prevalence of hepatitis C in prisons.
- Studies focusing on community treatment programmes.
- Articles discussing the cost effectiveness of either certain medication regimens or testing and treatment methods within a prison context.
- Research assessing the efficacy of particular medication regimens within prisons.
- Research assessing the efficacy of a particular screening tool were excluded, unless this screening tool formed part of a wider programme that was also discussed.

Articles were not excluded based on a standardised assessment of quality. Instead, judgements were made about the robustness of each piece of contributing evidence and its suitability for developing theories related to the testing, assessment, or treatment of viral hepatitis C in prison.

Appendix B: SystmOne templates and LBCSG forms

SystmOne forms, used to record data on blood-borne virus opt-out testing throughout the London prison estate. Mandatory tick boxes are denoted by “*”. Codes next to statements are the SystmOne READ codes assigned to each tick box. The first form recorded test offers, and tests completed, whilst the second recorded test results.

Blood Borne Virus Screening Page 2 of 3

Guidance Page | **BBV Screening** | Publication Details

BBV Screening

*Hepatitis B screening offered

Screening? Hepatitis B screening test (XaEXZ)
 Hepatitis B screening declined (XaLND)

*Hepatitis C screening offered

Screening? Hepatitis C screening (XaJh4)
 Hepatitis C screening declined (XaLNE)

*HIV test offered

Screening? HIV screening test (Xalon)
 HIV screening declined (XaL17)

Show recordings from other templates
 Show empty recordings

Information | Print | Suspend | Ok | Cancel | Show Incomplete Fields

Blood Borne Virus Screening Results Page 2 of 3

Guidance Page | **Screening Results** | Publication Details

Please back date the result to the same day as the sample was taken of the date shown on the result or letter.

Event details shown as the border to this template will allow you to change the event date for the whole template.
 If adding these results with out the patient being present, please also click on the Other Details icon and in the Contact section change the event type to Admin event and then click OK

Hepatitis B Core Antibody Result Hepatitis B core antibody negative (XaQe3)
 Hepatitis B core antibody positive (XaQe4)

Hepatitis B Surface Antigen Result Hepatitis B surface antigen negative (XaLQM)
 Hepatitis B surface antigen positive (43B4)

Hepatitis C Antibody Result Hepatitis C screening negative (XaPLZ)
 Hepatitis C screening positive (XaPLJ)

Hepatitis C PCR Result Hepatitis C viral ribonucleic acid PCR negative (XaOvh)
 Hepatitis C viral ribonucleic acid PCR positive (Xa/Bp)

Hepatitis C Genotype Result Hepatitis C genotype 1 (XaZSP)
 Hepatitis C genotype 2 (XaZSQ)
 Hepatitis C genotype 3 (XaZSS)
 Hepatitis C genotype 4 (XaZST)
 Hepatitis C genotype 5 (XaZSU)
 Hepatitis C genotype 6 (XaZSV)

HIV Result HIV negative (43C2)
 HIV positive (43C3)

Show recordings from other templates
 Show empty recordings

Information | Print | Suspend | Ok | Cancel | Show Incomplete Fields

LBCSG reporting forms

Version 1.0 (April 2017). Developed by the LBCSG, without input from myself or the UCL team.

BBV testing data collection

Prison Name	
Reporting start date	
Reporting end date	

		Stage	<i>Please fill in metrics in this column</i>
General		Total new receptions	
		Number offered test	
		Number tested	
HCV	Testing	Number positive for HCV antibody (DBST)	
		Number offered blood test (for confirmation)	
		Number RNA positive for HCV	
		Total number with previous diagnosis of HCV	
	Numbers by route of transmission	Intravenous drug use (IVDU)	
		Sexual transmission	
		Maternal transmission	
		Unknown	
		Other	
	CHC Staging: Fibrosis levels (ELF or Fibroscan)	Number with ELF>9.8 OR Fibroscan >11.5 (significant fibrosis)	
		Number with ELF>11.3 OR Fibroscan >12.5kPa (cirrhosis)	
	Referrals	Number of people with cirrhosis referred	
		Number offered treatment	
Number offered advice for future treatment			
HBV	Testing	Number positive for HBV antibody (DBST)	
		Number offered blood test (for confirmation)	
		Number RNA positive for HBV	
		Total number with previous diagnosis of HBV	
	Numbers by route of transmission	Intravenous drug use (IVDU)	
		Sexual transmission	
		Maternal transmission	
		Unknown	
		Other	
	HBV serology	Number with HBV DNA>2,000IU/ml	
		Number eAg+	
		Number eAg-	
	Fibrosis levels (ELF or Fibroscan)	Number with ELF>9.8 OR Fibroscan >11.5 (significant fibrosis)	
		Number with ELF>11.3 OR Fibroscan >12.5kPa (cirrhosis)	
	Referrals	Number of people with cirrhosis referred	
		Number offered treatment	
Number offered follow-up plan			
HIV	Testing	Number positive for HIV (DBST)	
		Number confirmed positive for HIV	
		Total number with previous diagnosis of HIV	
	Numbers by route of transmission	Intravenous drug use (IVDU)	
		Sexual transmission	
		Maternal transmission	
		Unknown	
		Other	
	Referrals	Number referred to specialist services	

Notes (Please enter any notes below)

Appendix B: Example LBCSG data report

Note to readers: because of space limitations, the data graphs referred to as “figures” in the report text have been omitted.

Yearly assessment

Reception-based testing

Between April 2017 and March 2018 there were 27,273 registered receptions, 19,664 recorded blood-borne virus (BBV) test offers, and 11,164 recorded BBV tests completed. This corresponded to a London-wide offer proportion (% of receptions offered a test) of 72% and a regional coverage (% of receptions tested) of 41%. Prison specific data are presented in table 1.

As expected, local prisons continue to offer more tests than those with fewer prison entrants (figure 1). However, a decrease in the number of tests completed between Q3 and Q4 in Prison 2, Prison 4, and Prison 6, resulted in a count close to Prison 5 and Prison 3 (figure 2). This Q4 decline was also observed in Prison 7 and Prison 8. In terms of numbers declining, Prison 6 and Prison 2 reported more people opting out, when compared to Prison 1, a prison that receives a similar number of receptions (figure 3).

NHS England targets are set at 100% of receptions offered a test and 50% (amber) or 75% (green) of receptions tested. The proportion offered a test ranged from 56-100%, with Prison 4 and Prison 3 reporting the highest values (92% and 100% respectively) (figure 4). A decline in Prison 4 between Q3 and Q4, corresponds with a switch from offering testing at first reception to offering at the point of testing (usually the morning after). Prison 2 has also been experimenting with how testing is offered, however it is currently unclear what is behind the decline in Prison 7.

Programme coverage ranged from 20-78%. Prison 3 is the only prison to report a yearly coverage >75% (green indicator). Prison 1, Prison 5, and Prison 7 reported a yearly coverage of ≥50% (amber indicator). Prison 2, Prison 4, Prison 6, and Prison 8 failed to achieve this target. All prisons, except Prison 1 and Prison 3, reported a drop in coverage between Q3 and Q4.

General population-based testing

In Q4, prisons began disaggregating the reporting of tests completed on reception and testing elicited at other times/via other methods. It was hoped that this would help the steering group better identify the different sources of testing within prisons, as well as address an issue with prisons reporting more offers than receptions per month. Prison 1, Prison 3, Prison 5, and Prison 7 all reported additional testing taking place (table 2). The

number of additional BBV tests ranged from 7-79. Only Prison 3 reported the different ways this testing was elicited.

Positivity

Out of 11317 (including additional testing) recorded BBV tests, 547 anti-HCV+ (4.9%), 253 HCV RNA+ (2.3%), 181 HBsAg+ (1.6%), and 82 HIV+ (0.7%) samples were positive. There is currently no means of distinguishing between new and previous infection. Estimates vary between prisons, with local prisons tending to report a higher anti-HCV sample positivity (table 3). In terms of volume, Prison 1 accounted for 50% of anti-HCV, 76% of HCV RNA, 30% of HBsAg, and 38% of HIV positive samples.

Interpretation

BBV test outcomes show a dip in performance in Q4. A drop in the offer proportion may reflect changes to the timing of the test offer, as prisons negotiate the tension that exists around the 100% offer target. Some prisons can achieve this target by offering on the first night, however concerns remain around patient receptiveness to the offer at this time. An assessment of test acceptability (proportion offered that accept), could help individual prisons balance quality and quantity, although data limitations need to be addressed first. Prisons reporting offer proportions <50% need to explore solutions to enhance quantity, without sacrificing the quality of the offer.

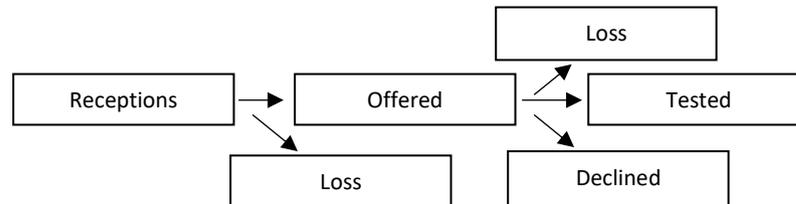
Several prisons reported a drop in the proportion of receptions tested between Q3 and Q4. It is unclear what was driving this. High numbers of declines in Prison 2 and Prison 6 suggest that greater focus should be placed on opt-out offer delivery within these establishments. The sudden drop in coverage in Prison 7 between Q3 and Q4 requires further exploration, but a note on the data reporting form implies that Q4 testing figures may not include individuals that had been tested previously.

The disaggregation of reception and general population-based testing may also have contributed to the drop-in test coverage. The small numbers reported by prisons, reinforces the idea that it is the reception-based opt-out programme that is driving BBV testing within the London estate.

Finally, data highlights a high anti-HCV prevalence estimate in local prisons. However, these prisons also tend to struggle to test >50% or more of their receptions. With a new NHS commitment to eliminate HCV by 2025, case detection within these establishments is becoming increasingly important and solutions are required that help healthcare teams, operating in these challenging environments, to sustainably test a high proportion of their monthly receptions.

Data considerations

Changes to data recording and reporting have been beneficial, but difficulties remain. One limitation relates to accurately calculating test uptake. With prisons now reporting numbers declining a test, “declined” and “tested” variables should equal the number of offers within a given month (or be less if there is loss between the offer and patient response).



However, Prison 5, Prison 7, Prison 2, and Prison 6 all reported more people testing and declining than were offered within a given month, resulting in a quarterly uptake >100%. This likely results from role-over between different months. Prison 8 is the only prison to consistently report offers = loss + declined (as would be expected if testing at the point of offer), although Prison 1 also reported this in Q4. Solutions to this limitation should be considered.

Another persistent limitation is variability in reporting. Prison 4 is now the only prison not reporting numbers declining. Prison 5, Prison 6, and Prison 7 do not report results of confirmation testing, which may relate to issues with laboratory contracts. Only Prison 3 reported justifications for opt-out in Q4. This inhibits the level of analysis that can be conducted, and prisons are encouraged to report as much data as can feasibly be acquired. Finally, this report did not cover the pathway outside opt-out testing. Issues with pulling this information out of SystmOne because of a lack of READ codes results in a large amount of missing data. Furthermore, roll over between months makes data interpretation increasingly difficult as you move along the pathway. A detailed look at how this data could be recorded is required, before meaningful analysis can take place.

Conclusions

Opt-out testing has been successfully implemented and an increase in testing across the estate is testament to the hard work of the prison healthcare teams. The steering group’s initial objective of overseeing opt-out implementation has been a success. However, the challenge now is to maintain and build on outcomes. Data collection and reporting was initially setup to oversee implementation. However, in order to support the new objectives (as reflected in the May Terms of Reference), more robust data is required.

Changes to the way data are recorded is required, in order to provide a system that is both easy for prisons to use and accurate, allowing patient journeys to be tracked across the pathway. Without this, there is a risk that policy decisions could be made, based on incorrect interpretations of the data.

Report developed by: Seth Francis-Graham (UCL) (25/05/2018).

Table. The number of receptions, BBV test offers, BBV tests completed, offer rate, and coverage from April 2017 and March 2018, broken down for the eight Greater London prisons. Mean and standard deviation calculated at a monthly level.

Prison	Reception (mean; standard deviation)	Offer (mean; standard deviation)	Tests completed (mean; standard deviation)	Offer proportion (%)	Coverage (%)
Prison 1	6088 (M=507; SD=56)	4926 (M=411; SD=47)	3630 (M=316; SD=52)	81	60
Prison 2	5044 (M=420; SD=44)	2833 (M=236; SD=81)	1032 (M=94; SD=33)	56	20
Prison 3	1124 (M=94; SD=18)	1124 (M=94; SD=18)	878 (M=72; SD=42)	100	78
Prison 4	5203 (M=434; SD=38)	4785 (M=399; SD=71)	1899 (M=35; SD=52)	92	36
Prison 5	2118 (M=177; SD=18)	1428 (M=119; SD=15)	1191 (M=100; SD=18)	67	56
Prison 6	5891 (M=491; SD=39)	3407 (M=284; SD=85)	1645 (M=147; SD=34)	58	28
Prison 7	1028 (M=86; SD=10)	565 (M=47; SD=20)	511 (M=41; SD=20)	55	50
Prison 8	777 (M=65; SD=24)	596 (M=50; SD=21)	378 (M=32; SD=15)	77	49

Table. Additional BBV testing of the general population, reported by four Greater London prisons in Q4. Mean and standard deviation calculated at a monthly level.

Prison	Number tested (mean; standard deviation)	Reported method of testing
Prison 1	79 (M=26; SD=5)	No details reported
Prison 3	57 (M=19; SD=16)	Testing elicited via men's health clinic, self-referral, awareness events, and testing of existing waiting list.
Prison 5	7 (M=2; SD=1)	No details reported
Prison 7	10 (M=3; SD=2)	No details reported

Table. Prison specific diagnostic data between April 2017 and March 2018. Anti-HCV+ = hepatitis C antibody positive; HCV RNA+ = hepatitis C RNA positive; HBsAg+ = hepatitis B surface antigen positive; HIV Ab/AgP24+ = HIV antibody and P24 antigen positive. Several prisons had issues following up with a PCR test for HCV, therefore RNA prevalence estimates are not presented.

Prison	Anti-HCV+	Anti-HCV prevalence estimate (%)	HCV RNA +	HBsAg+	HBsAg prevalence estimate (%)	HIV Ab/AgP24+	HIV prevalence estimate (%)
Prison 1	273	7.5	193	54	1.5	31	0.9
Prison 2	63	6.1	25	12	1.2	4	0.4
Prison 3	5	0.6	4	2	0.2	1	0.1
Prison 4	80	4.2	18	39	2.1	15	0.8
Prison 5	57	4.8	N/A	27	2.3	2	0.2
Prison 6	65	4.0	13	38	2.3	28	1.7
Prison 7	4	0.8	N/A	9	1.8	1	0.2
Prison 8	0	0	0	0	0	0	0

Appendix B: Individualised patient data capture form

NHS England (London) Health in Justice Blood Borne Virus Monthly Reporting



Introduction

Prison	[Redacted]	Period Ending	31 July 2018
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Contact details

Submission contact name	
Job title	
E-mail	
Telephone	

Please select your provider from the drop-down list

Instructions

In England, The burden of infection with Blood Borne Viruses (BBVs) is high amongst people in prison. PHE's Health and Justice 2015 report exposed the fact that 93% of disease reports in prison are due to two of these viruses, hepatitis B or hepatitis C viruses (HBV or HCV). The prevalence of HCV in particular is elevated in prison, with 9.4% of those tested reported to be chronically infected compared with 0.7% in the general adult population.

Despite the high burden of disease in people in prison, available data sources also show significant under-testing of prisoners. This is explained by several factors, with one of these being how prisoners are offered the opportunity to be tested. This report to be filled in monthly by each prison health provider will help analyse the effect of the opt-out process in test take up and resultant pathways.

Please follow the below instructions to fill all data about blood borne virus testing accurately:

1. Please use one row for each unique prisoner who has entered the system in the month to trace their pathway. Please ensure that a proper NOMIS prisoner number is included
2. The Date of Drop out in the last column is the date that the prisoner drops out the blood borne virus pathway.
3. Please fill in the sheet for new inmates in the previous month by **the 15th of the next month**. (E.g. data for all prisoners who entered the prison in July 2018 must be sent to the commissioner by August 15th)
4. Don't forget to update details of further tests by going back to the previous months (For e.g. enter details of HBV test for prisoner who entered the prison on 30th July 2018 in the July 2018 tab in September 2018)
5. The "Further CQUIN Indicator" sheet needs to be updated **quarterly** to reflect any change in staff.

If you have any queries regarding this process or the programme in general, please contact [Redacted]

BBV testing data

**NHS England (London) Health in Justice
Blood Borne Virus Monthly Reporting**



BBV Data Collection - Detailed Analysis	
Prison	
Reporting Period Start Date ->	01/04/2017
Reporting Period End Date ->	30/04/2017

Prison Number	Date of reception	Received Second Day Screen (Yes/ No/Pathway Exited)	Date of Second Day Screen	Offered test (Yes/ Pathway Exited)	Offer number(1st/2nd/3rd/4th/5th offer since reception)	Date offered test	Decision(Accept/decline)	Justification for opt-out (Drop down with N/A for those who accept)	If Justification for Opt-out is 'Other', enter reason here	Tested (Yes/ Pathway Exited)	Date tested
	02/04/2017	Yes	02/04/2017	Yes	1st offer since reception	02/04/2017		Other (please specify)			31/03/2017
	DD-MM-YYYY		DD-MM-YYYY			DD-MM-YYYY					DD-MM-YYYY
	DD-MM-YYYY		DD-MM-YYYY			DD-MM-YYYY					DD-MM-YYYY
	DD-MM-YYYY		DD-MM-YYYY			DD-MM-YYYY					DD-MM-YYYY

BBV assessment data

Date BBV results received	HCV Antibody Positive (Yes/No)	HBV Surface Antigen (Yes/No)	HDV Antibody Positive (Yes/No)	HIV Positive (Yes/No)	Previous diagnosis (Yes/No)	Patient informed (Yes/Pathway Exited)	Confirmation blood test (Yes/Pathway Exited)	Date of confirmation blood test	HCV RNA positive(Yes/No/NA)	HBV DNA positive(Yes/No/NA)	HDV RNA positive (Yes/No/NA)	Fibrosis Stage (F0/F1/F2/F3/F4/NA)	HIV RNA positive (Yes/No/NA)	Referred to hepatology(Yes/Pathway Exited/NA)	Date of referral (hepatology)	Referred to sexual health(Yes/Pathway Exited/NA)	Date of referral (sexual health)
DD-MM-YYYY								01/04/2017							02/04/2017		02/04/2017
DD-MM-YYYY								DD-MM-YYYY							DD-MM-YYYY		03/02/2018
DD-MM-YYYY								DD-MM-YYYY							DD-MM-YYYY		DD-MM-YYYY

BBV treatment data

HCV treatment offered (Yes/No-offered follow up plan/NA/Pathway Exited)	HCV treatment commenced - date	HCV treatment completed - date	HBV treatment offered (Yes/No-offered follow up plan/NA/Pathway exited)	HBV treatment commenced - date	HDV treatment offered (Yes/No-offered follow up plan/NA/Pathway Exited)	HDV treatment commenced - date	HIV treatment offered (Yes/ No/ NA/ Pathway Exited)	HIV treatment commenced - date	Date of Exiting Pathway	Exit Stage	Reason For Exit	Reason for Exit (Others)-Free Text
	DD-MM-YYYY	02/04/2017		02/04/2017		02/04/2017	Yes	02/04/2017	02/04/2017	Before 2nd Night Screen	Did Not Attend	
	DD-MM-YYYY	DD-MM-YYYY		DD-MM-YYYY		DD-MM-YYYY	Yes	DD-MM-YYYY	DD-MM-YYYY			
	DD-MM-YYYY	DD-MM-YYYY		DD-MM-YYYY		DD-MM-YYYY	Yes	DD-MM-YYYY	DD-MM-YYYY			
	DD-MM-YYYY	DD-MM-YYYY		DD-MM-YYYY		DD-MM-YYYY	Yes	DD-MM-YYYY	DD-MM-YYYY			

Appendix C: Rapid-realist review search strategy

Database: Ovid MEDLINE(R) Epub Ahead of Print, In-Process & Other Non-Indexed Citations, Ovid MEDLINE(R) Daily and Ovid MEDLINE(R) <1946 to Present>

Search Strategy:

-
- 1 Prisoners/ (15231)
 - 2 offender*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms] (10327)
 - 3 prisoner*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms] (18395)
 - 4 convict*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms] (5961)
 - 5 detainee*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms] (832)
 - 6 inmate*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms] (4702)
 - 7 incarcerated.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms] (5864)
 - 8 1 or 2 or 3 or 4 or 5 or 6 or 7 (36284)
 - 9 Prisons/ (8672)
 - 10 prison*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms] (26108)
 - 11 gaol*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms] (93)
 - 12 jail*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms] (2864)
 - 13 ((Correction* or penal or remand* or detention or custody) adj2 (centre or department or facility* or system*)).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms] (1989)
 - 14 Penitent*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms] (601)
 - 15 9 or 10 or 11 or 12 or 13 or 14 (28408)
 - 16 8 or 15 (44020)
 - 17 mass screening/ or mandatory testing/ (94669)

- 18 Diagnosis/ (17347)
- 19 "Diagnostic Techniques and Procedures"/ (2880)
- 20 (Mandatory adj (test* or screen* or diagnos* or identif* or assess*)).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms] (1349)
- 21 (Systematic* adj (test* or screen* or diagnos* or identif* or assess*)).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms] (11619)
- 22 (Routine adj (test* or screen* or diagnos* or identif* or assess*)).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms] (18344)
- 23 (Compulsory adj (test* or screen* or diagnos* or identif* or assess*)).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms] (121)
- 24 (Obligatory adj (test* or screen* or diagnos* or identif* or assess*)).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms] (87)
- 25 opt-out.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms] (1191)
- 26 opt* out.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms] (1561)
- 27 17 or 18 or 19 or 20 or 21 or 22 or 23 or 24 or 25 or 26 (144087)
- 28 16 and 27 (934)
- 29 limit 28 to yr="2000 - 2017" (662)

Appendix C: Rapid-realist review data extraction form

Descriptive Information	
Paper identification number	
First author	
Year of publication	
Title	
Country	
Aims/objectives	
Study design	
Methods	
Quality assessment score	
Dimensions of relevance	
Relevance score	
Disease(s) covered	

Opt-out screening information (context)	
Type of prison	
Prison population	
Physical context of the prison	
Social context of the prison	
Relevant educational activities	
Timing of opt-out offer	
Method of opt-out offer	
Method of sample acquisition	
Details of pre/post-test discussion/counselling	
Contextual issues	

Mechanisms and outcomes	
Mechanisms mentioned	
Temporal changes in mechanisms	
Social outcomes of programme	
Physical outcomes of programme	
Temporal changes in outcomes	

Theory matrix

<i>Intervention theory</i>	<i>Context</i>	<i>Mechanism</i>	<i>Outcome</i>
1.			
2.			
3.			
4.			
5.			

Appendix C: Rapid-realist review phase one and three search results

<i>First author, year</i>	<i>Title</i>	<i>Country</i>	<i>Format</i>	<i>Aims</i>
<i>Public Health England (2014)</i>	BBV Bulletin: Issue 2, July 2014	U.K.	Bulletin	A monthly update report covering the introduction of opt-out BBV testing in prisons
<i>Public Health England (2014)</i>	BBV Bulletin: Issue 3, September 2014	U.K.	Bulletin	A monthly update report covering the introduction of opt-out BBV testing in prisons
<i>Offender Health Research Network (2008)</i>	An evaluation of the reception screening process used in England/Wales	U.K.	Report	To evaluate reception screening and present views from a range of stakeholders regarding reception screening, including challenges to practice and suggestions for improvement
<i>Public Health England (2014)</i>	BBV testing flash cards	U.K.	Clinical guidance	To provide basic guidance for clinicians implementing opt-out BBV testing in the prison system
<i>Public Health England (2014)</i>	Opt-out BBV test algorithm	U.K.	Guidance	Details the recommended test algorithm for BBVs in prison
<i>Public Health England (2014)</i>	Opt-out blood borne virus test algorithm guidance notes	U.K.	Guidance	To provide guidance on the opt-out test algorithm for BBVs in the English prison system
<i>Public Health England (2014)</i>	Frequently asked questions to support the opt-out testing policy	U.K.	Guidance	To provide standard answers for frequently asked questions concerning opt-out BBV testing
<i>The Hepatitis C Trust (2016)</i>	Hepatitis C prevention, diagnosis, and treatment in prisons in England	U.K.	Report/guidance materials	To provide commissioners and prison healthcare teams with practical guidance regarding the implementation of opt-out BBV testing and related hepatitis C care pathways
<i>The Hepatitis C Trust (2016)</i>	The BBV opt-out testing policy for prisons in England: An analysis of need towards full implementation	U.K.	Report	Highlight practical advice from different prisons offering opt-out BBV testing
<i>GILEAD REACH training booklet (2015)</i>	Prison BBV Champions Training	U.K.	Handout	The training booklet provided by GILEAD Sciences Ltd. to prison healthcare to support implementation of opt-out BBV testing
<i>Public Health England (2016)</i>	BBV opt-out testing in Prisons – A London update	U.K.	Presentation on evaluation	Summarise the rationale of opt-out BBV testing in prisons and provide data on current testing rates for the various London prisons. Also provides recommendations informed by national Phase 1 pathfinder evaluation
<i>Leidel (2016)</i>	A theoretical framework for the evaluation of opt-out HIV testing	Australia	Journal article	To consider the application of three theories to the implementation and evaluation of an opt-out HIV testing programme: Behavioural Economics, the Health Belief Model, and Normalisation Process Theory
<i>Johnson (2004)</i>	Defaults and donation decisions	U.S.	Journal article	Review evidence that suggests the preference to become a donor is not well formed and that the donation decision is constructed in response to the question (opt-in/opt-out)
<i>Bronchetti (2011)</i>	When a nudge isn't enough: Defaults and saving among low-income tax filers	U.S.	NBER Working Paper	Present a field experiment that evaluates the effect of defaults on saving decisions among low-income tax filers

Phase one results continued

<i>First author, year</i>	<i>Title</i>	<i>Country</i>	<i>Format</i>	<i>Aims</i>
<i>Johnson (2000)</i>	Defaults, framing and privacy: Why opting in-opting out	U.S.	Journal article	Explore the issue of difference in opt-in and opt-out responses in light of current public debate concerning online privacy and permission for marketing
<i>Keller (2011)</i>	Enhanced active choice: A new method to motivate behaviour change	U.S.	Journal article	Present a series of studies that demonstrate the effectiveness of an alternative to opt-out (active choice), where there is no default, but decision makers are required to make a choice
<i>Halpern (2007)</i>	Harnessing the power of default options to improve health care	U.K.	Journal article	Discuss the role of defaults in healthcare
<i>Sunstein (2008)</i>	Nudge: Improving decision making about health, wealth and happiness	U.S.	Book	Applies behavioural economic “Nudge” theory to a range of social problems
<i>Montoy (2016)</i>	Patient choice in opt-in, active choice and opt-out HIV screening: randomized clinical trial	U.S.	Journal article	To explore the effect of default test offers – opt-in, opt-out, and active choice, on acceptance of HIV testing in an emergency department
<i>Bellman (2001)</i>	To opt-in or opt-out? It depends on the question	U.S.	Journal article	Systematically explore the influence of question framing and response defaults on consumers’ privacy preference

Phase three results

<i>First author, year</i>	<i>Title</i>	<i>Country</i>	<i>Disease</i>	<i>Population</i>	<i>Study design</i>	<i>Justification for inclusion</i>
<i>Khaw, 2007</i>	“I just keep thinking I haven’t got it because I’m not yellow’: a qualitative study of the factors that influence the uptake of Hepatitis C testing by prisoners	U.K.	HCV	Patients in prison	Qualitative interview	Article provided information on patient justifications for not undertaking hepatitis C testing within a prison context. Data used to reinforce several CMO configurations
<i>Rhodes, 2008</i>	The social production of hepatitis C risk among injecting drug users: a qualitative analysis	Mixed	HCV	Injecting drug users	Meta-ethnography	Article provided interesting insight into injecting drug users’ perceptions of hepatitis C and HIV and how risk perceptions shaped considerations of treatment
<i>Strauss, 2008</i>	Barriers and facilitators to undergoing hepatitis C virus testing through drug treatment programs	U.S.	HCV	Patients attending drug treatment programs	Qualitative interview	Article provided reasons for testing and not testing that were used to validate a number of CMO configurations. Article also highlighted that there were similar justifications for testing or not testing for HCV and HIV

Phase three results continued

First author, year	Title	Country	Disease	Population	Study design	Justification for inclusion
Harris, 2016	Finding the undiagnosed: a qualitative exploration of hepatitis C diagnosis delay in the United Kingdom	U.K.	HCV	People living with HCV	Qualitative interview/focus group	Aimed to explore the context of a diagnosis delay among people living with HCV in the UK. Article provided explanations for why individuals with HCV may avoid testing
The Hepatitis C Trust, 2012	Increasing hepatitis B and C testing in the prison setting: the use of new diagnostics at HMP Manchester	U.K.	HCV/HBV	Patients in prison	Report	Article provided information on barriers to testing within the prison setting that was used to validate CMO configurations related to fear of needles and stigma
Young, 2009	Opt-out testing for stigmatised diseases: a social psychological approach to understanding the potential effect of recommendations for routine HIV testing	U.S.	HIV	General population	Psychological experiment	Provided information on testing for a stigmatised disease. Articles idea about normative position and counter normative behaviour helped validate the Ma-Mi theory related to the role of stigma in encouraging and discouraging testing under different conditions
Noland, 2015	Understanding patients' perspectives on opt-out, incentivised and mandatory HIV testing	U.S.	HIV	Sero-positive and negative patients	Qualitative interviews	Article discussed the theory of opt-out testing for HIV. Helped validate a range of CMOs, as well as contribute ideas about the impact of the default effect during opt-out testing
Sabharwal, 2010	Jail-based providers' perceptions of challenges to routine HIV testing in New York City Jails	U.S.	HIV	Patients in prison	Mixed Methods	Article provided rare insight into healthcare worker perceptions of running a routine HIV testing service within high-turnover jails
MacDonald, 2006	People with problematic drug use and HIV/AIDS in European prisons: an issue of patient confidentiality	Mixed	Mixed	Prison staff, medical staff, and patients in prison	Interviews	Provides broad insight into issues of confidentiality throughout EU prisons in terms of the diagnosis and treatment of potentially stigmatising medical conditions. Data was used to reinforce theories related to confidentiality
Hickman, 2007	Increasing the uptake of hepatitis C virus testing among injecting drug users in specialist drug treatment and prison settings by using dried blood spots for diagnostic testing: a cluster randomised controlled trial	U.K.	HCV	Specialist Drug Treatment and Prison	Cluster randomised control trial	Article provided quantitative evidence regarding the method of sample acquisition and test uptake. Used to reinforce theories related to fear of an invasive test method
Craine, 2015	A stepped wedge cluster randomized control trial of dried blood spot testing to improve the uptake of hepatitis C antibody testing within UK prisons	U.K.	HCV	Prison	Stepped wedge cluster randomised control trial	Article provided quantitative evidence regarding method of sample acquisition and test uptake. Used to reinforce theories related to fear of an invasive test method

Appendix C: Opt-out (switching cost) form

We offer all new arrivals at this prison the opportunity to do a blood-borne virus test. This test is for hepatitis C, hepatitis B, and HIV. If you do not want to take a test, we need you to fill out this form. Any information you provide will be kept private.

By filling out this form, you are agreeing that you have declined a test for blood-borne viruses at this time. We will continue to offer testing throughout your stay in this prison. If you change your mind, tell the nurse and the test will be done.

Please tick all boxes that you agree with:

- I have been offered a test for blood-borne viruses.
- I understand that this test is for hepatitis C, hepatitis B, and HIV.
- I have been given information on these viruses.
- I understand that I could be infected, even if I am feeling well.
- I understand that I could be infected, even if I had a test recently.
- I understand that these viruses can be life threatening, unless diagnosed.
- I understand that there are treatments available for all three viruses.
- I understand that the test is free.
- I understand that testing is private.
- I understand that the test is a small finger prick.
- I understand that I can take advantage of this opportunity at any point during my stay in the prison, despite filling out this form.

Please tick the reason for not wanting to test (you can tick more than one):

- I tested for these viruses recently.
- I don't like the finger prick.
- I am not at risk.
- I don't think testing will be kept private.
- I am leaving the prison soon.
- I want time to think about it.
- I don't want to know whether I am infected right now.
- Other: _____

*****Please put form in the envelope provided and seal it. *****

Opt-out form feedback from people incarcerated within London prisons

Prisoners attending Hepatitis C Trust BBV educational events across the London prisons were asked to provide feedback by writing on the forms.

Underneath the statement that “Any information you provide will be private” one person wrote:

“First your in jail so its not. A lie”

Other prisoners suggested that the form was pointless, and that testing should be compulsory:

“I believe testing should be compulsory”

Others used the form as an opportunity to provide feedback on the overall testing process:

“Some people coming to jail might not want to no. Jail is anuff.”

“Have a real person at 2nd Day Screening to talk with the inmates”

“They should have a hep C rep in reception to offer & give advice on getting tested”

“Let them know how procedure done i.e. a little prick to the finger”

“I think everyone should be offered the test. Nurses should then explain with HIV + Hepatitis its about detecting the disease in its early stages and therefore is curable. Nurses should also explain that you can be infected but not have any pain or signs showing you have it”.

“I think every 1 who comes into prison should be seen on a 1-2-1 basis as soon as there admitted into prison as it’s a personal thing”

From sitting in on one of these feedback sessions, prisoners were frequently hesitant to critique the form and instead tried to fill it out. All individuals observed were able to complete the form.

Please provide a justification for your decision not to take advantage of this opportunity:

I dont need it

Please provide a justification for your decision not to take advantage of this opportunity:

I Dont think I need it

Please provide a justification for your decision not to take advantage of this opportunity:

I dont need to get tested im okay

Please provide a justification for your decision not to take advantage of this opportunity:

i do not think i need it.

Please provide a justification for your decision not to take advantage of this opportunity:

just dont want it.

Please provide a justification for your decision not to take advantage of this opportunity:

I didn't need it because i feel okay without it.

Appendix D: Consent and inclusion criteria

Consent during observation

Consent for observational data generation was guided by the following principles:

- If the staff member, conducting the activity under observation, does not provide consent, no observation will be carried out.
- In circumstances where observation of a process involving more than 4 individuals is carried out, and one individual (not a staff member conducting the activity) does not provide consent, observation of that individual will cease but observation of the other individuals will continue, provided they have given consent.
- In circumstances where observation of a process involves less than 4 individuals, if a single member does not provide consent for observation, all observations will cease.
- If a person in prison is unable to understand the information and provide verbal consent, either due to language barriers, distraction, or mental/physical morbidity, then observation of that individual will not be carried out. People observed during opt-out clinics where LanguageLine is used by the healthcare worker to communicate, will however be asked whether observation can take place via the translation service.

Eligibility criteria

Given that much of what takes place within prison can be sensitive in nature and in recognition of the vulnerability of all three respondent groups (particularly prisoners), I developed stringent exclusion criteria for both interviews and observation.

Inclusion criteria

Realist interview – prisoners:

- Housed within one of the selected prisons.
- Have been offered a test for blood-borne viruses during a testing clinic within the establishment where the interview will take place.
- Able to provide informed consent to participate in the research.
- Is not listed by prison authorities as “vulnerable”.
- Is not listed by prison authorities as a “risk”, either to themselves or staff.

Realist interview – prison officers:

- Officer currently is, or recently has been (within the last 2 months), responsible for the transportation and/or monitoring of people to health clinics or has managerial responsibility for this.
- They have the capacity and time to conduct an interview, without interfering with their prison duties.
- They are able to provide informed consent to participate in the research.

Realist interview – healthcare worker:

- They have delivered an opt-out BBV test within the past month or have relevant managerial experience of the testing programme.
- They have the capacity and time to conduct an interview without interfering with their clinic or administrative duties.
- They are able to provide informed consent to participate in the research.

Exclusion criteria

Realist interview – prisoners:

- Potential participants who, due to language or other special communication needs, are unable to understand the verbal explanations or written information given in English, were excluded.
- Prisoners with a vulnerable or risk status (e.g. identified by Safer Custody as a risk to either themselves or others, are participating in Therapeutic Community, are identified as High or Exceptional Risk, are diagnosed with a serious mental health condition or are exhibiting signs of a serious mental health condition, are identified by their Personal Officer as vulnerable at the time of the research, are E-listed, are participating in Psychologically Informed Planned Environments, and/or identified by the clinical care team as vulnerable due to medication or morbidity) were excluded from participation.
- Unable to provide any relevant information on opt-out BBV testing within the prison that the research is being conducted within.

Realist interview – officers:

- Unable to provide informed consent due to language or other special communication needs.
- Unable to participate in the interview without causing disruption to their prison duties.
- Has no experience of either managing areas where testing takes place, transporting prisoners to and from health clinics, monitoring prisoner movement to and from health clinics, and /or monitoring health clinics for two months (as of the date of recruitment).

Realist interview – health workers:

- Unable to provide informed consent due to language or other special communication needs.
- Unable to participate in the interview without causing disruption to their clinical/administrative duties.
- Has no experience of managing opt-out BBV testing or conducting BBV testing within the past month (as of the date of recruitment).

Appendix D: Example consent form (prisoner)

To accompany Participant Information group 3, version 1.0 (03/10/2017).

IRAS ID:

Location:

UCL Study ID:

CONSENT FORM

“Evaluating opt-out blood-borne virus testing within high-turnover London prisons: a realist process evaluation (student study).”

Please
initial box

Name of Researcher:

1. I confirm that I have read the information sheet dated.....
(version.....) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.
2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected.
3. I understand that the information collected about me will be used to support other research in the future and may be shared anonymously with other researchers.
4. I understand that my interview will be audio recorded. I understand that this information will be stored securely by UCL, transcribed by separate organisation anonymised and archived by UCL for 10 years.
5. I understand that the information I provide in this interview will be confidential, unless I notify the researcher of plans to harm myself or others, plans to break prison security rules, and/or disclose unreported offences.
6. I agree to take part in the above study.

Participant

Date

Signature

Research team member

Date

Signature

Appendix D: Example information sheet (prisoner)

Evaluating opt-out blood-borne virus testing within high-turnover London prisons: a realist process evaluation (student study).

Participant Information Sheet (version 1 group 3)

Dear Potential Participant,

Thank you for taking the time to read about this evaluation. **This evaluation is part of a University-based study that is separate from the prison.**

During this health appointment, you should have been offered a finger-prick test for blood-borne viruses. You are being invited to take part in an evaluation of this finger-prick test. This evaluation is being done by Mr. Seth Francis-Graham, a PhD researcher from UCL. Before you say whether you want to be involved, it is important that you read this sheet. If you agree to take part in this study, you will be asked to sign a Consent Form before the interview.

What is the evaluation about?

This evaluation study aims to look at the finger-prick test and learn more about how it works within this prison. We are wanting to hear about what you think of this test and ask you why some people may want to test, and others may not. We will use what you say to try and make improvements to the test process and the overall quality of service that is provided to you.

What will I have to do if I take part?

If you agree to take part, you will be asked a series of questions in an interview. There are no right or wrong answers, we are wanting to hear your opinions. The interview will be conducted at the prison by Mr. Seth Francis-Graham. We would like to audio record the interview and we will ask you if that is okay. The interview will not last longer than 1.5 hours and may be cut short depending on the wider prison regime. If there are any questions you do not want to answer, you do not have to do so.

Why should I take part?

This interview will be an opportunity for you to freely talk about what you think could improve the testing service. We will use your opinions to help provide a better service within this prison. We do not expect your involvement in the interview to put you at any risk. Questions will not cover any previous criminal behaviour or convictions.

Do I have to take part?

No, **participation in this evaluation is voluntary.** Whether you take part is your choice. If you decide you do not want to, you do not have to tell us why. **Your decision to take part or not, will not affect your healthcare, your prison sentence, your level of earned privileges, or your chance for parole.** If you are unsure about participation you can take 72 hours to think about it.

If you decide that you do not want to take part at any point, even after signing the consent form and starting the interview, you can leave the evaluation by letting Seth know. Please be aware however that we will be unable to remove anything you said during the interview.

If I agree to take part, what happens to what I say?

Anything you say during the interview will be **private**. All information provided during the interview will be digitised and securely stored on an encrypted server. These audio recordings will be transcribed by a reputable transcription company that commonly works with UCL. The selected company will be required to sign a standard guarantee from to say that they will handle the data in a manner conducive with UCL security policies. Transcripts will have any information that could be used to identify you redacted, in order to protect your anonymity.

Following evaluation completion, data will be stored securely in the UCL research data archive for 10 years and the UCL Research Data and Network Services Executive will manage the information. Please be aware that this **anonymous data** may be accessed by other researchers and used for future projects.

Anything you say during the interview will not be passed onto the prison authorities, unless you mention plans to harm yourself or others, report intention or previous actions that break prison rules, provide information that raises questions about radicalisation and/or discuss an unreported offence. Questions will be focused on the testing process and will not directly ask you about your previous criminal behaviour.

What happens to the results of the evaluation?

Evaluation findings will form part of a PhD thesis and a copy will be available from the UCL library, via their online repository. The findings from this work will also be viewed as a potential publication and the necessary arrangements will be made for submission to a peer-reviewed journal following evaluation completion. **Please be reassured that it will not be possible to identify you in any of these reports.**

What do I do now?

Please make sure you have read and understand the information. If you have any questions, please ask the nurse who provided the information to you or ask the nurse to call Mr. Seth Francis-Graham into the room. If you would like to take part, please tell the nurse. Your participation will need to be cleared with the prison before the interview takes place. If the prison does not give clearance you will be informed. If they do, you will be followed up for interview. For further information about funding, the ethical review process of the evaluation and contact details, please see pg. 3.

Further information or complaints

If you have questions, we encourage you to discuss this with Mr. Seth Francis-Graham (please see contact information). If you are unhappy about the way the interview was done, please send an email to the following address: [REDACTED]

[REDACTED] The UCL Research Incidents Office will acknowledge the

complaint in writing within 7 working days and appropriate action will be taken. **We acknowledge that you do not have access to a computer during your stay within the prison and therefore encourage you to work with a trusted member of staff to help you send this email.**

Evaluation funding and sponsorship

Sponsor: University College London (UCL).

Funder: National Institute for Health Research (NIHR) and the NHS Health in the Justice System.

Ethical review

This evaluation has undergone peer review by an academic from UCL who is not connected to it. It has also undergone review by the Joint Research Office. The evaluation has been approved by the Governing Governor of this establishment. The evaluation required independent review and approval from the Her Majesty's Prison and Probation Service: National Research Council.

Contact information

Name/position: Mr. Seth Francis-Graham, PhD researcher.

Face-to-face: Seth will be conducting work throughout the prison for several months. Please feel free to approach him and ask him about any questions that you may have.

Letter: If you wish to write a letter, please give this to a member of healthcare and ask them to give it to the healthcare manager. The manager will then send this letter on to Mr. Francis-Graham.

Appendix D: Example topic guide (prisoner)

Pre-interview checklist

- Respondent understands purpose of the interview and has read the information sheet.
- Aware that interview length flexible around wider prison regime.
- Ensure respondent knows about confidentiality and anonymity. If concerned at any point about confidentiality, encourage them to pause the interview.
- Respondent aware of rules surrounding notifiable information.
- Withdrawal from the study can take place at any time, but information provided during the interview will not be deleted.
- Provide details on wider support available to the respondent.
- Ensure respondent aware they do not have to answer any questions that they are not comfortable with.
- Consent taken.
- Ok to record. Aware that recording can be stopped at any time.
- Any questions?

*****Individual tested (from observation): yes/no*****

Opening questions

Question: Can you tell me a little about hepatitis C, hepatitis B, and HIV?

Question: Can you tell me a bit about the finger prick test they do at secondary screening?

Probes:

- What is being tested for?
- Why are we testing for that?

Question: How was testing offered to you?

Probe:

- Did they receive information on the viruses, treatment, vaccine etc.?

Question: Did you accept or decline testing when offered (clarification)?

Question: Can you tell me a bit about why you made that choice?

Probe:

- Try and get contextual information during choice justification (did they trust the healthcare worker etc).

Question: What reasons do you think others might give for making that decision?

Question: How important is the nurses' behaviour, in influencing your decision?

Question (if tested): Why might someone not want to take the test?

Question (if tested): Did the test hurt?

Question: Is there a difference between a nurse asking, "would you like a test" and being told "we need to test you?"

Probes:

- Is one perceived as mandatory?

Question: I have noticed that some people do not want to come to secondary screening. Why is this?

Question: I have also noticed that some people won't wait at secondary screening. Why is this?

Theory-related propositions

Question: Were you worried that you may have been infected with one of these viruses?

**

Follow up: So why did you make the decision to (not) test if you thought you may/may not be infected?

**

Question: How would someone be treated if others found out that they had one of these infections?

**

Follow up: What ways might someone find out that another person is positive?

**

Follow up: Could this influence peoples' decision to test?

Question: Would it be difficult to cope with having one of these infections within the prison? Why?

**

Follow up: Could this influence people's decision to get tested?

Question: What could help patient's feel more confident about dealing with a positive diagnosis?

**

Follow up: Could this encourage more people to get tested?

Probes:

- What is it about this that would encourage patients to test?

Question: A common justification I have heard for not wanting to test is not liking needles. Do you think this may be a reason for patients not wanting to test?

**

Follow up: Are certain people more likely to fear needles than others?

Question: What method of testing would you prefer: venous or finger prick?

**

Follow up: What is it about that method which makes it preferable?

Question: Did you feel like you were recommended to take a test?

**

Follow up: Is the fact that everyone is offered a test seen as a recommendation?

Question: Are there any reasons why you wouldn't follow the recommendation of a healthcare worker?

**

Follow up: Are certain people less likely to follow recommendations? Who and why?

Question: Would being offered testing on the first night of arrival affect your decision to test?

Probe:

- What is it about testing during that time that would influence your decision?

**

Closing question

Question: Is there anything else you think we should know about the overall topic?

Turn off recording device

Appendix D: Post-interview debrief sheet (prisoner)

Debrief Sheet

Thank you for participating in the interview. We hope it was done in a way that you found to be acceptable. If you require further information, please contact Mr. Seth Francis-Graham in the following ways:

1. **Face-to-face:** Seth will be conducting research throughout the prison for a number of months. Please feel free to approach him and ask him any questions that you may have.
2. **Letter:** If you wish to write a letter, please give this to a member of healthcare and ask them to give it to the healthcare manager. The manager will then send this letter on to Mr. Francis-Graham.

If you have a complaint about the way the interview was conducted, please collaborate with a trusted member of staff to send an email to: [REDACTED]
[REDACTED]

Sources of support within the prison

The Forward Trust Psychosocial Interventions: Provides support for drug and alcohol abuse and breaking the cycle of crime. Please ask your Wing/Personal officer to get [name removed] or [name removed] to contact you.

Healthcare Peers: There is peer support available to you within this prison. Each wing will have its own peer. Please ask a member of staff to direct you to one of these peers.

The Hepatitis C Helpline: The Hepatitis C Trust provides confidential support for those who have been diagnosed or are concerned about being diagnosed with a blood-borne virus. Please phone: [REDACTED]

Listeners: Listeners are people in the prison who are trained by the Samaritans and provide 24-hour support for people in distress. If you would like to speak to a Listener, you can approach them on the wing (they wear orange polo shirts) or ask a member of staff.

Insiders: Insiders are people in the prison who are available on the wings (they wear green polo shirts) to provide you with basic information on the induction process and services available in the prison.

Samaritans helpline: You can access the Samaritans directly via the pin phone on: [REDACTED]

Appendix D: Ethical collection and storage of qualitative data

Ethical consideration 1: Risk of coercion

There was a risk of coercion if I approached prisoners directly for participation in the research. Initial engagement, for either interviews or observation, was made by a member of the prison or healthcare staff.

Ethical consideration 2: Ulterior motives

Prisoners' willingness to participate in interviews was linked to the prison regime (i.e. people more likely to participate if the interview meant extra time out of the cell and decline when an interview meant missing association). When concerned that people were agreeing to interview, purely in order to escape captivity or to engage healthcare staff and request medical care, I did my best to try and clarify their intentions and ensure individuals were aware of what they were consenting to.

Ethical consideration 3: Comprehension of research

There was a risk that incarcerated persons would not be able to read or understand the written information provided. All written information was SMOG tested in an attempt to ensure a reading age of ~14. Written information was also read out, alongside other verbal information, where required.

Ethical consideration 4: Notifiable information

As a researcher in prison, I was obliged to pass on "notifiable information" to the prisoner's Offender Manager and/or complete a Security Information Report, as of PSI 22/2014 (AI 14/2012) "Research Applications" and Rule 51 of the Prison Rules (1999).

Notifiable information included plans to harm themselves (or others), information about previous undocumented crimes, radicalisation, and plans/behaviour that breaks prison rules. All prisoners were repeatedly warned of this risk throughout data generation. These warnings came in both written and verbal format. If a respondent began to stray into a topic that could have been risky, I provided a verbal warning.

Ethical consideration 5: Ensuring confidentiality

Prisons can be difficult places to ensure confidentiality. All interviews were completed in private rooms and all respondents were asked whether they felt comfortable with the confidentiality measures I had set-up.

During observations, prisoners and staff both attempted to read my field notes. I always allowed those individuals who had been observed, to read field notes that had been made about them. However, to ensure that they could not access information about others, I tried (as far as possible) to use pseudonyms or codes to refer to other individuals and I covered aspects of field notes that were not relevant

using blank paper. I also wrote notes in a deliberately scruffy manner, as some people attempted to walk past and scope the notes that I was making.

Safety consideration: Personal safety of the researcher

To ensure that I behaved in an appropriate manner within the prison, I familiarised myself with the follow prison documentation:

- PSI 55/2011 – “Management and Security of Keys and Locks”;
- AI 08/2016 – “Information Risk Management Policy”;
- AI 08/2015 – “Fire Safety in Prison Establishments”;
- PSI 25/2014 – “IT Security Policy”;
- PSI 24/2014 – “Information Assurance Policy”;
- PSI 03/2013 – “Medical Emergency Responses Codes”;
- PSI 29/2015 – “First Aid”.

I also attended “Security and Key Training”, hosted at Prison 1 and 2, where basic information on professional conduct and security within a prison environment was provided.

Data management:

All data were digitised and uploaded to the UCL Data Safe Haven, providing “Advanced Encryption Standard 256-bit”. Field notes were stored in a locked cabinet at UCL, whilst physical audio recordings were immediately destroyed following transfer to the Data Safe Haven.

Transcription of audio recording was undertaken by a trusted third part, who signed to confirm that they would comply with the necessary data security procedures stipulated by UCL. Transfer of audio recordings and transcripts was achieved using an encrypted upload and download system. All computers used to access the Data Safe Haven had appropriate security procedures in place, including passwords and antivirus software as per Her Majesty’s Prison and Probation Service: “IT Security Policy”.

All identifying information was redacted and prisons and participants provided pseudonyms. All interview recordings and transcripts were assigned a unique identifying code, recoded on the Data Safe Haven. All study related documents were archived at the UCL research data archive and responsibility transferred to the UCL Research Data and Network Services Executive.

Appendix D: Ethical approvals

Confirmation of service evaluation

Wed 13/12/2017, 15:05

Defining Research Leaflet.pdf

146 KB

Download

Save to OneDrive - University College London

Dear Seth and William

I have undertaken a review of the IRAS application, and my conclusion is that this application is for service evaluation rather than research as defined by the HRA.

My understanding is that you are looking to evaluate a current process of opt out of blood borne virus testing amongst the London prison population to establish how uptake could be improved.

My understanding is that this project has been designed to define the current process and evaluate what is happening now with a view to produce appropriate guidance to enhance the current process. In short, my understanding is that you are aiming to evaluate the current process to look to reconfiguring the service in the future.

In order for this to be considered research you should be attempting to derive generalizable new knowledge I believe this study is as you say evaluating an existing pathway which measures against current service without reference to a standard and is designed and to be conducted to solely define or judge current process and look to re configuring in the future.

I have attached the defining research information leaflet and a link to the HRA tool which I have looked at you can do this add the title details and print out for your information.

<http://www.hra-decisiontools.org.uk/research/>

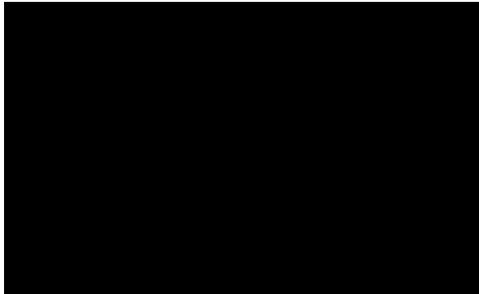
You will not require REC review or HRA approval to commence this project as a service evaluation but should make contact with the Clinical Governance Lead in this particular clinical area

Best wishes





HM Prison &
Probation Service



HM Prison and Probation Service
National Research Committee

Email: [REDACTED]

23 February 2018

APPROVED SUBJECT TO MODIFICATIONS – HMPPS RESEARCH

Ref: 2018-021

Title: Evaluating opt-out blood borne virus testing within high-turnover London prisons: a realist process-evaluation (student study).

Dear Professor Rosenberg,

Further to your application to undertake research across HMPPS, the National Research Committee (NRC) is pleased to grant approval in principle for your research. The Committee has requested the following modifications:

- The amount of time spent in each prison should be continuously reviewed and minimised wherever possible to reduce the resource demands on prison staff.
- The following should be included in all participation information sheets/consent forms:
 - Participants should be asked for their consent to the use of audio-recording equipment.
 - Participants should be informed that there will be neither advantage nor disadvantage as a result of their decision to participate or not participate in the research.
 - It must be made clear to research participants that they can refuse to answer individual questions or withdraw from the research until a designated point, and that this will not compromise them in any way.
 - Participants should consent to any follow-up contact and the method of this contact.
 - Participants should be informed how their data will be used and for how long it will be held.
- The following should also be included in the participation information sheets/consent forms for offenders:
 - Access to any HMPPS records for the participants should be explicitly covered.

- It needs to be clear that the following information has to be disclosed: behaviour that is against prison rules and can be adjudicated against, illegal acts, and behaviour that is potentially harmful to the research participant (e.g. intention to self-harm or complete suicide) or others.
- Potential avenues of support should be specified for those who are caused any distress or anxiety.
- The respondent should be asked to direct any requests for information, complaints and queries through their prison establishment/community provider. Direct contact details should not be provided.
- Under the Prison Act (as amended by the Offender Management Act 2007), mobile phones, cameras and sound recording devices are classified as list B items, requiring authorisation from Governing Governors / Directors of Contracted Prisons (or nominated persons) to take them into and use them in prison (PSI 10/2012 Conveyance and Possession of Prohibited Items and Other Related Offences).
- When using recording devices, the recordings should be treated as potentially disclosive and it is recommended that devices with encryption technology are used. Recordings should be wiped once they have been transcribed and anonymised unless there are clear grounds for keeping them any longer.
- The availability and appropriateness of key training remains at the discretion of individual establishments.
- Research data should be kept no longer than necessary, e.g. when the research is to be published and the scientific journal requires the original data to be kept for a specified period.

Before the research can commence you must agree formally by email to the NRC [REDACTED], confirming that you accept the modifications set out above and will comply with the terms and conditions outlined below and the expectations set out in the HMPPS Research Instruction

(<https://www.gov.uk/government/organisations/her-majestys-prison-and-probation-service/about/research>).

Please note that unless the project is commissioned by MoJ/HMPPS and signed off by Ministers, the decision to grant access to prison establishments, National Probation Service (NPS) divisions or Community Rehabilitation Company (CRC) areas (and the offenders and practitioners within these establishments/divisions/areas) ultimately lies with the Governing Governor/Director of the establishment or the Deputy Director/Chief Executive of the NPS division/CRC area concerned. If establishments/NPS divisions/CRC areas are to be approached as part of the research, a copy of this letter must be attached to the request to prove that the NRC has approved the study in principle. The decision to grant access to existing data lies with the Information Asset Owners (IAOs) for each data source and the researchers should abide by the data sharing conditions stipulated by each IAO.

Please note that a HMPPS/MoJ policy lead may wish to contact you to discuss the findings of your research. If requested, your contact details will be passed on and the policy lead will contact you directly. Please quote your NRC reference number in all future correspondence.

Yours sincerely, National Research Committee

Appendix E: Realist implementation theories

Theory	Context	Mechanism ----->		= Outcome(s) – formation of a programme resource
		+ Ancillary resource	Response	
Using pre-existing resources	Blood-borne virus testing requires access to prisoners, IT systems, and clinical resources	Pre-existing clinics already have these resources in place	Healthcare management consider it simpler to embed testing into a pre-existing clinic	Testing included within a pre-existing clinic rather than being performed separately
Dependence on officers	Certain clinics can be run at a time and place where the required prisoners are already present (first night). Others require officers to facilitate the clinic (secondary screening)	Clinic where testing takes place requires officer facilitation	Healthcare management will need to negotiate how officers will facilitate the clinic with prison management	Programme performance linked with the ability and willingness of officers, tasked to facilitate the clinic, to perform that duty
Opportunity cost	The prison has a regime to run, meaning certain clinics will have to take place concurrently with other activities (such as educational classes, visitation, gym, or association)	Healthcare management is required to negotiate the time at which the testing clinic takes place, balancing their need to engage people quickly with the need of the prison to run their regime	Healthcare management negotiate for BBV testing to take place at the same time as other activities, rather than when prisoners are locked in cells	Prisoners have to decide whether to attend a different activity or a healthcare clinic
Keeping clinics close	Healthcare clinics are often reliant on officers to facilitate and local prisons are large institutions that are difficult to navigate (both physically and because of security considerations). It is therefore easier for officers to facilitate a clinic that is closer to the desired prisoner population	There is the physical space available for blood-borne virus testing to take place close to newly arrived people. The prison Governor and healthcare management have a strong relationship	Healthcare management able to negotiate that blood-borne virus testing (or the clinic it is embedded within) can take place close to new arrivals	Officers do not have to escort people long distances across the prison for blood-borne virus testing
Balancing ownership and dependency	Healthcare staff in prison are frequently overstretched and may attempt to disavow themselves of responsibility of the additional burden of testing if they conceptualise this as the “BBV lead’s” job	BBV lead given a supervisory role with power and influence	BBV lead uses influence associated with their status to encourage other staff to engage	Reduces risk of person dependence
		More than one BBV lead so programme has greater capacity	BBV leads share responsibility for testing with other lead	Reduces risk of person dependence
Scattered prisoners	Prisons are often short on space, with large populations and the requirement to host multiple serves within their walls	Small unit, high influx of newly incarcerated individuals or slow relocation from unit, other uses of that space	Prison lacks space for new arrivals	Risk that new arrivals are scattered across the prison
		Large unit, controlled inflow and outflow of new arrivals, space reserved only for new arrivals	Prison has space for new arrivals	More likely that new arrivals can be concentrated in the appropriate area of the prison (i.e. the induction unit)

Supportive qualitative data (implementation)**Officer and healthcare staff relationships**

Field note extract (Prison 1): *The healthcare officer slumps and gives the BBV lead a joke pleading face, but the BBV lead smiles and tells her she “is the best”. When the officer leaves, the lead comments to me: “when you have good rapport with these people, you can do anything”.*

Field note extract (Prison 2): *As we walk back to the staff room where most primary care nurses congregate, I ask the BBV lead what her relationship is like with the officers. She tells me that she doesn’t know any of them and that, “I don’t even wanna get to know them cause they just don’t care about our job”. From observing the interaction between the BBV lead and officers, there doesn’t seem to be much rapport, mostly because she is so frustrated with them not providing access to patients for clinic.*

Staff avoid using a waiting list

Field note extract (Prison 2): *I ask one BBV lead whether both people wanted a BBV test and she responds, “yeah, they’ve both been put on the waiting list”. However, to my surprise the other BBV lead tells her to take them off, explaining “take them off the waiting list, otherwise it will just build-up and management are watching. I will catch them on the wing myself once we have the kits”. In my head I wonder how she will catch them, as she does not know who has been tested and who hasn’t.*

Paranoia about infection

Field note extract (Prison 2): *The patient asks, “has anyone got anything in here since you’ve been checking? I just want to know so I can stay away from them you know?” To my relief, the BBV lead tells him that she doesn’t know and even if she did, she wouldn’t be able to tell him.*

Field note extract (Prison 2): *I ask what they say is wrong with the prisoner, and the officer tells me that “they are saying it is probably a personality disorder”. I ask what is going to happen and he tells me that he suspects there will be a “planned intervention”. When I ask what that is he explains that it is when a team go in wearing body armour, shields, and batons, to extract a violent prisoner. He shows me his hands and notes that he is wearing gloves, saying “see I got these on just in case we do need to go in as there is blood everywhere and I don’t want to pick up hep-C ...”*

Divisions between PC and SM

Field note extract (Prison 2): *She looks to book the patient onto her secondary screening clinic list but notes that the SM team have been moving people onto her list to be seen. She gives a frustrated laugh, and comments “as if I haven’t got enough to do” and then deletes the individual from her list on SystmOne.*

Prison bureaucracy

Field note extract (Prison 2): *He explains that his main problem as an officer is trying to get his head around the “bureaucracy of the prison”. He tells me that as a new officer, it isn’t clear who he needs to speak to or where he needs to go to get anything done. I ask him whether he thinks it is the same thing for patients. He tells me that it is, “its’ not clear who is responsible for what and how they get things. If they don’t ask fifteen times, they don’t get anything they need. But the problem is,*

the more they ask, the less we listen to them. This just makes them nag more and it becomes a vicious cycle."

Patronage

Interview (Prison 2): Prisoner: *"Yeah few officers are half genuine. When you have an issue and you tell them about it, most will just say 'yeah yeah cool' and shrug you off. But we're not animals you know? I respect someone more if they would just say no but a lot of officers, they just want to do the job and go home without no bother. They go home and a few days later they come back and nothings been done, but you know I'm there waiting thinking 'this person promised me' but actually they have completely forgotten. We live on the fact that they said they would do something for you, we are relying on that as we have had our freedom taken away from us. It may seem like something little, but it's big to us ..."*

Degradation

Field note extract (Prison 2): *At this point in the conversation, the nurse jumps in saying "so as soon as they do the cutting, they get what they want". She continues by making a distinction between "cutting" and actual attempts at self-harm. The nurse candidate nods enthusiastically at this, saying "They know that's how they get what they want in this place". Laughing the nurse tells me that they are "crafty as well" because they will try and smear blood to make it look worse. The nurse candidate tells me that "they're not stupid though. They only do superficial cuts you know. Just enough to look bad so that they can get what they want". She tells me, "it's very stressful you know, and that is why nurses are leaving".*

Emergencies

Field note extract (Prison 2): *All of a sudden "code blue" sounds over the radio. The BBV lead swings back into action, grabbing a large red paramedic bag and heading out of the treatment room. I offer to open and lock doors for her as we make our way through C wing and towards the end of D wing ... When we arrive, there is already a group of officers and nurses both outside and inside the cell talking to him. We just stand around outside, pretty much surplus to requirement.*

Field note extract (Prison 2): *Suddenly the radio kicks in. There is a woman screaming for help from somewhere in the prison, followed by frantic radio chatter from officers asking for the location of the incident ... We can hear "general alarm on D-wing" being shouted down the radio. Suddenly the alarm sounds again, followed by "general alarm on G-wing". Reports are now also flying in of a man who had been attacked and has a laceration to his head and an officer being thrown down the stairs with a broken leg ... All thoughts of running a secondary screening clinic have quickly been forgotten. We move through A-wing towards the hub at a half-run, but suddenly the alarm goes again, with another general alarm and reports of a man having had his face sliced. The whole prison seems to be sliding into anarchy.*

Issues engaging prisoners on other wings (SM Prison 2)

Prison 2 (interview – hand recorded): *The nurse begins to talk about the screening process on the SM wing. He tells me that it is difficult to do secondary screening when the patients are located "off wing" as the SM team are not provided with any clinical rooms to see patients. He provides the example of J-wing and the clinic room. He highlights that PC use the room in the morning but that occasionally SM may be*

able to use it in the afternoon, with PCs permission. **SM HCW:** “When they’re on other wings, like C and G they can be very difficult to locate you know; as you don’t know any officers and people get moved around so much so they are hard to catch ... In the end you just hope that this individual is moved to this wing. On the other hand, some people do print out a hard copy [of the screening template] and go and do it, but you would not be able to do a BBV [test] on the wing like that ...”

Opt-out offer script

Prison 2 (interview): Seth: “And I have heard at other prisons they are using a kind of script, or set of words, to guide the delivery of an opt-out BBV test. Is there anything like that here?” **HCW (SM):** “No, we don’t have anything like that here.”

Prison 1 (interview): Seth: “Yeah, okay and I don’t know if this prison uses it, do you, have you seen an opt-out offer script which is like a set of words delivered in testing?” **HCW:** No. I’ve never seen that.”

What is opt-out?

Interview (Prison 1): Seth: “... and what does opt-out testing, the opt-out, focusing on that, what does that kind of mean to you? How does that differ from any other form of testing? (Long pause).” **HCW:** “I don’t (laughs). I’m trying to think of it compared to like the TB testing that we do ... but I, this is on like myself ... I see them as the same ... because we offer them and it’s still, regardless if it’s opt-out or opt-in, it’s still the person’s choice if they want to have it or not... so to me opt-out or opt-in or whatever it is doesn’t really make a difference.”

Interview (Prison 1): Seth: “What does opt out mean to you in your opinion?” **HCW:** “That we offer it ... unless they, well we offer it and ... they have the choice to say no, so it’s their... Erm, yes, it’s there and we give it to them unless they say no. We do it unless they say no.”

Interview (Prison 1): HCW: “And I think people misunderstood opt out ... and it’s only when it became quite clear that listen this is not a test that they can just say I don’t want, yeah. They need to have, you know sound rationale as to why they don’t want to have it and the nurse should be seen to have done her best to educate, erm the patient. But nurses see that as extra work, so they don’t engage.”

Interview (Prison 2): Seth: “... so I was wondering what you thought it was that makes something opt out testing, as opposed to say opt in, or mandatory testing, or ...?” **HCW:** “Well, I think to me, and I don’t know, I might ... I might be wrong, but I’m not understanding it well, and if that’s the case, then correct me, but I think it’s almost a default position, so in a way, you’re almost not giving people the option to think about it and decide. It’s not that you want to force people, but actually I don’t know, it’s like when you go to any other healthcare setting, I don’t know, you go to see your hospital team or whatever, and they say well sorry, this is not the test that ... and we just run them, and that’s the default position, so people don’t almost have to think about it.”

Care exhaustion

Interview (Prison 1): HCW: “We had this young man who came in from America. So, you can imagine he flew out of America on Tuesday, arrived in the UK on Wednesday. He wasn’t allowed to take his medication in transit ... Erm, he arrived at [Prison 1] ... I had to make a noise about this because the man came in here and

he was soaking wet, he was dripping. He'd opened his bowels, yeah, so he was smelling of poo, he was soaking wet, he was shivering ... he had terrible tremors. I thought he was going to pass out. And I was like 'hey, you know what's this?' And he's like 'I'm withdrawing from my medication', I was like 'well what medication is this?' And then I looked, and I was absolutely livid to find that the doctors had done their job, they'd prescribed the medication, but for three days, yeah, people are there, at a computer screen, they're dispensing medication, oh DNA [did not arrive], yeah?

Nobody bothered to say, you know, 'oh is he in his cell?' They say, 'we took the medication to the hatch', well there's no point taking the medication to the hatch, it needs to be in the person's body ...I brought it up in handover for them [management] to say there's a problem, then fix that problem. You don't say oh you see it's difficult on the weekend. If you know that there's this problem, yeah, you need to start sorting it out because one day we're going to have somebody who comes in with serious medication and then they die because 'oh we have this problem on the weekend'."

Seth: "Yeah, yeah."

HCW: "Do you understand what I'm saying? And this is the ... I don't know what word I can use to describe it, but it's almost like there's a care fatigue, yeah. Like they're tired of caring."

Confidentiality breach

Field note extract (Prion 1): *As I return, the nurse and healthcare officer are back in conference about the prisoner with HIV. The officer informs the nurse that he has gone to visitation, to which she exclaims "shit"! The nurse asks what time visitation finishes, and the healthcare officer tells us that it could be anywhere between 11:15 and 11:40. The officer tells us she is hesitant to collect the prisoner after, as roll call takes place at 11:50.*

The nurse explains that there is no sexual health clinic in the afternoon, so if they don't see the patient that morning, things could be delayed for another few days. The nurse tells the officer to try and get the patient back from visitation as quickly as possible. In the meantime, she tells us that she plans to prep the doctor and the sexual health nurse to await the patient. It is made clear to the healthcare officer that the patient needs to be seen because he is HIV positive.

Appendix F: Realist programme theories

Prisoner engagement

Theory	Context	Mechanism ----->		= Outcome
		+ Resource	Response	
Delayed engagement	<i>Prison that has a rapid population turnover</i>	<i>Delayed engagement</i>	<i>Some new arrivals already released or transferred out of the prison</i>	<i>Certain proportion of new arrivals miss the opportunity to be tested for infection</i>
Linking up – T1 Same time same place	<i>Officers and healthcare workers need to link-up to begin secondary screening procedures. The clinic is time pressured</i>	<i>Agreed time and agreed place to meet adhered to by both parties</i>	<i>Both parties converge at agreed time</i>	<i>Begin testing procedures on time</i>
		<i>Time and place to meet not adhered to by one or both groups</i>	<i>Officers will only wait for a certain amount of time before being redeployed (healthcare officers) or continue with running the regime (officers assigned to a wing)</i>	<i>Delayed commencement of clinic. Strained relationship between healthcare staff and officers. A certain proportion of new arrivals potentially missed</i>
Linking up – T2 wing-officers cancel clinic	<i>Officers assigned to a wing are busy and will prioritise the prison regime over facilitating healthcare</i>	<i>Officers working on a wing are short staffed and are therefore forced to prioritise certain activities</i>	<i>Officers running a wing will prioritise the regime (for which they are held directly responsible)</i>	<i>Officers may refuse to facilitate healthcare clinics when understaffed. A proportion of new arrivals are therefore missed initially</i>
Locating new arrivals – T1 accuracy of the list	<i>Prisons are large, and their populations are constantly shifting</i>	<i>Officers provided with a list that has accurate cell locations (produced using prison IT system)</i>	<i>Officers locate individuals required at the clinic</i>	<i>Prisoners engaged for secondary screening</i>
		<i>Officers provided with a list that has inaccurate cell locations (produced using healthcare IT system)</i>	<i>Officers will only spend a certain amount of time attempting to locate individuals</i>	<i>Proportion of new arrivals not engaged for clinic and so missed initially</i>
Locating new arrivals – T2 prisoners behind doors	<i>Officers will often not know prisoners by sight and when they are unlocked, prisoners will move around the wing and engage in various activities</i>	<i>New arrivals locked in cells and therefore immobile at time of secondary screening</i>	<i>Officers locate those required for clinic more easily</i>	<i>Easier for officers to engage and transport new arrivals to secondary screening</i>
		<i>New arrivals unlocked and therefore mobile at time of secondary screening</i>	<i>Officers will only spend a certain amount of time attempting to locate a prisoner before moving on</i>	<i>Proportion of new arrivals will not be located and therefore missed initially</i>
Location new arrivals – T3 outreach	<i>Frequently a proportion of new arrivals will need to be scattered across different wings of a prison because of space restrictions</i>	<i>Healthcare officers have the flexibility to move around the prison</i>	<i>Healthcare officers able to collect people from across the prison</i>	<i>People, no matter their location, can be brought to clinic</i>
		<i>Wing-officers are tied to the area that they have been assigned to by safety and regime considerations</i>	<i>Officers can only reliably collect people from the area that they have been assigned to manage</i>	<i>People located on different wings cannot be easily engaged and are therefore usually missed</i>

Prisoner engagement (continued)

Theory	Context	Mechanism ----->		= Outcome
		+ Resource	Response	
Locating new arrivals – T4 engaged in other activity	<i>The first few days in custody are an important opportunity to engage new arrivals in various services. People may be engaged in another activity in a different area of the prison when officers try to collect them for clinic</i>	<i>Individual not physically available</i>	<i>Officers unable to collect and transport them to the clinic</i>	<i>New arrivals cannot be engaged and so are missed initially</i>
Asking the person to attend – T1 can't or won't unlock	<i>Officers facilitating the clinic decide whether to unlock a prisoner or not. Prisoners may be volatile</i>	<i>Officers perceive a risk to either themselves or another individual's safety</i>	<i>Officers determine it inappropriate to unlock the individual</i>	<i>Individual cannot be engaged and so is missed initially</i>
Asking the person to attend – T2 complying with instruction	<i>Person has not been incarcerated before or does not speak English</i>	<i>Instruction given by a prison officer</i>	<i>Individual interprets the instruction as a mandatory command</i>	<i>Individual complies and attends the clinic</i>
Asking the person to attend – T3 semi-known opportunity cost	<i>Prisoner not aware what is taking place but wants to leave the cell</i>	<i>Instruction to leave acts as a semi-known opportunity cost</i>	<i>The instruction interpreted as an opportunity to leave the cell</i>	<i>Comply with attending the clinic</i>
	<i>Prisoner not aware what is taking place and has preference to stay in cell</i>		<i>Individual may want to better understand what is taking place</i>	<i>Individual may request more information</i>
Asking the person to attend – T4 opportunity cost	<i>Prisoner aware what is taking place and has a preference to see healthcare</i>	<i>Instruction to attend clinic acts as an opportunity cost</i>	<i>Individual prioritises clinic attendance</i>	<i>Complies with attending the clinic</i>
	<i>Prisoner aware what is taking place, but has a preference to stay in cell</i>		<i>Individual prioritises staying in their cell</i>	<i>Individual refuses to attend clinic.</i>
Asking the person to attend – T5 officer response to questions	<i>Prisoners may want to know what they are being asked to attend and what the clinic may involve – particularly if they do not want to leave their cell</i>	<i>Officer not motivated about getting people to the clinic</i>	<i>Officer becomes frustrated because the questions add extra time to the process of collecting people for clinic</i>	<i>Officer provides little additional information or information designed to get the person to decline to attend</i>
		<i>Officer motivated and views job as a primarily rehabilitative role</i>	<i>Questions viewed as an opportunity to encourage health-seeking behaviour</i>	<i>Officer recommends that the person attends, provides additional information, but presents the clinic as a choice</i>
		<i>Discipline focused officer who is motivated to get individuals to attend the clinic</i>	<i>Person's questions viewed as a challenge to authority</i>	<i>Coercive methods used to get the individual to agree to attend the clinic. This can escalate (if neither party will back down) to the point where physical conflict takes place</i>

Prisoner engagement (continued)

Theory	Context	Mechanism ----->		= Outcome
		+ Resource	Response	
Asking the person to attend – T6 secondary screening disclaimer	<i>Some prisoners have a preference not to attend the secondary screening clinic. The extent to which this desire is entrenched will vary</i>	<i>Signing a secondary screening disclaimer form is additional effort</i>	<i>Individual makes a snap decision to attend instead</i>	<i>Individual decides to attend clinic rather than sign the secondary disclaimer</i>
		<i>Form frames a person’s decision as a risky activity and something that could be used against them in the future</i>	<i>Individual rationalises that they should probably attend the clinic</i>	
		<i>Signing a form is additional effort</i>	<i>Effort of attending outweighs effort of signing form</i>	<i>Individual completes secondary disclaimer and is missed initially</i>
Transportation – T1 physically unable to attend	<i>Old Victorian prisons are large, have steep staircases, and are physically difficult to navigate owing to security features</i>	<i>Clinic takes place in a location that is physically inaccessible for those with certain physical disabilities</i>	<i>If officers are unable to provide an alternative method of access</i>	<i>Attendance is cancelled. Individual is missed</i>
Transportation – T2 socially unable to attend	<i>Prisoners designated as vulnerable (“VP”), cannot be mixed with the general population for their own safety</i>	<i>Officers unable to plot a route to the clinic, which avoids prisoners within general population</i>	<i>Officers will not risk mixing individuals designated as VP, with the general population</i>	<i>VP attendance cancelled. Individuals are missed</i>
Transportation – T3 physically distant	<i>Old Victorian prisons are large and physically difficult to navigate owing to security features. Clinics have set periods of time to be completed within the wider prison regime</i>	<i>People required to be seen are located in a section of the prison physically distant from the clinic</i>	<i>It takes longer for officers to locate and transport individuals to the clinic</i>	<i>Officers are able to bring fewer individuals within a set time. Some people may be missed because of a lack of time</i>
Transportation – T4 prisoner absconding	<i>Being unlocked to attend clinic is an important opportunity to be out of your cell. Clinics have set periods of time to be completed around the prison regime</i>	<i>If prisoners are not being effectively monitored</i>	<i>Some individuals take the opportunity to “wander off” and engage in other activities (e.g. dealing drugs)</i>	<i>Delays to getting people to clinic, as officers have to hunt missing prisoners down. Individuals potentially missed due to lack of time</i>
Keeping prisoners at the clinic – T1 cancelled clinic	<i>Prisoners may not wish to wait at a clinic for an extended period, particularly if the area is uncomfortable or they are missing a desirable activity</i>	<i>Prisoners may become frustrated and unruly about having to wait</i>	<i>Officers prioritise safety and security over running clinic</i>	<i>Clinic cancelled. All prisoners (regardless if they have been seen) returned to cells. People not already seen will be missed</i>
Keeping prisoners at the clinic – T2 institutional scramble	<i>Staff from other organisations also need to see new arrivals. Clinics have set periods of time to be completed around the prison regime. Secondary screening concentrated new arrivals in a location</i>	<i>Prisoners waiting for secondary screening present a potential opportunity for staff from other organisations to engage them</i>	<i>Staff from other organisations take the opportunity to conduct their own assessments with prisoners waiting</i>	<i>The logistics of the clinic may be interrupted, resulting in delays and logistical confusion. Some prisoners may be missed because of this</i>

Prisoner engagement (continued)

Theory	Context	Mechanism ----->		= Outcome
		+ Resource	Response	
Keeping prisoners at the clinic – T3 prisoners wanting to leave	<i>Because unlocking and transporting prisoners is a time consuming and resource intensive process (usually two officers involved), groups of prisoners may be asked to wait at a clinic to be seen by healthcare (rather than transporting people one at a time)</i>	<i>Short length of time to wait, nice waiting area, not missing another activity, want to see healthcare</i>	<i>Prisoners are more likely to prioritise waiting to see healthcare</i>	<i>People are retained at clinic</i>
		<i>Lengthy wait, locked in uncomfortable holding cell, not bothered about seeing healthcare, aware that they are missing a desirable activity</i>	<i>Prisoners are more likely to not prioritise waiting to see healthcare and may become angry with the situation</i>	<i>Certain individuals may attempt to leave before being seen</i>
Cancelled clinics – T1 emergency response	<i>Emergencies that require medical attention are common within prison</i>	<i>Dedicated emergency team</i>	<i>Emergency team responds</i>	<i>Other clinics not interrupted by emergencies</i>
		<i>All healthcare workers expected to respond, including those delivering secondary screening (where BBV testing takes place)</i>	<i>Healthcare workers prioritise responding to emergencies over running clinic</i>	<i>Secondary screening delayed or cancelled. Large numbers of new arrivals potentially missed</i>
Cancelled clinics – T2 priority	<i>Healthcare teams within prison are often short staffed as they struggle to recruit people to post, deal with holidays, and manage sickness</i>	<i>Healthcare team lack the capacity to deliver all services and the secondary screening clinic is not considered a core priority by management</i>	<i>Staff are redeployed by management to cover key clinics and services</i>	<i>Secondary screening cancelled. Large numbers of new arrivals missed</i>
Cancelled testing – T1	<i>A large number of BBV test kits are used up each day in local prisons and there can be delays to receiving re-supplies. Staff may also be forced to conduct testing in a location where test kits are not available</i>	<i>Without access to testing kits, it is not possible for healthcare workers to complete testing, but staff aware of waiting list</i>	<i>Healthcare worker offers testing but informs the individual they will have to be put on a waiting list</i>	<i>Person provided with the opportunity to test for blood-borne virus infection</i>
		<i>Without access to testing kits, it is not possible for healthcare workers to complete testing, and staff not aware of waiting list</i>	<i>Healthcare worker does not offer testing but proceeds with the rest of secondary screening</i>	<i>Person misses the opportunity to test for blood-borne virus infection</i>
Cancelled testing – T2 safety	<i>Prison can be a volatile environment and healthcare staff may face situations where they feel at physical risk</i>	<i>The person delivering testing feels that their personal safety is threatened</i>	<i>The member of staff will likely prioritise re-gaining their personal safety rather than offer testing</i>	<i>Prisoners miss the opportunity to test for blood-borne virus infection</i>

Test offer

Theory	Context	Mechanism ----->		= Outcome
		+ Resource	Response	
Timing the test offer – T1 offer upon entrance	<i>Secondary screening can be time consuming, repetitive, and people may make requests for assistance that cannot be addressed by the healthcare team</i>	<i>Healthcare worker offers blood-borne virus testing later in consultation</i>	<i>Some individuals will have become bored or frustrated and unreceptive to engaging with the healthcare service</i>	<i>Individual declines the test either to speed up the consultation process or as an act of protest</i>
		<i>Healthcare worker steers people towards preparing for a blood-borne virus test as soon as they enter the clinic room</i>	<i>Most individuals will be receptive to engaging with prison healthcare and are caught off guard as they enter</i>	<i>Individuals more likely to be consensually steered into accepting the test</i>
Timing the test offer – T2 framing testing as something to complete	<i>Many new arrivals in a local prison have unmet needs on the second day when blood-borne virus testing frequently takes place</i>	<i>The healthcare worker offers testing upon entrance and frames it as something that needs to be completed before they can go on to discuss the person’s needs</i>	<i>The individual may fear implications for their requests if they refuse or may simply be eager to progress the consultation onto addressing their requirements</i>	<i>Person more likely to comply with testing</i>
Timing the test offer – T3 rapport	<i>Contact before the test offer is an important opportunity for healthcare staff to establish rapport and trust</i>	<i>Healthcare worker takes time to assess their patient and treats them like a person, not a prisoner</i>	<i>Healthcare worker better able to interpret the individuals needs and provide person-centred care</i>	<i>Healthcare worker establishes a foundation of trust and maintains receptivity</i>
		<i>Healthcare worker does not take time to get to know the patient and instead follows the template questions (i.e. treating them as a prisoner to be processed)</i>	<i>Healthcare worker unable to interpret their patient’s needs and interacts with the individual in a robotic manner</i>	<i>Healthcare worker unable to establish trust or gather information that could help to encourage blood-borne virus testing. Patient likely to become less receptive</i>
Test offer – T1 targeted pre-test information	<i>Secondary screening time pressured</i>	<i>Healthcare workers required to balance testing success with length of time of the engagement</i>	<i>Employ targeted pre-test information</i>	<i>Helps to reduce chances of individuals automatically responding negatively to the test offer, but does not improve their knowledge of blood-borne viruses</i>
Test offer – T2 too much information puts people off	<i>Prisoners may not wish to spend a long time in the clinic and secondary screening involves a series of routine questions</i>	<i>By providing a long pre-test discussion, the consultation is extended, and the process of testing is distinguished from other aspects of the screening encounter</i>	<i>Some prisoners may become frustrated and disengage with the process to speed up the clinic. Others may believe that lots of information is being provided because testing is a “big deal”</i>	<i>Certain prisoners are incentivised to refuse testing, either to speed up the encounter or out of concerns related to testing</i>

Test offer (continued)

Theory	Context	Mechanism ----->		= Outcome
		+ Resource	Response	
Test offer – T3 information variability	<i>Healthcare workers are time pressured and over worked</i>	<i>Distracted when offering test</i>	<i>Unable to recall all information they usually provide</i>	<i>Variability in information provided</i>
Test offer – T4 opt-out or opt-in	<i>Offering testing as an opt-out is still not the norm for most healthcare workers within prison</i>	<i>Training on how to deliver an opt-out test and why wording is important. Healthcare worker believes this is important</i>	<i>Healthcare worker endeavours to change the way they present testing</i>	<i>Test delivered in an opt-out format</i>
		<i>Aware that opt-out requires a change in the way consent elicited but no clear guidance on what that involves</i>	<i>Healthcare worker develops their own approach to eliciting consent</i>	<i>Test delivered in an opt-out/hard opt-out format</i>
		<i>Healthcare worker not aware of what opt-out means</i>	<i>Default to a standard and safe way of eliciting consent</i>	<i>Test delivered in an opt-in format</i>
		<i>Healthcare worker aware that opt-out requires a change in the way consent is elicited and motivated to maximise testing</i>	<i>Motivated staff may stretch principles of consent to try and maximise testing</i>	<i>Testing likely to be delivered predominantly in a hard opt-out format and may become coercive</i>
Test offer – T5 dynamic	<i>Healthcare workers will be able to build rapport with different people to a greater or lesser extent. At times staff may feel physically intimidated by a person in prison</i>	<i>The member of the healthcare teams feels unconfident interacting with a certain individual</i>	<i>The healthcare worker worries that telling the individual they are going to be tested for a blood-borne virus will elicit a bad response</i>	<i>Healthcare worker switched to framing testing as opt-in</i>
		<i>The healthcare worker feels paternalistic about prisoner, considering them silly and unable to make appropriate decisions</i>	<i>Decides to tell prisoner what health interventions they will receive</i>	<i>Strays into an opt-out, hard opt-out, or even coercive test offer</i>
Test offer – T6 encouraging decline	<i>Healthcare workers were aware that certain information omitted or included, as well as certain ways of framing blood-borne virus testing, made people more or less likely to accept the test</i>	<i>Healthcare worker does not view testing for blood-borne viruses as an important part of the clinic interaction, is stressed, and/or overworked</i>	<i>The member of staff may tailor the test offer in a manner that they hope will discourage the individual from accepting the test</i>	<i>Person less likely to test, so the healthcare worker saves time and effort</i>
Test offer – T7 framing testing as “for the patient”	<i>A large proportion of new arrivals to a prison will not actively believe they need to test for BBV infection</i>	<i>Framing testing as “for the patient” provides a subtle recommendation that the patient should test. If the prisoner trusts the member of staff making this recommendation</i>	<i>Person perceives offer as an implicit recommendation from trusted expert</i>	<i>Individual more likely to follow the recommendation of perceived expert</i>

Test offer (continued)

Theory	Context	Mechanism ----->		= Outcome
		+ Resource	Response	
Test offer – T8 we are testing everyone	<i>A large proportion of new arrivals to a prison will not actively believe they need to test for BBV infection</i>	<i>Healthcare worker mentions that they are testing everyone as they enter the prison</i>	<i>Person perceives testing to be a routine process (potentially even mandatory)</i>	<i>Person likely to comply with the norm unless strong motivating factors to avoid testing</i>
Test offer – T9 it is just a finger prick	<i>Most people associate a blood test with venous sampling and aversion to this is common</i>	<i>Healthcare worker highlights that the blood sample is collected via a finger prick</i>	<i>Person understands how blood is collected and is able to more accurately assess the discomfort caused by the procedure</i>	<i>Person less likely to try and refuse testing because of misconception that it involves a venous sample</i>
Test offer – T10 environmental pressures	<i>Infection with a blood-borne virus is stigmatised in prison and officers and prisoners are concerned about becoming infected</i>	<i>Testing conducted in an open setting where everyone seems to be accepting the test and people's decision can be seen by others</i>	<i>Prisoner may fear declining testing as this would make them stand-out and therefore open to speculation that they might have an infection</i>	<i>Person more likely to comply with the norm unless they have other strong motivating factors to avoid testing</i>
Prisoner response – T1 person wants to test	<i>Certain people will want to test for a blood-borne virus (reassurance or confrontation)</i>	<i>Blood-borne virus test offer, where testing is promoted, explained as a simple process, and supportive information about testing presented</i>	<i>The test offer is interpreted as an opportunity to be reassured or confront and address actual serostatus</i>	<i>Individual likely to accept the test</i>
		<i>Interaction with the healthcare worker highlights potential costs (bad treatment, stigmatisation) associated with testing</i>	<i>Individual re-evaluates their desire to test under the current circumstances</i>	<i>Individual more likely to decline the test</i>
Prisoner response – T2 person has no clear preference about testing	<i>Certain people will lack any pre-formed preference regarding testing and usually view themselves as at a low risk of infection</i>	<i>Interaction with healthcare worker highlights few disincentives to test, promotes the benefits of knowing your serostatus, and presents the test as a simple process</i>	<i>Offer perceived as an opportunity to be reassured by a negative result</i>	<i>Individual steered towards taking a test</i>
		<i>Interaction with healthcare worker highlights, or fails to address, potential disincentives</i>	<i>The opportunity to test viewed as an unnecessary burden</i>	<i>Individual steered towards declining the test</i>
Prisoner response – T3 default effect	<i>A large proportion of people incarcerated in the prison will not have a strong preference about testing</i>	<i>Testing framed as an opt-out</i>	<i>Default effect steers people into going with the default option</i>	<i>People with no strong preference about testing steered into accepting</i>
		<i>Testing framed as an active choice to opt-in</i>	<i>Some people do not process the information</i>	<i>Individual declines testing automatically</i>
			<i>Some people reflect and decide they want to test whilst others decide they do not</i>	<i>Some people decline whilst others accept</i>

Test offer (continued)

Theory	Context	Mechanism ----->		= Outcome
		+ Resource	Response	
Reasons for decline (non-engagement) – T1 anger	<i>Newly incarcerated people can be angry for a variety of reasons when they arrive at the clinic</i>	<i>If this anger is placed on the authorities and health service</i>	<i>Individual likely to express anger by refusing to engage with health services</i>	<i>The individual is not receptive to engaging with healthcare services and so will decline interventions offered (including blood-borne virus testing), unless healthcare staff are able to build rapport and trust</i>
Reasons for decline (non-engagement) – T2 institutional distrust	<i>Prisoners may distrust the prison healthcare service, viewing it as “in league” with the wider prison service</i>	<i>Healthcare interventions and questioning linked with the criminal justice system. Testing delivered as an instruction (hard opt-out)</i>	<i>Individual suspects that the healthcare intervention and questioning are covert methods of collecting information to be used in court or a physical/psychological threat</i>	<i>Individual likely to refuse to engage with healthcare services and so will decline interventions offered (including blood-borne virus testing), unless healthcare staff are able to build rapport and trust</i>
Reasons for decline (mild disincentive) – T1 testing takes time	<i>Second day screening takes time to complete and testing takes longer than not testing</i>	<i>Person has a desire to leave clinic quickly (often because they are missing a desired activity taking place in another part of the prison)</i>	<i>Testing viewed as a barrier to completing the consultation process</i>	<i>More likely to decline in the hope of speeding up the clinic process</i>
Reasons for decline (mild disincentive) – T2 invasive procedure	<i>Many prisoners perceive themselves to be at a low, or no, risk of infection</i>	<i>Finger prick causes pain</i>	<i>Discomfort associated with the finger prick does not outweigh the perceived benefit of knowing serostatus</i>	<i>Individual more likely to decline</i>
Reasons for decline (strong aversion to testing) – T1 spiritual/religious	<i>Some prisoners have religious or spiritual beliefs that discourage engagement with certain types of medical intervention</i>	<i>Invasive medical procedure involving extraction of blood</i>	<i>Action perceived as something that goes against core beliefs</i>	<i>Individual likely to decline testing for blood-borne virus infection</i>
Reasons for decline (strong aversion to testing) – T2 phobia of invasive procedure	<i>An incision on the finger is an invasive procedure that involves small amounts of discomfort and blood</i>	<i>Phobic of blood and invasive procedures</i>	<i>Fears the process of sample acquisition</i>	<i>Individual more likely to decline</i>
Reasons for decline (strong aversion to testing) – T3 dealing with a positive diagnosis	<i>Prison is a stressful context in which to be diagnosed with a blood-borne virus</i>	<i>Person does not feel like they will receive the necessary psychological or physical support required for them to deal with a positive diagnosis</i>	<i>Individual feels unable to cope and panicked at the offer of a test for blood-borne virus infection</i>	<i>Individual more likely to decline</i>

Test offer (continued)

Theory	Context	Mechanism ----->		= Outcome
		+ Resource	Response	
Encouraging testing – T1 motivation	<i>Prisoners may need encouragement to test (particularly when testing offered as opt-in)</i>	<i>Healthcare worker busy and does not see the value in testing for blood-borne virus infection</i>	<i>Easier to accept hesitancy to test on face value</i>	<i>Healthcare worker does not attempt to encourage testing</i>
		<i>Healthcare worker is motivated to try and test most people</i>	<i>Healthcare worker sees the value in testing and so will try and counter prisoner concerns</i>	<i>Healthcare worker will attempt to encourage testing</i>
		<i>Healthcare worker extremely motivated to try and test most people</i>	<i>Healthcare worker interprets prisoner concerns as something that needs to be addressed</i>	<i>Healthcare worker will enthusiastically and persistently attempt to encourage testing</i>
Encouraging testing – T2 common approaches (not at risk)	<i>Prisoners may need encouragement to test (particularly when testing offered as opt-in). Person does not think they are at risk of infection</i>	<i>Healthcare worker is motivated to try and test most people</i>	<i>Healthcare worker provides targeted information designed to counteract prisoner concerns and cause re-evaluation</i>	<i>Further information about risk of transmission provided</i>
		<i>Healthcare worker extremely motivated to maximise testing</i>	<i>Healthcare worker provides targeted information designed to counteract prisoner concerns and cause re-evaluation</i>	<i>Risk factors about transmission in the prison may be exaggerated, potentially increasing paranoia and stigmatisation</i>
Encouraging testing – T3 common approaches (don't like the finger prick)	<i>Prisoners may need encouragement to test if they do not like the finger prick</i>	<i>Healthcare worker is motivated to try and test most people</i>	<i>Healthcare worker provides targeted information designed to counteract prisoner concerns and cause re-evaluation</i>	<i>Healthcare worker may provide reassurance that the test is “only small” and doesn't hurt. Some staff may prick themselves to demonstrate</i>
Encouraging testing – T4 creative approaches (religious or spiritual barriers)	<i>Some prisoners may not want to test as a result of religious or spiritual conviction</i>	<i>Extremely motivated healthcare worker approaches religious and spiritual leaders in the prison to sanction the test</i>	<i>Healthcare worker provides targeted information designed to counteract prisoner concerns and cause re-evaluation</i>	<i>Healthcare worker informs prisoner that testing has been sanctioned by an important religious figure relevant to their concerns</i>
Encouraging testing – T5 creative approaches (despondent with the system)	<i>Some prisoners are despondent with the system</i>	<i>Healthcare worker able to sense this emotion and motivated to maximise testing</i>	<i>Healthcare worker provides targeted information designed to counteract prisoner concerns and cause re-evaluation</i>	<i>Healthcare worker emphasises the separation between the health service and prison service and presents testing as a way of subverting the prison system (i.e. “don't imprison your health”)</i>
Encouraging testing – T6 creative approaches (putting it personal)	<i>Younger prisoner refusing testing</i>	<i>Healthcare worker able to understand the patient and is motivated to maximise testing</i>	<i>Healthcare worker provides targeted information designed to counteract prisoner concerns and cause re-evaluation</i>	<i>Information pertinent to a younger person (pregnancy and risk to children etc.) provided to patient</i>

Test offer (continued)

Theory	Context	Mechanism ----->		= Outcome
		+ Resource	Response	
Encouraging testing – T7 creative approaches (risk of violence)	<i>“White collar criminal” who is newly incarcerated or a vulnerable prisoner refusing testing</i>	<i>Healthcare worker observes the individual to be concerned about violence or at risk of violence and is motivated to maximise testing</i>	<i>Healthcare worker provides targeted information designed to counteract prisoner concerns and cause re-evaluation</i>	<i>Healthcare worker focuses on discussing risks of transmission due to violence in the prison</i>
Encouraging testing – T8 creative approaches (employing norms)	<i>Prisoner refuses to engage with testing</i>	<i>Healthcare worker motivated to maximise testing and recognises (consciously or unconsciously) the importance of normative behaviour</i>	<i>Healthcare worker provides targeted information designed to counteract prisoner concerns and cause re-evaluation</i>	<i>Healthcare worker tells prisoner that testing is “just a procedure” or that “everyone is doing it” to try and make them avoid counter normative behaviour</i>
Encouraging testing – T9 creative approaches (maintaining the default)	<i>Prisoner refuses to engage with testing</i>	<i>Healthcare worker motivated to maximise testing and has an implicit (or explicit) knowledge of the importance of defaults</i>	<i>Healthcare worker provides targeted information designed to counteract prisoner concerns and cause re-evaluation</i>	<i>Healthcare worker continues to prep for the test, maintaining the default as testing so that the prisoner feels like they have to justify their decision. Healthcare worker may ask for a “good reason” for not testing</i>
Collecting the sample – T1 healthcare worker skill	<i>Collecting a capillary sample of blood from a finger prick is difficult</i>	<i>Issues with collecting a sample creates delays and can be embarrassing</i>	<i>Avoidant healthcare worker attempts to avoid embarrassment</i>	<i>Testing not encouraged or at times discouraged</i>
			<i>Healthcare worker attempts to collect the sample for some time before giving up</i>	<i>Prisoner has to be rebooked, creating delays to testing that make risk attrition through release or transfer</i>

Catch-up activities

Theory	Context	Mechanism ----->		= Outcome
		+ Resource	Response	
Delayed engagement – T1	<i>Prisoners incarcerated within local prisons can be transferred or released quickly. Those that miss or decline secondary screening, miss testing for blood-borne viruses</i>	<i>Delayed engagement of missed prisoners</i>	<i>Risk that prisoner has already been released or transferred</i>	<i>Fewer people offered a chance to test for blood-borne virus infection</i>
Rolling to the next day – T1	<i>Prisoners that miss secondary screening need to be rebooked and seen</i>	<i>When individual is located on the first night centre, all resources required to engage them are already in place with a standard secondary screening clinic</i>	<i>Healthcare worker simply rolls the individual into the following day's clinic</i>	<i>Missed prisoner should be seen for secondary screening the next day</i>
Targeting activities – T1	<i>Prisoners will miss blood-borne various testing, either because they were resident in the prison before the programme went live, because they missed second day screening, or because they declined screening</i>	<i>By using a waiting list</i>	<i>Healthcare workers are able to target those people who have been missed</i>	<i>Offer testing in a manner that is roughly comprehensive</i>
		<i>No waiting list used</i>	<i>Healthcare workers can only actively engage prisoners on unreliable information (such as by sight) or have to rely on those who have not been tested self-referring</i>	<i>Testing not offered in a comprehensive manner to all new arrivals</i>
Accessing prisoners – T1 officer facilitation	<i>Prisoners that miss secondary screening or blood-borne virus testing may be located in cells scattered across the prison</i>	<i>Dedicated healthcare officers</i>	<i>Healthcare workers have the safety and flexibility to either approach prisoners on a wing or have them brought to a location to be offered testing</i>	<i>Testing can be offered to missed prisoners, regardless of their location</i>
		<i>No dedicated officers</i>	<i>Healthcare reliant on finding alternative modes of engagement (petitioning landing officers to unlock, engaging people when they are unlocked)</i>	<i>Some prisoners are easier to engage and offer testing than others, depending on their location</i>
Accessing prisoners – T2 busy landing officers	<i>Prisoners that miss secondary screening or blood-borne virus testing may be located in cells scattered across the prison</i>	<i>Busy landing officer relied on for access</i>	<i>Facilitating healthcare not part of their role and their priority must be running the regime of their wing and maintaining the safety of their prisoners</i>	<i>Facilitation becomes favour-based, with those healthcare workers that have good relationships with officers more likely to be able to persuade them to help</i>

Catch-up activities (continued)

Theory	Context	Mechanism ----->		= Outcome
		+ Resource	Response	
Accessing prisoners – T3 no officer support	<i>At different times, some prisoners will be locked in cells whilst others may be free on the wing (particularly cleaners)</i>	<i>No officers supplied to help healthcare workers conduct catch-up testing. Wing officers too busy to start unlocking prisoners</i>	<i>Healthcare workers cannot physically access prisoners in cells to perform testing</i>	<i>Prisoners who spend more time unlocked and out of their cell will be more likely to be offered a test to check for BBV infection</i>
Declining – T1	<i>When healthcare workers are struggling to access people for catch-up secondary screening</i>	<i>But perceive themselves to be under pressure to keep waiting lists down</i>	<i>They may begin to make judgements about who needs care</i>	<i>And encourage those that are perceived not to be in need to decline attending the catch-up appointment (in turn keeping waiting lists down) but reducing the numbers of prisoners offered a test for BBV infection</i>
Framing catch-up testing – T1 active engagement	<i>Prisoners that have missed the test offer may be scattered across different wings of the prison. Healthcare officers are free to move around the prison and are able to access prisoner's cells</i>	<i>Healthcare staff use healthcare officers as a means of actively engaging prisoners who they need to see in their cells</i>	<i>Because healthcare staff have come to the prisoner, they are able to present testing as a routine process</i>	<i>Testing can be naturally framed as opt-out to the prisoner (i.e. a routine procedure that happens to everyone)</i>
Framing catch-up testing – T2 passive engagement	<i>Prisoners that have missed the test offer may be scattered across different wings of the prison</i>	<i>When no healthcare officers are supplied, healthcare staff may resort to advertising testing on the wing to those people available</i>	<i>Staff are unable to actively engage everyone on the wing. Instead they advertise testing and rely on prisoners approaching themselves</i>	<i>Testing naturally framed as opt-in (i.e. prisoners have to approach and say they want to be tested)</i>
Catch-up testing on the wing – T1 location	<i>The wings of a prison can be a dangerous environment. The upper landings, and locations with certain types of offender, can be perceived by staff as particularly dangerous</i>	<i>Healthcare staff offer testing on the wing without officer escort</i>	<i>Healthcare management implement restrictions on where healthcare staff can deliver testing out of concerns for their safety</i>	<i>Certain areas of the prison are off-limits and therefore not covered by wing-based testing. Prisoners in these locations miss the opportunity to be tested</i>
Catch-up testing on the wing – T2 safety	<i>A prison can be a threatening environment. Risk to staff likely to fluctuate with changes in population and flaring gang or drug violence</i>	<i>Healthcare staff reliant on offering testing on the wing to catch-up those that declined secondary screening. The prison currently going through a period of increased violence</i>	<i>Healthcare management decide testing on the wing is too dangerous for staff to perform at this time</i>	<i>Wing-based testing is banned by managed and so does not take place. Prisoners no longer have the opportunity to be tested through this process</i>

Transformative mechanisms

Theory	Programme outcome	Mechanism ----->	= Contextual maintenance/transformation
Perpetuating prisons as “infectious environments”	<i>Healthcare workers provide very little information about blood-borne viruses during the test offer and at times may over-emphasise the risk of being infected to prisoners in the hope that they perceive themselves to be at risk and therefore more likely to test</i>	<i>Efforts by healthcare staff to encourage people to test may perpetuate a perception of prisons as dangerous and infectious environments</i>	<i>Culture of paranoia around infectious disease in prison formed or perpetuated amongst prisoners</i>
Routine offer leads to offer normalisation	<i>Opt-out programme successfully offers most new arrivals a test. Growing awareness amongst prisoners and officers that everyone is supposed to be offered a test for BBV infection</i>	<i>Being offered a BBV test becomes normalised by prisoners and officers</i>	<i>Being offered a test for BBV infection upon entrance to a prison becomes the expectation of prisoners and officers</i>
Routine testing leads to taking the test becoming the norm	<i>Opt-out programme successfully tests most new arrivals. There is growing awareness amongst prisoners and officers that most people accept a test offer, which is seen to be a routine part of medical checks upon entrance. Healthcare staff may present testing as a way of maintaining the “sterility” of the prison</i>	<i>Being tested for BBVs within prison becomes normalised</i>	<i>Prisoners accepting a test for BBV infection within prison becomes the expectation of other prisoners and staff in the prison. Some staff and prisoners that believe prisons are dangerous environments and feel at risk of infection may consider testing the “correct” thing to do for the wellbeing of others</i>

Supportive qualitative data (programme function)Very short stay prisoners

Interview (Prison 1): Seth: “So is there any way ... you mentioned those people who got missed because of the lockdown, is there any way people ... are there any other ways people can be missed completely from the system?” **HCW:** “... then there's some men who get discharged, you know they go to court the next day and they're gone.”

Healthcare staff and prisoner interaction

Field note extract (Prison 1): The prisoner healthcare “rep” highlights the BBV lead’s approach as a standout example of good practice, saying “she will always go out of her way to listen and provide support to those in need.” He tells me that rather than just “going through the motions”, prisoners respond when someone takes genuine interest in their wellbeing and care. He highlights trust and professionalism as central to the patient-provider interaction when within prison.

Field note extract (Prison 2): The BBV lead discusses various components of the screening that she feels are not pertinent. She tells me that if you do the full screening template, each secondary screening assessment takes 10 to 15 minutes and that she only has between 9:30 and 11:30, on a good day, to see potentially a large number (20+) of people. In order to make time, she tells me that you need to use “common sense” when dealing with people. Therefore, when a young person that looks visibly healthy comes into the clinic, she will miss parts of the screening template in order to save time.

Time pressures during secondary screening

Field note extract (Prison 2): I then spell out the situation, “so let me get this straight. You are expected to do a phlebotomy clinic at 09:00 and then start secondary screening after you have finished at around 09:45. When is induction? Okay so induction runs from 10:00-10:30 so you can’t see anyone during that time and food begins at eleven?” The BBV lead loudly and angrily tells me that this is the very situation, “this is ridiculous I only get half an hour to see people and I have to rely on officers to unlock them one at a time. It is actually getting worsen, worsen, worsen. In this situation I then have to go around all the people I can’t see and get them to sign to say they don’t want to see second day”.

Prisoners refusing to wait

Field note extract (Prison 1): I look through the open gap in the door and see another patient angrily telling the officer outside “I am going fucking back. Naaa I am sick of this shit I don’t wanna fucking wait”. There is a muffled voice as the officer responds, but the patient shouts “no fuck it. I want my association, take me back”. I see him, and the officer disappear into the corridor that leads back to E-wing and note that we have lost someone ...

Long pre-test discussion

Interview (Prison 1): “... cos we don’t (sighs). It’s more the time and if you do that for everyone, I feel that (long pause). I don’t, I feel like more people would say no to it if we went through it that much with everyone just because of the way prisoners are and when they come here to second day screening, they don’t want to be here,

so they want you to be ...as quick as you can ... so if you gave a thorough pre-talk I don't feel like it would be as effective ... for getting people to do BBV's."

Interview (Prison 2): HCW: "If I sat down and said to them like oh we're going to ... by the time I'd finished explaining I'd have put them off already and they would get pissed off, they want to go upstairs ... They want to get out and you will piss people off by doing that because they have short attention spans, some people. And you know they might be a little bit violent, you know they're aggressive and they don't want to know. They don't even want to be down with you anyway, they're just doing what you're telling them they need to do and then they'll go upstairs. So, if you start going into it then that's where you're going to go wrong."

Framing testing as compulsory

Field note extract (Prison 1): The nurse asks about the PhD and I explain that I am particularly interested in the way testing is offered ... He laughs and tells me, "I just try to make them think it's compulsory".

Prisoner translating

Field note extract (Prison 2): As the next prisoner enters the clinic room he is followed by a trustee, who warns us that he [the prisoner] may not be able to understand what we are asking him ... The BBV leads ask a few questions and the prisoner seems to understand what they are saying, so one begins to try and explain the BBV test. However, she is quickly met with a blank face, and so calls the trustee in from outside saying "actually can you explain that I am going to test him for hepatitis C, hepatitis B, and HIV. It is just routine in prison". The trustee nods and says something in Albanian. He waits for a response and then turns to the BBV lead saying, "Yeah, no problem".

Counter normative behaviour

Interview (Prison 1): Seth: "So why would someone not want to take one of those finger prick tests?" **Prisoner:** "Cos they know they've got it. That's it ain't it obviously. That's what I'd say. They know they got it and they don't want everyone to know."

Interview (Prison 1): Seth: "Yeah, how might you find out that someone has an infection?" **Prisoner:** "Erm obviously you can find out, erm for instance you could be with them here for instance with the nurse and I could be sitting outside, and he could be in here discussing his thing not knowing that I'm listening to everything."

Seth: "Oh cos the, the doors open?" **Prisoner:** "The doors open, confidentiality again so ..."

Interview (Prison 1): Seth: "Yeah and is it easy to maintain confidentiality in the clinic?" **HCW (Prison 1):** "Yeah, if you shut the door." **Seth:** "Well I've noticed, I've noticed certain nurses shut doors, but others don't." **HCW (Prison 1):** "If I don't feel safe, I won't shut the door. And again, that's security over healthcare ..."

Normalisation of testing in a stigmatised environment

Interview (Prison 1): BBV lead: "Yeah they're gauging, and they actually now see that this is a norm. I'm not testing a specific population so there's no, erm ... they can't sort of come up with any theory like err oh you must be diseased or there's a problem with this. Or this is only for specific people. So you're testing everybody,

whether they be straight, gay, green, yellow, or blue, you know. They're all having it, regardless of whether they're foreign nationals, whatever. Everybody is getting it done and erm a lot of them, especially the orderlies on the wings, some of them have gone around and they're like 'come on, big man, open the door, get your test'. Because of the relationship I have with them, 'where they're like oh Miss we can't come' ... [the orderlies] tell the boys and encourage them. And they're like 'come on big man, it's just a test, have it'. Or 'I've had it, no, no boss have it done' and then some of them visit with banter, like 'listen mate, I'm not sharing this cell if I don't know what you've got', you know. And so I think it's becoming normalised."

Reasons for testing

Field note extract (Prison 2): *I ask him why he decided to test, and he explains "well you see, I am one of those people who will test for anything. Even if I know I don't have it. But I just like to do it for confirmation you know?"*

Field note extract (Prison 2): Seth: *"Did you feel like you could say no to the test?"*

Prisoner: *"Well it never really occurred to me to say no, as they're medical staff and I felt like I should follow their advice".*

Reasons for not testing

Field note extract (Prison 2): *I ask, "so you don't think healthcare are doing these checks for your own benefit and to make sure that you are healthy?" He laughs and tells me that this is what appears to be on the surface, but that "they're making clones man. They're making clones and killing them and harvesting their organs. They're selling their organs, like their liver and kidneys and things. Look at all these wars and things and the way these governments like Russia, India, and where you're from [pointing at nurse] are killing their people. It's all for organs for the rich. They're cloning us and shit".*

I ask him whether he thinks I am part of the illuminati and he tells us that we (myself and the nurse are not) but that we're working for them indirectly, "you don't know that you are, but you are. Look around you. Look where we are. You don't have any control in your life. We are slaves to those guys. We are all slaves".

Interview (Prison 1): BBV lead: *"Okay so I had one guy who for religious reasons would not do the bloods and I don't understand this but it's not the Muslim, it's the Rastafarians ... Because they don't believe in blood shedding or leaving the body or stuff."*

Interview (Prison 1): Seth: *"And then you mentioned a drug user testing was a big step, why is that?"* **Prisoner:** *"People don't want to, people don't want to find out that they're HIV. It used to be a thing people put off because they didn't want to find out ... on top of your drug addiction and emotional problems, and family problems and their social problems, and their criminal problems. They didn't want to find out they'd a blood-borne virus on top of it so they'd avoid it."*

Field note extract (Prison 2): *I then enquire, "do you think some people may not like the finger prick?" He responds, "yeah, yeah my cellmate was like that. I had to work hard to get him to do the test. He told me because he is autistic, he is extremely sensitive, and he so didn't want to do it. I managed to persuade him in the end though". In my head I wonder about this exchange. I can't help but wonder about the motive of the respondent for encouraging his cellmate to test.*

Encouraging testing

Interview (Prison 1): BBV lead: "So you get people coming in and they're despondent and some of them have been in prisons where the healthcare isn't that great ... [but] you say to them, 'come on man this is the least the system can do for you is offer you this assessment ... It's one thing having lost your freedom, but [ignoring] your health, yeah, really? You're going to come into this manky place, you don't know if there's somebody who's just bled out in your cell and the Hepatitis virus is sitting there waiting for you to come'.

So, you enlighten them [that healthcare] is the one thing [these men have control over], every other decision has been made for them. And when you actually make them understand that, 'look okay you're going to do your time, but after that you've still got a life outside', they see this woman cares ... [and think] 'fuck them let me get my healthcare'. Do you understand what I'm saying?"

Consent

Interview (Prison 2): Seth: "And why did you want to take the test?" **Prisoner:** "I didn't think I had a choice to be honest, because I don't like needles, I wasn't that hot for it anyway. I was like to the nurse 'errrrrm' and she was like 'you have to do it', so yeah, I just went along with it." **Seth:** "Oh wow okay, so did you feel like it was mandatory?" **Prisoner:** "Most definitely."

Interview (Prison 2): Seth: "So you just got the finger prick test yeah? Did they tell you what was being tested for?" **Prisoner:** "Yeah, she said I was being tested for HIV and ... I don't know how to pronounce it ... " **Seth:** "Hepatitis C and B?" **Prisoner:** "Yeah, she said it was for 'em". **Seth:** "Yup, and did she provide you with any information about these diseases?" **Prisoner:** "Not about it no, like they just said I was being tested ... " **Seth:** "Right, did you feel like you had a choice about the test?" **Prisoner:** "Yeah, yeah [long pause] like yeah I knew I had a choice with it".

Interview (Prison 1): Seth: "... did they tell you anything about it or ...?" **Prisoner:** "No, it's just a procedure you know, they normally do it when we're in here." **Seth:** "Oh okay. Do you feel like you had a choice about it?" **Prisoner:** "Yeah of course, yeah of course." **Seth:** "Yeah? You felt like you could decline it ... " **Prisoner:** "Yeah of course, yeah man."

Catch-up testing cancelled (Prison 2)

Interview (Prison 2): Seth: "Erm, now I understand you used to do testing on the wings and at the gym. Can you tell me how that worked and why it stopped?"

BBV lead: "Err, we used to do it on the wings sometimes, erm because we wanted to up our testing and that was one way we were going to get people ... But the problem is at the minute, we know when things are becoming a bit unsettled and there's a lot of like gang violence and stuff ... at the minute it doesn't feel safe enough to do it on the wings." **Seth:** "Yeah, yeah. And that's come from your bosses as well hasn't it?" **BBV lead:** "Yeah, yeah that come ... yeah ... If I was there doing it on the wings at the minute, a lot of people would be like what's wrong with this girl? Why is she doing it at the minute? You're not meant to because as I said anything can happen."